

**AX 1-V6/SOP08/V6**

**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 well being 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 (if any):**

**Trial participant**  Yes  No

**If yes, please specify**

**Quality of data**  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:**