Serious Adverse Event (SAE) Notification

Study Information

Study Title

Protocol Number

Sponsor

Principal Investigator

Site

Patient Information

Screening/Subject ID

Initials

Date of Birth

Sex

SAE Details

Event Term / Diagnosis

Date of Onset

Date of Reporting

Seriousness Criteria

Outcome

Date of Outcome

Treatment / Action Taken

Study Drug/Intervention Withdrawn?

Concomitant Medication(s)

Relevant Medical History

Investigator's Assessment

Causality (related/unrelated)
Comments

Reporter Details

Name
Role
Contact Information
Date