**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 Approval  Validity 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* Enrolled: \_\_\_\_\_\_\_\_\_\_ * If total target accrual could not be achieved – Kindly provide reasons * Consent Withdrawn: \_\_\_\_\_\_\_ TMC Case No& Reason for withdrawal * Withdrawn by PI: \_\_\_\_\_\_\_\_\_ TMC Case No& Reason for withdrawal * Active intervention: \_\_\_\_\_\_\_\_\_\_ * Completed intervention and on Follow-up: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** |