



# SAE Evaluation Form—Initial

Participant Trial Number:      SAE reference number:

**Causality assessment by CI:**

Date passed to CI (or delegate\*) for causality assessment:   -    -

Further details requested by CI? Yes   → Details requested:  
 No

In the clinical opinion of the CI (or delegate\*) could this event have been related to the administration of the trial procedures?

Definitely  Probably  Possibly  Unlikely  Unrelated

CI (or clinical delegate of Sponsor) signature: \_\_\_\_\_ Date signed:   -    -

**Expectedness assessment:** (to be performed where either the site or the CI have indicated a possible causal relationship). If not applicable tick here:  N/A

Is this reaction expected according to the previously documented Related Serious Adverse Events :

Yes  → Record as Related SAE, no onward reporting required  
 No  → Expedite as Related and unexpected SAE. Expedite to REC events (within 15 calendar days)

Date expedited:   -    -

Name of person performing expectedness assessment: \_\_\_\_\_  
 \_\_\_\_\_

Signed: \_\_\_\_\_ Date:   -    -