ONSITE SERIOUS ADVERSE EVENT REPORT FORM

Coordinating Principal Investigator	
IRB Protocol No.	
Product Protocol No.	
Study Title	
Sponsor	
Name of Study Medicine	
Report Date	
Onset Date	
Date of First Use	

Patient Number	Age	Sex

Patient's history	
Laboratory findings	
SAE	
Treatment Outcome	
Management of Adverse Reaction	

Please check the ones applicable:

Seriousness:		**Relation to:**					
	Life Threatening	☐	Drug	☐	Device	☐	Study
	Death		Not related				
	Hospitalization		Possibly				
	Disability/Incapacity		Probably				
	Congenital Anomaly		Definitely related				
	Others (please specify)		Unknown				

*Please attach standard CIOMS report form

For IRB use:

Name of Reviewer:	Signature:	Date:

Changes in the protocol recommended?	☐ Yes	☐ No	Comments:
Changes to the informed consent from recommended?	☐ Yes	☐ No	Comments:

IRB FINAL ACTION	
☐	Request an amendment to the protocol or the consent form
☐	Request further information
☐	Suspend enrollment of new research participants
☐	Suspend all trial-related procedures
☐	Termination of the study
☐	Take note and continue monitoring
☐	Conduct study site visits
☐	Others (please specify