**Annexure**

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| **AX1-V6/SOP12/V6** |
| **Study Completion Report**  |
| TMC Project No. - Study Title: - Principal Investigator: -CTRI registration number - |
| Sponsor Name (if applicable)Funding Source -Account No - |
| Duration of the study -  |
| Date of IEC ApprovalValidity of approval given upto: Study Start Date - If delayed start -state reasons - Completion Date -  |
| **Summary of Protocol participants:** * Target accrual of study (entire study) including healthy volunteers, participants and biomedical samples/blocks)\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Total participants/samples to be recruited at TMC (IEC ceiling)\_\_\_\_\_\_\_\_\_\_
* Screened: \_\_\_\_\_\_\_\_\_\_
* Screen failures: \_\_\_\_\_\_\_\_\_\_
* Enrolled: \_\_\_\_\_\_\_\_\_\_
* If total target accrual could not be achieved – Kindly provide reasons
* Consent Withdrawn: \_\_\_\_\_\_\_ TMC Case No& Reason for withdrawal
* Withdrawn by PI: \_\_\_\_\_\_\_\_\_ TMC Case No& Reason for withdrawal
* Active intervention: \_\_\_\_\_\_\_\_\_\_
* Completed intervention and on Follow-up: \_\_\_\_\_\_\_\_\_\_(includes participants who had received intervention)
* Participants lost to follow up: \_\_\_\_\_\_\_\_\_\_
* Any other: \_\_\_\_\_\_\_\_\_\_
* Any Impaired participants
* None\_\_\_\_\_
* Physically \_\_\_\_\_
* Cognitively \_\_\_\_\_
* Both \_\_\_\_\_
 |
| No. of study arms/interventions :- |
| Objectives:- |
| Results (brief) (use extra blank sheets, if more space is required)-1. \* 250-300 words, with aims, methods, results, discussion and conclusion as in an abstract
2. Summary and Conclusions
3. Details of new leads/information obtained, if any:

\*Note: In case of Pharma sponsored projects, if the final report is not available from Sponsor, it may be submitted later to the IEC once it is ready. |
| Conclusion \* |
| Presentation/publication related to the data generated in this trial :Y/N* If yes: please enclose reprint of research publication
* Did you inform the funding agency/ TRAC- Yes / No
 |
| Serious Adverse Events at our center (Total number and type) Note : applicable for Interventional study |
| Whether all Serious Adverse Events were intimated to the IEC (Yes/No) |
| Protocol deviations/violations (Type and Number)Whether all Protocol deviations/violations were intimated to the IEC (Yes/No) |
| Please specify if the raw data was submitted to TMC- Research Administrative Council (TRAC) (applicable only for investigator initiated studies). Budget sanctioned- Rs.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Budget utilized-Rs.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_If underutilized provide reasons-(Kindly submit utilization certificate in case of institutional funded studies) |
| Signature of PI Date: **\*mandatory fields** |