INSTITUTIONAL ETHICS COMMITTEE

KLE University

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

(Deemed-to-be-University)

KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi - 10, Karnataka State, India

0831-2470400 www.kledeemeduniversity.edu.in E-mail:kleclinicalresearch@gmail.com

Ref: KAHER/IEC/2019-20/D- 06111900 1 *Date: 02/11/2019*

Accreditations

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IEC Meeting Agenda

Institutional Ethics Committee of KAHER, Belagavi

Tuesday, 12/11/2019 at: 03.30 PM

Venue: Site management Office, G+2, KLE's Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi

I. **New agendas for review and approval:** [Presentation from the PIs]

1. **Protocol Title:** The CRADLE-4 Trial-Planned early delivery versus expectant Management to Reduce Adverse pregnancy outcomes in pre-eclampsia in a low and middle-income setting.
   Dr. M B Bellad – PI
   Timing : 03:45 PM

2. **Protocol No: PMZ-1620/CT-3.1/2019 ; CT NOC No. CT/ND/66/2019**
   Protocol Title: A Prospective, Multi-Centric, randomized, Double-blind, Parallel, Phase-III Clinical Study to Assess Efficacy of PMZ-1620 along with Standard Treatment in patients of Acute Ischemic Stroke.
   Dr. Saroja A O – PI
   Timing : 04:00 PM

3. **Protocol No : 17-VIN-0072**
   Protocol Title : A Multicentre, Open-label, Balanced, Randomized, Two-Treatment, Two-Period, Single Dose, Cross-over, Bioequivalance Study of Bortezomib for Injection 3.5 mg/Vial of Dr. Reddy's Laboratoires Limited, India and VELCADE® (Bortezomib) for injection 3.5 mg/vial (Distributed and Marketed by : Millennium Pharmaceuticals, Inc., 40 Lansdowne Street, Cambridge, MA 02139) in Previously Untreated Multiple Myeloma and/or Relapsed Multiple Myeloma Patients.
   Dr. Rohan Bhise - PI
   Timing: 04:15 PM

4. **Protocol No : 1038-18**
   Protocol Title: A Multicentre, open-label, Balanced, Randomized, Two-Treatment, Three-Period, Three-Sequence, Single Oral Dose, Partial replicate, Cross-Over, Bioequivalence study comparing test formulation of capecitabine oral granules 500mg per packet (Manufactured by : Intas Pharmaceuticals Ltd, India) to reference formulation of Xeloda® (Capecitabine) tablets 500 mg (Distributed by : Genentech USA, Inc., A member of the Roche group, 1 DNA Way, South San Francisco, CA 94080-4990) in patients with metastatic breast cancer or metastatic colorectal cancer, alredy receiving a stable twice-daily dose of 1250 mg/m2, Equivalent to 2500 mg/m2 total daily dose Under Fed Condition''.
   Dr. Rohan Bhise - PI
   Timing : 04:30 PM

II. **Review of Proposals with Amendments:**

1. **Protocol No: CS2514-2017-0004**
   Protocol Title: A Randomized, Active-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Sulbactam-ETX2514 in the Treatment of Patients with Infections Caused by Acinetobacter baumannii-calcoaceticus Complex.
   Dr. Jayaprakash Appajigol – PI

2. **Protocol Title**: A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes Patients at High Cardiovascular Risk.
   Protocol number: EFC14828/Amplitude-O
   Dr.Prasad MR-PI
   - Subject Cards

III. **Review of Revised Project Proposals:**

1. **Protocol No: CTQJ230A12001**
   Protocol Title: Multi-center Cross-sectional Epidemiological study to characterize the prevalence and distribution of Lipoprotein (a) levels among patients with established cardiovascular disease.
   Dr. Prasad M R – PI (The above Study was Reviewed on 24 Aug 2019)

2. **Protocol No: 0979-1**
   Protocol Title: A Randomized, Multi-centre, open-Label, two-arm, Parallel, Clinical Study to evaluate the efficacy, safety and Tolerability of tacrolimus lipid suspension for enema of Intas pharmaceuticals Limited, India against CORTENEMA® (Hydrocortisone retention enema) of Anip Acquistion Company, USA in Adult patients with mild to moderate active left sided/distal ulcerative colitis refractory to mesalamine treatment.
   Dr. Santosh Dhananjay Hajare – PI (The above Study was reviewed on 30 Sep 2019)

3. **Protocol No: Protocol No: DUW-SHG/IN-01**
   Protocol Title: A Multicentric, open label, randomized, phase III study on the safety and efficacy of sofinox gel (SODIUM FUSIDATE equivalent to FUSIDIC ACID 2% w/w) in diabetic wound healing.
   Dr. Jayaprakash Appajigol- PI (The above Study was reviewed on 01 Apr 2019)

IV. **Review of Annual Report:**

-NIL-

V. **Review of Bi-Annual Report:**

1. **Protocol No: SH600003**
   Protocol Title: Immune Lot-to-Lot Consistency and Non-Inferiority of SHAN6™ Vaccine in Comparison to SHAN 5® + SHANIPV™ When Administered as Three Doses at 6-8, 10-12 and 14-16 Weeks of Age in Healthy Indian Infants, Concomitantly with Oral Rotavirus Vaccine.
   Dr. S M Dhaded - PI
   - IEC Notification of Study Status Letter Dated 24 Oct 2019

VI. **SAE reporting:**

1. **Protocol No: PCV-10-003**

   Protocol Title: "A Phase 3, Randomized, Double-Blind Study to Evaluate the Immunogenicity, Safety and Tolerability of Serum Institute of India's 10-valent Pneumococcal Conjugate Vaccine (PNEUMOSIL®) in Healthy Indian Infants.

   Dr. N S Mahantshetti - PI

   - IEC Notification of SAE Memorandum dated 30 Jul 2019 Letter Dated 21 Oct 2019

2. **Protocol No: 20150238**

   Protocol Title: A Multicenter, Multiple-dose, Active-controlled, Double- blind, double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride with Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects with Secondary Hyperparathyroidism

   Dr. Vernekar Ritesh Ramesh - PI

   - IEC Notification of SAE Summary Letter Dated 15 Oct 2019

3. **Protocol Title:** WHO ACTION - II TRIAL – A65916: A Multi-Country, Multi-Centre, Two-arm, Parallel, Double-Blind, Placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in late preterm period in hospitals in Low-resource countries to improve newborn outcomes.

   Dr. Shivaprasad S Goudar - PI

   - IEC Notification of SAE (Subject ID: 04292) Letter Dated 30 Sep 2019

VII. **Notifications of Study close-out/Archival:**

1. **Protocol No: D1699C00001**

   Protocol Title: Study to Evaluate the Effect of Dapagliflozin on the Incidence of Worsening Heart Failure or Cardiovascular Death in Patients with Chronic Heart Failure with Reduced Ejection Fraction.

   Dr. V A Kothiwale - PI

   - IEC Notification of Study Close-out, Archival of Study documents Letter Dated 12 Oct 2019

VIII. **Protocol deviation/violation/ termination:**

1. **Protocol No: HCR/IV/ADALI/01/2017**

   Protocol Title: A Phase IV Multi-Centric Post-Marketing Study Evaluating the Safety, Immunogenicity and efficacy of the marketed formulation of Hetero-Adalimumab

   Dr. Archana Uppin - PI

   - IEC Notification of protocol deviation Letter Dated 01 Oct 2019

2. **Protocol No: RLS/ONC/2016/03**

   Protocol Title: Prospective Multicenter Randomized Double-Blind Two Arm Parallel Group Active Control Comparative Clinical Study to Evaluate Efficacy and Safety of Rtpr-045/Xgeva for Prevention of Skeletal Related Events in Patient with Bone Metastasis from Solid Tumour.

   Dr. Kumar M. Vinchurkar - PI

   - IEC Notification of protocol deviation Letter Dated 01 Oct 2019

3. **Protocol No: INSLIL08556**

Protocol Title: A Randomized, 24-week, Controlled, Open Label, Parallel Arm, Multicenter Study Comparing the Efficacy and Safety of the Insulin Glargine/Lixisenatide Fixed Ratio Combination to Insulin Glargine in Type 2 Diabetes Patients, Inadequately Controlled on Basal Insulin with or without Metformin.

Dr. Vikranth Ghatnatti - PI

- IEC Notification of protocol deviation of Subject 356012-004 Letter Dated 04 Oct 2019.
- IEC Notification of protocol deviation of Subject 356012-009 Letter Dated 04 Oct 2019.

4. **Protocol No: BCD-057-02**

Protocol Title: A Multi-center Comparative Randomized Double-blind Study of the Efficacy and Safety of BCD-057-02 (INN; Adalimumab, CJSC BIOCAD, Russia) and Humira® (INN; Adalimumab Produced by Vetter Pharma) in Patients with Moderate to Severe Plaque Psoriasis.

Dr. Shivakumar K. Patil - PI

- IEC Notification of protocol deviation Letter Dated 04 Oct 2019

5. **Protocol No: 20150238**

Protocol Title: A Multicenter, Multiple-dose, Active-controlled, Double-blind, double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride with Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects with Secondary Hyperparathyroidism.

Dr. Vernekar Ritesh Ramesh - PI

- IEC Notification of protocol deviation Letter Dated 12 Oct 2019

6. **Protocol No: PMZ-1620/CLINICAL-2.3/2018; Version 02 dated 05 Jul 2018**

Protocol Title: A Prospective, Multicentric, Randomized, Double Blind, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Patients of Acute Spinal Cord Injury.

Dr. Sameer Haveri - PI

- IEC Notification of protocol deviation Letter Dated 05 Oct 2019

7. **Protocol No: 1002-043**

Protocol Title: A Randomized, Double-blind, Placebo-controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at high risk for, Cardiovascular Disease who are Statin Intolerant.

Dr. Kothiwale V.A - PI

- IEC Notification of protocol deviation Letter Dated 14 Oct 2019
- IEC Notification of Protocol deviation Letter Dated 18 Oct 2019

8. **Protocol No: CR172-17**

Protocol Title: A Multi Centre, open label, randomized (1:1), Parallel, Phase-II Study to evaluate the Safety, Tolerability and Immunogenicity of a 15-Valent Pneumococcal conjugate Vaccine (PCV-15) in healthy Subjects between 2-5 years of age (Group 1:15- Valent pneumococcal conjugate vaccine, group II: Prevnar 13).

Dr. N S Mahantshetti - PI

- IEC Notification of protocol deviation Letter Dated 15 Oct 2019.
- IEC Notification of protocol deviation Letter Dated 22 Oct 2019.

9. **Protocol No: PCV-10-003**

Protocol Title: "A Phase 3, Randomized, Double-Blind Study to Evaluate the Immunogenicity, Safety and Tolerability of Serum Institute of India's 10-valent Pneumococcal Conjugate Vaccine (PNEUMOSIL®) in Healthy Indian Infants."

Dr. N S Mahantshetti - PI

- IEC Notification of Protocol Deviation Letter Dated 15 Oct 2019
- IEC Notification of Protocol Deviation Letter Dated 22 Oct 2019

10. **Protocol No: 20160372**

Protocol Title: Post-marketing Phase 4 Study to Evaluate Safety, Tolerability, and Efficacy of Kyprolis® (Carfilzomib) in Indian Patients with Relapsed or Refractory Multiple Myeloma: A Prospective, Open-label, Non-comparative, Multicenter Study.

Dr. Rohan Bhise - PI

- IEC Notification of Protocol Deviation Letter Dated 15 Oct 2019

11. **Protocol No: CRSC16004**

Protocol Title: A Phase III, multicentre, randomized, observer blind, parallel group, three arms, controlled clinical trial to evaluate the efficacy and safety of topically applied Calcipotriol/AKVANO 50 µg/g cutaneous solution against Calcipotriol Ointment 50 micrograms/g, Sandoz and placebo in patients with mild to moderate plaque psoriasis

Dr. Snehal Lunge - PI

- IEC Notification of Protocol Deviation Letter Dated 17 Oct 2019

12. **Protocol No: CRL011813**

Protocol Title: A Randomized, Double blind, Multicenter, Three-arm, Parallel, Placebo-controlled, Clinical Study to Evaluate the Bioequivalence using Clinical Endpoint of Diclofenac Sodium Topical Gel, 1% (Encube Ethicals Private Limited, India) to Voltaren Gel (Diclofenac Sodium Topical Gel) 1% (Endo Pharmaceuticals Inc., USA) in Subjects with Osteoarthritis (OA) of the Knee.

Dr. Archana Uppin - PI

- IEC Notification of Protocol Deviation Letter Dated 31 Oct 2019
- IEC Notification of Missing IP Blinding Envelope from Kit No: 4216 to 4257 (42 Kits) Letter Dated
- IEC Notification of Missing Patient File #03033 Letter Dated

13. **Protocol Title**: Phase III Safety and Immunogenicity of an Investigational versus the Licensed Formulation of the Pentavalent Vaccine (DTwP-HepB-Hib) SHAN 5® when administered as Three Dose Primary Series at 6-8, 10-12 and 14-16 Weeks of Age in Healthy Indian Infants and Safety and Immunogenicity of the Investigational SHAN 5® Formulation when administered as a Single Booster Dose at 12-24 Months of Age.

Dr. S M Dhaded - PI

- IEC Notification of Protocol Deviation letter dated 24 Oct 2019

IX. The Committee will consider the following agendas which are for information.

1. **Protocol Number/ Title- CRSC16004,** "A Phase III, Multicentre, randomized, observer blind, parallel group, three arms, controlled clinical trial to evaluate the efficacy and safety of topically applied Calcipotriol /AKVANO 50 µg/g cutaneous solution against Calcipotriol Ointment 50 Micrograms/g, Sandoz and placebo in patients with mild to moderate plaque psoriasis.
   Dr. Snehal Lunge-PI
   - IEC Notification of Source document template Letter Dated 29 Oct 2019
   - IEC Notification of Adverse event Letter Dated 18 Oct 2019
   - IEC Notification for typo error in submission letter and approval Letter Dated 26 April 2018
   - IEC Notification of back translation certificate for addendum no.002 of consent for photograph Letter Dated 26 Apr 2018
   - IEC Notification of clinical trial agreement and source document template Letter Dated 27 Oct 2018

2. **Protocol Number**: EFC14875
   Protocol Title: A Randomized, Double-blind, Placebo-controlled, parallel-group, Multicenter study to demonstrate the effects of Sotagliflozin on cardiovascular and renal events in patients with Type 2 Diabetes, Cardiovascular Risk factors and moderately impaired renal function.
   Dr. Prasad M R- PI
   - IEC Notification of Safety Alert #721N, 73, 74IN, 75, 76IN Letter Dated 19 Oct 2019
   - IEC Notification of Safety Alert #80IN, #82IN, #83 Letter Dated 19 Oct 2019
   - IEC Notification of Safety Alert #77 Letter Dated 10 Oct 2019

3. **Protocol Number:** EFC148278
   Protocol Title: A Randomized, Double-blind, Placebo-controlled, parallel-group, Multicenter study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes patients at High Cardiovascular Risk.
   Dr. Prasad M R- PI
   - IEC Notification of Safety Alert #37 Letter Dated 24 Oct 2019
   - IEC Notification of Safety Alert #33 and #34IN Letter Dated 09 Oct 2019

4. **Protocol Number**: CQGE031C2302
   Protocol Title: A multicenter, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticarial (CSU) in adolescents and adults inadequately controlled with H1-antihistamines.
   Dr. Shivakumar K. Patil- PI
   - IEC Notification regarding inadvertently randomization of patient- 2508002 Letter Dated 23 Oct 2019

5. **Protocol Number:** BECT048/MRV-PIV/CTP-02
   Protocol Title: A Multicentric single arm non-comparative Phase-IV post marketing study to evaluate the safety and tolerability of Biological E's live Attenuated Measles-Rubella Vaccine (MR) in 9-12-month-old Healthy infant.
   Dr. N.S. Mahantshetti - PI

- IEC Notification of Investigator Undertaking for the above study Letter Dated 21 Oct 2019
- IEC Notification of Source Documents Template for above ref study Letter Dated 23 Oct 2019

6. **Protocol No: TX05-03**
   Protocol Title: A randomized, double blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin in subjects with HER2 positive early breast cancer.
   Dr. Mahesh Kalloli – PI
   - IEC Notification of CIOMS for above mentioned study Letter Dated 18 Oct 2019

7. **Protocol No: 14V-MC-JADY**
   Protocol Title: A Phase 3, Multicentre Study to Evaluate the Long-Term Safety and Efficacy of Barcitinib in Patients with Rheumatoid Arthritis.
   Dr. Shailesh V Udapudi - PI
   - IEC Notification of SAFRNS for above study Letter Dated 10 Oct 2019

8. **Protocol No: PCV-10-003**
   Protocol Title: A Phase 3, Randomized, Double-Blind study to evaluate the immunogenicity, Safety and Tolerability of Serum Institute of India's 10- Valent Pneumococcal Conjugate Vaccine (PNEUMOSIL) in healthy Infants.
   Dr. N. S. Mahantashetti - PI
   - IEC Notification of IB Version 4 Dated 29 Mar 2019 Letter Dated 22 Oct 2019

9. **Protocol No: GA29102**
   Protocol Title: Phase III, randomized, double-blind, Placebo-controlled, multicenter study to evaluate the efficacy (maintenance of remission) and safety of etrolizumab compared with placebo in patients with moderate to severe active ulcerative colitis who are naïve to TNF inhibitors.
   Dr. Vardaraj Pralhadarao Gokak-PI
   - IEC Notification of IB Version 13 dated 12 Sep 2019 Letter Dated 22 Oct 2019

10. **Protocol No: GA28951**
    Protocol Title: An open label extension and safety monitoring study of moderate to severe ulcerative Colitis patients previously enrolled in Etrolizumab phase II/III studies.
    Dr. Vardaraj Pralhadarao Gokak-PI
    - IEC Notification of IB Version 13 dated 12 Sep 2019 Letter Dated 22 Oct 2019

11. **Protocol No:SH600003**
    Protocol Title: Immune Lot-to-Lot Consistency and Non-Inferiority of SHAN6™ vaccine in Comparison to SHAN 5® + SHANIPV™ When Administered as Three Doses at 6-8, 10-12 and 14-16 weeks of age in Healthy Indian Infants, Concomitantly with Oral Rotavirus vaccine.
    Dr. S.M. Dhaded- PI
    - IEC Notification of IB Version 5.0 dated 10 Sep 2019 and summary of changes from Version 4.0 to Version 5.0 Letter Dated 24 Oct 2019

12. **Protocol No: ALK18/ENZ124-CETI**
    Protocol Title: A prospective, multicentre, randomized, double blind, parallel group study to compare the efficacy and safety of biosimilar cetuximab versus innovator cetuximab in

Combination with platinum-based chemotherapy in patients with recurrent loco regional or metastatic squamous cell carcinoma of the head and neck (SCCHN).

Dr. Mahesh Kalloli- PI

- IEC Review and Notification of Study Documents Letter Dated: 31 Oct 2019
  1. Subject's travel allowance should be included in the ICFs
  2. IEC member contact details to be printed in the ICFs
  3. Final CTA

13. Protocol No: DUW-SHG/IN-01

Protocol Title: A Multicentric, open label, randomized, phase III study on the safety and efficacy of sofinox gel (SODIUM FUSIDATE equivalent to FUSIDIC ACID 2% w/w) in Diabetic wound healing.

Dr. Jayaprakash Appajigol- PI

- IEC Notification of Study Documents Letter Dated 31 Oct 2019
  1. Summary of changes in protocol version 2 to version 3
  2. Protocol version 3 dated 10/4/19
  3. Summary of changes in the IB version 1 to version 2
  4. IB version 2 dated 10/4/19
  5. Summary of changes in case report form version 2 to version 3
  6. Case report form version 3 dated 10/4/19

14. Protocol No: 1038-18

Protocol Title: A Multicentre, open label, balanced, randomized, two treatment, three-period, three sequence, single oral dose, partial replicate, cross-over, bioequivalence study comparing test formulation of capecitabine oral granules 500mg per packet (manufactured by: Intas pharmaceuticals Ltd, India) to the reference formulation of Xeloda ® (capecitabine) tablets 500mg (Distributed by: Genentech USA Inc., A member of the Roche group, 1DNA way, south san Francisco, CA 94080-4990 in patients with metastatic breast cancer or metastatic colorectal cancer, already receiving a stable twice- daily dose of 1250mg/m 2 equivalent to 2500mg/m 2 total daily dose underfed condition.

Dr. Rohan Bhise- PI

- EC Notification of CTRI Registration (CTRI/2019/10/021793) Letter Dated 30 Aug 2019

VII. Any other matter with the permission of the chair

For your attention:

Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Prof. (Dr) M.S. Ganachari
Member-secretary of IEC

Prof. (Dr) M. S. Ganachari
Members Secretary, Institutional Ethics Committee
KLE Academy of Higher Education and Research, Belagavi

To:

Circular and Submission of IEC Dossier		
1)	**Dr. Subarna Roy,** Scientist 'F', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V. Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr. P. A. Patil,** Prof of Pharmacology [USM-KLE] IMP, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr. S. S. Goudar,** Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr. Yeshita Pujar,** Prof of Obstetrics & Gynecology, JNMC, Belagavi	Member
6)	**Dr. Roopa Bellad,** Prof of Pediatrics, J.N. Medical College, Belagavi	Member
7)	**Dr. Nayana Hashilkar,** Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
8)	**Mrs. Vaishnavi V Kivadasannavar,** M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
9)	**Shri.Tammanna Dadu Kore,** Farmer, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
10)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
11)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, KLE College of Pharmacy, Belagavi	Assistant Coordinator
12)	**Prof. (Dr.) M.S. Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
13)	**Dr. Sapna.K** Radiation Oncologist, KLE Society's Belgaum cancer Hospital, Belagavi-10	Independent Consultant
Administrators of KAHER (Deemed to be University)		
1)	The Registrar, KAHER, deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed University, Belagavi, For Information	Circular
Principal Investigators		
1)	**Dr. Saroja A O,** Consultant Neurologist, KLES Dr Prabhakar Kore Hospital & MRC, Belagavi-10	Circular
2)	**Dr. M B Bellad,** Professor of Obstetrics & Gynecology, KLES Dr Prabhakar Kore Hospital &MRC, Nehru Nagar, Belagavi-590 010, Karnataka, India.	Circular
3)	**Dr. Rohan Bhise,** Consultant Oncology Dept., KLES Dr Prabhakar Kore Hospital &MRC, Nehru Nagar, Belagavi-590 010, Karnataka, India.	Circular

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INSTITUTIONAL ETHICS COMMITTEE

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(Deemed-to-be-University)
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Accreditations
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Registrations
DCGI
OHRP

SMO

Ref: KAHER/IEC/2019-20/D- 040320008

Date: 02/Mar/202

Meeting Agenda

Institutional Ethics Committee of KAHER, Belagavi

Day, Date and Time: **Saturday, 14-Mar-2020** at **11:30 AM**

Venue: Site management Office, G+2, KLES Dr.PK Hospital &MRC, Nehru Nagar, Belagavi

I. New agendas for review and approval:[Presentation from the PIs]

1. **Protocol No:** GBS/04/DLBVN/2019
   Protocol Title: A Phase III Randomized, Multicenter, Open Label, Parallel Groups, Non-inferiority Study to Evaluate the Efficacy and Safety of Dalbavancin in Comparison with Comparator Regimen (Vancomycin Followed by Linezolid) for the Treatment of Patients with Acute Bacterial Skin and Skin Structure Infections (ABSSSIs)
   Dr. M.I.Uppin- PI
   Timings: 11:45 AM

2. **Protocol Title:** A Prospective, Double-blind, Randomized, Parallel-Group, Vehicle-Controlled, Multicenter Study to Evaluate the Safety and Bioequivalence of Mupirocin Cream USP 2% (Supplied by: Glasshouse Pharmaceuticals Limited Canada) using Mupirocin Cream USP 2% (Manufactured by: Glenmark Pharmaceuticals Inc; USA) as a Reference Product, in Subjects with Secondarily Infected Traumatic Skin Lesions
   Protocol Number: GH-SL-IN-01
   Dr. M.I.Uppin- PI
   Timings: 12:00 PM

3. **Protocol title:** Estimating the Burden of pediatric HIV in a "A" Category District, Karnataka: Morbidity and Mortality Trends Among the Children Pediatric HIV cohort (Phase-III)
   Dr.Mubashir Angolkar-PI
   Timings: 12:15 PM

II. Review of Proposals with Amendments:

2. **Protocol Title;** A 26 Week, randomized, open label, parallel-group comparison of SAR341402 Mix 70/30 to Novo Mix® in adult patients with diabetes Mellitus using Pre-mix Insulin Analogas
   Protocol No: EFC 15082/GEMELLIM
   - Amended[Version 2.0 dated: 11-Dec-2019] study documents for review and approval letter dated 05-Feb-2020

2. **Protocol Title:** A 52 week, phase3, multicenter, randomized double blind efficacy and safety study comparing GSK3196165 with placebo and with tofacitinib, in combination with methotrexate in participants with moderately to severely rheumatoid arthritis who have an inadequate response to methotrexate.
Protocol No: 201790
Dr.Archana Uppin-PI
- IEC approval for the online advertisements letter dated: 05-Feb-2020

II. Review of Revised Project Proposals:

1. **Protocol title :** A comparative, randomized, two arm, double blind parallel group multicentric, phase III clinical study to evaluate the efficacy, safety and tolerability of Netarsudil ophthalmic solution 0.02% W/V verses Timolol maleate Eye drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension .
Dr. Smitha K.S-PI
With reference IEC letter no: **KAHER/IEC/2019-20/D-100120016** and dated: **08-Jan-2020**.
IEC sought the following documents for final approval.
   1. Study Specific Insurance-valid through-28-09-2020
   2. CTRI- 2020/01/022619
   3. Final CTA
   4. CDSCO notification of additional site PI/Site

III. Review of Annual Report:

1. **Protocol title:** A randomized, double-blind, placebo-controlled study to assess the effects of Bempedoic Acid (ETC-1002) on the occurrence of major cardiovascular events in patients with, or at high risk for cardiovascular disease who are statin Intolerant.
Protocol No: 1002-043
Dr.Kothiwale V.A-PI
- IEC submission of study annual report letter Dated 01/Jan/2020

2. **Protocol Title:** Post marketing phase IV study to evaluate safety, tolerability and efficacy of Kyprolis (carfilzomib) in Indian patients with relapsed or refractory multiple myeloma prospective, open label, non-comparative, multicenter study.
Protocol No: 20160372
Dr. Rohan Bhise-PI
- IEC notification of annual report letter dated 10/Feb/2020

3. **Protocol title:** A phase 3, Randomised, Double-blind, parallel-group, vehicle controlled Multicentre Study of the efficacy and safety of Granexin gel in the treatment of diabetic foot Ulcer (GAIT 1)
Protocol No: 2015-DFU-301
Dr. Vikrant Ghatnatti-PI
- IEC notification of study progress report letter Dated:15/Dec/2019

IV. **SAE Reporting:**

1. **Protocol Title:** A Multicenter, Multiple-dose, Active-controlled, Double-blind,Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism
   Study No. 20150238
   Drug: Etelcalcetide
   Dr.Ritesh Vernekar-PI
   - IEC notification of Final Safety narrative for subject 21006 letter dated: 13-Dec-2019

2. **Protocol Title:** An open-label, muticenter, prospective, Phase-IV, interventional study to evaluate the safety, tolerability & efficacy of Dolutegravir (50 mg once daily) in treatment Naïve adult Indian subjects infected with HIV1, Eligible to receive dolutegravir with tenofovir &lamivudine.
   Protocol No: 109-04
   Dr.Dnyanesh Morkar-PI
   - IEC Notification of Initial SAE, CIOMS & Investigators letter for Subject No.109-04 which occurred at site -109 dated on 05/Feb/2020

3. **Protocol ID:** PCV-10-003
   Protocol Title: A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety, Tolerability, Immunogenicity and Non-Interference with Concomitant Vaccinations of Serum Institute of India's 10-Valent Pneumococcal Conjugate Vaccine (PNEUMOSIL®) in Healthy Indian Infants
   Dr.N.S.Mahantashetti-PI
   - IEC notification of other site Hamdard Institute of Medical Sciences letter dated:05/Nov/2019

4. **Protocol title:** A phase II/III, multicenter, randomized, open label, active controlled, clinical study to assess the immunogenicity and safety of tetanus toxoid, diphtheria toxoid, and acellular pertussis (tdap) vaccine manufactured by serum institute of india pvt. Ltd (SIIPL) in comparison with boostrix vaccine of GSK in healthy adults, adolescents and children in India.
   Dr.N.S.Mahantashetti-PI
   - IEC Notification of initial safety narrative report and initial CIOMS for subject 101-182 occurred at other site-101

5. **Protocol Title:** A phase II/III, multicenter, randomized, open label, active controlled, clinical study to assess the immunogenicity and safety of tetanus toxoid, and acellular pertussis (tdap) Vaccine manufactured by serum institute of India Pvt.Ltd. (SIIPL) in comparison with boostrix vaccine of GSK in healthy adults, adolescents and children in India
   Dr. N.S Mahantshetti-PI
   - IEC notification of Initial safety narrative report and Initial CIOMS for Subject 103-147 which occurred at other site-103

6. **Protocol Title:** A prospective, Multicenter, randomized, Double-blind, Parallel-group, Study to compare the efficacy and safety of GBR 200 (similar biologic of Trastuzumab) versus Innovator Trastuzumab both when given in combination with Paclitaxel in patients diagnosed with HER2 Positive Metastatic Brest Cancer.
   Dr.Mahesh Kalloli-PI
   - IEC Notification of final Safety Narrative for Subject 07-014 which occurred at other site 07.

VI. <u>Protocol deviation/violation/ termination:</u>

1. **Protocol No:** DMPL/P05-2017/CT/VN, version no : 2.0 rev no : 1.0
   Protocol title: a post marketing surveillance study (PMS) to evaluate safety and tolerability of VELNEZ as nasal pack after nasal surgery
   Dr. Shama Bellad-PI
   - IEC notification for protocol deviation letter dated18/Jan/2020

2. **Protocol Title:** A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism
   Protocol No. 20150238
   Dr.Ritesh Vernekar-PI
   - IEC notification of Protocol deviation regarding IP accountability missing from week 23 visit source for subject no: 23830016009 letters dated 22-01-2020.

3. **Protocol Title:** a phase III multicenter randomized observer blind parallel group three arms controlled clinical trial to evaluate the efficacy and safety of topically applied calcipotriol/ AKVANO 50mg/g cutaneous solution against calcipotriol ointment 50mg/g Sandoz and placebo in patients with mild to moderate plaque psoriasis
   Protocol No: CRSC16004
   Dr. Snehal Lunge-PI
   - IEC notification of lost follow up/protocol deviation letter dated 21/Oct/2019

4. **Protocol title:** a randomized double blind placebo controlled parallel group multicenter study to demonstrate the effects of Sotagliflozin on cardio vascular and renal events in patients with type 2 diabetes, cardio vascular risk factor and moderately impaired renal function
   Protocol no: EFC14875
   Dr Prasad M R-PI
   - IEC notification of protocol deviation dated 24/Jan/2020

5. **Protocol Title:** a randomized double blind placebo controlled parallel group multicenter study to evaluate effect of Efpeglenatide on cardiovascular Outcomes in Type 2Diabetes patients at High Cardiovascular Risk.
   Protocol No: EFC14828
   Dr.Prasad M R-PI
   - IEC notification of protocol deviation letter dated 23/Nov/2019

6. **Protocol title:** prospective, multicentre, randomised,double-blind,two arm, parallel group active control, comparative clinical study to evaluate efficacy and safety of R-TPR-045/Xgeva for prevention of skeletal related events in patients with bone metastases from solid tumours
Protocol No: RLS/ONC/2016/03
Dr.Kumar Vinchurkar-PI
    - IEC Notification of protocol deviation letter dated 23/Jan/2020

7. **Protocol title:** A phase 3, Randomised , Double-blind ,parallel-group, vehicle controlled Multicentre Study of the efficacy and safety of Granexin gel in the treatment of diabetic foot Ulcer (GAIT 1)
Protocol no: 2015-DFU-301
Dr. Vikrant Ghatnatti-PI
    - IEC notification of protocol deviation dated :20/Jan/2020
    - IEC notification of protocol deviation for Subject 06-008 Dated:30/Jan/2020

8. **Protocol Title:** randomised, controlled Open label clinical study to compare the Impact of Single transition from Enbrel auto-injector(AI) to YLB113 AI on safety, PK and compare Usability of both AIs in patients with Active Rheumatoid Arthritis (RA)
Protocol No: LRP-LYB113-2017-001
Dr. Archana Uppin-PI
    - IEC notification of Protocol deviation letter dated:07/Jan/2020

9. **Protocol title:** A 26 weeks randomized open label parallel group comparison of SAR341402 mix 70/30 to novo mix in adults with diabetes mellitus using pre-mix insulin analogs
Protocol No: EFC 15082/GEMLLIM
Dr. M. V. Jali
    - IEC notification of protocol deviation letter dated 05/Feb/2020

10. **Protocol title:** A randomized, double-blind, double-dummy, Muticenter, parallel, phase III study to evaluate the efficacy and safety of tacrolimus lipid tablets (manufactured by Intas pharmaceutical ltd.) compared to prograf (tacrolimus immediate release capsule-Astellas pharma Canada, inc) in adult patients with active rheumatoid arthritis who have resistance or intolerance to DMARDs.
Protocol No: 0978-17
Dr. Archana Uppin-PI
    - IEC notification of protocol deviation letter dated : 07/Feb/2020

11. **Protocol Title:** Post marketing phase IV study to evaluate safety, tolerability and efficacy of Kyprolis (carfilzomib) in Indian patients with relapsed or refractory multiple myeloma prospective, open label, non-comparative, multicenter study.
Protocol No: 20160372
Dr. Rohan Bhise-PI
    - IEC notification for protocol deviation letter dated:07/Jan/2020

VII. **Notifications of Study close-out/Archival:**

1. **Protocol No: MYL-14020-3001**
   Protocol Title: Multicentre, Double-Blind, Randomized, Parallel-Group study to Assess the Efficacy and safety of MYL-14020 Compared with Avastin®, in the first-Line Treatment of patients with Stage IV Non-Squamous Non-Small Cell Lung Cancer.
   Dr. Mahesh Kalloli – PI
   - Site close out and over all site status notification dated 24/Jan/2020 [Blinded Study]

VIII. **The Committee will consider the following agendas which are for information.**

1. **Protocol Title:** A 12 month Open-Label study to evaluate the safety and tolerability of pregabalin as adjunctive therapy in pediatric subjects 1 month to 16 years of age with partial Onset seizures and pediatric and adult subjects 5 to 65 years of age with primary generalized tonic clonic Seizure (A0081106)
   Dr. Mahesh kamate-PI
   - IEC notification of clinical study report.

2. **Protocol title:** A prospective, double-blind, Randomized, parallel-group, Vehicle-controlled, multicenter study to evaluate the safety and bioequivalence of mupirocin cream USP 2% (supplied by: glasshouse pharmaceuticals limited Canada) using Mupirocin cream USP% 2% (manufactured by pharmaceuticals Inc; USA) as a reference product, in subjects with secondarily infected Traumatic Skin lesions
   Protocol no: GH-SL-IN-01
   Dr. Mrutyunjaya Uppin-PI
   - IEC notifications of DCGI approval dated 01/11/2019 and insurance certificate letter Dated on 07-01-2020

3. **Protocol title:** A randomized, double blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin in subjects with HER2 positive early breast cancer.
   Protocol No: TX05 /Final version dated 30-01-2017
   Dr. Mahesh Kalloli – PI
   - IEC notification of Updated CTRI letter dated on 16/Jan/2020

4. **Protocol Title:** A randomized, double blind, multicentre, multinational comparative clinical study to compare efficacy and safety of INTP24 against Avastin in patients with unrespectable locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer.
   Protocol No: 0586-18_ version 1.1 dated 25-05-2019
   Dr. Mahesh Kalloli-PI
   - IEC notification of DCGI NOC letter dated 13/01/2020 for the protocol version 1.1 dated 25/May/2019.

5. **Protocol title:** a randomized double blind placebo controlled parallel group multicenter study to demonstrate the effects of Sotagliflozin on cardio vascular and renal events in patients with type 2 diabetes, cardio vascular risk factor and moderately impaired renal function
   Protocol no: EFC14875
   Dr. Prasad M R-PI
   - IEC notification of activity letter dated: 24/Jan/2020

- IEC notification of insurance certificate valid from 1/July/2019 to 30/Jun/2020 letter dated 8/Jan/2020
- IEC notification of Investigator Undertaking dated 29-11-2020 letter dated on 06-01-2020
- IEC notification of insurance certificate valid from 1/July/2019 to 30/Jun/2020 letter dated on 30-01-20

23. **Protocol Title:** EFC14828
Protocol Title: a randomized double blind placebo controlled parallel group multicenter study to evaluate effect of Efpeglenatide on cardiovascular Outcomes in Type 2Diabetes patients at High Cardiovascular Risk.
Dr.Prasad M R
    - IEC notification of unstability of sample resulting incomplete laboratory reports dated 31/Dec/2019
    - IEC notification of Temperature Excursion report letter dated:07/Jan/2020

24. **Protocol title** :multicenter single-dose , randomized , parallel arm two treatment bio equivalence study of Mylan's Iron dextran verses Allergans INFeD following a single intravenous injection in patients with Iron deficiency anemia
Protocol no: FEDX 1-19100
Dr. Arathi Darshan-PI
    - IEC notification of typo error in the EC submission and wrongly mention of the date in the protocol signature page

25. **Protocol Title :** A multicentre, randomized, Double-blind active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of chronic spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines
Protocol No: CQGE031C2302
Dr. Shivakumar Patil-PI
    - EC notification of Medication taken by subject- letter dated: 24/Jan/2020

26. **Protocol Title**: A randomized, 24-week, controlled, open label, parallel arm, multicentre study comparing the efficacy and safety of the Insulin glargine/Lixisenatide fixed ratio combination to insulin glargine in type II diabetes patients, adequately controlled on Basal Insulin with or without Metformin.
Protocol No: INSTALL 08556
Dr. Vikrant Ghatnatti-PI
    - IEC notification of used glucometer of 356012009 misplaced at site.

For your attention:
Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely, for, Jalimath 02/12/2020

Prof.(Dr) M.S.Ganachari
Member-secretary of IEC

Prof. (Dr) M. S. Ganachari
Members Secretary, Institutional Ethics Committee
KLE Academy of Higher Education and Research, Belagavi

To:

	Circular and Submission of IEC Dossier	
1.	**Dr. Subarna Roy,** Scientist 'F', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2.	**Dr. Harsha V.Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Scientific Member
3.	**Dr.P.A.Patil,** Prof of Pharmacology[USM-KLE]IMP,"VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4.	**Dr.S.S.Goudar,** Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5.	**Dr.Yeshita Pujar,** Prof of Obst&Gynace, JNMC, Belagavi	Member
6.	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
7.	**Dr.Nayana Hashilkar,** Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
8.	**Mrs.Vaishnavi V Kivadasannavar,** M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
9.	**Shri.Tammanna Dadu Kore,** Farmer, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
10.	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
11.	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, KLE College of Pharmacy, Belagavi	Scientific Member
12.	**Prof.(Dr.) M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
Administrators of KAHER(Deemed to be University)		
1.	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2.	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3.	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4.	Mrs. Rajeshwari - PRO –KAHER, Deemed University, Belagavi, For Information	Circular
Principal Investigators		
5.	**Dr. M.I.Uppin,** General Surgeon, Dept. of Surgery, KLES Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belagavi	Circular
6.	**Dr.Mubashir Angolkar,** Dept. Of Public Health, JNMC, KHAER, Belagavi-10	Circular

INSTITUTIONAL ETHICS COMMITTEE

KLE University

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

(Deemed-to-be-University)

KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi - 10, Karnataka State, India

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Ref: KAHER/IEC/2020-21/D- 1707200001 **Date: 13/07/2020**

Accreditations

NABH

FERCAP

SIDCER

Registrations

DCGI

OHRP

SMO

Meeting Agenda

Institutional Ethics Committee of KAHER, Belagavi

Saturday, 25/Jul/2020, At: 11.00 AM

Venue: Through Go to Meeting Application/and or KLE Site Management Office [Offline]

I. New agendas for review and approval:[Presentation from the PIs]

1. **Protocol Title:** A Phase III, Open-label, Randomized Study of Osimertinib with or without Platinum plus Pemetrexed Chemotherapy, as First-line Treatment in Patients with Epidermal Growth Factor Receptor (EGFR) Mutation- Positive, Locally Advanced or Metastatic Non-small Cell Lung Cancer (FLAURA2).
   Dr.Rohan Bhise-PI
   Timings: 11:15 to 11:30 AM

2. **Protocol No-**TQJ230A12301
   Protocol title- A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular event in patients with established cardiovascular disease
   Dr Prasad M R-PI
   Timings: 11:30 to 11:45 AM

3. **Protocol Title:** a Phase (III) study in patients with active rheumatoid arthritis on a stable dose of methotrexate
   Dr.Archana Uppin-PI
   Timings: 11:45 to 12:00 PM

4. **Protocol No-**RLS/PMS/2018/01
   Protocol title-prospective, multi-center, phase IV study to evaluate safety and efficacy of tenecteRel™ (tenecteplase manufacture by Reliance Life Sciences Pvt ltd)
   Protocol No: RLS/PMS/2017/01; Version 2.0, Dated: 24 Jun 2019
   Dr Sameer Amber-PI
   Timings: 12:15 to 12:30 PM

5. **Protocol No:** G7SYN/P-001/2019
   Protocol Title: A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Three-arm, Parallel Study to Evaluate the Bioequivalence using Clinical Endpoint of Tretinoin Gel microsphere, 0.08% (Encube Ethicals Private Limited, India) to Retin-A Micro® (tretinoin) Gel microsphere, 0.08% (Valeant Pharmaceuticals North America LLC, NJ 08807) in Subjects with Acne Vulgaris.
   Dr Shiva Kumar Patil -PI
   Timings: 12:30 to 12:45 PM

6. **Protocol Title:** COVID 19 prevalence during pregnancy outcomes in 8 low and middle income site: A global Network study
   Dr.S.S.Goudar-PI
   Timings: 12:45 to 01:00 PM

1. **Protocol Title:** A Randomized, Active-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Sulbactam-ETX2514 in the Treatment of Patients with Infections Caused by Acinetobacter baumannii- calcoaceticus Complex
   Protocol No: CS2514-2017-0004
   Dr.Jayaprakash Appajigol -PI
   - IEC Approval of Protocol amendment v 3.0 letter dated 06-Jun-2020

2. **Protocol No**: 1002-043
   Protocol Title: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at High Risk For, Cardiovascular Disease Who Are Statin Intolerant
   Dr.V.A. Kothiwale-PI
   - Protocol amendment Version 4.0 dated: 19-Dec-2019 Submitted for IEC Review and approval letter dated 09-May-2020

3. **Protocol No**: SAMSON-II
   Protocol Title: A Randomized, Double-blind, Parallel Group, Equivalence, Multicentre Phase III Trial to Compare the Efficacy, Safety, Pharmacokinetics and Immunogenicity of HD204 to Avastin® in patients with Metastatic or Recurrent Non-Squamous Non-Small Cell Lung Cancer
   Dr.Rohan Bhise-PI
   - Protocol amendment Version 2.0 dated: 22-Apr-2020

II. **Review of Proposal Revised Protocol:**
   - Nil

III. **Review of Annual Report:**

1. **Protocol No**: SII-Tdap/IN-02 V 2.0
   Protocol Title: A phase II/III, multicenter, randomized, open label, active controlled, clinical study to assess the immunogenicity and safety of tetanus toxoid, diphtheria toxoid, and acellular pertussis (Tdap) vaccine manufactured by Serum institute of India Pvt. Ltd. (SIIPL) in comparison with Boostrix® vaccine of GSK in healthy adults, adolescents and children
   Dr. N S Mahantshetti - PI
   - IEC submission of annual report letter dated 15 Jun 2020

2. **Protocol No:** BECT045/HepA- Phase- III/CTP-02
   Protocol No: BECT045/HepA-Phase-III/CTP-02
   Protocol Title: A single blind, parallel, randomized Phase-Ill comparative study to evaluate safety and immunogenicity of two intramuscular doses of inactivated Hepatitis A vaccine administered 6 months apart, in 1-15 year-old healthy Hepatitis A vaccine-na'ive children
   Dr. N S Mahantshetti – PI
   - IEC submission of annual report letter dated 18 Mar 2020

3. **Protocol No:** BECT048/MRV- PIV/CTP-02
   Protocol Title: "A Multicenter single arm non-comparative Phase-IV post marketing study to evaluate the safety and tolerability of Biological E's Live, Attenuate Measles Rubella Vaccine (MR) in 9-12 month old Healthy Infants.
   Dr. N S Mahantshetti - PI
   - IEC submission of annual report letter dated 25 Jun 2020

4. **Protocol No: CQGE031C2302**
   Protocol Title: A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines
   Dr. Shivkumar Patil- PI
   - IEC notification of annual report dated 8 Jun 2020

5. **Protocol Title:** A Randomized, Active-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Sulbactam-ETX2514 in the Treatment of Patients with Infections Caused by Acinetobacter baumannii- calcoaceticus Complex
   Protocol No: CS2514-2017-0004
   Dr.Jayaprakash Appajigol- PI
   - IEC submission of annual report letter dated 06 Jun 2020

III. **Review of Bi-Annual Report:**
   - Nil

IV. **SAE reporting**

1. **Protocol Title:** ACTION-II TRIAL-A65916: A multi-country, multi-centre, two-arm, parallel, double-blind, placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in the late preterm period in hospitals in low-resource countries to improve new-born outcomes".
   Protocol No: A65916
   Dr. Shivprasad S Goudar- PI
   - IEC Notification of SAE for research project dated 1 June 2020

V. **Protocol deviation/violation/ termination:**

1. **Protocol Title:** A phase II/III, multicenter, randomized, open label, active controlled, clinical study to assess the immunogenicity and safety of tetanus toxoid, diphtheria toxoid, and acellular pertussis (Tdap) vaccine manufactured by Serum institute of India Pvt. Ltd. (SIIPL) in comparison with Boostrix® vaccine of GSK in healthy adults, adolescents and children in India.
   Protocol Identifier: SII-Tdap/IN-02 V- 2.0 dated 14 Jun 2018
   Dr. N S Mahantshetti- PI
   - IEC notification of Protocol Deviation for visit out of window period dated on 25 Jun 2020

2. **Protocol No.:** CT-P16 3.1
   Protocol Title: A Double-Blind, Randomized, Active-Controlled, Parallel-Group, Phase 3 Study to Compare Efficacy and Safety of CT-P16 and EU-Approved Avastin® as First-Line Treatment for Metastatic or Recurrent Non-Squamous Non-Small Cell Lung Cancer

Dr. Mahesh kalloli- PI

- IEC notification of Protocol Deviations of subject no 51340001 letter dated: 16-Apr-2020

3. **Protocol Title:** A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of Bempedoic acid (ETC-1002) on the occurrence of major cardiovascular events in patients with or without, or at high risk for, cardiovascular disease who are statin intolerant
   Protocol Number: 1002-043
   Dr.V.A. Kothiwale -PI
   - IEC notification for the protocol deviation letter for subject no 4328011007 dated: 25-Jun-2020
   - IEC notification for the protocol deviation letter for subject no 4328011002 dated: 25-Jun-2020

4. **Protocol Title:** A randomized, Multi-Centre, open label, two-arm, parallel, clinical study to evaluate the efficacy, safety and tolerability of tacrolimus lipid suspension for enema of Intas Pharmaceuticals Limited, India against CORTENEMA® (Hydrocortisone retention enema) of Anip Acquisition Company, USA in adult patients with mild to moderately active left-sided/distal ulcerative colitis refractory to mesalamine treatment.
   Protocol No: 0979-17
   Dr. Santosh Hazare- PI
   - IEC Notification of Protocol Deviation for subject 107-0979-17-04letter dated: 02-Jun-2020
   - IEC Notification of Protocol Deviation for subject 107-0979-17-05letter dated: 02- Jun -2020
   - IEC Notification of Protocol Deviation for subject 107-0979-17-07letter dated: 02- Jun -2020
   - IEC Notification of Protocol Deviation for subject 107-0979-17-08letter dated: 02- Jun-2020
   - IEC Notification of Protocol Deviation for subject 107-0979-17-09 letter dated: 02- Jun-2020

5. **Protocol Title:** A Prospective, Multi-Centric, Randomized, Double-Blind, Parallel, Phase-III Study to Assess Efficacy of PMZ-2010 as a Resuscitative Agent for Hypovolemic Shock to be Used as an Adjuvant to Standard Shock Treatment.
   Protocol No: PMZ-1620/CT-3.1/2019, V 1.0/ 29 APRIL2019
   Dr. Sameer Haveri- PI
   - IEC Notification of Protocol Deviation for subject 07-002 letter dated: 21-Mar-2020

6. **Protocol Title:** A Comparative, Randomized, Two Arm, Double Blind, Parallel Group, Multicentric, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Netarsudil Ophthalmic Solution 0.02% w/v Versus Timolol Maleate Eye Drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension."
   Protocol No: APL/CT/18/03
   Dr. Smitha KS- PI
   - IEC Notification of Protocol Deviation for subject 06-001 letter dated: 05-Jun-2020
   - IEC Notification of Protocol Deviation for subject 06-002 letter dated: 05-Jun-2020

7. **Protocol Title:** A Randomized, Active-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Sulbactam-ETX2514 in the Treatment of Patients with Infections Caused by Acinetobacter baumannii- calcoaceticus Complex
   Protocol No: CS2514-2017-0004
   Dr.Jayaprakash Appajigol- PI

- IEC Notification of Protocol Deviation for subject 356-005-004 letter dated: 11-JUNE-2020

VI. **Study Closeout:**

- **Nil**

VII. **The Committee will consider the following agendas which are for information.**

1. **Protocol Title**: A phase II/III, multicenter, randomized, open label, active controlled, clinical study to assess the immunogenicity and safety of tetanus toxoid, diphtheria toxoid, and acellular pertussis (Tdap) vaccine manufactured by Serum institute of India Pvt. Ltd. (SIIPL) in comparison with Boostrix® vaccine of GSK in healthy adults, adolescents and children in India.
   Protocol Identifier: SII-Tdap/IN-02 V- 2.0 dated 14 Jun 2018
   Dr. N S Mahantshetti- PI
   - IEC notification of subject discontinuation in later dated 20 Jun 2020

2. **Protocol No/Title:** MYL-TLE 400-4001-"Multicenter, open label, randomized prospective, phase IV, interventional, non-inferiority study with blinded assessment, to evaluate the efficacy and safety of fixed dose combination (FDC) of tenofovir/Lamivudine/low dose Efavirenz(300/300/400mg) Vs. FDC of Tenofovir/Lamivudine//Efavirenz(300/300/600mg) in adult Indian patients who have HIV-1 infection".
   Dr. Dnyanesh Morkar- PI
   - IEC Notification of COVID -19 Checklist in later dated 30 June 2020

3. **Protocol No: 20140315**
   Protocol Title: Phase 3, randomized, open label, controlled, multiple-dose, efficacy, safety, pharmacokinetic and Pharmacodynamic study of etecalctide in pediatric subjects 28 days to <18 years of age with hyperparathyroidism and chronic kidney disease receiving maintenance hemodialysis
   Dr.Mahantesh Patil -PI
   - IEC notification of updated CRF letter dated 27 Jun 2020

4. **Protocol No:** LUF-44-001
   Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study
   Dr. Naveen Mullimani -PI
   - IEC notification of Methods of patient accrual letter dated: 18-Jun-2020

5. **Protocol No:** SII-Apenta/IN-02
   Protocol Title: A phase II/III, Multicentre, Randomized, open label, active-controlled study to assess the immunogenicity and safety of DTaP-IPV+Hib vaccine manufactured by serum institute of India Pvt.Ltd in comparison with pentaxim® in Indian toddlers and infants
   Dr.N.S.Mahantashetti -PI
   - IEC submission of continuation letter dated: 07-May-2020

6. **Protocol Title:** A Randomized double-blind placebo-controlled multicenter Phase 3 study of efficacy and safety of AR-301 as adjunct therapy to antibiotics in the treatment of Ventilator-Associated Pneumonia (VAP) caused by *S. aureus*
   Protocol Number: AR-301-002
   Dr. Jayapraksh Appajigol- PI
   - IEC notification of study documents and COVID guidelines Letter Dated 14-april-2020
   - IEC submission of additional documents letter dated 28 May 2020
   - IEC notification of updated investigators brochure letter dated 5 June 2020

7. **Protocol No:** RLS/DRM/2018/04; Version 2.0, Dated: 26 Jul 2019
   Protocol Title : Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-046/Stelara® in patients with moderate to severe plaque psoriasis
   Dr.Shiv kumar Patil-PI
   - IEC notification of documents letter dated:17-Jun-2020

8. **Protocol No:** 20140444
   Drug: Denosumab
   Protocol Title: A Phase 3 randomized, Double-blind, Placebo-Controlled, Parallel-group Study to evaluate the safety and Efficacy of Denosumab in pediatric Subjects with Glucocorticoid-induced Osteoporosis.
   Dr N S Mahantshetti-PI
   - IEC Submission of new CDSCO guidelines on conduct of clinical trials during COVID-19 pandemic letter dated 27 may 2020

9. **Protocol No :** 0137-18
   Protocol Title : A multicentric, open-label, multiple dose, balanced, randomized, two-treatment, two-Period, two-Sequence, full replicate, cross over study to evaluate bioequilance of Etoposide Capsules 100 mg (Intas Phramaceuticals Ltd. India) with Vepesid soft capsules 100 mg (Bristol-Myers Squibb S.r.l Itlay) in patients with metastatic small cell lung cancer(SCLC) under fasting conditions.
   Dr.Mahesh Kalloli -PI
   - IEC notification of study related documents letter dated: 8-Jun-2020

10. **Protocol No.** TX05-03 E amendment dated 01dated13 Dec 2018
    Protocol Title: A double-blinded extension study to provide adjuvant treatment with single agent Herceptin® or TX05 and assess continued safety and immunogenicity in subjects with HER2-positive early breast cancer following neoadjuvant treatment and surgical resection in Protocol TX05-03
    Dr.Mahesh Kalloli -PI
    - IEC notification of Informed consent documents v 3.0 letter dated: 09-june-2020
    - IEC notification of DCGI Acknowledgement of CTA, EC approval letter and ICF V 2.0 letter dated: 09-june-2020
    - IEC notification of change in protocol title and protocol no in EC Approval (letter dated 6/2/2020) dated 28 may 2020

11. **Protocol Title:** Prominent: Pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes.
Protocol No: K-877-302
Dr.V.A. Kothiwale-PI
    - IEC notification of CIOMS letter dated: 23 jun-2020
    - letter dated: 24 jun-2020
    - letter dated: 26 jun-2020
    - letter dated: 30 jun-2020
    - letter dated: 01 jul-2020
    - letter dated: 02 jul-2020
    - letter dated: 03 jul-2020
    - Investigator notification of six monthly line listing (6MLL) dated 2 Jul 2020

12. **Protocol Title:** A Multicentre, Open label, Balanced, Randomized, Two-treatment, Two-period, Single dose, Crossover, Bioequivalence study of Bortezomib for Injection 3.5 mg/vial of Dr. Reddy's Laboratories Limited, India and VELCADE® (bortezomib) for Injection 3.5 mg/vial (Distributed and Marketed by: Millennium Pharmaceuticals, Inc., 40 Landsdowne Street, Cambridge, MA 02139) in previously untreated Multiple Myeloma and/or Relapsed Multiple Myeloma patients
Protocol No: 17-VIN-0772
Dr. Rohan Bhise- PI
    - IEC notification of CIOMS letter dated: 27-May-2020

13. **Protocol No:** 20150238
Protocol Title: A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism
Dr. Ritesh Vernekar - PI
    - IEC notification of PEED for the subject no: 23830016003 letter dated: 11-Mar-2020
    - IEC notification of approval of remote SDV letter dated 29 May 2020

14. **Protocol Title:** "A Multicenter, Open-label, Single-arm, Study to Evaluate Safety and Tolerability of Repatha in Patients with Homozygous Familial Hypercholesterolemia (HoFH) in India"
Study Number: 20170199
Dr. V.A.Kothiwale- PI
    - IEC notification of CSR letter dated: 10-Jun-2020

15. **Protocol No:** CT/P015/CMR/16/03_01
Protocol Title: A phase III randomized, double Blind, parallel Group, placebo-controlled, Multi center, Multinational study to evaluate efficacy and safety of TRC150094 as an add on to standard of care in improving cardiovascular risk in subjects with diabetes dyslipidemia and hypertension.
Protocol No: CT/P015/CMR/16/03_01
Dr.Vikrant Ghatnatti –PI
    - IEC notification of SUSAR letter dated: 01-Jun-2020

16. **Protocol No**: PMZ-1620/CLINICAL-2.3/2018, v 2.0/05 Jul 2018
Study Protocol No.: PMZ-1620/CLINICAL-2.3/2018;DCGICTNOC No.:CT/ND/18/2018
Study Title: A Prospective, Multicentric, Randomized, Double Blind, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Patients of Acute Spinal Cord Injury
Dr.Sameer Haveri - PI
    - IEC Notification of final CRF Letter Dated: 06-Jun-2020

17. **Protocol No: TDM1.17.001.03**
Protocol Title : A prospective, randomized, multi center. Comparative. Open label, parallel study to evaluate the efficacy, safety and pharmacokinetics to Test- Trastuzumab Emtanstine (ZRC-3256 ; Cadila Healthcare Ltd)and Reference – Trastuzumab Emtanstine (Kadcyla®, a Product of Roche) in HER2 – positive metastatic Breast Cancer Patients.
Dr.Mahesh Kalloli –PI
    - IEC notification of protocol deviation, AE and lost to follow up letter dated 29 may 2020
    - IEC notification of review of undertaking by investigator letter dated 10 Jun 2020

18. **Protocol No:** 0586-18_ version 1.1 dated 25 Jul 2019
Protocol Title : A Randomized, Double- Blind, Multicentre, Mutinational Comparative Clinical Study To Compare The Effciacy And Safetyof INTP24 Against Avastin ® In Pateints With Unresectable, Locally Advanced, Recurrent Or Metastatic No-Sqaumous Non Small Cell Lung Cancer.
Dr.Mahesh Kalloli -PI
    - IEC notification of source template letter dated: 06-May-2020

19. **Protocol No:** 20160372
Protocol Title: Post Marketing Phase-4 Study To Evaluate Safety, Tolerability, And Efficacy Of Kyprolis® (Carfilzomib) In Indian Patients With Relapsed Or Refractory Multiple Myeloma: A Prospective, Open-Label, Non-Comparative, Multicentre Study
Dr. Rohan Bhise-PI
    - IEC notification of MEMO Novel coronavirus outbreak letter dated 10 Apr 2020

20. **Protocol No:** DMPL/P05-2017/CT/VN V2.0, Date-30.03.2018 titled "A post marketing surveillance study (PMS) to evaluate safety and tolerability of VELNEZ as nasal pack after nasal surgery"
Dr. Shama Bellad-PI
    - IEC notification of extension of insurance letter dated 27 Apr 2020

21. **Protocol No:** APL/CT/18/03
Protocol Title: A Comparative, Randomized, Two Arm, Double Blind, Parallel Group, Multicentric, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Netarsudil Ophthalmic Solution 0.02% w/v Versus Timolol Maleate Eye Drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension."
Dr. Smitha KS-PI
    - IEC notification of DCGI letter regarding conduct of clinical trial in present COVID -19 situation letter dated 05 Jun 2020

22. **Protocol No:** EFC14828_ Amplitude

Protocol Title: A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes Patients at High Cardiovascular Risk.

Dr. Prasad M R-PI

- IEC notification of document "study participation written notice "letter dated 05 Jun 2020

Yours truly

Prof.(Dr).M.S.Ganachari
Member Secretary of IEC

Prof. (Dr) M. S. Ganachari
Member Secretary - Institutional Ethics Committee
KLE Academy of Higher Education and Research

To:

Circular and Submission of IEC Dossier		
1)	**Dr. Subarna Roy,** Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi	Chairperson
2)	**Dr. Harsha V.Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** Prof of Pharmacology [USM-KLE] IMP, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
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6)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
7)	**Dr.Nayana Hashilkar,** Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
8)	**Mrs.Vaishnavi V Kivadasannavar,** M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member

9)	**Shri.Tammanna Dadu Kore,** Farmer, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
10)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
11)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, KLE College of Pharmacy, Belagavi	Assistant Coordinator
12)	**Prof.(Dr.) M.S.Ganachari,** Prof & HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
13)	**Dr.Sapna K,** Radiation Oncologist, Belgaum Cancer Hospital, Belgaum	Independent Consultant
14)	**Dr.V.A. Kothiwale,** Dept of General Medicine, KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi-10	Subject Expert
	Administrators of KAHER(Deemed to University)	
1)	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
	Principal Investigator	
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2)	**Dr.Rohan Bhise,** Medical Oncologist, KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi-10	Circular
3)	**Dr.Archana Uppin,** Dept. of Orthopedics, KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi-10	Circular
4)	**Dr.Shivakumar Patil,** Consultant Dermatologist, KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi-10	Circular
5)	**Dr.Sameer Ambar,** Consultant Cardiologist, KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi-10	Circular

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Ref: KAHER/IEC/2019-20/D- 23662013 **Date:** 17/06/2020

Accreditations

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Registrations

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Meeting Agenda

Institutional Ethics Committee of KAHER, Belagavi

Friday 26/Jun/2020, At: 03.30 PM

Venue: Through Go to Meeting Application/and or KLE Site Management Office [Offline]

I. New agendas for review and approval:[Presentation from the PIs]

1. **Protocol Title:** A Randomized double-blind placebo-controlled multicenter Phase 3 study of efficacy and safety of AR-301 as adjunct therapy to antibiotics in the treatment of Ventilator-Associated Pneumonia (VAP) caused by *S. aureus*
   Protocol Number: AR-301-002
   Dr.Jayaprakash Appajigol-PI – Project Number: **72067**]
   Timings: 03:45 to 04:00 PM
   - Submitted for IEC Review and approval on 11-Feb-2020

2. **Protocol:** 0568-18
   Protocol Title: A multicentric open label, balanced, randomized, two treatment, two period, two sequence, crossover, steady state, dosage strength equivalence study of clozapine extended release capsule 25 mg (lowest strength, 25 mg X 8 capsules) once daily (Test drug, Intas pharmaceuticals limited, India) with clozapine extended release capsule 200 mg (highest strength) once daily (Test drug, Intas pharmaceuticals limited, India) after multiple dose administration in adult schizophrenic patients under fasting conditions
   Dr.Sameeran Chate-PI [Project Number: **87294**]
   Timings: 04:00 to 04:15 PM
   - Submitted for IEC Review and approval on 26-Dec-2019

3. **Protocol Title**: A phase III, two arm, multi centric, randomized, open label, parallel study to compare pharmacodynamics of Goserelin 10.8 mg Injection (Eurofanna Laboratories S.A) administered subcutaneously with the reference drug ZOLADEX® 10.8 mg Injection (AstraZeneca) in patients with advanced prostate cancer.
   Protocol No: 1045-18
   Dr.Vikram Prabha-PI [Project Number: **85452**]
   Timings: 04:15 to 04:30 PM
   - Submitted for IEC Review and approval on 06-Jan-2020

4. **Protocol Title:** A randomized, open label, balanced, multicenter, tow-treatment, tow- period, two sequence, Two-way crossover, single dose, bioequilance study with pharmacokinetic endpoints of paclitaxel protein-Bound particles for injectable suspension (albumin Bound) 100 mg/vial at a dose of 260 mg/m2 of Ningo shouzheng Medicinal Research co., Ltd. With ABRAXANE® for injectable suspension (albumin Bound) 100 mg/vial at a dose of 260 mg/m2 of Celgene corporation, summit, NJ 07901 in breast cancer subjects after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy under fasting conditions.
   Dr.Rohan Bhise-PI [Project Number: **95821**]
   Timings: 04:30 to 04:45 PM
   - Submitted for IEC Review and approval on 14-Jan-2020

★Please note project number represents the online submitted protocol no's [eEC Software]

II. **Review of Proposals with Amendments:**

1. **Protocol No: 201790**

   Protocol Title: A 52-week, phase 3, multi centre, randomised, double-blind, efficacy and safety study comaparing GSK3196165 with placebo and with tofacitinib, in combination with methotrexate in participants with moderately to severely active rheumatoid arthritis who have an inadequate response to methotrexate

   Dr.Archana Uppin-PI

   - Submitted for IEC Review and approval on 05-Feb-2020

2. **Protocol Title:** A phase II/III, Multicentre, Randomized, open label, active-controlled study to assess the immunogenicity and safety of DTaP-IPV+Hib vaccine manufactured by serum institute of India Pvt.Ltd in comparison with pentaxim® in Indian toddlers and infants

   Protocol No: SII-a PENTA/IN-02

   Dr.N.S.Mamahatshetti-PI

   - Version 2.0 dated: 06-Feb-2020 Submitted for IEC Review and approval on 07-May-2020

3. **Protocol Title:** Prominent: Pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes.

   Protocol No: K-877-302

   Dr.V.A. Kothiwale-PI

   - Patient material submitted for review and approval letter dated 24-Feb-2020

III. **Review of Proposal Revised Protocol:**

- Nil

IV. **Review of Annual Report:**

- Nil

III. **Review of Bi-Annual Report:**

1. **Protocol No**: SAMSON-II

   Protocol Title: A Randomized, Double-blind, Parallel Group, Equivalence, Multicentre Phase III Trial to Compare the Efficacy, Safety, Pharmacokinetics and Immunogenicity of HD204 to Avastin® in patients with Metastatic or Recurrent Non-Squamous Non-Small Cell Lung Cancer

   Dr. Rohan Bhise- PI

   - IEC Submission of Study Status Biannual Report Letter Dated: 12 May 2020

IV. **SAE reporting**

- Nil

V. **Protocol deviation/violation/ termination:**

1. **Protocol Title**: I4V-MC-JADY (h): A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis

   Protocol No: 14-MC-JADY

   Dr.Shailesh Udapudi-PI

- IEC notification of Protocol Deviation[Late submission of SAFRNs Report] letter dated: 22-May-2020

2. **Protocol No.:** PMZ-1620/CLINICAL-2.3/2018;DCGICTNOC No.:CT/ND/18/2018
   Protocol Title: A Prospective, Multicentric, Randomized, Double Blind, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Patients of Acute Spinal Cord Injury
   Dr. Sameer Haveri- PI
   - IEC notification of Protocol Deviation for subject 05-005 letter dated: 21-May-2020
   - IEC notification of Protocol Deviation for subject 05-007 letter dated: 23-May-2020
   - IEC notification of Protocol Deviation for subject 05-008 letter dated: 23-May-2020

3. **Protocol Title:** A randomized, double-blind, placebo-controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhea in children.
   Protocol No: LPS14914/KIDDIE
   Dr.Mahantesh Patil-PI
   - IEC notification for the protocol deviation of subject no:356002000001 and 2 letter dated: 13-May-2020
   - IEC notification for the protocol deviation of subject no:356002000001 and 2 letter dated: 13-May-2020

4. **Protocol Title:** A Randomized, Active-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Sulbactam-ETX2514 in the Treatment of Patients with Infections Caused by Acinetobacter baumannii- calcoaceticus Complex. **Protocol No**: CS2514-2017-0004
   Protocol No: CS2514-2017-0004
   Dr. Jayapraksh Appajigol- PI
   - IEC Notification of Protocol Deviation for subject 356-005-003 letter dated: 18-May-2020
   - IEC Notification of Protocol Deviation for subject 356-005-004 letter dated: 18-May-2020

VI. Study Closeout:

- **Nil**

VII. The Committee will consider the following agendas which are for information.

1. **Protocol Title:** A Randomized, Active-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Sulbactam-ETX2514 in the Treatment of Patients with Infections Caused by Acinetobacter baumannii- calcoaceticus Complex.
   Protocol No: CS2514-2017-0004
   Dr. Jayapraksh Appajigol- PI
   - IEC Notification of Enrollment Hold in India due to COVID-19 letter dated: 07-May-2020
   - IEC Notification of Travel expenses for subject no:356-005-004 due to COVID-19 letter dated: 07-May-2020
   - IEC notification of IU letter dated: 11-May-2020
   - IEC Notification of Safety report letter dated: 05-May-2020

2. **Protocol no:** RLS/RES/2016/01: version 1.0, Administrative Amendment 1.0 dated: 8 Jun 2017
Protocol title: Prospective, multi-Centre, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-022/Xolair® in patients with moderate to severe persistent asthma.
Dr. Jyoti Hattiholi- PI
    - IEC Notification of Clinical study report- Omalizumab version 2.0 dated 06 Mar 2020 letter Dated:14 Mar 2020

3. **Protocol No: TDM1.17.001.03**
Protocol Title : A prospective, randomized, multi center. Comparative. Open label, parallel study to evaluate the Efficacy, Safety and pharmacokinetics to Test- Trastuzumab Emtanstine (ZRC-3256 ; Cadila Healthcare Ltd) and Reference – Trastuzumab Emtanstine (Kadcyla®, a product of Roche) in HER2 – positive metastatic Breast Cancer Patients.
Dr.Maheshkumar Kalloli-PI
    - IEC notification of renewed insurnace [valid through 19/03/2021] letter dated : 20-Mar-2020

4. **Protocol Title:** A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes Patients at High Cardiovascular Risk.
Protocol number: EFC14828/Amplitude-O
Dr. Prasad MR-PI
    - IEC notification DTP ICF letter dated: 20-Apr-2020

5. **Protocol Title:** A randomized, double-blind, placebo-controlled, parallel group, muticenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhea in children.
Protocol No: LPS14914/KIDDIE
Dr.Mahantesh Patil-PI
    - IEC notification for study biannual report letter dated: 13-May-2020

6. **Protocol Title:** ACTION-II TRIAL-A65916: A multi-country, multi-centre, two-arm, parallel, double-blind, placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in the late preterm period in hospitals in low-resource countries to improve new-born outcomes".
Dr. Shiva Prasad Goudar- PI
    - IEC Notification of DSMB Letter Dated 01-Jun-2020

7. **Protocol Title:** "Sit Down and Play"
Dr.S.M.Dhaded-PI
    - IEC notification of Subject recruitment strategy in view of COVID-19 letter dated:12-Jun-2020

8. **Protocol Title**: A phase II/III, multicenter, randomized, open label, active controlled, clinical study to assess the immunogenicity and safety of tetanus toxoid, diphtheria toxoid, and acellular pertussis (Tdap) vaccine manufactured by Serum institute of India Pvt. Ltd. (SIIPL) in comparison with Boostrix® vaccine of GSK in healthy adults, adolescents and children in India.
   Protocol Identifier: SII-Tdap/IN-02 V- 2.0 & 14 Jun 2018
   Dr.N.S.Mahantashetti-PI
   - IEC notification of Post vaccination blood sample collection letter dated: 26-May-2020
   - IEC notification of updated CTRI and insurance [valid through -28-02-2021] letter dated: 16-Mar-2020

9. **Protocol Title:** Post Marketing Phase-4 Study To Evaluate Safety, Tolerability, And Efficacy Of Kyprolis® (Carfilzomib) In Indian Patients With Relapsed Or Refractory Multiple Myeloma: A Prospective, Open-Label, Non-Comparative, Multicentre Study
   Protocol No: 20160372
   Dr.Rohan Bhise-PI
   - IEC notification of remote source data review and verification letter dated: 27-May-2020

10. **Protocol No:** NCS-549-17-CS
    Protocol Title: An open label, multicenter, randomized, balanced, two-treatment, two-period, two-sequence, single-dose, crossover, oral bioequivalence study of Methotrexate Tablets, USP 2.5mg from Lotus Pharmaceutical Co., Ltd., Taiwan compared with that of Methotrexate Tablets, USP 2.5 mg manufactured for DAVA Pharmaceuticals, Inc., in adult patients with mild to severe psoriasis or rheumatoid arthritis under fasting conditions.
    Dr. Archana Uppin- PI
    - EC Notification of Clinical study report Letter Dated:19-Mar-2020

11. **Protocol Title**: I4V-MC-JADY (h): A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis
    Protocol No: 14-MC-JADY
    Dr.Shailesh Udapudi-PI
    - IEC notification of last to follow up of the subject no:53824 (SSH) letter dated: 11-May-2020

12. **Protocol No:** XBR1001
    Protocol No: Xplore: A Phase III Double-Blind, Parallel Group, Multicenter Study to Compare the Efficacy and Safety of Xlucane versus Lucentis® in Patients with Neovascular Age-Related Macular Degeneration
    Dr.Smitha Prabhu-PI
    - IEC notification of study related documents letter dated: 11-Apr-2020

13. **Protocol Title:** Prominent: Pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes.
    Protocol No: K-877-302
    Dr.V.A. Kothiwale-PI
    - IEC notification of CIOMS letter dated: 06-Mar-2020

14. **Protocol:** An open label extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in Etrolizumb phase II/III studies.
    Protocol No: GA28951- Version 6 Dated 22 Oct 2015.

Dr. Vardaraj Pralhadarao Gokak- PI

- IEC notification of Biannual report letter dated: 14-May-2020

15. **Protocol No:** 20150238
Protocol Title: A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism
Dr. Ritesh Vernekar - PI
    - IEC approval of remote SDV letter dated: 29-May-2020
    - IEC notification of PEED for the subject no: 23830016005 letter dated: 11-mar-2020
    - IEC notification of Biannual report letter dated: 23-Mar-2020
    - IEC notification of Monitoring Discrepancies letter dated: 26-Apr-20 and notified on 10-Mar-2020
    - IEC notification of QLL-1 for the Indian SAE's: (Non-SUSAR's) letter dated on 28-May-2020

16. **Protocol No.:** PMZ-1620/CLINICAL-2.3/2018;DCGICTNOC No.:CT/ND/18/2018
Protocol Title: A Prospective, Multicentric, Randomized, Double Blind, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Patients of Acute Spinal Cord Injury
Dr. Sameer Haveri- PI
    - IEC notification of centralized Monitoring letter dated: 20-May-2020

17. **Protocol No: PMZ-1620/CT-3.1/2019; CT NOC No. CT/ND/66/2019**
Protocol Title: A Prospective, Multi-Centric, randomized, Double-blind, Parallel, Phase-III Clinical Study to Assess Efficacy of PMZ-1620 along with Standard Treatment in patients of Acute Ischemic Stroke.
Dr.Saroja O.A –PI
    - IEC notification of Centralized Monitoring letter dated: 20-May-2020
    - IEC notification of Withdrawal Consent of subject no:07-002 letter dated: 20-May-2020

18. **Protocol No:** 1002-043
Protocol Title: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of Bempedoic acid (ETC-1002) on the occurrence of major cardiovascular events in patients with or without, or at high risk for, cardiovascular disease who are statin intolerant
Dr.V.A Kothiwale - PI
    - Ethics Committee Notification of CIOMS Letter Dated: 28-May-2020

Yours truly

Prof.(Dr).M.S.Ganachari
Member Secretary of IEC

Prof. (Dr) M. S. Ganachari
Members Secretary, Institutional Ethics Committee
KLE Academy of Higher Education and Research, Belagavi

To:

Circular and Submission of IEC Dossier		
1)	**Dr. Subarna Roy,** Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V.Hegde**, Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** Prof of Pharmacology [USM-KLE] IMP, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar,** Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
6)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
7)	**Dr.Nayana Hashilkar,** Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
8)	**Mrs.Vaishnavi V Kivadasannavar,** M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
9)	**Shri.Tammanna Dadu Kore,** Farmer, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
10)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
11)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, KLE College of Pharmacy, Belagavi	Assistant Coordinator
12)	**Prof.(Dr.) M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
13)	**Dr.Sapna K,** Radiation Oncologist, Belgaum Cancer Hospital, Belgaum	Independent Consultant
Administrators of KAHER(Deemed to University)		
1)	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi-For Information	Circular
Principal Investigator		
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4)	**Dr.Vikram Prabha** Consultant Urologist, KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi-10	Circular

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Ref: KAHER/IEC/2020-21/D- 07112-0003

Date: 02/Nov/2020

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Meeting Agenda

Institutional Ethics Committee of KAHER, Belagavi – Thursday, 12/Nov/2020, At: 03.30 PM

Venue: KLE Site Management Office, KLES.Dr.Prabhakar Kore Hospital and MRC, Belagavi-10

I. New agendas for review and approval:[Presentation from the PIs]

1. **Protocol Title:** A Multicenter, Randomized, Double-Blind, Parallel-Group Study to Assess the Efficacy and Safety of Oral Etrasimod as Induction and Maintenance Therapy for Moderately to Severely Active Crohn's Disease

   Protocol No: APD334-202

   Dr.Santosh Hazare-PI

   Timings: 03:45 to 04:00 PM

2. **Protocol Title**: A prospective, interventional, randomized, double-blind, placebo-controlled study to evaluate the safety and effectiveness of IND02 capsules (Cinamune™) in hospitalized SARS-CoV2 positive patients with mild to moderate COVID-19, managed as per the Government of India COVID-19 management guidelines, at COVID-19 management centers offering integrated Ayurvedic care

   Protocol Identifier: IND02-ORAL-COVID-19

   Dr.Jayaprakash Appajigol-PI

   Timings: 04:00 to 04:15 PM

3. **Protocol No/Title: A** Phase-II clinical study to evaluate the efficacy and safety of NRC-2694-A in patients with Recurrent Head and Neck Squamous Cell Carcinoma

   Protocol Version and Date: V and 12-Dec-2019

   Dr.Mahesh kalloli-PI

   Timings: 04:15 to 04:30 PM

4. **Protocol Number:** 209564

   Protocol: A multi-centre long-term extension study to assess the safety and efficacy of GSK3196165 in the treatment of rheumatoid arthritis.

   Dr.Archana Uppin-PI

   Timings: 04:30 to 04:45 PM

II. **Review of Proposal Revised Protocol:**

- **Nil**

III. **Review of Protocol Amendments:**

- **Nil**

IV. **Review of Annual Report:**

1. **Protocol No: TX05**

   Protocol Title: Randomized, Double blind, parallel group phase III trial to compare the efficacy, safety and immunogenicity of TX05 with Herceptin in subject with HER2 positive early breast cancer

   Dr. Mahesh Kalloli-PI

   - IEC Notification of clinical trial update and request for continuation of One Year letter Dated 1-Oct -2020

2. **Protocol No**: SAMSON-II

   Protocol Title: Randomized double blind, Parallel group, and equivalence, Multicenter Phase III trial to compare the efficacy, safety, pharmacokinetics and immunogenicity of HD204 to Avastin® in patients in meta-static or recurrent non squamous non-small cell lung cancer

   Dr.Rohan Bhise-PI

   - IEC submission of study annual progress report

3. **Protocol No:** ALK18/ENZ124-CET1

   Protocol Title: Prospective, multi Centre, randomized, double blind, parallel group study to compare efficacy and safety of bio similar cetuximab versus innovator cetuximab in combination with platinum based chemotherapy in patients with recurrent loco regional of metastatic Squamous cell carcinoma of the head and neck (SCCHN)

   Dr. Mahesh Kalloli-PI

   - IEC submission of study annual report letter dated 12-Sep-20

4. **Protocol No:** 0978-17

   Protocol Title: a Randomized, Double Blind, Double-Dummy, Multi Center, Parallel, Phase III Study to Evaluate the Efficacy and Safety of Tacrolimus Lipid Tablets (Manufactured by Intas Pharmaceuticals Ltd) Compared to Prograf (Tacrolimus Immediate Release Capsules-Astellas Pharma Canada, Inc) in Adult Patients with Active Rheumatoid Arthritis Who Have Resistance OR Intolerance to DMARDs.

   Dr. Archana Uppin-PI

   - **IEC Notification** of Progress report Letter dated: 04-Jun-20

5. **Protocol No: 0979-17**

Protocol Title: A randomized, multi-centre, open label, two-arm, parallel, clinical study to evaluate the efficacy, safety and tolerability of tacrolimus lipid suspension for enema of Intas Pharmaceuticals Limited, India against CORTENEMA® (Hydrocortisone retention enema) of Anip Acquisition Company, USA in adult patients with mild to moderately active left-sided/distal ulcerative colitis refractory to mesalamine treatment.

Dr. Santosh Hajare-PI

- IEC notification of progress report Letter dated:24-Aug-20

V. **Review of Bi-Annual Report:**

6. **Protocol Title:** Prominent: Pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes.

Protocol No: K-877-302
Dr.V.A. Kothiwale-PI

- IEC Submission of study status biannual report Letter dated 20-Feb-20

7. **Protocol No:** 1002-043

Protocol Title: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at High Risk For, Cardiovascular Disease Who Are Statin Intolerant
Dr.V.A. Kothiwale-PI

- IEC Submission of study status biannual report Letter dated:02-Sep-20

VI. **SAE reporting:**

1. **Protocol No:** 1002-043

Protocol Title: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at High Risk For, Cardiovascular Disease Who Are Statin Intolerant

Dr.V.A.Kothiwale-PI

- IEC Notification of SAE Follow up letter for the subject no:4328011002- Event- Cardiogenic Shock letter dated: 20-Jul-20

2. **Protocol No:** 14 V-MC-JADY

Protocol Title: A Phase III multicenter study to evaluate the long term Safety and efficacy of Barcitinib in patient with Rheumatoid Arthritis

Dr.Shailesh V Udapudi-PI

- IEC Notification of SAE final report Letter dated on 16-Oct-2020

VII. Protocol deviation/violation/ termination:

1. **Protocol No.** TX05-03 E amendment dated 01dated13 Dec 2018

   Protocol Title: A double-blinded extension study to provide adjuvant treatment with single agent Herceptin® or TX05 and assess continued safety and immunogenicity in subjects with HER2-positive early breast cancer following neoadjuvant treatment and surgical resection in Protocol TX05-03

   Dr. Mahesh Kalloli-PI

   - IEC Notification of Protocol Deviation Letter Dated 04-Sep-2020

2. **Protocol No:** CQGE031C2302

   Protocol Title: A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines

   Dr. Shivkumar k Patil

   - IEC Notification for protocol deviation due to Covid 19 Situation letter Dated 22-Sep-2020

3. **Protocol No: 0978-17**

   Protocol Title: a Randomized, Double Blind, Double-Dummy, Multi Center, Parallel, Phase III Study to Evaluate the Efficacy and Safety of Tacrolimus Lipid Tablets (Manufactured by Intas Pharmaceuticals Ltd) Compared to Prograf (Tacrolimus Immediate Release Capsules-Astellas Pharma Canada, Inc) in Adult Patients with Active Rheumatoid Arthritis Who Have Resistance OR Intolerance to DMARDs.

   Dr. Archana Uppin-PI

   - IEC notification of protocol deviation letter dated 20-Sep2020

4. **Protocol No: SII- Tdap/IN-02**

   Protocol Title: A phase II/III, multicenter, randomized, open label, active controlled, clinical study to assess the immunogenicity and safety of tetanus toxoid, diphtheria toxoid, and acellular pertussis (Tdap) vaccine manufactured by Serum institute of India Pvt. Ltd. (SIIPL) in comparison with Boostrix® vaccine of GSK in healthy adults, adolescents and children in India.

   Protocol Identifier: SII-Tdap/IN-02 V- 2.0 dated 14 Jun 2018

   Dr.(Mrs.)N.S.Mahantashetti-PI

   - IEC notification protocol deviation for visit out of window period letter dated:21-Jul-20

5. **Protocol No: BACE CT-003**

   Protocol Title: Evaluation of Safety and efficacy of the BACE™ [Basal Annuloplasty of the cardia externally] device in the treatment of functional mitral valve regurgitation (FMR)

   Dr. Richard Saldanha-PI

   - IEC notification protocol deviation for visit out of window period Letter dated:25-Aug-20

VIII. Study Closeout:

1. **Protocol No**: GRC 27864-201

   Protocol Title: Study protocol GRC27864-201, titled A Phase II dose range finding 12 weeks Double blind, Randomized, parallel group study to evaluate safety and efficacy of GRC27864 in patients with moderate osteoarthritis pain.

   Dr.Shailesh V Udapudi

   - IEC Notification of clinical trial closure at site letter dated 25 September 2020

2. **Protocol No/Title:** MYL-TLE 400-4001-"Multicenter, open label, randomized prospective, phase IV, interventional, non-inferiority study with blinded assessment, to evaluate the efficacy and safety of fixed dose combination (FDC) of tenofovir/Lamivudine/low dose Efavirenz(300/300/400mg) Vs. FDC of Tenofovir/Lamivudine//Efavirenz(300/300/600mg) in adult Indian patients who have HIV-1 infection".

   Dr.Dnyanesh Morkar-PI

   - IEC Notification of closeout visit letter Dated 28 August 2020

IX. **The Committee will consider the following agendas which are for information.**

8. **Protocol No:** RLS/PMS/2017/01

   Protocol Title: A prospective, multicenter, Phase IV Study to evaluate safety and efficacy of TenecteRel™(tenecteplase manufactured by reliance life sciences pvt.ltd)

   Dr. Sameer Ambar-PI

   - IEC notification for renewal of insurance policy letter[30-Aug-2020 to 29-Aug-21] dated 26-Sep-2020

9. **Protocol No: TX05**

   Protocol Title: Randomized, Double blind, parallel group phase III trial to compare the efficacy, safety and immunogenicity of TX05 with Herceptin in subject with HER2 positive early breast cancer

   Dr. Mahesh Kalloli-PI

   - IEC notification of clinical trial update Letter dated 16 Sep 2020

10. **Protocol No:** CT/P015/CMR/16/03_01

    Protocol Title: A phase III randomized Double blind, parallel group, placebo controlled, multicenter, multinational study to evaluate efficacy and safety of TRC150094 as an Add on to standard of care in improving cardiovascular risk in subject with diabetes, Dyslipidemia and Hypertension.

    Dr.Vikranth Ghatnatti-PI

    - IEC notification of IB Version 10.0 dated 21 September 2020
    - IEC Notification of SUSAR letter dated 21 September 2020

11. **Protocol No:** SAMSON-II

Protocol Title: Randomized double blind, Parallel group, equivalence, Multicenter Phase III trial to compare the efficacy, safety, pharmacokinetics and immunogenicity of HD204 to Avastin® in patients in meta-static or recurrent non squamous non-small cell lung cancer

Dr. Rohan Bhise-PI

- IEC Notification of pregnant partner ICFs and protocol signature page letter dated 10-Sep-2020

12. **Protocol No:** G7SYN/P-001/2019

Protocol Title: A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Three-arm, Parallel Study to Evaluate the Bioequivalence using Clinical Endpoint of Tretinoin Gel microsphere, 0.08% (Encube Ethical Private Limited, India) to Retin-A Micro® (tretinoin) Gel microsphere, 0.08% (Valeant Pharmaceuticals North America LLC, NJ 08807) in Subjects with Acne Vulgaris.

Dr.Shivakumar K Patil-PI

- IEC Clarification letter for the documents submitted to IEC and correction in th serial number 06 in the initial approval letter dated on 1-Oct-20

13. **Protocol No:** 20150238

Protocol Title: A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism

Dr. Ritesh Vernekar - PI

- IEC Notification of SUSAR letter dated 25-Aug-20

14. **Protocol No:** ALK18/ENZ124-CET1

Protocol Title: Prospective, multi Centre, randomized, double blind, parallel group study to compare efficacy and safety of bio similar cetuximab versus innovator cetuximab in combination with platinum based chemotherapy in patients with recurrent loco regional of metastatic Squamous cell carcinoma of the head and neck (SCCHN)

Dr. Mahesh Kalloli

- IEC review and notification of CIOMS report of subject no 26-001(follow-up-01) Dated 01-Oct 2020.
  - Subject no. 15-004 (Follow-up-01) Dated: 16-Sep-20.
  - Subject no. 02-001 (Initial) Dated: 16-Sep-20.

15. **Protocol No: CLR_18_09**

Protocol Title: Pharmacodynamic bioequivalence of two formulation of Ipratopium Bromide (21mg) HFA in subjects with chronic obstructive pulmonary disease: A randomized observer blind three treatrments, three periods, Six sequences, single dose, Crossover, Placebo and active controlled comparative study.

Dr. Jyothi Hattiholi

- IEC notification of updated IB, updated insurance policy and certificate and COA Letter Dated 22-Sep-20

16. **Protocol No: 17-VIN-0772**

Protocol Title: A multi centre, open label, balanced, randomized, two treatments, two periods, single dose, crossover, bioequivalence study of Bortizomib, for injection, 3.5mg/vial of Dr. Reddys Laboratories ltd, India and VELCADE (Bortizomib) for injection 3.5 mg/vial (distributed and marketed by millennium Pharmaceutical, inc., 40 Landsdowne Street, Cambridge, MA 02139) in previously untreated multiple myeloma and / or relapsed multi myeloma patients.

Dr. Rohan Bhise

- IEC notification of case report form (final version 4.0) Letter Dated 14-Sep-20

17. **Protocol No: D5169C00001**

Protocol Title: A phase III, randomized study of Osimertinib with or without Platinum Plus Pemetrexed Chemotherapy, as First-line treatrment in patients with epidermal growth factor receptor (EGFR) mutation positive, Locally advanced or metastatic Non-small Cell Lung Cancer (FLAURA2).

Dr. Rohan Bhise

- IEC notification of final CTA letter Dated 07 August 2020

18. **Protocol No: 20160372**

Protocol Title: Post marketing phase IV study to evaluate safety, tolerability, and efficacy of Kyprolis® (Carfilzomib) in Indian Patients with relapsed or refractory, multiple Myeloma: A Prospective, non-Comparative multi Centre study

Dr. Rohan Bhise-PI

- IEC Notification of Quarterly line listing (Q2 Year 2020) Letter Dated: 31-Jul-20
- IEC Notification of insurance certificate letter Dated: 16-Jul-20

19. **Protocol No: 0566-18**

Protocol Title: A multi centric, open label, single arm study to evaluate the safety and efficacy of INTP26 (trastuzumab biosimilar) in patient with HER2- over expressing breast (early or Metastatic) cancer or metastatic gastric cancer Version 1.1 Dated 04 June

Dr. Mahesh Kalloli-PI

- IEC Notification of renewed insurance policy Letter Dated 14-Sep-20

20. **Protocol No: PACL-1-19101**

Protocol Title: A randomized, multi Centre, single dose, two treatment, two periods, crossover, bioequivalence study of Mylan Paclitaxel protein bound particle of injectable suspension (Albumin bound) and abraxis bioscience abraxin® for injectable suspension in 110 breast cancer patient after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.

Dr.Mahesh Kalloli-PI

- IEC Notification of DCGI NOC Letter dated: 18-May-20

21. **Protocol Title:** A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes Patients at High Cardiovascular Risk.

Protocol number: EFC14828/Amplitude-O
Dr.Prasad MR-PI

- IEC notification of NTF regarding age discrepancies in 356000100005 Subject Letter Dated:17-Sep-2020
- IEC Notification of study termination
- EC notification of NTF regarding discrepancy in start date of IMP administration of subject 356000100005 in SAE report dated:17-Sep-2020
- IEC notification of CIMOS dated: 25-Sep-20
- IEC Notification of safety alert #80 dated: 25-Sep-20

22. **Protocol No: CTQJ230A12301**

Protocol Title : Multi-center cross-sectional epidemiological study to characterize the prevalence and distribution of lipoprotéine(a) levels among patients with established cardiovascular disease

Dr.Prasad MR-PI

- IEC notification of procedure of trial conduct and monitoring activities dated 22-Sep-20
- IEC Notification of DCGI approval PA Version number 0.2 Dated 22-Sep-20

23. **Protocol Title:** Prominent: Pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes.

Protocol No: K-877-302

Dr.V.A. Kothiwale-PI

- IEC notification of DSMB letter Dated: 03-Sep-20

24. **Protocol No:** RLS/DRM/2018/04; Version 2.0, Dated: 26 Jul 2019

Protocol Title: Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-046 / Stelara® in patients with moderate to severe plaque psoriasis

Dr. Shivkumar K Patil-PI

- IEC Notification of renewed insurance policy Letter Dated:11-Sep-20

25. **Protocol No: 201790**

Protocol No: 201790 Protocol Title: A 52-week, phase 3, multi centre, randomised, double-Blind, Efficacy and Safety study comaparing GSK3196165 with placebo and with tofacitinib, in combination with Methotrexate in participants with moderately to severely active rheumatoid arthrites who have an inadequate response to Methotrexate.

Dr. Archana Uppin-PI

- EC Notification of draft screening visit source document Letter dated: 09-Jul-20

26. **Protocol No:** LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study

Dr.Navin Mullimani-PI

- IEC Notification of SAE Listing for the period between 3rd March 2020 to 2 September 2020 Letter dated: 25-Sep-20

27. **Protocol No: LPS14914/KIDDIE**

Protocol Title: A randomized, double-blind, placebo-controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhoea in children.

Protocol No: LPS14914/KIDDIE.

Dr. Mahantesh Patil-PI

- IEC Notification of clinical study report Letter Dated: 12-Sep-20

28. **Protocol No: 20140444**

Drug: Denosumab
Protocol Title: A Phase 3 randomized, Double-blind, Placebo-Controlled, Parallel-group Study to evaluate the safety and Efficacy of Denosumab in pediatric Subjects with Glucocorticoid-induced Osteoporosis.
Dr.(Mrs.)N.S Mahantshetti-PI

- IEC Notification of SUSARs letter Dated: 26-Aug-20
- IEC Notification of quarterly line listing (Q2 year 2020) Letter Dated: 31-Jul-2020

29. **Protocol No and Title**: I4V-MC-JADY (h): A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis

Dr.Shailesh V Udapudi-PI

- IEC Notification of Reminders on study execution Letter Date: 01-Sep-20
- IEC notification of study team unable to monitor temperature of IMP Dated:10-Sep-20

30. **Protocol Title**: Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-045 / Prolia® in post-menopausal women with osteoporosis.

Protocol No.: RLS/OST/2016/05; Version 3.0, Dated: 21 Dec 20 16
Dr. Sameer Haveri-PI

- IEC Notification of renewed insurance policy Letter dated:07-Sep-20

31. **Protocol Title:** A Randomized double-blind placebo-controlled multicenter Phase 3 study of efficacy and safety of AR-301 as adjunct therapy to antibiotics in the treatment of Ventilator-Associated Pneumonia (VAP) caused by S. aureus

Protocol Number: AR-301-002
Dr.Jayaprakash Appajigol-PI

- IEC notification of protocol clarification memo dated 26-Aug-20

32. **Protocol No**: 0006-20

Protocol Title: an open label, multicenter, randomized, parallel, single dose, comparative, bioavailability study of triamcinolone hexacetonide injectable suspension USP 20 mg/ml of Abbott Healthcare Private Limited, India (test) and triamcinolone hexacetonide injectable suspension USP 20 mg/ml suspension for injection of Intrapharm Laboratories Ltd, UK (Reference) in patients with Knee Osteoarthritis

Dr. Sameer Haveri-PI

- IEC Notification of DCGI Letter Dated: 10-Sep-20

Yours truly

Prof.(Dr).M.S.Ganachari

Member Secretary of IEC

Prof. (Dr) M. S. Ganachari
Member Secretary, Institutional Ethics Committee
KLE Academy of Higher Education and Research, Belagavi.

To:

Circular and Submission of IEC Dossier		
1)	**Dr. Subarna Roy,** Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi	Chairperson
2)	**Dr. Harsha V.Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** Prof of Pharmacology [USM-KLE] IMP, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar,** Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
6)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
7)	Dr.**Nayana Hashilkar,** Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
8)	**Mrs.Vaishnavi V Kivadasannavar,** M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
9)	Shri.**Mahantesh Sidramappa Amatur** Malapraba sugar factory M K Hubli, as Work Shop engineer, Belagavi-10	Member
10)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
11)	Mrs.**Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, KLE College of Pharmacy, Belagavi	Assistant Coordinator

12)	**Prof.(Dr.) M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary`
13)	**Dr.Sapna K,** Consultant Radiation oncologist, KLE Society Belgaum Cancer hospital, Belagavi-10	Independent Consultant
Administrators of KAHER(Deemed to University)		
1)	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
Principal Investigators		
1)	Dr.Santosh **Dhananjay Hajare,** *Consultant* Gastroenterologist, KLES Dr Prabhakar Kore Hospital & MRC, Belagavi-10	Circular
2)	**Dr. Jayapraksh. Appajigol,** Assoc. Prof. of Medicine, J.N. Medical College, Consultant Physician, KLES Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi-10	Circular
3)	**Dr. Maheshkumar Veeranna Kalloli,** Consultant, Dept. of Oncology KLES Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belgaum-590 010, Karnataka, India	Circular
4)	**Dr.Archana.M.Uppin,** Consultant Physician and rheumatologist, Dept. of Medicine, KLEs Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi-10	Circular

INSTITUTIONAL ETHICS COMMITTEE

KLE University

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

(Deemed-to-be-University)

KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi - 10, Karnataka State, India

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Ref: KAHER/IEC/2020-21/D- 09102000 Date: 05/Oct/2020

Accreditations

NABH

FERCAP

SIDCER

Registrations

DCGI

OHRP

SMO

Meeting Agenda

Institutional Ethics Committee of KAHER, Belagavi - Saturday, 17/Oct /2020, At: 11.00 AM

Venue: KLE Academic Council Hall, JNMC, KLE University, Belagavi-10

I. **New agendas for review and approval:**[Presentation from the PIs]

1. Protocol Title: "A Phase III, Comparative, Double Blind, Randomized, Multi-centric study to compare the Efficacy, Safety and Immunogenicity of Sun's Ranibizumab with Reference Biologic in Patients with Neovascular Age-related Macular degeneration (wet AMD)."
   Dr.Smitha.K.S-PI
   Timings: 11:15 to 11:30 AM

2. **Protocol No:** LUF-44-005
   Protocol Title: Safety and Efficacy of Trans arterial Chemoembolization with Lipiodol® in the treatment of inoperative Hepatocellular Carcinoma (HCC) in Indian Patients, Phase IV clinical Trial
   Dr.Navin Mullimani-PI
   Timings: 11:30 to 11:45 AM

3. **Protocol No**: 0006-20
   Protocol Title: an open label, multicenter, randomized, parallel, single dose, comparative, bioavailability study of triamcinolone hexacetonide injectable suspension USP 20 mg/ml of Abbott Healthcare Private Limited, India (test) and triamcinolone hexacetonide injectable suspension USP 20 mg/ml suspension for injection if Intrapharm Laboratories Ltd, UK (Reference) in patients with Knee Osteoarthritis
   Dr.Sameer Haveri-PI
   Timings: 11:45 to 12:00 PM

4. **Protocol** No: CQGE031C2302E1
   Protocol Title: A multi-center, randomized, double-blind and open label extension study to Evaluate the efficacy and safety of ligelizumab as retreatment, self-administered therapy and monotherapy in chronic spontaneous Urticaria patients who completed studies CQGE0312302, CQGE031C2303, CQGE031C2202 or CQGE031C11301.
   Dr.Shivakumar Patil-PI
   Timings: 12:00 to 12:15 PM

4. **Protocol Title**: RLS/PMS/2019/03; Version 2.0 dated: 02 Aug 2019
   Protocol Title: A prospective, Multi center, Phase, IV stud to evaluate safety and efficacy of SomatoRel™ (Recombinant Human Growth Hormone Manufactured by Reliance Life Sciences Pvt.Ltd) in growth hormone deficient children.
   Dr.Manjunath Goroshi-PI
   Timings: 12:15 to 12:30 PM

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II. **Review of Proposal Revised Protocol:**

-Nil

III. **Review of Protocol Amendments:**

1. **Protocol No: 201790**

Protocol Title: A 52-week, phase 3, multi centre, randomised, double-blind, efficacy and safety study comaparing GSK3196165 with placebo and with tofacitinib, in combination with methotrexate in participants with moderately to severely active rheumatoid arthritis who have an inadequate response to methotrexate

Dr.Archana Uppin-PI

- Review of protocol amendments Version 02 dated: 21-JAN-2020

2. **Protocol Title:** Phase 3, randomized, open label, controlled, multiple-dose, efficacy, safety, pharmacokinetic and Pharmacodynamic study of etecalcitide in pediatric subjects 28 days to <18 years of age with hyperparathyroidism and chronic kidney disease receiving maintenance hemodialysis

Protocol No: 20140315

Dr.Mahantesh Patil-PI

- Review of protocol amendments Version 3.0 dated: 09-Oct-2019 & its related documents

3. **Protocol No:** XBR1001

Protocol No: Xplore: A Phase III Double-Blind, Parallel Group, Multicenter Study to Compare the Efficacy and Safety of Xlucane versus Lucentis® in Patients with Neovascular Age-Related Macular Degeneration

Dr. Smitha K.S-PI

- Review of protocol amendments Version 03 dated: 06-May-2019 and its related documents

4. **Protocol No:** LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study

Dr.Navin Mullimani-PI

- ICD version 6.0 review and approval

5. **Study No:** 20140444

Drug: Denosumab

Protocol Title: A Phase 3 randomized, Double-blind, Placebo-Controlled, Parallel-group Study to evaluate the safety and Efficacy of Denosumab in pediatric Subjects with Glucocorticoid-induced Osteoporosis

Dr.N.S.Mahantashetti-PI

- Protocol Addendum Version 1.0 review and approval

IV. **Review of Annual Report:**

1. **Study Number:** GBR 200-301

Study Title: A Prospective, Multicenter, Randomized, Double-blind, Parallel-group, Study to Compare the Efficacy and Safety of GBR 200 (similar biologic of Trastuzumab) versus Innovator

Trastuzumab both when given in combination with Paclitaxel in patients diagnosed with HER2 Positive Metastatic Breast Cancer.

Dr.Maheshkumar Kalloli-PI

- IEC submission of Annual report letter dated: 04-May-20

2. **Protocol No:** XBR1001

   Protocol No: Xplore: A Phase III Double-Blind, Parallel Group, Multicenter Study to Compare the Efficacy and Safety of Xlucane versus Lucentis® in Patients with Neovascular Age-Related Macular Degeneration

   Dr.Smitha K.S-PI

   - IEC submission of study annual report letter dated: 31-Aug-2020

3. **Protocol No**: PMZ-1620/CLINICAL-2.3/2018, v 2.0/05 Jul 2018

   Study Protocol No.: PMZ-1620/CLINICAL-2.3/2018;DCGICTNOC No.:CT/ND/18/2018

   Study Title: A Prospective, Multicentric, Randomized, Double Blind, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Patients of Acute Spinal Cord Injury

   Dr.Sameer Haveri - PI

   - IEC notification of study annual/Progress report letter dated: 18-Feb-2020

III. **Review of Bi-Annual Report:**

- Nil

IV. **SAE reporting**

1. **Protocol No**: 1002-043

   Protocol Title: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at High Risk For, Cardiovascular Disease Who Are Statin Intolerant

   Dr.V.A. Kothiwale-PI

   - SAE Follow up letter for the subject no:4328011002- Event- Cardiogenic Shock letter dated: 20-Jul-2020

2. **Protocol No:** EFC14828_ Amplitude

   Protocol Title: A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes Patients at High Cardiovascular Risk.

   Dr. Prasad M R-PI

- IEC notification of SAE follow-up report of Subject No:356000100022 letter dated:21-07-20

V. Protocol deviation/violation/ termination:

1. **Protocol No:** DMPL/P05-2017/CT/VN V2.0, Date-30.03.2018 titled "A post marketing surveillance study (PMS) to evaluate safety and tolerability of VELNEZ as nasal pack after nasal surgery"

   Dr. Shama Bellad-PI

   - IEC notification of Protocol Deviation letter dated: 16-Mar-2020
   - IEC notification of Protocol Deviation letter dated: 19-May-2020

2. **Protocol No:** SII-Tdap/IN-02 V 2.0

   Protocol Title: A phase II/III, multicenter, randomized, open label, active controlled, clinical study to assess the immunogenicity and safety of tetanus toxoid, diphtheria toxoid, and acellular pertussis (Tdap) vaccine manufactured by Serum institute of India Pvt. Ltd. (SIIPL) in comparison with Boostrix® vaccine of GSK in healthy adults, adolescents and children

   Dr. N S Mahantshetti - PI

   - IEC submission of protocol deviation letter dated 21-Jul-2020

3. **Protocol No: CQGE031C2302**

   Protocol Title: A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines

   Dr. Shivkumar Patil- PI

   - IEC notification of Protocol Deviation due to COVID letter dated: 31-Jul-2020

4. **Protocol No:** EFC14828_ Amplitude

   Protocol Title: A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes Patients at High Cardiovascular Risk.

   Dr. Prasad M R-PI

   - IEC notification of protocol Deviation letter dated: 29-Aug-20

5. **Protocol No:** BECT045/HepA-Phase-III/CTP-02

   Protocol Title: A single blind, parallel, randomized Phase-Ill comparative study to evaluate safety and immunogenicity of two intramuscular doses of inactivated Hepatitis A vaccine administered 6 months apart, in 1-15 year-old healthy Hepatitis A vaccine-na'ive children

   Dr. N S Mahantshetti – PI

   - IEC notification of Protocol deviation due to COVID-19 letter dated: 20-Jun-20

6. **Protocol No:** BECT048/MRV- PIV/CTP-02

   Protocol Title: "A Multicenter single arm non-comparative Phase-IV post marketing study to evaluate the safety and tolerability of Biological E's Live, Attenuate Measles Rubella Vaccine (MR) in 9-12 month old Healthy Infants

   Dr.N.S.Mahantashetti-PI

   - IEC notification of Protocol deviation due to COVID-19 letter dated: 25-Jun-20

7. **Protocol No:** 0978-17

   Protocol Title: a Randomized, Double Blind, Double-Dummy, Multi Center, Parallel, Phase III Study to Evaluate the Efficacy and Safety of Tacrolimus Lipid Tablets (Manufactured by Intas Pharmaceuticals Ltd) Compared to Prograf (Tacrolimus Immediate Release Capsules-Astellas Pharma Canada, Inc) in Adult Patients with Active Rheumatoid Arthritis Who Have Resistance OR Intolerance to DMARDs.

   Dr.Archana Uppin-PI

   - IEC notification of Protocol Deviation letter dated: 14-Mar-20, 04-Aug-2020 and 27-Jul-2020

8. **Protocol Title:** I4V-MC-JADY-A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Barcitinib in Patients with Rheumatoid Arthritis.

   Dr.Shailesh Udapudi-PI

   - IEC notification of protocol Deviation letter dated: 22-May-20

9. **Protocol No**: PMZ-1620/CLINICAL-2.3/2018, v 2.0/05 Jul 2018

   Study Protocol No.: PMZ-1620/CLINICAL-2.3/2018;DCGICTNOC No.:CT/ND/18/2018

   Study Title: A Prospective, Multicentric, Randomized, Double Blind, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Patients of Acute Spinal Cord Injury

   Dr.Sameer Haveri-PI

   - IEC notification of Protocol Deviation Visit 04 of subject no: 05-006 dated: 24-Jun-2020

10. **Protocol No: TDM1.17.001.03**

Protocol Title : A prospective, randomized, multi center. Comparative. Open label, parallel study to evaluate the Efficacy, Safety and pharmacokinetics to Test- Trastuzumab Emtansine (ZRC-3256 ; Cadila Healthcare Ltd) and Reference – Trastuzumab Emtanstine (Kadcyla®, a Product of Roche) in HER2 – positive metastatic Breast Cancer Patients.

Dr.Mahesh Kalloli –PI

- IEC notification of protocol deviation letter dated: 28-Jul-2020

VI. **Study Closeout:**

1. **Protocol Title**:MYL-1402O-3001: Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.

Dr.Maheshkumar Kalloli-PI

- IEC notification of study completion report letter dated: 24-Jul-20
- IEC notification of study closure notification letter dated: 24-Aug-20

VII. **The Committee will consider the following agendas which are for information.**

1. **Protocol Title:** A phase II/III, multicenter, randomized, open label, active controlled, clinical study to assess the immunogenicity and safety of tetanus toxoid, diphtheria toxoid, and acellular pertussis (Tdap) vaccine manufactured by Serum institute of India Pvt. Ltd. (SIIPL) in comparison with Boostrix® vaccine of GSK in healthy adults, adolescents and children in India.

Protocol Identifier: SII-Tdap/IN-02 V- 2.0 dated 14 Jun 2018

Dr. N S Mahantshetti- PI

- IEC notification of subject discontinuation in later dated 20 Jun 2020
- IEC notification of subject dropout later dated 21-Jul-2020

2. **Protocol Title:** a single blind randomized active controlled Phase-III study to evaluate immunogenicity, safety, tolerability of a candidate 14-valent pneumococcal polysaccharide conjugate vaccine administered to 6-8 weeks old healthy Indian Infants in 6-10-14 weeks dosing schedule

Protocol No: BECT/PCV-Phase-III/CTP-02

Dr.N.S.Mahantashetti-PI

- IEC submission of CTRI-letter dated: 07-Feb-2020

3. **Protocol Title:** A randomized, open label, balanced, multicenter, tow-treatment, tow- period, two sequence, Two-way crossover, single dose, bioequilance study with pharmacokinetic endpoints of paclitaxel protein-Bound particles for injectable suspension (albumin Bound) 100 mg/vial at a dose of 260 mg/m2 of Ningo shouzheng Medicinal Research co., Ltd. With ABRAXANE® for injectable

suspension (albumin Bound) 100 mg/vial at a dose of 260 mg/m2 of Celgene corporation, summit, NJ 07901 in breast cancer subjects after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy under fasting conditions

Dr.Rohan Bhise-PI

- IEC notification of Below mentioned study documents letter dated: 07-Aug-2020
  - DCGI approval letter
  - CTRI registration
  - Risk area and Mitigation plan
  - Final Copy of Blank eCRF
  - Final CTA

4. **Protocol Title**: An Open-Label, Multicentre, Prospective, Phase-IV, Interventional Study To Evaluate The Safety, Tolerability And Efficacy Of Dolutegravir (50mg Once Daily) In Treatment Naïve Adult Indian Subjects Infected With HIV-1, Eligible To Receive To Dolutegravir With Tenofovir And Lamivudine.

   Dr.Dyanesh Morkar-PI

   - IEC notification of DCGI acknowledgment letter dated: 17-Jun-2020
   - IEC notification of COVID-19 checklist letter dated: 20-Jun-2020
   - IEC notification of study activities during COVID-19 pandemic letter dated: 17-Jun-2020

5. **Protocol Title:** A Multicentric, open label, single arm study to evaluate the safety and efficacy of INTP26 (trastuzumab biosimilar) in patients with HER2-overexpressing breast (early or metastatic) cancer or metastatic gastric cancer

   Protocol Number: 0566-18

   Dr.Mahesh Kalloli-PI

   - IEC notification of Patient information sheet and ICD and site operational Manual letter dated: 20-Jun-2020
   - IEC notification of Site Initiation Visit letter dated: 24-Jun-2020
   - IEC notification of Final e CRF letter dated: 12-Jun-2020

6. **Protocol No:** 0978-17

   Protocol Title: a Randomized, Double Blind, Double-Dummy, Multi Center, Parallel, Phase III Study to Evaluate the Efficacy and Safety of Tacrolimus Lipid Tablets (Manufactured by Intas Pharmaceuticals Ltd) Compared to Prograf (Tacrolimus Immediate Release Capsules-Astellas

Pharma Canada, Inc) in Adult Patients with Active Rheumatoid Arthritis Who Have Resistance OR Intolerance to DMARDs.

Dr.Archana Uppin-PI

- IEC notification of Insurance[01-Jul-20 to 30-Jun-2021] letter dated:07-Jul-2020
- IEC notification of CTRI-2019/04/018626] letter dated: 14-Jul-2020

7. **Protocol Title:** I4V-MC-JADY-A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.

   Dr.Shailesh Udapudi-PI

   - IEC notification of IP dispensing to subjects by DTP service using Marken Courier letter dated: 22-Apr-2020
   - IEC notification of remote SDV letter dated: 22-06-2020

8. **Protocol Title:** A Multicentre, Open label, Balanced, Randomized, Two-treatment, Two-period, Single dose, Crossover, Bioequivalence study of Bortezomib for Injection 3.5 mg/vial of Dr. Reddy's Laboratories Limited, India and VELCADE® (bortezomib) for Injection 3.5 mg/vial (Distributed and Marketed by: Millennium Pharmaceuticals, Inc., 40 Landsdowne Street, Cambridge, MA 02139) in previously untreated Multiple Myeloma and/or Relapsed Multiple Myeloma patients

   Protocol No.: 17-VIN-0772

   Dr.Rohan Bhise-PI

   - IEC notification of amended CTA dated 05-Aug-2020 letter dated: 07-Aug-2020

9. **Study No: 20140444**

   Drug: Denosumab

   Protocol Title: A Phase 3 randomized, Double-blind, Placebo-Controlled, Parallel-group Study to evaluate the safety and Efficacy of Denosumab in pediatric Subjects with Glucocorticoid-induced Osteoporosis

   Dr.N.S.Mahantashetti-PI

   - IEC notification of IB edition 8.1 dated 12-Jun-20 and letter dated: 27-Jun-20
   - IEC notification of renewed insurance letter dated: 22-Jun-2020
   - IEC notification of SUSARs letter dated; 07-Jul-20

10. **Protocol No.** TX05-03 E amendment dated 01dated13 Dec 2018 **Protocol Title:** A double-blinded extension study to provide adjuvant treatment with single agent Herceptin® or TX05 and assess continued safety and immunogenicity in subjects with HER2-positive early breast cancer following neoadjuvant treatment and surgical resection in Protocol TX05-03

    Dr.Mahesh kalloli-PI

- IEC notification of Updated IU letter dated: 13-Jul-20
- IEC notification of CIOMS letter dated: 06-Jul-20

11. **Protocol Title:** A Randomized, Active-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Sulbactam-ETX2514 in the Treatment of Patients with Infections Caused by Acinetobacter baumannii- calcoaceticus Complex

    Protocol No: CS2514-2017-0004

    Dr.Jayaprakash Appajigol -PI

    - IEC Notification of Expedited Safety report package letter dated 11-Sep-2020
    - IEC Notification of SUSAR line listing letter dated 04-Sep-2020
    - IEC notification of study restart and release hold letter dated : 18-Aug-20
    - IEC notification of Safety report letter dated : 13-Aug-2020
    - IEC notification of COVID-19 Local Laboratory memo letter dated : 13-May-2020

12. **Protocol Number:** GBR 200-301

    Study Title: A Prospective, Multicenter, Randomized, Double-blind, Parallel-group, Study to Compare the Efficacy and Safety of GBR 200 (similar biologic of Trastuzumab) versus Innovator Trastuzumab both when given in combination with Paclitaxel in patients diagnosed with HER2 Positive Metastatic Breast Cancer.

    Dr.Maheshkumar Kalloli-PI

    - IEC notification of IU letter dated:27-Aug-20
    - IEC notification of MOM and DSMB and IV letter dated : 26-Aug-20
    - IEC notification of study documents letter dated 20-Jul-2020

13. **Protocol No:** ALK18/EN124/-CET1

    Protocol Title: A prospective, multicenter, randomized, double blind, parallel group study to compare the efficacy and safety of biosimilar cetuximab versus innovator cetuximab in combination with platinum-based chemotherapy in patients with recurrent locoregional or metastatic squamous cell carcinoma of the head and neck (SCCHN)

    Dr.Maheshkumar Kalloli-PI

    - IEC notification of CIOMS report of subject no 23-005-Initial letter dated :07-Sep-2020
    - IEC notification of CIOMS report of subject no 23-005-FU letter dated :07-Sep-2020
    - IEC notification of CIOMS report of subject no 15-004 letter dated :07-Sep-2020
    - IEC notification of CIOMS report of subject no 04-002 letter dated :07-Sep-2020
    - IEC notification of CIOMS report of subject no 09-001 letter dated :07-Sep-2020

14. **Protocol Title:** I4V-MC-JADY-A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.

Dr.Shailesh Udapudi-PI

- IEC notification of IB dated 14-Aug-20 and letter dated-20-Aug-20
- IEC notification of Amendment letter of agreement dated: 05-Aug-20
- IEC notification of subject discontinuation from the study letter dated: 10-Mar-2020

15. **Research Project** "Sit Down and Play (SDP)"

Dr.S.M.Dhaded-PI

- IEC notification of Change In follow up visit due to COVID-19 letter dated: 23-Jul-20

16. **Protocol No:** XBR1001

Protocol No: Xplore: A Phase III Double-Blind, Parallel Group, Multicenter Study to Compare the Efficacy and Safety of Xlucane versus Lucentis® in Patients with Neovascular Age-Related Macular Degeneration

Dr.Smitha K.S-PI

- IEC notification of Expedited Safety report letter dated: 25-Aug-2020 and 05-Sep-20
- IEC notification of Expedited Safety report: Myocardial Infarction letter dated: 05-Sep-20
- IEC notification of Safety letter dated: 12-Aug-2020
- IEC notification of Safety letter dated: 07-Aug-2020

17. **Protocol No:** SII-Tdap/IN-02 V 2.0 dated: 14 Jun 2018

Protocol Title: A phase II/III, multicenter, randomized, open label, active controlled, clinical study to assess the immunogenicity and safety of tetanus toxoid, diphtheria toxoid, and acellular pertussis (Tdap) vaccine manufactured by Serum institute of India Pvt. Ltd. (SIIPL) in comparison with Boostrix® vaccine of GSK in healthy adults, adolescents and children

Dr. N S Mahantshetti – PI

- IEC notification of subject discontinuation letter dated: 20-Jun-20

18. **Protocol No/Title:** MYL-TLE 400-4001-"Multicenter, open label, randomized prospective, phase IV, interventional, non-inferiority study with blinded assessment, to evaluate the efficacy and safety of fixed dose combination (FDC) of tenofovir/Lamivudine/low dose Efavirenz(300/300/400mg) Vs. FDC of Tenofovir/Lamivudine//Efavirenz(300/300/600mg) in adult Indian patients who have HIV-1 infection".

Dr. Dnyanesh Morkar- PI

- IEC Notification of COVID -19 Checklist in later dated 30 June 2020

19. **Protocol Title:** A Two-Part, Open-Label, Randomized, Phase II/III Study of Dinutuximab and Irinotecan versus Irinotecan for Second Line Treatment of Subjects with Relapsed or Refractory Small Cell Lung Cancer

    Protocol Number: DIV-SCLC-301

    Dr.Maheshkumar Kalloli-PI

    - IEC notification of Clinical Study report letter dated: 06-Aug-20

20. **Protocol No:** 0568-18

    Protocol Title: A multicentric open label, balanced, randomized, two treatment, two period, two sequence, crossover, steady state, dosage strength equivalence study of clozapine extended release capsule 25 mg (lowest strength, 25 mg X 8 capsules) once daily (Test drug, Intas pharmaceuticals limited, India) with clozapine extended release capsule 200 mg (highest strength) once daily (Test drug, Intas pharmaceuticals limited, India) after multiple dose administration in adult schizophrenic patients under fasting conditions

    Dr.Sameeran Chate-PI

    - IEC notification of renewed insurance[01-Jul-2020 to 30-Jun-2021] letter dated: 13-Aug-2020

21. **Protocol No: 20140315**

    Protocol Title: Phase 3, randomized, open label, controlled, multiple-dose, efficacy, safety, pharmacokinetic and Pharmacodynamic study of etecalcitide in pediatric subjects 28 days to <18 years of age with hyperparathyroidism and chronic kidney disease receiving maintenance hemodialysis

    Dr.Mahantesh Patil -PI

    - IEC notification of Insurance Policy [01-Mar-20 to 28-Feb-21] letter dated 10-Mar-2020
    - IEC notification of quarterly line listing letter dated:18-May-20

22. **Protocol No:** LUF-44-001

    Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study

    Dr. Naveen Mullimani -PI

    - IEC notification of Remote Monitoring During COVID-19 letter dated: 13-Jul-2020
    - IEC notification of CIOMS-3 report letter dated: 31-Jul-2020

- IEC notification letter dated: 19-Mar-2020

23. **Protocol No**: PMZ-1620/CLINICAL-2.3/2018, v 2.0/05 Jul 2018

Study Protocol No.: PMZ-1620/CLINICAL-2.3/2018;DCGICTNOC No.:CT/ND/18/2018

Study Title: A Prospective, Multicentric, Randomized, Double Blind, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Patients of Acute Spinal Cord Injury

Dr.Sameer Haveri - PI

- IEC notification of COVID-19 guidance letter dated: 31-Mar-2020

24. **Protocol No:** SII-Apenta/IN-02

Protocol Title: A phase II/III, Multicentre, Randomized, open label, active-controlled study to assess the immunogenicity and safety of DTaP-IPV+Hib vaccine manufactured by serum institute of India Pvt.Ltd in comparison with pentaxim® in Indian toddlers and infants

Dr.N.S.Mahantashetti -PI

- IEC Notification of DCGI letter [dated 05-Jun-20] dated: 11-Jun-2020

25. **Protocol Number:** CT-P16 3.1

Protocol Title: A Double-Blind, Randomized, Active-Controlled, Parallel-Group, Phase 3 Study to Compare Efficacy and Safety of CT-P16 and EU-Approved Avastin® as First-Line Treatment for Metastatic or Recurrent Non-Squamous Non-Small Cell Lung Cancer

Dr.Maheshkumar Kalloli-PI

- IEC notification of final CTA letter dated: 06-Jul-2020
- IEC notification of DCGI approval for increased Patient Enrollment and COVID-19 Guidance letter dated: 20-Jul-20

26. **Protocol Title:** A randomized, double-blind, placebo-controlled, parallel group, muticenter, comparative study to assess the efficacy and safety of spores of Entergermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhoea in children.

Protocol No: LPS14914/KIDDIE

- IEC Notification of SASR#13 letter dated: 08-Jul-2020

27. **Protocol No : 0137-18**

Protocol Title : A multicentric, open-label, multiple dose, balanced, randomized, two-treatment, two-Period, two-Sequence, full replicate, cross over study to evaluate bioequilance of Etoposide

Capsules 100 mg (Intas Phramaceuticals Ltd. India) with Vepesid soft capsules 100 mg (Bristol-Myers Squibb S.r.l Itlay) in patients with metastatic small cell lung cancer(SCLC) under fasting conditions.

Dr.Maheshkumar Kalloli-PI

- IEC notification of Insurance certificate[01-Jul-2020 to 30-Jun-2021] letter dated: 10-Aug-2020

28. **Protocol No: CQGE031C2302**

Protocol Title: A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines

Dr. Shivkumar Patil- PI

- IEC notification of SUSAR letter dated: 24-Jun-20

29. **Protocol Title:** A Randomized double-blind placebo-controlled multicenter Phase 3 study of efficacy and safety of AR-301 as adjunct therapy to antibiotics in the treatment of Ventilator-Associated Pneumonia (VAP) caused by *S. aureus*

Protocol Number: AR-301-002

Dr. Jayapraksh Appajigol- PI

- IEC notification of Protocol clarification memo Letter Dated 18-Aug-2020
- IEC notification ACM India, Lab manual and CRF completion guidelines letter dated:18-Aug-20

30. **Protocol No:** 20150238

Protocol Title: A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism

Dr. Ritesh Vernekar - PI

- IEC notification of approval of SM and RM visit letter dated 13-Jul-2020
- IEC notification of Quarter-02 line listing SAEs letter dated: 10-Aug-2020
- IEC notification of eCRF letter dated: 09-Jul-2020
- IEC notification of Insurance certificate[01-May-20 to 30-Apr-2021] letter dated: 07-Jul-2020

31. **Protocol No**: SAMSON-II

Protocol Title: A Randomized, Double-blind, Parallel Group, Equivalence, Multicentre Phase III Trial to Compare the Efficacy, Safety, Pharmacokinetics and Immunogenicity of HD204 to Avastin® in patients with Metastatic or Recurrent Non-Squamous Non-Small Cell Lung Cancer

Dr.Rohan Bhise-PI

- IEC notification of Pharmacy manual letter dated: 25-Jul-2020

32. **Protocol No: CR176-17**

Protocol Title: A randomized, multiple-dose, double blind, placebo controlled, parallel group, sequential design, multicentric study to evaluate Efficacy and Safety of Beclomethasone Dipropionate Metered Dose Inhaler (Inhalation Aerosol) (0.04mg/ INH) in male and/ or female subjects with Asthma [Group I (Test): Beclomethasone Dipropionate 0.04 mg/ INH; Group II (Reference): QVAR® 40 mcg (Beclomethasone dipropionate HFA); and Group III: Placebo].

Dr.Gautham S-PI

- IEC notification of study closure report letter dated: 09-Jun-2020

33. **Protocol No: 201790**

Protocol Title: A 52-week, phase 3, multi centre, randomised, double-blind, efficacy and safety study comaparing GSK3196165 with placebo and with tofacitinib, in combination with methotrexate in participants with moderately to severely active rheumatoid arthritis who have an inadequate response to methotrexate

Dr.Archana Uppin-PI

- IEC notification of Investigator allert/Safety letter dated : 11-Jun-2020

34. **Protocol No**: 20160372

Protocol Title: Post Marketing Phase-4 Study To Evaluate Safety, Tolerability, And Efficacy Of Kyprolis® (Carfilzomib) In Indian Patients With Relapsed Or Refractory Multiple Myeloma: A Prospective, Open-Label, Non-Comparative, Multicentre Study

Dr. Rohan Bhise-PI

- IEC notification of MEMO Dated26-jun-2020 letter dated 07 Jul 2020
- IEC notification of SUSAR's letter dated: 03-Mar-2020

35. **Protocol No:** DMPL/P05-2017/CT/VN V2.0, Date-30.03.2018 titled "A post marketing surveillance study (PMS) to evaluate safety and tolerability of VELNEZ as nasal pack after nasal surgery"

Dr. Shama Bellad-PI

- IEC notification of study closures letter dated: 30-Jun-2020

36. **Protocol No:** 0978-17

Protocol Title: a Randomized, Double Blind, Double-Dummy, Multi Center, Parallel, Phase III Study to Evaluate the Efficacy and Safety of Tacrolimus Lipid Tablets (Manufactured by Intas Pharmaceuticals Ltd) Compared to Prograf (Tacrolimus Immediate Release Capsules-Astellas Pharma Canada, Inc) in Adult Patients with Active Rheumatoid Arthritis Who Have Resistance OR Intolerance to DMARDs.

Dr.Archana Uppin-PI

- IEC notification of Insurance certificate[01-Jul-2020 to 30-Jun-2021] letter dated: 27-Jul-20

37. **Protocol No:** EFC14828_ Amplitude

Protocol Title: A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes Patients at High Cardiovascular Risk.

Dr. Prasad M R-PI

- IEC notification of CIOMS- 356000100022- Adenocarcinoma Prostate with lymph node and Bony metastasis letter dated 25-Aug-2020.
- IEC notification of CIOMS- 356000100025- Coronary Revascularization –FU01 letter dated: 14-Aug-20
- IEC notification of CIOMS- 356000100025- Confirmed Coronary Revascularization letter dated: 25-Aug-20
- IEC notification of Safety alert#76IN&#77 letter dated:28-Aug-2020
- IEC notification of IP dispensing to subjects by DTP service using Marken Courier letter dated: 02-Jun-2020
- IEC notification of CIOMS- 356000100022- Suspected Prostate Cancer letter dated 12-Aug-2020.

Yours truly

Prof.(Dr).M.S.Ganachari

Member Secretary of IEC

Prof. (Dr) M. S. Ganachari
Members Secretary, Institutional Ethics Committee
KLE Academy of Higher Education and Research, Belagavi

To:

Circular and Submission of IEC Dossier		
1)	**Dr. Subarna Roy,** Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi	Chairperson
2)	**Dr. Harsha V.Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** Prof of Pharmacology [USM-KLE] IMP, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar,** Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
6)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
7)	**Dr.Nayana Hashilkar,** Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
8)	**Mrs.Vaishnavi V Kivadasannavar,** M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
9)	**Shri.Mahantesh Sidramappa Amatur** Malapraba sugar factory M K Hubli, as Work Shop engineer, Belagavi-10	Member
10)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
11)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, KLE College of Pharmacy, Belagavi	Assistant Coordinator
12)	**Prof.(Dr.) M.S.Ganachari,** Prof & HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
Administrators of KAHER(Deemed to University)		
1)	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular

Principal Investigator		
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2)	**Dr. Smitha K S,** Consultant, Dept. of Ophthalmology, KLES Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belgavi-590 010, Karnataka, India	Circular
3)	**Dr.Navin Mullimani,** Interventional radiologist, Department of surgery, KLEs Dr.Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi-10	Circular
4)	**Dr.Sameer Haveri,** Consultant Orthopedic Surgeon, KLES Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belgaum-590 010, Karnataka, India	Circular
5)	**Dr.Manjunath Goroshi,** Consultant Endocrinologist, KLES Dr.Prabhakar Kore Hospital, Belagavi-10	Circular

Institutional Ethics Committee

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(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)
KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State, India
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Ref: KAHER/IEC/2018-19/D- 2593 ***Date: 22/12/2018***

IEC Meeting Agenda

Institutional Ethics Committee of KAHER, Belagavi

Wednesday, 02/01/2019, At: 04.00 PM

Venue: Site management Office, G+2, KLES Dr.PK Hospital &MRC, Nehru Nagar, Belagavi

Accreditations:

NABH

FERCAP

Registrations:

DCGI

OHRP

I. New agendas for review and approval:

1. **Protocol Title:** Life: Low-birth weight infant feeding Exploration
   Dr.S.S.Goudar-PI

2. **Protocol Title:** CRADLE-4 Phase 1: The feasibility and acceptability of planned early delivery in pre-eclampsia in a Low and Middle-Income Setting.
   Dr.S.S.Goudar-PI

3. **Protocol Title:** Prevention of maternal and neonatal death/infections with a single oral dose of azithromycin in women in labor(in Low and middle income countries): a randomized controlled trial
   Dr.S.S.Goudar-PI

4. **Proposal title:** 'HBV genotypes and cancer predicting mutations in Hepatitis B Virus infected patients of North Karnataka Region'
   Dr.Mahantesh B Nagamoti-PI

5. **Project Title:** Performance, safety and efficacy of a New Cryotherapy Device for Cervical Dysplasia in Low and Middle Income countries.
   Dr.Anita Dalal-PI
   (The Above study was deferred from the last IEC Meeting)

II. Review of Proposals with Amendments:

1. **Protocol Title:** MYL-1402O-3001 :Multicenter, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First - line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.
   Dr.Maheshkumar Kalloli-PI

2. **Protocol Title:** "A randomized, 24-week, controlled, open label, parallel arm, multicenter study comparing the efficacy and safety of the insulin glargine/lixisenatide fixed ratio combination to insulin glargine in type 2 diabetes patients, inadequately controlled on Basal Insulin with or without Metformin"
   Protocol No: INSLIL08556
   Dr.Vikrant Ghatnatti-PI

III. Review of Revised Project Proposals:

1. **Protocol No:** CT/PAC/1701 (V.1.0) (India).
   Study Title: A Randomized, Open Label, Multi Center, Two Treatment, Two Period, Two Sequence, Single Dose, Crossover, Bioequivalence Study of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound), 100 mg/vial manufactured by Teva Pharmachemie, The Netherlands, for Teva Pharmaceuticals USA, and Abraxane® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension)(albumin-bound), 100 mg/vial manufactured by Abraxas BioScience LLC, USA for Celgene Corporation, USA in Patients with Metastatic Breast Cancer.
   Dr.Maheshkumar Kalloli-PI
   The following additional study documents submitted to IEC for review and approval

Sr. No	Name of Documents	Version No/Date
1.	DCGI Notification-Additional Sites	Dated 19 Nov 2018
2.	1572	Dated 27/Aug/2018
3.	Full insurance coverage & Insurance certificate	4067/97198826/03/000
4.	Clinical trial Agreement	19 Nov 2018
5.	Final CRF	05/oct/2018
6.	COA-Test	X495651 (Batch No)
7.	Memo-Test	Apr 2019
8.	COA-Reference	Jun 2019
9.	Source Template	NA
10.	Informed Consent documents (ICD) Marathi	Version 1.0 dated 31/May/2017 Translated from English to Marathi on 16 Aug 2018

11.	Informed Consent documents (ICD) Back translated from Marathi to English	Version 1.0 dated 31/May/2017 Back Translated from Marathi to English on 22 Aug 2018
12.	Translation Certificate	Version 1.0 dated 31/May/2017 Translated from English to Marathi on 16 Aug 2018
13.	Back Translation Certificate	Version 1.0 dated 31/May/2017 Back Translated from Marathi to English on 22 Aug 2018

IV. Review of Annual Report:

1. **BBIL/CTP/04/2010** study title:"A PHASE III, RANDOMIZED, MULTICENTERIC, CONTROLLED STUDY TO EVALUATE THE IMMUNOGENICITY AND SAFETY OF BBIL'S TYPHOID VI CAPSULAR POLYSACCHARIDE –TETANUS TOXOID PROTEIN CONJUGATE VACCINE Vs REFERENCE IN HEALTHY SUBJECTS".
   Dr.N.S.Mahantashetti-PI
   - IEC notification of study updates

V. SAE reporting:

-Nil

VI. Protocol deviation/violation/ termination:

1. **Study Title:** A Phase IV Multi-Centric Post-Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of the Marketed Formulation of Hetero –Adalimumab
   Protocol No: HCR/IV/ADALI/01/2017; Version: 1.0; Dated: 30 Jan 2017
   Dr.Archana Uppin-PI
   - IEC notification of protocol deviation letter dated 16/11/2018

2. **Protocol Number:** 13-VIN- 443
   Protocol Title: A multicenter, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL of Mylan Laboratories Limited, India with Doxorubicin Hydrochloride Liposome Injection for intravenous infusion 20 mg/10 mL Manufactured By: Sun Pharmaceutical Ind. Ltd., Halol Baroda Highway, Halol-389 350, Gujarat, India, administered in Female patients with ovarian cancer whose disease has progressed or recurred after platinum Based chemotherapy under fed condition.
   Dr.Maheshkumar Kalloli-PI
   - IEC notification of PD of patent No: R-01 and R-02 letter dated: 28/08/2018
   - IEC notification of PD of patent No: R-01 and R-02 letter dated: 12/11/2018

3. **Project CRL011812:** "A Randomized, Double blind, Multicenter, Three-arm, Parallel, Placebo-controlled, Clinical Study to Evaluate the Bioequivalence using Clinical Endpoint of Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel (Encube Ethicals Private Limited, India) to DUAC® Gel (Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel) (Stiefel Laboratories, Inc. Research Triangle Park, NC 27709) in Subjects with Acne Vulgaris."
   Dr.Shivakumar Patil-PI
   - IEC notification of Protocol deviation letter dated: 14/11/2018

4. **Protocol** PMZ-02; DCGI CT NOC No.: CT/ND/37/2016
Study Title: A Prospective, Multi-centric, Randomized, Double-blind, Parallel, Saline Controlled Phase II Safety and Efficacy study of PMZ-2010 as a resuscitative agent for Hypovolemic Shock due to excessive blood loss to be used along with standard shock treatment.
Dr.Madhav Prabhu-PI
    - IEC notification of PD letter dated:15/11/2018

VII. The Committee will consider the following agendas which are for information.

1. **Protocol Number: APL/CT/16/11**
Protocol Title: A Phase-III, Multicentric, Randomized, Double Blind, Placebo-Controlled, Comparative Clinical Study to Evaluate the Efficacy and Safety of Sildenafil Citrate 50 mg plus Dapoxetine 60 mg Tablet and Sildenafil Citrate 100 mg plus Dapoxetine 60 mg Tablet in the treatment of co-existing Erectile Dysfunction and Premature Ejaculation.
Dr.S.I.Neeli-PI
    - IEC notification of revised CTA and insurance policy letter dated: 26/11/2018

2. **Study Number:** GBR 200-301
Study Title: A Prospective, Multicenter, Randomized, Double-blind, Parallel-group, Study to Compare the Efficacy and Safety of GBR 200 (similar biologic of Trastuzumab) versus Innovator Trastuzumab both when given in combination with Paclitaxel in patients diagnosed with HER2 Positive Metastatic Breast Cancer.
Dr.Maheshkumar Kalloli-PI
    - IEC notification of Follow up 2 safety narrative for subject: 14014
    - IEC notification of Follow up 1 safety narrative for subject: 20007 site no: 20

3. **Protocol Title:** "A Multicenter, Open-label, Single-arm, Study to Evaluate Safety and Tolerability of Repatha in Patients with Homozygous Familial Hypercholesterolemia (HoFH) in India"
Study Number: 20170199
Dr.V.A.Kothiwale-PI
    - IEC notification of SUSAR's letter dated:08/11/2018
    - IEC notification of Discrepancy in main parent informed consent form
4. **Protocol:** An open label extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in Etrolizumb phase II/III studies.
Protocol No: GA28951- Version 6 Dated 22 Oct 2015.
Dr.Varadaraj Gokak-PI
    - IEC notification of eCRF and e CRF completion guidelines letter dated: 10/11/2018

5. **Project CRL011812:** "A Randomized, Double blind, Multicenter, Three-arm, Parallel, Placebo-controlled, Clinical Study to Evaluate the Bioequivalence using Clinical Endpoint of Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel (Encube Ethicals Private Limited, India) to DUAC® Gel (Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel) (Stiefel Laboratories, Inc. Research Triangle Park, NC 27709) in Subjects with Acne Vulgaris."
Dr.Shivakumar Patil-PI
    - IEC notification of discrepancies in ICF process of subject no: 11-009
    - IEC notification of discrepancies in ICF process of subject no: 11-021
    - IEC notification of discrepancies in ICF process of subject no: 11-031

6. **Study Number:** GBR 200-301
Study Title: A Prospective, Multicenter, Randomized, Double-blind, Parallel-group, Study to Compare the Efficacy and Safety of GBR 200 (similar biologic of Trastuzumab) versus Innovator Trastuzumab both when given in combination with Paclitaxel in patients diagnosed with HER2 Positive Metastatic Breast Cancer.
Dr.Maheshkumar Kalloli-PI
    - IEC notification of re-Labeling (GBR200)

7. **Protocol Number:** CLR_16_13
Protocol Title: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer.
Dr.Rohan Bhise-PI
    - IEC notification of Clarification letter dated: 26/11/2018

8. **Protocol Number: APL/CT/16/11**
Protocol Title: A Phase-III, Multicentric, Randomized, Double Blind, Placebo-Controlled, Comparative Clinical Study to Evaluate the Efficacy and Safety of Sildenafil Citrate 50 mg plus Dapoxetine 60 mg Tablet and Sildenafil Citrate 100 mg plus Dapoxetine 60 mg Tablet in the treatment of co-existing Erectile Dysfunction and Premature Ejaculation.
Dr.Maheshkumar Kalloli-PI
    - IEC notification of revised CTA
    - IEC notification of Revised Insurance policy 2018-2019

9. **Protocol title:** A Multi-Center, Open-Label, Balanced, Randomized, Two-Treatment, Two Sequence, Two Period, Crossover, Steady-State Bioequivalence Study of Imatinib Mesylate Tablets 400 mg (Test) of Eugia Pharma Specialities Limited, India (A joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited) and Gleevec® (Imatinib Mesylate) 400 mg Tablets (Reference) of Novartis Pharmaceuticals Corporation, USA in 36 adult patients with Chronic Myeloid Leukemia and/or Gastro Intestinal Stromal Tumors already receiving Imatinib Mesylate Tablets 400 mg under fed conditions
Protocol No: CR050-14
Dr.Rohan Bhise-PI
    - IEC notification of clinical study reports letter dated: 05/11/2018

10. **Protocol**: Phase III, Randomized, Double-blind, Placebo-controlled, multicenter study to evaluate the efficacy (maintenance of remission) and safety of Etrolizumab compared with placebo in patients with moderate to severe active Ulcerative Colitis who are naive to TNF inhibitors.
Protocol No: GA29102- Version 05 dated 28 Aug 2015
Dr.Varadaraj V Gokak- PI
    - IEC notification of DCGI approval for protocol amendment Version 6.0

11. **Protocol:** An open label extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in Etrolizumb phase II/III studies.
Protocol No: GA28951- Version 6 Dated 22 Oct 2015

Dr.Varadaraj V Gokak- PI

- IEC notification of DCGI approval for protocol amendment Version 7.0

12. **Protocol title:** A Multi-Center, Open-Label, Balanced, Randomized, Two-Treatment, Two Sequence, Two Period, Crossover, Steady-State Bioequivalence Study of Imatinib Mesylate Tablets 400 mg (Test) of Eugia Pharma Specialities Limited, India (A joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited) and Gleevec® (Imatinib Mesylate) 400 mg Tablets (Reference) of Novartis Pharmaceuticals Corporation, USA in 36 adult patients with Chronic Myeloid Leukemia and/or Gastro Intestinal Stromal Tumors already receiving Imatinib Mesylate Tablets 400 mg under fed conditions.
Protocol No: CR050-14
Dr.Rohan Bhise-PI
    - IEC notification of study update

13. **Protocol Title:** A multicenter, randomized, single-dose, parallel, two-treatment, bioequivalence study of Mylan's Ferric Carboxymaltose Injection 750mg/15mL (50mg/mL) with American Regent INC's INJECTAFER® (Ferric Carboxymaltose Injection 750mg/15mL [50mg/mL]) following a single intravenous dose of 750mg in adult male and female patients with iron deficiency anemia.
Protocol Number: **CR148-16**
Dr.Rohan Bhise-PI
    - IEC notification of DCGI Acknowledgement (Amendment 1.0)

14. **Protocol Title:** A Phase I/II, Double Blind, Placebo controlled, Randomized, Multicenter, prospective study to evaluate the Safety and Immunogenicity of a single dose 'Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized)' in healthy subjects.
Protocol Number: PBL/CR/2014/05/CT/DEN
Dr.Madhav Prabhu-PI
    - IEC notification of DCGI notification and DCGI approval letter dated: 30/10/2018

15. **Study Number/Name:** EFC14875 / the SCORED Trial
Study Title: "A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozins on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function."
Dr.Prasad M.R-PI
    - IEC notification of Safety alert dated: 03/12/2018
    - IEC notification of A-V ICF details dated: 22/11/2018
    - IEC notification of typo error letter dated:23/11/2018
    - IEC notification of typo error letter dated:13/11/2018
    - IEC notification of DCGI NOC for protocol amendments: 25/10/2018

16. **Protocol No:** CT/PAC/1701 (V.1.0) (India).
Study Title: A Randomized, Open Label, Multi Center, Two Treatment, Two Period, Two Sequence, Single Dose, Crossover, Bioequivalence Study of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound), 100 mg/vial manufactured by Teva Pharmachemie,

The Netherlands, for Teva Pharmaceuticals USA, and Abraxane® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension)(albumin-bound), 100 mg/vial manufactured by Abraxas BioScience LLC, USA for Celgene Corporation, USA in Patients with Metastatic Breast Cancer.

Dr.Maheshkumar Kalloli-PI

- IEC notification of updated CV and MRC

17. **Protocol No:** NCS-549-17-CS
Study Title: An open label, multicenter, randomized, balanced, two-treatment, two-period, two-sequence, single-dose, crossover, oral bioequivalence study of Methotrexate Tablets, USP 2.5mg from Lotus Pharmaceutical Co., Ltd., Taiwan compared with that of Methotrexate Tablets, USP 2.5 mg manufactured for DAVA Pharmaceuticals, Inc., in adult patients with mild to severe psoriasis or rheumatoid arthritis under fasting conditions.
Dr.Archana Uppin-PI
    - IEC notification of study documents letter dated 05/12/2018
    - IEC notification of study documents letter dated 31/10/2018

18. Protocol Number/ Title- [Pfizer, A0081105, "A randomized, double-blind, placebo-controlled, parallel group, multi-center trial of pregabalin as adjunctive therapy in pediatric and adult subjects with primary generalized tonic-clonic seizures", PAREXEL, 208238]
Dr.Mahesh Kamate-PI
    - IEC notification of SAE line listing report from 18-Jan-2013 through 08-Apr-2018

19. **Protocol Title:** A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism
Reference: Study No. 20150238
Drug: Etelcalcetide
Dr.Ritesh Vernekar-PI
    - IEC notification source templates letter dated on 24/10/2018

20. **Protocol Number:** 13-VIN- 443
Protocol Title: A multicenter, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL of Mylan Laboratories Limited, India with Doxorubicin Hydrochloride Liposome Injection for intravenous infusion 20 mg/10 mL Manufactured By: Sun Pharmaceutical Ind. Ltd., Halol Baroda Highway, Halol-389 350, Gujarat, India, administered in Female patients with ovarian cancer whose disease has progressed or recurred after platinum Based chemotherapy under fed condition.
Dr.Maheshkumar Kalloli-PI
    - IEC Notification of CIOMS-site_Q-02/FU04 letter dated: 20/10/2018
    - IEC Notification of CIOMS site_C-04/FU02 letter dated: 05/10/2018
    - IEC Notification of CIOMS site_C-04/FU02 letter dated: 12/10/2018
    - IEC Notification of CIOMS-site_D-04/FU01 letter dated: 04/10/2018

- IEC Notification of CIOMS-site_N-05/Initial letter dated: 19/10/2018
- IEC Notification of CIOMS-site_N-05/FU 02 letter dated: 19/10/2018
- IEC Notification of CIOMS-site_N-05/FU 01 letter dated: 12/10/2018
- IEC Notification of CIOMS-site_C-04/FU04 letter dated: 12/10/2018
- IEC Notification of CIOMS-site_C-04/FU03 letter dated: 15/10/2018
- IEC Notification of CIOMS-site_N-03/FU01 letter dated: 12/06/2018

21. **Protocol Title:** Phase III, Randomized, Double-blind, Placebo-controlled, multicenter study to evaluate the efficacy (maintenance of remission) and safety of Etrolizumab compared with placebo in patients with moderate to severe active Ulcerative Colitis who are naive to TNF inhibitors.
Protocol No: GA29102
And
Protocol Title: An open label extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in Etrolizumab phase II/III studies.
Protocol No: GA28951
Dr.Varadaraj Gokak-PI
    - IEC notification of Investigator's Brochure letter dated: 10/11/2018

22. **Protocol Title:** A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes Patients at High Cardiovascular Risk.
Protocol number: EFC14828/Amplitude-O
Dr.Prasad MR-PI
    - IEC notification of IB Edition 9 dated 29-May-2018
    - IEC notification of study documents letter dated: 30/11/2018

23. **Protocol Title:** A 12-week double-blind, randomized, multi-center study comparing the efficacy and safety of once monthly subcutaneous AMG 334 against placebo in adult episodic migraine patients (EMPOwER).
Protocol No.:CAMG334A2302
    - IEC notification of IB Edition 8.0 dated 23/10/2018 letter dated: 24/11/2018

24. **Protocol Title:** Prominent: Pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes.
Protocol No: K-877-302
    - IEC notification of SUSARs
      -Patient No: 2022-025- Decreased eGFR 32.3%-Follow Up01
      -Patient No: 7303-037- Stroke-Status: Initial
      -Patient No: 1007-019- Acute Pancreatitis-Status: FU5
      -SUSARs letter dated: 31/10/2018
      -SUSARs letter dated: 31/08/2018
      -SUSARs letter dated: 02/11/2018

25. Protocol Number: CLR_16_13
Protocol Title: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer.
Dr.Rohan Bhise-PI

- IEC notification of CIOMS letter dated:14/11/2018
- IEC notification of study documents dated:14/11/2018
  -eCRF Screen shots dated 09/June 2017
  -Insurance certificate from June 2017 to 2018

VIII.Any other matter with the permission of the chair

For your attention:
Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

for, Galinath

Prof.(Dr).M.S.Ganachari
Member-Secretary of IEC
Prof. (Dr) M. S. Ganachari
Members Secretary, Institutional Ethics Committee
KLE Academy of Higher Education and Research, Belagavi

To:

	Circular and Submission of IEC Dossier	
1)	**Dr. Subarna Roy,** Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V.Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** Prof of Pharmacology [USM-KLE] IMP, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar,** Prof. of Physiology, J.N. Medical College, Belagavi.	Member

5)	**Dr. M.V. Jali,** Chief Diabetologist, MD & CE, KLEs Dr.Prabhakar Kore Hospital and MRC, Belagavi	Member
6)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
7)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
8)	**Dr.Nayana Hashilkar,** Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
9)	**Mrs.Vaishnavi V Kivadasannavar,** M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
10)	**Shri.Tammanna Dadu Kore,** Farmer, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
11)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
12)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, KLE College of Pharmacy, Belagavi	Assistant Coordinator
13)	**Prof.(Dr.) M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
	Administrators of KAHER(Deemed to University)	
1)	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed University, Belagavi, For Information	Circular
	Principal Investigators	
1)	**Dr.S.S.Goudar,** Prof. of Physiology, J.N. Medical College, Belagavi.	Circular
2)	**Dr.Anita Dalal,** Prof of Gynecology, JNMC, KLEs Dr.Prabhakar Kore Hospital and MRC, Belagavi-10	Circular
3)	**Dr.Mahantesh Nagamoti,** Prof.of Microbiology, JNMC, Belagavi	Circular

Institutional Ethics Committee

KLE Academy of Higher Education and Research, Belagavi
[Formerly known as KLE University]
(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)
KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State, India
t: 0831-2470400 FAX: 0831-2493099 www.kledeemeduniversity.edu.in E-mail:kleclinicalresearch@gmail.com,

Ref: KAHER/IEC/2019-20/D- 28012036 **Date:** 20/Jan/2020

IEC Meeting Agenda

Institutional Ethics Committee of KAHER, Belagavi
Tuesday, 04/Feb/2020 at: 03:00 PM
Venue: Site management Office, G+2, KLE's Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi – 590010

Accreditations:

NABH

FERCAP

Registrations:

DCGI

OHRP

I. New agendas for review and approval: [Presentation from the PIs]

1. **Protocol No and Protocol title:** FEDX-1- 19100. "Multicenter, Single-dose, Randomized, Parallel Arm Two-treatment Bioequivalence Study of Mylan's Iron Dextran (50 mg/mL) versus Allergan's INFeD® (50 mg/mL) Following a Single Intravenous Injection in Patients with Iron Deficiency Anemia".
   Dr Arathi Darshan-PI
   Timings: 03:15 PM

2. **Protocol No.** TX05-03
   Protocol Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer.
   Dr.Maheshkumar Kalloli-PI
   Timings: 03:30 PM

II. Review of Proposals with Amendments:

1. **Protocol Title:** Post Marketing Phase-4 Study To Evaluate Safety, Tolerability, And Efficacy Of Kyprolis® (Carfilzomib) In Indian Patients With Relapsed Or Refractory Multiple Myeloma: A Prospective, Open-Label, Non-Comparative, Multicentre Study
   Protocol No: 20160372
   - Protocol amendment 1.0 dated 29-Oct-2019 and ICF Ind_4.0 dated 18-Nov-2019

2. **Protocol title:** A single blind randomized active controlled phase III study to evaluate immunogenicity, safety, tolerability of a candidate 14 valent pneumococcal polysaccharide conjugate vaccine administered to 6-8 weeks old healthy Indian infants in 6-10-14 weeks dosing schedule
   Protocol No: BECT051/PCV-Phase-III/CTP-02
   Dr. N.S.Mahanshetti – PI
   - Amended study documents

IEC Registrations:

- EC Reg. No.ECR/211/Inst/KA/2013/RR-19 – Under Rule New Drugs and Clinical Trials,2019
- OHRP Reg. No: IRB00008025 KLE University, IRB00001499 & FWA00024127.

III. Review of Proposal Revised Protocol:

1. **Protocol No: 201790**

Protocol Title: A 52-week, phase 3, multi centre, randomised, double-blind, efficacy and safety study comaparing GSK3196165 with placebo and with tofacitinib, in combination with methotrexate in participants with moderately to severely active rheumatoid arthritis who have an inadequate response to methotrexate.

Dr.Archana Uppin-PI

- IEC submission of study documents for final Approval

With reference to IEC letter No: 311019018 dated: 30/10/2019. IEC seeked the below mentioned study documents/clarification for further consideration and same submitted by PI

1. DCGI approval letter
2. CTRI/2019/12/022313
3. Additional Document-Import License No:TL/CT/19/000286

IV. Review of Annual Report:

- Nil

V. Review of Bi-Annual Report:

- Nil

VI. SAE reporting:

1. **Protocol no :** GBR 200-301

Protocol title: A prospective, multicentric, randomized, double blind, parallele group, study to compare the efficacy and safety of GBR 200 (similar biologic od Trastuzumab) versus innovator Trastuzumab both when given in combination with Paclitaxel in patients diagonosed with HER2 positive metastatic breast cancer

Dr. Mahesh Kalloli – PI

- IEC Notification of initial safety narrative for subject 07-014 occurred at site 07 letter dated 02 Jan 2020

VII. Protocol deviation/violation/ termination:

1. **Protocol No:** 14V-MC-JADY

Protocol Title: phase III, Multicenter study to evaluate the long term safety and efficacy of Baricitinib in patients with rheumatoid arthritis

Dr.Shailesh Udapudi

- IEC Notification of protocol deviation 02/Jan/2020

2. **Protocol No:GA29102**

Protocol Title: A phase III, Randomised, double blind, placebo controlled,Multicenter study to evaluate the efficacy (maintenance of remission) and safety of Etrolizumab compared eith placebo in patients with moderateto severe active ulcerative colitis who are naïve to TNF-inhibitor

Dr.V.P Gokak

- EC notification of PD dated 14 Dec 2019

3. **Protocol No: EFC14828**
Protocol Title: A Randomized, Double-blind, Placebo-controlled, parallel-group, Multicenter study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2Diabetes patients at High Cardiovascular Risk.
Dr. Prasad M R – PI
    - IEC notification of PD dated 31/12/2019

4. **Protocol no :** PBL/CR/2014/05/CT/DEN
Protocol title : A phase I/II, double blind, placebo controlled, randomized, multicentric, prospective study to evaluate the safety and immunogenicity of a single dose "Dengue tetravalent Vaccine, live attenuated (recombinant, lypohilized)" in healthy subjects
Dr. Madhav Prabhu – PI
    - IEC notification of PD letter dated 03 Jan 2020

5. **Protocol No: TX05-03**
Protocol Title: A randomized, double blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin in subjects with HER2 positive early breast cancer.
Dr. Mahesh Kalloli – PI
    - EC notification of PD letter dated 26 Dec 2019

6. **Protocol No:** EFC15082 / GEMELLI M
Protocol Title: A 26-week, Randomized, Open-label, Parallel-group Comparison of SAR341402 Mix 70/30 to NovoMix®30 in Adult Patients with Diabetes Mellitus using Pre-mix Insulin Analogs.
Dr. M. V. Jali – PI
    - IEC Notification of PD letter dated 24 Nov 2019
    - IEC Notification of PD letter dated 27 Nov 2019
    - IEC Notification of PD letter dated 24 Nov 2019

VIII. <u>The Committee will consider the following agendas which are for information.</u>

1. **Protocol No :** GA28951
Protocol Title : An open label extension and safety monitoring study of moderate to severe Ulcerative Coloitis patients previously enrolled in Etrolizumab phase II/III studies
Dr.V.P Gokak-PI
    - IEC Notification of DCGI Approval letter version 7.0 dated 30 Dec 2019

2. **Protocol No:** GA29102
Protocol Title: A phase III, Randomised, double blind, placebo controlled, Multicenter study to evaluate the efficacy (maintenance of remission) and safety of Etrolizumab compared eith placebo in patients with moderateto severe active ulcerative colitis who are naïve to TNF-inhibitor
Dr.V.P Gokak-I
    - IEC Notification of DCGI Approval letter version 6.0 dated 30 Dec 2019

3. **Study No.** 0927-17

Protocol Title: A multicentre, Open Label, Randomized, Two-Treatment, Two-Period, Two-Sequence, Single Dose, Cross-Over Study to Test Bioequivalence between Celerity's Doxorubicin Hydrochloride (Pegylated Liposomal) Injection 20mg/10ml (2mg/ml) and the Reference Product, Caelyx® [Doxorubicin Hydrochloride (Pegylated Liposomal) Injection 20 mg/10ml (2mg/ml)] in patients with Metastatic Breast Cancer.

Dr.Maheshkumar Kalloli-PI

- IEC Notification of Study Close-out Letter Dated 21-Dec-2019

4. **Protocol No:** LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study.

Dr.Navin Mulimani-PI

- IEC notification for revised group insurance dated 31/Dec/2019

5. **Protocol No :** SAMSON II

Protocol title: A randomised, double blind, parallel group, equivalence, multicentric phase III trial to compare the efficacy, safety, pharmacokinetics and immunogenicity of HD204 to avastin in patients with metastatic or recurrent non-squamous non small cell lung cancer

Dr. Rohan Bhinse – PI

- IEC notification of updated IU letter dated 18 Dec 2019
- IEC notification of below mentioned source documents dated 11 Dec 2019

IX. **<u>The Committee will consider the following agendas which are for information.</u>**

1. **Protocol no :** 0063-17

Protocol Title: A global, multicenter, three arms, open-label randomized study to evaluate the efficacy and safety of Nanosomal Docetaxel Lipid Suspension compared to Taxotere® (Docetaxel Injection Concentrate) in triple-negative breast cancer patients with locally advanced or metastatic breast cancer after failure to prior chemotherapy.

Dr.Rohan Bhise-PI

- SAE cross notification letter dated 02 Jan 2020

2. **Protocol No:** 0978-17

Protocol title: A Randomized, double blind, double-dummy, multicentric, parallel, phase III study to evaluate the efficacy and safety of Tacrolimus Lipid Tablets (manufactured by Intas pharmaceutical limted) compared to Prograf (tacrolimus immediate release capsules-Astellas pharma Canada, Inc) in adult patient with active rheumatoid arthritis who have resistance OR intolerance to DMARDs

Dr. Archana Uppin – PI

- EC notification of progress report for above referenced study dated 28 Dec 2019

3. **Protocol Title:** A randomized, double-blind, placebo-controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhoea in children.

Protocol No: LPS14941/KIDDIE

IEC Registrations:

- EC Reg. No.ECR/211/Inst/KA/2013/RR-19 – Under Rule New Drugs and Clinical Trials,2019
- OHRP Reg. No: IRB00008025 KLE University, IRB00001499 & FWA00024127.

Dr.Mahantesh Patil-PI

- IEC notification for SUSAR- report# 12 letter dated 27/12/2019

4. **Protocol No:** 20140444
   Protocol title: A phase III randomised, double blind, placebo controlled, parallel-group study to evaluate the safety and efficacy of Denosumab in paediatric subjects with glucocorticoid-induced Osteoporosis
   Dr.(Prof). N.S.Mahanshetti – PI
   1. IEC Notification of SUSAR letter dated 17 Dec 2019
   2. Quarterly line listing (Q3 year 2019) for the Indian SAEs (non-SUSARs) for IEC notification dated 10 Dec 2019

5. **Protocol No:** PMZ-1602/CT-3.1/2019;CTNOC No: CT/ND/66/2019
   Protocol title: A prospective, multicentric, randomized, double blind, parallel, phase III clinical study to assess efficacy of PMZ-1602 along with standard treatment in patients of acute ischemic stroke
   Dr. Saroja A.O - PI
   - IEC notification of site initiation visit letter dated 24 Dec 2019

6. **Protocol No:** 0927-17
   Protocol Title: A Multicentre, open label, randomized, two treatment, two period, two sequence single dose cross over study to test for bioequivalence between celerity's doxorubicin hydrochloride (pegylated liposomal) injection 20mg/10ml (2mg/ml) and the reference caelyx® [Doxorubicin hydrochloride pegylated liposomal injection 20mg/10ml (2mg/ml)] in patients with metastatic breast cancer
   Dr. Mahesh Kalloli – PI
   - IEC notification of misplaced of ECHO film and original ECG film for the subject no.:111-10 letter dated 20 Dec 2019

7. **Protocol Title:** A randomized, double-blind, placebo-controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhoea in children.
   Protocol No: LPS14914/KIDDIE
   Dr.Mahantesh Patil-PI
   - IEC notification to use of approved ICFs letter dated: 07 Dec 2019

8. **Protocol No:** SH600003
   Protocol title : The immune Lot-to Lot consistency and non-inferiority of SHAN6 vaccine in comparison to SHAN 5 + SHANIPV when administered as three doses at 6-8, 10-12 and 14-16 weeks of age in healthy Indian infants, concomitantly with oral rotavirus vaccine SH600003
   Dr.S.M.Dhaded - PI
   - IEC notification of CIOMS letter dated 04/Dec/2019

IEC Registrations:

- EC Reg. No.ECR/211/Inst/KA/2013/RR-19 – Under Rule New Drugs and Clinical Trials,2019
- OHRP Reg. No: IRB00008025 KLE University, IRB00001499 & FWA00024127.

9. **Protocol No:** 1002-043
Protocol Title: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at High Risk For, Cardiovascular Disease Who Are Statin Intolerant
Dr.V.A. Kothiwale-PI
   - Additional information regarding ethics committee notification for misplaced original source documents of subject No: 4328011002 letter dated 18 Dec 2019

10. **Protocol No:** EFC15082 / GEMELLI M
Protocol Title: A 26-week, Randomized, Open-label, Parallel-group Comparison of SAR341402 Mix 70/30 to NovoMix®30 in Adult Patients with Diabetes Mellitus using Pre-mix Insulin Analogs.
Dr. M. V. Jali – PI
   - IEC notification of SASR#05 for insulin aspart/SAR341402 dated 14 Dec 2019

For your attention:

Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Prof. (Dr) M.S. Ganachari

Member-secretary of IEC

To:

Circular and Submission of IEC Dossier		
1)	**Dr. Subarna Roy,** Scientist 'F', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V. Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member

3)	**Dr. P. A. Patil,** Prof of Pharmacology[USM-KLE]IMP,"VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr. S. S. Goudar,** Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr. Yeshita Pujar,** Prof of Obstetrics& Gynecology, JNMC, Belagavi	Member
6)	**Dr. Roopa Bellad,** Prof of Pediatrics, J.N. Medical College, Belagavi	Member
7)	**Dr. Nayana Hashilkar,** Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
8)	**Mrs. Vaishnavi V Kivadasannavar,** M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
9)	**Shri.Tammanna Dadu Kore,** Farmer, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
10)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
11)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, KLE College of Pharmacy, Belagavi	Scientific Member
12)	**Prof. (Dr.) M.S. Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
	Administrators of KAHER (Deemed to be University)	
1)	**The Registrar,** KAHER, deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed University, Belagavi, For Information	Circular
	Principal Investigators	
1)	**Dr. Maheshkumar Kalloli,** Consultant, Oncology Dept., KLES Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belgaum-590 010, Karnataka, India.	Circular
2)	**Dr. Aarthi Darshan,**Consultant Physician, Dept. of General Medicine, KLES Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belgaum-590 010, Karnataka, India.	Circular

IEC Registrations:

- EC Reg. No.ECR/211/Inst/KA/2013/RR-19 – Under Rule New Drugs and Clinical Trials,2019
- OHRP Reg. No: IRB00008025 KLE University, IRB00001499 & FWA00024127.

Institutional Ethics Committee

KLE Academy of Higher Education and Research, Belagavi
[Formerly known as KLE University]
(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)
KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State, India
(: 0831-2470400 FAX: 0831-2493099 www.kledeemeduniversity.edu.in E-mail:kleclinicalresearch@gmail.com,

Ref: KAHER/IEC/2019-20/D- 271219003 **Date:** 24/Dec/2019

IEC Meeting Agenda

Institutional Ethics Committee of KAHER, Belagavi
Saturday, 04/Jan/2020 at: 03:00 PM
Venue: Site management Office, G+2, KLE's Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi - 590010

Accreditations:

NABH

FERCAP

Registrations:

DCGI

OHRP

I. New agendas for review and approval: [Presentation from the PIs]

1. **Protocol No : 0137-18**
   Protocol Title : A multicentric, open-label, multiple dose, balanced, randomized, two-treatment, two-Period, two-Sequence, full replicate, cross over study to evaluate bioequilance of Etoposide Capsules 100 mg (Intas Phramaceuticals Ltd. India) with Vepesid soft capsules 100 mg (Bristol-Myers Squibb S.r.l Itlay) in patients with metastatic small cell lung cancer(SCLC) under fasting conditions.
   Dr.Maheshkumar Kalloli-PI
   Timing-03:15PM

2. **Protocol No:** RLS/DRM/2018/04; Version 2.0, Dated: 26 Jul 2019
   Protocol Title : Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-046 / Stelara® in patients with moderate to severe plaque psoriasis
   Dr.Shivakumar Patil-PI
   Timing-03:30PM

3. **Protocol Title:** A Comparative, Randomized, Two Arm, Double Blind, Parallel Group, Multicentric, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Netarsudil Ophthalmic Solution 0.02% w/v Versus Timolol Maleate Eye Drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension."
   Dr. Smitha K.S-PI
   Timing-03:45PM

4. **Protcol Title :** E Motive Trial : Early detection of postpartum haemorrhage and treatment using the World Health Organisation MOTIVE ' first response' bundle: A cluster randomized trial with health economic analysis and mixed-method evaluation
   Dr.Yeshita Pujar-PI
   Timing-04:00PM

II. Review of Proposals with Amendments:

1. **Protocol No:** EFC15082 / GEMELLI M
   Protocol Title: A 26-week, Randomized, Open-label, Parallel-group Comparison of SAR341402 Mix 70/30 to NovoMix®30 in Adult Patients with Diabetes Mellitus using Pre-mix Insulin Analogs.
   Dr. M. V. Jali – PI
   - Amended of version 2.0 patient dairies

IEC Registrations:

- EC Reg. No.ECR/211/Inst/KA/2013/RR-19 – Under Rule New Drugs and Clinical Trials,2019
- OHRP Reg. No: IRB00008025 KLE University, IRB00001499 & FWA00024127.

ok

III. Review of Proposal Revised Protocol:

1. **Protocol No: 201790**

   Protocol Title: A 52-week, phase 3, multi centre, randomised, double-blind, efficacy and safety study comaparing GSK3196165 with placebo and with tofacitinib, in combination with methotrexate in participants with moderately to severely active rheumatoid arthritis who have an inadequate response to methotrexate.

   Dr.Archana Uppin-PI

   With reference to IEC letter No: 311019018 dated: 30/10/2019. IEC seeked the below mentioned study documents/clarification for further consideration and same has been received

   1. DCGI approval letter
   2. CTRI/2019/12/022313
   3. Additional Document-Import License No:TL/CT/19/000286

2. **Protocol Title:** A randomized, double-blind, placebo-controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhoea in children.

   Protocol No: LPS14914/KIDDIE

   Dr.Mahantesh Patil-PI

   With reference to IEC letter no: KAHER/IEC/2019-20/D-1501019015 and dated 10/10/2019. IEC seeked the below mentioned study documents/clarification for further consideration and same has been received by the IEC.

   1. Addition of KLE site name in the DCGI notification letter dated: 04/Dec/19
   2. Final Executed Clinical Trial Agreement letter dated: 25/Nov/2019

IV. Review of Annual Report:

- Nil

V. Review of Bi-Annual Report:

1. **Protocol No:** LUF-44-001

   Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study.

   Dr.Navin Mulimani-PI

   - IEC Notification of study Annual report Letter Dated 10-Dec-2019

VI. SAE reporting:

1. **Protocol Title:** A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism

   Reference: Study No. 20150238

   Drug: Etelcalcetide

IEC Registrations:

- EC Reg. No.ECR/211/Inst/KA/2013/RR-19 – Under Rule New Drugs and Clinical Trials,2019
- OHRP Reg. No: IRB00008025 KLE University, IRB00001499 & FWA00024127.

Dr.Ritesh Vernekar-PI

- IEC notification of Final Safety narrative for subject 21006 letter dated: 13-Dec-2019

2. **Protocol ID:** PCV-10-003
   Protocol Title: A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety, Tolerability, Immunogenicity and Non-Interference with Concomitant Vaccinations of Serum Institute of India's 10-Valent Pneumococcal Conjugate Vaccine (PNEUMOSIL®) in Healthy Indian Infants
   - IEC notification of other site Hamdard Institute of Medical Sciences letter dated:05-Nov-2019

VII. Notifications of Study close-out/Archival:

1. **Protocol No:** CT/PAC/1701 (V.1.0) (India).
   Study Title: A Randomized, Open Label, Multi Center, Two Treatment, Two Period, Two Sequence, Single Dose, Crossover, Bioequivalence Study of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound), 100 mg/vial manufactured by Teva Pharmachemie, The Netherlands, for Teva Pharmaceuticals USA, and Abraxane® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension)(albumin-bound), 100 mg/vial manufactured by Abraxas BioScience LLC, USA for Celgene Corporation, USA in Patients with Metastatic Breast Cancer.
   - IEC Notification of Study Close-out Letter Dated 10-Dec-2019

VIII. Protocol deviation/violation/ termination:

1. **Protocol Title:** A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism
   Reference: Study No. 20150238
   Drug: Etelcalcetide
   Dr.Ritesh Vernekar-PI
   - IEC Notification of Protocol Deviation Letter for subject number 23830016009 letter Dated 19 Nov 2019
   - IEC notification of Protocol deviation of subject no:23830016005 letter dated: 18-Nov-2019

2. **Protocol Title:** A phase III, multicenter, randomized. Observer blind, parallel group, three arms, controlled clinical trial to evaluate the efficacy and safety of topically applied calcipotrial/AKVANO cutaneous solution against Daivonex® 50ug/g Cream, LEO and placebo in patients with mild to moderate plaque psoriasis.
   Study No: CRSC160004
   Dr.Snehal Lunge-PI
   - IEC notification of Number 06-017 Protocol Deviation letter dated: 07-Dec-2019

- IEC notification of Screening Number 06-009 Protocol Deviation letter dated: 07-Dec-2019

3. **Protocol No: EFC14828**
   Protocol Title: A Randomized, Double-blind, Placebo-controlled, parallel-group, Multicenter study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2Diabetes patients at High Cardiovascular Risk.
   Dr. Prasad M R – PI
   - IEC notification of protocol Deviation letter dated: 23-Nov-2019
     - 035000100008, 010,004,001,020,017,016,019 and 005

4. **Protocol No: EFC14875**
   Protocol Title: A Randomized, Double-blind, Placebo-controlled, parallel-group, Multicenter study to demonstrate the effects of Sotagliflozin on cardiovascular and renal events in patients with Type 2 Diabetes, Cardiovascular Risk factors and moderately impaired renal function.
   Dr. Prasad M R – PI
   - IEC notification of protocol Deviation letter dated: 23-Nov-2019
     - 035000500013,008 and 012

5. **Protocol No: INSLIL08556**
   Protocol Title: A Randomized, 24-week, Controlled, Open Label, Parallel Arm, Multicenter Study Comparing the Efficacy and Safety of the Insulin Glargine/Lixisenatide Fixed Ratio Combination to Insulin Glargine in Type 2 Diabetes Patients, Inadequately Controlled on Basal Insulin with or without Metformin.
   Dr. Vikranth Ghatnatti –PI
   - IEC notification of protocol Deviation of the subject no:356012004 and 356012009 letter dated 28-Nov-2019

6. **Protocol No**: 1002-043
   Protocol Title: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at High Risk For, Cardiovascular Disease Who Are Statin Intolerant
   Dr.V.A.Kothiwale-PI
   - IEC notification of Protocol deviation of 4328011002 letter dated: 09-Dec-2019

IX. **<u>The Committee will consider the following agendas which are for information.</u>**

1. **Protocol Title:** A Phase 2 dose- range finding 12-week, double-blind, randomized, parallel group study to evaluate safety and efficacy of GRC 27864 in patients with moderate osteoarthritis pain
   Dr.Shailesh Udapudi-PI
   - IEC notification of change in the name of Sponsor entity letter dated: 17-Dec-2019

IEC Registrations:

- EC Reg. No.ECR/211/Inst/KA/2013/RR-19 – Under Rule New Drugs and Clinical Trials,2019
- OHRP Reg. No: IRB00008025 KLE University, IRB00001499 & FWA00024127.

2. **Protocol No: 201790**
Protocol Title: A 52-week, phase 3, multi centre, randomised, double-blind, efficacy and safety study comaparing GSK3196165 with placebo and with tofacitinib, in combination with methotrexate in participants with moderately to severely active rheumatoid arthritis who have an inadequate response to methotrexate.
Dr.Archana Uppin-PI
    - IEC notification of typo error in approval letter dated : 10-Dec-2019
    - IEC notification of IU dated 08-Nov-2019 letter dated : 07-Dec-2019

3. **Protocol Title:** A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism
Reference: Study No. 20150238
Drug: Etelcalcetide
Dr.Ritesh Vernekar-PI
    - IEC notification of CIOMs letter dated: 04-Dec-2019

4. **Protocol Title:** A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism
Reference: Study No. 20150238
Drug: Etelcalcetide
Dr.Ritesh Vernekar-PI
    - IEC notification of QLL-03 for the Indian SAEs letter dated:14/Dec/2019

5. **Protocol No: MYL-14020-3001**
Protocol Title: Multicentre, Double-Blind, Randomized, Parallel-Group study to Assess the Efficacy and safety of MYL-14020 Compared with Avastin®, in the first-Line Treatment of patients with Stage IV Non-Squamous Non-Small Cell Lung Cancer.
Dr. Mahesh Kalloli – PI
    - IEC Notification of CIOMS letter dated: 17-Dec-2019

4. **Protocol No:** LUF-44-001
Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study.
Dr.Navin Mulimani-PI
    - IEC notification of Bi-Annual report letter dated: 28-Dec-2019
    - IEC notification of Certificate of analysis letter dated: 28-Nov-2019

IEC Registrations:

- EC Reg. No.ECR/211/Inst/KA/2013/RR-19 – Under Rule New Drugs and Clinical Trials,2019
- OHRP Reg. No: IRB00008025 KLE University, IRB00001499 & FWA00024127.

6. **Protocol No: EFC14875**

Protocol Title: A Randomized, Double-blind, Placebo-controlled, parallel-group, Multicenter study to demonstrate the effects of Sotagliflozin on cardiovascular and renal events in patients with Type 2 Diabetes, Cardiovascular Risk factors and moderately impaired renal function.

Dr. Prasad M R – PI

- IEC Notification of Safety Alert #109#110IN#111 Letter Dated 11-Dec-2019
- IEC Notification of Safety Alert #109#110IN#111 Letter Dated 16-Dec-2019
- IEC Notification of Safety Alert #104#105IN#106#107#108 Letter Dated 11-Dec-2019
- IEC Notification of Safety Alert #99#100IN#101#102#103 Letter Dated 11-Dec-2019
- IEC Notification of Safety Alert #96#97IN Letter Dated 11-Dec-2019
- IEC Notification of Safety Alert #93 and 94IN #95 Letter Dated 11-Dec-2019

5. **Protocol No: TDM1.17.001.03**

Protocol Title : A prospective, randomized, multi center. Comparative. Open label, parallel study to evaluate the efficacy, safety and pharmacokinetics to Test- Trastuzumab Emtanstine (ZRC-3256 ; Cadila Healthcare Ltd)and Reference – Trastuzumab Emtanstine (Kadcyla®, a product of Roche) in HER2 – positive metastatic Breast Cancer Patients.

Dr.Maheshkumar Kalloli-PI

- IEC notification of Insurance (Validity 19-Mar-2020) letter dated: 04-Dec-2019
- IEC notification of Note to File letter dated:04-Dec-2019

6. **Protocol Number:** CT-P16 3.1

Study Title: A Double-Blind, Randomized, Active-Controlled, Parallel-Group, Phase 3 Study to Compare Efficacy and Safety of CT-P16 and EU-Approved Avastin® as First-Line Treatment for Metastatic or Recurrent Non-Squamous Non-Small Cell Lung Cancer

Dr.Maheshkumar Kalloli-PI

- IEC notification of DCGI approval Version 2.0 dated 14-06-2019 letter dated:09-Dec-2019

7. **Protocol No: TX05-03**

Protocol Title: A randomized, double blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin in subjects with HER2 positive early breast cancer.

Dr. Mahesh Kalloli – PI

- IEC Notification of CIOMS letter dated: 16-Dec-2019

8. **Protocol No: 0927-17**

Protocol Title: A Multicentre, open label, randomized, two treatment, two period, two sequence single dose cross over study to test for bioequivalence between celerity's doxorubicin hydrochloride (pegylated liposomal) injection 20mg/10ml (2mg/ml) and the reference caelyx®

IEC Registrations:

- EC Reg. No.ECR/211/Inst/KA/2013/RR-19 – Under Rule New Drugs and Clinical Trials,2019
- OHRP Reg. No: IRB00008025 KLE University, IRB00001499 & FWA00024127.

[doxorubicin hydrochloride pegylated liposomal injection 20mg/10ml (2mg/ml)] in patients with metastatic breast cancer.

Dr. Mahesh Kalloli – PI

- IEC Notification of Note to file letter dated: 04-Dec-2019
- IEC Notification of updated CTRI-2018/0 letter dated: 04-Dec-2019

9. **Protocol No:** ALK18/EN124/-CET1

Protocol Title: A prospective, multicenter, randomized, double blind, parallel group study to compare the efficacy and safety of biosimilar cetuximab versus innovator cetuximab in combination with platinum-based chemotherapy in patients with recurrent locoregional or metastatic squamous cell carcinoma of the head and neck (SCCHN)

Dr.Maheshkumar Kalloli-PI

- IEC notification of ICDs clarification letter dated: 26-Nov-2019

10. **Protocol No** : 17-VIN-0772

Protocol Title : A Multicentre, Open-label, Balanced, Randomized, Two-Treatment, Two-Period, Single Dose, Cross-over, Bioequivalance Study of Bortezomib for Injection 3.5 mg/Vial of Dr. Reddy's Laboratoires Limited, India and VELCADE® (Bortezomib) for injection 3.5 mg/vial (Distributed and Marketed by : Millennium Pharmaceuticals, Inc., 40 Lansdowne Street, Cambridge, MA 02139) in Previously Untreated Multiple Myeloma and/or Relapsed Multiple Myeloma Patients.

Dr.Rohan Bhise-PI

- IEC notification of source documents letter dated:11-Dec-2019
- IEC notification of Error in in Validity- 30-Sep-2019 instead of 29-Feb-2020

11. **Protocol No:**0979-17

Protocol Title: A randomized, multi-centre, open label, two-arm, parallel, clinical study to evaluate the efficacy, safety and tolerability of tacrolimus lipid suspension for enema of Intas Pharmaceuticals Limited, India against CORTENEMA® (Hydrocortisone retention enema) of Anip Acquisition Company, USA in adult patients with mild to moderately active left-sided/distal ulcerative colitis refractory to mesalamine treatment.

Dr.Santosh Hazare-PI

- IEC notification of study documents letter dated: 12-Dec-2019

12. **Protocol No**: SAMSON-II

Protocol Title: A Randomized, Double-blind, Parallel Group, Equivalence, Multicentre Phase III Trial to Compare the Efficacy, Safety, Pharmacokinetics and Immunogenicity of HD204 to Avastin® in patients with Metastatic or Recurrent Non-Squamous Non-Small Cell Lung Cancer

Dr.Rohan Bhise-PI

- IEC notification of source documents letter dated: 11-Dec-2019

IEC Registrations:

- EC Reg. No.ECR/211/Inst/KA/2013/RR-19 – Under Rule New Drugs and Clinical Trials,2019
- OHRP Reg. No: IRB00008025 KLE University, IRB00001499 & FWA00024127.

13. **Protocol Title:** A randomized, double-blind, placebo-controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhoea in children.
Protocol No: LPS14914/KIDDIE
Dr.Mahantesh Patil-PI
    - IEC notification of Insurance certificate (Validity- 01-May-2019 to 30-Apr-2020) letter dated: 13-Dec-2019

14. **Protocol No: INSLIL08556**
Protocol Title: A Randomized, 24-week, Controlled, Open Label, Parallel Arm, Multicenter Study Comparing the Efficacy and Safety of the Insulin Glargine/Lixisenatide Fixed Ratio Combination to Insulin Glargine in Type 2 Diabetes Patients, Inadequately Controlled on Basal Insulin with or without Metformin.
Dr. Vikranth Ghatnatti -PI
    - IEC Notification of safety alert #30 to # 31 Letter Dated 18 Nov 2019

15. **Protocol No: 2015-DFU-301**
Protocol Title: A phase 3, Randomized, Double-blind, parallel-group, vehicle controlled, Multicenter study of the Efficacy and safety of Granexin gel in the treatment of Diabetic Foot Ulcer (GAIT 1)
Dr. Vikranth Ghatnatti-PI
    - IEC Notification of Source version 3.0 dated 23-Oct-2019 templates Letter Dated 18 Nov-2019

16. **Protocol No**: EFC15082 / GEMELLI M
Protocol Title: A 26-week, Randomized, Open-label, Parallel-group Comparison of SAR341402 Mix 70/30 to NovoMix®30 in Adult Patients with Diabetes Mellitus using Pre-mix Insulin Analogs.
Dr. M. V. Jali – PI
    - IEC notification of protocol amendment 1.0 dated 25-Nov-2019 letter dated: 19-Dec-2019

17. **Protocol Title:** A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism
Reference: Study No. 20150238
Drug: Etelcalcetide
Dr.Ritesh Vernekar-PI
    - IEC notification of Semi-annual safety report 01-Jan-2019 through 30 June 2019 letter dated: 04-Dec-2019.

IEC Registrations:

- EC Reg. No.ECR/211/Inst/KA/2013/RR-19 – Under Rule New Drugs and Clinical Trials,2019
- OHRP Reg. No: IRB00008025 KLE University, IRB00001499 & FWA00024127.

18. **Protocol No:** 20170199

Protocol Title: A Multicentre, Open-Label, Single-arm Study to evaluate safety and tolerability of Repatha in Patients with Homozygous familial Hypercholesterolemia (HoFH) in India"

Dr. V.A. Kothiwale - PI

- IEC Notification of Q3 Line listing for the Indian SAEs letter dated: 10-Dec-2019

19. **Protocol Title:** A randomized, double-blind, placebo-controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhoea in children.

Protocol No: LPS14914/KIDDIE

Dr.Mahantesh Patil-PI

- IEC notification of source document templates letter dated: 12-Dec-2019

20. **Protocol Title:** Prominent: Pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes.

Protocol No: K-877-302

Dr.V.A.Kothiwale-PI

- IEC notification of CIOMS letter dated: 12-Dec-2019

21. **Study Title**: A phase II/III, multicenter, randomized, open label, active controlled, clinical study to assess the immunogenicity and safety of tetanus toxoid, diphtheria toxoid, and acellular pertussis (Tdap) vaccine manufactured by Serum institute of India Pvt. Ltd. (SIIPL) in comparison with Boostrix® vaccine of GSK in healthy adults, adolescents and children in India. Protocol Identifier: SII-Tdap/IN-02 V- 2.0 dated 14 Jun 2018

Dr.N.S.Mahantashetti-PI

- IEC notification of ICF process and ICF activity sheet letter dated 02-Dec-2019
- IEC notification of typo error in letter dated 04 Jul 2019 and letter dated: 02-Dec-2019
- IEC notification of typo error in continuation letter dated 10 Jun 2019 and letter dated: 02-Dec-2019

22. **Trial No:** BECT /HepA-phase-111/045

Protocol No: BECT045/HepA-Phase-III/CTP-02

Study Title: A single blind, parallel, randomized Phase-Ill comparative study to evaluate safety and immunogenicity of two intramuscular doses of inactivated Hepatitis A vaccine administered 6 months apart, in 1-15 year-old healthy Hepatitis A vaccine-na'ive children

Dr.N.S.Mahantashetti-PI

- IEC notification of renewed insurance certificate letter dated: 22/Nov/2019

IEC Registrations:

- EC Reg. No.ECR/211/Inst/KA/2013/RR-19 – Under Rule New Drugs and Clinical Trials,2019
- OHRP Reg. No: IRB00008025 KLE University, IRB00001499 & FWA00024127.

23. **Protocol Title:** A 12-week double-blind, randomized, multi-center study comparing the efficacy and safety of once monthly subcutaneous AMG 334 against placebo in adult episodic migraine patients (EMPOwER).
Protocol No.:CAMG334A2302
Dr.Saroja A.O-PI
    - IEC notification of IB (Edition 8 and dated: 28-Oct-2019)and Summary of changes letter dated: 06-Dec-2019
    - IEC notification of SUSARs-01-April -2019 to 30-sep-2019 letter dated: 25-Nov-2019
    - IEC notification for CRF completion guidelines version 5.0

24. **Protocol title:** Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-024 / Lucentis® in patients with neovascular (wet) age-related macular degeneration
Protocol No.: RLS/OPT/2016/05; Version 2.0, Dated: 23 Jan 2017
Dr.Rekha Mudhol-PI
    - IEC notification of Protocol Deviation of the subject 71002-001 and 71002-002 letter dated: 22-Nov-2019

25. **Protocol Title:** A global, multicenter, three arms, open-label randomized study to evaluate the efficacy and safety of Nanosomal Docetaxel Lipid Suspension compared to Taxotere® (Docetaxel Injection Concentrate) in triple-negative breast cancer patients with locally advanced or metastatic breast cancer after failure to prior chemotherapy.
Study Title: 0063-17
Dr.Rohan Bhise-PI
    - IEC notification of study documents letter dated: 28-Nov-2019

26. **Protocol No**: 1002-043
Protocol Title: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at High Risk For, Cardiovascular Disease Who Are Statin Intolerant
Dr.V.A.Kothiwale-PI
    - IEC notification of SUSARS letter dated:20-Nov-2019
    - IEC notification of missed source document subject no:4328011002 letter dated:11-Nov-2019

27. **Protocol No: 20140315**
Protocol Title: Phase 3, Randomized, open label, controlled, multiple –dose, efficacy, safety, pharmacokinetics and pharmacodynamic study of Etelcacetide in pediatric subject 28 days to < 18 years of age with secondary hyperparathyroidism and chronic kidney disease receiving, Maintenance Hemodialysis.

IEC Registrations:

- EC Reg. No.ECR/211/Inst/KA/2013/RR-19 – Under Rule New Drugs and Clinical Trials,2019
- OHRP Reg. No: IRB00008025 KLE University, IRB00001499 & FWA00024127.

Dr. Mahantesh Patil - PI

- IEC Notification of typo error in IU dated 23-Nov-2019 instead of 25-Nov-2019

28. Study Protocol No.: PMZ-1620/CLINICAL-2.3/2018;DCGICTNOC No.:CT/ND/18/2018
Study Title: A Prospective, Multicentric, Randomized, Double Blind, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Patients of Acute Spinal Cord Injury

- IEC notification of Extension of shelf life of IMP letter dated: 10-Dec-2019
- IEC notification of study documents letter dated: 10-Dec-2019
  - CRF
  - Unscheduled Visit CRF
  - AE Form
  - SAE Form
  - Pregnancy Exposure Form

X. Any other matter with the permission of the chair

For your attention:

Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Prof. (Dr) M.S. Ganachari

Member-secretary of IEC

To:

Circular and Submission of IEC Dossier		
1)	**Dr. Subarna Roy,** Scientist 'F', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V. Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr. P. A. Patil,** Prof of Pharmacology[USM-KLE]IMP,"VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member

IEC Registrations:

- EC Reg. No.ECR/211/Inst/KA/2013/RR-19 – Under Rule New Drugs and Clinical Trials,2019
- OHRP Reg. No: IRB00008025 KLE University, IRB00001499 & FWA00024127.

7)	**Dr. Nayana Hashilkar,** Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
8)	**Mrs. Vaishnavi V Kivadasannavar,** M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
9)	**Shri.Tammanna Dadu Kore,** Farmer, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
10)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
11)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, KLE College of Pharmacy, Belagavi	Scientific Member
12)	**Prof. (Dr.) M.S. Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
	Administrators of KAHER (Deemed to be University)	
1)	**The Registrar,** KAHER, deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed University, Belagavi, For Information	Circular
	Principal Investigators	
1)	**Dr. Maheshkumar Veeranna Kalloli,** Consultant, Oncology Dept., KLES Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belgaum-590 010, Karnataka, India.	Circular
2)	**Dr.Shivakumar Patil,**Assistant Professor-JNMC, Consultant dermatologist and Dermatosurgeon, KLES Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belgaum-590 010, Karnataka, India	Circular
3)	**Dr.Smitha K S,** Consultant, Dept. of Ophthalmology, KLES Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belgavi-590 010, Karnataka, India.	Circular
4)	**Dr. Yeshita Pujar,** Prof of Obstetrics& Gynecology, JNMC, Belagavi	Circular

Institutional Ethics Committee

KLE Academy of Higher Education and Research, Belagavi
[Formerly Known as KLE University]
(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)
KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State, India
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Email:kleclinicalresearch@gmail.com

Ref: KAHER/IEC/2019-20/D- 07091901 ***Date: 04/09/2019***

IEC Meeting Agenda

Institutional Ethics Committee of KAHER, Belagavi

Friday, 13/09/2019 at: 03.30 PM

Venue: Site management Office, G+2, KLES Dr.PK Hospital &MRC, Nehru Nagar, Belagavi

I. New agendas for review and approval: [Presentation from the PIs]

1. **Protocol No:**0979-17
   Protocol Title: A randomized, multi-centre, open label, two-arm, parallel, clinical study to evaluate the efficacy, safety and tolerability of tacrolimus lipid suspension for enema of Intas Pharmaceuticals Limited, India against CORTENEMA® (Hydrocortisone retention enema) of Anip Acquisition Company, USA in adult patients with mild to moderately active left-sided/distal ulcerative colitis refractory to mesalamine treatment.
   Dr.Santosh Hajare-PI
   Timing: 03:45 PM

2. **Protocol No:** SAMSON-II
   A Randomized, Double-blind, Parallel Group, Equivalence, Multicentre Phase III Trial to Compare the Efficacy, Safety, Pharmacokinetics and Immunogenicity of HD204 to Avastin® in patients with Metastatic or Recurrent Non-Squamous Non-Small Cell Lung Cancer
   Dr.Rohan Bhise-PI
   Timing: 04:00 PM

3. **Protocol No:** ALK18/EN124/-CET1
   Protocol Title: A prospective, multicenter, randomized, double blind, parallel group study to compare the efficacy and safety of biosimilar cetuximab versus innovator cetuximab in combination with platinum-based chemotherapy in patients with recurrent locoregional or metastatic squamous cell carcinoma of the head and neck (SCCHN)
   Dr.Maheshkumar Kalloli-PI
   Timing: 04:15 PM

4. **Protocol No:**BSV-LEUPR_18_05
   Protocol Title: Efficacy, Safety, and Pharmaco-kinetics of Leuprolide Acetate for Injection 3.75mg (Depot) Administered in Subjects with Advanced Adenocarcinoma of Prostate: A Randomized, Active Controlled, Comparative, Open Label, Multi-Center, Phase 3 study.
   Dr.Maheshkumar Kalloli-PI
   Timing: 04:30 PM

Accreditations:

NABH

FERCAP

Registrations:

DCGI

OHRP

II. **Review of Proposals with Amendments:**

1. **Protocol Title:** Phase 3, randomized, open label, controlled, multiple-dose, efficacy, safety, pharmacokinetic and Pharmacodynamic study of etecalctide in pediatric subjects 28 days to <18 years of age with hyperparathyroidism and chronic kidney disease receiving maintenance hemodialysis

   Protocol No: 20140315

   Dr.Mahantesh Patil-PI

   - Amended study protocol supplement Version 1 date: 29-May-2019 for review and approval

2. **Protocol No: 2015-DFU-301**

   Protocol Title: A Phase 3, Randomized, Double-blind, Parallel-group,Vechile controlled, Multicentre Study of the Efficacy and safety of Granexin Gel in the Treatment of Diabetic Foot Ulcer (GAIT 1)

   Dr.Vikrant Ghatnatti-PI

   - Amended study protocol Version 7.0 date: 13-Jun-2019 for review and approval

III. **Review of Revised Project Proposals:**

1. **Protocol Title**: Immune Lot-to-Lot Consistency and Non-Inferiority of SHAN6™ vaccine in Comparison to SHAN 5® + SHANIPV™ When Administered as Three Doses at 6-8, 10-12 and 14-16 weeks of age in Healthy Indian Infants, Concomitantly with Oral Rotavirus Vaccine. SH600003.

   Dr.S.M.Dhaded-PI

   PI response letter have been received by the IEC on 30/08/2019. IEC reviewed and discussed the submitted responses by Principal Investigator.

   1. Home visit to be mentioned in protocol after vaccination; if unsolicited AE's or SAE's occurs.

      Response: as per the current protocol, a phone call is must 3 to 4 days after vaccination, this is to inquire occurrence of nay AEs and SAEs and to check the health status of the subjects
   2. Final CTA
   3. Subject travel allowance should be included in the ICFs

      Response: amended study ICF with translation and back translation certificates (Included TA per visit not more than Rs.550/-)
   4. Submission of multiple vials guidelines for leftover doses Disposing/Discarding and storage of used vials and same should be documented properly

      Response: Remaining quantity of vaccine, form multi dose vial after single dose administration will be retained at the site for accountability and return back to the sponsor at the end of the study
   5. CTRI- Certificate

      Response: CTRI registration certificate included with KLE site name

IV. **Review of Annual Report:**

1. **Research project** - "Breastfeeding Education Suppo
   Dr.N.S.Mahantashetti-PI

2. **Protocol Title: GS-US-419-3895:** "Combined Pha
   Controlled Studies Evaluating the Efficacy and S
   Maintenance of Remission in Subjects with Moderat
   Dr.V.P.Gokak-PI

V. **SAE reporting:**
   -Nil

VI. **Protocol deviation/violation/ termination:**

1. **Protocol Title:** LRP/YLB113/2017/001_ Randomi
   compare the impact of single transition from Enb
   safety, PK and compare usability of both AIs in
   (RA)
   Dr.Archana uppin-PI
   - IEC notification of Protocol Deviation letter

2. **Protocol Title:** MYL-1402O-3001: Multicentre,
   Study to Assess the Efficacy and Safety of MYL-1
   -line treatment of Patient with Stage IV Non-Squan
   Protocol Version 2.0 dated 04 April 2018
   Dr.Maheshkumar Kalloli-PI
   - IEC notification of PD letter dated: 23/08/20

3. **Protocol no:** RLS/ONC/2016/03
   Protocol title: Prospective, multi-Centre, random
   active control, comparative clinical study to evalua
   ® for prevention of Skeletal Related events in
   Tumours.
   Dr.Kumar M. Vinchurkar - PI
   - IEC notification of PD for subject no: 700
   - IEC notification of PD for subject no: 700

4. **Protocol Title:** A Multicenter, Multiple-dose
   dummy Study to Compare the Therapeutic Effic
   Hydrochloride With Intravenous Doses of Etelc
   Subjects With Secondary Hyperparathyroidism
   Reference: Study No. 20150238

IEC Registrations:

- Ref: EC Reg: No: EC/RENEW/INST/2019/3323 – Under
  [DCGI]
- OHRPReg.No:IRB00008025KLEUniversity, IRB00001499
- FWA00024127.

II. Review of Proposals with Amendments:

1. **Protocol Title:** Phase 3, randomized, open label, controlled, multiple-dose, efficacy, safety, pharmacokinetic and Pharmacodynamic study of etecalctide in pediatric subjects 28 days to <18 years of age with hyperparathyroidism and chronic kidney disease receiving maintenance hemodialysis

   Protocol No: 20140315

   Dr.Mahantesh Patil-PI

   - Amended study protocol supplement Version 1 date: 29-May-2019 for review and approval

2. **Protocol No: 2015-DFU-301**

   Protocol Title: A Phase 3, Randomized, Double-blind, Parallel-group,Vechile controlled, Multicentre Study of the Efficacy and safety of Granexin Gel in the Treatment of Diabetic Foot Ulcer (GAIT 1)

   Dr.Vikrant Ghatnatti-PI

   - Amended study protocol Version 7.0 date: 13-Jun-2019 for review and approval

III. Review of Revised Project Proposals:

1. **Protocol Title**: Immune Lot-to-Lot Consistency and Non-Inferiority of SHAN6™ vaccine in Comparison to SHAN 5® + SHANIPV™ When Administered as Three Doses at 6-8, 10-12 and 14-16 weeks of age in Healthy Indian Infants, Concomitantly with Oral Rotavirus Vaccine. SH600003.

   Dr.S.M.Dhaded-PI

   PI response letter have been received by the IEC on 30/08/2019. IEC reviewed and discussed the submitted responses by Principal Investigator.

   1. Home visit to be mentioned in protocol after vaccination; if unsolicited AE's or SAE's occurs.

      Response: as per the current protocol, a phone call is must 3 to 4 days after vaccination, this is to inquire occurrence of nay AEs and SAEs and to check the health status of the subjects
   2. Final CTA
   3. Subject travel allowance should be included in the ICFs

      Response: amended study ICF with translation and back translation certificates (Included TA per visit not more than Rs.550/-)
   4. Submission of multiple vials guidelines for leftover doses Disposing/Discarding and storage of used vials and same should be documented properly

      Response: Remaining quantity of vaccine, form multi dose vial after single dose administration will be retained at the site for accountability and return back to the sponsor at the end of the study
   5. CTRI- Certificate

      Response: CTRI registration certificate included with KLE site name

IV. **Review of Annual Report:**

1. **Research project** - "Breastfeeding Education Support Tool for Baby" (BEST4Baby)
   Dr.N.S.Mahantashetti-PI

2. **Protocol Title: GS-US-419-3895:** "Combined Phase 3, Double-blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Crohn's Disease."
   Dr.V.P.Gokak-PI

V. **SAE reporting:**

-Nil

VI. **Protocol deviation/violation/ termination:**

1. **Protocol Title:** LRP/YLB113/2017/001_ Randomized, Controlled open label clinical study to compare the impact of single transition from Enbrel® Auto-Injector (AI) to YLB113 AI on safety, PK and compare usability of both AIs in patients with Active Rheumatoid Arthritis (RA)
   Dr.Archana uppin-PI
   - IEC notification of Protocol Deviation letter dated: 20/08/2019

2. **Protocol Title:** MYL-1402O-3001: Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.
   Protocol Version 2.0 dated 04 April 2018
   Dr.Maheshkumar Kalloli-PI
   - IEC notification of PD letter dated: 23/08/2019

3. **Protocol no:** RLS/ONC/2016/03
   Protocol title: Prospective, multi-Centre, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-045 /Xgeva ® for prevention of Skeletal Related events in Patients with Bone Metastasis from Solid Tumours.
   Dr.Kumar M. Vinchurkar - PI
   - IEC notification of PD for subject no: 7007005 dated 27-Aug-2019
   - IEC notification of PD for subject no: 7007005 dated 10-Aug-2019

4. **Protocol Title:** A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism
   Reference: Study No. 20150238

Drug: Etelcalcetide

Dr.Ritesh Vernekar-PI

- IEC notification of Dosing Deviation dated: 28/08/2019

VII. <u>The Committee will consider the following agendas which are for information.</u>

1. **Protocol Title:** A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism

   Reference: Study No. 20150238

   Drug: Etelcalcetide

   Dr.Ritesh Vernekar-PI

   - IEC notification of Amended CTA letter dated: 30/08/2019
   - IEC notification of Non-SUSARs letter dated: 28/08/2019

2. **Protocol Title:** A global, multicenter, three arms, open-label randomized study to evaluate the efficacy and safety of Nanosomal Docetaxel Lipid Suspension compared to Taxotere® (Docetaxel Injection Concentrate) in triple-negative breast cancer patients with locally advanced or metastatic breast cancer after failure to prior chemotherapy.

   Study Title: 0063-17

   Dr.Rohan Bhise-PI

   - IEC notification of SAE Cross letter dated:05/07/2019

3. EFC15082 / GEMELLI M

   Protocol Title: A 26-WEEK, Randomized,Open-label, and Parallel-group Comparision of SAR341402 Mix 70/30 to NovoMix® 30 in Adult Patients with Diabetes Mellitus using Pre-mix Insulin Analogs.

   Dr. M V Jali – PI

   - **IEC submission of requested documents letter dated:**

   1) DCGI Approval letter dated 4 Apr 2019
   2) Final CTA

4. **Protocol No:** BBIL/ROTAVAC/III/2018

   Protocol Title: A Phase 3, Multicenter, Open Label, Randomized Clinical Trial To Evaluate Safety And Immunogenicity Of ROTAVAC®-20 ^{O}c And Rotavac 5CM Administered At Birth (Neonatal Schedule) And Additional Dose Versus Infant Schedule Against Rotavirus Gastroenteritis

   Dr.N.S.Mahantashetti-PI

   - IEC notification of renewed insurance letter dated:29/08/2019

5. **Research project - "Breastfeeding Education Support Tool for Baby" (BEST4Baby)**
   Dr.N.S.Mahantashetti-PI
   - IEC notification of Data collection for Focus Group Participant details

6. **Protocol No:** RLS/ONC/2016/03, Version 3.0, dated: 06/Sep/2018
   Protocol Title: Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-045/ Xgeva® for prevention of skeletal related events in patients with bone metastases from solid tumours
   Dr.Kumar Vinchurkar-PI
   - IEC notification of SAE cross report of subject no:7004009 at site 7004 letter dated: 31/08/2019
   - IEC notification of renewed insurance letter dated: 30/08/2019

7. **Protocol Title:** Phase 3, randomized, open label, controlled, multiple-dose, efficacy, safety, pharmacokinetic and Pharmacodynamic study of etecalctide in pediatric subjects 28 days to <18 years of age with hyperparathyroidism and chronic kidney disease receiving maintenance hemodialysis
   Protocol No: 20140315
   Dr.Mahantesh Patil-PI
   - IEC notification of study documents letter date: 10/08/2019

8. **Protocol No and Title: My Val-1:** A prospective, Multicentre, single arm, open label study of My Val™ transacattheter Aortic Valve replacement system in the treatment of severe symptomatic native aortic valve stenosis.
   Dr.Surseh Patted-PI
   - IEC notification of Final CTA letter dated: 17/7/2019

9. **Protocol Title:** "A randomized, 24-week, controlled, open label, parallel arm, multicenter study comparing the efficacy and safety of the insulin glargine/lixisenatide fixed ratio combination to insulin glargine in type 2 diabetes patients, inadequately controlled on Basal Insulin with or without Metformin"
   Protocol No: INSLIL08556
   Dr.Vikrant Ghatnatti-PI
   - IEC notification of CIOMS (safety Alert#21-24-26-28-29) letter dated:20/08/2019

10. **Protocol Title:** A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of Bempedoic acid (ETC-1002) on the occurrence of major cardiovascular events in patients with or without, or at high risk for, cardiovascular disease who are statin intolerant
    Protocol Number: 1002-043

Dr.V.A.Kothiwale-PI

- IEC notification of Final CTA letter dated: 11/07/2019

11. **Protocol Title:** LRP/YLB113/2017/001_ Randomized, Controlled open label clinical study to compare the impact of single transition from Enbrel® Auto-Injector (AI) to YLB113 AI on safety, PK and compare usability of both AIs in patients with Active Rheumatoid Arthritis (RA)

    Dr.Archana uppin-PI

    - IEC notification of SIAQ_English_V1_2018_Aug_05 letter dated: 20/08/2019

12. **Protocol Title:** "A Multicenter, Open-label, Single-arm, Study to Evaluate Safety and Tolerability of Repatha in Patients with Homozygous Familial Hypercholesterolemia (HoFH) in India"

    Study Number: 20170199

    Dr.V.A.Kothiwale-PI

    - IEC notification of Q2 year 2019 SUSARs letter dated: 23/08/2019

13. **Protocol No: 2015-DFU-301**

    Protocol Title: A Phase 3, Randomized, Double-blind, Parallel-group,Vechile controlled, Multicentre Study of the Efficacy and safety of Granexin Gel in the Treatment of Diabetic Foot Ulcer (GAIT 1)

    Dr.Vikrant Ghatnatti-PI

    - IEC notification of study documents letter dated: 27/08/2019

14. **Protocol No:** NCS-549-17-CS **Study Title:** An open label, multicenter, randomized, balanced, two-treatment, two-period, two-sequence, single-dose, crossover, oral bioequivalence study of Methotrexate Tablets, USP 2.5mg from Lotus Pharmaceutical Co., Ltd., Taiwan compared with that of Methotrexate Tablets, USP 2.5 mg manufactured for DAVA Pharmaceuticals, Inc., in adult patients with mild to severe psoriasis or rheumatoid arthritis under fasting conditions

    Dr.Archana Uppin-PI

    - IEC notification of amended study protocol Version 2.0 dated 26/08/2019 and letter dated:28/08/2019

VII. Any other matter with the permission of the chair

For your attention:

Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Prof.(Dr) M.S.Ganachari
Member-secretary of IEC

To:

Circular and Submission of IEC Dossier		
1)	**Dr. Subarna Roy**, Scientist 'F', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V.Hegde**, Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** Prof of Pharmacology [USM-KLE] IMP, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar**, Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
6)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
7)	**Dr.Nayana Hashilkar**, Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
8)	**Mrs.Vaishnavi V Kivadasannavar,** M.S.W,Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
9)	**Shri.Tammanna Dadu Kore,** Farmer, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
10)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
11)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, KLE College of Pharmacy, Belagavi	Assistant Coordinator
12)	**Prof.(Dr.) M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
13)	**Dr.Sapna.K** Radiation Oncologist, KLE society's Belgaum cancer hospital, Belagavi-10	Subject Expert
Administrators of KAHER(Deemed to be University)		
1)	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed University, Belagavi, For Information	Circular
Principal Investigators		
1)	**Dr.Santosh Dhananjay Hajare,** *Consultant* Gastroenterologist, KLES Dr Prabhakar Kore Hospital & MRC, Belagavi-10	Circular
2)	**Dr. Maheshkumar Veeranna Kalloli,** Consultant, Oncology Dept., KLES Dr Prabhakar Kore Hospital &MRC, Nehru Nagar, Belagavi-590 010, Karnataka, India.	Circular
3)	**Dr. Rohan Bhsie,** Consultant, Oncology Dept., KLES Dr Prabhakar Kore Hospital &MRC, Nehru Nagar, Belagavi-590 010, Karnataka, India.	Circular

INSTITUTIONAL ETHICS COMMITTEE

KLE University

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

(Deemed-to-be-University)

KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi - 10, Karnataka State, India

0831-2470400 www.kledeemeduniversity.edu.in E-mail:kleclinicalresearch@gmail.com

Ref: KAHER/IEC/2019-20/D- 06121901 6 ***Date:*** **30/Nov/2019**

Accreditations

NABH

FERCAP

SIDCER

Registrations

DCGI

OHRP

SMO

IEC Meeting Agenda

Institutional Ethics Committee of KAHER, Belagavi

Saturday, 14/Dec/2019 at : 03:00 PM

Venue: Site management Office, G+2, KLE's Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi - 590010

I. New agendas for review and approval: [Presentation from the PIs]

1. **Protocol Title :** Rotasiil® Vaccine Intussusception Surveillance in Kerala, Karnataka, Maharastra and Gujarat, India.
   Dr.(Mrs) N. S. Mahantshetti – PI
   Timing : 03:15 PM

2. **Protocol Title :** A Randomized, assessor-blind, parallel group, multicentre phase3 study to comapre the efficacy and saftey of HP-hMG and Menopur® in subjects undergoing controlled ovarian stimulation for ART.
   Protocol No : BSV_HP-hMG_18_08
   Dr.Swetha Patil-PI
   Timing : 03:30 PM

II. Review of Proposals with Amendments:

1. **Protocol No: BSV_LEUPER_18_05.**
   Protocol Title: efficacy, safety, and pharmacokinetics of Leuprolide Acetate for injection 3.75mg (Depot) Administered in Subjects with Advanced Adenocarcinoma of prostate: randomized, active controlled, comparative, open label, phase3 study.
   Dr. Mahesh Kalloli – PI
   - Amended study protocol and Informed Consent Documents

2. **Protocol No: EFC15082 / GEMELLI M**
   Protocol Title: A 26-week, Randomized, Open-label, Parallel-group Comparison of SAR341402 Mix 70/30 to NovoMix®30 in Adult Patients with Diabetes Mellitus using Pre-mix Insulin Analogs.
   Dr. M. V. Jali – PI
   - Amended study Informed Consent Documents

3. **Protocol Title:** A randomized, double-blind, placebo-controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhoea in children.
Protocol No: LPS14914/KIDDIE
Dr.Mahantesh Patil-PI
   - Amended core study information and ICDs

4. **Protocol No:**0979-17
Protocol Title: A randomized, multi-centre, open label, two-arm, parallel, clinical study to evaluate the efficacy, safety and tolerability of tacrolimus lipid suspension for enema of Intas Pharmaceuticals Limited, India against CORTENEMA® (Hydrocortisone retention enema) of Anip Acquisition Company, USA in adult patients with mild to moderately active left-sided/distal ulcerative colitis refractory to mesalamine treatment.
Dr.Santosh hazare-PI
   - Amended Study subject Diaries

III. **Review of Proposal Revised Protocol:**

1. **Protocol No: TDM1.17.001.03**

Protocol Title : A prospective, randomized, multi center. Comparative. Open label, parallel study to evaluate the efficacy, safety and pharmacokinetics to Test- Trastuzumab Emtanstine (ZRC-3256 ; Cadila Healthcare Ltd)and Reference – Trastuzumab Emtanstine (Kadcyla®, a product of Roche) in HER2 – positive metastatic Breast Cancer Patients.

Dr.Maheshkumar Kalloli-PI

With reference to IEC letter no: KAHER/IEC/D-311019020 and dated: 24/10/2019. The below mentioned IEC requested documents submitted by PI on 07-Nov-2019

1. Final clinical trial Agreement
2. Study/Site specific insurance {period of validity 20/03/2019 to 19/03/2020}
3. Subject travel allowance/EC member contact details should be in printed form
4. CTRI-14-Nov-2019

2. **Protocol No:** ALK18/EN124/-CET1

Protocol Title: A prospective, multicenter, randomized, double blind, parallel group study to compare the efficacy and safety of biosimilar cetuximab versus innovator cetuximab in combination with platinum-based chemotherapy in patients with recurrent locoregional or metastatic squamous cell carcinoma of the head and neck (SCCHN)

With IEC letter no: KAHER/IEC/2019-20/D-11119015 and dated: 18/09/2019. IEC requested documents submitted by PI

1. Revised ICD (Included subject's Travel allowance)
2. Revised ICD – included IEC member Contact details in the printed form
3. Final CTA

2. **Protocol No: HCR/III/BIMONTAR/06/2017**
   Protocol Title: A prospective multicentric double blind parallel group active controlled randomized study to evaluate the efficacy and safety of bilastine and montelukast fixed dose combination tablets in adult patients with allergic rhinitis
   Dr. Gautam. S –PI
   - IEC Submission of Query reply for EC approval with reference to IEC letter no: KAHER/IEC/2019-20/D-171019023 Letter Dated 14 Nov 2019
     - Final CTA
     - DCGI Approval Letter
     - Dr.Puneeth CO-I ICH GCP certificate, CV and MRC,
     - CTRI

IV. **Review of Annual Report:**

1. **Protocol No: GA28951**
   Protocol Title: An Open label extension and safety monitoring study of moderate to severe Ulcerative Colitis patients previously enrolled in Etrolizumub Phase II/III Studies.
   Dr. V.P. Gokak - PI
   - IEC Notification of study Annual report Letter Dated 23 Nov 2019

2. **Protocol No: GA29102**
   Protocol Title: Phase III, Randomized, Double-Blind, Placebo Controlled, Multicentre study to Evaluate the Efficacy (Maintenance of Remission) and safety of Etrolizumab compared with placebo in patients with moderate to severe active Ulcerative Colitis who are naïve to TNF inhibitors.
   Dr. V.P. Gokak - PI
   - IEC Notification of study Annual report Letter Dated 23 Nov 2019

3. **Protocol No: MYL-14020-3001**
   Protocol Title: Multicentre, Double-Blind, Randomized, Parallel-Group study to Assess the Efficacy and safety of MYL-14020 Compared with Avastin®, in the first-Line Treatment of patients with Stage IV Non-Squamous Non-Small Cell Lung Cancer.
   Dr. Mahesh Kalloli - PI
   - IEC Notification of study Annual report Letter Dated 07 Nov 2019

4. **Protocol Title: WHO ACTION-I Trial:** A multi-country, multi-centre, two-arm, parallel, double-blind, placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in the early preterm period in hospitals in low-resource countries to improve newborn outcomes.
   Dr. Shivaprasad S Goudar - PI
   - IEC Notification of Study progress and Request for Continuation of Approval Letter dated 25 Nov 2019

5. **Protocol Title: "Women First: preconception Maternal Nutrition"**
   Dr. Shivaprasad S Goudar - PI
   - IEC Notification of Study progress and Request for Continuation of Approval Letter dated 25 Nov 2019

6. **Protocol Title: ASIA Pregnancy Outcomes Study**
   Dr. Shivaprasad S Goudar - PI
   - IEC Notification of Study progress and Request for Continuation of Approval Letter dated 25 Nov 2019

7. **Protocol Title: Sit Down and Play**
   Dr. Shivaprasad S Goudar - PI
   - IEC Notification of Request for Continuation of Approval Letter dated 25 Nov 2019

8. **Protocol Title: "Maternal Newborn Health Registry"**
   Dr. Shivaprasad S Goudar - PI
   - IEC Notification of Study progress Report and Request for Continuation of Approval Letter dated 25 Nov 2019

9. **Protocol Title:** "Prevention of Maternal and Neo-Natal death/Infections with a Single oral dose of azithromycin in women in labor (in Low-and middle-income Countries): A Randomized Controlled Trial; The A PLUS Study
   Dr. Shivaprasad S Goudar - PI
   - IEC Notification of Request for Continuation of Approval Letter dated 25 Nov 2019

10. **Protocol Title:** "Low-birthweight infant feeding exploration (LIFE)
    Dr. Shivaprasad S Goudar - PI
    - IEC Notification of Request for Continuation of Approval Letter dated 25 Nov 2019

11. **Protocol Title:** "Helping Babies breath (HBB)" database NIH NICHD data and Specimen Hub, N-DASH as per the NICHD policy
    Dr. Shivaprasad S Goudar - PI
    - IEC Notification of Request for Approval Letter dated 27 Nov 2019

12. **Protocol Title: "Women First: preconception Maternal Nutrition"**
    Dr. Shivaprasad S Goudar - PI
    - IEC Notification of Study progress and Request for Continuation of Approval Letter dated 25 Nov 2019

13. **Protocol Title:** Prevalence and Outcomes of Abnormal continuous wave Doppler flow indicates in unselected obstetric population in low-and middle-income countries: The Umbiflow International Study (A65924)
    Dr. Yeshita Pujar - PI
    - IEC Notification of Request for Continuation of Approval Letter dated 25 Nov 2019

14. **Protocol Title:** Performance, Safety and Efficacy of a New Cryotherapy Device for Cervical Dysplasia in Low- and Middle-Income Countries
    Dr. Anita Dalal - PI
    - IEC Notification of Request for Continuation of Approval Letter Dated 25 Nov 2019

V. **Review of Bi-Annual Report:**

1. **Protocol No: PMZ-1620/CLINICAL-2.3/2018; Version 02 dated 05 Jul 2018**
   Protocol Title: A Prospective, Multicentric, Randomized, Double Blind, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Patients of Acute Spinal Cord Injury.
   Dr. Sameer Haveri - PI
   - IEC Notification of study Bi-Annual report Letter Dated 13 Nov 2019

2. **Protocol No: PMZ-2010/CT-3.1/2018**
   Protocol Title: A Prospective, Multicentric, Randomized, Double Blind, parallel Phase III Clinical Study to assess Efficacy of PMZ-2010 as a resuscitative agent for hypovolemic shock to be used as an adjuvant to standard shock treatment
   Dr. Sameer Haveri – PI
   - IEC Notification of study Bi-Annual report Letter Dated 18 Nov 2019

3. **Protocol No: BCD-057-2**
   Protocol title: A Multicenter Comparative Randomized Double-Blind Study of the Efficacy and Safety of Bcd-057 (Inn: Adalimumab, Jsc Biocad, Russia) And Humira (Inn: Adalimumab, Vetter Pharma) In Patients with Moderate to Severe Plaque Psoriasis.
   Drug: Adalimumab
   Dr. Shivakumar K. Patil-PI
   - IEC Notification of Study Bi-Annual Report Letter Dated 04 Apr 2019
   - IEC Notification of Study Bi-Annual Report Letter Dated 28 Sep 2019

VI. **SAE reporting:**

1. **Protocol No: BCD-057-2**
   Protocol title: A Multicenter Comparative Randomized Double-Blind Study of the Efficacy and Safety of Bcd-057 (Inn: Adalimumab, Jsc Biocad, Russia) And Humira (Inn: Adalimumab, Vetter Pharma) In Patients with Moderate to Severe Plaque Psoriasis.
   Drug: Adalimumab
   Dr. Shivakumar K. Patil-PI
   - IEC Notification of SAE Report of Urinary Tract Infection Final Report for the subject No: **68026 Letter** Dated 12 Nov 2019

VII. **Notifications of Study close-out/Archival:**

1. **Protocol No: CT/CLOB/PSO/16**
   Protocol title: A Multicentric, Assessor-Blind, Randomized, Active controlled, Parallel Design study comparing efficacy and safety of Clobetasol Propionate topical foam 0.05% vs. Clobetasol Propionate topical lotion 0.05% in patients with mild to moderate plaque type psoriasis (Scalp and Non-Scalp)
   Dr. Snehal Lunge -PI
   - IEC Notification of Study Close-out Letter Dated 21 Nov 2019

VIII. **Protocol deviation/violation/ termination:**

1. **Protocol No: 20160372**
   Protocol Title: Post-marketing Phase 4 Study to Evaluate Safety, Tolerability, and Efficacy of Kyprolis® (Carfilzomib) in Indian Patients with Relapsed or Refractory Multiple Myeloma: A Prospective, Open-label, Non-comparative, Multicenter Study.
   Dr. Rohan Bhise - PI
   - IEC Notification of Protocol Deviation Letter for IP administration process Letter Dated 15 Nov 2019

2. **Protocol No: BCD-057-2**
   Protocol title: A Multicenter Comparative Randomized Double-Blind Study of the Efficacy and Safety of Bcd-057 (Inn: Adalimumab, Jsc Biocad, Russia) And Humira (Inn: Adalimumab, Vetter Pharma) In Patients with Moderate to Severe Plaque Psoriasis.
   Drug: Adalimumab
   Dr. Shivakumar K. Patil-PI
   - IEC Notification of Protocol Deviation Letter Dated 24 Oct 2019

IX. **The Committee will consider the following agendas which are for information.**

1. **Protocol No: EFC14875**
   Protocol Title: A Randomized, Double-blind, Placebo-controlled, parallel-group, Multicenter study to demonstrate the effects of Sotagliflozin on cardiovascular and renal events in patients with Type 2 Diabetes, Cardiovascular Risk factors and moderately impaired renal function.
   Dr. Prasad M R – PI
   - IEC Notification of Safety Alert #63,64N,651N & #66 Letter Dated 29 Sep 2019
   - IEC Notification of Safety Alert #691N, #70 & 71IN Letter Dated 04 Oct 2019

2. **Protocol No: EFC14828**
   Protocol Title: A Randomized, Double-blind, Placebo-controlled, parallel-group, Multicenter study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2Diabetes patients at High Cardiovascular Risk.
   Dr. Prasad M R - PI
   - IEC Notification of Safety Alert #35IN & 36 Letter Dated 4 Oct 2019
   - IEC Notification of Safety Alert #32 Letter Dated 04 Oct 2019

3. **Protocol No: 20140444**
   Protocol Title: A phase III randomized, double blind, placebo controlled, parallel group study to evaluate the safety and efficacy of denosumab in pediatric subjects with glucocorticoid induced osteoporosis
   Dr. N.S. Mahantshetti-PI
   - IEC Notification of SUSAR's to the IEC Letter Dated 01 Oct 2019

4. **Protocol No: TX05-03**
   Protocol Title: A randomized, double blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin in subjects with HER2 positive early breast cancer.

Dr. Mahesh Kalloli – PI

- IEC Notification of Site Initiation Visit Letter Dated 12 Nov 2019
- IEC Notification of ICON laboratory manual, eCRF Completion guidelines Template and reference guide for the study Letter Dated 15 Nov 2019
- IEC Notification of CIOMS Letter Dated 26 Nov 2019
- IEC Notification of Amended CTA Letter Dated 26 Nov 2019

5. **Protocol No: 0927-17**

   Protocol Title: A Multicentre, open label, randomized, two treatment, two period, two sequence single dose cross over study to test for bioequivalence between celerity's doxorubicin hydrochloride (pegylated liposomal) injection 20mg/10ml (2mg/ml) and the reference caelyx® [doxorubicin hydrochloride pegylated liposomal injection 20mg/10ml (2mg/ml)] in patients with metastatic breast cancer.

   Dr. Mahesh Kalloli – PI

   - IEC Notification of final eCRF for above study Letter Dated 15 Nov 2019

6. **Protocol No: PMZ-1620/CT-3.1/2019; Version1.0/29 dated Apr 2019**

   Protocol Title: A Prospective, Multicentric, Randomized, Double Blind, parallel Phase III Clinical Study to assess Efficacy of PMZ-1620 along with Standard treatment in Patients nOf Acute Ischemic Stroke.

   Dr. Sameer Haveri – PI

   - IEC Notification of Renewed Clinical Trail Insurance Policy Letter Dated 15 Nov 2019

7. **Protocol No: INSLIL08556**

   Protocol Title: A Randomized, 24-week, Controlled, Open Label, Parallel Arm, Multicenter Study Comparing the Efficacy and Safety of the Insulin Glargine/Lixisenatide Fixed Ratio Combination to Insulin Glargine in Type 2 Diabetes Patients, Inadequately Controlled on Basal Insulin with or without Metformin.

   Dr. Vikranth Ghatnatti -PI

   - IEC Notification of safety alert #01 to #16 Letter Dated 17 Sep 2018

8. **Protocol No: 0978-17**

   Protocol Title: A Randomized, double-blind, double dummy, Multicenter Parallel phase III Study to evaluate the Efficacy and Safety of the tacrolimus lipid tablets (manufacturing by Intas pharmaceuticals ltd) compared to Prograf (tacrolimus immediate release capsule Astellas pharma Canada Inc.,) in adult patients with active rheumatoid arthritis who have resistance or intolerance to DMARDs.

   Dr. Archana Uppin - PI

   - IEC Notification of Patient Questionnaires and Investigator Questionnaire Letter Dated 12 Nov 2019
   - IEC Notification of source template, PK manual, IMP handling manual and eCRF completion guidelines Letter Dated 07 Nov 2019

9. **Protocol No: 2015-DFU-301**

Protocol Title: A phase 3, Randomized, Double-blind, parallel-group, vehicle controlled, Multicenter study of the Efficacy and safety of Granexin gel in the treatment of Diabetic Foot Ulcer (GAIT 1)

Dr. Vikranth Ghatnatti-PI

- IEC Notification of Study Documents Letter Dated 06-Nov-2019

10. **Protocol No: CS2514-2017-0004**

Protocol Title: A Randomized, active-controlled study to evaluate the Efficacy and safety of Intravenous sulbactam- ETX2514 in the Treatment of patients with infections Caused by Acinetobacter baumannii-calcoaceticus complex.

Dr. Jayaprakash Appajigol - PI

- IEC Notification of Source Documents Letter Dated 11-Nov-2019
    1) Adverse event Log
    2) Concomitant Log
    3) Day 1 activity Log source
    4) ICF Documents
    5) Progress Note
    6) Requisition Form
    7) Screening visit

11. **Protocol No: NCS-549-17-CS**

Protocol Title: An open label, multicenter, balanced, two-treatment, two-Period, two-Sequence, single-dose, cross over, oral bioequivalence study of Methotrexate Tablets, USP 2.5mg from Lotus Pharmaceutical Co.,Ltd., Taiwan compared with that of Methotrexate Tablets USP 2.5mg manufactured for DAVA pharmaceuticals, Inc., in adult patients with mild to severe psoriasis or rheumatoid arthritis under fasting conditions.

Dr. Archana Uppin - PI

- IEC Notification of Clarification letter for Documents Letter Dated 19 Sep 2019
    1) DCGI-NOC letter
    2) CTA
    3) PSP
- IEC Notification of Clarification letter for Letter Dated 15 Jul 2019, Letter Dated 20 Sep 2019

12. **Protocol No: GBR200-301**

Protocol Title: A Prospective, Multicenter, Randomized, Double-blind, Parallel group Study to Compare the Efficacy and Safety of GBR 200 (Similar biologic of Trastuzumab) versus Innovator Trastuzumab, both when Given in Combination with Paclitaxel in Patients Diagnosed with HER2 Positive Metastatic Breast Cancer.

Dr. Mahesh Kalloli –PI

- IEC Notification of Study Documents (DCGI Notification of Six-Monthly Report) Letter Dated 25 Nov 2019

13. **Protocol No: GA28951**

Protocol Title: An Open label extension and safety monitoring study of moderate to severe Ulcerative Colitis patients previously enrolled in Etrolizumub Phase II/III Studies.

Dr. V.P. Gokak - PI

- IEC Notification of Renewed Insurance policy Letter Dated 23 Nov 2019

14. **Protocol No: GA29102**

Protocol Title: Phase III, Randomized, Double-Blind, Placebo Controlled, Multicentre study to Evaluate the Efficacy (Maintenance of Remission) and safety of Etrolizumab compared with placebo in patients with moderate to severe active Ulcerative Colitis who are naïve to TNF inhibitors.

Dr. V.P. Gokak - PI

- IEC Notification of Renewed Insurance policy Letter Dated 23 Nov 2019

15. **Protocol No: 20170199**

Protocol Title: A Multicentre, Open-Label, Single-arm Study to evaluate safety and tolerability of Repatha in Patients with Homozygous familial Hypercholesterolemia (HoFH) in India"

Dr. V.A. kothiwale - PI

- IEC Notification of Investigator Brochure Edition 14.0 dated 02 Apr 2019 Letter Dated 22 Nov 2019

16. **Protocol No: 20140315**

Protocol Title: Phase 3, Randomized, open label, controlled, multiple –dose, efficacy, safety, pharmacokinetics and pharmacodynamic study of Etelcacetide in pediatric subject 28 days to < 18 years of age with secondary hyperparathyroidism and chronic kidney disease receiving, Maintenance Hemodialysis

Dr. Mahantesh Patil - PI

- IEC Notification of Updated IU Letter Dated 23 Nov 2019

17. **Protocol No: SHP640-301**

Protocol Title: A Phase 3, Multi-Centre, randomized, Double-Masked Study to evaluate the clinical efficacy and safety of SHP640 (PVP-Iodine 0.6% and Dexamethasone 0.1%) Ophthalmic Suspension compared to PVP-Iodine and Placebo in the Treatment of Adenoviral Conjunctivitis

Dr. Smitha K S - PI

- IEC Notification of Abbreviated Clinical Study Report Letter Dated 20 Nov 2019

18. **Protocol No: CTQJ230A12001**

Protocol Title: Multi-Centre Cross-Sectional epidemiological Study to characterize the prevalence and distribution of lipoprotein(a) levels among patients with established cardiovascular disease.

Dr. Prasad M R – PI

- IEC Notification of DCGI Approval Letter Dated 13 Mar 2019 & CTRI Updated Attached Letter Dated 23 Nov 2019

19. **Protocol Title**: A Phase 3, Randomized, Double-Blind, Parallel Group, Vehicle Controlled, Multicentre Study of the Efficacy and Safety of Granexin Gel in the Treatment of Diabetic Foot ulcer (GAIT 1)
    Dr. Vikrant Ghatnatti – PI
    - IEC Notification of Updated Source Template Version 3.0 dated 23 Oct 2019 Letter Dated 18 Nov 2019

20. **Protocol Title**: Performance, Safety and Efficacy of a New Cryotherapy Device for Cervical Dysplasia in Low- and Middle-Income Countries
    Dr. Anita Dalal - PI
    - IEC Notification of Approval Letter from Drugs Licensing Authority, UT of Daman and Diu, Ref Approval Letter No: KAHER/IEC/2019-20/D-2743 dated 03 Jan 2019 Letter Dated 22 Oct 2019
    - IEC Notification of Request for Approval of Informed Consent Forms Letter Dated 16 Nov 2019
    - IEC Notification of Request for Approval of Updated Pre-Screening Consent Forms Letter Dated 25 Nov 2019.

X. **IEC Member Monitoring Visit:**

1. **Protocol No: CRSC16004**
   Protocol Title: A phase III, Multicentre, randomized, observe blind, parallel group, three arms controlled clinical Trail to evaluate the efficacy and safety of topical applied of calcipotriol/AKVANO 50microgram/gram cutaneous solution against calcipotriol ointment 50microgram/gram, Sandoz and placebo in patients with mild to moderate plaque psoriasis
   Dr. Snehal Lunge - PI
   - IEC Monitoring Visit letter dated 13 Nov 2019

2. **Protocol No: MYL-14020-3001**
   Protocol Title: Multicentre, Double-Blind, Randomized, Parallel-Group study to Assess the Efficacy and safety of MYL-14020 Compared with Avastin®, in the first-Line Treatment of patients with Stage IV Non-Squamous Non-Small Cell Lung Cancer.
   Dr. Mahesh Kalloli - PI
   - IEC Monitoring Visit letter dated 22 Nov 2019

3. **Protocol No: BCD-057-2**
   Protocol Title: A Multicenter Comparative Randomized Double-Blind Study of the Efficacy and Safety of Bcd-057 (Inn: Adalimumab, Jsc Biocad, Russia) and Humira (Inn: Adalimumab, Vetter Pharma) In Patients with Moderate to Severe Plaque Psoriasis.
   Dr. Shivakumar Patil - PI
   - IEC Monitoring Visit letter dated 21 Nov 2019

4. **Protocol No: 14V-MC-JADY**
   Protocol Title: "A Phase III, Multicenter study to evaluate the long-term safety & efficacy of Baricitinibin patients with Rheumatoid Arthritis"
   Dr. Shailesh Udapudi - PI
   - IEC Monitoring Visit letter dated 22 Nov 2019

5. **Protocol No: DMPL/P05-2017/CT/VN**
   Protocol Title: A post marketing surveillance study (PMS) to evaluate safety and tolerability of VELNEZ as nasal pack after nasal surgery
   Dr. Shailesh Udapudi - PI
   - IEC Monitoring Visit letter dated 22 Nov 2019

XI. Any other matter with the permission of the chair

For your attention:
Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

07/Dec/2019

Prof. (Dr) M.S. Ganachari
Member-secretary of IEC

To:

Circular and Submission of IEC Dossier		
1)	**Dr. Subarna Roy,** Scientist 'F', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V. Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr. P. A. Patil,** Prof of Pharmacology[USM-KLE]IMP,"VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr. S. S. Goudar,** Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr. Yeshita Pujar,** Prof of Obstetrics& Gynecology, JNMC, Belagavi	Member

6)	**Dr. Roopa Bellad,** Prof of Pediatrics, J.N. Medical College, Belagavi	Member
7)	**Dr. Nayana Hashilkar,** Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
8)	**Mrs. Vaishnavi V Kivadasannavar,** M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
9)	**Shri.Tammanna Dadu Kore,** Farmer, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
10)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
11)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, KLE College of Pharmacy, Belagavi	Scientific Member
12)	**Prof. (Dr.) M.S. Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
13)	**Dr. Sapna. K** Radiation Oncologist, KLE Society's Belgaum cancer Hospital, Belagavi-10	Independent Consultant
14)	**Dr.Manisha Bhandankar,** Professor of Paediatrics – J.N.M.C, Nehru Nagar, Belagavi - 590010	Independent Consultant
	Administrators of KAHER (Deemed to be University)	
1)	**The Registrar**, KAHER, deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed University, Belagavi, For Information	Circular
	Principal Investigators	
1)	**Dr. N. S. Mahantshetti,** Professor of Paediatrics – J.N.M.C, Nehru Nagar, Belagavi - 590010	Circular
2)	**Dr. Mahesh Kalloli,** Consultant Surgical Oncologist, KLES Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi - 590010	Circular
3)	**Dr.Swetha Patil,** Infertility Consultant, KLES Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi - 590010	

Institutional Ethics Committee

KLE Academy of Higher Education and Research, Belagavi
[Formerly Known as KLE University]
(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)
KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State, India
(: 0831-2470400FAX:0831-2493099 www.kledeemeduniversity.edu.in
Email:kleclinicalresearch@gmail.com

Ref: KAHER/IEC/2019-20/D-13081900S. ***Date: 08/08/2019***

IEC Meeting Agenda

Institutional Ethics Committee of KAHER, Belagavi

Monday, 19/08/2019 at: 03.30 PM

Venue: Site management Office, G+2, KLES Dr.PK Hospital &MRC, Nehru Nagar, Belagavi

I. New agendas for review and approval: [Presentation from the PIs]

1. **Protocol Title**: Immune Lot-to-Lot Consistency and Non-Inferiority of SHAN6™ vaccine in Comparison to SHAN 5® + SHANIPV™ When Administered as Three Doses at 6-8, 10-12 and 14-16 weeks of age in Healthy Indian Infants, Concomitantly with Oral Rotavirus Vaccine. SH600003.
   Dr.S.M.Dhaded-PI
   Time: 3:45 PM

2. **Protocol No: CTQJ230A12001**
   Protocol Title : Multi-center cross-sectional epidemiological study to characterize the prevalence and distribution of lipoprotéine(a) levels among patients with established cardiovascular disease
   Dr. Prasad MR-PI
   Time: 04:00 PM

3. **Protocol No:** 0586-18
   Protocol Title : A randomized, Double- blind, multicentre, mutinational comparative clinical study to compare the effciacy and safetyof INTP24 against Avastin ® in pateints with unresectable, locally advanced, recurrent or metastatic no-sqaumous non small cell lung cancer.
   Dr.Maheshkumar Kalloli-PI
   Time: 04:15 PM

4. **Protocol No:** XBR1001
   Protocol No: Xplore: A Phase III Double-Blind, Parallel Group, Multicenter Study to Compare the Efficacy and Safety of Xlucane versus Lucentis® in Patients with Neovascular Age-Related Macular Degeneration
   Dr.Smitha K.S-PI
   Time: 04:30PM

Accreditations:

NABH

FERCAP

Registrations:

DCGI

OHRP

IEC Registrations:

- Ref: EC Reg: No: EC/RENEW/INST/2019/3323 – Under Rule 122DD of the Drugs and Cosmetics Rules 1945 [DCGI]
- OHRPReg.No:IRB00008025KLEUniversity, IRB00001499
- FWA00024127.

II. Review of Proposals with Amendments:

1. **Study Code: D1699C00001**
   Protocol: A Study to Evaluate the Effect of Dapagliflozin on the Incidence of worsening heart failure or Cardiovascular Death in patients with chronic Heart Failure with reduced Ejection Fraction.
   Dr.V.A.Kothiwale-PI

2. **Protocol Title:** A 12-week double-blind, randomized, multi-center study comparing the efficacy and safety of once monthly subcutaneous AMG 334 against placebo in adult episodic migraine patients (EMPOwER).
   Protocol No.:CAMG334A2302
   Dr.Saroja A.O-PI

3. **Protocol Title:** A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes Patients at High Cardiovascular Risk.
   Protocol number: EFC14828/Amplitude-O
   Dr.Prasad M.R-PI

4. **Protocol No:** LUF-44-001
   Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study
   Dr.Navin Mullimani-PI

III. Review of Revised Project Proposals:

1. **Clinical Trial Protocol** CQGE031C2302
   Protocol Title: A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines
   Dr.Shivakumar Patil-PI
   The following documents requested in the initial meeting, which was held on Wednesday, 26 June 2019 at 04:30 PM in SMO and same has been received by IEC.
   1. DCGI Approval letter
   2. Subject's travel allowance should be included in the ICFs
   3. Final CTA

IV. **Review of Annual Report:**

1. **Protocol Title:** "A randomized, 24-week, controlled, open label, parallel arm, multicenter study comparing the efficacy and safety of the insulin glargine/lixisenatide fixed ratio combination to insulin glargine in type 2 diabetes patients, inadequately controlled on Basal Insulin with or without Metformin"
   Protocol No: INSLIL08556
   Dr.Vikrant Ghatnatti-PI

V. **SAE reporting:**
-Nil

VI. **Protocol deviation/violation/ termination:**

1. **Protocol no:** RLS/RES/2016/01: version 1.0, Administrative Amendment 1.0 dated: 8 Jun 2017
   Protocol title: Prospective, multi-Centre, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-022/Xolair® in patients with moderate to severe persistent asthma.
   Dr.Jyothi Hattiholi-PI
   - IEC notification of PD for subject no: 6802 dated:02/08/2019

2. **Study Number:** GBR 200-301
   Study Title: A Prospective, Multicenter, Randomized, Double-blind, Parallel-group, Study to Compare the Efficacy and Safety of GBR 200 (similar biologic of Trastuzumab) versus Innovator Trastuzumab both when given in combination with Paclitaxel in patients diagnosed with HER2 Positive Metastatic Breast Cancer.
   Dr.Maheshkumar Kalloli-PI
   - IEC notification of PD letter dated: 26/07/2019

3. **Study Title:** A Prospective, Multi-Centric, Randomized, Double-Blind, Parallel, Phase-III Study to Assess Efficacy of PMZ-2010 as a Resuscitative Agent for Hypovolemic Shock to be Used as an Adjuvant to Standard Shock Treatment.
   Study Protocol No.: PMZ-2010/CT-3.1/2018;
   Dr.Sameer Haveri-PI
   - IEC notification of Protocol Deviation letter dated: 20/07/2019

VII. **The Committee will consider the following agendas which are for information.**

1. **Protocol Title:** A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism
   Reference: Study No. 20150238
   Drug: Etelcalcetide
   Dr.Ritesh Vernekar-PI
   - IEC notification of IB edition 10.0 dated May-2019 letter dated: 26/07/2019
   - IEC notification of Non-SUSARs letter dated:06/07/2019

4. **Protocol Title:** A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism
   Reference: Study No. 20150238
   Drug: Etelcalcetide
   Dr.Ritesh Vernekar-PI
   - IEC notification of Non-SUSARs letter dated: 26/07/2019

2. **Protocol No: 2015-DFU-301**
   Protocol Title: A Phase 3, Randomized, Double-blind, Parallel-group,Vechile controlled, Multicentre Study of the Efficacy and safety of Granexin Gel in the Treatment of Diabetic Foot Ulcer (GAIT 1)
   Dr.Vikrant Ghatnatti-PI
   - IEC notification of updated IU and Protocol Signature page: 27/07/2019
   - IEC notification of extension of shelf life of IMPs letter dated: 27/007/2019

3. **Protocol Title:** Prominent: Pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes.
   Protocol No: K-877-302
   Dr.V.A.Kothiwale-PI
   - IEC Notification of CIOMS letter dated: 19/07/2019

4. **Study No: 20140444**
   Drug: Denosumab
   Protocol Title: A Phase 3 randomized, Double-blind, Placebo-Controlled, Parallel-group Study to evaluate the safety and Efficacy of Denosumab in pediatric Subjects with Glucocorticoid-induced Osteoporosis
   Dr.N.S.Mahantashetti-PI
   - IEC notification of non-SUSARs letter dated: 22/07/2019

5. **Protocol Title:** An Open Labeled, Single Arm (Non-Comparative), Prospective Phase I Clinical Study To Evaluate The Safety, Tolerability And Immunogenicity Of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed), 11-Valent Of Panacea Biotec Ltd. In Healthy 12-23 Months Old PCV- naïve Toddlers.
   Protocol Number: PBL/CR/2018/01/CT/NUCO11
   Dr.N.S.Mahantashetti-PI
   - IEC notification of Insurance policy letter dated: 24/07/2019

3. **Study Code: D1699C00001**
   Protocol: A Study to Evaluate the Effect of Dapagliflozin on the Incidence of worsening heart failure or Cardiovascular Death in patients with chronic Heart Failure with reduced Ejection Fraction.
   Dr.V.A.Kothiwale-PI

- IEC notification of IU letter dated: 31/07/2019
- IEC notification of Periodic safety summary letter dated: 30/07/2019
- IEC notification of Investigators Brochure-Edition No: 15 letter dated: 30/07/2019

4. **Protocol No:** NCS-549-17-CS **Study Title:** An open label, multicenter, randomized, balanced, two-treatment, two-period, two-sequence, single-dose, crossover, oral bioequivalence study of Methotrexate Tablets, USP 2.5mg from Lotus Pharmaceutical Co., Ltd., Taiwan compared with that of Methotrexate Tablets, USP 2.5 mg manufactured for DAVA Pharmaceuticals, Inc., in adult patients with mild to severe psoriasis or rheumatoid arthritis under fasting conditions
   Dr.Archana Uppin-PI
   - IEC notification of Amended CTA letter dated: 15/07/2019

5. **Trial No:** BECT /HepA-phase-111/045
   Protocol No: BECT04S/HepA-Phase-III/CTP-02
   Study Title: A single blind, parallel, randomized Phase-Ill comparative study to evaluate safety and immunogenicity of two intramuscular doses of inactivated Hepatitis A vaccine administered 6 months apart, in 1-15 year-old healthy Hepatitis A vaccine-na'ive children.
   Dr.N.S.Mahantashetti-PI
   - IEC notification of final CTA letter dated: 23/07/2019

6. **Study Title:** A Phase IV Multi-Centric Post-Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of the Marketed Formulation of Hetero –Adalimumab **Protocol No:** HCR/IV/ADALI/01/2017; Version: 1.0; Dated: 30 Jan 2017
   Dr.Archana Uppin-PI
   - IEC notification of source templates letter dated|: 31/07/2019

7. **Study Title**: A phase II/III, multicenter, randomized, open label, active controlled, clinical study to assess the immunogenicity and safety of tetanus toxoid, diphtheria toxoid, and acellular pertussis (Tdap) vaccine manufactured by Serum institute of India Pvt. Ltd. (SIIPL) in comparison with Boostrix® vaccine of GSK in healthy adults, adolescents and children in India.
   Protocol Identifier: SII-Tdap/IN-02 V- 1.0 & 21 Nov 2017
   Dr.N.S.Mahantashetti-PI
   - IEC notification of ICF discrepancy of Subject no: 104051 letter dated: 11/07/2019

8. **Protocol Title:** "A randomized, 24-week, controlled, open label, parallel arm, multicenter study comparing the efficacy and safety of the insulin glargine/lixisenatide fixed ratio combination to insulin glargine in type 2 diabetes patients, inadequately controlled on Basal Insulin with or without Metformin"
   Protocol No: INSLIL08556
   Dr.Vikrant Ghatnatti-PI
   - IEC notification of Updated IU letter dated: 05/08/2019

VII. Any other matter with the permission of the chair

For your attention:
Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Prof.(Dr) M.S.Ganachari
Member-secretary of IEC

KLE Academy of Higher Education and Research * Deemed-to-be University * BELAGAVI

To:

Circular and Submission of IEC Dossier		
1)	**Dr. Subarna Roy,** Scientist 'F', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V.Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** Prof of Pharmacology [USM-KLE] IMP, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar**, Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
6)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
7)	**Dr.Nayana Hashilkar,** Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
8)	**Mrs.Vaishnavi V Kivadasannavar,** M.S.W,Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
9)	**Shri.Tammanna Dadu Kore,** Farmer, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
10)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member

11)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, KLE College of Pharmacy, Belagavi	Assistant Coordinator
12)	**Prof.(Dr.) M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
13)	**Dr.M.V.Jali,** MD and CE, KLES Dr.Prabhakar Kore Hospital and MRC, Belgavai-10	Subject Expert
Administrators of KAHER(Deemed to be University)		
1)	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed University, Belagavi, For Information	Circular
Principal Investigators		
1)	**Dr. S M Dhaded,** Professor of Paediatrics, JNMC, Consultant, KLES Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belgaum-590010	Circular
2)	**Dr. Prasad M.R** Consultant Cardiologist, Assistant Professor, JN Medical College, KLES Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi-10.	Circular
3)	**Dr. Maheshkumar Veeranna Kalloli,** Consultant, Oncology Dept., KLES Dr Prabhakar Kore Hospital &MRC, Nehru Nagar, Belagavi-590 010, Karnataka, India.	Circular
4)	**Dr.Smitha K S,** Consultant, Dept. of Ophthalmology, KLES Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belgavi-590 010, Karnataka, India	Circular

Institutional Ethics Committee

KLE Academy of Higher Education and Research, Belagavi
[Formerly Known as KLE University]
(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)
KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State, India
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Email:kleclinicalresearch@gmail.com

Ref: KAHER/IEC/2019-20/D- 240919008 ***Date: 20/09/2019***

IEC Meeting Agenda

Institutional Ethics Committee of KAHER, Belagavi

Monday, 30/09/2019 at: 03.30 PM

Venue: Site management Office, G+2, KLES Dr.PK Hospital &MRC, Nehru Nagar, Belagavi

I. New agendas for review and approval: [Presentation from the PIs]

1. **Protocol No:**0979-17
   Protocol Title: A randomized, multi-centre, open label, two-arm, parallel, clinical study to evaluate the efficacy, safety and tolerability of tacrolimus lipid suspension for enema of Intas Pharmaceuticals Limited, India against CORTENEMA® (Hydrocortisone retention enema) of Anip Acquisition Company, USA in adult patients with mild to moderately active left-sided/distal ulcerative colitis refractory to mesalamine treatment.
   Dr.Santosh Hajare-PI
   Timing: 03:45 PM
   Note : the study was deferred from the last meeting-13/Sep/2019 with Dossier No: 01

2. **Protocol Title:** A Multicentric, open label, single arm study to evaluate the safety and efficacy of INTP26 (trastuzumab biosimilar) in patients with HER2-overexpressing breast (early or metastatic) cancer or metastatic gastric cancer
   Protocol Number: 0566-18
   Dr.Maheshkumar Kalloli-PI
   Timing: 04:00 PM

3. **Protocol Title:** A randomized, double-blind, placebo-controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhea in children.
   Protocol No: LPS14914/KIDDIE
   Dr.Mahantesh Patil-PI
   Timing: 04:15 PM

4. **Protocol Title:** A Prospective, Multi-Centric, Double Blind, Parallel Group, Active Controlled Randomized Study to Evaluate the Efficacy and Safety of Bilastine and Montelukast Fixed Dose Combination tablets in Adult Patients with Allergic Rhinitis
   Protocol No: HCR/III/BIMONTAR/06/2017
   Dr.Gautam.S-PI
   Timing: 04:30 PM

Accreditations:

NABH

FERCAP

Registrations:

DCGI

OHRP

II. **Review of Proposals with Amendments:**

1. **Protocol Number:** CT-P16 3.1
   Study Title: A Double-Blind, Randomized, Active-Controlled, Parallel-Group, Phase 3 Study to Compare Efficacy and Safety of CT-P16 and EU-Approved Avastin® as First-Line Treatment for Metastatic or Recurrent Non-Squamous Non-Small Cell Lung Cancer
   Dr.Maheshkumar Kalloli-PI

2. **Protocol No:** 0586-18
   Protocol Title : A Randomized, Double- Blind, Multicentre, Mutinational Comparative Clinical Study To Compare The Effciacy And Safetyof INTP24 Against Avastin ® In Pateints With Unresectable, Locally Advanced, Recurrent Or Metastatic No-Sqaumous Non Small Cell Lung Cancer.
   Dr.Maheshkumar Kalloli-PI

III. **Review of Revised Project Proposals:**

1. **Protocol No:** EFC15082 / GEMELLI M
   Protocol Title: A 26-WEEK, Randomized,Open-label, and Parallel-group Comparision of SAR341402 Mix 70/30 to NovoMix® 30 in Adult Patients with Diabetes Mellitus using Pre-mix Insulin Analogs.
   Dr. M V Jali – PI
   IEC were requested the below mentioned study documents for further consideration and same has been received and reviewed by the IEC on 11/Sep/2019
   1. DCGI Conditional Approval Clarification Letter notification dated 16 Aug 2019
   2. Clinical trial agreement Notification letter dated: 28/08/2019
   3. Subject travel allowance included in the revised ICF version 0027/1.1.1 and letter dated:05/Sep/2019

IV. **IEC members study monitoring Visit:**

1. **Protocol No:** RLS/ONC/2016/03, Version 3.0, dated: 06/Sep/2018
   Protocol Title: Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-045/ Xgeva® for prevention of skeletal related events in patients with bone metastases from solid tumours
   Dr.Kumar Vinchurkar

2. **Protocol No:** PMZ-2010/CT-3.1/2018
   A Prospective Multicentric, Randomized, Double-Blind, Parallel, Phase-III Study to Assess Efficacy of PMZ_2010 as a Resuscitative Agent for Hypovolemic Shock to be used as an Adjuvant to Standard Shock Treatment
   Dr.Sameer Haveri-PI

3. **Protocol No: BCD-057-2**
   Protocol Title: A multi-centre comparative randomized double-blind study of the efficacy and safety of BCD-057 (INN: Adalimumab, JSC Biocad, Russia) and humira (INN: Adalimumab, Vetter Pharma) in patients with moderate to severe plaque psoriasis
   Dr. Shiva Kumar Patil-PI

4. **Protocol No:** BECT045/HepA-Phase-III/CTP_2
Protocol Title: A Single-Blind, Parallel, Randomized Phase-III comparative study to evaluate safety and immunogenicity of two intramuscular doses of inactivated Hepatitis-A vaccine administered 6 months apart, in 1-15-year-old Healthy Hepatitis-A vaccine-naïve children.
Dr.N.S.Mahantashetti-PI

V. **Review of Annual Report:**
-Nil

VI. **SAE reporting:**

1. **Protocol Title:** "The WHO ACTION (Antenatal Corticos Teroids for Improving Outcomes in preterm Newborns) Trials:"
WHO ACTION-II TRIAL - A65916: A multi-country, multi-center, two-arm, parallel, double-blind, placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in the late preterm period in hospitals in low-resource countries to improve newborn outcomes.
Dr.S.S.Goudar-PI
    - **SAE term:** Atomic Postpartum Hemorrhage of subject:04307
    - **SAE term:** Severe preeclampsia of subject: 04283
2. **Protocol Title:** A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism
Reference: Study No. 20150238
Drug: Etelcalcetide
Dr.Ritesh Vernekar-PI
    - **SAE term:** Cough, Breathlessness, hypertension (Hospitalization) of the subject No: 23830016005

VII. **Protocol deviation/violation/ termination:**

1. **Protocol number: POL7080-011-** A multicenter, open-label, randomized, active-controlled, parallel group, pivotal study to investigate the efficacy, safety and tolerability, and pharmacokinetics of murepavadin combined with one anti-pseudomonal antibiotic versus two anti-pseudomonal antibiotics in adult subjects with ventilator-associated bacterial pneumonia suspected or confirmed to be due to Pseudomonas aeruginosa
Dr.Madhav Prabhu-PI
    - IEC notification of **Study Termination** letter dated: 20/08/2019
2. **Protocol Title:** "A randomized, 24-week, controlled, open label, parallel arm, multicenter study comparing the efficacy and safety of the insulin glargine/lixisenatide fixed ratio combination to insulin glargine in type 2 diabetes patients, inadequately controlled on Basal Insulin with or without Metformin" **Protocol No:** INSLIL08556

Dr.Vikrant Ghatnatti-PI

- IEC notification of **Protocol deviation** letter dated: 06/09/2019

3. **Protocol No:** DMPL/P05-2017/CT/VN V2.0, Date-30.03.2018 titled "A post marketing surveillance study (PMS) to evaluate safety and tolerability of VELNEZ as nasal pack after nasal surgery"

   Dr.Shama Bellad-PI

   - IEC notification **Protocol deviation** letter dated: 30/08/2019

4. **Protocol Title:** LRP/YLB113/2017/001_ Randomized, Controlled open label clinical study to compare the impact of single transition from Enbrel® Auto-Injector (AI) to YLB113 AI on safety, PK and compare usability of both AIs in patients with Active Rheumatoid Arthritis (RA)

   Dr.Archana uppin-PI

   - IEC notification of **Protocol deviation** letter dated: 09/08/2019

5. **Protocol Title:** A Multicenter, Open-Label, Randomized, Two-Treatment, Two-Period, Two-Sequence, Single-Dose, Cross-Over, Study to Test for Bioequivalence between Celerity's Doxorubicin Hydrochloride (Pegylated Liposomal) Injection 20mg/10ml (2mg/ml) in Patients with Metastatic Breast Cancer.

   Study Title: 0927-17

   Dr. Mahesh Kalloli-PI

   - IEC notification of **Protocol deviation** letter dated: 05/07/**2019**

6. **Protocol No:** 2015028

   Protocol Title: A Multicenter, Multiple-Dose Activated-Controlled, Double-Blind, Double-Dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride with Intravenous Doses of Etelcalcitide (AMG 416) in Asia Haemodialysis Subjects with Secondary Hyperparathyroidism

   Dr. Ritesh Vernekar – PI

   - IEC notification of Protocol Deviation for subject no:23830016005 letter dated: 12/09/2019

7. **Protocol Title:** A Phase 3, Randomized, Double-blind, Parallel-Group, Vechile Controlled, Multicentre Study of the Efficacy and Safety of Granexin Gel in the Treatment of Diabetic Foot Ulcer (GAIT 1)

   Protocol No: 2015-DFU-301

   Dr. Vikrant Ghatnatti-PI

   - EC notification of protocol deviation for subject 06-007

8. **Protocol No:** D1699C00001-DAPA HF
Protocol Title: To Evaluate the Effect of Dapagliflozin on the Incidence of Worsening of Heart Failure or Cardiovascular Death in Patients with Chronic Heart Failure with Reduced Ejection Fraction.
Dr. Kothiwale V A – PI
    - IEC notification of Protocol Deviation letter dated: 07/09/2019

VIII. **The Committee will consider the following agendas which are for information.**

1. **Protocol Title:** Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a Phase IV Study
Study Code: LUF-44-001
Dr. Navin Mulimani-PI
    - IEC notification of CIOMS I Reports for SAE Occurred at Site #0122 dated 17/09/2019

2. **Protocol Title:** A Phase 3, Multi-center, Randomized, Double-Masked Study to Evaluate the Clinical Efficacy and Safety of SHP640 (PVP-Iodine 0.6% and Dexamethasone 0.1%) Ophthalmic Suspension Compared to PVP-Iodine and Placebo in the Treatment of Adenoviral Conjunctivitis
Protocol No: SHP640-301
Dr.Smitha K.S-PI
    - IEC notification of study closure notification letter dated: 06-Sep-2019
    - IEC notification of IEC SOP request letter dated: 09/09/2019

3. **Protocol No.** TX05-03
Protocol Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer.
Dr.Maheshkumar Kalloli-PI
    - EC notification of updated IU letter dated 02/09/2019

4. **Protocol Title:** NCS-549-17-CS
Protocol Title: An Open-Label, Multicentre, Randomized, balanced, Two-Treatment, Two-Period, Two-Sequence, Single-Dose, Crossover, Oral Bioequivalence study of Methotrexate Tablets, USP 2.5mg from Lotus Pharmaceuticals Co., Ltd., Taiwan compared with that of Methotrexate Tablets, USP 2.5 mg manufactured for DAVA Pharmaceuticals, Inc., in adult patients with mild to severe Psoriasis or Rheumatoid Arthritis under fasting Conditions
Dr. Archana Uppin-PI
    - IEC notification of protocol amendment letter dated 28/08/2019
    - IEC notification of IU and FDA 1572 letter dated: 11/09/2019
    - IEC notification of clarification letter dated: 12/09/2019

5. **Protocol Title:** A Multicenter, Open-Label, Randomized, Two-Treatment, Two-Period, Two-Sequence, Single-Dose, Cross-Over, Study to Test for Bioequivalence between Celerity's Doxorubicin Hydrochloride (Pegylated Liposomal) Injection 20mg/10ml (2mg/ml) in Patients with Metastatic Breast Cancer.
   Study Title: 0927-17
   Dr. Mahesh Kalloli-PI
   - IEC notification of SAE Cross letter dated:05/08/2019

6. **Protocol No :** ALK18/EN124/-CET1
   Protocol Title : A prospective, multicenter, randomized, double blind, parallel group study to compare the efficacy and safety of biosimilar cetuximab versus innovator cetuximab in combination with platinum-based chemotherapy in patients with recurrent locoregional or metastatic squamous cell carcinoma of the head and neck (SCCHN)
   Dr. Maheshkumar Kalloli-PI
   - IEC notification of CTRI document letter dated 18/Sep/2019
   - IEC notification of insurance policy letter dated: 09/09/2019

7. **Protocol No:** BECT/HepA-Phase-III/CTP-02
   Protocol Title: A Single BLIND, Parallel, Randomized Phase-III comparative study to Evaluate and Safety and Immunogenicity of two intramuscular doses of inactivated Hepatitis A Vaccine administered 6 months apart, in 1-15 old healthy Hepatitis A Vaccine-naïve child
   Dr.N.S.Mahantashetti-PI
   - IEC notification of Source Template Letter dated: 23/07/2019

8. **Study Title**: A multicenter, open label, randomized, balanced, two-treatment, three-period, three-sequence, single dose, replicate cross-over bioequivalence study of Doxorubicin Hydrochloride Liposome Injection 2mg/mL (50 mg/m2 dose) of Sun Pharmaceutical Industries Ltd., India with that of Caelyx® 2mg/mL [Doxorubicin Hydrochloride (Pegylated Liposomal)] concentrate for solution for infusion of Janssen-Cilag International NV, Belgium in stable advanced ovarian cancer patients who have failed a first-line platinum based chemotherapy regimen or stable metastatic breast cancer patients under fed (standardized light meal) condition.
   Study No.: 18-VIN-0314
   Dr.Maheshkumar Kalloli-PI
   - IEC notification of IU for the Protocol Amendement-02 letter dated: 09/09/2019
   - IEC notification of change in sponsors representative letter dated: 09/09/2019

9. **Protocol title** – A Phase 2, Dose Range Finding, 12-Week, Double-Blind, Randomized, Parallel Group to Evaluate safety and Efficacy of GRC 27864 in patients with Moderate Osteoarthritis Pain **Protocol No: GRC 27864-201**
   Dr. ShaileshV Udapudi-PI
   - IEC Notification of DCGI_NOC letter dated 17/Jul/2019
   - IEC Notification of Updated IU, PSP and Insurance letter dated 15/Jul/2019
   - IEC Notification of DCGI acknowledgement of EC Approval letter for Version 4.0 protocol letter dated 25/Jul/2019

- IEC notification of DCGI Acknowledgement of Typo error in DCGI Approval Letter for Version 4.0 Protocol.

10. **Protocol Title:** A Phase 3, Randomized, Double-blind, Parallel-Group, Vechile Controlled, Multicentre Study of the Efficacy and Safety of Granexin Gel in the Treatment of Diabetic Foot Ulcer (GAIT 1)
    Protocol No: 2015-DFU-301
    Dr. Vikrant Ghatnatti-PI
    - IEC Notification of Revised Protocol Clarification Letter for protocol version 6.0 dated 30/Jul/2018 letter dated: 16/Jul/2019
    - IEC notification of study documents letter dated:30/08/2019

11. **Protocol No and Title:** A Randomized, Double-Blind, Multicentre, Multinational Comparitive clinical study to compare the efficacy and safety of INTP® in patients with unresectable, Locally advanced, recurrent or Metastatic Non-squamous Non-small Lung Cancer
    Dr.Mahesh Kalloli - PI
    - IEC notification of FDA 3455 for IEC dated 05/Jul/2019

12. **Protocol Title:** "A randomized, Double-Blind, Multicentre, Three-Arm, Parallel, Placebo-Controlled, Clinical Study to evaluate the Bioequivalence using Clinical Endpoint of Clindamycin Phosphate 1.2% and Benzoyl peroxide 5% Gel (Encube Ethicals Private Limited, India) to DUAC ® Gel (Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel) (Stiefel Laboratories, Inc. Research Triangle Park, NC 27709) in Subjects with Acne Vulgaris.
    Protocol No: CRL011812
    Dr.Shivkumar Patil-PI
    - IEC notification of Close-Out Notification dated 17/Apr/2019

13. **Study Number:** GBR 200-301
    Study Title: A Prospective, Multicenter, Randomized, Double-blind, Parallel-group, Study to Compare the Efficacy and Safety of GBR 200 (similar biologic of Trastuzumab) versus Innovator Trastuzumab both when given in combination with Paclitaxel in patients diagnosed with HER2 Positive Metastatic Breast Cancer.
    Dr.Maheshkumar Kalloli-PI
    - IEC notification of Safety narrative subject 07-014 letter dated: 14/09/2019

14. **Protocol Title:** A Phase II/III, Multicentre, Randomized, Open-label, Active Controlled, Clinical study to assess the immunogenicity and safety of Tetanu8s Toxoid, Diphtheria Toxoid and Acellular Pertussis (Tdap) Vaccine manufactured by Serum Institute of India Pvt. Ltd. (SIIPL) in Comparison with Boostrix @ Vaccine of GSR in healthy Adults, Adolescents and children in india.
    Dr.N.S.Mahantashetti -PI
    - IEC notification of IU dated 10/Jun/2019
    - IEC notification of ICF discrepancy of subject 104051 letter dated 11/07/2019

15. **Protocol Title:** Post Marketing Phase-4 Study To Evaluate Safety, Tolerability, And Efficacy Of Kyprolis® (Carfilzomib) In Indian Patients With Relapsed Or Refractory Multiple Myeloma: A Prospective, Open-Label, Non-Comparative, Multicentre Study
Protocol No: 20160372
Dr.Rohan Bhise-PI

- IEC notification of Dear Investigator letter dated: 13/09/2019
- IEC notification of study document letter dated: 29/08/2019

16. **Protocol No:** CR172-17
Study Title: A Multi-Centre, Open label, Randomized (1:1), Parallel, Phase II Study to evaluate the Safety, Tolerability and Immunogenicity of a 15-Valent Pneumococcal Conjugate Vaccine (PCV15) in healthy subjects between 2-5 years of age (Group I: 15-Valent Pneumococcal Conjugate Vaccine, Group II: Prevnar 13®).
Dr. N.S.Mahantashetti-PI

- IEC notification of Typo Error in Note to File dated 16/03/2019 letter dated 25/07/2019

17. **Protocol No:** EFC15082
Protocol Title: A 26 Week, Randomized, Open-Label, Parallel-Group Comparison of SAR341402 Mix 70/30 to NovoMix® 30 in Adult Patients with Diabetes Mellitus using Pre-Mix Insulin Analogs
Dr. M V Jali – PI

- IEC Notification to Clarification Regarding the typo Error in Marathi Translation Certificate for Study Documents
- IEC notification of Typographical error in notification dated 5 sep 2019 and letter dated 16 sep 2019
- IEC notification of Clarification regarding the details of translation and back translation certificate information letter dated 16/sep/2019

18. **Protocol Number:** XBR1001/1009980
Protocol Title: A Phase III Double-Blind, Parallel Group Multicenter Study to Compare the Efficacy and Safety of Xlucane Versis Lucentis® in Patients with Neovascular Age-Related Macular Degeneration
Dr.Smitha K S _ PI

- IEC Notification to Clarification Letter for Typo Error in EC Submission and Approval Letter
- IEC Notification of CTA & Site Management Services Agreement Letter dated 24/Jun/2019

19. **Protocol No:** PBL/CR/2014/05/CT/DEN
Protocol Title: A phase I/II, Double-Blind, Placebo Controlled, Randomized, Multicenter, prospective Study to Evaluate the Safety and Immunogenicity of a single dose Dengue Tetravalent Vaccine, Live-Attenuated (Recombinant, Lyophilized) in Healthy Subjects.

Dr.Madhav Prabhu – PI

- IEC Notification of Dengue Occurrence Surveillance Document: 3 Years Post Vaccination Follow up; version 1 Letter dated 19/Jul/2019

20. **Protocol No:** EFC14828

Protocol Title: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes patients at High Cardiovascular Risk

Dr. Prasad M R – PI

- IEC Notification of Safety Alerts Letter dated 20/Feb/2019
- IEC Notification of Safety Alerts Letter dated 16/Apr/2019
- IEC Notification of Safety Alerts Letter dated 02/May/2019

21. **Protocol No:** MYL-14020

Protocol Title: Multicenter, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-14020 Compared with Avastin®, in the First-Line treatment of patients with Stage IV Non-Squamous Non-Small Cell Lung Cancer

Dr.Mahesh Kalloli – PI

- IEC Notification of Typo Error of Date Notification Letter dated 06/Aug/2019
-

22. **Protocol No:** D1699C00001-DAPA HF

Protocol Title: To Evaluate the Effect of Dapagliflozin on the Incidence of Worsening of Heart Failure or Cardiovascular Death in Patients with Chronic Heart Failure with Reduced Ejection Fraction.

Dr. Kothiwale V A – PI

- IEC Notification of Investigator's Undertaking dated 31/Jul/2019
- IEC Notification of Periodic Safety Summary of SUSAR's- Dapagliflozin dated 27/Jun/2019 letter dated 30/Jul/2019
- IEC Notification of SUSAR Line Listings for Investigator's dated 20/Jun/2019 letter dated 30/Jul/2019
- IEC Notification of Dapagliflozin IB Edition 15 Comparison table of Substantial Changes Letter dated 30/Jul/2019
- IEC Notification of Investigator's Brochure – Edition No. 15, 05/Jul/2019 Letter dated 30/Jul/2019
- IEC notification of End of study closure visit of all subjects letter dated: 07/09/2019
- IEC notification of DMC recommendation letter dated: 09/09/2019

23. **Protocol No:** 2015028

Protocol Title: A Multicenter, Multiple-Dose Activated-Controlled, Double-Blind, Double-Dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride with Intravenous Doses of Etelcalcitide (AMG 416) in Asia Haemodialysis Subjects with Secondary Hyperparathyroidism

Dr. Ritesh Vernekar – PI

- IEC Notification of Study Documents Letter dated 26/Jul/2019
- IEC Notification of QLL-1 for the Indian SAE's (Non-SUSARs) Letter dated 06/Jun/2019
- IEC notification of acknowledgment letter of DCGI for amendment 03 letter dated:03/07/2019

24. **Protocol Title:** A Randomized, 24 Weeks, Controlled, Open-Label, Parallel arm, Multicenter Study Comparing the Efficacy and Safety of the Insulin Glargine/Lixisenatide Fixed Ration combination to Insulin Glargine in Type 2 diabetes patients, inadequately controlled on Basal Insulin with or without Metformin.

Dr.Vikrant Ghatanatti-PI

- IEC Notification of Updated IU Letter dated 05/Aug/2019

25. **Protocol Title/No:17-101**: A Randomized, Open label, multi-center, two-treatment, two-period, two-sequence, two-way cross-over, multiple dose, steady state Bioequivalence (BE) study of Genus Life sciences Inc. Nilutamide Tablets 150 mg with NILANDRON® (Nilutamide) Tablets 150 mg from Concordia Pharmaceuticals Inc. in metastatic prostate cancer patients.
Protocol Version and date: Version 2.0, dated 19/Mar/2018
Dr.S.I.Neeli-PI

- IEC notification of study close out visit letter dated:30/08/2019

26. **Protocol No:** CTQJ230A12001
Protocol Title : Multi-center cross-sectional epidemiological study to characterize the prevalence and distribution of lipoprotéine(a) levels among patients with established cardiovascular disease

Dr. Prasad M R – PI

- IEC Notification of Final CTA

27. **Study Number/Name:** EFC14875 / the SCORED Trial
Study Title: "A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozins on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function."

Dr. Prasad M R – PI

- IEC Notification Safety Alert Report Letter dated 12/Jun/2019
- Safety Alert Report #34IN & 35 Letter dated 20/Jun/2019
- Safety Alert Report #41, 42IN & 43 Letter dated 10/Jul/2019
- Safety Alert Report #52 Letter dated 22/Jul/2019
- Safety Alert Report #46, 47IN Letter dated 22/Jul/2019
- Safety Alert Report #51 Letter dated 25/Jul/2019
- Safety Alert Report #48, 49IN & #50 Letter dated 25/Jul/2019
- Safety Alert Report #55IN, 56 Letter dated 06/Aug/2019
- Alert Report #57, #58IN, #59 Letter dated 14/Aug/2019
- Safety Alert Report #53IN, #54 Letter dated 19/Aug/2019

28. **Protocol Title:** A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes Patients at High Cardiovascular Risk.
Protocol number: EFC14828/Amplitude-O
Dr. Prasad M R – PI

- Safety Alert Report #20IN, #21 Letter dated 24/Jul/2019
- Safety Alert Report #22IN, #23 Letter dated 24/Jul/2019
- Safety Alert Report #26 Letter dated 22/Jul/2019
- Safety Alert Report #17IN, #18 Letter dated 24/Jul/2019
- Safety Alert Report #15 Letter dated 24/Jun/2019
- Safety Alert Report #19 Letter dated 24/Jun/2019
- Safety Alert Report #24, 25IN Letter dated 19/Aug/2019
- Safety Alert Serious Reaction #04 Letter dated 19/Aug/2019
- Safety Alert Report #28IN, 29 Letter dated 17/Aug/2019
- Safety Alert Report #30 Letter dated 09/Sep/2019
- Safety Alert Report #27 Letter dated 19/Aug/2019
- IEC Notification of CTA 1 Addendum Dated 06/Jun/2019 Letter dated 16/Aug/2019
- IEC notification for Clarification of Typo-Error Mentioned in EC Submission of Amendment 01 Letter dated 29/05/2019

29. **Protocol Title:** A global, multicenter, three arms, open-label randomized study to evaluate the efficacy and safety of Nanosomal Docetaxel Lipid Suspension compared to Taxotere® (Docetaxel Injection Concentrate) in triple-negative breast cancer patients with locally advanced or metastatic breast cancer after failure to prior chemotherapy.
Study Title: 0063-17
Dr.Rohan Bhise-PI

- IEC notification of SAE Cross letter dated:12/09/2019
- IEC notification of SAE Cross letter dated:09/09/2019
- IEC notification of Insurance certificate letter dated: 09/09/2019

30. **Protocol Title:** A 12-week double-blind, randomized, multi-center study comparing the efficacy and safety of once monthly subcutaneous AMG 334 against placebo in adult episodic migraine patients (EMPOwER).
Protocol No.:CAMG334A2302
Dr.Saroja A.O-PI

- IEC notification of IB letter dated: 10/09/2019

31. **Protocol No:** BBIL/ROTAVAC/III/2018
Protocol Title: A Phase 3, Multicenter, Open Label, Randomized Clinical Trial To Evaluate Safety And Immunogenicity Of ROTAVAC®-20 ^{O}c And Rotavac 5CM Administered At Birth (Neonatal Schedule) And Additional Dose Versus Infant Schedule Against Rotavirus Gastroenteritis

Dr.N.S.Mahantashetti-PI

- IEC notification of renewed insurance letter dated:29/08/2019

32. Research project - "Breastfeeding Education Support Tool for Baby" (BEST4Baby)
Dr.N.S.Mahantashetti-PI

- IEC notification of outcome questionaries' Version 2.00 letter dated:24/08/2019

VII. Any other matter with the permission of the chair

For your attention:

Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Dr.M.S.Ganachari
Member Secretary of IEC

Prof. Dr. M. S. Ganachari
Member Secretary, Institutional Ethics Committee
KLE Academy of Higher Education and Research, Belagavi

To:

	Circular and Submission of IEC Dossier	
1)	**Dr. Subarna Roy**, Scientist 'F', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V.Hegde**, Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** Prof of Pharmacology [USM-KLE] IMP, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar**, Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
6)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
7)	**Dr.Nayana Hashilkar**, Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
8)	**Mrs.Vaishnavi V Kivadasannavar**, M.S.W,Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
9)	**Shri.Tammanna Dadu Kore,** Farmer, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member

10)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
11)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, KLE College of Pharmacy, Belagavi	Assistant Coordinator
12)	**Prof.(Dr.) M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
13)	**Dr.Sapna.K** Radiation Oncologist, KLE society's Belgaum cancer hospital, Belagavi-10	Subject Expert
14)	Dr. M.V. Jali, Chief Diabetologist, KLES Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belgaum-590 010, Karnataka, India	Special Invitee
	Administrators of KAHER(Deemed to be University)	
1)	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed University, Belagavi, For Information	Circular
	Principal Investigators	
1)	**Dr.Santosh Dhananjay Hajare,** *Consultant* Gastroenterologist, KLES Dr Prabhakar Kore Hospital & MRC, Belagavi-10	Circular
2)	**Dr. Maheshkumar Veeranna Kalloli,** Consultant, Oncology Dept., KLES Dr Prabhakar Kore Hospital &MRC, Nehru Nagar, Belagavi-590 010, Karnataka, India.	Circular
3)	**Dr.Mahantesh Patil,** Professor of Pediatrics, JNMC, KLES Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi - 590 010,	Circular
4)	**Dr.Gautam S,** Consultant Pulmonologist, KLEs Dr.Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi-10	Circular

Institutional Ethics Committee

KLE Deemed to be University

(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)
KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State, India
Accredited "A" grade by NAAC '2nd Cycle' Placed in Category "A" by MHRD [GoI]
t: 0831-2470400 FAX: 0831-2493099 www.kledeemeduniversity.edu.in E-mail:kleclinicalresearch@gmail.com

Ref: KAHER/EC/2018-19/D- 3569 **Date: 26/02/2018**

IEC Meeting Agenda

Institutional Ethics Committee of KLEU, Belagavi
Monday, 12/03/2018, At: 4.00 PM
Venue: Site management Office

Accreditations:

NABH

FERCAP

Registrations:

DCGI

OHRP

I. Review of New Project Proposals:

1. **Protocol Title:** Phase IV Clinical trial to evaluate the safety & Efficacy of Gastica Drops
   Dr.N.S.Mahantashetti-PI

2. **Protocol Title:** Use of "BEMPU" in normal weight babies during transitional thermal adaptation
   Dr.Manisha Bhandankar-PI

3. **Protocol Title:** A Multicentre, Open label, Balanced, Randomized, Two-treatment, Two-period, Single dose, Crossover, Bioequivalence study of Bortezomib for Injection 3.5 mg/vial of Dr. Reddy's Laboratories Limited, India and VELCADE® (bortezomib) for Injection 3.5 mg/vial (Distributed and Marketed by: Millennium Pharmaceuticals, Inc., 40 Landsdowne Street, Cambridge, MA 02139) in previously untreated Multiple Myeloma and/or Relapsed Multiple Myeloma patients
   Study No.: 17-VIN-0772
   Dr.Rohan Bhise-PI

4. **Study Title**: A Randomized, Multiple-dose, Multicenter, Comparative, Parallel Study to Evaluate the Efficacy, Safety and Pharmacokinetic Characteristics of Intravenous Infusion of Trastuzumab (Test, Hetero) and Reference Medicinal Product (Reference, Roche) in combination with standard chemotherapy in Patients of HER2-positive Metastatic breast cancer (TRUMAB Study).
   Protocol No: HCR/III/TRUMAB/05/2016 V1.1 Dated: 26 Jul 2017
   Dr.Rohan Bhise-PI

5. **Protocol No:** NN BIAsp-4343
   Protocol Title: "A multi-Centre prospective, non-interventional study of ability and willingness to pay for BIAsp 30 in a real world population with type 2 diabetes mellitus"
   Dr.Vikrant Ghatnatti-PI

II. Review of Proposals with Revision and Amendments:

-No Amendments

III. Review of Revised Project Proposals:

Protocol Title: A multicentre, randomized, assessor blind, active controlled, comparative, phase IV study to assess the safety and efficacy of two fixed dose combinations (FDC) formulations of trypsin BP 48/96mg + bromelain 90/180mg + Rutoside trihydrate BP 100/200 mg viz. Phlogam® and Disperzyme® in post-operative inflammation in subjects undergoing minor surgery and dental procedures

Study Code: AKS_PHLOG_17_01

M.I.Uppin PI

The above study was reviewed in the IEC meeting which was held on 20/01/2018. IEC members sought the following documents/Clarification for further consideration and PI submitted to IEC on 08/02/2018.

1. Final Executed CTA
2. Renewal of study specific insurance
3. ICH-GCP training certificate (Principal Investigator)
4. Clarification for the inclusion of dental procedures in the study title(02/02/2018)

IV. Review of Annual Report

1) **Protocol Title**: A prospective, multicentric, randomized, open-label comparison of long acting basal insulin analog Glargine plus Glulisine with premixed Insulin in adult patients with type 2 diabetes Mellitus.
Protocol No: IDRFARH007
Dr.M.V.Jali-PI

V. SAE reporting

1) **Protocol No: BCD-021-02**
Study Title:" International multicenter randomized double blind phase III trial comparing safety and efficacy of BCD-021 (CJSC BIOCAD, Russia) and paclitaxel + carboplatin to Avastin® (F. Hoffmann-La Roche Ltd, Switzerland) and paclitaxel + carboplatin in inoperable or advanced non-squamous non-small-cell lung cancer patients. "
Dr.Mahesh Kumar Kalloli-PI
   - Subject no: 83-001_Medical Event_ Death-FU01

VI. Protocol deviation/violation/ termination:

1) **Protocol no:** RLS/RES/2016/01: version 1.0, dated: 05 Feb 2016
Protocol title: Prospective, multi-centre, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-022/Xolair® in patients with moderate to severe persistent asthma.
Dr.Jyothi Hattiholi-PI
Description of Deviation: the sub 6802-005 whose screening visit performed on 4/12/2017, randomization visit done on 11/12/2017 and dosing done on 28/12/2017. As per protocol dosing should be done within 21 days after screening but due to family emergency sub visited site for dosing, after 21 days of screening and dosing was performed.
2) **Protocol Number:** CLR_16_13
Protocol Title: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer.
Dr.Rohan Bhsie-PI

Description of Deviation 01: Sub_2201-Randomization procedure was performed on day 1 instead of Day -1.

Description of Deviation 02: Sub_2202-Randomization procedure was performed on day 1 instead of Day -1.

VII. The Committee will consider the following agendas which are for information.

1) **Protocol** PMZ-02; DCGI CT NOC No.: CT/ND/37/2016
Study Title: A Prospective, Multi-centric, Randomized, Double-blind, Parallel, Saline Controlled Phase II Safety and Efficacy study of PMZ-2010 as a resuscitative agent for Hypovolemic Shock due to excessive blood loss to be used along with standard shock treatment.
Dr.Madhav Prabhu-PI
   - IEC notification of Final executed CTA

2) **Study Title & Study Code:** Prospective, Randomized, Double Blinded, Parallel Group, Multicentric, Comparative Clinical study to compare efficacy and safety of oral CPL-2009-0031 of Cadila Pharmaceutical Limited, India against innovator Sitagliptin in patients with Uncontrolled Type -2 Diabetes Mellitus (T2DM). (CRSC16002).
Dr.Jayaprakash Appajigol-PI
   - IEC notification of DCGI notification of protocol addendum 001 dated 02/01/2018
   - IEC notification of CTA and Study specific insurance

3) **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
Dr.Jayaprakash Appajigol-PI
   - **IEC Notification of CIOMS**- Report:3001-00425_Event: Pericarditis (Previously elevated troponin: FU01
   - **IEC Notification of CIOMS** - Report: 3001-00207_1. Hepatic cytolysis 2.Mesentric ischemia 3. Posterior reversible encephalopathy syndrome Event: Pericarditis (Previously elevated troponin: FU09
   - **IEC Notification of CIOMS** - Report:00155_Event: Death due to Aggravation of the underlining disease (PT: condition Aggravated)
   - **IEC Notification of CIOMS** - Report:00156_Event: Aggravation of general condition resulted from Epstein Barrvirus Infection (PT: Epstein Barrvirus Infection)- Initial
   - **IEC Notification of CIOMS** - Report:00156_Event: Epstein Barrvirus Infection (PT: Epstein Barrvirus Infection)-FU02
   - **IEC Notification of CIOMS** - Report:00156_Event: Aggravation of general condition resulted from Epstein Barrvirus Infection (PT: Epstein Barrvirus Infection)-FU09
   - **IEC Notification of CIOMS** - Report:00116_Event: Death (Aggravated acute peritonitis due to descending colon perforation)- FU
   - **IEC Notification of CIOMS**-Report:00117_Event: Acute peritonitis due to gastrointestinal perforation – FU
   - **IEC Notification of CIOMS**-Report:00119_Event:Blood pressure Deceased – FU
   - **IEC Notification of CIOMS**-Report:3001-00126_Event:Periheral facial paralysis – FU V8

- **IEC Notification of CIOMS**-Report:3001-00402_Event:1.Cardiac Arrest 2.Brain embolic Infraction– FU01
- **IEC Notification of CIOMS**-Report:3001-00425_Event:Elevated troponin– Initial

4) **Protocol: EFC11570:** A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to evaluate the effect of Alirocumab (SAR236553/REGN727) on the occurrence of Cardiovascular Events in Patients who have recently experienced an Acute Coronary Syndrome.
Dr.Sanjay Porwal-PI
   - IEC Notification of CIOMS-SA:352-353 IN letter dated 04/12/2017
   - IEC Notification of CIOMS-SA:354-355 IN letter dated 04/12/2017
   - IEC Notification of CIOMS-SA:370-371IN letter dated 04/12/2017

5) **Protocol Number/ Title- [Pfizer, A0081105,** "A randomized, double-blind, placebo-controlled, parallel group, multi-center trial of pregabalin as adjunctive therapy in pediatric and adult subjects with primary generalized tonic-clonic seizures", PAREXEL, 208238]
Dr.Mahesh Kamate-PI
   - IEC notification of insurance certificate letter dated 17/02/2018
   - IEC notification of SAE line listing report from 18/01/2013 to 07 Nov 2017
   - IEC notification of SAE line listing report from 18/01/2013 to 05 Feb 2018

6) **Protocol Title:** Prominent: Pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes.
Protocol No: K-877-302
Dr.V.A.Kothiwale-PI
   - **IEC Notification of SUSAR**: Worsening of malignant arrhythmia_ Patient#1816-004-Initial
   - **IEC Notification of SUSAR:** Worsening of malignant arrhythmia_ Patient#1816-004-FU01
   - **IEC Notification of SUSAR**: Worsening of malignant arrhythmia_ Patient#1816-004-FU02
   - **IEC Notification of SUSAR:** Rashes on the body: trunk, limbs_ Patient#16012-102-FU01
   - **IEC Notification of SUSAR:** Rashes all over the body_ Patient#16012-102-FU02
   - **IEC Notification of SUSAR:** Transient Episode of unawareness while driving _ Patient#10039-102-Initial
   - **IEC Notification of SUSAR:** Transient Episode of unawareness while driving _ Patient#10039-102-FU01
   - **IEC Notification of SUSAR:** Acute pancreatitis_ Patient#1007-019-FU01
   - **IEC Notification of SUSAR:** Acute pancreatitis_ Patient#1007-019-FU02

7) **Protocol Title:** A randomized, prospective, open label, comparative, parallel group, multicenter 12 weeks study to evaluate efficacy, safety and tolerability of Glycopyrronium/Formoterol FDC 25mcg/12mcg twice daily in comparison with Glycopyrronium 50mcg once daily in patients with moderate to Severe Chronic Obstructive Pulmonary Disease (COPD)
Study code: CP/11/15

Dr.Jyothi Hattiholi-PI

- **IEC Notification of CTRI registry**-CTRI/2017/09/009804

8) **Protocol No/Title:** MYL-TLE 400-4001-"Multicenter, open label, randomized prospective, phase IV, interventional, non-inferiority study with blinded assessment, to evaluate the efficacy and safety of fixed dose combination (FDC) of tenofovir/Lamivudine/low dose Efavirenz(300/300/400mg) Vs. FDC of Tenofovir/Lamivudine//Efavirenz(300/300/600mg) in adult Indian patients who have HIV-1 infection"

Dr.Dyanesh Morkar-PI

- IEC Notification of source note templates

8) **Protocol Number: APL/CT/16/11**

Protocol Title: A Phase-III, Multicentric, Randomized, Double Blind, Placebo-Controlled, Comparative Clinical Study to Evaluate the Efficacy and Safety of Sildenafil Citrate 50 mg plus Dapoxetine 60 mg Tablet and Sildenafil Citrate 100 mg plus Dapoxetine 60 mg Tablet in the treatment of co-existing Erectile Dysfunction and Premature Ejaculation.

Dr.S.I.Neeli-PI

- IEC Notification of source note templates

9) **Protocol Title:** MYL-1402O-3001: Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer

Dr.Mahesh Kumar Kalloli-PI

- IEC notification of travel reimbursement missed in re-consent of subject no: 171004

6) **Study No:** CR150-16

Study Title: A Multicentric, Open-label, Randomized, Two Treatment, Two Sequence, Cross Over, Clinical Bioequivalence Study of Doxorubicin Hydrochloride Liposome Injection (IV) 2 mg/ml (50mg/m2) of Auromedics Pharma LLC, USA (Test) With Doxorubicin Hydrochloride Liposome Injection (IV) 2 mg/ml (50mg/m2) of Sun Pharmaceutical Industries, Inc, USA (Reference) in Ovarian Cancer Patients whose disease has progressed or recurred after platinum-based chemotherapy under fasting conditions

Dr.Rohan Bhise-PI

- IEC Notification of protocol wavier of subject no.107002

9) **Study No: CT/DOX/1602**

Protocol Title: An Open-Label, Multicentric, Randomized, Two Treatment, Three Period, Three Sequence, Semi-Replicate, Cross-Over, Comparative Bioavailability study of Doxorubicin Hydochloride Liposomal Injection 20mg/10mL (2mg/ml), concentrate for solution for infusion manufactured by Teva Pharmachemie, Netharlands with caelyx 20 mg/10ml (2mg/ml), [Doxorubicin hydrochloride Liposomal Injection] concentrate for solution for infusion Of Janssen-Cilag International NV, Belgium in advanced ovarian cancer and/or metastatic breast cancer patients under fasting condition.

Dr.Mahesh Kumar Kalloli-PI

- IEC Notification of SAE Description: 11-106 Breathlessness
- IEC Notification of 1. Protocol Deviation form 2. SAE Disease progression(Death)

10) **Protocol Title:** I4V-MC-JADY-A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Barcitinib in Patients with Rheumatoid Arthritis.
Dr.Shailesh Udapudi-PI
- IEC Notification of SAFRNS/CIOMS

11) **Protocol no:** RLS/RES/2016/01: version 1.0, dated: 05 Feb 2016
Protocol title: Prospective, multi-centre, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-022/Xolair® in patients with moderate to severe persistent asthma.
Dr.Jyothi Hattiholi-PI
- IEC Notification quarterly line listing letters 11/09/2017 to 10/12/2017

10) **Protocol Number:** CLR_16_13
Protocol Title: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer.
Dr.Rohan Bhsie-PI
- IEC Notification of CIOMS_ Report: Due analysis of Subject:1807/CHP

11) **Protocol Title:** "Better Birth: Trial of WHO Safe Childbirth Checklist Program"
Dr.B.S.Kodkany-PI
- IEC Notification of study close out, study summary and main outcomes publications

12) **Protocol ID:** PCV-10-003
Protocol Title: A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety, Tolerability, Immunogenicity and Non-Interference with Concomitant Vaccinations of Serum Institute of India's 10-Valent Pneumococcal Conjugate Vaccine (PNEUMOSIL®) in Healthy Indian Infants
Dr. (Mrs).N.S.Mahantashetti-PI
- IEC Notification of DCGI Submission letter

VIII. Any other matter with the permission of the chair

For your attention:

Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Prof.M.S.Ganachari
(Name & Signature of IEC,
Member-Secretary-KLEU, Belagavi)

To:

	Circular and Submission of IEC Dossier	
1)	**Dr. Subarna Roy**, Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V.Hegde**, Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar**, Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr. M.V. Jali**, MD & CE, KLEs Dr.Prabhakar Kore Hospital and MRC, Belagavi	Member
6)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
7)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
8)	**Dr.Nayana Hashilkar**, Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
9)	**Mrs.Vaishnavi V Kivadasannavar**, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
10)	**Shri.Tammanna Dadu Kore,** Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
11)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
12)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, Belagavi	Member
13)	**Prof.(Dr.)M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
	Administrators of KLE Deemed to be University	
1)	The Registrar, KLE Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KLE Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KLE Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO - KLE Deemed to be University, Belagavi, For Information	Circular
	Principal Investigators	
1)	**Dr.(Mrs)N.S.Mahantashetti,** Professor and Principle of J.N.Medical College, Belagavi.	Circular
2)	**Dr.Manisha Bhandankar**, Prof.of Paediatrics, KAHER's JNMC, Belagavi	Circular
3)	**Dr.Rohan Bhise**, Consultant, Dept.of Oncology, KLEs Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi	Circular
4)	**Dr.Vikarant Ghatanatti,** Consultant Endocrinologist, KLEs Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi	Circular

Institutional Ethics Committee

KLE Academy of Higher Education and Research, Belagavi
Deemed to-be-University
(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)
KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State, India
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Ref: KAHER/IEC/2018-19/D-39 ***Date: 04/04/2018***

IEC Meeting Agenda

Institutional Ethics Committee of KLEU, Belagavi
Friday, 13/04/2018, At: 4.00 PM
Venue: Site management Office

I. Review of New Project Proposals:

Accreditations:

NABH

1) **Project title:** Women First: (Preconception Maternal Nutrition) GWAS
Dr.S.S.Goudar-PI

2) **Protocol title:** Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-024 / Lucentis® in patients with neovascular (wet) age-related macular degeneration
Protocol No.: RLS/OPT/2016/05; Version 2.0, Dated: 23 Jan 2017
Dr.Rekha Mudhol-PI

FERCAP

3) **Study Number:** GBR 200-301
Study Title: A Prospective, Multicenter, Randomized, Double-blind, Parallel-group, Study to Compare the Efficacy and Safety of GBR 200 (similar biologic of Trastuzumab) versus Innovator Trastuzumab both when given in combination with Paclitaxel in patients diagnosed with HER2 Positive Metastatic Breast Cancer.
Dr.Maheshkumar Kalloli-PI

Registrations:

DCGI

4) **Study Number/Name:** (Ipca/HQAT/PIII-15)
Study Title: "Efficacy and Safety of Hydroxychloroquine and Atorvastatin Combination in Prevention of Diabetes in Patients with Dyslipidemia and Pre-diabetes: A Double Blind, Randomized Comparison with Atorvastatin Alone"
Dr.Vikrant Ghatanatti-PI

OHRP

5) **Project title:** HUMAN PULMONARY PARAGONIMIASIS IN CRAB EATING COMMUNITIES AND SMEAR NEGATIVE SUSPECTED TB CASES FROM STATES OF INDIA
Dr.Mahantesh B. Nagamoti-PI

01C

II. **Review of Proposals with Revision and Amendments:**

1. **Protocol Title:** "A Multicenter, Open-label, Single-arm, Study to Evaluate Safety and Tolerability of Repatha in Patients with Homozygous Familial Hypercholesterolemia (HoFH) in India"
   Study Number: 20170199
   Dr.V.A.Kothiwale-PI

III. **Review of Revised Project Proposals:**

- Nil

IV. **Review of Annual Report**

- Nil

V. **SAE reporting**

No- SAEs

VI. **Protocol deviation/violation/ termination:**

- Nil

VII. **The Committee will consider the following agendas which are for information.**

1) **Protocol No/Title:** MYL-TLE 400-4001-"Multicenter, open label, randomized prospective, phase IV, interventional, non-inferiority study with blinded assessment, to evaluate the efficacy and safety of fixed dose combination (FDC) of tenofovir/Lamivudine/low dose Efavirenz(300/300/400mg) Vs. FDC of Tenofovir/Lamivudine//Efavirenz(300/300/600mg) in adult Indian patients who have HIV-1 infection".
   Dr.Dnyanesh Morkar-PI
   - IEC notification of subject eligibility criteria check list version 2.0
   - IEC notification of CYP2B6 test error in the TRF

2) **Protocol ID:** PCV-10-003
   Protocol Title: A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety, Tolerability, Immunogenicity and Non-Interference with Concomitant Vaccinations of Serum Institute of India's 10-Valent Pneumococcal Conjugate Vaccine (PNEUMOSIL®) in Healthy Indian Infants
   Dr.N.S.Mahantashetti-PI
   - IEC notification of typo error in approvals letter
   - IEC notification of ICH- GCP training certificate of Sub-I

3) **Protocol No:** BCD-057- 2
   Study Title: "A Multicenter Comparative Randomized Double-blind Study of the Efficacy and Safety of BCD-057 (INN: Adalimumab, CJSC BIOCAD, Russia) and Humira@ (INN: Adalimumab, Vetter Pharma) in Patients with Moderate to Severe Plaque Psoriasis"
   Dr.Shivakumar Patil-PI
   - IEC notification of Final CTA

4) **Protocol No:** 1002-043
   Protocol Title: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at High Risk For, Cardiovascular Disease Who Are Statin Intolerant.
   Dr.V.A.Kothiwale-PI
   - IEC notification of clarification of typo error in submission letter

5) **Protocol title:** CT/CLOB/PSO/16, A Multicentric, assessor-blind, randomized, active controlled, parallel design study comparing efficacy and safety of clobetasol propionate topical foam 0.05% vs. clobetasol propionate lotion 0.05% in patients with mild to moderate plaque type psoriasis (scalp and non-scalp).
Dr.Snehal Lunge-PI
   - IEC notification of Executed CTA and study specific insurance

6) **Protocol** PMZ-02; DCGI CT NOC No.: CT/ND/37/2016
Study Title: A Prospective, Multi-centric, Randomized, Double-blind, Parallel, Saline Controlled Phase II Safety and Efficacy study of PMZ-2010 as a resuscitative agent for Hypovolemic Shock due to excessive blood loss to be used along with standard shock treatment.
Dr.Madhav Prabhu-PI
   - IEC notification of Source template and DCGI acknowledgement
   - IEC notification of final executed CTA

7) **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
Dr.Jayaprakash Appajigol-PI
   - IEC Notification of DMC
   - IEC Notification of CIOMS-
     - Report: 00146_Event-Progression of lung cancer: FU01
     - Report: 00170_Event-Death(Pneumonia): FU02
     - Report: 00171_Event-Cerebral Haemorrhage: Initial
     - Report: 00171_Event-Cerebral Haemorrhage: FU01
     - Report: 00172_Event-Multi organ failure due to DIC: Initial
     - Report: 00172_Event-Multi organ failure due to DIC: FU01
     - Report: 00175_Event-Shock Haemorrhage: Initial
     - Report: 00176_Event-Death: Initial
     - Report: 3001-00444_Event-Necrosis of toes and fingers: Initial
     - Report: 3001-00440_Event-Seizure: FU01
     - Report: 3001-00431_Event-Ischemic Hepatitis worsening: FU03
     - Report: 3001-00437_Event-Hyperosinophilia: FU01
     - Report: 3001-00438_Event-Hemotama on the right plural cavity: Initial
     - Report: 3001-00438_Event-Hematoma on the right pleural cavity: FU01
     - Report: 3001-00405_Event-worsening coagulopathy: FU02
     - Report: 00159_Event-CK increased: FU01
     - Report: 3001-00405_Event-Ischemic hepatitis worsening: FU02
     - Report: 3001-00440_Event-Seizure: Initial
     - Report: 00170_Event-Death: FU01
     - Report: 00161_Event-Previously black lung fluid: FU01
     - Report: 00159_Event-CK increased: FU02
     - Report: 00170_Event-Death: FU01

8) **Study Code: D1699C00001**
Protocol: A Study to Evaluate the Effect of Dapagliflozin on the Incidence of worsening heart failure or Cardiovascular Death in patients with chronic Heart Failure with reduced Ejection Fraction.
Dr.V.A.Kothiwale-PI
   - IEC notification of insurance certificate dated 28/02/2018

9) **Protocol No:** NN BIAsp-4343

Protocol Title: "A multi-Centre prospective, non-interventional study of ability and willingness to pay for BIAsp 30 in a real world population with type 2 diabetes mellitus"
Dr.Vikrant Ghatanatti-PI

- IEC Notification of ICH-GCP training certificate
- CTRI registry

10) **Protocol Number/ Title-** [Pfizer, A0081105, "A randomized, double-blind, placebo-controlled, parallel group, multi-center trial of pregabalin as adjunctive therapy in pediatric and adult subjects with primary generalized tonic-clonic seizures", PAREXEL, 208238]
Dr.Mahesh Kamate-PI

- IEC notification of Import license for drugs/drugs (DCGI) dated 02/02
- IEC notification of Investigator Brochure dated 21/02/2018

11) **Protocol Number/Title-**:[Pfizer, A0081106, "A 12-Month Open-Label Study To Evaluate The Safety And Tolerability Of Pregablin As Adjunctive Therapy In Pediatric Subjects 1 Month To 16 Years Of Age With Partial Onset Seizures And Pediatric And Adult Subjects 5 To 65 Years Of Age With Primary Generalized Tonic-Clonic Seizures", PAREXEL,207748]
Dr.Mahesh Kamate-PI

- IEC notification of Import license for drugs/drugs (DCGI) dated 07/02
- IEC notification of Investigator Brochure dated 21/02/2018

12) **Protocol Title:** MYL-1402O-3001: Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First - line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer
Dr.Mahesh Kumar Kalloli-PI

- IEC notification of discontinuation of subject:171005
- IEC notification CIOMS
  - Event: Coughing blood-Initial: subject no: 181002
  - Event: Acute angle closure glaucoma-Initial_ subject no: 170006
  - Event: Acute angle closure glaucoma-FU01_subject no: 170006
  - Event: Acute angle closure glaucoma-FU02_subject no: 170006
  - Event: Death-FU01_subject no: 163006
  - Event: Drowsiness-FU01_subject no: 160004
  - Event: Disease Progression-FU02_subject no: 160004
  - Event: Severe respiratory distress-FU01_subject no: 162002
  - Event: Death-FU01_subject no: 163007
  - Event: Fever, cough-Initial_subject no: 163007
  - Event: Anemia, thrmbocytophrenia-FU02_subject no: 163007
  - Event: Febrile Neutropenia, thrombocytopenia -Initial_ subject no: 177004
  - Event: Hypotension, Febrile Neutropenia -FU02_ subject no: 190006
  - Event: Pyothorax -FU06_ subject no: 171004
  - Event: Pyothorax -FU05_ subject no: 171005
  - Event: Pyothorax -FU06_ subject no: 171005
  - Event: Death-FU02_subject no: 177003
  - Event: Death –FU01_ subject no: 163005
  - Event: thrombocytopenia, hypotension, breathlessness, healing delayed, pyothorax - Initial_ subject no: 175007
  - Event: Diarrhea, Febrile Neutropenia-Initial_ subject no: 185003
  - Event: Diarrhea, Febrile Neutropenia-FU01_ subject no: 185003

- Event: Diarrhea, Neutropenia-FU01_ subject no: 185003
- Event: Diarrhea, Neutropenia-FU02_ subject no: 185003
- Event: Severe respiratory distress-Initial_ subject no: 162002

13) **Protocol Title:** Prominent: Pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes.
Protocol No: K-877-302
Dr.V.A.Kothiwale-PI

- **IEC Notification of SUSARs**
  - Toxic erythema-Patient no:16012-102/Country-Ukriane-FU03

14) **Study No: CT/DOX/1602**
Protocol Title: An Open-Label, Multicentric, Randomized, Two Treatment, Three Period, Three Sequence, Semi-Replicate, Cross-Over, Comparative Bioavailability study of Doxorubicin Hydochloride Liposomal Injection 20mg/10mL (2mg/ml), concentrate for solution for infusion manufactured by Teva Pharmachemie, Netharlands with caelyx 20 mg/10ml (2mg/ml), [Doxorubicin hydrochloride Liposomal Injection] concentrate for solution for infusion Of Janssen-Cilag International NV, Belgium in advanced ovarian cancer and/or metastatic breast cancer patients under fasting condition.
Dr.Mahesh Kumar Kalloli-PI

- IEC Notification of renewed insurance and stability memo
- IEC notification of Interim monitoring reports

15) Protocol No: **EFC13889/ODYSSEY EAST**: A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
Dr.V.A.Kothiwale-PI

- IEC notification of Data monitoring recommendation form
- IEC notification of CIOMS

16) **Protocol No.** – ZYAN1.16.001.01, A randomized, double blind, placebo controlled, parallel group, phase II multi-centric trial to assess safety, tolerability and efficacy of PHD-2 Inhibitor, ZYAN1 in the treatment of anemia in pre-dialysis chronic kidney disease patients.
Dr.Ravi Sarvi-PI

- IEC notification of Investigator undertaking

17) **Protocol Title:** "A Multicenter, Open-label, Single-arm, Study to Evaluate Safety and Tolerability of Repatha in Patients with Homozygous Familial Hypercholesterolemia (HoFH) in India"
Study Number: 20170199
Dr.V.A.Kothiwale-PI

- IEC notification of investigators brochure Edition 11.0 and summary of changes

VIII. Any other matter with the permission of the chair

For your attention:
Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Prof.(Dr).M.S.Ganachari
Member-Secretary of IEC
Belagavi

Member Secretary
ETHICS COMMITTEE (EC)
KLE University BELGAUM

	Circular and Submission of IEC Dossier	
1)	**Dr. Subarna Roy**, Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V.Hegde**, Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar**, Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr. M.V. Jali**, MD & CE, KLEs Dr.Prabhakar Kore Hospital and MRC, Belagavi	Member
6)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
7)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
8)	**Dr.Nayana Hashilkar**, Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
9)	**Mrs.Vaishnavi V Kivadasannavar**, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
10)	**Shri.Tammanna Dadu Kore,** Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
11)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
12)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, Belagavi	Assistant Coordinator
13)	**Prof.(Dr.)M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
	Administrators of KAHER(Deemed to be University)	
1)	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed to be University, Belagavi, For Information	Circular
	Principal Investigators	

1)	**Dr.S.S.Goudar,** Prof. of Physiology, J.N. Medical College, Belagavi.	Circular
2)	**Dr.Rekha Mudhol,** Prof.& Head , Dept of Ophthalmology, KLEs Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi	Circular
3)	**Dr.Mahesh Kumar Kalloli,** Consultant, Dept.of Oncology, KLEs Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi	Circular
4)	**Dr.Vikrant Ghatnatti,** Consultant Endocrinologist, KLES Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi	Circular
5)	**DrMahantesh B Nagamoti,** Professor of Microbiology, J.N.M.C, KAHER, Belagavi-10	Circular

Institutional Ethics Committee

KLE Academy of Higher Education and Research, Belagavi
Deemed to-be-University
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Ref: KAHER/IEC/2018-19/D- 567

Date: 01/06/2018

IEC Meeting Agenda

Institutional Ethics Committee of KLEU, Belagavi
Wednesday, 13/06/2018, At: 4.00 PM
Venue: Site management Office, G+2, KLES Dr.PK Hospital &MRC

I. Review of New Project Proposals:

Accreditations:

NABH

FERCAP

Registrations:

DCGI

OHRP

1. **Protocol Title: GS-US-419-3895:** "Combined Phase 3, Double-blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Crohn's Disease."

2. **Protocol Title: GS-US-419-3896:** "A Long-Term Extension study to evaluate the safety of filgotinib in subjects with Crohn's Disease."

3. **Protocol Title: GS-US-418-3898:** "Combined Phase 2b/3, Double-Blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Ulcerative Colitis".

4. **Protocol Title: GS-US-418-3899:** "A Long-Term Extension Study to Evaluate the Safety of Filgotinib in Subjects with Ulcerative Colitis".

Dr.Varadaraj Gokak- Principal Investigator for the above all studies

II. **Review of Proposals with Revision and Amendments:**
- Nil

III. **Review of Revised Project Proposals:**
- Nil

IV. **Review of Annual Report:**
- Nil

V. **SAE reporting**

1) **Protocol No: BCD-021-02**
Study Title:" International multicenter randomized double blind phase III trial comparing safety and efficacy of BCD-021 (CJSC BIOCAD, Russia) and paclitaxel + carboplatin to Avastin® (F. Hoffmann-La Roche Ltd, Switzerland) and paclitaxel + carboplatin in inoperable or advanced non-squamous non-small-cell lung cancer patients."
Dr.Maheshkumar Kalloli-PI
- IEC submission of Final report of SAE_Death of sub-83001

2) **Protocol Title:** A Multicentre, Open Label, Balanced, Randomized, Two Treatment, Two-Period, Two Sequence,, Single Dose, Cross-Over Bioequilance Study Of Doxorubicin Hydrochloric Liposome Injection 2 mg/ml Of Cipla Limited India, in comparison with Doxorubicin Hydrochloric Liposome Injection 2 mg/ml Sun Pharmaceutical Ind.Ltd India, In The Patients Of Ovarian Cancer Under Fasting Conditions
Protocol No: CRD/08
Other sites:

I. Dr.Bidisha Ghosh, IPGMER/SSKM Hospital, 244, AJC Bose road, Kolkata, West Bengal
- IEC notification of SAE-Fever with diarrhea of subject no:07-S-001(T-S)

II. Dr.Prasad Tanawade, Kolhapur cancer center, opp. Mayur petrol pump,Maharstra-416234
- IEC notification of SAE-Nausea, Vomiting and weakness of subject no:04-S-002(RRT)

VI. **Protocol deviation/violation/ termination:**

1) **Protocol No: BCD-021-02**
Study Title:" International multicenter randomized double blind phase III trial comparing safety and efficacy of BCD-021 (CJSC BIOCAD, Russia) and paclitaxel + carboplatin to Avastin® (F. Hoffmann-La Roche Ltd, Switzerland) and paclitaxel + carboplatin in inoperable or advanced non-squamous non-small-cell lung cancer patients."
Dr.Maheshkumar Kalloli-PI
- Protocol deviation for performed random glucose instead of fasting glucose
- Protocol deviation for Dose Postponed of the subject:83007
- Protocol deviation for Dose Postponed due to AE of subject 83005
- Protocol deviation due to technical problem at hospital CT Scan center
- Protocol deviation for not recording of nominee details in ICF

VII. **The Committee will consider the following agendas which are for information.**

1. **Study Protocol No.: LRP/LNP3794/2016/006**
Study Protocol Title: A Phase II/III Pivotal, Open-label, Randomized, 3-Arm Study to Assess the Efficacy of LNP3794 Monotherapy or in Combination with Docetaxel, Compared with Docetaxel Alone, in Patients with RAS Mutation-Positive Locally Advanced and Metastatic Non-Small Cell Lung Cancer
Dr.Maheshkumar Kalloli-PI

- IEC notification of Case report form(Version 1.0 dated 05/02/2018)

2. **Protocol 3-001:** A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   Dr.Jayaprakash Appajigol-PI
   - IEC notification of CIOMS
     - REAP-00184-Event: Death_ Initial
     - REAP-3001-00410-Event: Severe bleeding, hemorrhagic shock, cardiac arrest_FU01
     - REAP-3001-00444-Event: Necrosis of toes and fingers _ initial
     - REAP-3001-00444-Event: Hemotype _ initial
     - REAP-3001-00444-Event: Necrosis of toes and fingers _ FU01
     - REAP-00176-Event: Death_Status: FU01
     - REAP-00179-Event: Death_Status: Initial
     - REAP-00180-Event: Death_Initial
     - REAP-00184-Event: Death_Initial
     - REAP-00184-Event: Death _ FU01
     - REAP-00185-Event: Intra-cerebral haemorrhage _ Initial
     - REAP-00188-Event: White Blood cell ↓, Neutrophil count ↓_Initial
     - REAP-00192-Event: Death _ Initial
     - REAP-3001-00440-Event: Seizure_ FU02
     - REAP-3001-00440-Event: Seizure_ FU03
     - REAP-3001-00440-Event: Seizure_ FU04
     - REAP-3001-00440-Event: Seizure_ FU05
     - REAP-3001-00437-Event: Hypereosinophilia_ FU02
     - REAP-3001-00437-Event: Hypereosinophilia_ FU03
     - REAP-3001-00438-Event:Hematoma on the right plural cavity _ FU02

3. **Study No:** CR150-16
   Study Title: A Multicentric, Open-label, Randomized, Two Treatment, Two Sequence, Cross Over, Clinical Bioequivalence Study of Doxorubicin Hydrochloride Liposome Injection (IV) 2 mg/ml (50mg/m2) of Auromedics Pharma LLC, USA (Test) With Doxorubicin Hydrochloride Liposome Injection (IV) 2 mg/ml (50mg/m2) of Sun Pharmaceutical Industries, Inc, USA (Reference) in Ovarian Cancer Patients whose disease has progressed or recurred after platinum-based chemotherapy under fasting conditions.
   Dr.Rohan Bhise-PI
   - IEC submission of Investigator Brochure- letter dated: 25/04/2018

4. **Protocol Title:** MYL-1402O-3001: Multicenter, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer
   Dr.Mahesh Kumar Kalloli-PI
   - IEC Notification of CIOMS-
     - Subject No: 163009_ Initial _Event: cellulitis
     - Subject No: 163009_ FU01 _Event: cellulitis
     - Subject No: 163009_ FU02_Event: cellulitis
     - Subject No: 194003_Initial_Event: Febrile neutropenia
     - Subject No: 190010_FU02_Event: Death
     - Subject No: 181011_ Initial_Event: Neutropenia Diarrhea
     - Subject No: 181008_ FU03_Event: Death
     - Subject No: 181011_ FU04_Event: Death
     - Subject No: 186012_ Initial_Event: Ear infection, general weakness

- Subject No: 186012_ FU01_Event: Ear infection
- Subject No: 186012_ FU02_Event: Ear infection
- Subject No: 178007_ FU02_Event: chemotherapy induced Neutropenia, Pancytopenia, superadded infection, hemoptysis
- Subject No: 178007_FU01_Event: Hemoptysis, cough, fever
- Subject No: 178007_FU01_Event: Neutropenia, Pancytopenia, superadded infection
- Subject No: 177004_FU01_Event: Febrile neutropenia, Thrombocytopenia
- Subject No: 190011_ Initial_Event: Breathlessness

5. **Project CRL011813:** A Randomized, Double blind, Multicenter, Three-arm, Parallel, Placebo-controlled, Clinical Study to Evaluate the Bioequivalence using Clinical Endpoint of Diclofenac Sodium Topical Gel, 1% (Encube Ethicals Private Limited, India) to Voltaren Gel (Diclofenac Sodium Topical Gel) 1% (Endo Pharmaceuticals Inc., USA) in Subjects with Osteoarthritis (OA) of the Knee.

   Dr.Archana Uppin-PI

   - IEC submission of Final CTA letter dated 16/05/2018
   - IEC submission of WOMAC osteoarthritis Index LK3.1

6. **Protocol Number:** APL/CT/12/001

   Protocol Title: "A Comparative, Two Arm, Randomized, Double Blind, Parallel Group, Multicentric, Non-Inferior Clinical Study to Evaluate Efficacy, Safety and Tolerability of Iguratimod Tablets 25 mg as an add on Therapy over Methotrexate Tablets 15 mg Vs. Methotrexate Tablets 25 mg for the treatment of Patients with active Rheumatoid Arthritis"

   Dr.Archana Uppin-PI

   - IEC notification of amended CTA letter dated 18/05/2018

7. **Study Number:** GBR 200-301

   Study Title: A Prospective, Multicenter, Randomized, Double-blind, Parallel-group, Study to Compare the Efficacy and Safety of GBR 200 (similar biologic of Trastuzumab) versus Innovator Trastuzumab both when given in combination with Paclitaxel in patients diagnosed with HER2 Positive Metastatic Breast Cancer.

   Dr.Mahesh Kalloli-PI

   - IEC notification of Final CTA

8. **Project CRL011812:** "A Randomized, Double blind, Multicenter, Three-arm, Parallel, Placebo-controlled, Clinical Study to Evaluate the Bioequivalence using Clinical Endpoint of Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel (Encube Ethicals Private Limited, India) to DUAC® Gel (Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel) (Stiefel Laboratories, Inc. Research Triangle Park, NC 27709) in Subjects with Acne Vulgaris."

   Dr.Shivakumar Patil-PI

   - IEC submission of final CTA letter dated: 15/05/2018

9. **Protocol Number:** 13-VIN- 443

   Protocol Title: A multicenter, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL of Mylan Laboratories Limited, India with Doxorubicin Hydrochloride Liposome Injection for intravenous infusion 20 mg/10 mL Manufactured By: Sun Pharmaceutical Ind. Ltd., Halol Baroda Highway, Halol-389 350, Gujarat, India, administered in Female patients with ovarian cancer whose disease has progressed or recurred after platinum Based chemotherapy under fed condition.

   Dr.Maheshkumar Kalloli-PI

- IEC notification of CIOMS_Subject ID:C-02-Event: hospitalization secondary to acute gastritis

10. **Protocol Number:** CLR_16_13
Protocol Title: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer.
Dr.Rohan Bhise-PI
    - IEC notifications of CIOMS
        - Site no:22_Subject ID:2401/DDM_Event: Breast infection
11. **Protocol No: BCD-021-02**
Study Title:" International multicenter randomized double blind phase III trial comparing safety and efficacy of BCD-021 (CJSC BIOCAD, Russia) and paclitaxel + carboplatin to Avastin® (F. Hoffmann-La Roche Ltd, Switzerland) and paclitaxel + carboplatin in inoperable or advanced non-squamous non-small-cell lung cancer patients."
Dr.Maheshkumar Kalloli-PI
    - IEC notification of subject CT Scan was performed outside the hospital
12. **Protocol: EFC13889/ODYSSEY EAST:** A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
Dr.V.A.kothiwale-PI
    - IEC notification DMC recommendation form letter dated 17/05/2018.
13. **Protocol No/Title:** MYL-TLE 400-4001-"Multicenter, open label, randomized prospective, phase IV, interventional, non-inferiority study with blinded assessment, to evaluate the efficacy and safety of fixed dose combination (FDC) of tenofovir/Lamivudine/low dose Efavirenz(300/300/400mg) Vs. FDC of Tenofovir/Lamivudine//Efavirenz(300/300/600mg) in adult Indian patients who have HIV-1 infection"
Dr.Dnyanesh Morkar-PI
    - IEC notification of TLE-400-4001 remote monitoring
14. **Protocol title:** CT/CLOB/PSO/16, A Multicentric, assessor-blind, randomized, active controlled, parallel design study comparing efficacy and safety of clobetasol propionate topical foam 0.05% vs. clobetasol propionate lotion 0.05% in patients with mild to moderate plaque type psoriasis (scalp and non-scalp).
Dr.Snehal Lunge-PI
    - IEC submission of additional documents letter dated: 18/05/2018
15. **Protocol Title:** Prominent: Pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes.
Protocol No: K-877-302
    - IEC notification of SUSAR
        - Patient#7030-070- Significant aggravation of CKD-status: Initial
        - Patient#7030-070- Significant aggravation of CKD-status: FU01
        - Patient#7030-070- Significant aggravation of CKD-status: FU02
        - Patient#7030-019- Acute Pancreatitis of CKD-status: FU03
        - Patient#7030-019- Acute Pancreatitis of CKD-status: FU04
16. **Protocol No:** DMPL/P05-2017/CT/VN V2.0, Date-30.03.2018 titled "A post marketing surveillance study (PMS) to evaluate safety and tolerability of VELNEZ as nasal pack after nasal surgery"
Dr.Shama Bellad-PI
    - IEC notification of translation/back translation certificates and GMP certificates

17. **Protocol :** VRL/CSE-1034/05/2012 "A Randomized, Double-blind, Double-dummy, Active-controlled, Multi-centre Trial to Compare the Efficacy and Safety of CSE-1034 (Ceftriaxone+ Sulbactam+ EDTA) with Meropenem in Infections Caused by β – Lactamase (ESBL and MBL) producing Gram Negative Bacteria."
Dr.Madhav Prabhu-PI
    - IEC notification study close out and Clinical study report

18. **Protocol Title:** A prospective, Multi-centric, Double blinded, parallel group, active controlled randomized study to evaluate the efficacy and safety of bilastine in adult and adolescent patients with seasonal allergic reactions.
Protocol No: HCR/III/BISAR/03/2017
    - IEC members Monitoring visit

VIII. Any other matter with the permission of the chair

For your attention:
Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Prof.(Dr).M.S.Ganachari
Member-Secretary of IEC
Belagavi

Member Secretary
ETH
KLE

To:

	Circular and Submission of IEC Dossier	
1)	**Dr. Subarna Roy,** Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V.Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar,** Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr. M.V. Jali,** MD & CE, KLEs Dr.Prabhakar Kore Hospital and MRC, Belagavi	Member
6)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
7)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
8)	**Dr.Nayana Hashilkar,** Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
9)	**Mrs.Vaishnavi V Kivadasannavar,** M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
10)	**Shri.Tammanna Dadu Kore,** Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
11)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
12)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, Belagavi	Assistant Coordinator
13)	**Prof.(Dr.)M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
	Administrators of KAHER(Deemed to be University)	
1)	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed to be University, Belagavi, For Information	Circular
	Principal Investigators	
1)	**Dr. Vardaraj Pralhadarao Gokak** Consultant Gastroenterologist, KLES Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi - 590010, Karnataka, India	Circular

Institutional Ethics Committee

KLE Academy of Higher Education and Research, Belagavi
[Formerly Known as KLE University]
(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)
KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State, India
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Ref: KAHER/IEC/2018-19/D- 1564 ***Date: 10/09/2018***

IEC Meeting Agenda
Institutional Ethics Committee of KAHER, Belagavi
Friday, 21/09/2018, At: 4.00 PM
Venue: Site management Office, G+2, KLES Dr.PK Hospital &MRC, Nehru Nagar, Belagavi

I. New agenda for review and approval:

1. **Study Title:** A randomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose, crossover, steady state bioequivalence study of Everolimus tablets, 10 mg of Biocon Pharma Limited, India vs. Afinitor®(Everolimus) tablets, 10 mg of Novartis Pharmaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients.
   Study No.: 18-VIN-0384
   Dr.Maheshkumar Kalloli-PI

2. **Study Title:** A RANDOMIZED, OPEN LABEL, TWO TREATMENT, TWO PERIOD, TWO SEQUENCE, SINGLE DOSE, CROSSOVER, COMPARATIVE BIOAVAILABILITY STUDY OF LEUPROLIDE ACETATE DEPOT SUSPENSION 7.5 MG OF SUN PHARMACEUTICAL INDUSTRIES LIMITED AND LUPRON DEPOT (LEUPROLIDE ACETATE) DEPOT SUSPENSION 7.5 MG OF ABBVIE INC., UNDER FASTING CONDITION, IN PROSTATIC CARCINOMA PATIENTS UNDERGOING INITIAL THERAPY
   Protocol No: LPL_7.5I_4653_16
   Dr.Maheshkumar Kalloli-PI

3. **Protocol No: 2015-DFU-301**
   Protocol Title: A Phase 3, Randomized, Double-blind, Parallel-group,Vechile controlled, Multicentre Study of the Efficacy and safety of Granexin Gel in the Treatment of Diabetic Foot Ulcer (GAIT 1)
   Dr.Vikrant Ghatnatti-PI

4. **Protocol No:** 0555-17
   Protocol title: A double blind, double dummy, randomized, prospective, two arm, parallel, multicenter, Phase IV clinical trial evaluate efficacy and safety of Gabapin NT (fixed dose combination Gabapentin and Notriptyline) in comparison with gabapentin in patients with neuropathic pain.
   Dr.Prakash Mahantshetti-PI
   - The above study protocol was deferred from the last IEC meeting [29/08/2018](File No:03)

5. Presentation of **IEC study Updates**- By Chairman/Member Secretary of IEC

II. **Review of Proposals with Revision and Amendments:**

1. **Protocol Number: PBL/CR/2014/05/CT/DEN**
   Protocol Title: A Phase I/II, Double Blind, Placebo controlled, Randomized, Multicenter, prospective study to evaluate the Safety and Immunogenicity of a single dose 'Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized)' in healthy subjects.
   Dr.Madhav Prabhu-PI

2. **Study No: 20140444**
   Drug: Denosumab
   Protocol Title: A Phase 3 randomized, Double-blind, Placebo-Controlled, Parallel-group Study to evaluate the safety and Efficacy of Denosumab in pediatric Subjects with Glucocorticoid-induced Osteoporosis.
   Dr.N.S.Mahantashetti-PI

III. **Review of Revised Project Proposals:**

-Nil

IV. **Review of Annual Report: IEC notifications of study Updates(2017-2018)**

1. **Protocol Title:** A prospective, Multi-centric, Double blinded, parallel group, active controlled randomized study to evaluate the efficacy and safety of bilastine in adult and adolescent patients with Seasonal Allergic Rhinitis.
   Protocol No: HCR/III/BISAR/03/2017
   Dr.BhagyaSri Patil-PI

2. **Protocol No:** BCD-057- 2
   Study Title: "A Multicenter Comparative Randomized Double-blind Study of the Efficacy and Safety of BCD-057 (INN: Adalimumab, CJSC BIOCAD, Russia) and Humira@ (INN: Adalimumab, Vetter Pharma) in Patients with Moderate to Severe Plaque Psoriasis"
   Dr.Shivakumar Patil-PI

3. **Protocol title:** CT/CLOB/PSO/16, A Multicentric, assessor-blind, randomized, active controlled, parallel design study comparing efficacy and safety of clobetasol propionate topical foam 0.05% vs. clobetasol propionate lotion 0.05% in patients with mild to moderate plaque type psoriasis (scalp and non-scalp).
   Dr.Snehal Lunge-PI

4. **Study Title & Study Code:** Prospective, Randomized, Double Blinded, Parallel Group, Multicentric, Comparative Clinical study to compare efficacy and safety of oral CPL-2009-0031 of Cadila Pharmaceutical Limited, India against innovator Sitagliptin in patients with Uncontrolled Type -2 Diabetes Mellitus (T2DM). (CRSC16002).
   Dr.Jayaprakash Appajigol-PI

5. **Study Title:** A Phase IV Multi-Centric Post-Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of the Marketed Formulation of Hetero –Adalimumab
   Protocol No: HCR/IV/ADALI/01/2017; Version: 1.0; Dated: 30 Jan 2017
   Dr.Archana Uppin-PI

6. **Protocol Title:** A Two-Part, Open-Label, Randomized, Phase II/III Study of Dinutuximab and Irinotecan versus Irinotecan for Second Line Treatment of Subjects with Relapsed or Refractory Small Cell Lung Cancer
   Protocol Number: DIV-SCLC-301
   Dr.Mahesh Kumar Kalloli-PI

7. **Study Title:** Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-045 / Prolia® in post-menopausal women with osteoporosis.
   Protocol No.: RLS/OST/2016/05; Version 3.0, Dated: 21 Dec 20 16
   Dr.Sameer Haveri-PI

8. **Project CRL011813:** A Randomized, Double blind, Multicenter, Three-arm, Parallel, Placebo-controlled, Clinical Study to Evaluate the Bioequivalence using Clinical Endpoint of Diclofenac Sodium Topical Gel, 1% (Encube Ethicals Private Limited, India) to Voltaren Gel (Diclofenac Sodium Topical Gel) 1% (Endo Pharmaceuticals Inc., USA) in Subjects with Osteoarthritis (OA) of the Knee.
   Dr.Archana Uppin-PI

9. **Study Number:** GBR 200-301
   Study Title: A Prospective, Multicenter, Randomized, Double-blind, Parallel-group, Study to Compare the Efficacy and Safety of GBR 200 (similar biologic of Trastuzumab) versus Innovator Trastuzumab both when given in combination with Paclitaxel in patients diagnosed with HER2 Positive Metastatic Breast Cancer.
   Dr.Maheshkumar Kalloli-PI

10. **Protocol No:** 1002-043
    Protocol Title: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at High Risk For, Cardiovascular Disease Who Are Statin Intolerant.
    Dr.V.A.Kothiwale-PI

11. **Protocol title:** An open label, single- arm, Multicenter, Phase IV trial to evaluate the safety of Firmagon® in androgen deprivation therapy in Indian patients diagnosed with advanced hormone-dependent Prostate cancer
    Protocol No: 000201/Version 2.0 dated 28 Jan 2016
    Dr.S.I.Neeli-PI

12. **Study Title:** A Phase IV Multi-Centric Post-Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of the Marketed Formulation of Hetero –Adalimumab
    Protocol No: HCR/IV/ADALI/01/2017; Version: 1.0; Dated: 30 Jan 2017
    Dr.Archana Uppin-PI

13. **Protocol No: BCD-021-02**
Study Title:" International multicenter randomized double blind phase III trial comparing safety and efficacy of BCD-021 (CJSC BIOCAD, Russia) and paclitaxel + carboplatin to Avastin® (F. Hoffmann-La Roche Ltd, Switzerland) and paclitaxel + carboplatin in inoperable or advanced non-squamous non-small-cell lung cancer patients. "
Dr.Maheshkumar Kalloli-PI

14. **Protocol Title:** Evaluation of Safety and efficacy of the BACE™ [Basal Annuloplasty of the cardia externally] device in the treatment of functional mitral valve regurgitation (FMR)
Dr.Richard S-PI

15. **Protocol title:** A randomized, prospective, open label, comparative, parallel group, multicentre 12 weeks study to evaluate efficacy, safety and tolerability of Glycopyrronium/Formoterol FDC 25mcg/12mcg twice daily in comparison with Glycopyrronium 50mcg once daily in patients with moderate to Severe Chronic Obstructive Pulmonary Disease (COPD).
Study code: CP/11/15
Dr.Jyothi Hattiholi-PI

16. **Protocol title:** A Multi-Center, Open-Label, Balanced, Randomized, Two-Treatment, Two Sequence, Two Period, Crossover, Steady-State Bioequivalence Study of Imatinib Mesylate Tablets 400 mg (Test) of Eugia Pharma Specialities Limited, India (A joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited) and Gleevec® (Imatinib Mesylate) 400 mg Tablets (Reference) of Novartis Pharmaceuticals Corporation, USA in 36 adult patients with Chronic Myeloid Leukemia and/or Gastro Intestinal Stromal Tumors already receiving Imatinib Mesylate Tablets 400 mg under fed conditions.
Protocol No: CR050-14
Dr.Rohan Bhise-PI

17. **Study No: CT/DOX/1602**
Protocol Title: An Open-Label, Multicentric, Randomized, Two Treatment, Three Period, Three Sequence, Semi-Replicate, Cross-Over, Comparative Bioavailability study of Doxorubicin Hydochloride Liposomal Injection 20mg/10mL (2mg/ml), concentrate for solution for infusion manufactured by Teva Pharmachemie, Netharlands with caelyx 20 mg/10ml (2mg/ml), [Doxorubicin hydrochloride Liposomal Injection] concentrate for solution for infusion Of Janssen-Cilag International NV, Belgium in advanced ovarian cancer and/or metastatic breast cancer patients under fasting condition.
Dr.Maheshkumar Kalloli-PI

V. **SAE reporting:**

1. **Protocol No: BCD-021-02**
Study Title:" International multicenter randomized double blind phase III trial comparing safety and efficacy of BCD-021 (CJSC BIOCAD, Russia) and paclitaxel + carboplatin to Avastin® (F. Hoffmann-La Roche Ltd, Switzerland) and paclitaxel + carboplatin in inoperable or advanced non-squamous non-small-cell lung cancer patients. "
Dr.Maheshkumar Kalloli-PI

- IEC notification of Final SAE report of the subject no:BCD-021-02

VI. Protocol deviation/violation/ termination:

1. **Study Code: D1699C00001**
   Protocol: A Study to Evaluate the Effect of Dapagliflozin on the Incidence of worsening heart failure or Cardiovascular Death in patients with chronic Heart Failure with reduced Ejection Fraction.
   Dr.V.A.Kothiwale-PI
   - IEC notification of PD for Missed ePRO letter dated 25/08/2018
2. **Protocol IDRFARH007:** "A Prospective, Multicentre, Randomized, Open-Label Comparison of Long-Acting Basal Insulin Analog Glargine plus Glulisine with Premixed Insulin in Adult Patients with Type 2 Diabetes Mellitus.
   Dr.M.V.Jali-PI
   - IEC notification of Protocol Deviation letter dated 31/03/2018
   - IEC notification of Protocol Deviation letter dated 30/06/2018
3. **Protocol:** MYL-1402O-3001 :Multicenter, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.
   Dr.Mahesh Kumar Kalloli-PI
   - Protocol Deviation of the subject 17102 letter dated 21/08/2018
4. **Protocol** PMZ-02; DCGI CT NOC No.: CT/ND/37/2016
   Study Title: A Prospective, Multi-centric, Randomized, Double-blind, Parallel, Saline Controlled Phase II Safety and Efficacy study of PMZ-2010 as a resuscitative agent for Hypovolemic Shock due to excessive blood loss to be used along with standard shock treatment.
   Dr.Madhav Prabhu-PI
   - IEC notification of PD of the subject No:08-004 letter dated: 22/08/2018
   - IEC notification of PD of the subject Nos:08-001 and 08-002-letter dated: 28/08/2018

VII. The Committee will consider the following agendas which are for information.

1. **Protocol Title:** Phase III, Randomized, Double-blind, Placebo-controlled, multicenter study to evaluate the efficacy (maintenance of remission) and safety of Etrolizumab compared with placebo in patients with moderate to severe active Ulcerative Colitis who are naive to TNF inhibitors.
   Protocol No: GA29102
   And
   Protocol Title: An open label extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in Etrolizumab phase II/III studies.
   Protocol No: GA28951
   Dr.Varadaraj Gokak-PI
   IEC Notification of SUSARs
   - Event-Thumb swelling Report: Initial letter dated 26/07/2018
   - Event-Fever Report: FU letter dated 26/07/2018
   - Event-Haemolytic anaemia Report: Initial letter dated 26/07/2018
   - Event-Listeria meningitis Report: Initial letter dated 26/07/2018
   - Event-Tooth abscess, Headache Report: FU dated 26/07/2018
   - Event-Chronic myeoproliferative disease jak 2 Mutation Report: FU letter dated 26/07/2018
   - Event-Acute abdominal pain Report: FU letter dated 26/07/2018
   - Event-Lung adenocarcinoma Report: Initial letter dated 26/07/2018
   - Event-Right arm cellulitis Report: Initial letter dated 26/07/2018

- Event-Toxoplasmosis chorioretintis in right eye Report: Initial letter dated 26/07/2018
- Event-Acute Abdominal pain Report: Initial letter dated 26/07/2018
- Event-Erosive cheilitis Report: Initial letter dated 26/07/2018
- Event-Primary myelogenous leukemia pre-fibrotic stage Report: Initial letter dated 26/07/2018
- Event-Partial bowel obstruction Report: Initial letter dated 26/07/2018
- Event-Partial bowel obstruction Report: FU letter dated 26/07/2018
- Event-Listeria meningitis Report: Initial letter dated 26/07/2018
- Event-Biliary Lithiasis Report: FU letter dated 26/07/2018
- Event-Worsening of crohn's disease Report: Initial letter dated 26/07/2018
- Event-Acute abdominal pain, UTI Report: FU dated 26/07/2018
- Event-Erosive Cheilitis Report: FU letter dated 26/07/2018
- Event-Cytomegalovirus colitis Report: Initial letter dated 26/07/2018
- Event-Blast Cell proliferation Report: FU letter dated 26/07/2018
- Event-Henoch schonlein Report: FU letter dated 26/07/2018
- Event-Suspected pemfigoid Report: Initial letter dated 26/07/2018
- Event-biliary lithiasis Report: Initial letter dated 26/07/2018

2. **Project CRL011812:** "A Randomized, Double blind, Multicenter, Three-arm, Parallel, Placebo-controlled, Clinical Study to Evaluate the Bioequivalence using Clinical Endpoint of Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel (Encube Ethicals Private Limited, India) to DUAC® Gel (Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel) (Stiefel Laboratories, Inc. Research Triangle Park, NC 27709) in Subjects with Acne Vulgaris."
   Dr.Shivakumar Patil-PI
   - IEC notification of Source documents
   - IEC notification of Investigator Undertaking, FDA Form 1572 and 3455
   - IEC notification of DCGI Can of IU letter dated 14/08/2018
   - Note to file letter dated 24/08/2018
3. **Protocol:** MYL-1402O-3001 :Multicenter, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.
   Dr.Mahesh Kumar Kalloli-PI
   - IEC notification of CIOMS letter dated 30/08/2018
   - IEC notification of acknowledge Memo letter dated 04/05/2018
4. **Protocol** No:PMZ-2010
   Study Title: A Prospective, Multi-centric, Randomized, Double-blind, Parallel, Saline Controlled Phase II Safety and Efficacy study of PMZ-2010 as a resuscitative agent for Hypovolemic Shock due to excessive blood loss to be used along with standard shock treatment.
   Dr.Madhav Prabhu-PI
   - IEC Notification of use of paper CRF
   - IEC notification of extension of shelf life of the IP
   - IEC notification of trial Insurance

5. **Protocol Number:** CLR_16_13
Protocol Title: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer.
Dr.Rohan Bhise-PI
   - IEC notification of Insurance certificate 2018-2019 letter dated:01/09/2019
   - IEC notification of typographical error in CIOMS letter dated 14/08/2018
   - IEC notification of Continuation of approval

6. **Protocol Title**: SHP640-301_ A Phase 3, Multi-center, Randomized, Double-Masked Study to Evaluate the Clinical Efficacy and Safety of SHP640 (PVP-Iodine 0.6% and Dexamethasone 0.1%) Ophthalmic Suspension Compared to PVP-Iodine and Placebo in the Treatment of Adenoviral Conjunctivitis.
Dr.Smitha K.S-PI
   - IEC Notification of discrepancies found in Adult and parent consents

7. **Protocol title:** A randomized, prospective, open label, comparative, parallel group, multicentre 12 weeks study to evaluate efficacy, safety and tolerability of Glycopyrronium/Formoterol FDC 25mcg/12mcg twice daily in comparison with Glycopyrronium 50mcg once daily in patients with moderate to Severe Chronic Obstructive Pulmonary Disease (COPD)
Study code: CP/11/15
Dr.Jyothi Hattiholi-PI
   - IEC notification of Amended study documents letter dated 14/08/2018

9. **Protocol title:** Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-024 / Lucentis® in patients with neovascular (wet) age-related macular degeneration
Protocol No.: RLS/OPT/2016/05; Version 2.0, Dated: 23 Jan 2017
Dr.Rekha Mudhol-PI
   - IEC notification of Final CTA and DCGI approval letter

10. **Protocol Title:** A prospective, Multi-centric, Double blinded, parallel group, active controlled randomized study to evaluate the efficacy and safety of bilastine in adult and adolescent patients with Seasonal Allergic Rhinitis.
Protocol No: HCR/III/BISAR/03/2017
Dr.Bhagyasri Patil-PI
   - IEC Notification of Updated IU letter dated 17/01/2018

11. **Protocol IDRFARH007:** "A Prospective, Multicentre, Randomized, Open-Label Comparison of Long-Acting Basal Insulin Analog Glargine plus Glulisine with Premixed Insulin in Adult Patients with Type 2 Diabetes Mellitus.
Dr.M.V.Jali-PI
   - IEC notification of SUSARS letter dated 21/08/2018

12. **Study Code: D1699C00001**
Protocol: A Study to Evaluate the Effect of Dapagliflozin on the Incidence of worsening heart failure or Cardiovascular Death in patients with chronic Heart Failure with reduced Ejection Fraction.
Dr.V.A.Kothiwale-PI
    - IEC notification of PD for Minor protocol amendment letter dated 31/08/201

13. **Protocol Number:** 13-VIN- 443
Protocol Title: A multicenter, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL of Mylan Laboratories Limited, India with Doxorubicin Hydrochloride Liposome Injection for intravenous infusion 20 mg/10 mL Manufactured By: Sun Pharmaceutical Ind. Ltd., Halol Baroda Highway, Halol-389 350, Gujarat, India, administered in Female patients with ovarian cancer whose disease has progressed or recurred after platinum Based chemotherapy under fed condition.
Dr.Maheshkumar Kalloli-PI
    - IEC notification of CIOMS letter dated 16/08/2018
    - IEC notification of CIOMS letter dated 17/08/2018
    - IEC notification of CIOMS letter dated 18/08/2018
    - IEC notification of CIOMS letter dated 20/08/2018

14. **Protocol Title:** Prominent: Pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes.
Protocol No: K-877-302
Dr.V.A.Kothiwale-PI
    - IEC notification of SUSARs letter dated 05/07/2018

15. **Protocol No:** DMPL/P05-2017/CT/VN V2.0, Date-30.03.2018 titled "A post marketing surveillance study (PMS) to evaluate safety and tolerability of VELNEZ as nasal pack after nasal surgery"
Dr.Shama Bellad-PI
    - IEC submission of study Undertaking by the PI

16. **Study Title:** A Phase IV Multi-Centric Post-Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of the Marketed Formulation of Hetero –Adalimumab
Protocol No: HCR/IV/ADALI/01/2017; Version: 1.0; Dated: 30 Jan 2017
Dr.Archana Uppin-PI
    - IEC notification of ASAS response assessment scale
    - Source document template

VIII. Any other matter with the permission of the chair

For your attention:
Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

10/09/2018

Prof.(Dr).M.S.Ganachari

Prof. (Dr) M. S. Ganachari
Members Secretary, Institutional Ethics Committee
To Academy of Higher Education and Research, Belagavi

	Circular and Submission of IEC Dossier	
1)	**Dr. Subarna Roy,** Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V.Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar,** Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr. M.V. Jali,** MD & CE, KLEs Dr.Prabhakar Kore Hospital and MRC, Belagavi	Member
6)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
7)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
8)	**Dr.Nayana Hashilkar,** Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
9)	**Mrs.Vaishnavi V Kivadasannavar,** M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
10)	**Shri.Tammanna Dadu Kore,** Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
11)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
12)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, Belagavi	Assistant Coordinator
13)	**Prof.(Dr.)M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
14)	**Dr.Sapna,** Independent Consultant(IEC), Radiation Oncologist, KLE Society's Belgaum cancer hospital, Belagavi-10	External member

	Administrators of KAHER(Deemed to be University)	
1)	The Registrar, KAHER, Deemed University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed University, Belagavi, For Information	Circular
	Principal Investigators	
1)	**Dr.Maheshkumar Kalloli,** Consultant, Oncology Dept., KLES Dr. Prabhakar Kore Hospital &MRC, Nehru Nagar, Belagavi-590 010	Circular
2)	**Dr.Vikrant Ghatnatti,** Consultant Endocrinologist, KLES Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi	Circular
3)	**Dr.Prakash Mahantshetti,** Department of Neurology, KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi-10	Circular

Institutional Ethics Committee

KLE Academy of Higher Education and Research, Belagavi
Deemed to-be-University
(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)
KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State, India
(: 0831-2470400 FAX: 0831-2493099 www.kledeemeduniversity.edu.in Email:kleclinicalresearch@gmail.com

Ref: KAHER/IEC/2018-19/D- 377 ***Date: 15/05/2018***

IEC Meeting Agenda

Institutional Ethics Committee of KLEU, Belagavi
Friday, 25/05/2018, At: 4.00 PM
Venue: Site management Office, G+2, KLES Dr.PK Hospital &MRC

I. Review of New Project Proposals:

1) **Research Project Title:** "prevalence and outcomes of abnormal continuous wave Doppler flow indicates in unselected obstetric populations in low and middle income countries"
Dr.Yeshita V.Pujar-PI

2) **Protocol Title:** "A multicenter, open label, prospective study to evaluate safety and effectiveness of the safety syringe developed by Alfa Corpuscles Pvt. Ltd., India in patients who require dose administration by parenteral route using the syringe or phlebotomy procedures as a part of their treatment/ diagnosis."
Dr.Dyanesh Morkar-PI

3) **Protocol Title:** A 12-week double-blind, randomized, multi-center study comparing the efficacy and safety of once monthly subcutaneous AMG 334 against placebo in adult episodic migraine patients (EMPOwER).
Protocol No.:CAMG334A2302
Dr.Saroja A.O-PI

4) **Study Title:** A Phase IV Multi-Centric Post-Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of the Marketed Formulation of Hetero –Adalimumab
Protocol No: HCR/IV/ADALI/01/2017; Version: 1.0; Dated: 30 Jan 2017
Dr.Archana Uppin-PI

5) **Project CRL011813:** A Randomized, Double blind, Multicenter, Three-arm, Parallel, Placebo-controlled, Clinical Study to Evaluate the Bioequivalence using Clinical Endpoint of Diclofenac Sodium Topical Gel, 1% (Encube Ethicals Private Limited, India) to Voltaren Gel (Diclofenac Sodium Topical Gel) 1% (Endo Pharmaceuticals Inc., USA) in Subjects with Osteoarthritis (OA) of the Knee.
Dr.Archana Uppin-PI

Accreditations:
NABH
FERCAP
Registrations:
DCGI
OHRP

II. Review of Proposals with Revision and Amendments:

6. **Protocol Title**: SHP640-301_ A Phase 3, Multi-center, Randomized, Double-Masked Study to Evaluate the Clinical Efficacy and Safety of SHP640 (PVP-Iodine 0.6% and Dexamethasone 0.1%) Ophthalmic Suspension Compared to PVP-Iodine and Placebo in the Treatment of Adenoviral Conjunctivitis.
   Dr.Smitha K.S-PI
7. **Protocol No**: 1002-043
   Protocol Title: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at High Risk For, Cardiovascular Disease Who Are Statin Intolerant
   Dr.V.A.Kothiwale-PI
8. **Research project titled:** "ASIA Pregnancy Outcomes Study"
   Dr.S.S.Goudar- Site Coordinator
   - Review and approval of Updated data forms

III. Review of Revised Project Proposals:

1. **Protocol title:** Hospital based Caner registry work (HBCR) under NCRPs
   Dr.Sujata M. Jali –PI
   The above protocol was discussed in the previous meeting, which was held on 12/Mar/2018.

IV. Review of Annual Report:

1. **Protocol Title:** "Maternal Docosa-Hexanoic Acid (DHA) Supplementation and offspring neurodevelopment in India – (DHANI-2)".
   Dr.M.K.Swamy-PI
   - Request for continuation of Approval

V. SAE reporting

No- SAEs

VI. Protocol deviation/violation/ termination:

1. **Study Code: D1699C00001**
   Protocol: A Study to Evaluate the Effect of Dapagliflozin on the Incidence of worsening heart failure or Cardiovascular Death in patients with chronic Heart Failure with reduced Ejection Fraction.
   Dr.V.A.Kothiwale-PI
   Protocol Deviation of subject: E3515501, E3515502 and E3515503 letter dated: 20/Mar/2018
   - E3515502 letter dated:01/Mar/2018
   - E3515501 letter dated:01/Mar/2018

VII. The Committee will consider the following agendas which are for information.

1. **Study Protocol No.: LRP/LNP3794/2016/006**
   Study Protocol Title: A Phase II/III Pivotal, Open-label, Randomized, 3-Arm Study to Assess the Efficacy of LNP3794 Monotherapy or in Combination with Docetaxel, Compared with Docetaxel Alone, in Patients with RAS Mutation-Positive Locally Advanced and Metastatic Non-Small Cell Lung Cancer
   Dr.Maheshkumar Kalloli-PI
   - IEC notification of CIOMS letter dated: 21/04/2018
2. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   Dr.Jayaprakash Appajigol-PI

- IEC notification of IB version 10.0 with summary changes of version 9.0 to 10.0 letter dated: 29/04/2018

3. **Protocol No.** – ZYAN1.16.001.01, A randomized, double blind, placebo controlled, parallel group, phase II multi-centric trial to assess safety, tolerability and efficacy of PHD-2 Inhibitor, ZYAN1 in the treatment of anemia in pre-dialysis chronic kidney disease patients.
   Dr.Ravi Sarvi-PI
   - IEC notification of reset date extension of ZYANI tablet 100mg, 150 mg and 200 mg and Placebo tablets
   - IEC submission of Investigator Undertaking
4. **Protocol title:** A randomized, prospective, open label, comparative, parallel group, multicentre 12 weeks study to evaluate efficacy, safety and tolerability of Glycopyrronium/Formoterol FDC 25mcg/12mcg twice daily in comparison with Glycopyrronium 50mcg once daily in patients with moderate to Severe Chronic Obstructive Pulmonary Disease (COPD)
   Study code: CP/11/15
   Dr.Jyothi Hattiholi-PI
   - IEC notification of renewal of insurance letter dated:05/02/2018
5. **Study No: 20140444**
   Drug: Denosumab
   Protocol Title: A Phase 3 randomized, Double-blind, Placebo-Controlled, Parallel-group Study to evaluate the safety and Efficacy of Denosumab in pediatric Subjects with Glucocorticoid-induced Osteoporosis
   Dr.N.S.Mahantashetti-PI
   - IEC submission of CTRI registration no: REF/2018/04/019477

6. **Protocol Title:** A multicentre, randomized, assessor blind, active controlled, comparative, phase IV study to assess the safety and efficacy of two fixed dose combinations (FDC) formulations of trypsin BP 48/96mg + bromelain 90/180mg + Rutoside trihydrate BP 100/200 mg viz. Phlogam® and Disperzyme® in post-operative inflammation in subjects undergoing minor surgery and dental procedures
   Study Code: AKS_PHLOG_17_01
   Dr.M.I.Uppin-PI
   - IEC notification of Global assessment scale by patient and investigator and CRF TOTPAR scale
7. **Protocol Number:** CLR_16_13
   Protocol Title: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer.
   Dr.Rohan Bhise-PI
   - IEC notification of CIOMS- site no:22
     - Subject: 4008/A-M_ SAE- stomatitis Febrile Neutropenia Pneumonia and shock
     - Subject: 2413/JGK_ SAE- Breathlessness due to pleural effusion
8. **Protocol Title**: A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy, Pharmacokinetics, Pharmacodynamics and Safety of LNP1892 (Monotherapy) in Chronic Kidney Disease (CKD) Patients with Secondary Hyperparathyroidism (SHPT), On Dialysis and Not on Dialysis.
   Protocol No-LRP/LNP1892/2016/007
   Dr.Mallikarjun S Karishetti-PI
   - IEC notification of withholding 25 mg OD arm for Not-on-dialysis

9. **Study No:** CR150-16
Study Title: A Multicentric, Open-label, Randomized, Two Treatment, Two Sequence, Cross Over, Clinical Bioequivalence Study of Doxorubicin Hydrochloride Liposome Injection (IV) 2 mg/ml (50mg/m2) of Auromedics Pharma LLC, USA (Test) With Doxorubicin Hydrochloride Liposome Injection (IV) 2 mg/ml (50mg/m2) of Sun Pharmaceutical Industries, Inc, USA (Reference) in Ovarian Cancer Patients whose disease has progressed or recurred after platinum-based chemotherapy under fasting conditions.
Dr.Rohan Bhise-PI
   - IEC submission of Investigator Brochure- version 1.0 release date: 29/09/2017

10. **Study No: CT/DOX/1602**
Protocol Title: An Open-Label, Multicentric, Randomized, Two Treatment, Three Period, Three Sequence, Semi-Replicate, Cross-Over, Comparative Bioavailability study of Doxorubicin Hydochloride Liposomal Injection 20mg/10mL (2mg/ml), concentrate for solution for infusion manufactured by Teva Pharmachemie, Netharlands with caelyx 20 mg/10ml (2mg/ml), [Doxorubicin hydrochloride Liposomal Injection] concentrate for solution for infusion Of Janssen-Cilag International NV, Belgium in advanced ovarian cancer and/or metastatic breast cancer patients under fasting condition.
Dr.Maheshkumar Kalloli-PI
   - IEC notification of stability memo for test product s

11. **Study Code: D1699C00001**
Protocol: A Study to Evaluate the Effect of Dapagliflozin on the Incidence of worsening heart failure or Cardiovascular Death in patients with chronic Heart Failure with reduced Ejection Fraction.
Dr.V.A.Kothiwale-PI
   - **IEC notification of updated ICF**

12. **Protocol Title:** MYL-1402O-3001: Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer
Dr.Mahesh Kumar Kalloli-PI
   - IEC Notification of CIOMS-
     - Subject No: 190010_FU01_Event: Death
     - Subject No: 181008_FU02_Event: Death
     - Subject No: 190011_FU01_Event: Lower respiratory tract infection
     - Subject No: 179015_FU02_Event: Breathlessness

VIII. Any other matter with the permission of the chair

For your attention:
Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Prof.(Dr).M.S.Ganachari
Member-Secretary of IEC
Belagavi

To:

	Circular and Submission of IEC Dossier	
1)	**Dr. Subarna Roy,** Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V.Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar**, Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr. M.V. Jali**, MD & CE, KLEs Dr.Prabhakar Kore Hospital and MRC, Belagavi	Member
6)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
7)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
8)	**Dr.Nayana Hashilkar**, Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
9)	**Mrs.Vaishnavi V Kivadasannavar**, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
10)	**Shri.Tammanna Dadu Kore,** Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
11)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
12)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, Belagavi	Assistant Coordinator
13)	**Prof.(Dr.)M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
	Administrators of KAHER(Deemed to be University)	
1)	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed to be University, Belagavi, For Information	Circular
	Principal Investigators	
1)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Circular
2)	**Dr.Sujta M.Jali,** Prof.& HOD of Paediatrics, KLES Dr.Prabhakar Kore Hospital & MRC, Belagavi	Circular
3)	**Dr.Saroja A.O,** Neurophysician, KLES Dr.Prabhakar Kore Hospital and Professor, Dept. Of Neurology, JNMC, Belagavi	Circular
4)	**Dr.Dyanesh Morkar** Dept. of Medicine, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590 010, Karnataka, India	Circular
5)	**Dr.Archana.M.Uppin**, Consultant Physician and rheumatologist, Dept. Of Medicine, KLES Dr. Prabhakar Kore Hospital and MRC, Belagavi-10.	Circular

Institutional Ethics Committee

KLE Academy of Higher Education and Research, Belagavi
Deemed to-be-University
(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)
KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State, India
t: 0831-2470400 FAX: 0831-2493099 www.kledeemeduniversity.edu.in Email:kleclinicalresearch@gmail.com

Ref: KAHER/IEC/2018-19/D- 173 **Date: 17/04/2018**

IEC Meeting Agenda
Institutional Ethics Committee of KLEU, Belagavi
Friday, 27/04/2018, At: 4.00 PM
Venue: Site management Office

I. Review of New Project Proposals:

1. **Study Title**: A phase II/III, multicenter, randomized, open label, active controlled, clinical study to assess the immunogenicity and safety of tetanus toxoid, diphtheria toxoid, and acellular pertussis (Tdap) vaccine manufactured by Serum institute of India Pvt. Ltd. (SIIPL) in comparison with Boostrix® vaccine of GSK in healthy adults, adolescents and children in India.
Protocol Identifier: SII-Tdap/IN-02 V- 1.0 & 21 Nov 2017
Dr.(Mrs) N.S.Mahantashetti-PI

2. **Protocol Title**: A multicenter, open label, randomized, balanced, two treatment, three period, three sequence, reference replicate crossover, single dose, bioequivalence study of Capecitabine Tablets 500 mg of Qilu Pharmaceutical Co., Ltd, China in comparison with XELODA® (Capecitabine) Tablets 500 mg, Distributed by Genentech USA, Inc. following a single oral dose administration in adult cancer patients under fed condition.
Protocol No: 17-VIN-0855, Version 03, Dated 19 Mar 2018
Dr.Maheshkumar Kalloli-PI

3. **Project CRL011812:** "A Randomized, Double blind, Multicenter, Three-arm, Parallel, Placebo-controlled, Clinical Study to Evaluate the Bioequivalence using Clinical Endpoint of Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel (Encube Ethicals Private Limited, India) to DUAC® Gel (Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel) (Stiefel Laboratories, Inc. Research Triangle Park, NC 27709) in Subjects with Acne Vulgaris."
Dr.Shivakumar Patil-PI

4. **Protocol No:** DMPL/P05-2017/CT/VN V2.0, Date-30.03.2018 titled "A post marketing surveillance study (PMS) to evaluate safety and tolerability of VELNEZ as nasal pack after nasal surgery"
Dr.Shama Bellad-PI

Accreditations:
NABH
FERCAP
Registrations:
DCGI
OHRP

II. **Review of Proposals with Revision and Amendments:**

5) **Protocol Title:** A Two-Part, Open-Label, Randomized, Phase II/III Study of Dinutuximab and Irinotecan versus Irinotecan for Second Line Treatment of Subjects with Relapsed or Refractory Small Cell Lung Cancer
Protocol Number: DIV-SCLC-301
Dr.Maheshkumar Kalloli-PI

III. **Review of Revised Project Proposals:**

- Nil

IV. **Review of Annual Report**

1) **Protocol Number/ Title-** [Pfizer, A0081105, "A randomized, double-blind, placebo-controlled, parallel group, multi-center trial of pregabalin as adjunctive therapy in pediatric and adult subjects with primary generalized tonic-clonic seizures", PAREXEL, 208238]
Dr.Mahesh Kamate-PI

V. **SAE reporting**

No- SAEs

VI. **Protocol deviation/violation/ termination:**

1) **Protocol Title:** MYL-1402O-3001: Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer
Dr.Mahesh Kumar Kalloli-PI
   - IEC Notification of Protocol deviation of the following subjects-171010,171011,171005 and 171004 letter dated 04/04/2018

2) **Study Title:** A Multicenter, Open Label, Balanced, Randomized, Two-Treatment, Two-Period, Two-Sequence, Single Dose, Cross-Over Bioequivalence Study of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL) of Cadila Healthcare Limited, India in comparison with Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL), of Sun Pharmaceutical Ind. Ltd, India, in the Patients of Ovarian Cancer under fasting conditions
Protocol No: 038-16
Dr.Maheshkumar Kalloli-PI
   - IEC Notification of Protocol deviation of the following subject 106-038-16-03 letter dated 09/04/2018

VII. **The Committee will consider the following agendas which are for information.**

1) **Protocol** PMZ-02; DCGI CT NOC No.: CT/ND/37/2016
Study Title: A Prospective, Multi-centric, Randomized, Double-blind, Parallel, Saline Controlled Phase II Safety and Efficacy study of PMZ-2010 as a resuscitative agent for Hypovolemic Shock due to excessive blood loss to be used along with standard shock treatment.
Dr.Madhav Prabhu-PI
   - IEC notification of Kannada ICF and Translation certificate

2) **Protocol No:** NN BIAsp-4343
Protocol Title: "A multi-Centre prospective, non-interventional study of ability and willingness to pay for BIAsp 30 in a real world population with type 2 diabetes mellitus"

Dr.Vikrant Ghatanatti-PI

- IEC Notification of CTA and DCGI inclusion of site name

3) **Protocol Number/ Title-** [Pfizer, A0081105, "A randomized, double-blind, placebo-controlled, parallel group, multi-center trial of pregabalin as adjunctive therapy in pediatric and adult subjects with primary generalized tonic-clonic seizures", PAREXEL, 208238]
Dr.Mahesh Kamate-PI
   - IEC notification of SAE line listing report from 18/Jan/2013 to 21/Mar/2018
4) **Protocol Title:** MYL-1402O-3001: Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer
Dr.Mahesh Kumar Kalloli-PI
   - IEC Notification of CIOMS-
     - Subject No: 179015_FU01_Event: Sudden onset of breathlessness
     - Subject No: 181008_Initial_Event: Sudden Cardiac arrest
     - Subject No: 181002_FU01_Event: Disease Progression
     - Subject No: 177004_FU03_Event: Febrile neutropenia & Thrombocytopenia
     - Subject No: 190010_Initial_Event: Cardiac arrest
     - Subject No: 179015_Initial_Event: Sudden onset of breathlessness
   - IEC notification of
     - Updated Investigator Undertaking
     - Updated FDA-1572
     - Updated Disclosure Financial Interests
5) **Study Title:** A Multicenter, Open Label, Balanced, Randomized, Two-Treatment, Two-Period, Two-Sequence, Single Dose, Cross-Over Bioequivalence Study of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL) of Cadila Healthcare Limited, India in comparison with Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL), of Sun Pharmaceutical Ind. Ltd, India, in the Patients of Ovarian Cancer under fasting conditions
Protocol No: 038-16
Dr.Maheshkumar Kalloli-PI
   - IEC Notification of SAE description letter dated 09/04/2018
6) **Protocol Title:** I4V-MC-JADY-A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
Dr.Shailesh Udapudi-PI
   - IEC Notification of DCGI approval letter
   - IEC Notification of Investigator Brochure for Barcitinib (LY3009104)
7) **Protocol title:** A randomized, prospective, open label, comparative, parallel group, multicentre 12 weeks study to evaluate efficacy, safety and tolerability of Glycopyrronium/Formoterol FDC 25mcg/12mcg twice daily in comparison with Glycopyrronium 50mcg once daily in patients with moderate to Severe Chronic Obstructive Pulmonary Disease (COPD)
Study code: CP/11/15
Dr.Jyothi Hattiholi-PI
   - IEC Notification of Updated insurance- Policy No: OG19-1919-3306-00000001

VIII. Any other matter with the permission of the chair

For your attention:
Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Prof.(Dr).M.S.Ganachari
Member-Secretary of IEC
Belagavi

Member Secretary
ETHICS COMMITTEE (EC)
KLE University, BELGAUM

To:

Circular and Submission of IEC Dossier		
1)	**Dr. Subarna Roy,** Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V.Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar**, Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr. M.V. Jali**, MD & CE, KLEs Dr.Prabhakar Kore Hospital and MRC, Belagavi	Member
6)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
7)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
8)	**Dr.Nayana Hashilkar**, Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
9)	**Mrs.Vaishnavi V Kivadasannavar,** M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
10)	**Shri.Tammanna Dadu Kore,** Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
11)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
12)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, Belagavi	Assistant Coordinator

13)	**Prof.(Dr.)M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
	Administrators of KAHER(Deemed to be University)	
1)	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed to be University, Belagavi, For Information	Circular
	Principal Investigators	
1)	**Dr.(Mrs)N.S.Mahantashetti,** Professor of Paediatrics and Principle of J.N.Medical College, Belagavi.	Circular
2)	**Dr.Mahesh Kumar Kalloli,** Consultant, Dept. Of Oncology, KLEs Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi	Circular
3)	**Dr.Shivakumar Patil,** Consultant dermatologist, Dept. Of Dermatology, KLEs Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi	Circular
4)	**Dr.Shama Bellad,** Department of ENT, K.L.E.S. Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010, KARNATAKA, INDIA	Circular

Institutional Ethics Committee

KLE Academy of Higher Education and Research, Belagavi
Deemed to-be-University
(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)
KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State, India
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Ref: KAHER/IEC/2018-19/D- 753. ***Date: 18/06/2018***

IEC Meeting Agenda

Institutional Ethics Committee of KLEU, Belagavi
Friday, 29/06/2018, At: 4.00 PM
Venue: Site management Office, G+2, KLES Dr.PK Hospital &MRC

I. Review of New Project Proposals:

Accreditations:

NABH

FERCAP

Registrations:

DCGI

OHRP

1. **Study Number**: 18-VIN-0272 (Protocol Number: CRD/24)
   Protocol Title: A multicenter, open label, randomized, two treatment, four period, replicate crossover, single dose, bioequivalence study of paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial by Cipla Ltd., India with ABRAXANE® for injectable suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) 100 mg/vial by Celgene Corporation, USA in breast cancer patients after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.
   Dr.Maheshkumar Kalloli-PI

2. **Protocol Title:** -An open-label, single arm and multi-centered study to evaluate the efficacy, safety and tolerability of lipid based tacrolimus ointment 0.1% of Intas Pharmaceuticals Limited, India in patients of oral lichen planus.
   Study No.804-16
   Dr.Shivakumar Patil-PI

3. **Protocol Title:** "A randomized, 24-week, controlled, open label, parallel arm, multicenter study comparing the efficacy and safety of the insulin glargine/lixisenatide fixed ratio combination to insulin glargine in type 2 diabetes patients, inadequately controlled on Basal Insulin with or without Metformin"
   Protocol No: INSLIL08556
   Dr. Vikrant Ghatnatti-PI

4. **Protocol Title:** A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism
   Reference: Study No. 20150238
   Drug: Etelcalcetide
   Dr.Ritesh Vernekar-PI

II. **Review of Proposals with Revision and Amendments:**

1. **Protocol Title:** An open label extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in Etrolizumab phase II/III studies.
   Protocol No: GA28951
   Dr.Varadaraj Gokak-PI

2. **Protocol Title:** Phase III, Randomized, Double-blind, Placebo-controlled, multicenter study to evaluate the efficacy (maintenance of remission) and safety of Etrolizumab compared with placebo in patients with moderate to severe active Ulcerative Colitis who are naive to TNF inhibitors.
   Protocol No: GA29102
   Dr.Varadaraj Gokak-PI

3. **Protocol Title:** I4V-MC-JADY-A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   Dr. S.V.Udapudi- PI

III. **Review of Revised Project Proposals:**

- Nil

IV. **Review of Annual Report:**

1. **Protocol Title**: **CARDLE-3** (Community Blood Pressure Measurement in Rural Africa and Asia: the detection of Underlying Pre-eclampsia and Shock) stepped- wedge Randomized Control Trial.
   Dr.M.B.Bellad-PI
   - IEC notification study close out with annual report
2. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   Dr.Jayaprakash Appajigol-PI
   - IEC notification study close out with annual report

V. **SAE reporting**

- Nil

VI. **Protocol deviation/violation/ termination:**

1. **Protocol Title:** I4V-MC-JADY-A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   Dr. S.V.Udapudi- PI
   - Protocol deviation of the following subjects: 53824, 68572 and 53824 letter dated: 05/06/2018
2. **Protocol Number:** CLR_16_13
   Protocol Title: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer.
   Dr.Rohan Bhise-PI
   - Protocol Deviation: Subject No: 2205_at Cycle 02- time: 36 hrs. samples not collected.
3. **Study Title:** A Multicenter, Open Label, Balanced, Randomized, Two-Treatment, Two-Period, Two-Sequence, Single Dose, Cross-Over Bioequivalence Study of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL) of Cadila Healthcare Limited, India in comparison with Doxorubicin

Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL), of Sun Pharmaceutical Ind. Ltd, India, in the Patients of Ovarian Cancer under fasting conditions.

Study Number: 038-16

Dr.Maheshkumar Kalloli-PI

- Protocol deviation of subject no:106-038-16-03 letter dated 31/05/2018

VII. <u>The Committee will consider the following agendas which are for information.</u>

1. **Protocol Title:** I4V-MC-JADY-A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   Dr. S.V.Udapudi- PI
   - IEC notification of Amended CTA
2. **Study Title:** A Phase IV Multi-Centric Post-Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of the Marketed Formulation of Hetero –Adalimumab
   Protocol No: HCR/IV/ADALI/01/2017; Version: 1.0; Dated: 30 Jan 2017
   Dr.Archna Uppin-PI
   - IEC notification of study specific insurance-letter dated 25/05/2018
3. **Protocol Title:** Evaluation of Safety and efficacy of the BACE™ [Basal Annuloplasty of the cardia externally] device in the treatment of functional mitral valve regurgitation (FMR)
   Dr.Richard Saldhana-PI
   - IEC notification of Non-conduct of A-V consenting
4. **Protocol:** A Phase III, randomized, double-blind, active, controlled, multinational, multicentre, non-inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum hemorrhage during the third stage of labour in women delivering vaginally.
   Protocol Number: A65870
   Dr.S.S.Goudar-PI
   - IEC notification of End of trial
6. **Protocol Title**: A multicenter, open label, randomized, balanced, two treatment, three period, three sequence, reference replicate crossover, single dose, bioequivalence study of Capecitabine Tablets 500 mg of Qilu Pharmaceutical Co., Ltd, China in comparison with XELODA® (Capecitabine) Tablets 500 mg, Distributed by Genentech USA, Inc. following a single oral dose administration in adult cancer patients under fed condition.
   Protocol No: 17-VIN-0855, Version 03, Dated 19 Mar 2018
   Dr.Mahesh Kumar Kalloli-PI
   - IEC notification of CTA letter dated: 28/04/2018
7. **Protocol No.: LRP/LNP3794/2016/006**
   Protocol Title: A Phase II/III Pivotal, Open-label, Randomized, 3-Arm Study to Assess the Efficacy of LNP3794 Monotherapy or in Combination with Docetaxel, Compared with Docetaxel Alone, in Patients with RAS Mutation-Positive Locally Advanced and Metastatic Non-Small Cell Lung Cancer
   Dr.Mahesh Kumar Kalloli-PI
   - IEC notification of CIOMS-SAE-Dyspnea Grade III of Subject: 238001_Initial Report
6. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   Dr.Jayaprakash Appajigol-PI
   - IEC notification of CIOMS
     - REAP-00139-Event: Prolongation of PT-INR_ Initial
     - REAP-00192-Event: rhabdomylosis_ FU01
     - REAP-00192-Event: Exacerbation of rhabdomylosis_ FU02

- REAP-00192-Event: Exacerbation of rhabdomylosis_ FU03
- REAP-00184-Event: Death_ FU01
- REAP-00141-Event: Cardiac arrest _ FU01
- REAP-00141-Event: No AE- previously reported as platelets decreased _ FU01
- REAP-3001-00126-Event: Peripheral facial paralysis_FU0 V8
- REAP-3001-00413-Event: Decrease Glasgow coma score _Initial
- REAP-3001-00413-Event: Decrease Glasgow coma score _FU01
- REAP-3001-00413-Event: Decrease Glasgow coma score _FU02
- REAP-3001-00165-Event: Cerebral infarction _FU01
- REAP-3001-00148-Event: Organ failure _ FU01
- REAP-3001-00431-Event: Ischemic hepatitis worsening _ FU01
- REAP-3001-00438-Event: Hematoma on the right pleural cavity _ FU01
- REAP-3001-00438-Event: Hypereosiniphilia _ Initial
- REAP-3001-00440-Event: seizure _ Initial
- REAP-000170-Event: Death _ FU01
- REAP-000161-Event:Previouly black lung fluid _ FU01
- REAP-3001-00431-Event: ischemic hepatitis worsening _ FU02
- REAP-000133-Event:Postoperative reperforation _ FU02
- REAP-000159-Event:CK increased _ FU01
- REAP-000159-Event:CK increased _ FU02
- REAP-000120-Event:Chronic subdural hematoma _ Initial
- REAP-3001-00405-Event:Elevated INR _ Initial
- REAP-20150020-Event:Pseudoaneurym _ Initial
- REAP-00071-Event:Death _ Initial
- REAP-000198-Event:Intra-Abdominal haemorrhage_ Initial

7. **Study No:** 20140444
   Drug: Denosumab
   Protocol Title: A Phase 3 randomized, Double-blind, Placebo-Controlled, Parallel-group Study to evaluate the safety and Efficacy of Denosumab in pediatric Subjects with Glucocorticoid-induced Osteoporosis.
   Dr.N.S.Mahantashetti-PI
   - IEC notification of CTRI letter dated 26/05/2018
8. **Protocol Title:** -An open-label, single arm and multi-centered study to evaluate the efficacy, safety and tolerability of lipid based tacrolimus ointment 0.1% of Intas Pharmaceuticals Limited, India in patients of oral lichen planus.
   Study No.804-16
   Dr.Shivakumar Patil-PI
   - IEC submission of –
     - DCGI Acknowledgment letter
     - CTRI registration
     - Final executed CTA on 15/05/2018
9. **Protocol No:** 1002-043
   Protocol Title: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at High Risk For, Cardiovascular Disease Who Are Statin Intolerant.
   Dr.V.A.Kothiwale-PI
   Site No: 28011
   - IEC submission of CIOMS report letter dated: 09/June/2018

10. **Study Number:** GBR 200-301
Study Title: A Prospective, Multicenter, Randomized, Double-blind, Parallel-group, Study to Compare the Efficacy and Safety of GBR 200 (similar biologic of Trastuzumab) versus Innovator Trastuzumab both when given in combination with Paclitaxel in patients diagnosed with HER2 Positive Metastatic Breast Cancer.
Dr.Maheshkumar Kalloli-PI
    - IEC submission of CTRI details
11. **Project CRL011813:** A Randomized, Double blind, Multicenter, Three-arm, Parallel, Placebo-controlled, Clinical Study to Evaluate the Bioequivalence using Clinical Endpoint of Diclofenac Sodium Topical Gel, 1% (Encube Ethicals Private Limited, India) to Voltaren Gel (Diclofenac Sodium Topical Gel) 1% (Endo Pharmaceuticals Inc., USA) in Subjects with Osteoarthritis (OA) of the Knee.
Dr.Archana Uppin-PI
    5. IEC submission of DCGI NOC and Final CRF letter dated: 06/06/2017
12. **Protocol No: EFC11570:** "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''
Dr.Sanjay Porwal-PI
    - IEC notification of subjects not returned IP kits letter dated 30/05/2018
    - IEC notification of subjects not returned 08 thermal packs and 03 gel packs letter dated: 30/05/2018
    - IEC notification of eCRF version 17.0
    - IEC notification of 12th Semi Annual Report letter dated 30/05/2018
13. **Protocol Number:** A65913 and A65916
Protocol Title: "The WHO ACTION (Antenatal CorticosTeroids for Improving Outcomes in preterm Newborns) Trials: WHO ACTION-I TRIAL - A65913 and WHO ACTION-II TRIAL - A65916"
Dr.Shivaprasad Goudar-PI
    - IEC notification of replacement of IP ampoules letter dated 22/05/2018
    - IEC notification of Destruction of IP ampoules letter dated 22/05/2018
14. **Protocol: EFC13889/ODYSSEY EAST:** A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
Dr.V.A.Kothiwale-PI
    - IEC notification of IB Edition 11 dated 18 Jan 2018 and change tracking form of IB letter dated 17/05/2018
15. **Protocol No: BCD-021-02**
Study Title:" International multicenter randomized double blind phase III trial comparing safety and efficacy of BCD-021 (CJSC BIOCAD, Russia) and paclitaxel + carboplatin to Avastin® (F. Hoffmann-La Roche Ltd, Switzerland) and paclitaxel + carboplatin in inoperable or advanced non-squamous non-small-cell lung cancer patients."
Dr.Maheshkumar Kalloli-PI
    6.IEC notification of SAE final report latter dated: 20/12/2017.
16. **Protocol Number:** CLR_16_13
Protocol Title: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer.

Dr.Rohan Bhise-PI

- IEC notification of CIOMS_FEVER-subject no:3206/R-M

17. **Protocol title:** Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-024 / Lucentis® in patients with neovascular (wet) age-related macular degeneration
    Protocol No.: RLS/OPT/2016/05; Version 2.0, Dated: 23 Jan 2017
    Dr.Rekha Mudhol-PI
    - IEC notification of CTA and DCGI approval letter dated 04/06/2018
    - Amended ICF version 2.0 dated 04/06/2018
18. **Protocol Number:** 13-VIN- 443
    Protocol Title: A multicenter, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL of Mylan Laboratories Limited, India with Doxorubicin Hydrochloride Liposome Injection for intravenous infusion 20 mg/10 mL Manufactured By: Sun Pharmaceutical Ind. Ltd., Halol Baroda Highway, Halol-389 350, Gujarat, India, administered in Female patients with ovarian cancer whose disease has progressed or recurred after platinum Based chemotherapy under fed condition.
    Dr.Maheshkumar Kalloli-PI
    - IEC notification of DCGI letter dated 02/06/2018
19. **Study Title**: Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-045 / Prolia® in post-menopausal women with osteoporosis.
    Protocol No.: RLS/OST/2016/05; Version 3.0, Dated: 21 Dec 2016
    Dr.Sameer Haveri-PI
    - Amended ICF version 2.0 dated 04/06/2018

VIII. Any other matter with the permission of the chair

For your attention:
Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

18/06/2018

Prof.(Dr).M.S.Ganachari
Member-Secretary of IEC
Belagavi

Member Secretary
ETHICS COMMITTEE (EC)
KLE U... BELGAUM

To:

	Circular and Submission of IEC Dossier	
1)	**Dr. Subarna Roy,** Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V.Hegde,** Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar**, Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr. M.V. Jali,** MD & CE, KLEs Dr.Prabhakar Kore Hospital and MRC, Belagavi	Member
6)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
7)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
8)	**Dr.Nayana Hashilkar**, Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
9)	**Mrs.Vaishnavi V Kivadasannavar**, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
10)	**Shri.Tammanna Dadu Kore,** Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
11)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
12)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, Belagavi	Assistant Coordinator
13)	**Prof.(Dr.)M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
14)	**Dr.Sapna,** Independent Consultant(IEC), Radiation Oncologist, KLE Society's Belgaum cancer hospital, Belagavi-10	External member
	Administrators of KAHER(Deemed to be University)	
1)	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed to be University, Belagavi, For Information	Circular
	Principal Investigators	
1)	**Dr. Maheshkumar Veeranna Kalloli,** Consultant, Oncology Dept., KLES Dr. Prabhakar Kore Hospital &MRC, Nehru Nagar, Belagavi-590 010.	Circular

2)	**Dr.Shivakumar Patil**,Assistant Professor, Consultant dermatologist and Dermatosurgeon,KLES Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belgaum-590 010, Karnataka, India	Circular
3)	**Dr.Vikrant Ghatnatti,** Consultant Endocrinologist, KLES Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi	Circular
4)	**Dr.Ritesh Vernekar,** Consultant Nephrologist, KLES Dr.Prabhakar Kore Hospital & MRC, Nehru Nagr, Belagavi	Circular

Institutional Ethics Committee

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Deemed to-be-University
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Ref: KAHER/IEC/2018-19/D- 3750 .

Date: 17/03/2018

IEC Meeting Agenda

Institutional Ethics Committee of KLEU, Belagavi
Friday, 30/03/2018, At: 4.00 PM
Venue: Site management Office

Accreditations:

NABH

FERCAP

Registrations:

DCGI

OHRP

I. Review of New Project Proposals:

1) **Protocol title:** A Multi-Center, Open-Label, Balanced, Randomized, Two-Treatment, Two Sequence, Two Period, Crossover, Steady-State Bioequivalence Study of Imatinib Mesylate Tablets 400 mg (Test) of Eugia Pharma Specialities Limited, India (A joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited) and Gleevec® (Imatinib Mesylate) 400 mg Tablets (Reference) of Novartis Pharmaceuticals Corporation, USA in 36 adult patients with Chronic Myeloid Leukemia and/or Gastro Intestinal Stromal Tumors already receiving Imatinib Mesylate Tablets 400 mg under fed conditions.
Protocol No: CR050-14
Dr.Rohan Bhise-PI

2) **Protocol Number:** 13-VIN- 443
Protocol Title: A multicenter, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL of Mylan Laboratories Limited, India with Doxorubicin Hydrochloride Liposome Injection for intravenous infusion 20 mg/10 mL Manufactured By: Sun Pharmaceutical Ind. Ltd., Halol Baroda Highway, Halol-389 350, Gujarat, India, administered in Female patients with ovarian cancer whose disease has progressed or recurred after platinum Based chemotherapy under fed condition.
Dr.Mahesh Kumar Kalloli

3) **Protocol No:** BCD-057- 2
Study Title: "A Multicenter Comparative Randomized Double-blind Study of the Efficacy and Safety of BCD-057 (INN: Adalimumab, CJSC BIOCAD, Russia) and Humira@ (INN: Adalimumab, Vetter Pharma) in Patients with Moderate to Severe Plaque Psoriasis"
Dr.Shivakumar Patil-PI

4) **Study Title**: Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-045 / Prolia® in post-menopausal women with osteoporosis.
Protocol No.: RLS/OST/2016/05; Version 3.0, Dated: 21 Dec 20 16
Dr. Sameer Haveri-PI

II. **Review of Proposals with Revision and Amendments:**

I. **Protocol No:** NN BIAsp-4343
Protocol Title: "A multi-Centre prospective, non-interventional study of ability and willingness to pay for BIAsp 30 in a real world population with type 2 diabetes mellitus"
Dr.M.V.Jali-PI

II. **Protocol title:** "A Phase 3 Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Safety and Efficacy of Denosumab in Pediatric Subjects With Glucocorticoid-induced Osteoporosis."
Study No: 20140444
Dr.N.S.Mahatashetti-PI

III. **Review of Revised Project Proposals:**

1) **Protocol Title:** "A Multicenter, Open-label, Single-arm, Study to Evaluate Safety and Tolerability of Repatha in Patients with Homozygous Familial Hypercholesterolemia (HoFH) in India"
Study Number: 20170199
Dr.V.A.Kothiwale-PI
During the **Institutional Ethics Committee (IEC) meeting of KLE University held on Tuesday, 30th January 2018 at 03:30 PM.** The IEC members sought the following documents for further consideration and PI submitted to IEC on 05/03/2018
    1) Final Executed CTA
    2) DCGI approval letter (NOC)

The following documents/clarifications have to be submitted:
1) Insurance Certificate (With Study Specific)
2) CTRI registry
3) Genetic consent was not approved by IEC.

IEC notification of below mentioned documents in addition to the above submitted documents
1) eCRF specification generated on 23/01/2018
2) IB Edition 10.0 dated 22 July 2017

IV. **Review of Annual Report**

1) **Protocol:** "Aspirin Supplementation for Pregnancy Indicated Risk Reduction in Nulliparas (ASPIRIN)"
Dr.S.S.Goudar-PI

V. **SAE reporting**
No- SAEs

VI. **Protocol deviation/violation/ termination:**

1) **Protocol Title:** MYL-1402O-3001: Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First - line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer
Dr.Mahesh Kumar Kalloli-PI
    - IEC notification of Protocol deviation of subjects-171001,171004,171006 and 171011 letter dated 19/02/2018

VII. The Committee will consider the following agendas which are for information.

1) **Protocol** PMZ-02; DCGI CT NOC No.: CT/ND/37/2016
Study Title: A Prospective, Multi-centric, Randomized, Double-blind, Parallel, Saline Controlled Phase II Safety and Efficacy study of PMZ-2010 as a resuscitative agent for Hypovolemic Shock due to excessive blood loss to be used along with standard shock treatment.
Dr.Madhav Prabhu-PI
   - IEC notification of investigator undertaking

2) **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
Dr.Jayaprakash Appajigol-PI
IEC Notification of CIOMS-
   - Report: 3001-00126_Event: Peripheral facial paralysis: FU V8
   - Report: 00154_Event-Cerbaral Haemorrhage PT: Initial
   - Report:3001-00390_Event:Cardiac tumor with active bleeding– FU06
   - Report:00133_Event: Postoperative reperforation– FU01
   - Report:3001-00424_Event:Hemotoma of abdominal cavity– Initial
   - Report: 00161_Event-Balck Lung fluid PT(Pleural Effusion): Initial
   - Report: 00119_Event-Blood pressure decreased PT: FU02
   - Report: 00159_Event-CK increased : Initial
   - Report: 00165_Event-Cerbaral Infarction: Initial

3) **Protocol Number: APL/CT/16/11**
Protocol Title: A Phase-III, Multicentric, Randomized, Double Blind, Placebo-Controlled, Comparative Clinical Study to Evaluate the Efficacy and Safety of Sildenafil Citrate 50 mg plus Dapoxetine 60 mg Tablet and Sildenafil Citrate 100 mg plus Dapoxetine 60 mg Tablet in the treatment of co-existing Erectile Dysfunction and Premature Ejaculation.
Dr.S.I.Neeli-PI
   - IEC Notification of instruction for using stopwatch

4) **Protocol Title:** MYL-1402O-3001: Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First - line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer
Dr.Mahesh Kumar Kalloli-PI
   - IEC notification CIOMS
     - Event: Death-FU: Initial subject no: 171003
     - Event: Drowsiness-FU: Initial subject no: 160004
     - Event: Febrile Neutropenia-FU: 02_subject no: 160006
     - Event: Febrile Neutropenia -FU: Initial subject no: 185003
     - Event: Death -FU:03_subject no: 160002

5) **Study No: CT/DOX/1602**
Protocol Title: An Open-Label, Multicentric, Randomized, Two Treatment, Three Period, Three Sequence, Semi-Replicate, Cross-Over, Comparative Bioavailability study of Doxorubicin Hydochloride Liposomal Injection 20mg/10mL (2mg/ml), concentrate for solution for infusion manufactured by Teva Pharmachemie, Netharlands with caelyx 20 mg/10ml (2mg/ml), [Doxorubicin hydrochloride Liposomal Injection] concentrate for solution for infusion

Of Janssen-Cilag International NV, Belgium in advanced ovarian cancer and/or metastatic breast cancer patients under fasting condition.

Dr.Mahesh Kumar Kalloli-PI

- IEC Notification of SAE Description: Aspiration Pneumonia
- IEC Notification of Aspiration Pneumonia

6) **Study Title:** A Multicenter, Open Label, Balanced, Randomized, Two-Treatment, Two-Period, Two-Sequence, Single Dose, Cross-Over Bioequivalence Study of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL) of Cadila Healthcare Limited, India in comparison with Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL), of Sun Pharmaceutical Ind. Ltd, India, in the Patients of Ovarian Cancer under fasting conditions.

Study Number: 038-16

Dr.Mahesh Kumar Kalloli-PI

- SAE Cross Notification to IEC letter dated 19/02/2018

7) **Protocol Number**: LRP/LNP1892/2016/007

Protocol Title: "A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy, Pharmacokinetics, Pharmacodynamics and Safety of LNP1892 (Monotherapy) in Chronic Kidney Disease (CKD) Patients with Secondary Hyperparathyroidism (SHPT), On Dialysis and Not on Dialysis."

Dr.Mallikarjun S Karishetti-PI

- IEC notification of SAE at site 107_ Event: Cardiogenic shock due to myocardial infarction

8) **Protocol Number:** CLR_16_13

Protocol Title: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer.

Dr.Rohan Bhise-PI

- IEC Notification of Safety analysis report for sub:3901/SMM(site #39-HCG cancer center

9) **Study No: 20140444**

Drug: Denosumab

Protocol Title: A Phase 3 randomized, Double-blind, Placebo-Controlled, Parallel-group Study to evaluate the safety and Efficacy of Denosumab in pediatric Subjects with Glucocorticoid-induced Osteoporosis.

Dr.N.S.Mahatashetti-PI

- IEC notification of Clinical trial agreement

10) **Protocol Title:** A Two-Part, Open-Label, Randomized, Phase II/III Study of Dinutuximab and Irinotecan versus Irinotecan for Second Line Treatment of Subjects with Relapsed or Refractory Small Cell Lung Cancer

Protocol Number: DIV-SCLC-301

Dr.Maheshkumar Kalloli-PI

- IEC notification of Protocol clarification letter dated 24/02/2018

11) **Protocol-**Comparative evaluation of immunogenicity of various schedules, delivery options to provide fractional dose Inactivated Poliovirus Vaccine (IPV) in routine immunization in the post

tOPV-bOPV period: A multicentric open label randomized controlled trial"(India IPV fractional dose study).
Protocol No.: PBL/CR/2016/02/CT/fIPV (Version 01 dated 24/08/2016)
Dr.N.S.Mahatashetti-PI

- IEC notification of final technical report
- IEC notification of Interim monitoring reports

12) **Protocol Title:** A Multicentre, Open Label, Balanced, Randomized, Two Treatment, Two-Period, Two Sequence,, Single Dose, Cross-Over Bioequilance Study Of Doxorubicin Hydrochloric Liposome Injection 2 mg/ml Of Cipla Limited India, in comparison with Doxorubicin Hydrochloric Liposome Injection 2 mg/ml Sun Pharmaceutical Ind.Ltd India, In The Patients Of Ovarian Cancer Under Fasting Conditions
Protocol No: CRD/08
Dr.Rohan Bhsie-PI
IEC notification of below mentioned documents

- Protocol version 04 (dated 09/02/2018)
- Protocol amendment History

13) **Protocol Title:** Evaluation of Safety and efficacy of the BACE™ [Basal Annuloplasty of the cardia externally] device in the treatment of functional mitral valve regurgitation (FMR)
Dr.Richard Saldana-PI

- IEC notification of typo error EC submission letter dated 06/12/2017

14) **Protocol Title:** "A Multicenter, Open-label, Single-arm, Study to Evaluate Safety and Tolerability of Repatha in Patients with Homozygous Familial Hypercholesterolemia (HoFH) in India"
Study Number: 20170199
Dr.V.A.Kothiwale-PI

- IEC notification of typo error EC submission letter dated 16/01/2018

VIII. Any other matter with the permission of the chair

For your attention:
Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Prof.(Dr).M.S.Ganachari
Member-Secretary of IEC
Belagavi

Member Secretary
ETHICS COMMITTEE (EC)
KLE University, BELGAUM

To:

	Circular and Submission of IEC Dossier	
1)	**Dr. Subarna Roy**, Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi	Chairman
2)	**Dr. Harsha V.Hegde**, Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.	Member
3)	**Dr.P.A.Patil,** "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.	Member
4)	**Dr.S.S.Goudar**, Prof. of Physiology, J.N. Medical College, Belagavi.	Member
5)	**Dr. M.V. Jali**, MD & CE, KLEs Dr.Prabhakar Kore Hospital and MRC, Belagavi	Member
6)	**Dr.Yeshita Pujar,** Prof of Obst & Gynace, JNMC, Belagavi	Member
7)	**Dr.Roopa Bellad,** Prof of Paediatrics, J.N. Medical College, Belagavi	Member
8)	**Dr.Nayana Hashilkar**, Prof. of Pharmacology, J.N. Medical College, Belagavi.	Member
9)	**Mrs.Vaishnavi V Kivadasannavar**, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.	Member
10)	**Shri.Tammanna Dadu Kore,** Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213	Member
11)	**Shri. Praveen Hiremath,** Advocate, Anjaneya Nagar, Belagavi.	Member
12)	**Mrs.Geetanjali Salimath,** Asst.Prof. Dept. Of Pharmacy Practice, Belagavi	Assistant Coordinator
13)	**Prof.(Dr.)M.S.Ganachari,** Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.	Member-Secretary
14)	**Dr.Sapna,** Radiation oncologist, Belgaum cancer hospital, Belagavi	External-Member
	Administrators of KLE Deemed to be University	
1)	The Registrar, KAHER, Deemed to be University, JNMC Campus, Belagavi - For Information	Circular
2)	The Special Officer to Vice-Chancellor, KAHER, Deemed to be University, JNMC Campus, Belagavi -For Information	Circular
3)	The Finance officer, KAHER- Deemed to be University, JNMC Campus, Belagavi- For Information	Circular
4)	Mrs. Rajeshwari - PRO –KAHER, Deemed to be University, Belagavi, For Information	Circular
	Principal Investigators	
1)	**Dr.Rohan Bhise**, Consultant, Dept.of Oncology, KLEs Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi	Circular
2)	**Dr.Mahesh Kumar Kalloli**, Consultant, Dept.of Oncology, KLEs Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi	Circular
3)	**Dr.Shivakumar Patil,** Consultant dermatologist, Dept.of Dermatology, KLEs Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi	Circular
4)	**Dr. Sameer Haveri,** Consultant orthopedics, Dept.of Orthopedics, KLEs Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi	Circular

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JNMC Campus, Nehru Nagar, Belgaum-590 010, Karnataka State, India
[Established under Section 3 of the UGC Act, 1956 vide MHRD, G.O.I Notification No.F.9-19/2000-U.3(A) dt. 13th April 2006]
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Ref: KLEU/EC/2017-18/D-426 ***Date: 18/05/2017***

Circular

The meeting of **Ethics Committee (EC)** of the **KLE University** is convened on **Friday, 26th May 2017, 04:00 pm** at **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New protocol for Approval

1. **Research Project:** "Women's perceptions of informed consent request daringly early labour: a Questionnaire for participation in the WHO CHAMPION Trial"
   Dr.Shivaprasad S Goudar-PI
2. **WHO ACTION-II TRIAL:**
   A65913: A multi-country, multi-centre, two-arm, parallel, double-blind, placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in the early preterm period in heath facilities in low-resource settings to improve new born outcomes.
   Dr. Shivaprasad S Goudar-PI
3. **Protocol:** A retrospective, Single-center, study to evaluate safety and performance of the Evermine 50-50μm Everolimus Eluting Coronary Stent System (EES) in the treatment of patients with de novo coronary artery lesions.
   Dr.Suresh V Patted-PI
   Note: above study was referred from the previous meeting and the respective documents have been already dispatched with previous circular.

II. Agenda: For Ongoing Trial Approval:

4. **Protocol:** "Comparative evaluation of immunogenicity of various schedules and delivery options to provide fractional Dose Inactivated Poliovirus Vaccine in routine immunization in the post tOPV-bOPV period: A multi-centric open label randomized controlled trial"(India fractional dose IPV study)
   Dr.N.S.Mahantashetti-PI
   - EC Review and Approval of clinical Trial Documents

III. The Committee considered the following agendas which were for information:

1. **Protocol No: NCS-353-15-CS**
   Study Title: An open label, randomized, balanced, two treatment, two period, two sequence, single dose, crossover, oral bioequivalence study of 600mg/m2 of Vinorelbine soft capsule from lotus pharmaceutical co., Ltd., Taiwan compared with that of 60 mg/m2 of NAVELBINE® soft capsule marketed by PIERRE FABRE Limited, Winchester Hampshire S023 7DR, United Kingdom, in adult, patients with advanced breast cancer under fed conditions.
   Dr.Mahesh Kumar Kalloli-PI
   - EC Notification of Protocol Deviation

- EC Notification of Study update

2. **Research Project:**"Aspirin Supplementation for Pregnancy Indicated Risk Reduction in Nulliparas (ASPIRIN)"
   Dr.Shivaprasad S Goudar-PI
   - EC Notification of DMC letter

3. **Research Project:** "Women First: Preconception Maternal Nutrition
   Dr.B S Kodkany-PI
   - EC Notification of DMC letter
4. **Research Project:** Maternal New Health Registry
   Dr.B S Kodkany-PI
   - EC Notification of DMC letter
5. **Protocol Title:** "Better Birth: Trial of WHO Safe Childbirth Checklist Program" in Uttar Pradesh.
   Dr.B S Kodkany-PI
   - EC Notification of progress Report and requisition letter for continuation of approval letter
6. **A65870:** A phase III, randomised, double-blind, active, controlled, multinational, multicentre, non inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum haemorrhage during the third stage of labour in women delivering vaginally.
   Dr.Shivaprasad S Goudar-PI
   - EC notification of ICF memo dated 08-Nov-2016
   - EC notification of annual Status Report
   - EC notification of observations during monitoring visit Pt No:08737)
   - EC notification of observations during monitoring visit(Pt No:09035)
   - EC notification of observations during monitoring visit(Pt No:09185)
7. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy
   Dr.Jayaprakash Appajigol-PI
   - EC notification of **CIOMS** Report-001-00335 Event:1-Elevated Liver Enzymes(GLDH)-**Initial**
   - EC notification of **CIOMS** Report-00094 **Event:** left Cerebellar haemorrhage - **Initial**
   - EC notification of **CIOMS** Report-00096 **Event**: idiopathic thrombocytopenic purpura **-Initial**
   - EC notification of **CIOMS** Report-3001-00339 **Event**: Necrotic toes-**Initial**
   - EC Notification of Continuation of approval above referenced study

8. **Protocol:** "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of

Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''

Dr.Sanjay Porwal-PI

- EC Notification of Protocol Deviation with Subject No:356103021
- EC Notification of 11th Semiannual Report
- EC Notification of IB, Edition 10 dated 27/02/2017
- EC Notification of CIOMS (SA#281IN)
- EC Notification of CIOMS (SA#284&285IN)
- EC Notification of CIOMS (SA#286&287IN)
- EC Notification of CIOMS (SA#288&289IN)
- EC Notification of CIOMS (SA#290-291 IN)
- EC Notification of CIOMS (SA#292 IN)
- EC Notification of CIOMS (SA#293 IN)
- EC Notification of CIOMS (SA#294-295 IN)
- EC Notification of CIOMS (SA#296-297 IN)

9. **Protocol:CRL091523:**A Multi-Centre, Randomized, Open-Label, Two Period, TwoTreatment, Two Sequence, Multiple-Dose, Crossover, Bioequivalence Study of Pramipexole Prolonged Release Tablets 3.15 mg of Mylan Laboratories Ltd., India with Sifrol® 3.15 mg (Pramipexole) depottabletter (depot tablet) of Boehringer Ingelheim International GmbH, Germany in Patients with Idiopathic Parkinson's disease. PROTOCOL VERSION: 1.0, dated 16 Sep 2015

   Dr.Madhav Prabhu-PI

   - EC Notification of close out letter

10. **Protocol:** A multicentre, open label, balanced, Randomized, two treatment, three period, three sequence, reference replicate crossover, single dose, oral bioequilance study of Capecitabine film coated tablets 500mg of shilpa medicare Limited, India and Xeloda® Film Coated tablets 500mg(Capecitabine) marketed by Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City,AL7 1 TW United Kingdom following single oral dose of 2000mg (4×500mg) in adult human cancer patients under fed conditions.

    Protocol No: P-762/16

    Dr.Mahesh Kumar Kalloli-PI

    - EC Notification of Fully executed CTA

11. Protocol:"A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".

    Dr.V.A.Kothiwale-PI

    - EC notification of site closure memorandum

12. **Protocol: EFC13889/ODYSSEY EAST:** A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727)

Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
Dr.V.A.Kothiwale-PI

- EC Notification of Investigator Brochure
- EC Notification of CIOMS (Safety Alert#90&91IN)
- EC Notification of CIOMS (Safety Alert#92&93IN)
- EC Notification of CIOMS (Safety Alert#94&95 IN)
- EC Notification of CIOMS (Safety Alert#96&97 IN)
- EC Notification of CIOMS (Safety Alert#98&99 IN)
- EC Notification of CIOMS (Safety Alert#100&101 IN)
- EC Notification of CIOMS (Safety Alert#102&103 IN)
- EC Notification of CIOMS (Safety Alert#104 IN)
- EC Notification of CIOMS (SA#105&106IN)'
- EC Notification of SASR#11

13. **Protocol title:** A Randomized, Double –blind, Placebo-controlled Study to Evaluate the Long-term safety and Efficacy of Darbepoetin Alfa Administered at 500µg Once-Every-3-Weeks in Anaemic Subjects with Advanced Stage Non-small Cell Lung Cancer Receiving Multi Cycle Chemotherapy.
Dr.Rohan Bhise-PI
    - EC notification of Memorandum for darbepoetin Alfa,20070782-Early study termination
14. **Reaserch Project**: "Evaluation of the introduction of a novel device in the management and shock in pregnancy in low-resource settings" under CARDLE III (Community Blood Pressure Measurement in Rural Africa and Asia: the detection of Underlying Pre-eclampsia and Shock) stepped- wedge Randomized Control Trial.
Dr.S S Goudar-PI
    - EC Submission of Data collection tools
15. **Protocol ID No:** CRL121526
Protocol Title: "A Randomized, Open-Label, Two Period, Two-Treatment, Two Sequence, Single-Dose, Crossover, Bioequivalence Study of Paclitaxel Protein-bound Particles for Injectable Suspension (albumin-bound) of Panacea Biotec, India with ABRAXANE® (Paclitaxel Protein-bound Particles for Injectable Suspension) (albumin-bound) manufactured for Celgene Corporation, Summit, NJ in Patients with Metastatic Breast Cancer under Fasting Conditions.",
Dr.Rohan Bhise-PI
    - EC Notification of CIOMS
16. **Protocol :** VRL/CSE-1034/05/2012 "A Randomized, Double-blind, Double-dummy, Active-controlled, Multi-centre Trial to Compare the Efficacy and Safety of CSE-1034 (Ceftriaxone+ Sulbactam+ EDTA) with Meropenem in Infections Caused by β – Lactamase (ESBL and MBL) producing Gram Negative Bacteria."

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t: 0831-2470400 FAX: 0831-2493099 www.kleuniversity.edu.in E-mail: kleclinicalresearch@gmail.com

Dr.Madhav Prabhu-PI

- EC Notification of study update

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia to Member Secretary.

Yours truly,

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Member Secretary)

Member Secretary
ETHICS COMMITTEE (EC)
KLE University, BELGAUM

To: All the members:

1) Dr. Subarna Roy, Scientist 'E', Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2) Dr. M.S.Ganachari, Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3) Dr. Harsha V.Hegde, Scientist 'C' ICMR (RMRC), Nehru Nagar, Belagavi.
4) Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5) Dr. M.V. Jali, MD & CEO KLE Dr.Prabhakar Kore Hospital and MRC, Belagavi.
6) Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7) Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi
8) Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC,Belagavi
9) Dr.Nayana Hashilkar, Asso.Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10) Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.
11) Shri.Tamanna Dadu Kore,Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213
12) Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13) Mrs.Geetanjali Salimath, Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14) The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
15) The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
16) Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

KLE UNIVERSITY

JNMC Campus, Nehru Nagar, Belgaum-590 010, Karnataka State, India

[Established under Section 3 of the UGC Act, 1956 vide MHRD, G.O.I Notification No.F.9-19/2000-U.3(A) dt. 13th April 2006]

Accredited "A" grade by NAAC **Placed in Category "A" by MHRD [GoI]**

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Ref: KLEU/EC/2016-17/D- 3462 **Date: 31/12/2016**

Circular

The meeting of **Ethics Committee (EC)** of the **KLE University** is convened on **Friday, 6th January 2017, 04:30 pm** at **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New protocol

1. **ACTION-I TRIAL-A65913:** A multi-country, multi-centre, two-arm, parallel, double-blind, placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in the early preterm period in heath facilities in low-resource settings to improve new born outcomes.
   Dr. Shivaprasad S Goudar-PI
2. **Protocol:** Maternal Nutritional Status and Pancreatic Beta Cell function in Asian Indian infants-an exploratory sub-study within the DHANI trial (ABCs in Infants)
   Dr.Mahesh Kamate-PI
3. **Protocol no:** RLS/RES/2016/01: version 1.0, dated: 05 Feb 2016
   Protocol title: Prospective, multi-centre, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-022/Xolair® in patients with moderate to severe persistent asthma.
   Dr.Jyothi hattiholi –PI

   Note: above study was referred from the previous meeting and the respective documents have already been dispatched with previous circular

II. The Committee will consider the following agendas which are for information:

1. **Protocol No: NCS-353-15-CS**

   Study Title: An open label, randomized, balanced, two treatment, two period, two sequence, single dose, crossover, oral bioequivalence study of 600mg/m2 of Vinorelbine soft capsule from lotus pharmaceutical co., Ltd., Taiwan compared with that of 60 mg/m2 of NAVELBINE® soft capsule marketed by PIERRE FABRE Limited, Winchester Hampshire S023 7DR, United Kingdom, in adult, patients with advanced breast cancer under fed conditions.
   Dr.Mahesh Kumar Kalloli-PI
   - **EC notification of study update**

2. **Protocol:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When Evolocumab (AMG 145) is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".

Dr.V.A.Kothiwale-PI
Site No: 30031

- **EC notification of DMC letter**

3. **Title of Study**: An Open label Clinical Study to Determine the Specificity and Sensitivity of Algorithm (Software) developed by Bosch using Bosch Mobile non-mydriatic fundus camera comparing it with mydriatic 7-Standard Field Stereoscopic Digital Color Fundus Photography(EDTRS) done in patients with undiagnosed diabetic retinopathy(Symptomatic/asymptomatic)
   Dr.Smitha Prabhu-PI
   - **EC notification of study update**
4. **Protocol no:R2014006**
   Protocol: A Phase IV, Non comparative, Open label, Multicentric Trial to Evaluate the Safety and Efficacy of SYNRIAM® in the Treatment of Acute Uncomplicated Plasmodium vivax Malaria.
   Dr.Raju H Badigar-PI
   - **EC notification of study update**
5. **Protocol :** VRL/CSE-1034/05/2012 "A Randomized, Double-blind, Double-dummy, Active-controlled, Multi-centre Trial to Compare the Efficacy and Safety of CSE-1034 (Ceftriaxone+ Sulbactam+ EDTA) with Meropenem in Infections Caused by β – Lactamase (ESBL and MBL) producing Gram Negative Bacteria."
   Dr.Madhav Prabhu-PI
   - **EC notification of study update**
6. **Protocol: MK- 0822-018-01** a phase III randomised, placebo-controlled clinical trial to assess the safety and efficacy of odanacatib (MK-0822) to reduce the risk of fracture in osteoporotic postmenopausal women treated with vitamin D and calcium.
   Dr.Rajendra Bhandankar-PI
   - **EC notification of non resolvable COV Observations**
   - **EC notification of study completion**
   - **EC notification of CIOMS**
7. **Protocol**: A randomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose, crossover, pivotal steady state bioequivalence study of Everolimus 10 mg tablet, Manufactured by Teva Pharmaceuticals - Pliva Croatia Ltd., Prilaz baruna Filipovica 25, 10000 Zagreb Croatia vs. Afinitor®(Everolimus) 10 mg tablet of Novartis Pharmaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients under fasting conditions.
   Dr.Mahesh Kalloli-PI
   - **EC notification of Clinical Study Report**
   - **EC notification of CRF**

KLE UNIVERSITY
JNMC Campus, Nehru Nagar, Belgaum-590 010, Karnataka State, India
[Established under Section 3 of the UGC Act, 1956 vide MHRD, G.O.I Notification No.F.9-19/2000-U.3(A) dt. 13th April 2006]
Accredited "A" grade by NAAC
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t: 0831-2470400 FAX: 0831-2493099 www.kleuniversity.edu.in E-mail: kleclinicalresearch@gmail.com ,

8. **Protocol Title:** "Maternal Docosa-Hexanoic Acid (DHA) Supplementation and offspring neurodevelopment in India – (DHANI-2)".
   Dr.Sweta Khandelwal -PI
   EC notification of SAE's
   - **SAE 01: Congenital anomaly detected leading to medical termination of pregnancy at 14 weeks 6 days** for Subject no: **R0413**
   - **SAE 02: Preterm labour leading to still birth at 20 weeks 6 days** for subject no: **R0445**
   - **SAE 03: Intrauterine death** for subject no:**R0259**
   - **SAE 04:** stillbirth for sub subject no:**R0292**
   - **SAE 05: Intrauterine death leading to still birth at 33 weeks due to preeclampsia (with fetal growth restriction)** for Subject no:**R0407**
   - **SAE06: Intrauterine death leading to still birth at 37 weeks** for subject ID:**0218**
9. **Protocol Title: I4V-MC-JADY (d) & (c)** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   Dr.shailesh Udupudi-PI
   - **EC notification of SAE- Cellulites of right great toe** for subject **ID-68571**
10. **Protocol:** A multicentre, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial of Cipla Ltd., India with ABRAXANE for Injectable Suspension (Paclitaxel protein-bound particles for injectable suspension) Manufactured for :Celgene Corporation Summit, USA in Breast cancer patients after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.
    Dr.Rohan Bhise-PI
    - **EC notification of Clinical Study Report**

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia to Member Secretary.

Yours truly,

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Chairman/Member Secretary)

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To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2. Dr. M.S.Ganachari, Prof.& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3. Dr. Harsha V.Hegde, Scientist 'C' ICMR (RMRC), Nehru Nagar, Belagavi.
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5. Dr. M.V. Jali, MD & CEO KLE Dr.Prabhakar Kore Hospital and MRC, Belagavi.
6. Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7. Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi
8. Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC,Belagavi
9. Dr.Nayana Hashilkar, Asso.Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10. Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.
11. Shri.Tamanna Dadu Kore,Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213
12. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13. Mrs.Geetanjali Salimath, Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14. Dr.Shivaprasad S Goudar, Research Co-Ordinator,JNMC-women's & Childrens Health Research Unit,JNMC,Belagavi-10
15. Dr.Mahesh Kamate, Professor of Pediatric Neurology, In charge of child development centre, KLE's Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belgavi.
16. The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
17. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
18. Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2017-18/D- 4018

Date: 01/03/2017

Circular

The meeting of **Ethics Committee (EC)** of the **KLE University** is convened on **Monday, 6th March 2017, 04:00 pm** at **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New protocol

1. **Protocol:** A Study to Evaluate the Effect of Dapagliflozin on the Incidence of worsening heart failure or Cardiovascular Death in patients with chronic Heart Failure with reduced Ejection Fraction.
   Dr. V A Kothiwale-PI
2. **Protocol:** A Study to Evaluate the Effect of Dapagliflozin on Renal Outcomes and Cardiovascular Mortality in Patients with Chronic Kidney Disease.
   Study Code: D169AC00001
   Dr. Mallikarjun S Karishetti-PI
3. **Protocol:** An open label extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in Etrolizumb phase II/III studies.
   Protocol No: GA28951- Version 6 Dated 22 Oct 2015
   Dr. Vardaraj Pralhadarao Gokak-PI
4. **Protocol:** Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter Study to evaluate the efficacy (maintenance of remission) and safety of Etrolizumb compared with placebo in patients with moderate to severe active Ulcerative Colitis who are maive to TNF inhibitors.
   Protocol No: GA29102- Version 05 dated 28 Aug 2015
   Dr. Vardaraj Pralhadarao Gokak-PI
5. **Protocol** PMZ-02; DCGI CT NOC No.: CT/ND/37/2016
   Study Title: A Prospective, Multi-centric, Randomized, Double-blind, Parallel, Saline Controlled Phase II Safety and Efficacy study of PMZ-2010 as a resuscitative agent for Hypovolemic Shock due to excessive blood loss to be used along with standard shock treatment.
   Dr.Madhav Prabhu-PI
6. **Research Title**: Mixed-Methods research study to explore women's abortion-related decision making processes, and provider attitudes in Belagavi, Karnataka in Collaboration with JNMC Women's and children's Health Research Unit".
   Dr.Shivanad C Mastiholi-PI
7. **Protocol:** Maternal Nutritional Status and Pancreatic Beta Cell function in Asian Indian infants-an exploratory sub-study within the DHANI trial (ABCs in Infants)
   Dr.Mahesh Kamate-PI
   Note: above study was referred from the previous meeting and the respective documents have been already dispatched with previous circular.

8. EC Accreditation of NABH
9. Requirement of One Research Pharmacist in SMO
10. ICH-GCP Training For New EC Members

II. The Committee will consider the following agendas which are for information:

1. **Protocol No: NCS-353-15-CS**
   Study Title: An open label, randomized, balanced, two treatment, two period, two sequence, single dose, crossover, oral bioequivalence study of 600mg/m2 of Vinorelbine soft capsule from lotus pharmaceutical co., Ltd., Taiwan compared with that of 60 mg/m2 of NAVELBINE® soft capsule marketed by PIERRE FABRE Limited, Winchester Hampshire S023 7DR, United Kingdom, in adult, patients with advanced breast cancer under fed conditions.
   Dr.Mahesh Kumar Kalloli-PI
   - EC notification of Clarification in approval letter dated 28 Sep 2016
   - EC Notification of ERRATA Template
   - EC Notification of **Severe Adverse Event "Breast Abscess"** subject no:**49**
2. **Protocol:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When Evolocumab (AMG 145) is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   Dr.V.A.Kothiwale-PI
   Site No: 30031
   - EC notification of quarterly line listing from period 1st Oct 2016through 31st Dec2016
   - EC Notification SUSAR's letter dated 08/01/2017.
   - EC Notification SUSAR's letter dated 12/01/2017.
   - EC notification of **Memo100 Completion of site activities-23Jan 2017.**
3. **Protocol:CRL091523:** A Multi-Centre, Randomized, Open-Label, Two Period, TwoTreatment, Two Sequence, Multiple-Dose, Crossover, Bioequivalence Study of Pramipexole Prolonged Release Tablets 3.15 mg of Mylan Laboratories Ltd., India with Sifrol® 3.15 mg (Pramipexole) depottabletter (depot tablet) of Boehringer Ingelheim International GmbH, Germany in Patients with Idiopathic Parkinson's disease.
   Dr.Madhav Prabhu-PI
   - EC notification of Study Update
4. **Protocol Title:** "Maternal Docosa-hexaenoic acid (DHA) Supplementation and offspring neurodevelopment in India (DHANI-2) randomized controlled trial".
   Dr.M.K Swamy-PI
   - **EC notification of SAEs**
5. **Protocol No: EFC13889/ODYSSEY EAST:** A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.

Dr.V.A.Kothiwale-PI

- EC notification of CIOMS(SA#53)
- EC notification of CIOMS(SA#56 and SA#57)
- EC notification of CIOMS(SA#66 and SA#67)
- EC notification of CIOMS(SA#68 and SA#69)
- EC notification of CIOMS(SA#62 and SA#63)
- EC notification of CIOMS(SA#65)
- EC notification of CIOMS(SA#67)
- EC notification of CIOMS(SA#70)
- EC notification of CIOMS(SA#70)
- EC notification of inadvertent use of expiry kits to collect blood sample.

6. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy

   Dr.Jayaprakash Appajigol-PI

   - EC notification of **CIOMS** Report-3001-00296 Event:1-Small bowel Ishemia,2-Necrotizing fasciitis-**Initial Report**
   - EC notification of **CIOMS** Report-3001-00296 Event:1-Small bowel Ishemia,2-Necrotizing fasciitis-**Follow up01**
   - EC notification of **CIOMS** Report-3001-00296 Event:1-Small bowel Ishemia,2-Necrotizing fasciitis-**Follow up02**
   - EC notification of **CIOMS** Report-3001-00231 Event:1-Left Ventricular thrombus,2-Embolic cerebral infraction-Follow up 06
   - EC notification of **CIOMS** Report-3001-00231 Event: Death follow up 01

7. **Project # MYL-1402O-3001**:Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.

   Dr.Mahesh Kumar-PI

   - EC notification of Clinical Trial Agreement
   - EC Notification of Master CRF template
   - EC Notification of typographical error letter dated **23/10/2016**
   - EC notification of approval of the study documents
   - EC notification of CTRI Registration **(CTRI/2016/007557)**

8. **Protocol title:** "women first: Preconception Maternal Nutrition –Neurodevelopment Assessment"

   Dr.Shivaprasad S Goudar-PI

   - EC Approval of Updated Protocol And New Data Forms

9. **Project:** Maternal Newborn Health Registry

   Dr.B.S.Kodkany-PI

   - EC notification of approval of Data Forms

10. **Protocol title: "Better Birth: Trail of Who SAFE Child birth Check list Program" Dr.B.S.Kodkany-PI**
    - EC notification of Updated versions of Documents
11. **Protocol:** "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''
    Dr.Sanjay Porwal-PI
    - EC Notification of CIOMS(SA#242 in & corrigendum to SA #136 and #204)
    - EC Notification of CIOMS(SA#256&257)
    - EC Notification of Study Update
12. Protocol Number/ Title- [Pfizer, A0081105, "A randomized, double-blind, placebo-controlled, parallel group, multi-center trial of pregabalin as adjunctive therapy in pediatric and adult subjects with primary generalized tonic-clonic seizures", PAREXEL, 208238]
    Dr.Mahesh Kamate-PI
    - EC Notification of SAE Line listing Report
13. **Protocol Title:** "Effects of a yoga-based cardiac rehabilitation programme (Yoga-CaRe) on cardiovascular health: a clinical trial (India) and mechanistic study (UK)"
    Dr.Prasad MR-PI
    - EC Notification of Clinical Trial Agreement
14. **Protocol Title: I4V-MC-JADY** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
    Dr.Shailesh Udapudi-PI
    - EC notification of Missed dose for the Subject 53824,68571,68572
    - EC Notification for SAE clarification letter dated 16/09/2016
    - EC notification of SAE "Cellulitis of right great toe" Subject No:**68571-Follow up-01 (site:432)**
    - EC notification of SAE "Viral Fever with Thrombocytopenia" Subject ID:**68572-Final Report (site:432)**
    - EC Notification clarification for typhographical error letter dated 16/Sept/2016
    - EC notification of Investigators's Brochure for Baricitinib(LY3009104) dated (12/01/2017)
    - EC Notification of SAFRANS/CIOMS
15. **Protocol:** A seamless, sequential Phase III, multicenter, randomized, single-blind study to evaluate the immunogenicity, reactogenicity and safety of ROTAVAC 5C new formulations of the live attenuated rotavirus vaccine as a 3 dose series when compared with existing ROTAVAC® in healthy infants.
    Protocol Number: BBIL/ROTA/C/III/2014
    Dr.N.S.Mahantashetti-PI
    - EC Notification of SAE of others site

- EC Notification of Protocol Deviation letter dated 04/01/2017
- EC Notification of SAE of others site letter dated 15/12/2016

16. **Protocol: MK- 0822-018-01** a phase III randomized, placebo-controlled clinical trial to assess the safety and efficacy of odanacatib (MK-0822) to reduce the risk of fracture in osteoporotic postmenopausal women treated with vitamin D and calcium.
Dr.Rajendra Bhandankar-PI
    - EC Notification of study documents for archival

17. **Protocol ID No:** CRL121526

Protocol Title: "A Randomized, Open-Label, Two Period, Two-Treatment, Two Sequence, Single-Dose, Crossover, Bioequivalence Study of Paclitaxel Protein-bound Particles for Injectable Suspension (albumin-bound) of Panacea Biotec, India with ABRAXANE® (Paclitaxel Protein-bound Particles for Injectable Suspension) (albumin-bound) manufactured for Celgene Corporation, Summit, NJ in Patients with Metastatic Breast Cancer under Fasting Conditions".
Dr.Rohan Bhise-PI
    - EC Notification of CRF
    - EC Notification of Protocol Deviation

18. **Protocol:** A multicentre, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial of Cipla Ltd., India with ABRAXANE for Injectable Suspension (Paclitaxel protein-bound particles for injectable suspension) Manufactured for :Celgene Corporation Summit, USA in Breast cancer patients after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.
Study No.: 15-VIN-258
Dr.Rohan Bhise-PI
    - EC Notification of close out Visit.

19. **Protocol No:A65870:** A phase III, randomized, double Blind- active, Controlled, multinational, Multicentre, non inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum haemorrhage during the third stage of labour in women delivering vaginally"
Dr.S S Goudar-PI
    - EC Notification of SAE: Death for subject ID: 10932.

20. **Protocol:** Phase III Clinical Trial entitled''Comparative Efficacy, Safety and Tolerability of Silver Sulfadiazine Cream (Nanonized) 0.5% w/w and Silverex Cream 1% w/w in the Prophylaxis of Infection in Burn Wounds – A Double-blind, Randomized, Pivotal Study''
Dr.Rajesh Powar-PI
    - EC Notification of close out Visit.

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21. Protocol Number: CLR_16_13
Protocol Title: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer.
Dr.Rohan Bhise-PI

- EC Notification of typographical error in the Submission Letter.

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia to Member Secretary.

Yours truly,

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Chairman/Member Secretary)

Member Secretary
ETHICS COMMITTEE (EC)
KLE University, BELGAUM

To: All the members:

1) Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2) Dr. M.S.Ganachari, Prof.& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3) Dr. Harsha V.Hegde, Scientist 'C' ICMR (RMRC), Nehru Nagar, Belagavi.
4) Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5) Dr. M.V. Jali, MD & CEO KLE Dr.Prabhakar Kore Hospital and MRC, Belagavi.
6) Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7) Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi
8) Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC,Belagavi
9) Dr.Nayana Hashilkar, Asso.Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10) Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.
11) Shri.Tamanna Dadu Kore,Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213
12) Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.

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13) **Mrs.Geetanjali Salimath,** Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14) **Dr. V A Kothiwale** Prof. Dept of Medicine & Vice –Principal JNMC, Belgaum.
15) **Dr. Vardaraj Pralhadarao Gokak**-Consultant Gastroenterologist and Asst.Professor, KLE's Dr.Prabhakar Kore Hoaspital&MRC, Belagavi
16) **Dr. Mallikarjun S Karishetti-** Chief Consultant Nephrology, KLE'S Dr.Prabhakar Hospital &MRC,Belagavi
17) **Dr. Madhav Prabhu**, Consultant (General Medicine), KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belgaum- 590010
18) **Dr.Shivanad C Mastiholi-**, Asst.Professor, Dept of Community Medicine KLE University's JNMC, Belagavi.
19) **Dr.Mahesh Kamate,** Professor of Pediatric Neurology, In charge of child development centre, KLE's Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belgavi.
20) The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
21) The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
22) Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2017-18/D-4351

Date: 01/04/2017

Circular

The meeting of **Ethics Committee (EC)** of the **KLE University** is convened on **Saturday, 08th April 2017, 04:00 PM** at **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: Expedited Review And Approval:

1. **Protocol:** A multicentre, open label, balanced, Randomized, two treatment, three period, three sequence, reference replicate crossover, single dose, oral bioequilance study of Capecitabine film coated tablets 500mg of shilpa medicare Limited, India and Xeloda® Film Coated tablets 500mg(Capecitabine) marketed by Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City,AL7 1 TW United Kingdom following single oral dose of 2000mg (4×500mg) in adult human cancer patients under fed conditions.
   Protocol No: P-762/16
   Dr.Mahesh Kumar Kalloli-PI

II. The Committee will consider the following agendas which are for information:

1. **Protocol:** A prospective, Post-marketing, Single-centre, study to evaluate safety and performance of the Evermine 50-50µm Everolimus Eluting Coronary Stent system (EES) in the treatment of patients with *de novo* coronary artery Lesions.
   Protocol version: 1.0.0 Dated 23rd Nov 2016
   Dr.Surseh Patted-PI
   - **EC Notification of CTRI Registration and Technical work sheet**
2. **Protocol:** A prospective, Single-centre, Observational, real world, Post-marketing surveillance to evaluate safety and performance of the BioMimeTM Morph Sirolimus Eluting Coronary Stent System for very long coronary lesions.
   Dr.Surseh Patted-PI
   - **EC Notification of CTRI Registration and Technical work sheet**
3. Protocol No: 20110118:"A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease
   Dr.V.A.Kothiwale-PI
   - EC notification of Final Monitoring Visit and Safety letter.
   - EC Notification of SUSAR's
4. **Protocol 3-001:** A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy

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Dr.Jayaprakash Appajigol-PI

- EC notification of **CIOMS** Report-REAP-00089 Event: Activated partial thromboplastin time prolonged-**Initial Report**
- EC notification of **CIOMS** Report-REAP-00089 Event: Activated partial thromboplastin time prolonged-**Follow up**

5. **Protocol:** "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''

Dr.Sanjay Porwal-PI

- EC Notification of CIOMS(SA#280&278)
- EC Notification of CIOMS(SA#278&279)
- EC Notification of CIOMS(SA#274&275)
- EC Notification of CIOMS(SA#276&277IN)
- EC Notification of CIOMS(SA#278&279IN)
- EC Notification of CIOMS(SA#280,corrigendum to SA#278)

6. **Protocol:** A phase III, randomized, double-blind, active, controlled, multinational, multicentre, non inferioritytrial using carbetocin roomtemperature stable (RTS) for the prevention ofpostpartum haemorrhage during the third stage oflabour in women delivering vaginally.

Dr.Shivaprasad S Goudar-PI

- **EC Notification of Investigator's Brochure memo**

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia to Member Secretary.

Yours truly,

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Member Secretary)

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KLE UNIVERSITY

JNMC Campus, Nehru Nagar, Belgaum-590 010, Karnataka State, India

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To: All the members:

1) Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2) Dr. M.S.Ganachari, Prof.& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3) Dr. Harsha V.Hegde, Scientist 'C' ICMR (RMRC), Nehru Nagar, Belagavi.
4) Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
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6) Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
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8) Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC,Belagavi
9) Dr.Nayana Hashilkar, Asso.Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10) Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.
11) Shri.Tamanna Dadu Kore,Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213
12) Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13) Mrs.Geetanjali Salimath, Asst.Prof. Dept.of Pharmacy Practice, Belagavi
14) Dr. Maheshkumar Veeranna Kalloli, Consultant, Oncology Dept., KLES Dr Prabhakar Kore Hospital & Medical Research Center,Nehru Nagar, Belgaum-590 010, Karnataka, India
15) The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
16) The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
17) Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2017-18/D- 1660 ***Date: 05/09/2017***

Circular

The meeting of **Ethics Committee** is Convened on ***Tuesday, 12th September 2017*** at **4:00 PM in Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New protocol for Approval

1) **Protocol Title:** A Two-Part, Open-Label, Randomized, Phase II/III Study of Dinutuximab and Irinotecan versus Irinotecan for Second Line Treatment of Subjects with Relapsed or Refractory Small Cell Lung Cancer
Protocol Number: DIV-SCLC-301
Dr.Mahesh Kumar Kalloli-PI
Note: above study was deferred from the previous meeting and the respective documents have been already dispatched with previous circular (31/08/2017).

2) **Study Title:** A Multicenter, Open Label, Balanced, Randomized, Two-Treatment, Two-Period, Two-Sequence, Single Dose, Cross-Over Bioequivalence Study of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL) of Cadila Healthcare Limited, India in comparison with Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL), of Sun Pharmaceutical Ind. Ltd, India, in the Patients of Ovarian Cancer under fasting conditions.
Dr.Mahesh Kumar Kalloli-PI

II) Agenda: For ongoing trial protocol:

3) **Protocol Title**: "A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy, Pharmacokinetics, Pharmacodynamics and Safety of LNP1892 (Monotherapy) in Chronic Kidney Disease (CKD) Patients with Secondary Hyperparathyroidism (SHPT), On Dialysis and Not on Dialysis."
Dr.Mallikarjun Karishetti-PI
- EC submission of study and study related documents for approval

III) Agenda: For Upcoming EC accreditation of FERCAP
- Greetings to FERCAP Assessors
- Review of survey forms of FERCAP trainee
- Review of survey forms of FERCAP surveyor

4) **The Committee will consider the following agendas which are for information:**

1) **Protocol No: 20110118**:"A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
Dr.V.A.Kothiwale-PI
- EC notification of Final clinical study report

2) **Protocol Title:** MYL-1402O-3001 :Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With

Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.

Dr.Mahesh Kalloli-PI

- EC notification of discrepancy in SAE analysis report letter dated 04/09/2017

3) **Protocol Title:** A Two-Part, Open-Label, Randomized, Phase II/III Study of Dinutuximab and Irinotecan versus Irinotecan for Second Line Treatment of Subjects with Relapsed or Refractory Small Cell Lung Cancer
Protocol Number: DIV-SCLC-301
Dr.Mahesh Kumar Kalloli-PI
   - EC notification of revised investigator Undertaking final CRF
4) **Protocol Title**: I4V-MC-JADY-A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
Dr.ShaileshV Udapudi-PI
   - EC notification of requisition of Re-approval
   - EC notification of Investigators Brochure for Barcitinib(LY3009104)
5) **Study Code:**D169AC00001
Protocol: A study to evaluate the effect of Dapagliflozin on renal outcomes and cardiovascular mortality in patients with chronic kidney disease
Dr.Mallikarjun S Karishetti-PI
   - EC notification of CTRI registration(CT/2017/08/009535)
6) **Study Title:** An open label, randomized, balanced, two-treatment, two-period, two-sequence, single-dose, crossover, oral bioequivalence study of 60 mg/m2 of Vinorelbine soft capsule from Lotus Pharmaceutical Co., Ltd., Taiwan compared with that of 60 mg/m2 of NAVELBINE® soft capsule marketed by PIERRE FABRE Limited, Winchester Hampshire S023 7DR, United Kingdom, in adult, patients with advanced breast cancer under fed conditions.
Dr.Mahesh Kumar-PI
   - EC notification of protocol Non compliance
7) **Study No: CT/DOX/1602**
Protocol Title: An Open-Label, Multicentric, Randomized, Two Treatment, Three Period, Three Sequence, Semi-Replicate, Cross-Over, Comparative Bioavailability study of Doxorubicin Hydochloride Liposomal Injection 20mg/10mL (2mg/ml), concentrate for solution for infusion manufactured by Teva Pharmachemie, Netharlands with caelyx 20 mg/10ml (2mg/ml), [Doxorubicin hydrochloride Liposomal Injection] concentrate for solution for infusion Of Janssen-Cilag International NV, Belgium in advanced ovarian cancer and/or metastatic breast cancer patients under fasting condition.
Dr.Mahesh Kumar-PI
   - EC notification of essential Documents

4. Protocol No: **EFC13889/ODYSSEY EAST**: A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
Dr.V.A.Kothiwale-PI

- EC notification of CIOMS(SA#7 IN)
- EC notification of CIOMS(SA#120&121IN)
- EC notification of CIOMS(SA#139&140IN)
- EC notification of CIOMS(SA#141&142IN)

Yours truly,

Prof. (Dr).M. S. Ganachari
(Name & Signature of Ethics Committee
Member Secretary)

Member Secretary
ETHICS COMMITTEE (EC)
KLE University, BELGAUM

To:

1) Dr. Subarna Roy, Scientist 'E', ICMR- National Institute of Traditional Medicine, Belagavi.
2) Dr. M.S.Ganachari, Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3) Dr. Harsha V.Hegde, Scientist 'C' ICMR- National Institute of Traditional Medicine, Belagavi.
4) Dr. P. A. Patil, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5) Dr. M.V. Jali, MD & CEO KLE Dr. Prabhakar Kore Hospital and MRC, Belagavi.
6) Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7) Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi
8) Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC, Belagavi
9) Dr.Nayana Hashilkar,Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10) Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.
11) Shri.Tamanna Dadu Kore, Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213
12) Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13) Mrs.Geetanjali Salimath, Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14) **Dr. Maheshkumar Veeranna Kalloli,** Consultant, Oncology Dept., KLES Dr Prabhakar Kore Hospital &MRC, Nehru Nagar, Belagavi-590 010.
15) The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
16) The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
17) Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2017-18/D- 4130. ***Date: 14/03/2017***

Circular

The meeting of **Ethics Committee (EC)** of the **KLE University** is convened on **Monday, 20th March 2017, 04:00 PM** at **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: Expedited Review And Approvals:

1. A prospective, multicentric, randomized, open-label comparision of long acting basal insulin analog Glargine plus Glulisine with premixed Insulin in adult patients with type 2 daibetes Mellitus.
   Dr.M.V.Jali-PI
2. "A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Long-term Safety and Efficacy of Darbepoetin Alfa Administered at 500 µg Once-Every-3-Weeks in Anemic Subjects With Advanced Stage Non-small Cell Lung Cancer Receiving Multi-cycle Chemotherapy."
   Dr.Rohan Bhise-PI

II. The Committee will consider the following agendas which are for information:

1. **Study Title:** A Prospective, Multi-centric, Randomized, Double-blind, Parallel, Saline Controlled Phase II Safety and Efficacy study of PMZ-2010 as a resuscitative agent for Hypovolemic Shock due to excessive blood loss to be used along with standard shock treatment.
   Study Protocol No.: PMZ-02; DCGI CT NOC No.: CT/ND/37/2016
   Dr.Madhav Prabhu-PI
   - **EC Notification of Renewed Insurance**
2. Protocol Number/ Title- [Pfizer, A0081105, "A randomized, double-blind, placebo-controlled, parallel group, multi-center trial of pregabalin as adjunctive therapy in pediatric and adult subjects with primary generalized tonic-clonic seizures", PAREXEL, 208238]
   Dr.Mahesh Kamate-PI
   - **EC Notification of budget Modification**
3. **Protocol No: EFC13889/ODYSSEY EAST**: A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
   Dr.V.A.Kothiwale-PI
   - EC notification of CIOMS(SA#60 &61)
   - EC notification of CIOMS(SA#71 &72)
   - EC notification of CIOMS(SA#73)
   - EC notification of CIOMS(SA#74 &75)
   - EC notification of CIOMS(SA#76)

- EC notification of CIOMS(SA#77 &78IN)
- EC notification of CIOMS(SA#79 &80)

4. **Protocol 3-001:** A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy
   Dr.Jayaprakash Appajigol-PI
   - EC notification of **CIOMS** Report-3001-00289 Event:1-Descending arota thrombus,2-Ischemic bowel/duodenal performation - **Follow up-03**
5. **Protocol:** "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''
   Dr.Sanjay Porwal-PI
   - EC Notification of Continuation of Approval
   - EC Notification of SUSAR's
   - EC Notification of CIOMS(SA#242 in & corrigendum to SA #136 and #204)
   - EC Notification of CIOMS(SA#256&257)
   - EC Notification of Study Update
   - **Protocol No: NCS-353-15-CS**
6. **Study Title:** An open label, randomized, balanced, two treatment, two period, two sequence, single dose, crossover, oral bioequivalence study of 600mg/m2 of Vinorelbine soft capsule from lotus pharmaceutical co., Ltd., Taiwan compared with that of 60 mg/m2 of NAVELBINE® soft capsule marketed by PIERRE FABRE Limited, Winchester Hampshire S023 7DR, United Kingdom, in adult, patients with advanced breast cancer under fed conditions.
   Dr.Mahesh Kumar Kalloli-PI
   - EC notification of Typographical Error in the study Update.
7. **Protocol ID No:** CRL121526

   Protocol Title: "A Randomized, Open-Label, Two Period, Two-Treatment, Two Sequence, Single-Dose, Crossover, Bioequivalence Study of Paclitaxel Protein-bound Particles for Injectable Suspension (albumin-bound) of Panacea Biotec, India with ABRAXANE® (Paclitaxel Protein-bound Particles for Injectable Suspension) (albumin-bound) manufactured for Celgene Corporation, Summit, NJ in Patients with Metastatic Breast Cancer under Fasting Conditions".
   Dr.Rohan Bhise-PI
   - EC Notification of CIOMS
8. **Protocol:** An Open label Clinical Study to Determine the Specificity and Sensitivity of Algorithm (Software) developed by Bosch using Bosch Mobile non-mydriatic fundus camera comparing it with mydriatic 7-Standard Field Stereoscopic Digital Color Fundus Photography(EDTRS) done in patients with undiagnosed diabetic retinopathy(Symptomatic/asymptomatic)

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Dr.Smitha Prabhu-PI

- EC Notification of clinical Study Report(CSR)

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia to Member Secretary.

Yours truly,

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Member Secretary)

Member Secretary
ETHICS COMMITTEE (EC)
KLE

To: All the members:

1) Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2) Dr. M.S.Ganachari, Prof.& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3) Dr. Harsha V.Hegde, Scientist 'C' ICMR (RMRC), Nehru Nagar, Belagavi.
4) Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5) Dr. M.V. Jali, MD & CEO KLE Dr.Prabhakar Kore Hospital and MRC, Belagavi.
6) Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7) Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi
8) Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC,Belagavi
9) Dr.Nayana Hashilkar, Asso.Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10) Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.

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13) **Mrs.Geetanjali Salimath,** Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14) Dr.Rohan Bhise, Consultant,Dept.of Oncology , KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi. Principal Investigator -For Information.
15) The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
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17) Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2017-18/D- 2325 **Date: 08/11/2017**

IEC Meeting Agenda

Institutional Ethics Committee, KLE University
Monday, 20/11/2017, At: 4.00 PM
Venue: Site management Office

I. **Agenda: New protocol for Approval:**

1. **Protocol: NN BIAsp-4343** "A multi-centre prospective, non-interventional study of ability and willingness to pay for BIAsp 30 in a real world population with type 2 diabetes mellitus"
   Dr.M.V.Jali-PI
2. **Protocol Title** A Phase-IV Post-Marketing Clinical Study Evaluating the Efficacy, Safety and Tolerability of Hetero's FDC Sofosbuvir+Ledipasvir in Indian, Adult Chronic Hepatitis-C Patients
   Protocol No: HCR/IV/Sofos-Ledip/12/2015
   Dr.Santosh Hajare –PI
3. **Protocol Title:** A Phase-IV Post-Marketing Clinical Study Evaluating the Efficacy, Safety and Tolerability of Hetero - Sofosbuvir in Indian, Adult Chronic Hepatitis-C Patients (HeSoC Study)
   Protocol No: HCR/IV/Sofos/03/2015
   Dr.Santosh Hajare –PI
4. **Study Protocol No.: LRP/LNP3794/2016/006**
   Study Protocol Title: A Phase II/III Pivotal, Open-label, Randomized, 3-Arm Study to Assess the Efficacy of LNP3794 Monotherapy or in Combination with Docetaxel, Compared with Docetaxel Alone, in Patients with RAS Mutation-Positive Locally Advanced and Metastatic Non-Small Cell Lung Cancer
   Dr.Mahesh Kumar Kalloli-PI

II. **Review of Proposals with Revision and Amendments:**

5. **Protocol:** An open label extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in Certolizumab phase II/III studies.
   Protocol No: GA28951
   Dr.Varadaraj Prahldrao Gokak-PI
6. **Protocol**: Phase III, Randomized, Double-blind, Placebo-controlled, multicenter study to evaluate the efficacy (maintenance of remission) and safety of Etrolizumab compared with placebo in patients with moderate to severe active Ulcerative Colitis who are naive to TNF Inhibitors.
   Protocol No: GA29102
   Dr.Varadaraj Prahldrao Gokak-PI

III. **The Committee will consider the following agendas which are for information.**

1) **Protocol title:** A multicenter, open label, balanced, randomized, two treatment, three period, three sequence, reference replicate crossover, single dose, oral bioequivalence study of Capecitabine Film Coated Tablets 500mg of Shilpa Medicare Limited, India and Xeloda® Film Coated Tablets 500mg (Capecitabine) marketed by Roche Registration Limited, 6 Falcon Way, Shire Park,

Welwyn Garden City, AL7 1 TW United Kingdom following single oral dose of 2000mg (4x500mg) in adult human cancer patients under fed conditions.

Dr.Mahesh Kumar Kalloli-PI

- EC notification of Clinical study report
- EC notification of study site close out

2) **Protocol Title:** 3-001 A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.

Dr.Japrakash Appajigol-PI

- EC notification of updated insurance certificate letter dated 23/10/2017
- **EC notification of CIOMS** Report:3001-00289 Event: Descending aorta thrombus and Ischemic Bowel/Duodenal perfusion-FU04
- **EC notification of CIOMS** Report:REAP00135 Event: Multi organ Failure-Initial
- **EC notification of CIOMS** Report:REAP00133 Event: Postoperative perfusion-Initial
- **EC notification of CIOMS** Report: IPN1-00002 Event: Lung Cancer-Initial
- **EC notification of CIOMS** Report:3001-00379 Event: Cardiac tumor with active bleeding Report: Initial
- **EC notification of CIOMS** Report:3001-00390 Event: Cardiac tumor with active bleeding Report: FU01
- **EC notification of CIOMS** Report:3001-00390 Event: Cardiac tumor with active bleeding Report: FU02
- **EC notification of CIOMS** Report:REAP-00125 Event: Chills Report: Initial
- **EC notification of CIOMS** Report:REAP-00125 Event: Chills Report: FU 01
- **EC notification of CIOMS** Report:3001-00366 Event: Brain atrophia of Posterior fossa(Brain atrophia of posterior atrophy) Report: FU 02

3) **Protocol:** "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''

Dr.Sanjay Porwal-PI

- EC Re- notification of CIOMS letter dated: 05/10/2017
- EC notification of incorrect date in the EC notification letter
- EC Submission of Clarification letter for Re-Notification of Safety alert
- EC notification of CIOMS(Safety alert-SA#175IN)

4) **Protocol Title:** I4V-MC-JADY-A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.

Dr.Shailesh Udapudi-PI

- EC notification of IB (LY3009104) dated (27/10/2017)

5) **Protocol Title:** A Two-Part, Open-Label, Randomized, Phase II/III Study of Dinutuximab and Irinotecan versus Irinotecan for Second Line Treatment of Subjects with Relapsed or Refractory Small Cell Lung Cancer

Protocol Number: DIV-SCLC-301

Dr.Mahesh Kumar Kalloli-PI

- EC notification of protocol clarification letter#2, dated 15/Jul/2017
- EC notification of the part 1 study of SRC meeting letter

6) **Protocol Title:** MYL-1402O-3001 :Multicenter, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First - line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.

Dr.Mahesh Kalloli-PI

- EC notification of SAE-**Death** Subject No: 171007 Final - Report: 24/10/2017
- EC notification of SAE-**Prophylaxis** Subject No: 171005-Initial Report: 27/10/2017
- EC notification of renewed insurance
- EC notification of CIOMS for Subject ID:16606 of FU01-Event: Terminal cardiorespiratory arrest, Leukopenia
- EC notification of CIOMS for Subject ID:165016 of Initial-Event: Death
- EC notification of CIOMS for Subject ID:171005 of Initial -Event: Gastroenteritis
- EC notification of CIOMS for Subject ID:171005 of FU02 -Event: Allergic reaction
- EC notification of CIOMS for Subject ID:171006 of FU01 -Event: Allergic reaction
- EC notification of CIOMS for Subject ID:171008 of Initial -Event: Gastroenteritis
- EC notification of CIOMS for Subject ID:171008 of FU03 -Event: Death
- EC notification of CIOMS for Subject ID:185001 of FU01 -Event: Febrile Neutropenia
- EC notification of CIOMS for Subject ID:187003 of FU01-Event: Death
- EC notification of CIOMS for Subject ID:187003 of FU02-Event: Death
- EC notification of CIOMS for Subject ID:186004 of FU02 -Event: Death
- EC notification of CIOMS for Subject ID:186006 of Initial -Event: Death
- EC notification of CIOMS for Subject ID:187001 of Initial-Event: Breathlessness
- EC notification of CIOMS for Subject ID:187001 of FU01-Event: Death
- EC notification of CIOMS for Subject ID:187003 of Initial-Event: terminal cardiorespiratory arrest, Leukopenia
- EC notification of CIOMS for Subject ID:292001 of Initial-Event: Vomiting

7) **Protocol Number/ Title-** [Pfizer, A0081105, "A randomized, double-blind, placebo-controlled, parallel group, multi-center trial of pregabalin as adjunctive therapy in pediatric and adult subjects with primary generalized tonic-clonic seizures", PAREXEL, 208238]

Dr.Mahesh Kamate-PI

- EC notification of SAE line listing report from 18/Jan/2017 through 09/Oct/2017

8) **Protocol IDRFARH007:** "A Prospective, Multicenter, Randomized, Open-Label Comparison of Long-Acting Basal Insulin Analog Glargine plus Glulisine with Premixed Insulin in Adult Patients with Type 2 Diabetes Mellitus.

Dr.M.V.Jali-PI

- EC notification of protocol deviation letter dated 28/10/2017

9) **Protocol title:** A Randomized, Double –blind, Placebo-controlled Study to Evaluate the Long-term safety and Efficacy of Darbepoetin Alfa Administered at 500µg Once-Every-3-Weeks in Anaemic Subjects with Advanced Stage Non-small Cell Lung Cancer Receiving Multi Cycle Chemotherapy.

Dr.Rohan Bhise-PI

- EC notification of Investigator brochure 17.0 dated 17/Jul/2017

10) **Any other matter with the permission of the chair**

For your attention:

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia, to Member Secretary.

Yours truly,

09/11/2017

Prof. (Dr).M. S. Ganachari
(Name & Signature of Ethics Committee
Member Secretary)

Member Secretary
ETHICS COMMITTEE (EC
KLE University, BELGAUM

To:

1) Dr. Subarna Roy, Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi.
2) Dr. M.S.Ganachari, Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3) Dr. Harsha V.Hegde, Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.
4) Dr. P. A. Patil, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5) Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
6) Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi
7) Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC, Belagavi
8) Dr.Nayana Hashilkar, Prof. of Pharmacology, J.N. Medical College, Belagavi.

9) Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.

10) Shri.Tamanna Dadu Kore, Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213

11) Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.

12) Mrs.Geetanjali Salimath, Asst.Prof. Dept. Of Pharmacy Practice, Belagavi

13) **Dr. M.V. Jali,** MD & CE, KLEs Dr.Prabhakar Kore Hospital and MRC, Belagavi.

14) **Dr.Santosh Dhananjay Hajare,** Consultant Gastroenterologist, KLES Dr. Prabhakar Kore Hospital & MRC,Belagavi-10

15) **Dr. Maheshkumar Veeranna Kalloli,** Consultant, Oncology Dept., KLES Dr. Prabhakar Kore Hospital &MRC, Nehru Nagar, Belagavi-590 010.

16) The Registrar, KLE University, JNMC Campus, Belagavi –For Information.

17) The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.

18) Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2017-18/D- 1720 ***Date: 07/09/2017***

Circular

The meeting of **Ethics Committee** is Convened on ***Saturday, 16th September 2017*** at **4:00 PM** in **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New protocol for Approval:

1) **Protocol Title:** A Multicentre, Open Label, Balanced, Randomized, Two Treatment, Two-Period, Two Sequence,, Single Dose, Cross-Over Bioequilance Study Of Doxorubicin Hydrochloric Liposome Injection 2 mg/ml Of Cipla Limited India, in comparison with Doxorubicin Hydrochloric Liposome Injection 2 mg/ml Sun Pharmaceutical Ind.Ltd India, In The Patients Of Ovarian Cancer Under Fasting Conditions
Protocol No: CRD/08
Dr.Rohan Bhise-PI

II. The Committee will consider the following agendas which are for information:

1) **Protocol Title:** MYL-1402O-3001 :Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.
Dr.Mahesh Kalloli-PI
   - EC notification of CIOMS for Subject ID:175002 of Initial-Event: Acute Kidney Injury and dehydration
   - EC notification of CIOMS for Subject ID:175002 of FU-01-Event: Death
   - EC notification of CIOMS for Subject ID:175002 of FU-02-Event: Death
   - EC notification of CIOMS for Subject ID:175002 of FU-03-Event: Death
   - EC notification of CIOMS for Subject ID:186004 of Initial-Event: Septic shock
2) **Study Code:**D169AC00001
Protocol: A study to evaluate the effect of Dapagliflozin on renal outcomes and cardiovascular mortality in patients with chronic kidney disease
Dr.Mallikarjun S Karishetti-PI
EC notification of study Documents letter dated: 01/Sep/2017
3) **Study Code: D1699C00001**
Protocol: A Study to Evaluate the Effect of Dapagliflozin on the Incidence of worsening heart failure or Cardiovascular Death in patients with chronic Heart Failure with reduced Ejection Fraction.
Dr.Kothiwale-PI
EC notification of study Documents letter dated: 01/Sep/2017
4) Protocol No: **EFC13889/ODYSSEY EAST**: A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
Dr. V.A.Kothiwale-PI

SK

- EC notification of CIOMS(SA#329&330IN)
- EC notification of CIOMS(SA#135&136IN)

5) **Protocol Title:** 3-001 A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
Dr.Japrakash Appajigol-PI
   - EC notification of CIOMS

Yours truly,

Prof. (Dr).M. S. Ganachari
(Name & Signature of Ethics Committee
Member Secretary)
To:

1) Dr. Subarna Roy, Scientist 'E', ICMR- National Institute of Traditional Medicine, Belagavi.
2) Dr. M.S.Ganachari, Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3) Dr. Harsha V.Hegde, Scientist 'C' ICMR- National Institute of Traditional Medicine, Belagavi.
4) Dr. P. A. Patil, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5) Dr. M.V. Jali, MD & CEO KLE Dr. Prabhakar Kore Hospital and MRC, Belagavi.
6) Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7) Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi
8) Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC, Belagavi
9) Dr.Nayana Hashilkar,Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10) Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.

11) Shri.Tamanna Dadu Kore, Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213
12) Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13) Mrs.Geetanjali Salimath, Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14) **Dr.Rohan Bhise,** Dept. of Oncology, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590 010,Karnataka,India
15) The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
16) The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
17) Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2017-18/D- 185 ***Date: 21/04/2017***

Circular

The meeting of **Ethics Committee (EC)** of the **KLE University** is convened on Thursday, **27th April 2017, 04:00 pm** at **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New protocol for Approval

1. **Research Project** "Sit Down and Play(SDP")
   Dr.S.M.Dhaded-PI
2. **Protocol Title:** A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy, Pharmacokinetics, Pharmacodynamics and Safety of LNP1892 (Monotherapy) in Chronic Kidney Disease (CKD) Patients with Secondary Hyperparathyroidism (SHPT), On Dialysis and Not on Dialysis
   Dr. Mallikarjun S karishetti-PI
3. **Protocol:** A retrospective, Single-center, study to evaluate safety and performance of the Evermine 50-50µm Everolimus Eluting Coronary Stent System (EES) in the treatment of patients with de novo coronary artery lesions.
   Dr.Suresh V Patted-PI
4. **Protocol No :** 17-VIN-0028
   Protocol: An open label, balanced, randomized, two-treatment, two-sequence, two-period, crossover, multi center, multiple dose steady state bioequivalence study of Everolimus tablets 10 mg of Dr. Reddy's Laboratories Limited, India comparing with that of AFINITOR® (everolimus) tablets 10 mg, Manufactured by Novartis Pharma Stein AG Stein, Switzerland in subjects of advanced renal cell carcinoma (RCC) who are already receiving Everolimus at a stable dose of 10 mg once a day as their individual therapy.
   Dr.Mahesh Kumar Kalloli-PI
5. **Study No: CT/DOX/1602**
   Protocol Title: An Open-Label, Multicentric, Randomized, Two Treatment, Three Period, Three Sequence, Semi-Replicate, Cross-Over, Comparative Bioavailability study of Doxorubicin Hydochloride Liposomal Injection 20mg/10mL (2mg/ml), concentrate for solution for infusion manufactured by Teva Pharmachemie, Netharlands with caelyx 20 mg/10ml (2mg/ml), [Doxorubicin hydrochloride Liposomal Injection] concentrate for solution for infusion Of Janssen-Cilag International NV, Belgium in advanced ovarian cancer and/or metastatic breast cancer patients under fasting condition.
   Dr.Mahesh Kumar Kalloli-PI
6. **Protocol No:** #CBT124/CT/002
   Protocol :A randomized ,double-blind, multicentric, parallel group study comparing efficacy , safety and immunogenicity of CBT124 , a candidates biosimilarbevacizumab in

combination with carboplatin and paclitaxel with EU sourced Avastin in combination with carboplatin and paclitaxel in first-line treatment for patients with stage IV (unresectable recurrent disease or metastatic) nonsquamous non-small cell lung cancer NSCLC)
Dr.Rohan Bhise-PI

II. Agenda: For Ongoing Trial Approval:

7. **Protocol title:** A Randomized, Double –blind, Placebo-controlled Study to Evaluate the Long-term safety and Efficacy of Darbepoetin Alfa Administered at 500µg Once-Every-3-Weeks in Anaemic Subjects with Advanced Stage Non-small Cell Lung Cancer Receiving Multi Cycle Chemotherapy.
   Dr.Rohan Bhise-PI
   - Ethics Committee submission of ICF Documents for approval

III. The Committee considered the following agendas which were for information:

1. **A65870:** A phase III, randomised, double-blind, active, controlled, multinational, multicentre, non inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum haemorrhage during the third stage of labour in women delivering vaginally.
   Dr.Shivaprasad S Goudar-PI
   - EC notification of insurance letter through 01/Oct/2017
   - EC Notification of Update in Recruitment number from 1600 to 1800 participants
2. **Study No: CT/DOX/1602**
   Protocol Title: An Open-Label, Multicentric, Randomized, Two Treatment, Three Period, Three Sequence, Semi-Replicate, Cross-Over, Comparative Bioavailability study of Doxorubicin Hydochloride Liposomal Injection 20mg/10mL (2mg/ml), concentrate for solution for infusion manufactured by Teva Pharmachemie, Netharlands with caelyx 20 mg/10ml (2mg/ml), [Doxorubicin hydrochloride Liposomal Injection] concentrate for solution for infusion Of Janssen-Cilag International NV, Belgium in advanced ovarian cancer and/or metastatic breast cancer patients under fasting condition.
   Dr.Mahesh Kumar Kalloli-PI
   - EC Notifications of Insurance certificate and DCGI Approval letter
3. **Protocol Title** "A Randomized, Open-Label, Two Period, Two-Treatment, Two Sequence, Single-Dose, Crossover, Bioequivalence Study of Paclitaxel Protein-bound Particles for Injectable Suspension (albumin-bound) of Panacea Biotec, India with ABRAXANE® (Paclitaxel Protein-bound Particles for Injectable Suspension) (albumin-bound) manufactured for Celgene Corporation, Summit, NJ in Patients with Metastatic Breast Cancer under Fasting Conditions".
   Dr.Rohan Bhise-PI
   - **EC Notification of CIOMS letter dated:13/04/2017**

4. **Protocol Title:**"Aspirin Supplementation for Pregnancy Indicated Risk Reduction in Nulliparas (ASPIRIN)"
   Dr.M.C.Metgud-PI
   - **SAE** Term- **Maternal Death** subject ID:1-08-0049-F
     Initial Report: 30/03/2017
     Final Report: 31/03/2017
5. **Protocol title:** A multicenter, open label, balanced, randomized, two treatment, three period, three sequence, reference replicate crossover, single dose, oral bioequivalence study of Capecitabine Film Coated Tablets 500mg of Shilpa Medicare Limited, India and Xeloda® Film Coated Tablets 500mg (Capecitabine) marketed by Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1 TW United Kingdom following single oral dose of 2000mg (4x500mg) in adult human cancer patients under fed conditions
   Dr.Mahesh Kumar Kalloli-PI
   - EC Notification of investigator brochure, subject Randomization work Sheet and Copy of CRF worksheets
   - EC notification of Memo100 Completion of site activities-23Jan 2017.
   - EC notification of DCGI letter
4. **Protocol Title:** "Maternal Docosa-hexaenoic acid (DHA) Supplementation and offspring neurodevelopment in India (DHANI-2) randomized controlled trial".
   Dr.M.K Swamy-PI
   - **EC notification of SAE**
     SAE Term: Preterm premature rupture of membrane [**PPROM]** delivered a 540gm baby which was afresh **still birth:** for Subject no: **R0572**
5. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy
   Dr.Jayaprakash Appajigol-PI
   - EC notification of **CIOMS** Report-3001-00092 Event:1-Multi Organ failure-**Follow up01**
6. **Protocol Title:** Evaluation of efficacy, safety and tolerability of a combination therapy with chlorzoxazone and ibuprofen compared to ibuprofen alone in the symptomatic treatment of Acute Low Back Pain (LBP): An open lable, prospective, observational study
   Dr.R.B.Uppin-PI
   - EC Notification of Archival of study documents

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Please make it convenient to attend the meeting and, communicate if you seek leave of absentia to Member Secretary.

Yours truly,

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Member Secretary)

Member Secretary
ETHICS COMMITTEE (EC)
KLE University, BELGAUM

To: All the members:

1) Dr. Subarna Roy, Scientist 'E', Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2) Dr. M.S.Ganachari, Prof.& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3) Dr. Harsha V.Hegde, Scientist 'C' ICMR (RMRC), Nehru Nagar, Belagavi.
4) Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5) Dr. M.V. Jali, MD & CEO KLE Dr.Prabhakar Kore Hospital and MRC, Belagavi.
6) Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7) Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi
8) Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC,Belagavi
9) Dr.Nayana Hashilkar, Asso.Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10) Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.
11) Shri.Tamanna Dadu Kore,Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213
12) Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13) Mrs.Geetanjali Salimath, Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14) **Dr. S M Dhaded**, Professor of Paediatrics, JNMC,Consultant, KLES Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belgaum-590010
15) **Dr.Suresh V Patted,** Professor and HOD of Cardiology department, J.N.Medical Collage, Belagavi-10

16) **Dr. Mallikarjun S Karishetti-** Chief Consultant Nephrology, KLE'S Dr.Prabhakar Hospital &MRC,Belagavi
17) **Dr. Mahesh Kalloli,** Consultant,Dept.of Oncology , KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi.
18) **Dr.Rohan Bhise,**Dept. of Oncology, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi - 590 010
19) The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
20) The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
21) Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2017-18/D- 894 **Date: 05/07/2017**

Circular

The meeting of **Ethics Committee** meeting that was scheduled to happen on the **Wednesday 28th June 2017** has been postponed to ***Monday 10th July 2017*, 4:00 PM** at **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New protocol for Approval

1. **Study No: 20140444**
   Drug: Denosumab
   Protocol Title: A Phase 3 randomized, Double-blind, Placebo-Controlled, Parallel-group Study to evaluate the safety and Efficacy of Denosumab in pediatric Subjects with Glucocorticoid-induced Osteoporosis
   Dr.N.S.Mahantashetti-PI
2. Protocol Number: APL/CT/12/001
   Protocol Title: "A Comparative, Two Arm, Randomized, Double Blind, Parallel Group, Multicentre, Non-Inferior Clinical Study to Evaluate Efficacy, Safety and Tolerability of Iguratimod Tablets 25 mg as an add on Therapy over Methotrexate Tablets 15 mg Vs. Methotrexate Tablets 25 mg for the treatment of Patients with active Rheumatoid Arthritis "
   Dr.Archana Uppin -PI
3. **Protocol:** A retrospective, Single-center, study to evaluate safety and performance of the Evermine 50-50μm Everolimus Eluting Coronary Stent System (EES) in the treatment of patients with de novo coronary artery lesions.
   Dr. Suresh V Patted-PI
   Note: above study was deferred from the previous meeting and the respective documents have been already dispatched with previous circular **(27/Apr/2017).**
4. **Protocol title: Breastfeeding Education Support Tool for Baby (BEST4Baby)**
   Dr.N.S.Mahantashetti-PI
   Note: Additional Agenda

II. Agenda: For Ongoing Trial Approval:

5. **Protocol:** "Comparative evaluation of immunogenicity of various schedules and delivery options to provide fractional Dose Inactivated Poliovirus Vaccine in routine immunization in the post tOPV-bOPV period: A multi-centric open label randomized controlled trial"(India fractional dose IPV study)
   Dr.N.S.Mahantashetti-PI
   - EC Review and Approval of clinical Trial Documents

   Note: Documents Circulated in the Previous Meeting **(3)**
6. **Protocol No: EFC13889/ODYSSEY EAST**: A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727)

Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
Dr.V.A.Kothiwale-PI

- EC Review and Approval of Trial Participation Pocket Card

7. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   Dr.Jayaprakash Appajigol-PI
   - EC Review and Approval of Protocol amendment and ICF Amendment
8. **Protocol Title:** I4V-MC-JADY-A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   Dr.S V Udapudi-PI
   - EC review and approval of revised study documents
9. **Protocol no: CLR_15_06**
   Protocol Title: A Multi-Center, Open-Label, Randomized, Crossover, Aqueous Humor Bioequivalence Study of Loteprednol Etabonate Ophthalmic Suspension 0.5% (Sun Pharmaceutical Industries, Ltd.) and Lotemax® (Loteprednol Etabonate Ophthalmic Suspension 0.5%; Bausch & Lomb, Inc.) in Subjects With Indicated Bilateral Cataract Surgery.
   Dr. Rekha Mudhol-PI
   - EC review and approval of study documents.
10. **Study No: CT/DOX/1602**
    Protocol Title: An Open-Label, Multicentric, Randomized, Two Treatment, Three Period, Three Sequence, Semi-Replicate, Cross-Over, Comparative Bioavailability study of Doxorubicin Hydochloride Liposomal Injection 20mg/10mL (2mg/ml), concentrate for solution for infusion manufactured by Teva Pharmachemie, Netharlands with caelyx 20 mg/10ml (2mg/ml), [Doxorubicin hydrochloride Liposomal Injection] concentrate for solution for infusion Of Janssen-Cilag International NV, Belgium in advanced ovarian cancer and/or metastatic breast cancer patients under fasting condition.
    Dr.Mahesh Kalloli-PI
    - EC review and approval of study documents.

III. The Committee considered the following agendas which were for information:

1. **Protocol No: NCS-353-15-CS**
   Study Title: An open label, randomized, balanced, two treatment, two period, two sequence, single dose, crossover, oral bioequivalence study of 600mg/m2 of Vinorelbine soft capsule from lotus pharmaceutical co., Ltd., Taiwan compared with that of 60 mg/m2 of NAVELBINE® soft capsule marketed by PIERRE FABRE Limited, Winchester Hampshire S023 7DR, United Kingdom, in adult, patients with advanced breast cancer under fed conditions.
   Dr.Mahesh Kumar Kalloli-PI
   - EC Notification of Protocol Deviation
   - EC Notification of Study update

2. **Research Project:**"Aspirin Supplementation for Pregnancy Indicated Risk Reduction in Nulliparas (ASPIRIN)"
   Dr.Shivaprasad S Goudar-PI
   - EC Notification of DMC letter
   - EC Notification of SAE: Post-Partum Haemorrahage
3. **Research Project:** "Women First: Preconception Maternal Nutrition
   Dr.B S Kodkany-PI
   - EC Notification of DMC letter
4. **Research Project:** Maternal New Health Registry
   Dr.B S Kodkany-PI
   - EC Notification of DMC letter
5. **Protocol Title:** "Better Birth: Trial of WHO Safe Childbirth Checklist Program" in Uttar Pradesh.
   Dr.B S Kodkany-PI
   - EC Notification of progress Report and requisition letter for continuation of approval letter
6. **A65870:** A phase III, randomised, double-blind, active, controlled, multinational, multicentre, non inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum haemorrhage during the third stage of labour in women delivering vaginally.
   Dr.Shivaprasad S Goudar-PI
   - EC notification of ICF memo dated 08-Nov-2016
   - EC notification of annual Status Report
   - EC notification of observations during monitoring visit (Pt No:08737)
   - EC notification of observations during monitoring visit(Pt No:09035)
   - EC notification of observations during monitoring visit(Pt No:09185)
   - EC Notification of Details of medical management Provided and health status of the subject No:08666
   - EC Notification of Details of medical management Provided and health status of the subject No:08595
7. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy
   Dr.Jayaprakash Appajigol-PI
   - EC notification of **CIOMS** Report-001-00335 Event:1-Elevated Liver Enzymes(GLDH)-**Initial**
   - EC notification of **CIOMS** Report-00094 **Event:** left Cerebellar haemorrhage - **Initial**
   - EC notification of **CIOMS** Report-00096 **Event**: idiopathic thrombocytopenic purpura -**Initial**
   - EC notification of **CIOMS** Report-00096 **Event**: idiopathic thrombocytopenic purpura -**Final**
   - EC notification of **CIOMS** Report-00089 **Event**: Activated partial thromboplastin time prolonged-**Initial**

- EC notification of **CIOMS** Report-3001-00339 **Event**: Necrotic toes-**Initial**
- EC notification of **CIOMS** Report-3001-00339 **Event**: Necrotic toes- **follow Up-01**
- EC notification of **CIOMS** REAP-00092 **Event**: Multi-Organ failure-**FUp-01**
- EC Notification of Continuation of approval above referenced study
- EC Notification of updated Investigator brochure version#9.0 dated 24/Apr/2017

8. **Protocol:** "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''

   Dr.Sanjay Porwal-PI

   - EC Notification of Protocol Deviation with Subject No:356103021
   - EC Notification of 11th Semiannual Report
   - EC Notification of IB, Edition 10 dated 27/02/2017
   - EC Notification of CIOMS (SA#281IN)
   - EC Notification of CIOMS (SA#284&285IN)
   - EC Notification of CIOMS (SA#286&287IN)
   - EC Notification of CIOMS (SA#288&289IN)
   - EC Notification of CIOMS (SA#290-291 IN)
   - EC Notification of CIOMS (SA#292 IN)
   - EC Notification of CIOMS (SA#293 IN)
   - EC Notification of CIOMS (SA#294-295 IN)
   - EC Notification of CIOMS (SA#296-297 IN)
   - EC Notification of CIOMS (SA#298-299 IN)
   - EC Notification of CIOMS (SA#300-301IN)
   - EC Notification of CIOMS (SA#302-303IN)
   - EC Notification of CIOMS (SA#304-305IN)
   - EC Notification of CIOMS (SA#310-311IN)
   - EC Notification of CIOMS (SA#312 IN)
   - EC Notification of CIOMS (SA#313-314 IN)
   - EC Notification of Insurance Certificate
   - EC Notification of Protocol Deviation
   - EC Notification of issue- regarding subject card

9. **Protocol:CRL091523:**A Multi-Centre, Randomized, Open-Label, Two Period, TwoTreatment, Two Sequence, Multiple-Dose, Crossover, Bioequivalence Study of Pramipexole Prolonged Release Tablets 3.15 mg of Mylan Laboratories Ltd., India with Sifrol® 3.15 mg (Pramipexole) depottabletter (depot tablet) of Boehringer Ingelheim International GmbH, Germany in Patients with Idiopathic Parkinson's disease. PROTOCOL VERSION: 1.0, dated 16 Sep 2015

   Dr.Madhav Prabhu-PI

   - EC Notification of close out letter

10. **Protocol:** A multicentre, open label, balanced, Randomized, two treatment, three period, three sequence, reference replicate crossover, single dose, oral bioequilance study of Capecitabine film coated tablets 500mg of shilpa medicare Limited, India and Xeloda® Film Coated tablets 500mg(Capecitabine) marketed by Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City,AL7 1 TW United Kingdom following single oral dose of 2000mg (4×500mg) in adult human cancer patients under fed conditions.
    Protocol No: P-762/16
    Dr.Mahesh Kumar Kalloli-PI
    - EC Notification of Fully executed CTA
    - EC Notification of Protocol Deviation
11. **Protocol:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
    Dr.V.A.Kothiwale-PI
    - EC notification of site closure memorandum
    - EC Notification of PK Sampling discrepancies
    - EC Notification of Note to file(NTF)
    - EC Notification of Protocol Deviation
12. **Protocol: EFC13889/ODYSSEY EAST:** A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
    Dr.V.A.Kothiwale-PI
    - EC Notification of Investigator Brochure
    - EC Notification of CIOMS (Safety Alert#90&91IN)
    - EC Notification of CIOMS (Safety Alert#92&93IN)
    - EC Notification of CIOMS (Safety Alert#94&95 IN)
    - EC Notification of CIOMS (Safety Alert#96&97 IN)
    - EC Notification of CIOMS (Safety Alert#98&99 IN)
    - EC Notification of CIOMS (Safety Alert#100&101 IN)
    - EC Notification of CIOMS (Safety Alert#102&103 IN)
    - EC Notification of CIOMS (Safety Alert#104 IN)
    - EC Notification of CIOMS (SA#105&106IN)'
    - EC Notification of SASR#11
13. **Protocol title:** A Randomized, Double –blind, Placebo-controlled Study to Evaluate the Long-term safety and Efficacy of Darbepoetin Alfa Administered at 500µg Once-Every-3-Weeks in Anaemic Subjects with Advanced Stage Non-small Cell Lung Cancer Receiving Multi Cycle Chemotherapy.
    Dr.Rohan Bhise-PI

- EC notification of Memorandum for darbepoetin Alfa,20070782-Early study termination
- EC notification of Memorandum primary Analysis/ Final Database
- EC Notification of SUSAR's

14. **Reaserch Project**: "Evaluation of the introduction of a novel device in the management and shock in pregnancy in low-resource settings" under CARDLE III (Community Blood Pressure Measurement in Rural Africa and Asia: the detection of Underlying Pre-eclampsia and Shock) stepped- wedge Randomized Control Trial.
Dr.S S Goudar-PI
    - EC Submission of Data collection tools

15. **Protocol ID No:** CRL121526
Protocol Title: "A Randomized, Open-Label, Two Period, Two-Treatment, Two Sequence, Single-Dose, Crossover, Bioequivalence Study of Paclitaxel Protein-bound Particles for Injectable Suspension (albumin-bound) of Panacea Biotec, India with ABRAXANE® (Paclitaxel Protein-bound Particles for Injectable Suspension) (albumin-bound) manufactured for Celgene Corporation, Summit, NJ in Patients with Metastatic Breast Cancer under Fasting Conditions.",
Dr.Rohan Bhise-PI
    - EC Notification of CIOMS

16. **Protocol** : VRL/CSE-1034/05/2012 "A Randomized, Double-blind, Double-dummy, Active-controlled, Multi-centre Trial to Compare the Efficacy and Safety of CSE-1034 (Ceftriaxone+ Sulbactam+ EDTA) with Meropenem in Infections Caused by β – Lactamase (ESBL and MBL) producing Gram Negative Bacteria."
Dr.Madhav Prabhu-PI
    - EC Notification of study update

17. **Project # MYL-1402O-3001**:Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.
Dr. Mahesh Kumar Kalloli-PI
    - EC notification of **CIOMS** MFR No:2017M1035938 **Event:**1-**Death**:-**Initial**
    - EC notification of **CIOMS** MFR No:2017M1031977 **Event:**1-Febrile Neutropenia, hyponatremia-**Follow Up-1**
    - EC notification of **CIOMS** MFR No:-2017M1030833 **Event:**1-Febrile neutropenia, Sepsis-**Follow Up-02**
    - EC notification of **CIOMS** MFR No:-2017M1027701 **Event:**1-Dyspnoea-**Initial**
    - EC notification of **CIOMS letter dated on: 08/Jun/2017**

18. **Protocol:** A randomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose, crossover, pivotal steady state bioequivalence study of Everolimus 10 mg tablet, Manufactured by Teva Pharmaceuticals - Pliva Croatia Ltd., Prilaz baruna Filipovica 25, 10000 Zagreb Croatia vs. Afinitor®(Everolimus) 10 mg

tablet of Novartis Pharmaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients under fasting conditions

Dr. Mahesh Kumar Kalloli – PI

- EC Notification of retrieval of study Documents for USFDA Audit

19. **Protocol Title:** "Maternal Docosa-hexenoic acid (DHA) Supplementation and offspring neurodevelopment in India – (DHANI-2)".
    Dr.M.K. Swamy-PI
    - EC notification of SAE event: Fresh stillbirth
20. **Project # CRL121429 :** A Randomized, Open-Label, Two Period, Two-Treatment, Two Sequence, Crossover, Multiple-Dose, Steady State, Bioequivalence Study of Clozapine Tablets 100 mg of Cadila healthcare Ltd., India with Clozaril® (Clozapine) Tablets 100mg Manufactured by: Novartis Pharmaceutical corporation, Suffern, New York 10901 in Patients with Schizophrenia or Schizoaffective Disorder under Fasting Conditions.
    Dr.N.M.Patil-PI
    - EC Notification of study Close out
21. **Protocol Number: PBL/CR/2013/01/CT/EFPOL**
    PROTOCOL TITLE: An Open Label, Randomized, Multicenter study to Evaluate and Compare the Immunogenicity and Reactogenicity of DTwP-Hib-IPV vaccine (EasyfourPol™, Panacea Biotec Ltd.) with Quadrovax™ (Tetravalent DTwP/Hib Vaccine, Serum Institute of India Ltd.) Co administered with Imovax Polio® (Salk Based inactivated Polio Vaccine, Sanofi Pasteur India Pvt. Ltd.) in Healthy Infants.
    Dr.N.S.Mahantashetti-PI
    - EC Notification of Protocol Deviation
22. **Study No: R2014006**
    Study Title: A Phase IV, Non comparative, open label, Multicentric Trial to Evaluate the Safety and Efficacy of SYNRIAM® in the Treatment of Acute Uncomplicated Plasmodium vivax Malaria.
    Dr.Raju Badigar-PI
    - EC Notification of Study Close Out and Clinical Study Report
23. **Protocol title:** A Randomized, Double –blind, Placebo-controlled Study to Evaluate the Long-term safety and Efficacy of Darbepoetin Alfa Administered at 500µg Once-Every-3-Weeks in Anaemic Subjects with Advanced Stage Non-small Cell Lung Cancer Receiving Multi Cycle Chemotherapy.
    Dr.Rohan Bhise-PI
    - EC notification of Study Update
24. **Protocol Title:** I4V-MC-JADY-A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
    Dr.S V Udapudi-PI
    - EC Notification of SAE Follow Up Report-02

- EC Notification of Protocol Deviation
- EC Notification of

25. **Protocol Title:** A seamless, sequential Phase III, multicenter, randomized, single-blind study to evaluate the immunogenicity, reactogenicity and safety of ROTAVAC 5C new formulations of the live attenuated rotavirus vaccine as a 3 dose series when compared with existing ROTAVAC® in healthy infants.
Dr.N.S.Mahantashetti-PI
    - EC notification of Updated Insurance
    - EC Notification of Study Closure

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia to Member Secretary.

Yours truly,

Prof.(Dr).M. S. Ganachari
(Name & Signature of Ethics Committee Member Secretary)

Member Secretary
ETHICS COMMITTEE (EC)
KLE University, BELGAUM

To: All the members:

1) Dr. Subarna Roy, Scientist 'E', Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2) Dr. M.S.Ganachari, Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3) Dr. Harsha V.Hegde, Scientist 'C' ICMR (RMRC), Nehru Nagar, Belagavi.
4) Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5) Dr. M.V. Jali, MD & CEO KLE Dr.Prabhakar Kore Hospital and MRC, Belagavi.
6) Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7) Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi
8) Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC,Belagavi

9) Dr.Nayana Hashilkar, Asso.Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10) Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.
11) Shri.Tamanna Dadu Kore, Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213
12) Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13) **Mrs.Geetanjali Salimath,** Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14) **Dr.Mahantashetti,** Professor and Principle of JNM Medical College, Belagavi.
15) **Dr.Surseh Patted**, Professor and HOD of Cardiology department, J.N.Medical College, Belagavi-10
16) **Dr.Archana M. Uppin,** Consultant Physician and rheumatologist, Dept of Medicine, KLEs Dr. Prabhakar Kore Hospital and MRC, Belagavi.
17) **The Registrar**, KLE University, JNMC Campus, Belagavi –For Information.
18) **The Special Officer** to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
19) **Mrs. Rajeshwari** - PRO - KLE University, Belagavi -For Information.

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KLE UNIVERSITY

JNMC Campus, Nehru Nagar, Belgaum-590 010, Karnataka State, India

Accredited "A" grade by NAAC

Placed in Category "A" by MHRD [GoI]

Ethics Committee Office

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Ref: KLEU/EC/2017-18/D- 809

Date: 23/06/2017

Circular

The meeting of **Ethics Committee (EC)** of the **KLE University** is convened on **Wednesday, 28th June 2017, 04:00 pm** at **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New protocol for Approval

1. **Study No: 20140444**
   Drug: Denosumab
   Protocol Title: A Phase 3 randomized, Double-blind, Placebo-Controlled, Parallel-group Study to evaluate the safety and Efficacy of Denosumab in pediatric Subjects with Glucocorticoid-induced Osteoporosis
   Dr.N.S.Mahantashetti-PI
2. Protocol Number: APL/CT/12/001
   Protocol Title: "A Comparative, Two Arm, Randomized, Double Blind, Parallel Group, Multicentre, Non-Inferior Clinical Study to Evaluate Efficacy, Safety and Tolerability of Iguratimod Tablets 25 mg as an add on Therapy over Methotrexate Tablets 15 mg Vs. Methotrexate Tablets 25 mg for the treatment of Patients with active Rheumatoid Arthritis "
   Dr.Archana Uppin -PI
3. **Protocol:** A retrospective, Single-center, study to evaluate safety and performance of the Evermine 50-50µm Everolimus Eluting Coronary Stent System (EES) in the treatment of patients with de novo coronary artery lesions.
   Dr. Suresh V Patted-PI
   Note: above study was deferred from the previous meeting and the respective documents have been already dispatched with previous circular **(27/Apr/2017).**

II. Agenda: **For Ongoing Trial Approval:**

4. **Protocol:** "Comparative evaluation of immunogenicity of various schedules and delivery options to provide fractional Dose Inactivated Poliovirus Vaccine in routine immunization in the post tOPV-bOPV period: A multi-centric open label randomized controlled trial"(India fractional dose IPV study)
   Dr.N.S.Mahantashetti-PI
   - EC Review and Approval of clinical Trial Documents

   Note: Documents Circulated in the Previous Meeting **(3)**
5. **Protocol No: EFC13889/ODYSSEY EAST**: A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
   Dr.V.A.Kothiwale-PI
   - EC Review and Approval of Trial Participation Pocket Card

6. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   Dr.Jayaprakash Appajigol-PI
   - EC Review and Approval of Protocol amendment and ICF Amendment
7. **Protocol Title:** I4V-MC-JADY-A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   Dr.S V Udapudi-PI
   - EC review and approval of revised study documents
8. **Protocol no: CLR_15_06**
   Protocol Title: A Multi-Center, Open-Label, Randomized, Crossover, Aqueous Humor Bioequivalence Study of Loteprednol Etabonate Ophthalmic Suspension 0.5% (Sun Pharmaceutical Industries, Ltd.) and Lotemax® (Loteprednol Etabonate Ophthalmic Suspension 0.5%; Bausch & Lomb, Inc.) in Subjects With Indicated Bilateral Cataract Surgery.
   Dr. Rekha Mudhol-PI
   - EC review and approval of study documents.
9. **Study No: CT/DOX/1602**
   Protocol Title: An Open-Label, Multicentric, Randomized, Two Treatment, Three Period, Three Sequence, Semi-Replicate, Cross-Over, Comparative Bioavailability study of Doxorubicin Hydochloride Liposomal Injection 20mg/10mL (2mg/ml), concentrate for solution for infusion manufactured by Teva Pharmachemie, Netharlands with caelyx 20 mg/10ml (2mg/ml), [Doxorubicin hydrochloride Liposomal Injection] concentrate for solution for infusion Of Janssen-Cilag International NV, Belgium in advanced ovarian cancer and/or metastatic breast cancer patients under fasting condition.
   Dr.Mahesh Kalloli-PI
   - EC review and approval of study documents.

III. **The Committee considered the following agendas which were for information:**

1. **Protocol No: NCS-353-15-CS**
   Study Title: An open label, randomized, balanced, two treatment, two period, two sequence, single dose, crossover, oral bioequivalence study of 600mg/m2 of Vinorelbine soft capsule from lotus pharmaceutical co., Ltd., Taiwan compared with that of 60 mg/m2 of NAVELBINE® soft capsule marketed by PIERRE FABRE Limited, Winchester Hampshire S023 7DR, United Kingdom, in adult, patients with advanced breast cancer under fed conditions.
   Dr.Mahesh Kumar Kalloli-PI
   - EC Notification of Protocol Deviation
   - EC Notification of Study update
2. **Research Project:**"Aspirin Supplementation for Pregnancy Indicated Risk Reduction in Nulliparas (ASPIRIN)"
   Dr.Shivaprasad S Goudar-PI
   - EC Notification of DMC letter

- EC Notification of SAE: Post-Partum Haemorrahage

3. **Research Project:** "Women First: Preconception Maternal Nutrition
   Dr.B S Kodkany-PI
   - EC Notification of DMC letter
4. **Research Project:** Maternal New Health Registry
   Dr.B S Kodkany-PI
   - EC Notification of DMC letter
5. **Protocol Title:** "Better Birth: Trial of WHO Safe Childbirth Checklist Program" in Uttar Pradesh.
   Dr.B S Kodkany-PI
   - EC Notification of progress Report and requisition letter for continuation of approval letter
6. **A65870:** A phase III, randomised, double-blind, active, controlled, multinational, multicentre, non inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum haemorrhage during the third stage of labour in women delivering vaginally.
   Dr.Shivaprasad S Goudar-PI
   - EC notification of ICF memo dated 08-Nov-2016
   - EC notification of annual Status Report
   - EC notification of observations during monitoring visit (Pt No:08737)
   - EC notification of observations during monitoring visit(Pt No:09035)
   - EC notification of observations during monitoring visit(Pt No:09185)
   - EC Notification of Details of medical management Provided and health status of the subject No:08666
   - EC Notification of Details of medical management Provided and health status of the subject No:08595
7. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy
   Dr.Jayaprakash Appajigol-PI
   - EC notification of **CIOMS** Report-001-00335 Event:1-Elevated Liver Enzymes(GLDH)-**Initial**
   - EC notification of **CIOMS** Report-00094 **Event:** left Cerebellar haemorrhage - **Initial**
   - EC notification of **CIOMS** Report-00096 **Event**: idiopathic thrombocytopenic purpura **-Initial**
   - EC notification of **CIOMS** Report-00096 **Event**: idiopathic thrombocytopenic purpura **-Final**
   - EC notification of **CIOMS** Report-00089 **Event**: Activated partial thromboplastin time prolonged-**Initial**
   - EC notification of **CIOMS** Report-3001-00339 **Event**: Necrotic toes-**Initial**
   - EC notification of **CIOMS** Report-3001-00339 **Event**: Necrotic toes- **follow Up-01**

- EC notification of **CIOMS** REAP-00092 **Event:** Multi-Organ failure-**FUp-01**
- EC Notification of Continuation of approval above referenced study
- EC Notification of updated Investigator brochure version#9.0 dated 24/Apr/2017

8. **Protocol:** "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''

   Dr.Sanjay Porwal-PI

   - EC Notification of Protocol Deviation with Subject No:356103021
   - EC Notification of 11th Semiannual Report
   - EC Notification of IB, Edition 10 dated 27/02/2017
   - EC Notification of CIOMS (SA#281IN)
   - EC Notification of CIOMS (SA#284&285IN)
   - EC Notification of CIOMS (SA#286&287IN)
   - EC Notification of CIOMS (SA#288&289IN)
   - EC Notification of CIOMS (SA#290-291 IN)
   - EC Notification of CIOMS (SA#292 IN)
   - EC Notification of CIOMS (SA#293 IN)
   - EC Notification of CIOMS (SA#294-295 IN)
   - EC Notification of CIOMS (SA#296-297 IN)
   - EC Notification of CIOMS (SA#298-299 IN)
   - EC Notification of CIOMS (SA#300-301IN)
   - EC Notification of CIOMS (SA#302-303IN)
   - EC Notification of CIOMS (SA#304-305IN)
   - EC Notification of CIOMS (SA#310-311IN)
   - EC Notification of CIOMS (SA#312 IN)
   - EC Notification of CIOMS (SA#313-314 IN)
   - EC Notification of Insurance Certificate
   - EC Notification of Protocol Deviation
   - EC Notification of issue- regarding subject card

9. **Protocol:CRL091523:**A Multi-Centre, Randomized, Open-Label, Two Period, TwoTreatment, Two Sequence, Multiple-Dose, Crossover, Bioequivalence Study of Pramipexole Prolonged Release Tablets 3.15 mg of Mylan Laboratories Ltd., India with Sifrol® 3.15 mg (Pramipexole) depottabletter (depot tablet) of Boehringer Ingelheim International GmbH, Germany in Patients with Idiopathic Parkinson's disease. PROTOCOL VERSION: 1.0, dated 16 Sep 2015

   Dr.Madhav Prabhu-PI

   - EC Notification of close out letter

10. **Protocol:** A multicentre, open label, balanced, Randomized, two treatment, three period, three sequence, reference replicate crossover, single dose, oral bioequilance study of

Capecitabine film coated tablets 500mg of shilpa medicare Limited, India and Xeloda® Film Coated tablets 500mg(Capecitabine) marketed by Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City,AL7 1 TW United Kingdom following single oral dose of 2000mg (4×500mg) in adult human cancer patients under fed conditions.

Protocol No: P-762/16

Dr.Mahesh Kumar Kalloli-PI

- EC Notification of Fully executed CTA
- EC Notification of Protocol Deviation

11. **Protocol:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".

Dr.V.A.Kothiwale-PI

- EC notification of site closure memorandum
- EC Notification of PK Sampling discrepancies
- EC Notification of Note to file(NTF)
- EC Notification of Protocol Deviation

12. **Protocol: EFC13889/ODYSSEY EAST:** A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.

Dr.V.A.Kothiwale-PI

- EC Notification of Investigator Brochure
- EC Notification of CIOMS (Safety Alert#90&91IN)
- EC Notification of CIOMS (Safety Alert#92&93IN)
- EC Notification of CIOMS (Safety Alert#94&95 IN)
- EC Notification of CIOMS (Safety Alert#96&97 IN)
- EC Notification of CIOMS (Safety Alert#98&99 IN)
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tablet of Novartis Pharmaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients under fasting conditions
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    - EC Notification of study Close out
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Dr.N.S.Mahantashetti-PI

    - EC Notification of Protocol Deviation

22. **Study No: R2014006**
Study Title: A Phase IV, Non comparative, open label, Multicentric Trial to Evaluate the Safety and Efficacy of SYNRIAM® in the Treatment of Acute Uncomplicated Plasmodium vivax Malaria.
Dr.Raju Badigar-PI
    - EC Notification of Study Close Out and Clinical Study Report
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Dr.S V Udapudi-PI

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25. **Protocol Title:** A seamless, sequential Phase III, multicenter, randomized, single-blind study to evaluate the immunogenicity, reactogenicity and safety of ROTAVAC 5C new formulations of the live attenuated rotavirus vaccine as a 3 dose series when compared with existing ROTAVAC® in healthy infants.
Dr.N.S.Mahantashetti-PI
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    - EC Notification of Study Closure

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia to Member Secretary.

Yours truly,

Prof.(Dr).M. S. Ganachari
(Name & Signature of Ethics Committee Member Secretary)

Member Secretary
ETHICS COMMITTEE (EC)
KLE University, BELGAUM

To: All the members:

1) Dr. Subarna Roy, Scientist 'E', Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2) Dr. M.S.Ganachari, Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3) Dr. Harsha V.Hegde, Scientist 'C' ICMR (RMRC), Nehru Nagar, Belagavi.
4) Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5) Dr. M.V. Jali, MD & CEO KLE Dr.Prabhakar Kore Hospital and MRC, Belagavi.
6) Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7) Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi

8) Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC,Belagavi
9) Dr.Nayana Hashilkar, Asso.Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10) Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.
11) Shri.Tamanna Dadu Kore, Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213
12) Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13) **Mrs.Geetanjali Salimath,** Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14) **Dr.Mahantashetti,** Professor and Principle of JNM Medical College, Belagavi.
15) **Dr.Surseh Patted**, Professor and HOD of Cardiology department, J.N.Medical College, Belagavi-10
16) **Dr.Archana Uppin,** Consultant Physician and rheumatologist, Dept of Medicine, KLEs Dr. Prabhakar Kore Hospital and MRC, Belagavi.
17) **The Registrar**, KLE University, JNMC Campus, Belagavi –For Information.
18) **The Special Officer** to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
19) **Mrs. Rajeshwari** - PRO - KLE University, Belagavi -For Information.

KLE UNIVERSITY
JNMC Campus, Nehru Nagar, Belgaum-590 010, Karnataka State, India
[Established under Section 3 of the UGC Act, 1956 vide MHRD, G.O.I Notification No.F.9-19/2000-U.3(A) dt. 13th April 2006]
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Ref: KLEU/EC/2017-18/D- 1936 ***Date: 25/09/2017***

Circular

Ethics Committee members training on SOP is convened on **Thursday, 28th September 2017** from **3:00PM to 4:00PM** at **Site Management Office**, KLEs Dr.Prabhakar Kore Hospital & MRC, and Belagavi.

Agenda:

1. Amended SOP training
2. To Discuss Non-compliance observation by NABH and FERCAP accreditation assessors

In view of this all the Ethics Committee members requested to make it convenient to attend the meeting. If you have any questions, please contact Member-Secretary.

Yours Truly,

Prof. (Dr).M.S.Ganachari
Member-Secretary, Ethics Committee
KLE University, Belagavi

Member Secretary
ETHICS COMMITTEE (EC
KLE University, BELGAU

Note: Any other matter from the chairman permission

To:-

1) Dr. Subarna Roy, Scientist 'C', ICMR- National Institute of Traditional Medicine, Belagavi.
2) Dr. M.S.Ganachari, Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.

3) Dr. Harsha V.Hegde, Scientist 'D' ICMR- National Institute of Traditional Medicine, Belagavi.
4) Dr. P. A. Patil, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5) Dr. M.V. Jali, MD & CEO KLE Dr. Prabhakar Kore Hospital and MRC, Belagavi.
6) Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7) Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi
8) Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC, Belagavi
9) Dr.Nayana Hashilkar,Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10) Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.
11) Shri.Tamanna Dadu Kore, Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213
12) Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13) Mrs.Geetanjali Salimath, Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14) The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
15) The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
16) Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KAHER/EC/2017-18/D-2767 ***Date: 18/12/2017***

IEC Meeting Agenda

Institutional Ethics Committee of KLEU, Belagavi
Friday, 29/12/2017, At: 3:00 PM
Venue: Site management Office

I. Agenda: New protocol for Approval:

1. **Research Project:** "ASIA Pregnancy outcomes study"
   Dr.S.S.Goudar-PI

2. **Protocol Number: APL/CT/16/11**
   Protocol Title: A Phase-III, Multicentric, Randomized, Double Blind, Placebo-Controlled, Comparative Clinical Study to Evaluate the Efficacy and Safety of Sildenafil Citrate 50 mg plus Dapoxetine 60 mg Tablet and Sildenafil Citrate 100 mg plus Dapoxetine 60 mg Tablet in the treatment of co-existing Erectile Dysfunction and Premature Ejaculation.
   Dr.S.I Neeli-PI

3. **Study Title & Study Code:** Prospective, Randomized, Double Blinded, Parallel Group, Multicentric, Comparative Clinical study to compare efficacy and safety of oral CPL-2009-0031 of Cadila Pharmaceutical Limited, India against innovator Sitagliptin in patients with Uncontrolled Type -2 Diabetes Mellitus (T2DM). (CRSC16002).
   Dr.Jayaprakash Appajigol-PI

4. **Study Title:** " A Prospective, multicenter, randomized, open-label, active-controlled, two-parallel groups, phase 3 study to compare the efficacy and safety of masitinib at 7.5mg/kg/day to decarbonize in the treatment of patients with non-resectable or metastatic stage 3 or stage 4 melanoma carrying a mutation in the juxta membrane domain of c-kit."
   Study Number: [AB08026]
   Dr.Mahesh Kumar Kalloli

5. **Study Title:** "A Multicenter, double blind, active controlled, parallel group, two arm, bioequilance study with clinical endpoint comparing brinzolamide 1% and brimonidine tartrate 0.2% ophthalmic suspension (Manufacture by Teva Pharmaceutical Industries, Ltd., Kfar saba, Israel for Actavis LLC, USA), TO SIMBRINZA ®(brinzolamide 1% and brimonidine tartrate 0.2%) ophthalmic suspension of Alcon laboratories, Inc., USA in the treatment of chronic open angle gluacoma or ocular hypertension in both eyes."
   Dr.Smith K.S-PI

6. **Protocol Title:** Prophylaxis of Thromboembolism in Critically III Patients Using Combined Intermittent Pneumatic Compression and Pharmacologic Prophylaxis Versus Pharmacologic Prophylaxis Alone: A Multicenter Randomized Controlled trial.
Version Number: Version 5, May 14, 2015
Dr.M.I.Uppin-PI

II. **Agenda: Protocols for Full board review:**

1. **Study Protocol No.: LRP/LNP3794/2016/006**
Study Protocol Title: A Phase II/III Pivotal, Open-label, Randomized, 3-Arm Study to Assess the Efficacy of LNP3794 Monotherapy or in Combination with Docetaxel, Compared with Docetaxel Alone, in Patients with RAS Mutation-Positive Locally Advanced and Metastatic Non-Small Cell Lung Cancer
Dr.Mahesh Kumar Kalloli-PI
   - IEC submission of additional Study documents for full board review

III. **The Committee will consider the following agendas which are for information.**

1) **Study Protocol No.: LRP/LNP3794/2016/006**
Study Protocol Title: A Phase II/III Pivotal, Open-label, Randomized, 3-Arm Study to Assess the Efficacy of LNP3794 Monotherapy or in Combination with Docetaxel, Compared with Docetaxel Alone, in Patients with RAS Mutation-Positive Locally Advanced and Metastatic Non-Small Cell Lung Cancer
Dr.Mahesh Kumar Kalloli-PI
   - IEC notification of Study documents for review and approval

2) **Protocol Title:** A Phase-III, Multicentric, Randomized, Double Blind, Placebo-Controlled, Comparative Clinical Study to Evaluate the Efficacy and Safety of Sildenafil Citrate 50 mg plus Dapoxetine 60 mg Tablet and Sildenafil Citrate 100 mg plus Dapoxetine 60 mg Tablet in the treatment of co-existing Erectile Dysfunction and Premature Ejaculation.
Protocol Number: APL/CT/16/11
Dr.S.I Neeli-PI
   - IEC notification of Final Executed CTA

3) **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
Dr.Jayaprakash Appajigol-PI
   - IEC notification Of CIOMS- REAP-00109-**Event**-Post Haemorrhage- FU01
   - IEC notification Of CIOMS- REAP-00143-**Event**-APTT Prolonged –Initial
   - IEC notification Of CIOMS- REAP-3001-00410-**Event**-Sever bleeding, hemorrhagic shock, cardiac arrest – Initial
   - IEC notification Of CIOMS- REAP-00148-**Event**- Organ Failure –Initial
   - IEC notification Of CIOMS- REAP-3001-00409-**Event**- Cardio-respiratory arrest – Initial
   - IEC notification Of CIOMS- REAP-00146-**Event**- Progression of lung Cancer –Initial

- IEC notification Of CIOMS- REAP-00141-**Event-** Cardiac arrest –Initial
- IEC notification Of CIOMS- REAP-00141-**Event-** Cardiac arrest –FU01
- IEC notification Of CIOMS- REAP-00140-**Event-** Sepsis – FU01
- IEC notification Of CIOMS- REAP-3001-00366-**Event-** Brain Atrophia of posterior fossa – FU03
- IEC notification Of CIOMS- REAP-3001-00405-**Event-** Elevated INR – Initial
- IEC notification Of CIOMS- REAP-3001-00405-**Event-** Bilateral digital gangrene – FU-02
- IEC notification Of CIOMS- REAP-00136-**Event-** No adverse Event – FU-01
- IEC notification Of CIOMS- REAP-00139-**Event-** Prolongation of PT-INR – Initial
- IEC notification Of CIOMS- REAP-00136-**Event-** platelets decreased – Initial
- IEC notification Of CIOMS- REAP-3001-00390-**Event-** Cardia tumor with active bleeding – FU-03
- IEC notification Of CIOMS- REAP-3001-00390-**Event-** Cardia tumor with active bleeding – FU-04
- IEC notification Of CIOMS- IPN1-00002 **Event-** Lung Cancer – FU-01
- IEC notification Of CIOMS- REAP-00138 **Event-** 1. Ventricular Fibrillation, Right thigh amputation – Initial
- IEC notification Of CIOMS- REAP-00139 **Event-** Prolongation of PT-INR – Initial
- IEC notification Of CIOMS- REAP-00140 **Event-** Death – Initial
- IEC notification Of CIOMS- REAP-30001-00405 **Event-** Elevated PT– Initial
- IEC notification Of CIOMS- REAP-30001-00405 **Event-** Elevated PT– FU01
- IEC notification Of CIOMS- REAP-30001-00409 **Event-** Cardio-respiratory arrest– FU01

4) **Protocol Number:** CLR_16_13
Protocol Title: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer.
Dr.Rohan Bhise-PI
   - IEC notification of Study update
   - IEC Notification of SAE of term Fever- final follow up report for Sub:2202

5) **Study Code: D1699C00001**
Protocol: A Study to Evaluate the Effect of Dapagliflozin on the Incidence of worsening heart failure or Cardiovascular Death in patients with chronic Heart Failure with reduced Ejection Fraction.
Dr.V.A.Kothiwale-PI
   - IEC Notification of IB for Dapagliflozin, Edition 13, dated 03 Nov 2016
   - IEC notification of Investigator Undertaking

6) **Protocol Title:** An open label extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in Etrolizumab phase II/III studies.

Protocol No: GA28951
Dr.Varadaraj Gokak –PI

- IEC notification of clarification letter for TB and Dysplasia screening procedure

7) **Protocol Title:** Phase III, Randomized, Double-blind, Placebo-controlled, multicenter study to evaluate the efficacy (maintenance of remission) and safety of Etrolizumab compared with placebo in patients with moderate to severe active Ulcerative Colitis who are naive to TNF inhibitors.
Protocol No: GA29102
Dr.Varadaraj Gokak –PI

- IEC notification of clarification letter for TB and Dysplasia screening procedure

8) **Study No:** CR150-16
Study Title: A Multicentric, Open-label, Randomized, Two Treatment, Two Sequence, Cross Over, Clinical Bioequivalence Study of Doxorubicin Hydrochloride Liposome Injection (IV) 2 mg/ml (50mg/m2) of Auromedics Pharma LLC, USA (Test) With Doxorubicin Hydrochloride Liposome Injection (IV) 2 mg/ml (50mg/m2) of Sun Pharmaceutical Industries, Inc, USA (Reference) in Ovarian Cancer Patients whose disease has progressed or recurred after platinum-based chemotherapy under fasting conditions
Dr.Rohan Bhise-PI

- IEC notification of Protocol Waiver

9) **Protocol** - NN BIAsp-4343 "A multi-centre prospective, non-interventional study of ability and willingness to pay for BIAsp 30 in a real world population with type 2 diabetes mellitus"
Dr.M.V.Jali-PI

- IEC Notification of ICF version clarification letter dated: 23/11/2017

10) **Protocol Title:** "Comparative evaluation of immunogenicity of various schedules and delivery options to provide fractional Dose Inactivated Poliovirus Vaccine in routine immunization in the post tOPV-bOPV period: A multi-centric open label randomized controlled trial" (India fractional dose IPV study)
Dr.N.S.Mahatashetti-PI

- IEC Notification of SAE occurred at MOSC Kolenchery

11) **Study Title: EFC13889/ODYSSEY EAST**: A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
Dr.V.A.Kothiwale-PI

- IEC Notification of SASR#12
- IEC Notification of Final CRF
- IEC Notification of CIOMS(SA# 364 &365N)
- IEC Notification of CIOMS(SA# 180 &181N)
- IEC Notification of CIOMS(SA# 178 &179N)
- IEC Notification of CIOMS(SA# 176 &177N)
- IEC Notification of CIOMS(SA# 174 &175N)

- IEC Notification of CIOMS(SA# 173)
- IEC Notification of CIOMS(SA# 171 &172N)
- IEC Notification of CIOMS(SA# 170)
- IEC Notification of CIOMS(SA# 168 &169N)
- IEC Notification of CIOMS(SA# 166 &167N)
- IEC Notification of CIOMS(SA# 164 &165N)
- IEC Notification of CIOMS(SA# 162 &163N)
- IEC Notification of CIOMS(SA# 160 &161N)
- IEC Notification of CIOMS(SA# 158 &159N)
- IEC Notification of CIOMS(SA# 156 &157N)
- IEC Notification of CIOMS(SA# 154 &155N)
- IEC Notification of CIOMS(SA# 152 &153N)
- IEC Notification of CIOMS(SA# 150 &151N)
- IEC Notification of CIOMS(SA# 148 &149N)
- IEC Notification of CIOMS(SA# 146 &147N)
- IEC Notification of CIOMS(SA# 144 &145N)

12) **Protocol:** "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''

Dr.Sanjay Porwal-PI

- **IEC notification of CIOMS** (SA #368-369 IN) letter dated: 26/11/2017
- **IEC notification of CIOMS** (SA #372-373 IN) letter dated: 04/12/2017
- **IEC notification of CIOMS** (SA #362-336 IN) letter dated: 07/11/2017
- **IEC notification of CIOMS** (SA #358-359 IN) letter dated: 27/10/2017

13) **Protocol No: NCS-353-15-CS**

Study Title: An open label, randomized, balanced, two treatment, two period, two sequence, single dose, crossover, oral bioequivalence study of 600mg/m2 of Vinorelbine soft capsule from lotus pharmaceutical co., Ltd., Taiwan compared with that of 60 mg/m2 of NAVELBINE® soft capsule marketed by PIERRE FABRE Limited, Winchester Hampshire S023 7DR, United Kingdom, in adult, patients with advanced breast cancer under fed conditions.

Dr.Mahesh Kalloli-PI

- IEC notification of Study close out visit
- IEC Notification of study close out and study update report

14) **Protocol Title:** "Maternal Docosa-Hexanoic Acid (DHA) Supplementation and offspring neurodevelopment in India – (DHANI-2)".

Dr.M.K.Swamy-PI

i. IEC submission of SAE- Left sided isolated syndactyly of fingers and toes of Subject ID:**R0817**-Final Report: 15/09/2017

15) Study No: CT/DOX/1602

Protocol Title: An Open-Label, Multicentric, Randomized, Two Treatment, Three Period, Three Sequence, Semi-Replicate, Cross-Over, Comparative Bioavailability study of Doxorubicin Hydochloride Liposomal Injection 20mg/10mL (2mg/ml), concentrate for solution for infusion manufactured by Teva Pharmachemie, Netharlands with caelyx 20 mg/10ml (2mg/ml), [Doxorubicin hydrochloride Liposomal Injection] concentrate for solution for infusion Of Janssen-Cilag International NV, Belgium in advanced ovarian cancer and/or metastatic breast cancer patients under fasting condition.

Dr.Rohan Bhise-PI

- IEC notification of stability evaluation

16) Project # MYL-1402O-3001: Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.

Dr.Mahesh Kumar Kalloli-PI

- IEC notification of SAE term of Pyothorax-Subject No:171005
- IEC notification of CIOMS-Sub:175007- adverse event Breathlessness Hypotension thrombocytopenia, Healing delayed: FU02
- IEC notification of CIOMS-Sub:175007- adverse event Breathlessness Hypotension thrombocytopenia, Healing delayed: FU03
- IEC notification of CIOMS-Sub:186006- adverse event: Loose motion: FU02
- IEC notification of CIOMS-Sub:186006- adverse event: Loose motion: FU03
- IEC notification of CIOMS-Sub:186006- adverse event: Loose motion: FU04
- IEC notification of CIOMS-Sub:165016- adverse event: Death: FU01
- IEC notification of CIOMS-Sub:187003- adverse event: Death: FU02

17) Any other matter with the permission of the chair

For your attention:

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia, to Member Secretary.

Yours truly,

KLE Academy of Higher Education and Research Deemed-to-be University BELAGAVI

Prof. (Dr).M. S. Ganachari
(Name & Signature of Ethics Committee
Member Secretary-KLE U, Belagavi)

To:

1) Dr. Subarna Roy, Scientist 'E', ICMR-NITM, Nehru Nagar, Belagavi.

2) Dr. M.S.Ganachari, Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3) Dr. Harsha V.Hegde, Scientist 'D' ICMR-NITM, Nehru Nagar Belagavi.
4) Dr. P. A. Patil, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5) Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
6) Dr. M.V. Jali, MD & CE, KLEs Dr.Prabhakar Kore Hospital and MRC, Belagavi
7) Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi
8) Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC, Belagavi
9) Dr.Nayana Hashilkar, Prof. of Pharmacology, J.N. Medical College, Belagavi.
10) Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.
11) Shri.Tamanna Dadu Kore, Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213
12) Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13) Mrs.Geetanjali Salimath, Asst.Prof. Dept. Of Pharmacy Practice, Belagavi
14) **Dr.Sapna,** Independent Consultant(IEC), Radiation Oncologist, KLE Society's belgaum cancer hospital, Belagavi-10
15) **Dr. Jayaprakash. Appajigol,** Principal Investigator & Asst. Prof. of Medicine, J.N. Medical College, Consultant Physician, KLES Dr Prabhakar Kore Hospital & MRC, Belagavi
16) **Dr.S.I.Neeli,** Consultant Urologist, KLES Dr Prabhakar Kore Hospital & MRC, Belagavi
17) **Dr.Mahesh Kalloli,** Dept. of Oncology, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590 010,
18) **Dr.Smitha K S,** Dept. of Ophthalmology, KLES Dr Prabhakar Kore Hospital & Medical Research Center, Belagavi
19) **Dr.M.I.Uppin,** General Surgeon, Dept. of Surgery, KLES Dr Prabhakar Kore Hospital & Medical Research Center, Belagavi
20) The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
21) The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
22) Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2017-18/D- 1964 **Date: 28/09/2017**

Circular

The meeting of **Ethics Committee** is Convened on ***Friday, 06th October 2017*** at **4:00 PM** in **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New protocol for Approval:

1) **Protocol No**: BCD-021-02
Protocol Title: " International multicenter randomized double blind phase III trial comparing safety and efficacy of BCD-021 (CJSC BIOCAD, Russia) and paclitaxel + carboplatin to Avastin® (F. Hoffmann-La Roche Ltd, Switzerland) and paclitaxel + carboplatin in inoperable or advanced non-squamous non-small-cell lung cancer patients. "
Dr.Mahesh Kumar Kalloli-PI

2) **Protocol Title: A** Post marketing Randomized Placebo Controlled Study to evaluate the Efficacy of Study Product UPLAT® (*Carica papaya* leaf Extract + *Tinospora cardifolia* Extract) in the Cancer Patients with Thrombocytopenia induced by Chemotherapy
Study Number: SPL/UP/2017/01
Dr.Rohan Bhise-PI

3) **Protocol No.** – ZYAN1.16.001.01, A randomized, double blind, placebo controlled, parallel group, phase II multi-centric trial to assess safety, tolerability and efficacy of PHD-2 Inhibitor, ZYAN1 in the treatment of anemia in pre-dialysis chronic kidney disease patients.
Dr.Ravi Sarvi-PI

II) Agenda: For ongoing trial protocol:

4) **Protocol no:** RLS/RES/2016/01: version 1.0, dated: 05 Feb 2016
Protocol title: Prospective, multi-centre, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-022/Xolair® in patients with moderate to severe persistent asthma.
Dr.Jyothi Hattiholi-PI

- EC review and approval of Protocol Amendment

III). The Committee will consider the following agendas which are for information.

1) **Research Project:** "Aspirin Supplementation for Pregnancy Indicated Risk Reduction in Nulliparas (ASPIRIN)"
Dr.S.S.Goudar-PI
    - EC notification of SAE: Maternal death of Sub ID:**1-08-0856-W**
2) **Protocol Title:** "Maternal Docosa-Hexanoic Acid (DHA) Supplementation and offspring neurodevelopment in India – (DHANI-2)".
Dr.M.K.Swamy-PI
    - EC Notification of SAE: **Still Birth** of Subject ID:**R0747**
3) **Protocol Title:** MYL-1402O-3001 :Multicenter, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With

OK

Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.

Dr.Mahesh Kalloli-PI

- EC Notification SAE: **Gastroentrititis** of Subject: **171006**
- EC notification of Investigator Brochure Version 3.0 May 2017
- EC notification of Corrected ICF and translation certificate Version 1.2 17/Aug/2016
- EC notification of CIOMS for Subject ID:165002n of FU-02-Event:Febrile Neutropenia, Hypnatremia
- EC notification of CIOMS for Subject ID:185001of FU-01-Event: Febrile Neutropenia
- EC notification of CIOMS for Subject ID:171006 of Initial-Event: Anaphylaxis
- EC notification of CIOMS for Subject ID:170004 of FU-02-Event: Death
- EC notification of CIOMS for Subject ID:172016 of FU-01-Event: Death
- EC notification of CIOMS for Subject ID:170004 of FU-03-Event: Death
- EC notification of CIOMS for Subject ID:172016 of Initial-Event: death
- EC notification of CIOMS for Subject ID:16606 of Initial-Event: Leukopenia & Thrombocytopenia

4) **Study Title:** A Multicenter, Open Label, Balanced, Randomized, Two-Treatment, Two-Period, Two-Sequence, Single Dose, Cross-Over Bioequivalence Study of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL) of Cadila Healthcare Limited, India in comparison with Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL), of Sun Pharmaceutical Ind. Ltd, India, in the Patients of Ovarian Cancer under fasting conditions.

Dr.Mahesh Kumar Kalloli-PI

- EC Notification of final e CRF documents

5) Protocol No: **EFC13889/ODYSSEY EAST**: A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.

Dr. V.A.Kothiwale-PI

- EC notification of CIOMS(SA#137&138IN)
- EC notification of CIOMS(SA#329&330IN)
- EC notification of CIOMS(SA#135&136IN)
- EC notification of Protocol Deviation letter dated 18/08/2017

6) **Protocol Title:** 3-001 A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.

Dr.Japrakash Appajigol-PI

- EC notification of CIOMS Repot 3001-00296 of FU-02-Event: small bowel ischemia, Necrotizing fasciitis
- EC notification of CIOMS REAP-00117 of Initial -Event: Death

- EC notification of CIOMS Report 3001-00366 of Initial -Event: brain atrophia of posterior fossa
- EC notification of CIOMS Report 3001-00366 of FU:01 -Event: brain atrophia of posterior fossa
- EC notification of CIOMS REAP-00116 of Initial -Event: Death
- EC notification of CIOMS Report 3001-00371 of Initial -Event: Cellulitis(L)leg
- EC notification of CIOMS Report 3001-0000374 of Initial -Event: Asystole
- EC notification of CIOMS Report IPF1-00005 of Initial -Event: Acute exacerbation of idiopathic pulmonary fibrosis
- EC notification of CIOMS Report 3001-00223 of FU:03 -Event: Ventricular tachycardia

7) **Protocol Title: A65870:** A phase III, randomised, double-blind, active, controlled, multinational, multicentre, non inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum haemorrhage during the third stage of labour in women delivering vaginally.
Dr.Shivaprasad S Goudar-PI
   - EC Submission of CRA Monitoring Report dated 18-09-2017

8) **Protocol:** "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''
Dr.Sanjay Porwal-PI
   - EC Notification of Protocol Deviation letter dated 31/08/2017

9) **Protocol Number: CLR_16_13**
Protocol Title: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer.
Dr.Rohan Bhise-PI
   - **EC Notification of Typographical error**

10) **Protocol Number**: APL/CT/12/001
Protocol Title: "A Comparative, Two Arm, Randomized, Double Blind, Parallel Group, Multicentric, Non-Inferior Clinical Study to Evaluate Efficacy, Safety and Tolerability of Iguratimod Tablets 25 mg as an add on Therapy over Methotrexate Tablets 15 mg Vs. Methotrexate Tablets 25 mg for the treatment of Patients with active Rheumatoid Arthritis "
Dr.Archana M Uppin-PI
   - EC Notification Source documents templates

11) **Protocol ID No:** CRL121526

Protocol Title: "A Randomized, Open-Label, Two Period, Two-Treatment, Two Sequence, Single-Dose, Crossover, Bioequivalence Study of Paclitaxel Protein-bound Particles for Injectable Suspension (albumin-bound) of Panacea Biotec, India with ABRAXANE® (Paclitaxel Protein-bound Particles for Injectable Suspension) (albumin-bound) manufactured for Celgene Corporation, Summit, NJ in Patients with Metastatic Breast Cancer under Fasting Conditions.",
Dr.Rohan Bhise-PI

- EC Notification of Study Update and EC Request for Continuation of Approval

12) **Protocol Number: LRP/LNP1892/2016/007**
Protocol Title: "A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy, Pharmacokinetics, Pharmacodynamics and Safety of LNP1892 (Monotherapy) in Chronic Kidney Disease (CKD) Patients with Secondary Hyperparathyroidism (SHPT), On Dialysis and Not on Dialysis."
Dr.Mallikarjun S Karishetti-PI

- EC Submission of Following documents
  1) **Insurance Note**
  2) **CTRI registration certificate**
  3) **Final Executed CTA**

13) **Protocol title:** A Randomized, Double –blind, Placebo-controlled Study to Evaluate the Long-term safety and Efficacy of Darbepoetin Alfa Administered at 500µg Once-Every-3-Weeks in Anaemic Subjects with Advanced Stage Non-small Cell Lung Cancer Receiving Multi Cycle Chemotherapy.
Dr.Rohan Bhise-PI

- EC Notification of SUSARs

Yours truly,

Prof. (Dr).M. S. Ganachari
(Name & Signature of Ethics Committee
Member Secretary)

Member Secretary
ETHICS COMMITTEE (EC
KLE University, BELGAU

To:

1) Dr. Subarna Roy, Scientist 'C', ICMR- National Institute of Traditional Medicine, Belagavi.

2) Dr. M.S.Ganachari, Prof& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3) Dr. Harsha V.Hegde, Scientist 'D' ICMR- National Institute of Traditional Medicine, Belagavi.
4) Dr. P. A. Patil, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5) Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
6) Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi
7) Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC, Belagavi
8) Dr.Nayana Hashilkar, Prof. of Pharmacology, J.N. Medical College, Belagavi.
9) Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.
10) Shri.Tamanna Dadu Kore, Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213
11) Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
12) Mrs.Geetanjali Salimath, Asst.Prof. Dept. Of Pharmacy Practice, Belagavi
13) **Dr. Maheshkumar Veeranna Kalloli,** Consultant, Oncology Dept., KLES Dr Prabhakar Kore Hospital &MRC, Nehru Nagar, Belagavi-590 010.
14) **Dr.Rohan Bhise,** Dept. of Oncology, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590 010,Karnataka,India
15) **Dr.Ravi Sarvi, Dept. of Nephrology,** KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 10
16) The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
17) The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
18) Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2015-16/D- 5493. *Date: 25/03/2016*

Circular

The meeting of Ethics **Committee** (EC) of the **KLE University** is convened on **Friday, 01th April 2016, 04:00 pm** at **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New Protocol for Approval:

1. **Protocol: VRL/CSE-1034/05/2012.** "A Randomized, Double-blind, Double-dummy, Active-controlled, Multi-centre Trial to compare the Efficacy and Safety of CSE-1034 (Ceftriaxone+Sulbactam+EDTA) with Meropenem in Infections Caused by β – Lactamase (ESBL and MBL) producing Gram Negative Bacteria."
   Dr. Madhav Prabhu – PI

2. **Protocol: CRL091523. "A Multi-Centre** Randomized, Open-Label, Two Period, Two-Treatment, Two Sequence, Multiple-Dose, Crossover, Bioequivalence Study of Pramipexole Prolonged Release Tablets 3.15 mg of Mylan Laboratories Ltd., India with Sifrol® 3.15 mg (Pramipexole) depottabletter(depot tablet) of Boehringer Ingelheim International GmbH, Germany in Patients with Idiopathic Parkinson's disease."
   Dr. Madhav Prabhu – PI

3. **Protocol: CLR_15_12.** "A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study Of Paclitaxel Injection Concentrate For Nano-Dispersion (PICN) And Abraxane® In Subjects With Locally Recurrent Or Metastatic Breast Cancer.
   Dr.Rohan Bhise – PI

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4. **Protocol: EFC13889/ODYSSEY EAST**: A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab **(SAR236553/REGN727)** Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.

   Dr.V. A. Kothiwale – PI

II. Agenda: For Ongoing Trial Approval:

1. **Protocol: BBIL/ROTA5C/III/2014**:"A seamless, sequential phase III, multicenter, Ramdomized, single –blind study, to evaluate immunogenicity, reactogenicity and safety of ROTAVAC 5C new formulation of the live attenuated rotavirus vaccine as a 3 dose series when compared with existing ROTAVAC in healthy infants.

   Dr.(Mrs) N.S. Mahantshetti - PI

   - EC notification of amendments for review and approval.

2. **Protocol: EFC11570:** A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to evaluate the effect of Alirocumab (SAR236553/REGN727) on the occurrence of Cardiovascular Events in Patients who have recently experienced an Acute Coronary Syndrome

   Dr. Sanjay Porwal – PI

   - Submission & approval of revised Protocol Amendment 8 and Informed Consent Forms Version 2.0

3. **Protocol: 15-VIN-258**: A multicentre, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial of Cipla Ltd., India with ABRAXANE for Injectable Suspension (Paclitaxel protein-bound particles for Injectable

suspension) Manufactured for :Celgene Corporation Summit, USA in Breast cancer patients after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.

Dr. Rohan Bhise - PI

- Provision of EC requirement as per approval letter dated 01 Dec 2015.
- Notification of typographical error in submission letter dated 16/ 12/ 2015 and approval letter dated 19/ 02/ 2016.
- EC notification of DCGI acknowledgement letter for approval.
- EC notification of DCGI Acknowledgement letter for discontinuation of AV recording of the ICF.

4. **Protocol: # CRL121429** : A Randomized, Open-Label, Two Period, Two-Treatment, Two Sequence, Crossover, Multiple-Dose, Steady State, Bioequivalence Study of Clozapine Tablets 100 mg of Cadila healthcare Ltd., India with Clozaril® (Clozapine) Tablets 100mg Manufactured by: Novartis Pharmaceutical corporation, Suffern, New York 10901 in Patients with Schizophrenia or

Schizoaffective Disorder under Fasting Conditions.

Dr. N. M. Patil - PI

- Study documents for EC notification.
- Documents for EC notification dated 08/03/2016

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5. **"Aspirin supplementation for Pregnancy Indicated Risk Reduction in Nulliparas (ASPIRIN)"**

   Dr. B. S. Kodkany – PI

   - EC notification for the final approval for the conduct of trial.
   - EC notification for exemption from Audio-Visual recording of the informed consent process.

III. <u>The Committee will consider the following agendas which are for information:</u>

Reading & Approving the CIOMS received.

1. A Phase III, randomized, double-blind, active, controlled, multinational, multicentre, non-inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum hemorrhage during the third stage of labour in women delivering vaginally. A65870, ver. 1.2 dated 12/03/2015

   Dr. S. S. Goudar - PI

   - EC notification of Non-inclusion of minors.

2. **Protocol: 20110118**:"A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".

   Dr. V. A. Kothiwale - PI

   - EC notification of Follow up 2 letters for SAE {**Stress Induced Reversible Ischemia Status Post CABG**} for subject no. 11830050002.
   - EC notification of six monthly safety update reports for the study.
   - EC notification of DMC letter dated 25 Jan 2016.

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- EC notification of SAE reimbursement of protocol 20110118 for subject no 11830031011.
- EC notification of Follow up 1 letters for SAE {**Chronic Unstable Angina**) for subject no. 11830029033.
- EC notification of Follow up 1 letters for SAE {**Death**} for subject no. 11830055038.

3. **Protocol Title: EFC11570**:"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome"

   Dr. Sanjay Porwal – PI

   - EC notification of Protocol Deviation of subject no. 356103023.
   - EC notification of CIOMS (safety alert # 124 & 125IN).
   - EC notification of CIOMS (safety alert # 132 & 133IN).
   - EC notification of CIOMS (safety alert # 130 & 131IN).

4. **Protocol Title:** A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.

   Dr. Jayprakash Appajigol – PI

   - EC notification of CIOMS of Initial with event Death dated 18/ 01/ 2016.
   - EC notification of CIOMS of Follow-up7 with event of 1. Hepatic cytolysis, 2.Mesentric ischemia, 3.Posterior reversible encephalopathy syndrome dated 26/ 01/ 2016
   - EC notification of CIOMS of Initial with event Myocarditis dated 29/ 01/ 2016.
   - EC notification of CIOMS of Follow-up 1 with event of Myocarditis dated 05/ 02/ 2016.
   - EC notification of CIOMS of Follow-up 8 with event of 1.Hepatic cytolysis 2. Mesentric ischemia 3. Posterior reversible encephalopathy syndrome dated 05/ 02/ 2016

- EC notification of CIOMS of Follow-up 1 with event Death (Cardiac failure), PT Cardiac failure dated 10/ 02/ 2016.
- EC notification of completed CIOMS 1 form for the SAE (Acute Respiratory Distress Syndrome) of subject no. 44160014 dated 18/ 02/ 2016.
- EC notification of CIOMS 1 with event of Acute Respiratory Distress Syndrome of Subject no. 44160014 dated 25/ 02/ 2016
- EC notification of Initial letters for SAE {Chronic Unstable Angina} for Subject no.11830029033 dated 15/ 02/ 2016.
- EC notification of Follow up 2 letters for SAE {Chronic Unstable Angina} for Subject no. 11830029033 dated 17/ 02/ 2016.
- EC notification of CIOMS of Subject no.44160015.
- EC notification of CIOMS of follow-up 2 with event of Myocarditis dated 25/ 02/ 2016.
- EC notification of CIOMS of Initial with event 1) Cerebral Infarction,2) Embolism from left ventricular thrombus dated 26/ 02/ 2016.
- EC notification of CIOMS of Follow-up 2 with event 1)Medullary Ischemia 2) Paraplegia dated 26/ 02/ 2016.
- EC notification of CIOMS of Initial with event Segmental occlusion of right radial artery dated 04/03/2016.
- EC notification of CIOMS of Follow-up 1 with event of Segmental occlusion of right radial artery dated 11/03/2016.
- EC notification of **DMC recommendation**.

5. **Protocol No: EFC11570**:"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome"

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Dr. Sanjay Porwal – PI

- EC notification of CIOMS (safety alert # 134 & 135IN).
- EC notification of CIOMS (safety alert # 108 & 109IN)
- EC notification of CIOMS (safety alert # 136 & 137IN)
- EC notification of CIOMS (safety alert # 138)`

6. Any other matter with the permission of the Chairperson.

For your attention:

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia, to Member Secretary.

Yours truly,

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Chairman/Member Secretary)

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To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2. Dr. M.S.Ganachari, Prof.& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3. Dr. Harsha V.Hegde, Scientist'C' ICMR (RMRC), Nehru Nagar, Belagavi.
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5. Dr.S.S.Goudar,Prof.& HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
6. Dr. M.V. Jali, MD & CEO KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi.
7. Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi.
8. Dr.Hema Dhumale, Prof of of Obst & Gynace, JNMC,Belagavi.
9. Dr.Nayana Hashilkar, Asso.Prof. of Pharmacology, J.N. Medical College, Belagavi.
10. Mrs. Lalan Prabhu, Ramadev Galli, Belagavi.
11. Mr. B.N. Metagudmath, Retired Dy.SP, Vigilance Officer, KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi.
12. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13. Mrs.Geetanjali Salimath, Asst.Prof., Dept.of Pharmacy Practice, Belagavi.
14. Dr. N. M. Patil, Prof. & HOD,Dept.of Psychiatry , KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi. For Information.
15. The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
16. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
17. Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Accredited "A" grade by NAAC | Placed in Category "A" by MHRD [GoI]

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Ref: KLEU/EC/2016-17/D- 2163 ***Date: 09/09/2016***

Circular

The meeting of Ethics **Committee (EC)** of the **KLE University** is convened on **Thursday, 15th September 2016, 04:00 pm** at **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New Protocol for Approval:

1) **Ref: Protocol Number: CLR_16_13**
Protocol Title: A Randomized, Open label, Two Period, single Dose, Crossover, Bioavailability Study Of Paclitaxel Injection Concentrate for Nano-Dispersion (PICN) And Abraxane ® In Subjects with locally Recurrent Or Metastatic Breast Cancer
Dr. Rohan Bhise -PI
2) **Reference**: An Open-Label, Multicentric, Randomized, Two Treatment, Three Period, Three Sequence, Semi-Replicate, Cross-Over, Bioequivalence Study Of Pegylated Liposomal doxorubicin hydrochloride Concentrate For Solution For Fusion 2mg/Ml(20mg/10ml) manufactured by Actavis Italy SpA, Nerviano, Italy For Actavis Group PTC ehf, Iceland with caelyx 2 mg/ml concentrate for solution for infusion [Pegylated liposomal doxorubicin hydrochloride concentrate (20mg/10ml)] Of Janssen-Cilag International NV, Belgium in advanced ovarian cancer and/or metastatic breast cancer patients under fasting condition.
Dr. Mahesh Kumar Veeranna Kalloli - PI
3) **Reference:Protocol Number/ Title-** [Pfizer, A0081105, "A randomized, double-blind, placebo-controlled, parallel group, multi-center trial of pregabalin as adjunctive therapy in pediatric and adult subjects with primary generalized tonic-clonic seizures", PAREXEL, 208238]
Dr. Mahesh kamate-PI
4) Title of Study:An Open label Clinical Study to Determine the Specificity and Sensitivity of Algorithm (Software) developed by Bosch using Bosch Mobile non-mydriatic fundus camera comparing it with mydriatic 7-Standard Field Stereoscopic Digital Color Fundus Photography(EDTRS) done in patients with undiagnosed diabetic retinopathy(Symptomatic/asymptomatic)
Dr. Smitha .K.S-PI

II) Agenda: For Ongoing Trial Approval:

5) **Reference: Protocol no: CLR_15_06**
Protocol Title: A Multi-Center, Open-Label, Randomized, Crossover, Aqueous Humor Bioequivalence Study of LoteprednolEtabonate Ophthalmic Suspension 0.5% (Sun Pharmaceutical Industries, Ltd.) and Lotemax® (LoteprednolEtabonate Ophthalmic Suspension 0.5%; Bausch & Lomb, Inc.) in Subjects With Indicated Bilateral Cataract Surgery.
Dr.Rekha Mudhol-PI

01C

- Submission of study related documents for the review and approval.

6) **Ref:** A Randomized, Double-Blind, Placebo-Controlled, and Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the occurrence of Cardiovascular Events in Patients who have recently experienced an Acute Coronary Syndrome.

Dr.Sanjay Porwal-PI

- Submission of Protocol Amendment 11, Informed Consent Forms Ver3.1 and Patient Retention Brochure for above referenced study.

7) **Ref: BBIL/CTP/04/2010** study title:"A PHASE III, RANDOMIZED, MULTICENTERIC, CONTROLLED STUDY TO EVALUATE THE IMMUNOGENICITY AND SAFETY OF BBIL'S TYPHOID VI CAPSULAR POLYSACCHARIDE –TETANUS TOXOID PROTEIN CONJUGATE VACCINE Vs REFERENCE IN HEALTHY SUBJECTS".

Dr. (Mrs.) N.S. Mahantshetti-PI

- Submissions of 5 year follow up of above referenced study.

III. The Committee will consider the following agendas which are for information:

1) **Protocol:** "A Seamless, Sequential Phase III, Randomized, Multicenter, Single –Blind Study to Evaluate Immunogenicity, Safety and Reactogenicity of ROTAVAC 5C Formulation of the Live Attenuated Rotavirus Vaccine as a 3 Dose Series When Compared With ROTAVAC in Infants.
Protocol No-BBIL/ROTA5C/III/2014
Dr. (Mrs.) N.S. Mahantashetti-PI
No. of **SAE's** reported: 01 Dated 12/08/2016
SAE: lower Respiratory Tract Infection for subject no: **205063**

2) **Protocol Title:** "Maternal Docosa-hexenoic acid (DHA) Supplementation and offspring neurodevelopment in India – (DHANI-2)".
Dr.M.K. Swamy-PI
No. of **SAE's** reported: 02
- **SAE 01**: **Diarrhoea Leading to Death** for Subject no: **R0044-C** (Child) Dated 13/08/2016.
- **SAE 02**: **Advanced Peterm labour leading to stillbirth** for subject no: **R0291-C** (Child) Dated: 13/08/2016.

3) **Protocol Number: A65870;** A Phase III, randamozide, double-blind, active, controlled, multinational, multicenter , non inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum hemorrhage during the third stage of labour in women delivering vaginally
Dr.Yeshita.V.Pujar-PI
No of **SAE** reported: **02**
- **SAE 01: Dissociate disorder of pregnancy** for subject study ID: **08530** Dated:30/07/2016
- **SAE 02: a). Altered Sensorium b).convulsions** for subject study ID: **08595** Dated: 06/08/2016

4) **Protocol:15-VIN-284:** A randomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose, crossover, pivotal steady state bioequivalence study of Everolimus 10 mg tablet, Manufactured by Teva Pharmaceuticals - Pliva Croatia Ltd., Prilaz baruna Filipovica 25, 10000 Zagreb Croatia vs. Afinitor®(Everolimus) 10 mg tablet of Novartis Pharmaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients under fasting conditions.

Dr.Mahesh Kumar Kalloli-PI

- EC Notification of initial letter of SAE- Diarrhea Grade III with mild Weakness subject no: Q-15-284-002 at site Q. Date: 04/07/2016.
- EC Notification of initial and follow up of letter of SAE: **Death** for Subject no: Q-15-284-001) at site Q. Date: 14/07/2016.
- EC Notification of final analysis report for SAE: **Death** for subject no: Q-15-284-001/JCM at site Q. Date: 02/08/2016

5) **Protocol: 20110118**:"A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".

Dr. V. A. Kothiwale – PI

- EC Notification of SUSARs (10 June 2016 to 01 Jul 2016).
- EC notification of protocol deviation to EC of sub.no.11830031022.
- EC Notification of SUSARs (5 July to 30 July 2016)

6) **Protocol**: "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".

Dr. V. A. Kothiwale – PI

- EC Notification Of Additional Guidance For Investigational Product Administration

7) **Protocol**: "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".

Dr. V. A. Kothiwale – PI

- EC Notification of DMC Letter dated 26/07/2016.

8) **Protocol**: "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".

Dr. V. A. Kothiwale – PI

- EC Notification of inadvertent error in vital status consent Indian version 2.

9) **Ref:** A Randomized Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome.
Dr.Sanjay Porwal-PI
   - EC Notification of CIOMS **(safety alert # 181 & 189 IN)** dated 08/08/2016.
   - EC Notification of CIOMS **(safety alert # 182-183IN)** dated 08/08/2016.
   - EC Notification of CIOMS **(safety alert # 192 & 193IN)** dated 08/08/2016.
   - EC Notification of CIOMS **(safety alert # 194 & 195IN)** dated 08/08/2016.
   - EC Notification of CIOMS **(safety alert # 201 and 202IN)** dated 08/08/2016.
   - EC Notification of CIOMS **(safety alert # 204 & 205 IN)** dated 08/08/2016.

10) **Ref:** A Randomized Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome.
Dr.Sanjay Porwal-PI
   - EC Notification of eCRF Version 15.0

11) **Ref:** A Randomized Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome.
Dr.Sanjay Porwal-PI
   - EC Notification of Protocol Deviation

12) **Study title**: "effects of a yoga based cardiac rehabilitation programme on cardiovascular health: A clinical trial(India) and Mechanistic study(UK)
Dr.Sanjay Porwal-PI
   - Change of PI for Protocol entitled.

13) **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
Dr. Jayaprakash. Appajigol – PI
   - EC Notification of CIOMS (REAP-0006) dated 14/062016.
   - EC Notification of CIOMS (REA-20160071) dated 14/06 2016.
   - EC Notification of CIOMS (REA-20160071) dated 30/06/2016.
   - EC Notification of CIOMS (REAP-0006) dated 25/08/2016.
   - EC Notification of CIOMS (IPF-00002) dated 25/08/2016.
   - EC Notification of CIOMS (3001-00231) dated 25/08/2016
   - EC Notification of CIOMS (IPF-00002) dated 25/08/2016

14) **Protocol: 20110118**: A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease.
Dr. Shivakumar -Sub-I
   - EC Notification of Semi Annual update reports

15) **Protocol: EFC13889/ODYSSEY EAST**: A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab **(SAR236553/REGN727)** Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
Dr. V. A. Kothiwale – PI
- EC Notification of Updated Investigator undertaking above mentioned study.

16) **Reference:** An Open Label, Randomized, Multicenter study to evaluate and Compare the Immunogenicity and Reactogenicity of DTwP-Hib-IPV vaccine (EasyfourPol™, Panacea Biotec Ltd.) with Quadrovax™ (Tetravalent DTwP/Hib Vaccine, Serum Institute of India Ltd.) Co administered with Imovax Polio® (Salk Based inactivated Polio Vaccine, Sanofi Pasteur India Pvt. Ltd.) in Healthy Infants
Protocol Number: PBL/CR/2013/01/CT/EFPOL
Version Number: 03 dated 31-08-15
Dr. N.S Mahantashetti- PI
- EC Notification of Case Report Form.

17) **Reference:** An Open Label, Randomized, Multicenter study to evaluate and Compare the Immunogenicity and Reactogenicity of DTwP-Hib-IPV vaccine (EasyfourPol™, Panacea Biotec Ltd.) with Quadrovax™ (Tetravalent DTwP/Hib Vaccine, Serum Institute of India Ltd.) Co administered with Imovax Polio® (Salk Based inactivated Polio Vaccine, Sanofi Pasteur India Pvt. Ltd.) in Healthy Infants
Protocol Number: PBL/CR/2013/01/CT/EFPOL
Version Number: 03 dated 31-08-15
Dr. N.S Mahantashetti- PI
- EC notification of CTRI and CTA

18) **Ref:** " A 12 –Months Open Label study to Evaluate the Safety and Tolerability of Pregabalin as Adjuvant Therapy in Pediatric Subjects 1 months to 16 years of age with partial onset seizures and pediatric subjects 5 to 65 years of age with Primary Generalized Tonic-Clonic Seizures sponsored by Pfizer".
Dr. Mahesh Kamate-PI
- EC notification of clinical trial agreement.

19) **Ref:** Evaluation of Efficacy, Safety and Tolerability of a combination therapy with Chlorzoxazone and Ibuprofen compared to Ibuprofen alone in the symptomatic treatment of Acute Low Back pain(LBP): An open lable, prospective, multicentre, observational Study
Site No. 2
Dr.R.B.Uppin-PI
- EC Notification of audio-video consent form for above mentioned study.

20) **Protocol No.**WAT/LTPNL/2015: An Open Label, Randomized, Multicentric, Two Treatment, Single Dose, Parallel Group Two Stage Adaptive Design Bioequivalence

Study of Loteprednol Etabonate Ophthalmic Suspension, 0.5 % in Aqueous Humor of Patients Undergoing Indicated Cataract Surgery.

Dr.Smitha K.S-PI

- EC Notification of Clinical Study Report

21) **Ref:** A multicentre, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial of Cipla Ltd., India with ABRAXANE for Injectable Suspension (Paclitaxel protein-bound particles for injectable suspension) Manufactured for :Celgene Corporation Summit, USA in Breast cancer patients after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.
Protocol No.: 15-VIN-258

Dr. Rohan Bhise –PI

- EC notification of Clinical Trial Agreement Addendum-01

22) **Ref: Protocol: MK- 0822-018-01** a phase III randomized, placebo-controlled clinical trial to assess the safety and efficacy of odanacatib (MK-0822) to reduce the risk of fracture in osteoporotic postmenopausal women treated with vitamin D and calcium.

Dr.Rajendra Bhandankar-PI

- EC Notification of CIOMS Report letter dated 09/08/2016.

23) Ref: Protocol No. RLS/CAD/2015/02: " Prospective, multi-centre, randomized, two-arm, parallel group, active-control, comparative study to evaluate efficacy and safety of R-TPR-012/ Metalyse® in patients with ST segment elevation Myocardial Infarction (STEMI)"

- EC Notification for consideration of Dr.Sanjay Porwal for the above mentioned new study.

24) **Ref.: Project # CRL121429 :** A Randomized, Open-Label, Two Period, Two-Treatment, Two Sequence, Crossover, Multiple-Dose, Steady State, Bioequivalence Study of Clozapine Tablets 100 mg of Cadila healthcare Ltd., India with Clozaril® (Clozapine) Tablets 100mg Manufactured by: Novartis Pharmaceutical corporation, Suffern, New York 10901 in Patients with Schizophrenia or Schizoaffective Disorder under Fasting Conditions.

Dr. N. M. Patil-PI

- EC notification of clinical study update

25) **Ref.: Project # CRL121429 :** A Randomized, Open-Label, Two Period, Two-Treatment, Two Sequence, Crossover, Multiple-Dose, Steady State, Bioequivalence Study of Clozapine Tablets 100 mg of Cadila healthcare Ltd., India with Clozaril® (Clozapine) Tablets 100mg Manufactured by: Novartis Pharmaceutical corporation, Suffern, New York 10901 in Patients with Schizophrenia or Schizoaffective Disorder under Fasting Conditions.

Dr. N. M. Patil-PI

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t: 0831-2470400 FAX: 0831-2493099 www.kleuniversity.edu.in E-mail: kleclinicalresearch@gmail.com ,

- EC notification of clinical study Report

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia to Member Secretary.

Yours truly,

09/09/2016

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Chairman/Member Secretary)

Member Secretary
ETHICS COMMITTEE (EC)
KLE University, BELGAUM

To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2. Dr. M.S.Ganachari, Prof.& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3. Dr. Harsha V.Hegde, Scientist 'C' ICMR (RMRC), Nehru Nagar, Belagavi.
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5. Dr. M.V. Jali, MD & CEO KLE Dr.Prabhakar Kore Hospital and MRC, Belagavi.
6. Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7. Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi.
8. Dr.Hema Dhumale, Prof of Obst & Gynacecolgy, JNMC, Belagavi.
9. Dr.Nayana Hashilkar, Asso.Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10. Mrs. Lalan Prabhu, Ramadev Galli, Belagavi.
11. Mr. B.N. Metagudmath, Retired Dy.SP, Vigilance Officer, KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi.

12. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13. Mrs.Geetanjali Salimath, Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14. Dr. Rohan Bhise Dept. of Oncology, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi.
15. Dr. Maheshkumar Veeranna Kalloli, Consultant, Oncology Dept., KLES Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belgaum.
16. Dr.Mahesh Kamate, professor of Pediatric Neurology, In charge of child development centre, KLES Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belgavi
17. Dr.Smitha Prabhu, Consultant, Dept. of Ophthalmology, KLES Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belagavi
18. The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
19. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
20. Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2016-17/D- 1036

Date: 15/06/2016

Circular

The meeting of Ethics **Committee (EC)** of the **KLE University** is convened on **Monday, 20th June 2016, 04:00 pm** at **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New Protocol for Approval:

1. **Protocol No. : CLR_15_06**
   Protocol Title:A Multi-Center, Open-Label, Randomized, Crossover, Aqueous Humor Bioequivalence Study of LoteprednolEtabonate Ophthalmic Suspension 0.5% (Sun Pharmaceutical Industries, Ltd.) and Lotemax® (LoteprednolEtabonate Ophthalmic Suspension 0.5%; Bausch & Lomb, Inc.) in Subjects With Indicated Bilateral Cataract Surgery.
   Dr. Rekha Mudhol – PI
2. **Protocol No.:CRL 121526**
   Protocol Title:-A randomized, open label, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) of Panacea Biotec, India with ABRAXANE® (Paclitaxel protein-bound particles for injectable suspensio (Albumin bound) manufactured for Celgene Corporation, Summit, NJ in patients with metastatic breast cancer under fasting conditions.
   Dr.Rohan Bhise – PI

II. Agenda: For Ongoing Trial Approval:

3. **Protocol: 20110118**:"A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   Dr. V. A. Kothiwale – PI

- Review and approval of Fourier Neurological Questions Implementation at EOS visits for EC.

III. The Committee will consider the following agendas which are for information:

1. **Protocol: EFC13889/ODYSSEY EAST**: A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
   Dr.Sanjay Porwal-PI

- EC Notification of CIOMS (safety alert # 171 & 172 IN) dated 23/05/2016.

OFFICE OF THE REGISTRAR
KLE UNIVERSITY
BELAGAVI
16 JUN 2016
Inward No. 26 Sign.

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- EC Notification of CIOMS **(safety alert # 165IN)** dated 10/05/2016.
- EC Notification of CIOMS **(safety alert # 166 & 167IN)** dated 31/05/2016.
- EC Notification of CIOMS **(safety alert # 169 & 170IN)** dated 19/05/2016.

2. **Protocol: 20110118**:"A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".

   Dr. V. A. Kothiwale – PI
   - EC Notification of SUSARs (20 May 2016 to 01 June 2016)
   - EC Notification of SUSARs (02 June 2016 to 09 June 2016)
   - EC notification of protocol deviation to EC of sub.no.11830031022.

3. **Protocol: ACTA/PAC/2015** -A randomized, open label, multi centric, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial manufactured by Sindan Pharma for Actavis and Abraxane® 100 mg/vial (Albumin bound Paclitaxel 260 mg/m2) intravenous infusion manufactured by Celgene Europe limited, United Kingdom in patients with metastatic breast cancer.

   Dr. Mahesh Kumar Veeranna Kalloli – PI
   - EC Notification of correction of typographical error in the submission letter dated 11/Apr/2016

4. **Ref: Protocol:** A multicentre, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial of Cipla Ltd., India with ABRAXANE for Injectable Suspension (Paclitaxel protein-bound particles for injectable suspension) Manufactured for :Celgene Corporation Summit, USA in Breast cancer patients after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.

   Study No.: 15-VIN-258

   Dr.Rohan Bhise-PI
   - EC Notification of PI analyzed report of SAE – Death

5. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.

   Dr. Jayaprakash. Appajigol – PI
   - EC Notification of CIOMS(REAP-0006) dated 14 JUNE 2016
   - EC Notification of CIOMS(REA-20160071) dated 14 JUNE 2016

6. Any other matter with the permission of the Chairperson.

For your information:
Please make it convenient to attend the meeting and, communicate if you seek leave of absentia, to Member Secretary.

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Yours truly,

Member Secretary
IEC-HSCS COMMITTEE (EC)
KLE University, BELGAUM

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Chairman/Member Secretary)

To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2. Dr. M.S.Ganachari, Prof.& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3. Dr. Harsha V.Hegde, Scientist'C' ICMR (RMRC), Nehru Nagar, Belagavi.
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5. Dr. M.V. Jali, MD & CEO KLE Dr.Prabhakar Kore Hospital and MRC, Belagavi.
6. Dr.S.S.Goudar,Prof.& HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7. Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi.
8. Dr.Hema Dhumale, Prof of of Obst & Gynace, JNMC,Belagavi.
9. Dr.Nayana Hashilkar, Asso.Prof. of Pharmacology, J.N. Medical College, Belagavi.
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14. Dr.Rekha Mudhol,Prof.Dept.of Opthalomology, JNMC, Belagavi. Principal Investigator -For Information.
15. Dr.Rohan Bhise, Consultant,Dept.of Oncology , KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi. Principal Investigator -For Information.
16. The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
17. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
18. Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2016-17/D- 1582

Date: 19/07/2016

Circular

The meeting of Ethics **Committee (EC)** of the **KLE University** is convened on **Wednesday, 27th July 2016, 04:00 pm** at **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New Protocol for Approval:

1) **Protocol No.: PBL/CR/2013/01/CT/EFPOL**
Protocol Title: An open label, Randomized, multicentre study to evaluate and compare the immunogenicity and Reactogenicity of DTwP-Hib-IPV vaccine (EasyfourPol ™, Panacea Biotec Ltd.) with Quadrovax ™ (Tetravalent DTwP/Hib vaccine, Serum Institute of India Ltd.) Co administered with Imovax Polio® (Salk based inactivated Polio Vaccine. Sanofi Pasteur India Pvt. Ltd.) in Healthy Infants.
Dr.Mahantasheeti –PI
2) **Protocol No. :**
Protocol Title: Evaluation of efficacy, safety and tolerability of a combination therapy with chlorzoxazone and ibuprofen compared to ibuprofen alone in the symptomatic treatment of Acute Low Back Pain (LBP): An open lable, prospective, observational study
Dr.R.B.Uppin-PI
3) **Protocol No.: PBL/CR/2014/05/CT/DEN**
Protocol Title: A Phase I/II, Double Blind, Placebo controlled, Randomized Multicenter, prospective study to evaluate the Safety and Immunogenicity of a single dose 'Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized)' in healthy subjects.
Dr. Madhav Prabhu-PI

II. Agenda: For Ongoing Trial Approval:

4) **Protocol: EFC13889/ODYSSEY EAST**: A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
Dr. V. A. Kothiwale – PI
- EC Submission of Review and Approval.

5) **Protocol:** "Effects of a yoga-based cardiac rehabilitation programme (Yoga-CaRe) on cardiovascular health: a clinical trial (India) and mechanistic study (UK)"
Dr.Sanjay porwal-PI
- Discontinuation as PI for Protocol entitled.

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6) **Protocol:** A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When Evolocumab (AMG 145) is Used in Combination With Statin Therapy In Patients with Clinically Evident Cardiovascular Disease.
Dr. V. A. Kothiwale – PI

- Submission of documents for ethics committee approval and notification.

III. <u>The Committee will consider the following agendas which are for information:</u>

Protocol: EFC13889/ODYSSEY EAST: A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Alirocumab (SAR236553/REGN727) Versus Ezetimibe in Asia in High Cardiovascular Risk Patients with Hypercholesterolemia Not Adequately Controlled With Their Statin Therapy.
Dr.Sanjay Porwal-PI

- EC Notification of CIOMS **(safety alert # 171 & 172 IN)** dated 23/05/2016.
- EC Notification of CIOMS **(safety alert # 165IN)** dated 10/05/2016.
- EC Notification of CIOMS **(safety alert # 166 & 167IN)** dated 31/05/2016.
- EC Notification of CIOMS **(safety alert # 169 & 170IN)** dated 19/05/2016.
- EC Notification of CIOMS **(safety alert # 169 & 170IN)** dated 29/06/2016.
- EC Notification of CIOMS **(safety alert # 180& 181IN)** dated 20/06/2016.

2. **Protocol: 20110118**:"A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
Dr. V. A. Kothiwale – PI

- EC Notification of SUSARs (10 June 2016 to 01 Jul 2016).
- EC notification of protocol deviation to EC of sub.no.11830031022.

3. **Protocol: ACTA/PAC/2015** -A randomized, open label, multi centric, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial manufactured by Sindan Pharma for Actavis and Abraxane® 100 mg/vial (Albumin bound Paclitaxel 260 mg/m2) intravenous infusion manufactured by Celgene Europe limited, United Kingdom in patients with metastatic breast cancer.
Dr. Mahesh Kumar Veeranna Kalloli – PI

- EC Notification of correction of typographical error in the submission letter dated 11/Apr/2016.

4. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
Dr. Jayaprakash. Appajigol – PI

- EC Notification of CIOMS (REAP-0006) dated 14/062016.

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- EC Notification of CIOMS (REA-20160071) dated 14/06 2016.
- EC Notification of CIOMS (REA-20160071) dated 30/06/2016.

5. **Protocol:15-VIN-284:** A randomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose, crossover, pivotal steady state bioequivalence study of Everolimus 10 mg tablet, Manufactured by Teva Pharmaceuticals - Pliva Croatia Ltd., Prilaz baruna Filipovica 25, 10000 Zagreb Croatia vs. Afinitor®(Everolimus) 10 mg tablet of Novartis Pharmaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients under fasting conditions.
Dr.Mahesh Kumar Kalloli-PI
   - EC Notification of initial letter of SAE-{Diarrhea Grade III with mild Weakness}-subject no: Q-15-284-002 at site Q. Date: 04/07/2016.
   - EC Notification of initial and follow UP of letter of SAE: **Death.** Subject no: Q-15-284-001) at site Q. Date-14/07/2016.

Any other matter with the permission of the Chairperson

For your attention:

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia to Member Secretary.

Yours truly,

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Chairman/Member Secretary)

To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2. Dr. M.S.Ganachari, Prof.& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3. Dr. Harsha V.Hegde, Scientist'C' ICMR (RMRC), Nehru Nagar, Belagavi.
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5. Dr. M.V. Jali, MD & CEO KLE Dr.Prabhakar Kore Hospital and MRC, Belagavi.

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Office of the Registrar, KLE University,
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6. Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7. Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi.
8. Dr.Hema Dhumale, Prof of Of Obst & Gynace, JNMC, Belagavi.
9. Dr.Nayana Hashilkar, Asso.Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10. Mrs. Lalan Prabhu, Ramadev Galli, Belagavi.
11. Mr. B.N. Metagudmath, Retired Dy.SP, Vigilance Officer, KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi.
12. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13. Mrs.Geetanjali Salimath, Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14. Dr.Mahantasheeti, Professor, JNM Medical College, Belagavi.
15. Dr.B.S.Uppin, Professor in K.L.E University, J.N.Medical College, Belagavi.
16. Dr.Madhav Prabhu, Asso. Prof. Dept. of Medicine, J.N.Medical College, Belagavi.
17. The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
18. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
19. Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2016-17/D- 3388

Date: 22/12/2016

Circular

The meeting of **Ethics Committee (EC)** of the **KLE University** is convened on **Thursday, 29th December 2016, 04:00 pm** at **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New protocol

1. **Protocol:** A prospective, Single-centre, Observational, real world, Post-marketing surveillance to evaluate safety and performance of the BioMime™ Morph Sirolimus Eluting Coronary Stent System for very long coronary lesions.
   Dr.Surseh V Patted-PI
2. **Protocol no:** RLS/RES/2016/01: version 1.0, dated: 05 Feb 2016
   Protocol title: Prospective, multi-centre, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-022/Xolair® in patients with moderate to severe persistent asthma.
   Dr.Jyothi hattiholi –PI
3. **Protocol:** A prospective, Post-marketing, Single-centre, study to evaluate safety and performance of the Evermine 50-50µm Everolimus Eluting Coronary Stent system (EES) in the treatment of patients with *de novo* coronary artery Lesions.
   Protocol version: 1.0.0 Dated 23rd Nov 2016
   Dr.Surseh V Patted-PI
4. **Accreditation of Forum for ethical review committees in Asia and the western pacific(FERCAP)**

II. The Committee will consider the following agendas which are for information:

1. **Protocol No: NCS-353-15-CS**
   Study Title: An open label, randomized, balanced, two treatment, two period, two sequence, single dose, crossover, oral bioequivalence study of 600mg/m2 of Vinorelbine soft capsule from lotus pharmaceutical co., Ltd., Taiwan compared with that of 60 mg/m2 of NAVELBINE® soft capsule marketed by PIERRE FABRE Limited, Winchester Hampshire S023 7DR, United Kingdom, in adult, patients with advanced breast cancer under fed conditions.
   Dr.Mahesh Kumar Kalloli-PI
   - **EC notification of insurance document valid till 30-November-2017**
   - **EC notification of CRF Version**

2. **Protocol** I4V-MC-JADY- A phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Barcitinib in Patients with Rheumatoid Arthritis.
   Dr.Shailesh Udapudi-PI
   - **EC notification of SAFRONS/CIOMS**
   - **EC notification of Updated Insurance document valid up to 31-Aug-2019**
3. **Protocol Number:** A seamless, sequential Phase III, multicenter, randomized, single-blind study to evaluate the immunogenicity, reactogenicity and safety of ROTAVAC 5C new formulations of the live attenuated rotavirus vaccine as a 3 dose series when compared with existing ROTAVAC® in healthy infants.

   Dr .N.S.Mahantashetti-PI
   - **EC notification of Protocol Deviation**
   - **EC notification of ICF- EC Contact details**
   - **EC notification of Study Update**
   - **EC notification of SAE of Others sites**
4. **Protocol:** Prospective, Multi-centric, Double-blind, Comparative, Clinical Study to Compare the Efficacy and Safety of Intravenous Ulinastatin versus Placebo Adjunct To Standard Supportive Care In Subjects With Severe Sepsis, A Phase IV Study.
   Dr.Pournima Patil-PI
   - **EC notification of CTA**
5. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''
   Dr.Sanjay Porwal-PI
   - **EC Notification of CIOMS(Safety alert#243 and 244IN,**corrigendum to SA#136,SA#139,SA#161,SA#168,SA#207,SA#215,SA#220)
   - **EC Notification of CIOMS(Safety alert#245)** dated 29/11/2016
   - **EC Notification of CIOMS(** Safety alert#**246 and 247IN,** Corrigendum To SA#244)
   - **EC Notification of DMC(Data Monitoring Committee) letter**
6. **Protocol:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When Evolocumab (AMG 145) is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   Dr.V.A.Kothiwale-PI
   Site No: 30031

- **EC Notification of SUSAR's** dated 07/Nov/2016
- **EC Notification of SUSAR's** dated 08/ Dec/2016
- **EC Notification of Outstanding IP, Placebo and Atorvaststin.**

7. **Protocol** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When Evolocumab (AMG 145) is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   Dr.V.A.Kothiwale-PI
   Site No: 30064
   - **EC Notification of follow Up End Point** { Generalized Tonic Clonic Convulsion and Sudden Cardio respiratory Arrest Lead to Death} **dated 05/ 12/2016**
8. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   Dr.Jayaprakash Appajigol-PI
   - **EC notification of CIOMS** Report#3001-00291 **Event:** Multiple acute atrial fibrillation episodes, Initial dated 07-12-2016
   - **EC notification of CIOMS** Report#3001-00289 **Event**: 1.Descending aorta thrombus,2.Ishemic bowel/Duodenal perfusion, Follow up-02 dated 07-12-2016
   - **EC notification of CIOMS** Report#3001-00200 **Event:** Post-extubation stridor, Follow up-05 dated 07-12-2016
   - **EC notification of CIOMS** Report#REA-00057 **Event:** anaphylactic Shock, Follow up-05 dated 07-12-2016
   - **EC notification of CIOMS** Report#3001-00291 **Event:** Multiple acute atrial fibrillation episodes, Follow up-V1 dated 015-12-2016
   - **EC notification of CIOMS** Report#3001-00289 **Event:**1.Descending aorta Thrombus,2.Ischemic Bowel/Duodenal Perforation Follow up02 dated 015-12-2016
9. **Protocol:** A multicentre, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial of Cipla Ltd., India with ABRAXANE for Injectable Suspension (Paclitaxel protein-bound particles for injectable suspension) Manufactured for :Celgene Corporation Summit, USA in Breast cancer patients after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.
   Dr.Rohan Bhise-PI
   Study No.: 15-VIN-258

- **EC notification of CIOMS** Dated:12/12/2016
- **EC notification of CIOMS** Dated:12/12/2016
- **EC notification of CIOMS** Dated:12/12/2016

10. **Protocol:** A multicenter, open label, balanced, randomized, two treatment, two-period crossover, multi-dose, steady state, bioequivalence study of Nevirapine 400 mg prolonged release tablets, Manufactured by Amneal Pharmaceuticals Pvt. Ltd. India compared to Viramune 400 mg prolonged release tablets, Marketed by Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany in adult HIV1 infected patients under fasting condition.
Study No.: 15-VIN-479
Dr.Dnynesh N Morkar-PI
    - **EC Notification of study initiation**

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia to Member Secretary.

Yours truly,

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Chairman/Member Secretary)
Member Secretary
ETHICS COMMITTEE (EC)
KLE University, BELGAUM

To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2. Dr. M.S.Ganachari, Prof.& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3. Dr. Harsha V.Hegde, Scientist 'C' ICMR (RMRC), Nehru Nagar, Belagavi.
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5. Dr. M.V. Jali, MD & CEO KLE Dr.Prabhakar Kore Hospital and MRC, Belagavi.

6. Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7. Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi
8. Dr.Yeshita Pujar, Prof of Obst & Gynace, JNMC,Belagavi
9. Dr.Nayana Hashilkar, Asso.Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10. Mrs.Vaishnavi V Kivadasannavar, M.S.W, Virupaxi Residency 2nd Main, 5th Cross, Sadashiva Nagar, Belagavi.
11. Shri.Tamanna Dadu Kore,Layperson, Near Shanthi Sagar School, Manjari, Chikkodi, Belagavi-591213
12. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13. Mrs.Geetanjali Salimath, Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14. Dr.SureshV Patted, Professor and HoD of Cardiology department, J.N.Medical College, Belagavi-10
15. Dr.Jyothi Hattiholi, Asst.Prof. Dept of Respiratory Medicine, J.N.Medical College, Belagavi-10
16. The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
17. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
18. Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2016-17/D- 3146 ***Date: 26/11/2016***

Circular

The meeting of **Ethics Committee (EC)** of the **KLE University** is convened on **Tuesday, 29th November 2016, 04:30 pm at Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New Protocol for Approval:

- **There is no new protocol for approval**

II.The Committee will consider the following agendas which are for information:

1. **Reference:** Project # MYL-1402O-3001 :Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.
   Dr.Mahesh Kumar Kalloli-PI
   - **EC notification of insurance document valid till 30-septmeber-2017**
2. **Reference:** Project # MYL-1402O-3001 :Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.
   Dr.Mahesh Kumar Kalloli-PI
   - **EC notification of DCGI approval letter**
3. **Reference**: A randomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose, crossover, pivotal steady state bioequivalence study of Everolimus 10 mg tablet, Manufactured by Teva Pharmaceuticals - Pliva Croatia Ltd., Prilaz baruna Filipovica 25, 10000 Zagreb Croatia vs. Afinitor®(Everolimus) 10 mg tablet of Novartis Pharmaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients under fasting conditions.
   Dr.Mahesh Kumar Kalloli-PI
   - **EC notification of addendum1 Clinical Trial Agreement**
4. **Reference**: A randomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose, crossover, pivotal steady state bioequivalence study of Everolimus 10 mg tablet, Manufactured by Teva Pharmaceuticals - Pliva Croatia Ltd., Prilaz baruna Filipovica 25, 10000 Zagreb Croatia vs. Afinitor®(Everolimus) 10 mg tablet of Novartis Pharmaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients under fasting conditions.
   Dr.Mahesh Kumar Kalloli-PI
   - **EC notification of protocol deviation**

5. **Ref: Protocol** I4V-MC-JADY- A phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Barcitinib in Patients with Rheumatoid Arthritis.
   Dr.Shailesh Udapudi-PI
   - **EC notification for Data Monitoring Committee (DMC) Letter**
6. **Ref:**"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''
   Dr. Sanjay Porwal-PI
   - **EC notification of typographical error noted in EC submission dated 10-Feb-2015**
7. **PROTOCOL TITLE:** An Open Label, Randomized, Multicenter study to Evaluate and Compare the Immunogenicity and Reactogenicity of DTwP-Hib-IPV vaccine (EasyfourPol™, Panacea Biotec Ltd.) with Quadrovax™ (Tetravalent DTwP/Hib Vaccine, Serum Institute of India Ltd.) Co administered with Imovax Polio® (Salk Based inactivated Polio Vaccine, Sanofi Pasteur India Pvt. Ltd.) in Healthy Infants.

   Dr .N.S.Mahantashetti-PI

   - **EC notification of updated Insurance**
8. **Ref:**"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''
   Dr. Sanjay Porwal-PI
   - **EC notification of Protocol Deviation**
9. **Ref:**"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''
   Dr. Sanjay Porwal-PI
   - **EC notification of 10th Semi Annual Safety Report**
10. **Ref:**"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''
    Dr. Sanjay Porwal-PI
    - **EC Clarification of submission of CTRI letter**
11. **Ref:**"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of

Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''

Dr. Sanjay Porwal-PI

- **EC notification of Clarification of Discrepancy letter dated 22 Jun 2016**

12. **Protocol title:** A Multi-Centre, Randomized, Open-Label, Two Period, TwoTreatment, Two Sequence, Multiple-Dose, Crossover, Bioequivalence Study of Pramipexole Prolonged Release Tablets 3.15 mg of Mylan Laboratories Ltd., India with Sifrol® 3.15 mg (Pramipexole) depottabletter (depot tablet) of Boehringer Ingelheim International GmbH, Germany in Patients with Idiopathic Parkinson's disease. PROTOCOL VERSION: 1.0, dated 16 Sep 2015

Dr.Madhav Prabhu-PI

- **EC notification of protocol Deviation**

13. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.

Dr.Jayaprakash Appajigol-PI

- **EC notification of DMC letter dated 07 Nov 2016**

14. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.

Dr.Jayaprakash Appajigol-PI

- EC notification of CIOMS Report#3001-00231 dated 14-Nov-2016
- EC notification of CIOMS Report# 30001-00231 follow up dated 25-Nov-2016
- EC notification of CIOMS Report#REA-00057 initial dated 09-Nov-2016
- EC notification of CIOMS Report#REA-00057 dated follow up 16-Nov-2016
- EC notification of CIOMS Report#IPF-00002 follow up dated 19-Nov-2016
- EC notification of CIOMS Report# 30001-00289 initial dated 25-Nov-2016
- EC notification of CIOMS Report#30001-00289 follow up 1 dated 25-Nov-2016

15. **Ref:**"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome''

Dr. Sanjay Porwal-PI

- EC notification of CIOMS Safety alert#212-#213IN dated 09-Nov-2016
- EC notification of CIOMS Safety alert#199-#200IN dated 09-Nov-2016
- EC notification of CIOMS Safety alert#207IN dated 09-Nov-2016
- EC notification of CIOMS Safety alert#190-#191IN dated 09-Nov-2016
- EC notification of CIOMS Safety alert#239-#240IN dated 15-Nov-2016
- EC notification of CIOMS Safety alert#237-#238IN dated 14-Nov-2016
- EC notification of CIOMS Safety alert#236IN dated 14-Nov-2016
- EC notification of CIOMS Safety alert#234-#235IN dated 05-Nov-2016
- EC notification of CIOMS Safety alert#224-#225IN dated 10-Nov-2016

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- EC notification of CIOMS Safety alert#232-#233IN dated 04-Nov-2016
- EC notification of CIOMS Safety alert#229-#230IN dated 04-Nov-2016
- EC notification of CIOMS Safety alert#231-#215IN dated 09-Nov-2016
- EC notification of CIOMS Safety alert#217-#218IN dated 26-Oct-2016
- EC notification of CIOMS Safety alert#222-#223IN dated 12-Oct-2016
- EC notification of CIOMS Safety alert#212-#213IN dated 09-Nov-2016
- EC notification of CIOMS Safety alert#228-#226IN dated 25-Oct-2016
- EC notification of CIOMS Safety alert SA#219IN dated 04-Oct-2016
- EC notification of CIOMS Safety alert#214IN dated 20-Oct-2016
- EC notification of CIOMS Safety alert#220-#221-#219IN dated 04-Oct-2016
- EC notification of CIOMS Safety alert#226-#227IN dated 11-Oct-2016
- EC notification of CIOMS (safety alert#215-#216IN) dated 09-Nov-2016

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia to Member Secretary.

Yours truly,

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Chairman/Member Secretary)

Member Secretary
ETHICS COMMITTEE (EC)
KLE University, BELGAUM

To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2. Dr. M.S.Ganachari, Prof.& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3. Dr. Harsha V.Hegde, Scientist 'C' ICMR (RMRC), Nehru Nagar, Belagavi.

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4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5. Dr. M.V. Jali, MD & CEO KLE Dr.Prabhakar Kore Hospital and MRC, Belagavi.
6. Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
7. Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi.
8. Dr.Hema Dhumale, Prof of Obst & Gynacecolgy, JNMC, Belagavi.
9. Dr.Nayana Hashilkar, Asso.Prof. Of Pharmacology, J.N. Medical College, Belagavi.
10. Mrs. Lalan Prabhu, Ramadev Galli, Belagavi.
11. Mr. B.N. Metagudmath, Retired Dy.SP, Vigilance Officer, KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi.
12. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13. Mrs.Geetanjali Salimath, Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14. The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
15. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
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Ref: KLEU/EC/2016-17/D- 2761 **Date: 15/10/2016**

Circular

The meeting of **Ethics Committee (EC)** of the **KLE University** is convened on **Thursday, 20th October 2016, 04:00 pm** at **Site Management Office (SMO), KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New Protocol for Approval:

1.Protocol-Comparative evaluation of immunogenicity of various schedules, delivery options to provide fractional dose inactivated poliovirus vaccine (IPV) in routine immunization in the post tOPV-tOBV period: A multicentric open label randomized controlled trial"(India IPV fractional dose study)
Protocol No.: PBL/CR/2016/02/CT/fIPV (version 01 dated 24/08/2016)
Dr.N.S Mahantashetti-PI

2.Reference: Project # MYL-1402O-3001 :Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer.
Dr.Mahesh Kumar Kalloli-PI

3. A 12-MONTH OPEN-LABEL STUDY TO EVALUATE THE SAFETY AND TOLERABILITY OF PREGABLIN AS ADJUNCTIVE THERAPY IN PEDIATRIC SUBJECTS 1 MONTH TO 16 YEARS OF AGE WITH PARTIAL ONSET SEIZURES AND PEDIATRIC AND ADULT SUBJECTS 5 TO 65 YEARS OF AGE WITH PRIMARY GENERALIZED TONIC-CLONIC SEIZURES
Protocol Number: A0081106
Dr.Mahesh Kamate-PI

II. Agenda: For Ongoing Trial Approval:

4. Ref: Protocol Number: CLR_16_13
Protocol Title: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer.
Dr.Rohan Bhise-PI

- EC submission of amended study documents for review and approval

III.The Committee will consider the following agendas which are for information:

1. **Protocol No: NCS-353-15-CS**

   Study Title: An open label, randomized, balanced, two treatment, two period, two sequence, single dose, crossover, oral bioequivalence study of 600mg/m2 of Vinorelbine

soft capsule from lotus pharmaceutical co., Ltd., Taiwan compared with that of 60 mg/m2 of NAVELBINE® soft capsule marketed by PIERRE FABRE Limited, Winchester Hampshire S023 7DR, United Kingdom, in adult, patients with advanced breast cancer under fed conditions.

Dr. Mahesh Kumar Kalloli- PI

- EC notification of CTRI Registration document and DCGI Acknowledgement letter

2. Protocol Title: "Maternal Docosa-hexenoic acid (DHA) Supplementation and offspring neurodevelopment in India – (DHANI-2)"
Dr.M.K.Swamy-PI
   - **SAE: Early neonatal Death** of child of Subject no: **R0089-C** (Child)

3. **"Protocol Number: A65870; A Phase III, randamozide, double-blind, active, controlled, multinational, multicenter , non inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum hemorrhage during the third stage of labour in women delivering vaginally"**
Dr.Yeshita.V.Pujar- Sub-I
   - **SAE: Convulsions** for subject **ID: 08666**
4. Research project titled **"Aspirin Supplementation for Pregnancy Indicated Risk Reduction in Nulliparas (ASPIRIN)."**
Dr. M.C.Metgud Co-PI
No of SAE: 03
   - **SAE 01: PV bleeding** for subject ID: **1-08-0247-B**
   - **SAE 02: PV bleeding** for subject ID: **1-08-0326-F**
   - **SAE 03: Bleeding per vagina** for subject ID: **1-08-0045-N**

5. **Ref: Protocol** I4V-MC-JADY- A phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Barcitinib in Patients with Rheumatoid Arthritis.
Dr.Shailesh Udapudi-PI
   - **SAE: Viral fever with thrombocytopenia** for subject no: **68572**
6. **Ref:** Protocol: MK- 0822-018-01
Study Title: a phase III randomised, placebo-controlled clinical trial to assess the safety and efficacy of odanacatib (MK-0822) to reduce the risk of fracture in osteoporotic postmenopausal women treated with vitamin D and calcium.
Dr. Rajendra Bhandankar-PI
   - EC notification of sponsor's letter of Discontinuation of the Odancatib (MK-0822) Program
7. **Reference: Protocol Number/ Title- [Pfizer, A0081105, "A randomized, double-blind, placebo-controlled, parallel group, multi-center trial of pregabalin as**

adjunctive therapy in pediatric and adult subjects with primary generalized tonic-clonic seizures", PAREXEL, 208238]

Dr. Mahesh Kamate-PI

- EC notification of type error in the submission letter
- EC notification of CTRI registration for additional sites dated 15/Jul/2015
- EC notification of DCGI Approval letter of the site dated 09/Sept/2016
- EC notification of Undertaking of the principle investigator dated 03/Oct/2016 and CV Dated 29/Sep/2016.

8. **Reference Protocol Title: I4V-MC-JADY Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.**
   Dr.Shailesh Udapudi –PI
   - EC notification of protocol Deviation for subject no:**53824**
9. **Reference Protocol Title: I4V-MC-JADY Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.**
   Dr.Shailesh Udapudi –PI
   - EC notification of protocol Deviation of missed dose for subject no:**68572**
10. **Reference Protocol Title: I4V-MC-JADY Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.**
    Dr.Shailesh Udapudi –PI
    - EC notification of protocol Deviation for subject no:**68571** for visit **11**
11. **Reference Protocol Title: I4V-MC-JADY Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.**
    Dr.Shailesh Udapudi –PI
    - EC notification of protocol Deviation for subject no:**53824 for visit 11**
12. **Reference: Protocol no:** CLR_15_06
    Protocol Title: A Multi-Center, Open-Label, Randomized, Crossover, Aqueous Humor Bioequivalence Study of Loteprednol Etabonate Ophthalmic Suspension 0.5% (Sun Pharmaceutical Industries, Ltd.) and Lotemax® (Loteprednol Etabonate Ophthalmic Suspension 0.5%; Bausch & Lomb, Inc.) in Subjects With Indicated Bilateral Cataract Surgery.
    Dr.Rekha Mudhol-PI
    - EC notification of renewed insurance policy period is from 01-Jul-2016 to 30-Jun-2017
13. **Protocol Title** "A Randomized, Open-Label, Two Period, Two-Treatment, Two Sequence, Single-Dose, Crossover, Bioequivalence Study of Paclitaxel Protein-bound

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Particles for Injectable Suspension (albumin-bound) of Panacea Biotec, India with ABRAXANE® (Paclitaxel Protein-bound Particles for Injectable Suspension) (albumin-bound) manufactured for Celgene Corporation, Summit, NJ in Patients with Metastatic Breast Cancer under Fasting Conditions".
Protocol ID No: CRL121526
Dr. Rohan Bhise-PI

- EC notification of CTRI registration letter.

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia to Member Secretary.

Yours truly,

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Chairman/Member Secretary)

To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2. Dr. M.S.Ganachari, Prof.& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3. Dr. Harsha V.Hegde, Scientist 'C' ICMR (RMRC), Nehru Nagar, Belagavi.
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5. Dr. M.V. Jali, MD & CEO KLE Dr.Prabhakar Kore Hospital and MRC, Belagavi.
6. Dr.S.S.Goudar, Prof. & HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.

7. Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi.
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12. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13. Mrs.Geetanjali Salimath, Asst.Prof. Dept.of Pharmacy Practice, Belagavi.
14. Dr.Mahantasheeti, Professor, JNM Medical College, Belagavi.
15. Dr. Maheshkumar Veeranna Kalloli, Consultant, Oncology Dept., KLES Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belgaum.
16. Dr.Mahesh Kamate, Professor of Pediatric Neurology, Incharge of child development centre, KLES Dr Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belgavi
17. The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
18. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
19. Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2015-16/D-4764 ***Date: 21/01/2016***

Circular

The meeting of Ethics **Committee (EC)** of the **KLE University** is convened on **Thursday, 28th January 2016, 04:00 pm** at **Site Management Office (SMO), KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belagavi.**

I. Agenda: New Protocol for Approval:

1. **Protocol: CRL121429 :** A Randomized, Open-Label, Two Period, Two-Treatment, Two Sequence, Crossover, Multiple-Dose, Steady State, Bioequivalence Study of Clozapine Tablets 100 mg of Cadila healthcare Ltd., India with Clozaril® (Clozapine) Tablets 100mg Manufactured by: Novartis Pharmaceutical corporation, Suffern, New York 10901 in Patients with Schizophrenia or Schizoaffective Disorder under Fasting Conditions.

   Dr. N. M. Patil - PI

II. Agenda: For Ongoing Trial Approval:

1. **Protocol:** A multicentre, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial of Cipla Ltd., India with ABRAXANE for Injectable Suspension (Paclitaxel protein-bound particles for Injectable suspension) Manufactured for :Celgene Corporation Summit, USA in Breast cancer patients after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.
   - Study documents for EC review & approval
2. **Protocol:** 20110118:"A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".

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- Study documents for EC review & approval

III. The Committee will consider the following agendas which are for information:

Reading & Approving the CIOMS received.

1. **Protocol Title: I4V-MC-JADZ:** A Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Moderately to Severely Active Rheumatoid Arthritis Who Have had Limited or No Treatment with Disease Modifying Antirheumatic Drugs.

   Dr. Shailesh Udapudi – PI

   - EC notification of missing points in approval letter dated 05/10/2013

2. **Protocol Title:** "A Phase Bridging study to evaluate the Immunogenicity and Safety of a Pentavalent Vaccine (DTwP-HepB-Hib) Shan 5 (with Shanta pertussis) as Compared to the licensed vaccine Shan 5 (with imported pertussis) when administered as three dose primary series at 6-8, 10-12 and 14-16 Weeks of Age in Healthy Indian Infants".

   Dr. S. M. Dhaded – PI

   - EC notification of status report for the above study.
   - EC notification of Protocol Deviations of sub. 012-0027.

3. **Protocol Title:** A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.

   Dr. Jayaprakash Appajigol – PI

   - EC notification of DCGI approval for Protocol Amendment 4.0 dated 23/10/2015.
   - EC notification of Clinical Trial Update till 07 Jan 2016 for above mentioned study.
   - EC notification of CIOMS dated 30/DEC /2015.
   - EC notification of CIOMS dated 05/JAN /2016.

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4. **Protocol:** 20110118:"A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".

   Dr. V. A. Kothiwale – PI

   - EC Notification of Study Progress Report
   - EC Notification of DCGI approval dated 29/12/2015
   - EC notification of initial letters for SAE **(STRESS INDUCED REVERSIBLE ISCHEMIA STATUS POST CABG)** at site no.30050 of sub.no.11830050002
   - EC notification of initial letters for SAE Hospitalization for Increase in heart failure(Cardiac failure aggravated) of sub. no 11830050002 at site no. 30050
   - EC notification of follow up 1 letters for SAE Hospitalization for Increase in heart failure(Cardiac failure aggravated) of sub. no 11830050002 at site no. 30050
   - EC notification of initial letters for SAE {LEFT CORONA RADIATE INFARCT WITH RIGHT SIDE HEMIPARESIS}for sub.no. 11830013010 at site no 30013.
   - EC notification of initial letters for SAE{CHRONIC STABLE ANGINA FIXED THRESHOLD}for sub.no. 11830029031 at site no 30029.

5. **Protocol:** A Phase III study to evaluate immune non-inferiority and safety of all in one liquid formulation of a live attenuated tetravalent (G1-G4) Bovine-Human Reassortant Rotavirus Vaccine (BRV-TV) to a licensed vaccine Rotateq when administered concomitantly with other routinely recommended vaccines for the age. BRV07, Version1.0

   Dr. S. M. Dhaded – PI

   - EC notification and review of final study updates
   - EC notification of study completion & site closeout for the study BRV07

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Any other matter with the permission of the Chairperson.

For your attention:

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia, to Member Secretary.

Yours truly,

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Chairman/Member Secretary)

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To: All the members:

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14. Dr. N. M. Patil, Prof. & HOD,Dept.of Psychiatry , KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi. For Information.
15. The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
16. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
17. Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2015-16/D- 1337 **Date: 03/07/2015**

Circular

The meeting of Ethics **Committee (EC)** of the **KLE University** is convened on **Wednesday, 08th July 2015, 04:00 pm** at **Site Management Office (SMO), KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belgaum.**

I. Agenda: New Protocol for Approval:

1. **Protocol:** "A Phase III, randomized, double-blind, active-controlled, multinational, multicenter, non-inferiority trial using Carbetocin room temperature stable (RTS) for preventing postpartum haemorrhage during the third stage of labour in women delivering vaginally"
   Dr. S.S.Goudar – PI
2. **Protocol:** A Prospective, Multi-centre, Double-blind, Randomized trial of Saroglitazar 4 mg versus Placebo in Patients with Non-Alcoholic Steatohepatitis.
   Dr. Santosh Hajare – PI
3. **Protocol:** A Phase IV, Non comparative, Open label, Multicentric Trial to Evaluate the Safety and Efficacy of SYNRIAM® in the Treatment of Acute Uncomplicated Plasmodium vivax Malaria" study number R2014006.
   Dr. Raju.H.Badiger – PI

II. Agenda: For Ongoing Trial Approval:

4. **Protocol**: A Phase IV, single dose, open labelled, comparative, randomized controlled study to evaluate the immunogenicity and safety of BBIL's JENVAC (Inactivated JE Vaccine) vs. Chinese SA-14-14-2 (Live JE Vaccine) vaccine in healthy volunteers – Immunogenicity and safety following booster dose after 1 year.
   Dr. Mrs.N.S.Mahantashetti – PI
5. **Protocol**: "Aspirin Supplementation for Pregnancy Indicated Risk Reduction in Nulliparas (ASPIRIN)"
   Dr.B.S.Kodkany– PI

III. The Committee will consider the following agendas which are for information:

1. **Reading & Approving the CIOMS received.**
2. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   - EC Notification of PI analysis of;

   SAE 1: Worsening of heart failure for subject no. 11830031035
   SAE 2: Vertigo for subject no. 11830031002
   SAE 2: Congestive cardiac failure for subject no. 11830031032

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3. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   - EC Notification of CIOMS
4. **a. Protocol Title: I4V-MC-JADX:** A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Inadequate Response to Conventional Disease-Modifying Antirheumatic Drugs with Moderately to Severely Active Rheumatoid Arthritis.

   b.Protocol Title: I4V-MC-JADZ: A Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Moderately to Severely Active Rheumatoid Arthritis Who Have had Limited or No Treatment with Disease Modifying Antirheumatic Drugs.

   c. Protocol Title: I4V-MC-JADY(C): A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   - EC Notification of request for consideration of Nonpharmacogenetic/Biomarker sample for the above referenced studies.
5. **Protocol Title: I4V-MC-JADY(C):** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   - EC Notification of protocol deviation for subject no.53824 for visit no.003
6. **Protocol Number: EFC11570**: "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome"
   - EC Notification of CIOMS
7. Any other matter with the permission of the Chair.

Note: Documents no.1&2 have already been circulated

For your Attention: Please make it convenient to attend the meeting and, communicate if you seek leave of absentia, to Member Secretary.

Yours truly,

(Dr. M.S.Ganachari)
(Name & Signature of Ethics Committee Chairman/Member Secretary)

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To: All the members:

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3. Dr. Harsha V.Hegde, Scientist'B' ICMR (RMRC), Nehru Nagar, Belgaum
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6. Dr. M.V. Jali, MD & CEO KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum.
7. Dr. M. K. Swamy, Prof.& HOD, Obst & Gynace., JNMC, Belgaum.
8. Dr. (Mrs) Manisha R.Bhandankar, Associate Prof., Dept. of Paediatrics, JNMC, Belgaum, JNMC, Belgaum.
9. Mrs. Lalan Prabhu, Ramadev Galli, Belgaum
10. Mr. B.N. Metagudmath, Retired Dy.SP, Vigilance Officer, KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum.
11. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belgaum.
12. Dr. Santosh Hajare –Principal Investigator, Consultant Gastroenterology, KLE's Dr. Prabhakar Kore Hospital and Medical Research Center, Belgaum.
13. Dr. Raju.H.Badiger–Principal Investigator, Asst. Prof., Dept. of Medicine, JNMC, Belgaum.
14. The Registrar, KLE University, JNMC Campus, Belgaum–For Information.
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Ref: KLEU/EC/2015-16/D- 4231 ***Date: 04/12/2015***

Circular

The meeting of Ethics **Committee (EC)** of the **KLE University** is convened on **Friday, 11th December 2015, 04:00 pm** at **Site Management Office (SMO), KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belgaum.**

I. Agenda: New Protocol for Approval:

1. **Protocol:** A randomized open label multi-center study to compare immunogenicity and safety of BBIL's ROTAVAC® to GSK's ROTARIX® rotavirus vaccine when administered orally to infants aged 6-8 weeks.

   Study No: BBIL/ROTA/IV-2/2015, Version No:1.0

   Dr. (Mrs.) N.S Mahantashetti

II. Agenda: For Ongoing Trial Approval:

1. **Protocol:** A Phase III, randomized, double-blind, active, controlled, multinational, multicentre, non-inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum hemorrhage during the third stage of labour in women delivering vaginally.

   Protocol Number: A65870, ver. 1.2 dated 12/03/2015

   Dr.Shivprasad Goudar – PI

2. **Project:** "Evaluation of the introduction of a novel device in the management of hypertention and shock in pregnancy in low-resource settings" under CRADLE III."

   Dr.Shivprasad Goudar – PI

III. The Committee will consider the following agendas which are for information:

Reading & Approving the CIOMS received.

1. **Protocol Title: I4V-MC-JADY:** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   - EC notification SAFRNS/ CIOMS dated 24/07/2015 to 07/11/2015

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- Submission of Investigators Brochure for Baricitinib (LY3009104)

2. **Protocol Title: I4V-MC-JADZ:** A Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Moderately to Severely Active Rheumatoid Arthritis Who Have had Limited or No Treatment with Disease Modifying Antirheumatic Drugs.
   - EC Clarification for the missed documents in the submission letter.
   - EC Notification of Protocol Deviation of Subject No 68573 on visit 13.
   - EC Notification of site close out.
3. **Protocol**: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to evaluate the effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in patients who have recently experienced an Acute Coronary Syndrome". EFC11570
   - Submission of EC fees for review & approval dated 09/11/2015
   - Notification of Memo 24 Mar 2015 for Exterior mark on Auto – Injector.
   - Notification of corrected copy of Insurance certificate dated 18 Aug 2015 valid from 01 May 2015 to 30 April 2016.
   - Notification of 7th Semi Annual Safety Report (SASR) for Alirocumab.
   - EC Notification of Memo 02(IN) for GSR 889 (E).
   - Notification of DMC Recommendation form for meeting dated 12 May 2015.
   - EC Notification of protocol deviation for subject no 356103003.
   - EC Notification of Instruction for reporting Allergic Reactions.
   - EC Notification of Instruction for reporting Allergic Reactions.
4. Protocol No: 20110118:"A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".

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- EC Notification of Updated Investigator Undertaking dated 27 Oct 2015.
- Study documents for EC Notification.
- EC Notification of INITIAL letters for SAE {ANGINA AT REST} for subject no. 11830066019 at site no.30066.

5. **Protocol**: A randomized, open label, multi centric, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial manufactured by Sindan Pharma for Actavis LLC, USA and Abraxane 100 mg/vial (Albumin bound Paclitaxel 260 mg/m2) intravenous infusion AbraxisBioScience LLC, New Jersey in patients with metastatic breast cancer.
   - EC notification of study update dated 28 Oct 2015.
6. **Protocol**: A Phase IV, single dose, open labeled, comparative, randomized, controlled study to evaluate the immunogenicity and safety of BBIL's JENVAC (Inactivated JE Vaccine) vs. Chinese SA-14-14-2 (Live JE Vaccine) vaccine in healthy volunteers- Immunogenicity and safety following dose after 1 year.
   - EC Notification of DCGI approval letter to conduct the study dated 15 Oct 2015.
7. **Protocol**: An Open Label, Randomized, Multicentric, Two Treatment, Single Dose, Parallel Group Two Stage Adaptive Design Bioequivalence Study of Loteprednol Etabonate Ophthalmic Suspension, 0.5 % in Aqueous Humor of Patients Undergoing Indicated Cataract Surgery.
   - EC Notification for protocol deviation.
8. **Protocol:** "A Phase Bridging study to evaluate the Immunogenicity and Safety of a Pentavalent Vaccine (DTwP-HepB-Hib) Shan 5 (with Shanta pertussis) as Compared to the licensed vaccine Shan 5 (with imported pertussis) when administered as three dose primary series at 6-8, 10-12 and 14-16 Weeks of Age in Healthy Indian Infants".

   Dr.S. M. Dhaded – PI
   - Submission of addendum to the Clinical Trial Agreement.

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- EC Notification of CIOMS dated 23 Nov 2015.

8. **Protocol:** A multicenter, open label, balanced, randomized, two treatment, two-period crossover, multi-dose, steady state, bioequivalence study of Nevirapine 400 mg prolonged release tablets, Manufactured by Amneal Pharmaceuticals Pvt. Ltd. India compared to Viramune 400 mg prolonged release tablets, Marketed by Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany in adult HIV1 infected patients under fasting condition.
   Study No.: 15-VIN-479
   - EC Notification of CTRI registration letter & BE NOC to conduct the study.
9. Any other matter with the permission of the Chairperson.

For your attention:

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia, to Member Secretary.

Yours truly,

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Chairman/Member Secretary)

Member Secretary
ETHICS COMMITTEE (EC)
KLE University, BELGAUM

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To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR (RMRC), Nehru Nagar, Belagavi.
2. Dr. M.S.Ganachari, Prof.& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3. Dr. Harsha V.Hegde, Scientist'B' ICMR (RMRC), Nehru Nagar, Belagavi.
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5. Dr.S.S.Goudar,Prof.& HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
6. Dr. M.V. Jali, MD & CEO KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi.
7. Dr.Rupa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi.
8. Dr.Hema Dhumale, Prof of of Obst & Gynace, JNMC,Belagavi.
9. Dr.Naina Hashilkar, Asso.Prof. of Pharmacology, J.N. Medical College, Belagavi.
10. Mrs. Lalan Prabhu, Ramadev Galli, Belagavi.
11. Mr. B.N. Metagudmath, Retired Dy.SP, Vigilance Officer, KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi.
12. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13. Mrs.Geetanjali Salimath, Asst.Prof., Dept.of Pharmacy Practice, Belagavi.
14. Dr.(Mrs).N.S.Mahantshetti, Professor Dept.of Pediatrics, Principal, J.N.Medical College, Belagavi For Information..
15. The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
16. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
17. Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2015-16/D-1942 ***Date: 14/08/2015***

Circular

The meeting of Ethics **Committee (EC)** of the **KLE University** is convened on **Thursday, 20th August 2015, 04:00 pm** at **Site Management Office (SMO), KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belgaum.**

I. Agenda: New Protocol for Approval:

1. **Protocol Title:** "Evaluation of the introduction of a novel device in the management of hypertension and shock in pregnancy in low-resource settings" under CRADLE III (Community Blood Pressure Measurement in Rural Africa and Asia: the Detection of Underlying Pre-eclampsia and Shock) Stepped-Wedge Randomized Control Trial
   Dr.M.B.Bellad– PI

II. Agenda: For Ongoing Trial Approval:

2. **Protocol Title: I4V-MC-JADY(C):** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   Dr. S.V.Udapudi – PI
   - Revised Patient information and consent form

III. The Committee will consider the following agendas which are for information:

1. **Reading & Approving the CIOMS received.**
2. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   - EC notification of initial SAE at site no.11830029020
   - EC clarification for discrepancies noted in the approval letter
3. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   - EC Notification of CIOMS
4. **Protocol**: A Phase IIb/III Randomized Multicenter Active Control to evaluate Efficacy and Safety of topical application of recombinant Lysostaphin (150µg/g) gel formulation in subjects with uncomplicated Staphylococcus aureus and Methicillin resistant Staphylococcus aureus skin and skin structure infections.

- EC Notification of below mentioned document
  Additional site DCGI approval letter dated 17-Jan-2015

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5. **Protocol Title: I4V-MC-JADZ:** A Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Moderately to Severely Active Rheumatoid Arthritis Who Have had Limited or No Treatment with Disease Modifying Antirheumatic Drugs.
   - EC Notification of CIOMS
   - EC Notification of blinded investigator line listing
6. **Protocol Title: I4V-MC-JADY(C):** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   - EC Notification of blinded investigator line listing
   - EC Notification of insurance certificate extended upto 31-May-2020

   Protocol: MK- 0822-018-01 a phase III randomised, placebo-controlled clinical trial to assess the safety and efficacy of odanacatib (MK-0822) to reduce the risk of fracture in osteoporotic postmenopausal women treated with vitamin D and calcium.
   - EC Notification of CIOMS
7. **Protocol Number: EFC11570**: "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome"
   - EC Notification of SUSARS
8. **Protocol Number: WAT/LTPNL/2015:** An Open Label, Randomized, Multicentric, Two Treatment, Single Dose, Parallel Group Two Stage Adaptive Design Bioequivalence Study of Loteprednol Etabonate Ophthalmic Suspension, 0.5 % in Aqueous Humor of Patients Undergoing Indicated Cataract Surgery.
   - Clarification for inaccuracies in letter of submission to EC dated 26-May-2015 and 7-Jul-2015
   - EC clarification for discrepancies noted in the approval letters dated 24-Jun-2015 and 23-Jul-2015
9. **BBIL/ROTA5C/III/2014**: "A seamless, sequential phase III, multicenter, Ramdomized, single – blind study, to evaluate immunogenicity, reactogenicity and safety of ROTAVAC 5C new formulation of the live attenuated rotavirus vaccine as a 3 dose series when compared with existing ROTAVAC in healthy infants "
   - Notification for protocol deviations for subject no.s 105012, 105015, 105017, 105028, 105029, 105033
10. **Protocol**: A randomized, open label, multi centric, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial manufactured by Sindan Pharma for Actavis LLC, USA and Abraxane 100 mg/vial (Albumin bound Paclitaxel 260 mg/m^2) intravenous infusion AbraxisBioScience LLC, New Jersey in patients with metastatic breast cancer.

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- Notification for protocol deviation for subject no.1023

11. Any other matter with the permission of the Chair.

For your Attention: Please make it convenient to attend the meeting and, communicate if you seek leave of absentia, to Member Secretary.

Yours truly,

(Dr. M.S.Ganachari)
(Name & Signature of Ethics Committee Chairman/Member Secretary)

To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR, Opp. KLES Hospital and MRC, Nehru Nagar, Belgaum.
2. Dr. Harsha V.Hegde, Scientist'B' ICMR (RMRC), Nehru Nagar, Belgaum
3. Dr. M.V. Jali, MD & CEO KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum.
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belgaum.
5. Dr.S.S.Goudar,Prof.& HOD of Physiology, J.N. Medical College, Belgaum.
6. Dr. M. K. Swamy, Prof.& HOD, Obst & Gynace., JNMC, Belgaum.
7. Dr. (Mrs) Manisha R.Bhandankar, Associate Prof., Dept. of Paediatrics, JNMC, Belgaum, JNMC, Belgaum.
8. Mrs. Lalan Prabhu, Ramadev Galli, Belgaum
9. Mr. B.N. Metagudmath, Retired Dy.SP, Vigilance Officer, KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum.
10. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belgaum.
11. Dr. M.S.Ganachari, Prof. & HOD of Pharmacy Practice, KLE College of Pharmacy, Belgaum.
12. Dr. M.B.Bellad–Principal Investigator, Prof., Dept. of Gynaecology, JNMC, Belgaum.
13. The Registrar, KLE University, JNMC Campus, Belgaum–For Information.
14. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belgaum–For Information.
15. Mrs. Rajeshwari - PRO - KLE University, Belgaum.

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Ref: KLEU/EC/2015-16/D- 4208 (CA) ***Date: 28/12/15***

Ethics Committee (EC)

Minutes of the meeting held on **Monday, 21st December 2015, 04:00 pm,** at **Site Management Office, KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Belagavi.**

The members present at the approval meeting met the requirements of the quorum set down in the EC operating procedures and as per ICH GCP & Schedule Y requirements.
The members who attended the meeting held on **Monday, 21st December 2015, 04:00 pm** at **Site Management Office (SMO),** at which time the proposals were discussed are listed below:

Following members of the Ethics Committee were present:

1. Dr. Subarna.Roy, Scientist'E'Officer-in-charge, RMRC, Belagavi	**Chairman**
2. Dr. Harsha V.Hegde Scientist'C' ICMR (RMRC), Nehru Nagar, Belagavi	Member
3. Dr. M.V.Jali, M.D & CE, KLE's Dr. Prabhakar Kore Hospital & MRC, Belagavi	Member
4. Dr. P. A. Patil, "VISHILIP" 23-A, Basav Colony,Bauxite Rd, Belagavi	Member
5. Dr. S.S.Goudar, Prof of Physiology, JNMC, Belagavi	Member
6. Dr. Roopa M. Bellad, Prof. Dept Of Pediatrics, JNMC Belagavi	Member
7. Dr. Nayana K. Hashilkar, Asso. Prof. of Pharmacology, JNMC, Belagavi	Member
8. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi	Member
9. Mrs. Lalan Prabhu, Ramadev Galli, Belagavi	Member
10. Mr. B.N.Metagudmath, Retd. Dy.SPs, Vigilance Officer, KLESH, Belagavi	Member
11. Dr. M.S.Ganachari, Prof. & HOD, Pharmacy Practice Dept., Belagavi	**Member-Secretary**

Following members of the committee were unable to attend the meeting, as they were on duty leave on some official work:-

1. Dr. Hema Dhumale, Prof. Of Obst & Gynaecology, JNMC, Belagavi	Member
2. Mrs. Geetanjali Salimath, Asst. Prof., Dept. of Pharmacy Practice, Belagavi	Member

NOTE: It is to be noted that neither PI nor any of the proposed study team members of the concerned study were present during the decision-making procedures of the Ethics Committee, and members who are independent of the Investigator and the Sponsor of the trial, have voted/ provided opinion on the trials.

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I. Agenda: New Protocol for Approval:

1. **Protocol:** GN-LDA.8.1 Aspirin Supplementation for Pregnancy Indicated Risk reduction In Nulliparous" (ASPIRIN) Trial version 1.1 dated March 21, 2015

Dr. B.S. Kodkany – PI

The Ethics Committee of KLE University reviewed the following documents:

1. Aspirin protocol version 1.1 dated March 21, 2015 formatted in the appendix X as per requirement of Schedule Y of DCGI (Adapted to comply with legal age of consent in India i.e. 18 years and above (as mentioned in the protocol page numbers 7 & 19 under informed consent process).
2. **Informed Consent Forms:**
   - English Informed consent form Version 2.1 dated December 17, 2015
   - Kannada Informed consent form Version 2.1 dated December 17, 2015
   - Marathi Informed consent form Version 2.1 dated December 17, 2015
3. **Data Forms:**
   - ASP00 dated 10 December 2015 - Contact Information Form
   - ASP 01 dated. 10 December 2015 - Initial Screening Form
   - ASP 02 dated. 10 December 2015 - Ultrasound Screening Form
   - ASP 03 dated. 10 December 2015 - Hemoglobin Monitoring
   - ASP 04 dated. 10 December 2015 - Clinical Assessment Form
   - ASP 05 dated. 10 December 2015 - Tracking Form
   - ASP 06 dated. 10 December 2015 - Bi-weekly Monitoring Form
   - ASP 07 dated. 10 December 2015 - Blood Pressure Monitoring Form
   - ASP 08 dated. 10 December 2015 - Unscheduled or Emergency Medical Visit Form
   - ASP 09 dated. 10 December 2015 - Serious Adverse Event (SAE) Form
   - ASP 10 dated. 10 December 2015 - Study Withdrawal/Closeout Form
   - ASP 11 dated. 10 December 2015 - Protocol Deviation Form

Discussion points:

During the Ethics Committee (EC) meeting of KLE University held on **Monday, 21st December, 2015 at 04:00 pm** at **Site Management Office,** KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Belgaum, Your referenced letter and the above submitted documents were examined and discussed. After reviewing, Ethics Committee decided to **approve the study documents for the conduct of the above referenced study.**

The study is approved through 20 December 2016 (for the period of 1 year).

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Note: Following members abstained from the voting process –

1. Dr Shivaprasad Goudar, Prof of Physiology, JNMC, Belagavi
2. Dr. M.S.Ganachari, Prof. & HOD, Pharmacy Practice Dept., Belagavi

II. Agenda: For Ongoing Trial Approval:

2. **Protocol Title: Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.

The Ethical Committee of KLE University reviewed the following documents:

1. Enclosure 1 - Protocol 3-001 version 4.0 dated 23-Oct-2015
2. Enclosure 2 - Summary of changes letter (from version 3.0 to version 4.0)
3. Enclosure 3 – ICF India English version 4.0 dated 03 Nov 2015 derived from Master ICF version 4.0 dated 23 Oct 2015
4. Enclosure 4 – Summary of changes from India Specific ICF version 3.1 dated 19 Oct 2015 to ICF version 4.0 dated 03 Nov 2015
5. Enclosure 5 – ICF India version 4.0 dated 03 Nov 2015 – Hindi, translated from English to Hindi on 20 Nov 2015
6. Enclosure 6 - ICF India version 4.0 dated 03 Nov 2015 – Marathi, translated from English to Marathi on 20 Nov 2015
7. Enclosure 7 - ICF India version 4.0 dated 03 Nov 2015 – Kannada, translated from English to Kannada on 20 Nov 2015
8. Enclosure 8 - ICF India version 4.0 dated 03 Nov 2015 – English, back translated from Hindi to English on 03 Dec 2015
9. Enclosure 9 - ICF India version 4.0 dated 03 Nov 2015 – English, back translated from Marathi to English on 03 Dec 2015
10. Enclosure 10 - ICF India version 4.0 dated 03 Nov 2015 – English, back translated from Kannada to English on 03 Dec 2015
11. Enclosure 11 – Translation certificate pertaining to translation of English ICF version 4.0 dated 03 Nov 2015 to Hindi language on 20 Nov 2015
12. Enclosure 12 – Translation certificate pertaining to translation of English ICF version 4.0 dated 03 Nov 2015 to Marathi language on 20 Nov 2015

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13. Enclosure 13 - Translation certificate pertaining to translation of English ICF version 4.0 dated 03 Nov 2015 to Kannada language on 20 Nov 2015
14. Enclosure 14 – Back Translation Certificate pertaining to back translation of Hindi ICF version 4.0 dated 03 Nov 2015 to English language on 03 Dec 2015
15. Enclosure 15 – Back Translation Certificate pertaining to back translation of Marathi ICF version 4.0 dated 03 Nov 2015 to English language on 03 Dec 2015
16. Enclosure 16 - Back Translation Certificate pertaining to back translation of Kannada ICF version 4.0 dated 03 Nov 2015 to English language on 03 Dec 2015

Discussion points:

At the Ethics Committee meeting held on **Monday 21st December, 2015 at 4.00pm at Site Management Office, KLES Dr Prabhakar Kore Hospital & MRC, Belgaum,** Ethics Committee decided to **approve the protocol amendment # 4 and related documents of the above referenced study**

III. The Committee considered the following agendas which are for information:

Reading & Approving the CIOMS received.

1. **Protocol Title: I4V-MC-JADY:** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   - EC notification SAFRNS/ CIOMS dated 24/07/2015 to 07/11/2015
   - Submission of Investigators Brochure for Baricitinib (LY3009104)
2. **Protocol Title: I4V-MC-JADZ:** A Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Moderately to Severely Active Rheumatoid Arthritis Who Have had Limited or No Treatment with Disease Modifying Antirheumatic Drugs.
   - EC Clarification for the missed documents in the submission letter.
   - EC Notification of Protocol Deviation of Subject No 68573 on visit 13.
   - EC Notification of CIOMS from 03/Nov/2014 to 25/Nov/2014
   - EC Notification of site close out.

3. **Protocol**: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to evaluate the effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in patients who have recently experienced an Acute Coronary Syndrome". EFC11570
   - Submission of EC fees for review & approval dated 09/11/2015
   - Notification of Memo 24 Mar 2015 for Exterior mark on Auto – Injector.
   - Notification of corrected copy of Insurance certificate dated 18 Aug 2015 valid from 01 May 2015 to 30 April 2016.
   - Notification of 7th Semi Annual Safety Report (SASR) for Alirocumab.
   - EC Notification of Memo 02(IN) for GSR 889 (E).
   - Notification of DMC Recommendation form for meeting dated 12 May 2015.
   - EC Notification of protocol deviation for subject no 356103003.
   - EC Notification of Instruction for reporting Allergic Reactions..
4. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   - EC Notification of Updated Investigator Undertaking dated 27 Oct 2015.
   - Study documents for EC Notification.
   - EC Notification of INITIAL letters for SAE {ANGINA AT REST} for subject no. 11830066019 at site no.30066.
5. **Protocol**: A randomized, open label, multi centric, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial manufactured by Sindan Pharma for Actavis LLC, USA and Abraxane 100 mg/vial (Albumin bound Paclitaxel 260 mg/m2) intravenous infusion AbraxisBioScience LLC, New Jersey in patients with metastatic breast cancer.

- EC notification of study update dated 28 Oct 2015.

6. **Protocol**: A Phase IV, single dose, open labeled, comparative, randomized, controlled study to evaluate the immunogenicity and safety of BBIL's JENVAC (Inactivated JE Vaccine) vs. Chinese SA-14-14-2 (Live JE Vaccine) vaccine in healthy volunteers- Immunogenicity and safety following dose after 1 year.
   - EC Notification of DCGI approval letter to conduct the study dated 15 Oct 2015.
7. **Protocol**: An Open Label, Randomized, Multicentric, Two Treatment, Single Dose, Parallel Group Two Stage Adaptive Design Bioequivalence Study of Loteprednol Etabonate Ophthalmic Suspension, 0.5 % in Aqueous Humor of Patients Undergoing Indicated Cataract Surgery.
   - EC Notification for protocol deviation.
8. **Protocol:** "A Phase Bridging study to evaluate the Immunogenicity and Safety of a Pentavalent Vaccine (DTwP-HepB-Hib) Shan 5 (with Shanta pertussis) as Compared to the licensed vaccine Shan 5 (with imported pertussis) when administered as three dose primary series at 6-8, 10-12 and 14-16 Weeks of Age in Healthy Indian Infants".

   Dr.S. M. Dhaded – PI
   - Submission of addendum to the Clinical Trial Agreement.
   - EC Notification of CIOMS dated 23 Nov 2015.
9. **Protocol:** A multicenter, open label, balanced, randomized, two treatment, two-period crossover, multi-dose, steady state, bioequivalence study of Nevirapine 400 mg prolonged release tablets, Manufactured by Amneal Pharmaceuticals Pvt. Ltd. India compared to Viramune 400 mg prolonged release tablets, Marketed by Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany in adult HIV1 infected patients under fasting condition.

   Study No.: 15-VIN-479
   - EC Notification of CTRI registration letter & BE NOC to conduct the study.
   - EC Notification of Errata No.2

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10. Any other matter with the permission of the Chairperson.

- **Table Agenda: Following notifications were considered with the permission of the chairperson**

11. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
    - EC Notification of CIOMS of 24 Nov 2015
    - EC Notification of CIOMS of 30 Nov 2015
    - EC Notification of CIOMS of 03 Dec 2015
    - EC Notification of Informed consent form Ver 3.1 dated 19 Oct 2015

Yours truly,

28/12/2015

Dr. (Prof.) M.S.Ganachari
(Name & Signature of Ethics Committee Chairman/Member Secretary)

Member Secretary
ETHICS COMMITTEE (EC)
KLE University, BELGAUM

To:
The Members, Ethics Committee – KLE University, Belgaum.
Cc:

1. Director, KLE University Research Foundation, Belgaum.
2. The Chairman, Site Management Office, KLES Prabhakar Kore Hospital and Medical Research Centre, Belgaum.
3. The Member-Secretary, Site Management Office, KLES Prabhakar Kore Hospital and Medical Research Centre, Belgaum.
4. The Registrar, KLE University, JNMC Campus
5. Mrs. Rajeshwari - PRO - KLE University, Belgaum.

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Ref: KLEU/EC/2014-15/D-903.

Date: 05/06/2015

Circular

The meeting of Ethics **Committee (EC)** of the **KLE University** is convened on **Thursday, 11th June 2015, 04:00 pm** at **Site Management Office (SMO), KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belgaum.**

I. Agenda: New Protocol for Approval:

1. **Protocol**: "A Phase Bridging study to evaluate the Immunogenicity and Safety of a Pentavalent Vaccine (DTwP-HepB-Hib) Shan 5 (with Shanta pertussis) as Compared to the licensed vaccine Shan 5 (with imported pertussis) when administered as three dose primary series at 6-8, 10-12 and 14-16 Weeks of Age in Healthy Indian Infants" .

   Dr. S.M.Dhaded – PI

2. **Protocol:** A Prospective, Multi-centre, Double-blind, Randomized trial of Saroglitazar 4 mg versus Placebo in Patients with Non-Alcoholic Steatohepatitis.

   Dr. Santosh Hajare – PI

3. **Protocol**: A randomized, open label, multi centric, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial manufactured by Sindan Pharma for Actavis LLC, USA and Abraxane 100 mg/vial (Albumin bound Paclitaxel 260 mg/m^2) intravenous infusion AbraxisBioScience LLC, New Jersey in patients with metastatic breast cancer.

   Dr. Mahesh Kalloli – PI

4. **Protocol:** A Development and validation of a comprehensive clinical and neuropsychological test battery for use in the Indian contest for patients with vascular cognitive Impairment.

   Dr. Saroja A.O – PI

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5. An Open Label, Randomized, Multicentric, Two Treatment, Single Dose, Parallel Group Two Stage Adaptive Design Bioequivalence Study of Loteprednol Etabonate Ophthalmic Suspension, 0.5 % in Aqueous Humor of Patients Undergoing Indicated Cataract Surgery.

Dr. Smitha K.S– PI

II. Agenda: For Ongoing Trial Approval:

6. **Protocol**: A Phase IIb/III Randomized Multicenter Active Control to evaluate Efficacy and Safety of topical application of recombinant Lysostaphin (150μg/g) gel formulation in subjects with uncomplicated Staphylococcus aureus and Methicillin resistant Staphylococcus aureus skin and skin structure infections.

Dr. Shivakumar – PI

III. The Committee will consider the following agendas which are for information:

1. **Reading & Approving the CIOMS received.**
2. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   - SAE 1: Worsening of heart failure for subject no. 11830031035
   - SAE 2: Vertigo for subject no. 11830031002
   - SAE 2: Congestive cardiac failure for subject no. 11830031032
3. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   - EC Notification of SUSAR no.3001-00150 of follow up#1 and follow up#2.
   - **SAE 1: Acute respiratory distress syndrome and death** for subject no.44160007

4. **Protocol Title: I4V-MC-JADZ:** A Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Moderately to Severely Active Rheumatoid Arthritis Who Have had Limited or No Treatment with Disease Modifying Antirheumatic Drugs.
   - EC Notification of protocol deviation for subject no.68571 for visit no.005 & visit no.001
   - EC Notification of protocol deviation for subject no.68570 for visit no.001

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- EC Notification of protocol deviation for subject no.685712 for visit no.001
- EC Notification of protocol deviation for subject no.53824 for visit no.001& visit no.002

5. **Protocol Title: I4V-MC-JADY(C):** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   - EC Notification of protocol deviation for subject no.68571 for visit no.005
   - EC Notification of DCGI approval for addendum letter dated 24/04/2015
6. **Protocol no.: BRV07, Version1.0 titled:** "A Phase III study to evaluate immune non-inferiority and safety of all in one liquid formulation of a live attenuated tetravalent (G1-G4) Bovine-Human Reassortant Rotavirus Vaccine (BRV-TV) to a licensed vaccine Rota Teq when administered as three dose series to Indian infants concomitantly with other routinely recommended vaccines for the age.
   - EC Notification of SAE(Initial)- Broncho pneumonia associated with rickets for subject no.03-082 at site no.03
   - EC Notification of SAE(Follow-up)- Broncho pneumonia for subject no.03-081 at site no.03
   - EC Notification of SAE(Initial)- Broncho pneumonia for subject no.03-082 at site no.03
   - EC Notification of SAE(Initial)- Acute gastroenteritis for subject no.05-087 at site no.05
   - EC Notification of SAE(Initial)- Bronchiolitis for subject no.11-046 at site no.11
   - EC Notification of protocol deviation for subject no.10-039
   - EC Notification of adverse event for subject no.10-053
   - EC Notification of Insurance certificate from 05/01/15 to 04//30/16
7. Any other matter with the permission of the Chair.

For your Attention: Please make it convenient to attend the meeting and, communicate if you seek leave of absentia, to Member Secretary.

Yours truly,

(Dr. M.S.Ganachari)
(Name & Signature of Ethics Committee Chairman/Member Secretary)

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To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR, Opp. KLES Hospital and MRC, Nehru Nagar, Belgaum.
2. Dr. M.S.Ganachari, Prof. & HOD of Pharmacy Practice, KLE College of Pharmacy, Belgaum.
3. Dr. Harsha V.Hegde, Scientist'B' ICMR (RMRC), Nehru Nagar, Belgaum
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belgaum.
5. Dr.S.S.Goudar,Prof.& HODof Physiology, J.N. Medical College, Belgaum .
6. Dr. M.V. Jali, MD & CEO KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum.
7. Dr. M. K. Swamy, Prof.&HOD, Obst & Gynace., JNMC, Belgaum.
8. Dr. (Mrs) Manisha R.Bhandankar, Associate Prof., Dept. of JNMC, Belgaum, JNMC, Belgaum.
9. Mrs. Lalan Prabhu, Ramadev Galli, Belgaum
10. Mr. B.N. Metagudmath, Retired Dy.SP, Vigilance Officer, KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum.
11. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belgaum.
12. Dr. S.M.Dhaded – Principal Investigator, Prof. Dept.of Pediatrics, JNMC, Belgaum
13. Dr. Santosh Hajare –Principal Investigator, Consultant Gastroenterology, KLE's Dr. Prabhakar Kore Hospital and Medical Research Center, Belgaum.
14. Dr. Mahesh Kalloli – Principal Investigator, Head and neck Surgeon, KLE's Dr. Prabhakar Kore Hospital and Medical Research Center, Belgaum.
15. Dr. Saroja A.O – Principal Investigator, Neurologist, Dept.of Neuromedicine, KLE's Dr. Prabhakar Kore Hospital and Medical Research Center, Belgaum.
16. Dr. Smitha K.S– Principal Investigator, Consultant Ophthalmologist, KLE's Dr. Prabhakar Kore Hospital and Medical Research Center, Belgaum.
17. The Registrar, KLE University, JNMC Campus, Belgaum–For Information.
18. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belgaum –For Information.
19. Mrs. Rajeshwari - PRO - KLE University, Belgaum.

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Ref: KLEU/EC/2014-15/D- 3897

Date: 12/02/2015

Circular

The meeting of Ethics **Committee (EC)** of the **KLE University** is convened on **Thursday, 19th February 2015, 04:00 pm** at **Site Management Office (SMO), KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belgaum.**

I. Agenda: New Protocol for Approval:

1. **Protocol Number: EFC11570**: "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome" **Dr. Sanjay Porwal – PI**
2. A Phase IV, Randomized, factorial assigned, Open labelled, study to evaluate the non-interference in immune response of Typhoid Vi Capsular Polysaccharide - Tetanus Toxoid Conjugate Vaccine (Typbar-TCV) administered to children at 9 months, to measles vaccine given concomitantly. **Dr. (Mrs.) N.S. Mahantshetti – PI**

II. The Committee will consider the following agendas which are for information:

1. **Reading & Approving the CIOMS received.**
2. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".

- EC Notification of SAE- {**Myocardial Infarction**} for subject no.11830055032 at site no.30055
- EC Notification of SAE- {**Increase in congestive heart failure cardiogenic shock sepsis acute renal failure**} for subject no.11830050032 at site no.30055
- EC Notification of follow-up-1 letter of SAE
- EC Notification of follow-up-2 letter of SAE
- EC Notification of SAE- {**Fracture left Femur**} for subject no.11830055047 at site no.30053
- EC Notification of SAE- {**Progression of stroke**} for subject no.11830065032 at site no.30065
- EC Notification of SAE- {**Breathlessness cough**} for subject no.11830029025 at site no.30029
- EC Notification of revised Insurance certificate from 18/01/2015 to 17/01/2016

6. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.

- EC Notification of Initial **SAE 03**-Acute respiratory failure due to hospital acquired pneumonia} for subject no.44160002 on 27/01/15

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7. **Protocol no.: BBIL/ROTA/IV/2013**: "Phase IV, multicenter, randomized, single-blind, study to evaluate the immunogenicity, reactogenicity & safety of the live attenuated rotavirus vaccine ROTAVAC® as a 3 dose series when administered simultaneously with or without the buffering agent following in healthy infants".
- EC Notification of study close out

7. Any other matter with the permission of the Chair.

For your Attention: Please make it convenient to attend the meeting and, communicate if you seek leave of absentia, to Member Secretary.

Yours truly,

(Dr. M.S.Ganachari)
(Name & Signature of Ethics Committee Chairman/Member Secretary)

To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR, Opp. KLES Hospital and MRC, Nehru Nagar, Belgaum.
2. Dr. M.S.Ganachari, Prof. & HOD of Pharmacy Practice, KLE College of Pharmacy, Belgaum.
3. Dr. Harsha V.Hegde, Scientist'B' ICMR (RMRC), Nehru Nagar, Belgaum
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belgaum.
5. Dr.S.S.Goudar,Prof.& HODof Physiology, J.N. Medical College, Belgaum
6. Dr. M.V. Jali, MD & CEO KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum.
7. Dr. M. K. Swamy, Prof.&HOD, Obst & Gynace., JNMC, Belgaum.
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9. Mrs. Lalan Prabhu, Ramadev Galli, Belgaum
10. Mr. B.N. Metagudmath, Retired Dy.SP, Vigilance Officer, KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum.
11. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belgaum.
12. Dr. (Mrs).N.S.Mahantshetti, Professor and Head of Pediatrics, J.N.Medical College, Belgaum-**Principal Investigator.**

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13. Dr.Sanjay Porwal, Consultant Cardiologist, KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum **Principal Investigator.**
14. The Registrar, KLE University, JNMC Campus, Belgaum–For Information.
15. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belgaum –For Information.
16. Mrs. Rajeshwari - PRO - KLE University, Belgaum.

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Ref: KLEU/EC/2015-16/D-4428 ***Date: 19/12/2015***

Circular

The meeting of Ethics **Committee (EC)** of the **KLE University** is convened on **Monday, 21st December 2015, 04:00 pm** at **Site Management Office (SMO), KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belgaum.**

I. Agenda: For Ongoing Trial Approval:

1. **Protocol:** GN-LDA.8.1 Aspirin Supplementation for Pregnancy Indicated Risk reduction In Nulliparous" (ASPIRIN) Trial version 1.1 dated March 21, 2015
   Dr. B.S. Kodkany – PI

II. The Committee will consider the following agendas which are for information:

Reading & Approving the amendment documents received.

1. **Protocol Title: Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   - **EC submission of amendment documents for the above study.**
2. Any other matter with the permission of the Chairperson.

For your attention:

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia, to Member Secretary.

Yours truly,

Dr. (Prof.) M. S. Ganachari
(Name & Signature of Ethics Committee Chairman/Member Secretary)

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To: All the members:

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2. Dr. M.S.Ganachari, Prof.& HOD of Pharmacy Practice, KLE College of Pharmacy, Belagavi.
3. Dr. Harsha V.Hegde, Scientist'B' ICMR (RMRC), Nehru Nagar, Belagavi.
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belagavi.
5. Dr.S.S.Goudar,Prof.& HOD of Physiology, –Principal Investigator, J.N. Medical College, Belagavi.
6. Dr. M.V. Jali, MD & CEO KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi.
7. Dr.Roopa Bellad, Prof of Paediatrics, J.N. Medical College, Belagavi.
8. Dr.Hema Dhumale, Prof of of Obst & Gynace, JNMC,Belagavi.
9. Dr.Naina Hashilkar, Asso.Prof. of Pharmacology, J.N. Medical College, Belagavi.
10. Mrs. Lalan Prabhu, Ramadev Galli, Belagavi.
11. Mr. B.N. Metagudmath, Retired Dy.SP, Vigilance Officer, KLES Dr.Prabhakar Kore Hospital and MRC, Belagavi.
12. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belagavi.
13. Mrs.Geetanjali Salimath, Asst.Prof., Dept.of Pharmacy Practice, Belagavi.
14. Dr.(Mrs).N.S.Mahantshetti, Professor Dept.of Pediatrics, Principal, J.N.Medical College, Belagavi For Information..
15. The Registrar, KLE University, JNMC Campus, Belagavi –For Information.
16. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belagavi –For Information.
17. Mrs. Rajeshwari - PRO - KLE University, Belagavi -For Information.

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Ref: KLEU/EC/2015-16/D- 2766 ***Date: 15/10/2015***

Circular

The meeting of Ethics **Committee (EC)** of the **KLE University** is convened on **Wednesday, 21st October 2015, 04:00 pm** at **Site Management Office (SMO), KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belgaum.**

I. Agenda: New Protocol for Approval:

1. **Protocol:** A multicenter, open label, balanced, randomized, two treatment, two-period crossover, multi-dose, steady state, bioequivalence study of Nevirapine 400 mg prolonged release tablets, Manufactured by Amneal Pharmaceuticals Pvt. Ltd. India compared to Viramune 400 mg prolonged release tablets, Marketed by Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany in adult HIV1 infected patients under fasting condition.
   Study No.: 15-VIN-479
   Dr.Dyanesh Morkar– PI
2. **Protocol**: A multicentre, open label, randomized, balanced, two treatment, two period, two sequence, two way crossover, single dose, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial of Cipla Ltd., India with ABRAXANE for Injectable Suspension (Paclitaxel protein-bound particles for injectable suspension) Manufactured for :Celgene Corporation Summit, USA in Breast cancer patients after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.
   Study No.: 15-VIN-258
   Dr.Rohan Bhise– PI

II. Agenda: For Ongoing Trial Approval:

1. **Protocol Number: EFC11570**: "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of

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Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome"

Dr.Sanjay Powar– PI

III. <u>The Committee will consider the following agendas which are for information:</u>

1. **Reading & Approving the CIOMS received.**
2. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   - EC notification of initial SAE(Angina) at site no.30066 of sub.no.11830066019
   - EC notification of SAE(Angina) follow up 1 at site no.30066 of sub.no.11830066019
   - EC notification of initial SAE(Death) at site no.30074 of sub.no.11830074011
   - EC notification of SAE(Left ventricular failure) follow up 1 at site no.30074 of sub.no.11830074018
   - EC notification of SAE(Ishaemic heart disease) follow up 1 at site no.30029 of sub.no.11830029020
   - EC notification of SAE(Acute exacerbation of obstructive airway disease) follow up 1 at site no.30071 of sub.no.11830071036
3. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   - EC Notification of DMC Recommendation dated 05 Aug 2015
   - EC Notification of CIOMS dated 24 SEP 2015
   - EC Notification of Clinical trial Update till 24 SEP 2015
   - EC Notification of CIOMS dated 30 SEP 2015
   - EC Notification of CIOMS dated 06 OCT 2015

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- EC Notification of Liability Insurance
- EC Notification of updated IU and FDA 1572

4. **Protocol Title: I4V-MC-JADX:** A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Inadequate Response to Conventional Disease-Modifying Antirheumatic Drugs with Moderately to Severely Active Rheumatoid Arthritis.
   - EC Notification of the confirmation of the destruction of the DNA Samples
5. **Protocol Title: I4V-MC-JADY:** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   - EC Notification of the confirmation of the destruction of the DNA Samples
   - EC Notification of clinical trials laboratory kits destruction
6. **Protocol Title: I4V-MC-JADZ:** A Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Moderately to Severely Active Rheumatoid Arthritis Who Have had Limited or No Treatment with Disease Modifying Antirheumatic Drugs.
   - EC Notification of protocol deviation
   - EC Notification of the confirmation of the destruction of the DNA Samples
7. **Protocol Title: ACTA/PAC/2013: Protocol**: A randomized, open label, multi centric, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial manufactured by Sindan Pharma for Actavis LLC, USA and Abraxane 100 mg/vial (Albumin bound Paclitaxel 260 mg/m^2) intravenous infusion AbraxisBioScience LLC, New Jersey in patients with metastatic breast cancer.
   - EC Notification of protocol deviation

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8. **Protocol Title: BBIL/ROTA5C/III/2014**:"A seamless, sequential phase III, multicenter, Ramdomized, single –blind study, to evaluate immunogenicity, reactogenicity and safety of ROTAVAC 5C new formulation of the live attenuated rotavirus vaccine as a 3 dose series when compared with existing ROTAVAC in healthy infants "
   - EC Notification for protocol deviation.
9. **Protocol Title: R2013007:** Comparative Efficacy, Safety and Tolerability of FDC of Cephalexin Extended Release (375 mg) and Clavulanate Potassium (125 mg) Tablets with Cephalexin Extended Release (375 mg) Tablets in the Treatment of uncomplicated Skin and Soft Tissue Infections – A Randomized, Double-blind Study.
   - EC notification for center wise clinical study report.
   - EC Notification of protocol deviation
10. **Protocol Title: MK-0822-018-01:** Phase III Randomized, Placebo –Controlled Clinical Trial to Assess the Safety and Efficacy of Odanacatib (MK-0822) to Reduce the Risk of Fracture in Osteoporotic Post menopausal Women Treated With Vitamin D and Calcium.
   - EC Notification of CIOMS dated 14 SEP 2015
   - EC Notification of Amended CTA
11. **Protocol**: A randomized, open label, multi centric, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial manufactured by Sindan Pharma for Actavis LLC, USA and Abraxane 100 mg/vial (Albumin bound Paclitaxel 260 mg/m^2) intravenous infusion AbraxisBioScience LLC, New Jersey in patients with metastatic breast cancer.
   - EC Notification of Amended CTA
12. **Protocol Number TRI08888 GARFIELD:** "Prospective, multicentre, international registry of male and female patients newly diagnosed with atrial fibrillation".
   - EC Notification of Amended ICF

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- EC Notification of change over from cohort-4 to cohort-4

13. **Protocol:** A Phase IV, Non comparative, Open label, Multicentric Trial to Evaluate the Safety and Efficacy of SYNRIAM® in the Treatment of Acute Uncomplicated Plasmodium vivax Malaria" study number R2014006.
    - EC Notification of
14. **Protocol:** FDC of Cephalexine ER and Clavulanate Potassium Tablets in URTI
    - EC Notification of study close out.
15. Any other matter with the permission of the Chair.

Note: In protocol no.1 please ignore the documents related to Pharmacogenetics ICF's from 8 to 14.

For your attention:

Please make it convenient to attend the meeting and, communicate if you seek leave of absentia, to Member Secretary.

Yours truly,

KLE UNIVERSITY'S BELAGAVI

Dr. (Prof.) M. S. Ganachari

(Name & Signature of Ethics Committee Chairman/Member Secretary)

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To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR, Opp. KLES Hospital and MRC, Nehru Nagar, Belgaum.
2. Dr. M.S.Ganachari, Prof. & HOD of Pharmacy Practice, KLE College of Pharmacy, Belgaum.
3. Dr. Harsha V.Hegde, Scientist'B' ICMR (RMRC), Nehru Nagar, Belgaum
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belgaum.
5. Dr.S.S.Goudar,Prof.& HOD of Physiology, –Principal Investigator, J.N. Medical College, Belgaum.
6. Dr. M.V. Jali, MD & CEO KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum.
7. Dr.Rupa Bellad, Prof of Paediatrics, J.N. Medical College, Belgaum.
8. Dr.Hema Dhumale, Prof of of Obst & Gynace, JNMC,Belagavi
9. Dr.Naina Hashilkar, Asso.Prof. of Pharmacology, J.N. Medical College, Belgaum.
10. Mrs. Lalan Prabhu, Ramadev Galli, Belgaum
11. Mr. B.N. Metagudmath, Retired Dy.SP, Vigilance Officer, KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum.
12. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belgaum.
13. Mrs.Geetanjali Salimath, Asst.Prof., Dept.of Pharmacy Practice, Belgaum.
14. Dr.Dyanesh Morkar –Principal Investigator, Asso. Prof., Dept. of Medicine, JNMC, Belgaum.
15. Dr.Rohan Bhise- Principal Investigator, Asst.Prof., Dept. of Medicine, JNMC, Belgaum.
16. The Registrar, KLE University, JNMC Campus, Belgaum–For Information.
17. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belgaum–For Information.
18. Mrs. Rajeshwari - PRO - KLE University, Belgaum.

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Ref: KLEU/EC/2014-15/D- 4304.

Date: 23/03/2015

Circular

The meeting of Ethics **Committee (EC)** of the **KLE University** is convened on **Friday, 27th March 2015, 04:00 pm** at **Site Management Office (SMO), KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belgaum.**

I. Agenda: New Protocol for Approval:

1. **Protocol Number: Aspirin supplementation for pregnancy indicated risk reduction in Nulliparas (ASPIRIN) Dr. Shivaprasad Goudar – PI**

II. Agenda: For Ongoing Trial Approval:

2. **Protocol:** Effects of a Yoga-based cardiac rehabilitation programme (Yoga-Care) on cardiovascular health: a clinical trial (India) and mechanistic study (UK). **Dr. Sanjay Porwal – PI**

III. The Committee will consider the following agendas which are for information:

1. **Reading & Approving the CIOMS received.**
2. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   - EC Notification of **Initial SAE letter-** {**Accelerated Hypertension**} for subject no.20110118
3. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   - EC Notification of CIOMS for subject ID's 36010006,44160004
   - EC Notification of SUSAR for subject ID 36010006,20080004
   - **Protocol Title: I4V-MC-JADY(C):** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   - EC Notification of SAFRNS/CIOMS from 05/12/13 to 04/06/14.
   - EC Notification of Blinded Investigator Line Listing from 05/02/15 to 09/03/15, approved on 05/02/15.
   - EC Notification of protocol deviation for subject no.53824 for visit no.002
   - EC Notification of protocol deviation for subject no.53824 for visit no.003
   - EC Notification of DCGI approval letter dated 16/02/2015
   - EC Notification of adverse event occurred for subject no.68572
   - EC Notification of SAFRNS/CIOMS from 26/11/14 to 04/02/15
4. **Protocol Title: I4V-MC-JADZ:** A Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Moderately to

dlc

Severely Active Rheumatoid Arthritis Who Have had Limited or No Treatment with Disease Modifying Antirheumatic Drugs.

- EC Notification of SAFRNS/CIOMS from 05/02/15 to 09/03/15.
- EC Notification of Blinded Investigator Line Listing from 05/02/15 to 09/03/15, approved on 05/02/15.
- EC Notification of SAFRNS/CIOMS from 26/11/14 to 04/02/15

5. **Protocol Title: I4V-MC-JADX:** A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Inadequate Response to Conventional Disease-Modifying Antirheumatic Drugs with Moderately to Severely Active Rheumatoid Arthritis.

- EC Notification of study close out.

6. **Protocol Number: EFC11570**: "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome"

- EC Notification of DCGI NOC dated dated 20/02/2015
- EC Notification of Insurance certificate valid from 23/02/2015 to 22/02/2016
- EC Notification of final CTA
- EC Notification of response to EC queries.

7. **Protocol no.: BRV07, Version1.0 titled:** "A Phase III study to evaluate immune non-inferiority and safety of all in one liquid formulation of a live attenuated tetravalent (G1-G4) Bovine-Human Reassortant Rotavirus Vaccine (BRV-TV) to a licensed vaccine Rota Teq when administered as three dose series to Indian infants concomitantly with other routinely recommended vaccines for the age.

- EC Notification of SAE- Right sided aspiration pneumonia for subject no.09-065 at site no.09
- EC Notification of SAE- Broncho pneumonia for subject no.03-005 at site no.03
- EC Notification of SAE- Respiratory tract infection for subject no.04-017 at site no.04
- EC Notification of SAE- Urinary tract infection for subject no.11-057 at site no.11
- EC Notification of SAE- Viral associated wheeze for subject no.12-009 at site no.12
- EC Notification of SAE- Acute Bronchiolitis for subject no.05-046 & 05-047 at site no.46 & 47
- EC Notification of adverse event occurred for subject no.10-001 & 10-019
- EC Notification of study status
- EC Notification of additional 30 subjects

8. **Protocol No: "BBIL/ROTA/IV/2013**: "Phase IV, multicenter, randomized, single-blind, study to evaluate the immunogenicity, reactogenicity & safety of the live attenuated rotavirus vaccine

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ROTAVAC® as a 3 dose series when administered simultaneously with or without the buffering agent following in healthy infants".

- EC Notification of SAE's at different sites.

9. Any other matter with the permission of the Chair.

For your Attention: Please make it convenient to attend the meeting and, communicate if you seek leave of absentia, to Member Secretary.

Yours truly,

(Dr. M.S.Ganachari)
(Name & Signature of Ethics Committee Chairman/Member Secretary)

To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR, Opp. KLES Hospital and MRC, Nehru Nagar, Belgaum.
2. Dr. M.S.Ganachari, Prof. & HOD of Pharmacy Practice, KLE College of Pharmacy, Belgaum.
3. Dr. Harsha V.Hegde, Scientist'B' ICMR (RMRC), Nehru Nagar, Belgaum
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belgaum.
5. Dr.S.S.Goudar,Prof.& HODof Physiology, J.N. Medical College, Belgaum **& Principal Investigator.**
6. Dr. M.V. Jali, MD & CEO KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum.
7. Dr. M. K. Swamy, Prof.&HOD, Obst & Gynace., JNMC, Belgaum.
8. Dr. (Mrs) Manisha R.Bhandankar, Associate Prof., Dept. of Paediatrics, JNMC, Belgaum.
9. Mrs. Lalan Prabhu, Ramadev Galli, Belgaum
10. Mr. B.N. Metagudmath, Retired Dy.SP, Vigilance Officer, KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum.
11. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belgaum.
12. The Registrar, KLE University, JNMC Campus, Belgaum–For Information.
13. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belgaum –For Information.
14. Mrs. Rajeshwari - PRO - KLE University, Belgaum.

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Ref: KLEU/EC/2015-16/D- 1715 *Date: 25/06/15*

Ethics Committee (EC)

Minutes of the meeting held on **Thursday, 11th June 2015, 04:00 pm** at **Site Management Office, KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Belgaum.**

The members present at the approval meeting met the requirements of the quorum set down in the EC operating procedures and as per ICH GCP & Schedule Y requirements.
The members who attended the meeting held on **Thursday, 11th June 2015, 04:00 pm** at **Site Management Office (SMO),** at which time your proposals were discussed are listed below:

Following Members of the Committee were present:

NAMES OF MEMBERS WITH DESIGNATION	ROLE IN THE EC	GENDER
1. **Dr. Subarna.Roy**, Scientist'E' Officer-in-charge, ICMR (RMRC), Belgaum	**Chairman**	Male
2. **Dr. P. A. Patil**, Joint Director, KLE University Research Foundation	**Basic Medical Scientists**	Male
3. **Dr. M. K. Swamy**, Prof, Obst & Gynace., JNMC, Belgaum.	**Clinician**	Male
4. **Mr. B.N.Metagudmath**, Retd. Dy.SPs, Vigilance Officer, KLESH, Belgaum	**Lay person**	Male
5. **Mrs. Lalan Prabhu**, Ramadev Galli, Belgaum	**Social Worker**	Female
6. **Shri. Praveen Hiremath**, Advocate Anjaneya Nagar, Belgaum	**Legal Expert**	Male
7. **Dr. M.S.Ganachari**, Prof. & HOD, Pharmacy Practice Dept., Belgaum	**Member-Secretary**	Male

Following members of the committee were unable to attend the meeting, as they were on leave due to some official work:-

1. **Dr. Harsha V.Hegde**, Scientist'B' ICMR (RMRC), Nehru Nagar, Belgaum	**Basic Science Scientists**	Male

2.	**Dr. S.S.Goudar**, Prof of Physiology, JNMC, Belgaum	**Basic Medical Scientists**	Male
3.	**Dr. M.V.Jali**, Prof of Diabetology, Medicine dept., JNMC, Belgaum	**Clinician**	Male
4.	**Dr. (Mrs.) Manisha R. Bhandankar**, Dept. of Paediatrics, JNMC, Belgaum	**Clinician**	Female

NOTE: It is to be noted that neither PI nor any of the proposed study team members of the concerned study were present during the decision-making procedures of the Ethics Committee, and members who are independent of the Investigator and the Sponsor of the trial, have voted/ provided opinion on the trials.

I. Agenda: New Protocol for Approval:

1. **Protocol**: "A Phase III Bridging study to evaluate the Immunogenicity and Safety of a Pentavalent Vaccine (DTwP-HepB-Hib) Shan 5 (with Shanta pertussis) as Compared to the licensed vaccine Shan 5 (with imported pertussis) when administered as three dose primary series at 6-8, 10-12 and 14-16 Weeks of Age in Healthy Indian Infants".

Dr. S.M.Dhaded – PI

EC received **12 copies** of each of following study related documents vide letter dated **23/05/2014**.

1. Clinical Trial Protocol (Version 1.0_10 Oct 2014)
2. Investigator's Brochure (Version 1.0_10 Sep 2014)
3. Case Report Form (Non Annotated)
4. Audio Visual Consent Form (Version 1.0_10 Oct 2014) in English, Hindi, Marathi &Kannada languages with Translation Certificates
5. Informed Consent Form (Version 1.0_10 Oct 2014) in English, Hindi, Marathi &Kannada languages with Translation Certificates
6. Diary Cards (Part A & Part B) in English, Hindi, Marathi &Kannada languages with Translation Certificates(Version 1.0_10 Oct 2014)

7. Audio Visual Consent Form (Version 1.0_10 Oct 2014), Informed Consent Form (Version 1.0_10 Oct 2014) and Part A & Part B Diary Cards(Version 1.0_10 Oct 2014)translated from Hindi, Marathi &Kannada languages to English with Translation Certificates
8. Principal Investigator's CV and MRC
9. Investigator's Undertaking
10. Insurance Policy
11. Investigator's Agreement with the Sponsor, [Confidentiality Disclosure Agreement (CDA) and Clinical Trial Agreement (CTA) – Draft]
12. Acknowledgement of Regulatory Dossier submission to DCGI

Discussion points:

At the Ethics Committee meeting held on **Thursday, 11th June 2015, 04.00 pm, at Site Management Office, KLES Dr Prabhakar Kore Hospital & MRC, Belgaum,** Ethics Committee decided to **approve for the conduct of the above referenced study and the related study documents.**

The study is approved through 10/June/2016 (for the period of 1 year).

2. **Protocol:** A Prospective, Multi-centre, Double-blind, Randomized trial of Saroglitazar 4 mg versus Placebo in Patients with Non-Alcoholic Steatohepatitis.
   Dr. Santosh Hajare – PI
   Note: Protocol discussion was deferred to next meeting as PI was unable to present the study.

3. **Protocol**: A randomized, open label, multi centric, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Paclitaxel protein-bound particles for injectable suspension (albumin-bound) 100 mg/vial manufactured by Sindan Pharma for Actavis LLC, USA and Abraxane 100 mg/vial (Albumin bound Paclitaxel 260 mg/m^2) intravenous infusion AbraxisBioScience LLC, New Jersey in patients with metastatic breast cancer.
   Dr. Mahesh Kalloli – PI

EC has received from you **12 copies** of each of following study related documents vide letter dated **16/May/2015**.

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Sr. No.	DOCUMENT	VERSION NO.& DATE
1.	Study Protocol	Version 4 Amendment 1dated 8 April 2015
2.	CV+MRC	-------
3.	Investigator Undertaking	Dated 5 May 2015.
4.	CRF	Version 3 dated 13 Feb 2015.
5.	Informed Consent document(English)	Version 6, dated 12 Mar 2015
6.	Informed Consent document-Hindi Translated From Informed Consent document-English Version 6, dated 12 March 2015	Version 6, dated 12 Mar 2015, translated on 18th March 2015.
7.	Back Translated Informed Consent Document from Hindi to English	Version 6, dated 12 March 2015, translated on 18th March 2015.
8.	Informed Consent document-Kannada Translated From Informed Consent document-English Version 6, dated 12 March 2015	Version 6, dated 12 March 2015, translated on 18th March 2015.
9.	Back Translated Informed Consent Document from Kannada to English.	Version 6, dated 12 March 2015, translated on 18th March 2015.
10.	Informed Consent document-Marathi Translated From Informed Consent document-English Version 6, dated 12 March 2015	Version 6, dated 12 March 2015, translated on 18th March 2015.

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11.	Back Translated Informed Consent Document from Marathi to English.	Version 6, dated 12 March 2015, translated on 18th March 2015.
12.	Translation certificate from English to Kannada.	Version 6, dated 12 March 2015, translated on 18th March 2015.
13.	Back translation certificate from Kannada to English.	Version 6, dated 12 March 2015, translated on 18th March 2015.
14.	Translation certificate from English to Hindi	Version 6, dated 12 March 2015, translated on 18th March 2015.
15.	Translation certificate from Hindi to English	Version 6, dated 12 March 2015, translated on 18th March 2015.
16.	Translation certificate from English to Marathi	Version 6, dated 12 March 2015, translated on 18th March 2015.
17.	Translation certificate from Marathi to English	Version 6, dated 12 March 2015, translated on 18th March 2015.

The following documents were submitted to EC on 12/06/2015:

- DCGI approval dated 13 May 2015
- Insurance dated 9 Jan 2015 till 26 Nov 2015
- CTRI/2015/03/005653

Discussion points:

At the Ethics Committee meeting held on **Thursday, 11th June 2015, 04.00 pm, at Site Management Office, KLES Dr Prabhakar Kore Hospital & MRC, Belgaum,** Ethics Committee decided to **approve for the conduct of the above referenced study and the related study documents.**

The study is approved through 10/June/2016 (for the period of 1 year).

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4. **Protocol:** A Development and validation of a comprehensive clinical and neuropsychological test battery for use in the Indian contest for patients with vascular cognitive Impairment.
   Dr. Saroja A.O – PI

EC has received from you **12 copies** of each of following study related documents.

Sr. No	DOCUMENT	Page No.
1	Study Protocol	1 - 28
2	Addendum to protocol	29 - 31
3	ICMR VCI Project Annual Report 2014	32 - 52
4	English ICF for illiterates	53 - 56
5	Kannada ICF for illiterates	57 - 60
6	CRF for Illiterates	61 – 100
7	ICMR letters	101 – 105
8	Investigators CV	106 - 111
9	Demographics	112 - 122

10	ICMR VCI Project Stroke Proforma	123 – 131
11	ICMR – VCI Clinical Proforma	132 – 134

The study is subjected to EC fee waiver(Project of ICMR)

Discussion points:

At the Ethics Committee meeting held on **Thursday, 11th June 2015, 04.00 pm, at Site Management Office, KLES Dr Prabhakar Kore Hospital & MRC, Belgaum,** Ethics Committee decided to **approve for the conduct of the above referenced study and the related study documents.**

The study is approved through 10/June/2016 (for the period of 1 year).

5. An Open Label, Randomized, Multicentric, Two Treatment, Single Dose, Parallel Group Two Stage Adaptive Design Bioequivalence Study of Loteprednol Etabonate Ophthalmic Suspension, 0.5 % in Aqueous Humor of Patients Undergoing Indicated Cataract Surgery.

   Dr. Smitha K.S– PI

EC has received from you **12 copies** of each of following study related documents vide letter dated 07/04/2014.

Sr. No.	DOCUMENT	VERSION NO.& DATE
1.	Study Protocol (WAT/LTPNL/2015)	Version 01, dated 14 Apr 2015
2.	Protocol Signature page	Signed and dated on 22 Apr 15
3.	English Informed Consent Form	Version 1 dated 20/APR/15
4.	Marathi Informed Consent Form	Site Specific Version 01 dated 19 May 15
5.	Hindi Informed Consent Form	Site Specific Version 01 dated 19 May 15

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6.	Kannada Informed Consent Form	Site Specific Version 01 dated 19 May 15
7.	Translation certificates for Hindi, Marathi and Kannada	Dated 19 May 2015
8.	Back Translation Marathi Informed Consent Form	Specific Version 01 dated 12 May 15
9.	Back Translation Hindi Informed Consent Form	Version 01 dated 12 May 15
10.	Back Translation certificates for Hindi, Marathi	Dated 12 May 2015
11.	Case Report Form	Draft 20 April 15
12.	Investigator CV & MRC	Signed and dated on 22 Apr 15
13.	Investigator Undertaking	Signed and dated on 22Apr 15
14.	FDA form 1572	Signed and dated on 22 Apr 15
15.	Draft CTA	-
16.	Insurance Policy	Valid from 27 Nov 14 to 26 Nov 16
17.	DCGI submission acknowledgement.	Dated 14 May 2015

The following document was submitted to EC on 12/06/2015:

- DCGI approval dated 04 June 2015

NOTE: The study should be initiated only after submission of **following documents to EC**

- **Separate AV Informed consent form**
- **CTRI**
- **Final CRF**
- **Final CTA**
- **Comprehensive Insurance letter** with mention of site name/PI name

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Discussion points:
At the Ethics Committee meeting held on **Thursday, 11th June 2015, 04.00 pm, at Site Management Office, KLES Dr Prabhakar Kore Hospital & MRC, Belgaum,** Ethics Committee decided to **approve for the conduct of the above referenced study and the related study documents.**

The study is approved through 10/June/2016 (for the period of 1 year).

II. Agenda: For Ongoing Trial Approval:

6. **Protocol**: A Phase IIb/III Randomized Multicenter Active Control to evaluate Efficacy and Safety of topical application of recombinant Lysostaphin (150µg/g) gel formulation in subjects with uncomplicated Staphylococcus aureus and Methicillin resistant Staphylococcus aureus skin and skin structure infections.

Dr. Shivakumar – PI
Discussion points:

At the Ethics Committee meeting held on **Thursday, 11th June 2015, 04.00 pm**, at Site Management Office, KLES Dr Prabhakar Kore Hospital & MRC, Belgaum, Ethics Committee decided to **approve study related documents** of the above referenced study.

III. The Committee considered the following agendas for information which were reviewed and approved:

1. **Reading & Approving the CIOMS received.**
2. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   - SAE 1: Worsening of heart failure for subject no. 11830031035
   - SAE 2: Vertigo for subject no. 11830031002
   - SAE 2: Congestive cardiac failure for subject no. 11830031032

Discussion Points: During its meeting, Ethics Committee reviewed the submitted documents of the above referenced study and found **narration ethical,** the SAE reported is appropriate and all the relevant documents are present. It was noted that the clinical trial subject has been provided with **free medical**

management, for eg.CBC, X-ray, LFT, Mini renal profile, etc. and has been recovered and discharged from the hospital for (as per the 'Appendix XI of Schedule Y' provided by Investigator). Hence, it is evident that the above SAE reported is not related to the Clinical drug or study drug.

3. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   - EC Notification of SUSAR no.3001-00150 of follow up#1 and follow up#2.
   - **SAE 1: Acute respiratory distress syndrome and death** for subject no.44160007

Discussion Points: During its meeting, Ethics Committee reviewed the submitted documents of the above referenced study and found **narration ethical,** the SAE reported is appropriate and all the relevant documents are present. As 'Death' is the potential end point, compensation is not applicable. Hence, it is evident that the above SAE reported is not related to the Clinical drug or study drug.

4. **Protocol Title: I4V-MC-JADZ:** A Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Moderately to Severely Active Rheumatoid Arthritis Who Have had Limited or No Treatment with Disease Modifying Antirheumatic Drugs.
   - EC Notification of protocol deviation for subject no.68571 for visit no.005 & visit no.001
   - EC Notification of protocol deviation for subject no.68570 for visit no.001
   - EC Notification of protocol deviation for subject no.685712 for visit no.001
   - EC Notification of protocol deviation for subject no.53824 for visit no.001& visit no.002
5. **Protocol Title: I4V-MC-JADY(C):** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   - EC Notification of protocol deviation for subject no.68571 for visit no.005
   - EC Notification of DCGI approval for addendum letter dated 24/04/2015
6. **Protocol no.: BRV07, Version1.0 titled:** "A Phase III study to evaluate immune non-inferiority and safety of all in one liquid formulation of a live attenuated tetravalent (G1-G4) Bovine-Human Reassortant Rotavirus Vaccine (BRV-TV) to a licensed vaccine Rota Teq when administered as three dose series to Indian infants concomitantly with other routinely recommended vaccines for the age.
   - EC Notification of SAE(Initial)- Broncho pneumonia associated with rickets for subject no.03-082 at site no.03
   - EC Notification of SAE(Follow-up)- Broncho pneumonia for subject no.03-081 at site no.03
   - EC Notification of SAE(Initial)- Broncho pneumonia for subject no.03-082 at site no.03

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- EC Notification of SAE(Initial)- Acute gastroenteritis for subject no.05-087 at site no.05
- EC Notification of SAE(Initial)- Bronchiolitis for subject no.11-046 at site no.11
- EC Notification of protocol deviation for subject no.10-039
- EC Notification of adverse event for subject no.10-053
- EC Notification of Insurance certificate from 05/01/15 to 04//30/16

Yours truly,

(Dr. (Prof.) M.S.Ganachari)
(Name & Signature of Ethics Committee Chairman/Member Secretary)

To:
The Members, Ethics Committee – KLE University, Belgaum.
Cc:

1. Director, KLE University Research Foundation, Belgaum.
2. The Chairman, Site Management Office, KLES Prabhakar Kore Hospital and Medical Research Centre, Belgaum.
3. The Member-Secretary, Site Management Office, KLES Prabhakar Kore Hospital and Medical Research Centre, Belgaum.
4. The Registrar, KLE University, JNMC Campus
5. Mrs. Rajeshwari - PRO - KLE University, Belgaum.

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Ref: KLEU/EC/2014-15/D- 82 **Date: 25/02/15**
09/04/2015

Ethics Committee (EC)

Minutes of the meeting held on **Thursday, 19th February 2015, 04:00 pm** at **Site Management Office, KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Belgaum.**

The list of all the members of ethics committee along with their qualification, affiliations and designation who attended the meeting, held on **Thursday, 19th February 2015, 04:00 pm, at Site Management Office at K.L.E.S Dr. Prabhakar Kore Hospital and Medical Research Centre,** Nehru Nagar, Belgaum–590010, Karnataka, India, at which time the following proposals were discussed, is listed below:

Following Members of the Committee were present:

NAMES OF MEMBERS WITH QUALIFICATION, DESIGNATION AND AFFILIATIONS	ROLE IN THE EC	GENDER
1. **Dr. Subarna.Roy**, Scientist'E' Officer-in-charge, ICMR (RMRC), Belgaum	**Chairman**	Male
2. **Dr. Harsha V.Hegde,** Scientist'B' ICMR (RMRC), Nehru Nagar, Belgaum	**Basic Science Scientists**	Male
3. **Dr. P. A. Patil,** Joint Director, KLE University Research Foundation.	**Basic Medical Scientists**	Male
4. **Dr. M.V.Jali,** Prof of Diabetology, Medicine dept., JNMC, Belgaum	**Clinician**	Male
5. **Dr. M. K. Swamy,** Prof&HOD,Obst&Gynace., JNMC,Belgaum	**Clinician**	Male
6. **Dr. (Mrs) Manisha R. Bhandankar,** Assoc. Prof.Dept.of Paediatrics, JNMC, Belgaum	**Clinician**	Female

7.	**Mr. B.N.Metagudmath**, Retd. Dy.SPs, Vigilance Officer, KLESH, Belgaum	**Lay person**	Male
8.	**Mrs. Lalan Prabhu**, Ramadev Galli, Belgaum	**Social Worker**	Female
9.	**Shri. Praveen Hiremath**, Advocate Anjaneya Nagar, Belgaum	**Legal Expert**	Male
10.	**Dr. M.S.Ganachari**, Prof. & HOD, Pharmacy Practice Dept., Belgaum	**Member-Secretary**	Male

Following Members of the committee were unable to attend the meeting, as they had some urgent work to be attended:-

1.	**Dr. S.S.Goudar**, Prof. of Physiology, JNMC, Belgaum	**Clinician**	Male

I. Agenda: New Protocol for Approval:

1. **Protocol Number: EFC11570**: "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome"

EC received **12 copies** of each of following study related documents from PI.

Sr. No.	Document Name	Version & Date
01	CLINICAL TRIAL PROTOCOL AMENDMENT 6 (GLOBAL)	Protocol Amendment No 6 dated 05-Dec- 2013
02	AMENDED CLINICAL TRIAL PROTOCOL 6 (PA6)	Version 2 dated 05-Dec-2013
03	INVESTIGATOR'S BROCHURE	Edition 07 dated 23-May-2014
04	DCGI approval letter for Sites	Dated 03-Feb-2014, 31-Mar-2014 & 27-Oct-2014
05	DCGI Export Licence/No objection	Dated 03-Feb-2014

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	Certificate (NOC)	
06	DCGI Import Licence	Dated 03-Feb-2014
07	DCGI Submission acknowledgment copy of Amended Protocol 6 (version 2 dated 05-Dec-2013)	Dated 26-Mar-2014
08	DCGI Approval letter for Amended Protocol 6 (version 2 dated 05-Dec-2013)	Dated 03-Sep-2014
09	Data Monitoring Committee (DMC) Recommendation Form for meeting	Dated 13-Jun-2013
10	Data Monitoring Committee (DMC) Recommendation Form for meeting	Dated 24-Mar-2014
11	Memo # 012 regarding IP Transportation Coolers (Cooling Bags and Heavy Duty Insulated Bags)	Dated 17-Dec-2013
12	Memo # 014 regarding Updating reference for ICH document regarding highly effective contraceptives	Dated 18-Feb-2014
13	Tomato Shaped Timer	EFC11570 Version 1.0 dated 30 January 2014 Sanofi Version 3 : 17 December 2013
14	Insurance Certificate, Bajaj Allianz General Insurance	Valid till 30-Apr-2015
15	Odyssey_CTRI Number	CTRI/2014/02/004387

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16	Odyssey_GP Letter	Version 1.0 dated 06-Sep-2012
17	Odyssey_Placebo Justification letter from Sponsor	Dated 14-Nov-2012
18	Exco InTouch Data Protection Statement	Issue 2 dated 24-Sep-2010
19	English Main ICF	India Version 1.1 Dated 29 Jan 2015
20	Hindi Main ICF with Translation Certificates	India Version 1.1 Dated 29 Jan 2015 Hindi Translation dated 29 Jan 2015
21	Back translation of Hindi Main ICF with Back-translation Certificates	India Version 1.1 Dated 29 Jan 2015 Hindi Back Translation dated 30 Jan 2015
22	Marathi Main ICF with Translation Certificates	India Version 1.1 Dated 29 Jan 2015 Marathi Translation dated 29 Jan 2015
23	Back translation of Marathi Main ICF with Back-translation Certificates	India Version 1.1 Dated 29 Jan 2015 Marathi Back Translation dated 30 Jan 2015
24	Kannada Main ICF with Translation Certificates	India Version 1.1 Dated 29 Jan 2015 Kannada Translation dated 29 Jan 2015
25	Back translation of Kannada Main ICF with Back-translation Certificates	India Version 1.1 Dated 29 Jan 2015 Kannada Back Translation dated 30 Jan 2015

26	English Pharmacogenetics ICF	India Version 1.1 Dated 29 Jan 2015
27	Hindi Pharmacogenetics ICF with Translation Certificates	India Version 1.1 Dated 29 Jan 2015 Hindi Translation dated 29 Jan 2015
28	Back translation of Hindi Pharmacogenetics ICF with Back-translation Certificates	India Version 1.1 Dated 29 Jan 2015 Hindi Back Translation dated 30 Jan 2015
29	Marathi Pharmacogenetics ICF with Translation Certificates	India Version 1.1 Dated 29 Jan 2015 Marathi Translation dated 29 Jan 2015
30	Back translation of Marathi Pharmacogenetics ICF with Back-translation Certificates	India Version 1.1 Dated 29 Jan 2015 Marathi Back Translation dated 30 Jan 2015
31	Kannada Pharmacogenetics ICF with Translation Certificates	India Version 1.1 Dated 29 Jan 2015 Kannada Translation dated 29 Jan 2015
32	Back translation of Kannada Pharmacogenetics ICF with Back-translation Certificates	India Version 1.1 Dated 29 Jan 2015 Kannada Back Translation dated 30 Jan 2015
33	English AVR ICF	AV India Version 1.0 dated 15-Dec-2014
34	Hindi AVR with Translation Certificates	A V India Version 1.0 dated 15-Dec-2014 Hindi Translation dated 15-Dec-2014
35	Back translation of Hindi AVR with	A V India Version 1.0 dated 15-Dec-

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	Back-translation Certificates	2014 Hindi Back Translation dated 16-Dec-2014
36	Marathi AVR with Translation Certificates	A V India Version 1.0 dated 15-Dec-2014 Marathi Translation dated 19-Dec-2014
37	Back translation of Marathi AVR with Back-translation Certificates	A V India Version 1.0 dated 15-Dec-2014 Marathi Back Translation dated 20-Dec-2014
38	Kannada AVR with Translation Certificates	A V India Version 1.0 dated 15-Dec-2014 Kannada Translation dated 15-Dec-2014
39	Back translation of Kannada AVR with Back-translation Certificates	A V India Version 1.0 dated 15-Dec-2014 Kannada Back Translation dated 16-Dec-2014
	Patient Materials and Other Study Related Documents	
40	EFC11570_English_EQ-5D Questionnaire	Final Version 2.0 (India-English)-04-Oct-2012
41	EFC11570_Hindi_EQ-5D Questionnaire	Final Version 2.0 (India-Hindi)–04Oct2012
42	EFC11570_Marathi_EQ-5D	Final Version 2.0 (India-Marathi)–

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	Questionnaire	04Oct2012
43	EFC11570_Kannada_EQ-5D Questionnaire	Final Version 2.0 (India-Kannada)– 04Oct2012
44	English IFU (Auto-Injector Instruction for use)	IFU V5.0, Appendix to R727_R_050 02.Aug.2012
45	Hindi IFU (Auto-Injector Instruction for use) with Translation Certificate	IFU V5.0 Appendix to R727_R_050 02Aug12 Translated from English to Hindi on 25/OCT/2012
46	Back translation of Hindi IFU (Auto-Injector Instruction for use) with Back-translation Certificate	Hindi Back translation of IFU V5.0 Appendix to R727_R_050 02Aug12 dated 18/DEC/2012
47	Marathi IFU (Auto-Injector Instruction for use) with Translation Certificate	IFU V5.0 Appendix to R727_R_050 02Aug12 Translated from English to Marathi on 13/SEP/2012
48	Back translation of Marathi IFU (Auto-Injector Instruction for use) with Back-translation Certificate	Marathi Back translation of IFU V5.0 Appendix to R727_R_050 02Aug12 dated 18/DEC/2012
49	Kannada IFU (Auto-Injector Instruction for use) with Translation Certificate	IFU V5.0 Appendix to R727_R_050 02Aug12 Translated from English to Kannada on 13/SEP/2012
50	Back translation of Kannada IFU (Auto-Injector Instruction for use) with Back-	Kannada Back translation of IFU V5.0 Appendix to R727_R_050 02Aug12

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	translation Certificate	dated 18/DEC/2012
51	English PAC (Patient Alert Card)	PAC English version 5 dated 13 Sep 2012 India version 1.0 dated 19 Sep 2012
52	Hindi PAC (Patient Alert Card) with Translation Certificate	PAC English version 5 dated 13 Sep 2012 India version 1.0 dated 19 Sep 2012 Hindi Version 1.0 dated 15 Nov 2012
53	Back translation of Hindi PAC (Patient Alert Card) with Back-translation Certificate	PAC English version 5 dated 13 Sep 2012 India version 1.0 dated 19 Sep 2012 Hindi Version 1.0 dated 15 Nov 2012 English BT version 1.0 dated 04 Dec 2012
54	Marathi PAC (Patient Alert Card) with Translation Certificate	PAC English version 5 dated 13 Sep 2012 India version 1.0 dated 19 Sep 2012 Marathi Version 1.0 dated 15 Nov 2012
55	Back translation of Marathi PAC (Patient Alert Card) with Back-translation Certificate	PAC English version 5 dated 13 Sep 2012 India version 1.0 dated 19 Sep 2012 Marathi Version 1.0 dated 15 Nov 2012 English BT version 1.0 dated 04 Dec 2012
56	Kannada PAC (Patient Alert Card) with Translation Certificate	PAC English version 5 dated 13 Sep 2012 India version 1.0 dated 19 Sep 2012 Kannada Version 1.0 dated 15 Nov 2012
57	Back translation of Kannada PAC (Patient Alert Card) with Back-translation Certificate	PAC English version 5 dated 13 Sep 2012 India version 1.0 dated 19 Sep 2012 Kannada Version 1.0 dated 15 Nov 2012 English BT version 1.0 dated 04 Dec 2012

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58	EFC11570_English Patient Diary (PD)	EFC11570_Patient Diary_English_Version 1.0_06 Sept 2012
59	EFC11570_ Hindi Patient Diary (PD)	EFC11570_Patient Diary_Final English Version 1.0 Dated 06 Sep 2012 EFC11570_Patient Diary_Final Hindi Version 1.0 Dated 15 Nov 2012
60	Back translation of EFC11570_ Hindi Patient Diary (PD) with Back – translation certificate	EFC11570_Patient Diary_Final Hindi Version 1.0 Dated 15 Nov 2012 EFC11570_Patient Diary_Final BT English Version 1.0 Dated 15 Nov 2012
61	EFC11570_ Marathi Patient Diary (PD)	EFC11570_Patient Diary_Final English Version 1.0 Dated 06 Sep 2012 EFC11570_Patient Diary_Final Marathi Version 1.0 Dated 15 Nov 2012
62	Back translation of EFC11570_ Marathi Patient Diary (PD) with Back – translation certificate	EFC11570_Patient Diary_Final Marathi Version 1.0 Dated 15 Nov 2012 EFC11570_Patient Diary_Final BT English Version 1.0 Dated 15 Nov 2012
63	EFC11570_ Kannada Patient Diary (PD)	EFC11570_Patient Diary_Final English Version 1.0 Dated 06 Sep 2012 EFC11570_Patient Diary_Final Kannada Version 1.0 Dated 15 Nov 2012
64	Back translation of EFC11570_ Kannada Patient Diary (PD) with Back	EFC11570_Patient Diary_Final

	–translation certificate	Kannada Version 1.0 Dated 15 Nov 2012 EFC11570_Patient Diary_Final BT English Version 1.0 Dated 15 Nov 2012
65	English_ Patient Retention Text Message Text_India_COV10658	Odyssey Outcomes_Patient retention text message text_COV10658_v1.0_ 12Feb2013_India (English)
66	Hindi _ Patient Retention Text Message Text_India_COV10658	Odyssey Outcomes_Patient retention text message text_COV10658_v1.0_ 12Feb2013_India (Hindi)
67	Marathi _ Patient Retention Text Message Text_India_COV10658	Odyssey Outcomes_Patient retention text message text_COV10658_v1.0_ 12Feb2013_India (Marathi)
68	Kannada _ Patient Retention Text Message Text_India_COV10658	Odyssey Outcomes_Patient retention text message text_COV10658_v1.0_ 12Feb2013_India (Kannada)
69	Translation Certificate for Patient Retention Text Message	Certificate Signed by Vendor on 12-Feb-2013
70	English_ Patient Retention Additional Text Messages	EFC11570-COV10660
71	Hindi _ Patient Retention Additional Text Messages	EFC11570-COV10660
72	Marathi _ Patient Retention Additional Text Messages	EFC11570-COV10660
73	Kannada _ Patient Retention Additional Text Messages	EFC11570-COV10660

74	Translation Certificate for Patient Retention Additional Text Messages	Certificate Signed by Vendor on 25-Oct-2012
75	English Packaging Instructions (Insulated Bag 6.1L)	Version 01 dated 30-May-2013
75	Hindi Packaging Instructions (Insulated Bag 6.1L)	Packaging Instructions, Hindi for India, Version 1.0, dated 05MAR2014.
76	Back translation of Hindi Packaging Instructions (Insulated Bag 6.1L)	Packaging Instructions, Hindi for India, Back translation, Version 1.0, dated 05MAR2014
77	Translation and Back translation Certificate for Packaging Instructions – Hindi	Certificate Signed by Vendor on 5-Mar-2014
78	Marathi Packaging Instructions (Insulated Bag 6.1L)	Packaging Instructions, Marathi for India, Version 1.0, dated 05MAR2014.
79	Back translation of Marathi Packaging Instructions (Insulated Bag 6.1L)	Packaging Instructions, Marathi for India, Back translation, Version 1.0, dated 05MAR2014
80	Translation and Back translation Certificate for Packaging Instructions – Marathi	Certificate Signed by Vendor on 5-Mar-2014
81	Kannada Packaging Instructions (Insulated Bag 6.1L)	Packaging Instructions, Kannada for India, Version 1.0, dated 05MAR2014.
82	Back translation of Kannada Packaging Instructions (Insulated Bag 6.1L)	Packaging Instructions, Kannada for India, Back translation, Version 1.0, dated 05MAR2014
83	Translation and Back translation Certificate for Packaging Instructions –	Certificate Signed by Vendor on 5-Mar-

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	Kannada	2014
84	**DCRI Patient Recruitment Materials:**	
	a) English_ Pre-Randomization Brochure b) Hindi _ Pre-Randomization Brochure c) Back-translation - Hindi Pre-Randomization Brochure d) Marathi _ Pre-Randomization Brochure e) Back-translation - Marathi Pre-Randomization Brochure f) Kannada _ Pre-Randomization Brochure g) Back-translation - Kannada Pre-Randomization Brochure	a) Version 1.0 20-Jun-2013 UKEng-542 b) Version 1.0 20-Jun-2013 HindIND-422 c) Version 1.0 20-Jun-2013 d) Version 1.0 20-Jun-2013 MaraIND-446 e) Version 1.0 20-Jun-2013 f) Version 1.0 20-Jun-2013 KannIND-430 g) Version 1.0 20-Jun-2013
	h) English_ Patient Flipbook i) Hindi _ Patient Flipbook j) Back-translation - Hindi _ Patient Flipbook k) Marathi _ Patient Flipbook l) Back-translation - Marathi _ Patient Flipbook m) Kannada _ Patient Flipbook n) Back-translation - Kannada _ Patient Flipbook	h) Version 2.0 21-Jan-2014 UKEng-541 i) Version 2.0 21-Jan-2014 HindIND-421 j) Version 2.0 21-Jan-2014 k) Version 2.0 21-Jan-2014 MaraIND-445 l) Version 2.0 21-Jan-2014 m) Version 2.0 21-Jan-2014 KannIND-429 n) Version 2.0 21-Jan-2014
	o) English_ Participant Reference Guide p) Hindi _ Participant Reference Guide q) Back-translation - Hindi Participant Reference Guide r) Marathi _ Participant Reference Guide	o) Version 2.0 21-Jan-2014 p) Version 2.0 21-Jan-2014 q) Version 2.0 21-Jan-2014 r) Version 2.0 21-Jan-2014

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	s) Back-translation - Marathi Participant Reference Guide t) Kannada _ Participant Reference Guide u) Back-translation - Kannada Participant Reference Guide	s) Version 2.0 21-Jan-2014 t) Version 2.0 21-Jan-2014 u) Version 2.0 21-Jan-2014
	v) English_ Participant Welcome Letter w) Hindi _ Participant Welcome Letter x) Back-translation Hindi _ Participant Welcome Letter y) Marathi _ Participant Welcome Letter z) Back-translation Marathi _ Participant Welcome Letter aa) Kannada _ Participant Welcome Letter bb) Back-translation Kannada _ Participant Welcome Letter	v) Dated 12-Feb-2013 w) Dated 12-Feb-2013 x) Dated 12-Feb-2013 y) Dated 12-Feb-2013 z) Dated 12-Feb-2013 aa) Dated 12-Feb-2013 bb) Dated 12-Feb-2013
	cc) English_ IP storage guidance Dos & Don'ts dd) Hindi _ IP storage guidance Dos & Don'ts ee) Back-translation Hindi IP storage guidance Dos & Don'ts ff) Marathi _ IP storage guidance Dos & Don'ts gg) Back-translation Marathi IP storage guidance Dos & Don'ts hh) Kannada _ IP storage guidance Dos & Don'ts ii) Back-translation Kannada IP storage guidance Dos & Don'ts	cc) EFC11570 Version 3.0_ROW, 3-Jul-2013 UKEng-564 dd) EFC11570 Version 3.0_ROW, 3-Jul-2013 HindIND-602 ee) EFC11570 Version 3.0_ROW 3-Jul-2013 ff) EFC11570 Version 3.0_ROW, 3-Jul-2013 MaraIND-605 gg) EFC11570 Version 3.0_ROW 3-Jul-2013 hh) EFC11570 Version 3.0_ROW, 3-Jul-

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		2013 KannIND-603 **ii)** EFC11570 Version 3.0_ROW 3-Jul-2013
85	Translation certificate for DCRM-Form English to Hindi	Certificate Signed by Vendor on 5-Jun-2014
86	Back -translation certificate for DCRM-Form Hindi to English	Certificate Signed by Vendor on 5-Jun-2014
87	Translation certificate for DCRM-Form English to Marathi	Certificate Signed by Vendor on 5-Jun-2014
88	Back -translation certificate for DCRM-Form Marathi to English	Certificate Signed by Vendor on 5-Jun-2014
89	Translation certificate for DCRM-Form English to Kannada	Certificate Signed by Vendor on 5-Jun-2014
90	Back -translation certificate for DCRM-Form Kannada to English	Certificate Signed by Vendor on 5-Jun-2014
91	EFC11570_English Patient Advert (Poster & Leaflet) Size A3 for India	EFC11570_Patient Poster A3 v1.0 dated 28-Oct-2013 EFC11570_English Patient Poster A3 for India v1.0 dated 19-May-2014
92	EFC11570_ Hindi Patient Advert (Poster & Leaflet) Size A3 for India with Translation & Validation	EFC11570_Patient Poster A3 v1.0 dated 28-Oct-2013

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	Certificates	EFC11570_English Patient Poster A3 for India v 1.0 dated 19-May-2014 EFC11570_ Hindi Patient Poster A3 for India v 1.0 dated 23-Jun-2014
93	EFC11570_ Marathi Patient Advert (Poster & Leaflet) Size A3 for India with Translation & Validation Certificates	EFC11570_Patient Poster A3 v1.0 dated 28-Oct-2013 EFC11570_English Patient Poster A3 for India v 1.0 dated 19-May-2014 EFC11570_ Marathi Patient Poster A3 for India v 1.0 dated 23-Jun-2014
94	EFC11570_ Kannada Patient Advert (Poster & Leaflet) Size A3 for India with Translation & Validation Certificates	EFC11570_Patient Poster A3 v1.0 dated 28-Oct-2013 EFC11570_English Patient Poster A3 for India v 1.0 dated 19-May-2014 EFC11570_ Kannada Patient Poster A3 for India v 1.0 dated 23-Jun-2014
95	EFC11570_English Patient Advert (Poster & Leaflet) Size A4 for India	EFC11570_Patient Leaflet A4 v1.0 dated 28-Oct-2013 EFC11570_English Patient Leaflet A4 for India v1.0 dated 19-May-2014
96	EFC11570_ Hindi Patient Advert (Poster & Leaflet) Size A4 for India with Translation & Validation Certificates	EFC11570_Patient Leaflet A4 v1.0 dated 28-Oct-2013 EFC11570_English Patient Leaflet A4 for India v 1.0 dated 19-May-2014

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		EFC11570_Hindi Patient Leaflet A4 for India v 1.0 dated 23-Jun-2014
97	EFC11570_ Marathi Patient Advert (Poster & Leaflet) Size A4 for India with Translation & Validation Certificates	EFC11570_Patient Leaflet A4 v1.0 dated 28-Oct-2013 EFC11570_English Patient Leaflet A4 for India v 1.0 dated 19-May-2014 EFC11570_Marathi Patient Leaflet A4 for India v 1.0 dated 23-Jun-2014
98	EFC11570_ Kannada Patient Advert (Poster & Leaflet) Size A4 for India with Translation & Validation Certificates	EFC11570_Patient Leaflet A4 v1.0 dated 28-Oct-2013 EFC11570_English Patient Leaflet A4 for India v 1.0 dated 19-May-2014 EFC11570_ Kannada Patient Leaflet A4 for India v 1.0 dated 23-Jun-2014
99	EFC11570_English Patient Advert (Poster & Leaflet) Size A5 for India	EFC11570_Patient Leaflet A5 v1.0 dated 28-Oct-2013 EFC11570_English Patient Leaflet A5 for India v1.0 dated 19-May-2014
100	EFC11570_ Hindi Patient Advert (Poster & Leaflet) Size A5 for India with Translation & Validation Certificates	EFC11570_Patient Leaflet A5 v1.0 dated 28-Oct-2013 EFC11570_English Patient Leaflet A5 for India v 1.0 dated 19-May-2014 EFC11570_ Hindi Patient Leaflet A5 for India v 1.0 dated 23-Jun-2014

101	EFC11570_ Marathi Patient Advert (Poster & Leaflet) Size A5 for India with Translation & Validation Certificates	EFC11570_Patient Leaflet A5 v1.0 dated 28-Oct-2013 EFC11570_English Patient Leaflet A5 for India v 1.0 dated 19-May-2014 EFC11570_ Marathi Patient Leaflet A5 for India v 1.0 dated 23-Jun-2014
102	EFC11570_ Kannada Patient Advert (Poster & Leaflet) Size A5 for India with Translation & Validation Certificates	EFC11570_Patient Leaflet A5 v1.0 dated 28-Oct-2013 EFC11570_English Patient Leaflet A5 for India v 1.0 dated 19-May-2014 EFC11570_ Kannada Patient Leaflet A5 for India v 1.0 dated 23-Jun-2014
103	Pictures of Cool Bag (bag will be provided to patients)	Description: Sky Blue color cooling bag
104	Pictures of White Tote Bag (bag will be provided to patients for initial supplies)	Description: PET 12+40, White Polyethylene middle-density thickness 4.5/100 Foam 0.8 mm White Handle size 330 x 80 x 210 mm (LxlxH)
105	Pictures of Sharps Container (Sharp container will be provided to patients)	Description: Sharp container clear 2 Quarts, 15.875cm (H) x 12.065cm (D) x 27.305cm (W) supply code SPC2.
106	Pictures of Insulated Bag (bag will be provided to patients on a case by case basis)	Description: Technical Data Sheet Cool Insulated Bag 6.1 L, Used with 4 ICE Packs N2GT, For products to be maintained at 2 to 8 degrees V01 dated

		30/05/2013
107	EFC11570_Odyssey_Full eCRF (01 CD)	Version dated 12-Oct-2012
108	Video on Odyssey Study Drug Administration (01 CD).	Video only, no audio. To be shown to patients at site only
109	CV of Principal Investigator Dr. Sanjay Porwal	CV signed by PI dated 10-JAN-2015
110	MRC of Dr. Sanjay Porwal	MRC Reg. No.- 42,756
111	Investigator Undertaking of Dr. Sanjay Porwal	Signed by PI dated 10-Jan-2015
112	Draft Clinical Trial Agreement	Draft

During the Ethics Committee (EC) meeting of KLE University held on Ethics Committee has received the additional documents on **23/02/2015** for which PI was asked to submit to EC, during the meeting held and are being included in this approval letter.

- DCGI approval for the additional site

NOTE: The study should be initiated only after submission to Ethics Committee of the following upon receiving of the same.

- Letter of CTRI registration
- Insurance letter to be renewed at the time of expiry which is Valid till 30-Apr-2015

Discussion points:

At the Ethics Committee meeting held on **Thursday, 19th February 2015, 04.00 pm, at Site Management Office, KLES Dr Prabhakar Kore Hospital & MRC, Belgaum,** Ethics Committee decided to **approve for the conduct of the above referenced study and the related study documents.**

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The study is approved through 18/ February /2016 (for the period of 1 year).

2. **BBIL/ROTA5C/III/2014**: "A seamless, sequential phase III, multicenter, Ramdomized, single –blind study, to evaluate immunogenicity, reactogenicity and safety of ROTAVAC 5C new formulation of the live attenuated rotavirus vaccine as a 3 dose series when compared with existing ROTAVAC in healthy infants ".

The Ethics Committee of KLE University reviewed the following documents: 12 copies (submitted on 06/02/2015 and resubmitted on 11/03/2015 with additional documents)

S.NO	Document
1.	**DCGI Approval (Dated 29.01.2015)**
2.	**Clinical Trial Protocol (version 1.1 Dated July 2,2014)**
3.	**CTRI Registration No. CTRI/2015/02/005577 Dated:24/02/2015**
4.	**Informed Consent Document (Subject Information Sheet & Informed Consent Form) Exploratory Phase** • English ICD version 1.2 dated 30.01.2015 Translated from version 1.0 dated 26.07.2014 • Hindi Version No1.2 dated 30.01.2015 Translated from ICD English version 1.0 dated 26.07.2014 • Marathi Version No 1.2 dated 30.01.2015 Translated from ICD English version 1.0 dated 26.07.2014 • Kannada _Version No 1.2 dated 30.01.2015 2014 Translated from ICD English version 1.0 dated 26.07.2014
5.	**Informed Consent Document (Subject Information Sheet & Informed Consent Form) Confirmatory Phase** • English ICD version 1.2 dated 30.01.2015 Translated from version 1.0 dated 23.09.2014 • Hindi Version No1.2 dated 30.01.2015 Translated from ICD English version 1.0 dated 23.09.2014 • Marathi Version No 1.2 dated 30.01.2015 Translated from ICD English version

	1.0 dated 23.09.2014 • Kannada _Version No 1.2 dated 30.01.2015 2014 Translated from ICD English version 1.1dated 23.09.2014
6.	Back Translation Certificate
7.	Case Report form
8.	Diary Card **(Version 1.0 September 25,2014)**
9.	Investigator Brochure
10.	Undertaking of Investigator and CV
11.	Clinical Trial agreement **Dated:20/12/2014**
12.	Product insert
13.	Insurance policy period **Dated 23/02/2015 to 22/02/2016**
14.	References

iscussion points:

After due consideration, the committee has decided to approve the conduct of the aforementioned study as well as all the study related documents in its presented form at KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum - 590010, Karnataka, India.
The study is approved through 18th February 2016 (for the period of 1 year)

II. The Committee considered the following agendas which were for information:

1. **Reading & Approving the CIOMS received.**
2. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   - EC Notification of SAE- {**Myocardial Infarction**} for subject no.11830055032 at site no.30055

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- EC Notification of SAE- {**Increase in congestive heart failure cardiogenic shock sepsis acute renal failure**} for subject no.11830050032 at site no.30055
- EC Notification of follow-up-1 letter of SAE
- EC Notification of follow-up-2 letter of SAE
- EC Notification of SAE- {**Fracture left Femur**} for subject no.11830055047 at site no.30053
- EC Notification of SAE- {**Progression of stroke**} for subject no.11830065032 at site no.30065
- EC Notification of SAE- {**Breathlessness cough**} for subject no.11830029025 at site no.30029
- EC Notification of revised Insurance certificate from 18/01/2015 to 17/01/2016

3. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   - EC Notification of final **SAE 03**-Acute respiratory failure due to hospital acquired pneumonia} for subject no.44160002 on 27/01/15
4. **Protocol no.: BBIL/ROTA/IV/2013**: "Phase IV, multicenter, randomized, single-blind, study to evaluate the immunogenicity, reactogenicity & safety of the live attenuated rotavirus vaccine ROTAVAC® as a 3 dose series when administered simultaneously with or without the buffering agent following in healthy infants".
   - EC Notification of study close out
5. **Protocol I4L-MC-ABEL:** A Prospective, Randomized, Open-Label Comparison of a Long-Acting Basal Insulin Analog, LY2963016, to Lantus® in Combination with Mealtime Insulin Lispro in Adult Patients with Type 1 Diabetes Mellitus: The ELEMENT 3 Study
   - EC Notification of study close out

Yours truly,

(Dr. (Prof.) M.S.Ganachari)
(Name & Signature of Ethics Committee Chairman/Member Secretary)

To:
The Members, Ethics Committee – KLE University, Belgaum.

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Cc:

1. Director, KLE University Research Foundation, Belgaum.
2. The Chairman, Site Management Office, KLES Prabhakar Kore Hospital and Medical Research Centre, Belgaum.
3. The Member-Secretary, Site Management Office, KLES Prabhakar Kore Hospital and Medical Research Centre, Belgaum.
4. The Registrar, KLE University, JNMC Campus
5. Mrs. Rajeshwari - PRO - KLE University, Belgaum.

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Ref: KLEU/EC/2015-16/D-1714.

Date: 24/07/15

Ethics Committee (EC)

Minutes of the meeting held on **Wednesday, 08th July, 04:00 pm** at **Site Management Office, KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Belgaum.**

The members present at the approval meeting met the requirements of the quorum set down in the EC operating procedures and as per ICH GCP & Schedule Y requirements.
The members who attended the meeting held on **Wednesday, 08th July, 04:00 pm** at **Site Management Office (SMO),** at which time your proposals were discussed are listed below:

Following Members of the Committee were present:

NAMES OF MEMBERS WITH DESIGNATION	ROLE IN THE EC	GENDER
1. **Dr. Subarna.Roy**, Scientist'E' Officer-in-charge, ICMR (RMRC), Belgaum	Chairman	Male
2. **Dr. Harsha V.Hegde,** Scientist'B' ICMR (RMRC), Nehru Nagar, Belgaum	Basic Science Scientists	Male
3. **Dr. S.S.Goudar**, Prof of Physiology, JNMC, Belgaum	Basic Medical Scientists	Male
4. **Dr. P. A. Patil**, Joint Director, KLE University Research Foundation	Basic Medical Scientists	Male
5. **Dr. M. K. Swamy**, Prof, Obst & Gynace., JNMC, Belgaum.	Clinician	Male
6. **Dr. (Mrs.) Manisha R. Bhandankar,** Dept. of Paediatrics, JNMC, Belgaum	Clinician	Female
7. **Mr. B.N.Metagudmath**, Retd. Dy.SPs, Vigilance Officer, KLESH, Belgaum	Lay person	Male
8. **Mrs. Lalan Prabhu**, Ramadev Galli, Belgaum	Social Worker	Female
9. **Shri. Praveen Hiremath**, Advocate Anjaneya Nagar, Belgaum	Legal Expert	Male

o/c.

10. Dr. M.S.Ganachari, Prof. & HOD, Pharmacy Practice Dept., Belgaum	**Member-Secretary**	Male

Following member of the committee was unable to attend the meeting, as he was on leave due to some official work:-

1. Dr. M.V.Jali, Prof of Diabetology, Medicine dept., JNMC, Belgaum	**Clinician**	Male

NOTE: It is to be noted that neither PI nor any of the proposed study team members of the concerned study were present during the decision-making procedures of the Ethics Committee, and members who are independent of the Investigator and the Sponsor of the trial, have voted/ provided opinion on the trials.

I. Agenda: New Protocol for Approval:

1. **Protocol:** "A Phase III, randomized, double-blind, active-controlled, multinational, multicenter, non-inferiority trial using Carbetocin room temperature stable (RTS) for preventing postpartum haemorrhage during the third stage of labour in women delivering vaginally"
   Dr. S.S.Goudar – PI

The Ethics Committee of KLE University reviewed the following documents:

1. Carbetocin RTS for preventing postpartum haemorrhage: a randomized non-inferiority controlled trial - HRP Research proposal version 28 May 2014 including Annexes 1-12 for Trial A65870.
2. Approval letter from Research Ethics Review Committee, World Health Organization, Geneva dated 02 June 2014.
3. Information sheet for women attending antenatal care visits at the hospital participating in the Research: Carbetocin RTS for preventing postpartum haemorrhage and Certificate of Consent for Women to Sign; English version dated June 10, 2014
4. Information Sheet for women in labour attending the hospital participating in the Research: Carbetocin RTS for preventing postpartum haemorrhage and Certificate of Consent for Women to Sign; English version dated June 10, 2014
5. Information sheet for women attending antenatal care visits at the hospital participating in the Research: Carbetocin RTS for preventing postpartum haemorrhage and Certificate of Consent for Women to Sign; Kannada version dated June 10, 2014
6. Information Sheet for women in labour attending the hospital participating in the Research: Carbetocin RTS for preventing postpartum haemorrhage and Certificate of Consent for Women to Sign; Kannada version dated June 10, 2014

7. Information sheet for women attending antenatal care visits at the hospital participating in the Research: Carbetocin RTS for preventing postpartum haemorrhage and Certificate of Consent for Women to Sign; Marathi version dated June 10, 2014
8. Information Sheet for women in labour attending the hospital participating in the Research: Carbetocin RTS for preventing postpartum haemorrhage and Certificate of Consent for Women to Sign; Marathi version dated June 10, 2014

Discussion points:

During the Ethics Committee (EC) meeting of KLE University held on **Wednesday, 8th July 2015 at 04:00 pm** at **Site Management Office,** KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Belgaum, Your referenced letter and the above submitted documents were examined and discussed. After reviewing, Ethics Committee decided to **approve the study documents of the above referenced study.**

2. **Protocol:** A Prospective, Multi-centre, Double-blind, Randomized trial of Saroglitazar 4 mg versus Placebo in Patients with Non-Alcoholic Steatohepatitis.
   Dr. Santosh Hajare – PI

Note: The above protocol was taken review and approval from the last meeting as it had been deferred. EC has received from **12 copies** of each of following study related documents vide letter dated **6-June-2015.**

- Investigator Brochure – Version No -4.0 dated 31st October 2013
- Protocol – SARO.14.001.01.PROT Version No – 1.0 dated 02nd April 2014
- Case Report Form – Version No – 1.0 Dated 03rd April 2014
  - Screening Form
  - Enrollment Form
- Informed Consent Document – SARO.14.001.01.ICD, Version No – 1.0 dated 3rd April 2014
  - English
  - Hindi
  - Marathi & Kannada
- Back translation of Informed Consent Document – Version No - 1.0 dated 3rd April 2014
  - Hindi
  - Marathi & Kannada

- Informed Consent Document for Audio video recording (Version No – 1.0 dated 03rd April 2014) which is made in order to incorporate the audio-visual process as per the DCGI order dated 19th November 2013 in following languages.
  - English
  - Hindi
  - Marathi & Kannada
- Informed Consent Document for Audio video recording (Version No – 1.0 dated 03rd April 2014) which is made in order to incorporate the audio-visual process as per the DCGI order dated 19th November 2013 in following languages:
  - Hindi, Marathi & Kannada
- Accuracy certificate of Informed Consent Document – Version No – 1.0 dated 03rd April 2014
  - Hindi, Marathi & Kannada
- Insurance Policy No :- 21230036120500000001
- Draft CTA
- DCGI Approval F. No 12-05/05-DC (Pt.B) dated 23rd September 2014 granting permission to conduct Phase 3 clinical trial.

Enclosed separately

- Undertaking of the Investigator
- CV of the investigator

Discussion points:
At the Ethics Committee meeting held on **Wednesday, 8th July 2015, 04.00 pm, at Site Management Office, KLES Dr Prabhakar Kore Hospital & MRC, Belgaum,** Ethics Committee decided to **approve for the conduct of the above referenced study and the related study documents.**

NOTE: The study should be initiated only after submission of **following documents to EC**

- DCGI NOC letter with mention of site name in it.
- **Comprehensive Insurance letter** with mention of protocol title(study specific)
- **CTRI letter**

The study is approved through 07/July/2016 (for the period of 1 year).

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3. **Protocol:** A Phase IV, Non comparative, Open label, Multicentric Trial to Evaluate the Safety and Efficacy of SYNRIAM® in the Treatment of Acute Uncomplicated Plasmodium vivax Malaria" study number R2014006.
   Dr. Raju.H.Badiger – PI

EC has received from **12 copies** of each of following study related documents vide letter dated **26-June-2015**.

S.No	Document
1.	**Clinical Trial Protocol** - Version 1.1 dated 19.06.2015
2.	**Case Report Form** - Study No.R2014006, CRF Version 1.1 dated 17.04.2015 supersedes Version 1 dated 17.11.2014 **Unscheduled visit booklet** - Study No.R2014006, CRF Version 1.1 dated 17.04.2015 supersedes Version 1 dated 17.11.2014 **Serious Adverse Event and Clinical Trial Pregnancy booklet** - Study No.R2014006, Version 1.1 dated 17.04.2015 supersedes Version 1 dated 17.11.2014
3.	**Investigator Brochure** Version No: 9, Release date 18 September 2013

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4.	**Consent/Assent for Audio– visual recording of Informed Consent/ Assent process** • Study Number: R2014006_English _Audio–visual recording of Informed Consent/ Assent procedure_ Version 1 Dated 17.11.2014 • Study Number: R2014006_Hindi_Audio–visual recording of Informed Consent/ Assent procedure_Version 1 Dated 26.02.2015 Translated from English_Audio– visual recording of Informed Consent/ Assent procedure_Version 1 Dated 17.11.2014. • Study Number: R2014006_Kannada_Audio–visual recording of Informed Consent/ Assent procedure_Version 1 Dated 26.02.2015Translated from English_Audio– visual recording of Informed Consent/ Assent procedure_Version 1 Dated 17.11.2014 • Study Number: R2014006_Telugu_Audio–visual recording of Informed Consent/ Assent procedure_Version 1 Dated 26.02.2015Translated from English_Audio– visual recording of Informed Consent/ Assent procedure_Version 1 Dated 17.11.2014 **Informed Consent Document (Subject Information Sheet & Informed Consent Form)** • Study Number: R2014006 ICD English Version No 2 dated 12 June 2015 supersedes ICD English Version 1.1 dated 25 March 2015 • Study Number: R2014006_ICD_Hindi_Version No 2 dated 15 June 2015 supersedes ICD Hindi Version 1.1 dated 25 March 2015 • Study Number: R2014006_ICD_Kannada_Version No 2 dated 15 June 2015 supersedes ICD Kannada Version 1.1 dated 25 March2015 • Study Number: R2014006_ICD_Telugu_Version No 2 dated 15 June 2015 supersedes ICD Telugu Version 1.1 dated 25 March2015
5.	**Advertisement** • Study Number: R2014006_English Advertisement Version 1 dated 17.11.2014 • Study Number: R2014006_Hindi _Version No 1 dated 26.02.2015 Translated from Advertisement English Version 1 dated 17.11.2014 • Study Number: R2014006_Advertisement_Kannada_Version No 1 dated 26.02.2015 Translated from Advertisement EnglishVersion 1 dated 17.11.2014 • Study Number: R2014006_Advertisement_Telugu_Version No 1 dated 26.02.2015 Translated from Advertisement English Version1 dated 17.11.2014
6.	**Medication compliance card** • Study Number: R2014006_English MCC Version 1 Dated 17.11.2014

	• Study Number: R2014006_Hindi _Version No 1 dated 26.02.2015 Translated from MCC English Version 1 dated 17.11.2014 • Study Number: R2014006_MCC_Kannada _Version No 1 dated 26.02.2015 Translated from MCC English Version 1 dated17.11.2014 • Study Number: R2014006_MCC_Telugu_Version No 1 dated 26.02.2015 Translated from MCC English Version 1 dated 17.11.2014
7.	**Investigator Undertaking**
8.	**Curriculum Vitae of the Investigator**
9.	**Insurance Policy**
10	**Clinical Trial Agreement – draft**
11	**DCGI No Objection Certificate**
12	**CTRI Registration Document**
13	**Press Release: Sun Pharma- Ranbaxy Merger**

The following documents were submitted to EC on 12/06/2015:

- NOC letter from DCGI with the site name included.
- Study specific comprehensive Insurance letter

Discussion points:

At the Ethics Committee meeting held on **Wednesday, 8th July 2015, 04.00 pm, at Site Management Office, KLES Dr Prabhakar Kore Hospital & MRC, Belgaum,** Ethics Committee decided to **approve for the conduct of the above referenced study and the related study documents.**

The study is approved through 07/July/2016 (for the period of 1 year).

II. Agenda: For Ongoing Trial Approval:

4. Protocol: A Phase IV, single dose, open labelled, comparative, randomized controlled study to evaluate the immunogenicity and safety of BBIL's JENVAC (Inactivated JE Vaccine) vs. Chinese SA-

14-14-2 (Live JE Vaccine) vaccine in healthy volunteers – Immunogenicity and safety following booster dose after 1 year.

The Ethics Committee of KLE University reviewed the following documents ON 03-06-2015:

Document	Version	Dated
1)Subject diary card	Version 1.2 (Addendum)	18/03/2015
2)Letter to DCGI	Version 1.2 (addendum)	24-APR-2015
3)study protocol	Version 1.2 (addendum)	18-03-2015
4)Informed Consent Documents(Subject information Sheet & Informed consent form) Exploratory Phase • English _Addendum_ Audio– visual recording of Informed Consent/ Assent procedure_ Version 1.2 Dated 06-apr-2015		

Discussion points:

At the Ethics Committee meeting held on **Wednesday, 8th July 2015, 04.00 pm**, at Site Management Office, KLES Dr Prabhakar Kore Hospital & MRC, Belgaum, Ethics Committee decided to **approve study related documents** of the above referenced study.

5. **Protocol**: "Aspirin Supplementation for Pregnancy Indicated Risk Reduction in Nulliparas (ASPIRIN)"
   Dr.B.S.Kodkany– PI

The Ethics Committee of KLE University reviewed the following documents:

1. Amended English Informed Consent dated 26 May 2015
2. Amended Kannada Informed Consent, dated 26 May 2015
3. Amended Marathi Informed Consent, dated 26 May 2015
4. Amended Hindi Informed Consent, dated 26 May 2015

Discussion points:

During the Ethics Committee (EC) meeting of KLE University held on Wednesday, 8th July 2015 at 04:00 pm at Site Management Office, KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Belgaum, Your referenced letter and the above submitted documents were examined and discussed. After reviewing, Ethics Committee decided to approve the study documents of the above referenced study.

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III. The Committee will consider the following agendas which are for information:

1. **Reading & Approving the CIOMS received.**
2. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   - EC Notification of PI analysis of;

   SAE 1: Worsening of heart failure for subject no. 11830031035
   SAE 2: Vertigo for subject no. 11830031002
   SAE 2: Congestive cardiac failure for subject no. 11830031032
3. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   - EC Notification of CIOMS
4. **a. Protocol Title: I4V-MC-JADX:** A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Inadequate Response to Conventional Disease-Modifying Antirheumatic Drugs with Moderately to Severely Active Rheumatoid Arthritis.

   b.Protocol Title: I4V-MC-JADZ: A Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Moderately to Severely Active Rheumatoid Arthritis Who Have had Limited or No Treatment with Disease Modifying Antirheumatic Drugs.

   c.Protocol Title: I4V-MC-JADY(C): A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   - EC Notification of request for consideration of Nonpharmacogenetic/Biomarker sample for the above referenced studies.

Discussion points:

The **Ethics Committee** received your reference letter dated 30 Jun 2015 requesting for EC clarification for the above mentioned subject.

Request put up:

- During the visit of Mr. Sanjay Majumdar (Sponsor) and Mr. Mahesh Raut (CRA) on 25 Jun 2015, they informed us regarding the Non-Pharmacogenomics Biomarkers Study required for the research. They clarified that the Biomarkers are Non-Pharmacogenomics and it will not be utilized for

Pharmacogenomics study. Thus they requested as per the protocol to permit the collected Biomarker samples which will be used for Non-Pharmacogenomics studies.

- Further to the clarification letter received from EC dated 02-May-15 Ref: KLEU/EC/2015-16/D-520 where EC clarified that Biomarker Samples are considered as Pharmacogenomics studies, I have received further clarification from the study sponsor and as per the protocols of the above reference studies kindly note that the Biomarker Samples in these studies will be used for NonPharmacogenetic analysis only and are required part of the study.
- As per the Protocol Section 10.4.3.2 of JADX and JADZ study and Section 10.4.2.1 of study JADY it is stated that Biomarker samples are non-pharmacogenetic, and is a required part of the study, please find below the section as defined in the protocol:

Nonpharmacogenetic/Biomarker Stored Samples
Collection of samples for nonpharmacogenetic biomarker research is a required part of this study. Serum, plasma, whole blood RNA, and urine samples will be collected at the times specified in the study schedule of the protocol.

Samples may be used for research on the drug target, disease process, pathways associated with disease state, mechanism of action of baricitinib, and/or research method or in validating diagnostic tools or assay(s) related to RA.

Samples will be identified by the patient number (coded) and stored for up for a maximum of 15 years after the last patient visit for the study at a facility selected by the sponsor.

Discussion: As per the discussions in the meeting held on **Wednesday 08th July 2015, 04:00 pm** at **Site Management Office (SMO), KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belgaum,** here is the **response** provided by **Ethics Committee** after reviewing it.

Ethics Committee has noted the mention of- Biomarker samples are non-pharmacogenetic as per the Protocol Section 10.4.3.2 of JADX and JADZ study and Section 10.4.2.1 of study JADY and reviewed the same. In the unanimous opinion of the EC members, **Biomarker samples should be used for Non-**

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Pharmacogenetic analysis only and samples for the same purpose can be collected in the present JADY study.

Note: Pharmacogenomic study in any form is not approved by the Ethics Committee.

5. **Protocol Title: I4V-MC-JADY(C):** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   - EC Notification of protocol deviation for subject no.53824 for visit no.003
6. **Protocol Number: EFC11570**: "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome"
   - EC Notification of CIOMS

Yours truly,

(Dr. (Prof.) M.S.Ganachari)
(Name & Signature of Ethics Committee Chairman/Member Secretary)

To:
The Members, Ethics Committee – KLE University, Belgaum.

Cc:

1. Director, KLE University Research Foundation, Belgaum.
2. The Chairman, Site Management Office, KLES Prabhakar Kore Hospital and Medical Research Centre, Belgaum.
3. The Member-Secretary, Site Management Office, KLES Prabhakar Kore Hospital and Medical Research Centre, Belgaum.
4. The Registrar, KLE University, JNMC Campus
5. Mrs. Rajeshwari - PRO - KLE University, Belgaum.

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Ref: KLEU/EC/2014-15/D- 81

Date: 31/01/15
09/4/15

Ethics Committee (EC)

Minutes of the meeting held on **Friday, 23rd January 2015, 04:00 pm** at **Site Management Office, KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Belgaum.**

The list of all the members of ethics committee along with their qualification, affiliations and designation who attended the meeting, held on **Friday, 12th December 2014, 04:00 pm, at Site Management Office at K.L.E.S Dr. Prabhakar Kore Hospital and Medical Research Centre,** Nehru Nagar, Belgaum–590010, Karnataka, India, at which time the following proposals were discussed, is listed below:

Following Members of the Committee were present:

NAMES OF MEMBERS WITH QUALIFICATION, DESIGNATION AND AFFILIATIONS	ROLE IN THE EC	GENDER
1. **Dr. Subarna.Roy,** Scientist'E' Officer-in-charge, ICMR (RMRC), Belgaum	**Chairman**	Male
2. **Dr. Harsha V.Hegde,** Scientist'B' ICMR (RMRC), Nehru Nagar, Belgaum	**Basic Science Scientists**	Male
3. **Dr. P. A. Patil,** Joint Director, KLE University Research Foundation.	**Basic Medical Scientists**	Male
4. **Dr. M.V.Jali,** Prof of Diabetology, Medicine dept., JNMC, Belgaum	**Clinician**	Male
5. **Mr. B.N.Metagudmath,** Retd. Dy.SPs, Vigilance Officer, KLESH, Belgaum	**Lay person**	Male
6. **Mrs. Lalan Prabhu,** Ramadev Galli, Belgaum	**Social Worker**	Female
7. **Shri. Praveen Hiremath,** Advocate Anjaneya Nagar, Belgaum	**Legal Expert**	Male
8. **Dr. M.S.Ganachari,** Prof. & HOD, Pharmacy Practice Dept., Belgaum	**Member-Secretary**	Male

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Following Members of the committee were unable to attend the meeting, as they had some urgent work to be attended:-

1.	**Dr. S.S.Goudar**, Prof. of Physiology, JNMC, Belgaum	**Basic Medical Scientists**	Male
2.	**Dr. M. K. Swamy,** Prof&HOD,Obst&Gynace., JNMC,Belgaum	**Clinician**	**Male**
3.	**Dr. (Mrs) Manisha R. Bhandankar,** Assoc. Prof.Dept.of Paediatrics, JNMC, Belgaum	**Clinician**	Female

I. Agenda: Ongoing Protocols for Approval:

1. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease". **Dr. Kothiwale – PI**

EC received **12 copies** of each of following study related documents vide your letter dated **17/12/2014** from PI.

a. Superseding Protocol amendment 05 dated 18 Sep 2014
b. Revised Main Informed consent form - Indian version 6.0, dated 15 Oct 2014 in English and translated in Hindi, Marathi & Kannada
c. Screening Informed consent form - Indian version 6.0, dated 15 Oct 2014 in English and translated in Hindi, Marathi & Kannada
d. Summary of changes document for Informed Consent form
e. Translation and Back Translation certificates for Hindi, Marathi & Kannada

Discussion points:

During the Ethics Committee (EC) meeting of KLE University held on **Friday, 23rd January 2015, 04:00 pm at Site Management Office, KLES Dr. Prabhakar Kore Hospital & Medical Research Center,**

Belgaum, Your referenced letter and the above submitted documents were examined and discussed. After reviewing, Ethics Committee decided **to approve the documents of the above referenced study.**

2. **Protocol Title: I4V-MC-JADY(C):** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis. **Dr.S.V.Udapudi – PI**

EC received **12 copies** of each of following study related documents vide your letter dated **27/12/2014** from PI.

- Protocol Amendment I4V-MC-JADY (e)approved on 30-Oct-2014 (no. of copies: 13)
- Protocol Addendum JADY (8.1) approved on 20-Nov-2014 (no. of copies: 13)
- India Specific ICF Version: 08-Dec-2014(no. of copies: 13)
- India Specific ICF Version: 08-Dec-2014: Hindi Translation Version: 26-Dec-2014 (with translation certificate)(no. of copies: 13)
- India Specific ICF Version: 08-Dec-2014: Kannada Translation Version: 01-Jan-2015 (with translation certificate)(no. of copies: 13)
- India Specific ICF Version: 08-Dec-2014: Marathi Translation Version: 08-Jan-2015 (with translation certificate)(no. of copies: 13)

Discussion points:

During the Ethics Committee (EC) meeting of KLE University held on **Friday, 23rd January 2015, 04:00 pm at Site Management Office, KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Belgaum,** Your referenced letter and the above submitted documents were examined and discussed. After reviewing, Ethics Committee decided **to approve the documents of the above referenced study.**

3. **Addendum to Protocol:** A Phase IV, Randomized, factorial assigned, Open labelled, study to evaluate the non- interference in immune response of Typhoid Vi Capsular Polysaccharide - Tetanus Toxoid Conjugate Vaccine (Typbar-TCV) administered to children at 9 months, to measles vaccine given concomitantly. **Dr. (Mrs.) N.S. Mahantshetti – PI**

EC received **12 copies** of each of following study related documents vide your letter dated 23/12/2014 from PI.

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Sl. No	Documents
1.	DCGI acknowledgement letter Dated 08/12/2014
2.	**Addendum on Audio- visual recording of Informed Consent/ Assent process** • English _Addendum_ Audio– visual recording of Informed Consent/ Assent procedure_ Version 1.1 Dated 2.12.14 • Hindi_Addendum_Audio–visual recording of Informed Consent/ Assent procedure_Version 1.1 Dated 2.12.14 • Marathi_Addendum_Audio–visual recording of Informed Consent/ Assent procedure_Version 1.1 Dated2.12.14 • Kannada _Addendum_Audio–visual recording of Informed Consent/ Assent procedure_Version 1 Dated 09.05.2014 Translated from English _Addendum_ Audio– visual recording of Informed Consent/ Assent procedure_ Version 1.1 Dated 2.12.14

Discussion points:

During the Ethics Committee (EC) meeting of KLE University held on **Friday, 23rd January 2015, 04:00 pm at Site Management Office, KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Belgaum,** Your referenced letter and the above submitted documents were examined and discussed. After viewing, Ethics Committee decided **to approve the documents of the above referenced study.**

II.The Committee considered the following agendas which were for information:

1. **Reading & Approving the CIOMS received.**
2. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   - EC Notification of SAE- {**Bilateral Pleural effusion**} for subject no.11830031035 on 30/12/2014
   - EC Notification of follow-up-1 letter of SAE- {SAE term upgraded from **Bilateral Pleural effusion** to **Acute heart failure secondary to undue exertion**} on 02/01/2015

Discussion Points: During its meeting, Ethics Committee reviewed the submitted documents of the above referenced study and found **narration ethical,** the SAE reported is appropriate and all the relevant documents are present. EC was informed that the clinical trial subject has been **provided with free**

medical management and discharged from the hospital after the recovery and details about the same was reported to EC (as per the 'Appendix XI' of 'Schedule Y' of Amended D&C Act 2013).

- EC Notification of "DCGI notification letter dated 08-Dec-2014"
- EC Notification of DMC letter dated 25 -Nov-2014

3. **Protocol Number: I2R-MC-BIDB:** A Comparison of LY2605541 versus Insulin Glargine as Basal Insulin Treatment in Cobmination with Oral Anti-Hyperglycemia Medications in Insulin – Naïve Patients with Type 2 Diabetes Mellitus: An Open-Label, Randomized, 52-week Study.
   - EC Notification of trial cancellation
4. **Protocol: Phase III Clinical Trial entitled** "Comparative Efficacy, Safety and Tolerability of Silver Sulfadiazine Cream (Nanonized) 0.5% w/w and Silverex Cream 1% w/w in the Prophylaxis of Infection in Burn Wounds – A Double-blind, Randomized, Pivotal Study''
   - EC Notification of trial cancellation letter dated 19/12/2014
5. **Protocol:**Comparative Efficacy, Safety and Tolerability of Fixed Dose Combination of Cephalexin Extended Release (375 mg) and Clavulanate Potassium (125 mg) Tablets with Cephalexin Extended Release (375 mg) Tablets in the Treatment of Uncomplicated Skin and Soft Tissue Infections- A Randomized, Double-blind Study.
   - EC Notification of DCGI NOC for phase III study
6. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   - EC Notification of Initial **SAE 01**-{Worsened Renal Failure} for subject no.44160004 on 09/01/15
   - EC Notification of Notification **of SAE 02 -{Cerebro vascular accident-Right cerebral Artery Infarct}** for subject no.44160002 on 03/10/14

Discussion Points: During its meeting, Ethics Committee reviewed the submitted documents of the above referenced study and found **narration ethical,** the SAE reported is appropriate and all the relevant documents are present. EC was informed that the clinical trial subject has been **provided with free medical management** and discharged from the hospital after the recovery and details about the same was reported to EC (as per the 'Appendix XI' of 'Schedule Y' of Amended D&C Act 2013).

- EC Notification of protocol deviation for subject no.44160002
- EC Notification of CIOMS

IV.With permission of the chair, review and approval of the following protocols were considered

1. **Protocol Title:** "Effect of Docosa-hexaenoic acid (DHA) Supplementation during pregnancy on Newborn outcomes in India – the DHANI randomized controlled trial". **Dr.Kodakany-PI**

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EC received **12 copies** of each of following study related documents vide your letter dated **23/01/2015** from PI.

The modifications made in the protocol are as follows:

1. **Modified** DHANI study protocol version 3.1 dated15th May 2014.
2. **Modified** DHANI Patient Information Sheet version 3.1 dated 21st November 2014.
3. **Modified** Informed Consent Form version 3.1 dated 28th November 2014.
4. **Modified** Questionnaires version 3.1 dated 21st November 2014 along with SAE reporting form.

Discussion points:

During the Ethics Committee (EC) meeting of KLE University held on **Friday, 23rd January 2015, 04:00 pm at Site Management Office, KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Belgaum,** Your referenced letter and the above submitted documents were examined and discussed. After reviewing, Ethics Committee decided **to approve the documents of the above referenced study.**

2. **Protocol Title:** CLIP (Community Level Interventions for Pre-eclampsia) Cluster Randomized Controlled Trial, India. **Dr.M.B.Bellad-PI**

EC received **12 copies** of each of following study related documents vide your letter dated **23/01/2015** from PI.

1. Consent form for MNH registry –Marathi, Dated 11th November 2014
2. Consent form for Participant in Intervention Cluster -Marathi with Dated 11th November 2014
3. MNH supplement form 1, English, Version 7 Dated 26th September 2014
4. MNH supplement form 1, Kannada, Version 7 Dated 26th September 2014
5. MNH supplement form 2, English, Version 7 Dated 3rd December 2014
6. MNH supplement form 2, Kannada, Version 7 Dated 3rd December 2014
7. MNH supplement form 3, English, Version 7 Dated 3rd December 2014
8. MNH supplement form 3, Kannada, Version 7 Dated 3rd December 2014

Discussion points:

During the Ethics Committee (EC) meeting of KLE University held on **Friday, 23rd January 2015, 04:00 pm at Site Management Office, KLES Dr. Prabhakar Kore Hospital & Medical Research Center,**

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Belgaum, Your referenced letter and the above submitted documents were examined and discussed. After reviewing, Ethics Committee decided **to approve the documents of the above referenced study.**

Yours truly,

(Dr. (Prof.) M.S.Ganachari)
(Name & Signature of Ethics Committee Chairman/Member Secretary)

To:
The Members, Ethics Committee – KLE University, Belgaum.
Cc:

1. Director, KLE University Research Foundation, Belgaum.
2. The Chairman, Site Management Office, KLES Prabhakar Kore Hospital and Medical Research Centre, Belgaum.
3. The Member-Secretary, Site Management Office, KLES Prabhakar Kore Hospital and Medical Research Centre, Belgaum.
4. The Registrar, KLE University, JNMC Campus
5. Mrs. Rajeshwari - PRO - KLE University, Belgaum.

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Ref: KLEU/EC/2015-16/D- 83

Date: 06/04/15
09/04/15

Ethics Committee (EC)

Minutes of the meeting held on **Friday, 27th March 2015, 04:00 pm** at **Site Management Office, KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Belgaum.**

The list of all the members of ethics committee along with their qualification, affiliations and designation who attended the meeting, held on **Thursday, 19th February 2015, 04:00 pm, at Site Management Office at K.L.E.S Dr. Prabhakar Kore Hospital and Medical Research Centre,** Nehru Nagar, Belgaum–590010, Karnataka, India, at which time the following proposals were discussed, is listed below:

Following Members of the Committee were present:

NAMES OF MEMBERS WITH QUALIFICATION, DESIGNATION AND AFFILIATIONS	ROLE IN THE EC	GENDER
Following Members of the EC Committee were present:		
1. Dr. Subarna.Roy, Scientist'E'Officer-in-charge, RMRC, Belgaum	**Chairman**	
2. Dr. Harsha V.Hegde Scientist'B' ICMR (RMRC), Nehru Nagar, Belgaum	Member	
3. Dr. P. A. Patil, Joint Director, KLE University Research Foundation	Member	
4. Dr. S.S.Goudar, Prof of Physiology, JNMC, Belgaum	Member	
5. Dr. M. K. Swamy, Prof, Obst & Gynace., JNMC Belgaum	Member	
6. Dr. (Mrs) Manisha R.Bhandankar, Assoc. Prof, Paediatrics, JNMC, Belgaum	Member	
7. Mr. B.N.Metagudmath, Retd. Dy.SPs, Vigilance Officer, KLESH, Belgaum	Member	
8. Mrs. Lalan Prabhu, Ramadev Galli, Belgaum	Member	
9. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belgaum	Member	
10. Dr. M.S.Ganachari, Prof. & HOD, Pharmacy Practice Dept., Belgaum	**Member-Secretary**	

Following Member of the committee was unable to attend the meeting, as he was on duty leave on some official work:-

1. Dr. M.V.Jali, Prof of Diabetology, Medicine dept., JNMC, Belgaum	Member	

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I. Agenda: New Protocol for Approval:
Protocol Number: Aspirin supplementation for pregnancy indicated risk reduction in Nulliparas (ASPIRIN)

EC received **12 copies** of each of following study related documents from PI.

1. Aspirin Protocol V 1.1 dated 21 March 2015
2. English Informed Consent, dated 10 March 2015
3. Kannada Informed Consent, dated 10 March 2015
4. Marathi Informed Consent, dated 10 March 2015
5. Hindi Informed Consent, dated 10 March 2015
6. English Audio Video Informed Consent (AV), dated 10 March 2015
7. Kannada Audio Video Informed Consent (AV), dated 10 March 2015
8. Marathi Audio Video Informed Consent (AV), dated 10 March 2015
9. Hindi Audio Video Informed Consent (AV), dated 10 March 2015
10. ASP01_Initial.Screening_March.10.2015
11. ASP02_Ultrasound.Screening_March.10.2015
12. ASP03_HB.monitoring_March.10.2015
13. ASP04_Clinical.Assessment.Form_March.13.2015
14. ASP05_Biweekly_monitoring_March.13.2015
15. ASP06_BP.Monitoring_March.13.2015
16. ASP07_Unscheduled.Emergency.FU_March.13.2015
17. ASP08_Serious.Adverse.Events_Mar.13.2015
18. ASP09_Study.Withdrawal_March.13.2015
19. ASP10_Protocol.Deviation_March.10.2015
20. AspLog_screening.log_March.13.2015

Discussion points:

During the Ethics Committee (EC) meeting of KLE University held on **Friday, 27th March, 2015 at 04:00 pm** at **Site Management Office,** KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Belgaum, Your referenced letter and the above submitted documents were examined and discussed. After reviewing, Ethics Committee decided to **approve the study documents for the conduct of the above referenced study.**

The study is approved through 26/ March /2016 (for the period of 1 year).

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Note: Following members abstained from the voting process -

1. Dr Shivaprasad Goudar, Prof of Physiology, JNMC, Belgaum
2. Dr. M.S.Ganachari, Prof. & HOD, Pharmacy Practice Dept., Belgaum

II. Agenda: For Ongoing Trial Approval:

Protocol: Effects of a Yoga-based cardiac rehabilitation programme (Yoga-Care) on cardiovascular health: a clinical trial (India) and mechanistic study (UK).

The Ethics Committee of KLE University reviewed the following documents for review and approval [12 copies]:-

1. Protocol version 3.0 dated 30/December/2014
2. CRF-002, CRF-003, CRF-010
3. Summary of changes

- Letter of EC Fee waiver.

Discussion points:

During the Ethics Committee (EC) meeting of KLE University held on **Friday, 27th March 2015, 04:00 pm at Site Management Office, KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Belgaum,** Your referenced letter and the above submitted documents were examined and discussed. After reviewing, Ethics Committee **decided to approve the documents** of the above referenced study.

II. The Committee considered the following agendas which were for information:

1. **Reading & Approving the CIOMS received.**
2. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".

- EC Notification of **Initial SAE letter- {Accelerated Hypertension}** for subject no.20110118 submitted on 17/03/2015
- EC Notification of **Final SAE letter- {Accelerated Hypertension}** for subject no.20110118 follow up-I submitted on 20/03/2015
- EC Notification of **Initial SAE letter-{Worsening of heart failure}** for subject no.11830031035 submitted on 20/03/2015
- EC Notification of **Final SAE letter- {Accelerated Hypertension}** for subject no. 11830031035 follow up-I submitted on 20/03/2015

Discussion Points: During its meeting, Ethics Committee reviewed the submitted documents of the above referenced study and found **narration ethical,** the SAE reported is appropriate and all the relevant documents are present. EC was informed that the clinical trial subject has been **provided with free medical management** and discharged from the hospital after the recovery and details about the same was reported to EC (as per the 'Appendix XI' of 'Schedule Y' of Amended D&C Act 2013).

3. EC Notification of **Final SAE letter- Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   - EC Notification of CIOMS for subject ID's 36010006,44160004
   - EC Notification of SUSAR for subject ID 36010006,20080004
   - **Protocol Title: I4V-MC-JADY(C):** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis.
   - EC Notification of SAFRNS/CIOMS from 05/12/13 to 04/06/14.
   - EC Notification of Blinded Investigator Line Listing from 05/02/15 to 09/03/15, approved on 05/02/15.
   - EC Notification of protocol deviation for subject no.53824 for visit no.002
   - EC Notification of protocol deviation for subject no.53824 for visit no.003
   - EC Notification of DCGI approval letter dated 16/02/2015
   - EC Notification of adverse event occurred for subject no.68572
   - EC Notification of SAFRNS/CIOMS from 26/11/14 to 04/02/15
4. **Protocol Title: I4V-MC-JADZ:** A Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Moderately to Severely Active Rheumatoid Arthritis Who Have had Limited or No Treatment with Disease Modifying Antirheumatic Drugs.
   - EC Notification of SAFRNS/CIOMS from 05/02/15 to 09/03/15.
   - EC Notification of Blinded Investigator Line Listing from 05/02/15 to 09/03/15, approved on 05/02/15.
   - EC Notification of SAFRNS/CIOMS from 26/11/14 to 04/02/15
5. **Protocol Title: I4V-MC-JADX:** A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Inadequate Response to Conventional Disease-Modifying Antirheumatic Drugs with Moderately to Severely Active Rheumatoid Arthritis.
   - EC Notification of study close out.
6. **Protocol Number: EFC11570**: "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of

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Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome"

- EC Notification of DCGI NOC dated dated 20/02/2015
- EC Notification of Insurance certificate valid from 23/02/2015 to 22/02/2016
- EC Notification of final CTA
- EC Notification of response to EC queries.

7. **Protocol no.: BRV07, Version1.0 titled:** "A Phase III study to evaluate immune non-inferiority and safety of all in one liquid formulation of a live attenuated tetravalent (G1-G4) Bovine-Human Reassortant Rotavirus Vaccine (BRV-TV) to a licensed vaccine Rota Teq when administered as three dose series to Indian infants concomitantly with other routinely recommended vaccines for the age.

- EC Notification of SAE- Right sided aspiration pneumonia for subject no.09-065 at site no.09
- EC Notification of SAE- Broncho pneumonia for subject no.03-005 at site no.03
- EC Notification of SAE- Respiratory tract infection for subject no.04-017 at site no.04
- EC Notification of SAE- Urinary tract infection for subject no.11-057 at site no.11
- EC Notification of SAE- Viral associated wheeze for subject no.12-009 at site no.12
- EC Notification of SAE- Acute Bronchiolitis for subject no.05-046 & 05-047 at site no.46 & 47
- EC Notification of adverse event occurred for subject no.10-001 & 10-019
- EC Notification of study status
- EC Notification of additional 30 subjects

8. **Protocol No: "BBIL/ROTA/IV/2013**: "Phase IV, multicenter, randomized, single-blind, study to evaluate the immunogenicity, reactogenicity & safety of the live attenuated rotavirus vaccine ROTAVAC® as a 3 dose series when administered simultaneously with or without the buffering agent following in healthy infants".

- EC Notification of SAE's at different sites.

Yours truly,

(Dr. (Prof.) M.S.Ganachari)
(Name & Signature of Ethics Committee Chairman/Member Secretary)

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To:
The Members, Ethics Committee – KLE University, Belgaum.
Cc:

1. Director, KLE University Research Foundation, Belgaum.
2. The Chairman, Site Management Office, KLES Prabhakar Kore Hospital and Medical Research Centre, Belgaum.
3. The Member-Secretary, Site Management Office, KLES Prabhakar Kore Hospital and Medical Research Centre, Belgaum.
4. The Registrar, KLE University, JNMC Campus
5. Mrs. Rajeshwari - PRO - KLE University, Belgaum.

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Ref: KLEU/EC/2014-15/D- 3543. ***Date: 19/01/2015***

Circular

The meeting of Ethics **Committee (EC)** of the **KLE University** is convened on **Friday, 23rd January 2014, 04:00 pm** at **Site Management Office (SMO), KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belgaum.**

I. Agenda: For Ongoing Trial's Approval:

1. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease". **Dr. Kothiwale - PI**
2. **Protocol Title: I4V-MC-JADY(C):** A Phase 3, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Rheumatoid Arthritis. **Dr.S.V.Udapudi – PI**
3. **Addendum to Protocol:** A Phase IV, Randomized, factorial assigned, Open labelled, study to evaluate the non- interference in immune response of Typhoid Vi Capsular Polysaccharide - Tetanus Toxoid Conjugate Vaccine (Typbar-TCV) administered to children at 9 months, to measles vaccine given concomitantly. **Dr. (Mrs.) N.S. Mahantshetti – PI**

II. The Committee will consider the following agendas which are for information:

1. **Reading & Approving the CIOMS received.**
2. **Protocol No: 20110118:** "A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease".
   - EC Notification of SAE- {**Bilateral Pleural effusion**} for subject no.11830031035 on 30/12/2014
   - EC Notification of follow-up-1 letter of SAE- {SAE term upgraded from **Bilateral Pleural effusion** to **Acute heart failure secondary to undue exertion**} on 02/01/2015
   - EC Notification of "DCGI notification letter dated 08-Dec-2014"
   - EC Notification of DMC letter dated 25 -Nov-2014
3. **Protocol Number: I2R-MC-BIDB:** A Comparison of LY2605541 versus Insulin Glargine as Basal Insulin Treatment in Cobmination with Oral Anti-Hyperglycemia Medications in Insulin – Naïve Patients with Type 2 Diabetes Mellitus: An Open-Label, Randomized, 52-week Study.
   - EC Notification of trial cancellation
4. **Protocol: Phase III Clinical Trial entitled** "Comparative Efficacy, Safety and Tolerability of Silver Sulfadiazine Cream (Nanonized) 0.5% w/w and Silverex Cream 1% w/w in the Prophylaxis of Infection in Burn Wounds – A Double-blind, Randomized, Pivotal Study''

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- EC Notification of trial cancellation letter dated 19/12/2014

5. **Protocol:**Comparative Efficacy, Safety and Tolerability of Fixed Dose Combination of Cephalexin Extended Release (375 mg) and Clavulanate Potassium (125 mg) Tablets with Cephalexin Extended Release (375 mg) Tablets in the Treatment of Uncomplicated Skin and Soft Tissue Infections- A Randomized, Double-blind Study.
   - EC Notification of DCGI NOC for phase III study
6. **Protocol 3-001**: A randomized double-blind, placebo-controlled, Phase-3 study to assess the safety and efficacy of ART-123 in subject with severe sepsis and coagulopathy.
   - EC Notification of Initial **SAE 01**-{Worsened Renal Failure} for subject no.44160004 on 09/01/15
   - EC Notification of Notification **of SAE 02 -{Cerebro vascular accident-Right cerebral Artery Infarct}** for subject no.44160002 on 03/10/14
   - EC Notification of protocol deviation for subject no.44160002
   - EC Notification of CIOMS
7. Any other matter with the permission of the Chair.

For your Attention: Please make it convenient to attend the meeting and, communicate if you seek leave of absentia, to Member Secretary.

Yours truly,

(Dr. M.S.Ganachari)
(Name & Signature of Ethics Committee Chairman/Member Secretary)

OFFICE OF THE REGISTRAR KLE UNIVERSITY, BELAGAVI

To: All the members:

1. Dr. Subarna Roy, Scientist 'E', Officer-in-Charge, Regional Medical Research Center, ICMR, Opp. KLES Hospital and MRC, Nehru Nagar, Belgaum.
2. Dr. M.S.Ganachari, Prof. & HOD of Pharmacy Practice, KLE College of Pharmacy, Belgaum.
3. Dr. Harsha V.Hegde, Scientist'B' ICMR (RMRC), Nehru Nagar, Belgaum
4. Dr. P. A. Patil, Joint Director, KLE University Research Foundation, "VISHILP" 23-A, IInd main, IInd cross, Basav Colony, Bauxite Road, Belgaum.
5. Dr.S.S.Goudar,Prof.& HODof Physiology, J.N. Medical College, Belgaum
6. Dr. M.V. Jali, MD & CEO KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum.
7. Dr. M. K. Swamy, Prof.&HOD, Obst & Gynace., JNMC, Belgaum.

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8. Dr. (Mrs) Manisha R.Bhandankar, Associate Prof., Dept. of Paediatrics, JNMC, Belgaum.
9. Mrs. Lalan Prabhu, Ramadev Galli, Belgaum
10. Mr. B.N. Metagudmath, Retired Dy.SP, Vigilance Officer, KLES Dr.Prabhakar Kore Hospital and MRC, Belgaum.
11. Shri. Praveen Hiremath, Advocate, Anjaneya Nagar, Belgaum.
12. Dr. Kothiwale Prof.& Head, Dept.of Medicine, J.N.Medical College, Belgaum.-**Principal Investigator**–For Information(SAE presentation).
13. Dr.Jayaprakash, Assoc. Prof. Dept. of Medicine, J.N.Medical College, Belgaum.-**Principal Investigator**–For Information(SAE presentation).
14. Dr.M.B.Bellad, Professor of Obstetrics and Gynecology, J.N.Medical College, Belgaum.-**Principal Investigator**–For Information(SAE presentation).
15. The Registrar, KLE University, JNMC Campus, Belgaum–For Information.
16. The Special Officer to Vice-Chancellor, KLE University, JNMC Campus, Belgaum –For Information.
17. Mrs. Rajeshwari - PRO - KLE University, Belgaum.