Summary of adverse event reports from the investigators at SCTIMST

(This form should be submitted along with the adverse event reports to the IEC)

1. IEC No. :

2. Project title :

3. Project (in SCTIMST) Start date: End date :

4. Number of patients in the study

No of Patients in the Study:	**Total Planned:**	**No Recruited:**
Total number of centres(globally):		
Number of countries including India in which the study is being carried out:		
Total (in all centers for MCTs):		
In our center:		

5. Summary of adverse event (*pl add additional rows to the table as needed*)

SAE No or Patient ID	Date of event	Patient Age / Sex	Centre	Brief description of the event & remarks of PI at SCTIMST on possible relationship of the adverse event with the study drug	Remarks of the investigator who reported the adverse event

6. Grouping of SAEs by event type (where more than one patient has had the same SAE) *(Pl add additional rows to the table as needed*

Sl. No	Event nature / type	Total no of events	No of patients	Remarks

7. a) Previous reports of similar adverse event in this study (please list the number of cases and references, if any).

b) Do you wish to revise the earlier report submitted? If so, in what way?

8. With this profile of SAE would you justify the inclusion criteria? Under what circumstances would you remove a study subject?

9. Do you wish continue or stop the study?

10. Any patients recruited in our center had an adverse event of similar nature?

Name of Principal Investigator
Signature and date