



AX1-V2/SOP-08/V2
Deviation (D) / Violation (V)
Reporting Form

(PLEASE REPORT SINGLE EVENT IN ONE REPORTING FORM)

Specify if D/V- _____

Note-

Protocol deviation: Changes or alterations in the conduct of the trial which do not have a major impact on the participant's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

Protocol violation: Changes or alterations in the conduct of the trial that may affect the participant's rights, safety, or wellbeing or alter the risk benefit ratio, and/or affect the participants' willingness to participate in the study, and/or impact the completeness, accuracy and reliability of the study data.

IEC Project No.:

Project Title:

Participant Case No.:

Trial Id:

Date of Occurrence: dd/mm/yyyy

Total number of deviations /violations/ reported till date on the study:

Total number of similar deviations /violations/ occurred for the same trial:

Phase of Study i.e. Active Intervention/Completed Intervention/Follow up:

Study status:

IEC approval Date-

Target recruitment -

No. of participants recruited:

- D/V identified by-**
- Principal Investigator / study team
 - Sponsor / Monitor
 - DSMU/IEC

Classify the lapse (Tick the appropriate box) :

- Consenting
- Enrollment
- Protocol procedure
- Laboratory assessment
- Investigational Product
- Safety Reporting
- Source documentation
- Staff
- Participant non-compliance
- Others (Please specify)

Complete Details of D/V:

Impact on Trial participant (if any):

Yes No

If yes, please specify:

Impact on Quality of data (if any):

Yes No

If yes, please specify:

Action taken by PI/Co-PI/Co-I:

Are any changes to the project/protocol required?

Yes No

If yes, please specify the changes of Protocol:

Name of PI:

Sign of PI:

Date: