

Participant ID

Report Date

Type of Report: Initial Follow-up Final (Note: If this report is for a prior event that is now resolved, please mark as "Final" not "Initial")

Date of Onset: [ ] [ ] / [ ] [ ] / [ ] [ ] [ ] [ ]

Date of Resolution: [ ] [ ] / [ ] [ ] / [ ] [ ] [ ] [ ] (if any)

Categorization:

- Death Disability Other
Life threatening event Congenital anomaly/birth defect
Overnight hospitalization (or prolongation) Medical intervention required to prevent death/disability

Grade of Risk:

- None Severe
Mild Life-threatening or disabling
Moderate Fatal

Attribution of relatedness to study:

- Unrelated/Not Unlikely/remotely Possibly Probably Definitely

Attribution of expected nature given study or population:

- Anticipated Anticipated but greater than expected Unanticipated

Resolution:

- Recovered/resolved Not recovered/resolved
Recovering/resolving Fatal
Resolved with sequelae Lost to follow-up/unknown

Study action:

- No action/change Alter study procedure explain:
Discontinue permanently Other explain:
Discontinue temporarily

Signature of study PI

Date

Comments:

Comments text area

