



AX1-V2/SOP-12/V2 Study Completion Report

Study Completion Report
BBCI Project No. - Study Title: - Principal Investigator: -
Sponsor - Funding Source - Account No -
Duration of the study -
Date of IEC Approval- Study Start Date - If delayed start -state reasons - Completion Date -
Summary of Protocol participants: <ul style="list-style-type: none">○ Target accrual of study (entire study) including healthy volunteers, participants and biomedical samples/blocks) _____○ Total participants/samples to be recruited at BBCI (IEC ceiling) _____○ Screened: _____○ Screen failures: _____○ Enrolled: _____○ If total target accrual could not be achieved – Kindly provide reasons○ Consent Withdrawn: _____ BBCI Case No& Reason for withdrawal○ Withdrawn by PI: _____ BBCI Case No& Reason for withdrawal○ Active intervention: _____○ Completed intervention and on Follow-up: _____(includes participants who had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<ul style="list-style-type: none">● None _____

<ul style="list-style-type: 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 <ul style="list-style-type: none">• 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 BBCI - (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**

