



# SAE Evaluation Form

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  No

Details requested:

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

*(Please note: CI or clinical delegate assessing causality must be on the coordinating centre delegation log with responsibility code 3)*

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: \_\_\_\_\_

*(Please note: Person performing the expectedness assessment must be on the coordinating centre delegation log with responsibility code 4 )*

Signed: \_\_\_\_\_

Date:   -    -