

### AX3-V6/SOP09/V6.1

#### Off Site Safety Reports Log

NOTE to PI:

1. Please log in details of Off Site Safety Reports.
2. The following log has to be maintained continuously until the end of the study.
3. This log should be timely submitted to the IEC Secretariat. The log must be submitted to the IEC Secretariat immediately, if prompt reporting is required and/or if a trend related to the occurrence of SAE is observed.
4. Please note the complete set of Off-Site Safety Reports need not be sent to IEC Secretariat as and when received. If the IEC needs to review the reports, they can request copies at any time.

Project No.	: -
Project Title	: -
Total Sample Size	: -
Total No. of patients to be enrolled	: -
No. of Participants already enrolled	: -
No. of patients active on Treatment	: -
No. of patients on Follow up	: -
No. of Patients lost to follow up	: -
No. of Consent Withdrawn	: -
No. of patients withdrawn by Principal Investigator	: -
No. of patients completed treatment	: -

S. No.	Country	Date of Onset	Adverse event	Out Come	Remarks

PI Assessment:

Do you observe a trend?  Yes  No  NA

Name and Signature of Principal Investigator:

Date: