Annexure

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- Consent Withdrawn: _____TMC Case No& Reason for withdrawal
- Withdrawn by PI: _____TMC Case No& Reason for withdrawal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)- a) * 250-300 words, with aims, methods, results, discussion and conclusion as in an abstract b) Summary and Conclusions c) 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**