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Decision Tree for Adverse Event Reporting – NON CTIMPS

You have identified an Adverse Event

Is it serious?

A **Serious** Adverse Event (SAE) is any adverse event that:

- results in death
- is a life-threatening situation
- requires hospitalisation or prolongation of hospitalisation
- results in persistent or significant disability or incapacity
- consists of a congenital abnormality or birth defect

Check the definition of **Serious** in each Protocol

No → AE

Yes → SAE

Can it be attributed to the study / intervention / procedure?

- **No** → AE
- **Possibly / Yes** → Related Event

Can it be attributed to the study / intervention / procedure?

Clinical decision, using professional judgement. Check protocol for any specific requirements in each study.

- **No** → SAE
- **Possibly / Yes** → Serious Related Event

Is it consistent with the available information?

Refer to the safety information provided for this specific study.

- **Yes** → Serious Related Event
- **No** → Unexpected Serious Related Event