

Annual Report Template

Sl.No	Particulars	(to be Filled by the Investigator)
1.	Protocol No:	
2.	Principal Investigator:	
3.	Name of the Co-Investigator:	
4.	Date of start of study –Site Initiation Visit	
5.	Proposed date of Completion	
6.	Duration of the study:	
7.	PI Presented to IEC Meeting –	
8.	IEC initial Decision letter	
9.	IEC Final Approval Date if Applicable	
10.	Amendments if any: Approval given for the Amendment:	
11.	Financial Status:	
12.	Objectives:	
13.	Sample size	
14.	Does the Study involve recruitment of participants Total Number of study participants enrolled/Drop out/Failure/Ongoing	
15.	Have any ethical concerns occurred during this period, if Yes Give Details	
16.	Report of DSMB	
17.	Summary of the work done (preferably in 1-2 paragraphs)	
18.	Number on study/follow-up:	
19.	Number of AE/SAE:	
20.	Completion/Termination of the study – date	
21.	Any protocol deviation and violations:	
22.	Validity of IEC Approval	
23.	Signature of the Principal Investigator with date	