**Decision Tree for Adverse Event Reporting**

**You have identified an Adverse Event**

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**Definitions of serious**

* Results in death
* Is life threatening
* Requires hospitalisation/ prolongation of hospitalisation
* Results in persistent/significant disability or incapacity
* Consists of a congenital abnormality or birth defect

No

Yes

AE (all)

SAE (all)

**Can it be attributed to the study?**

No

Possibly/Yes

AE (all)

Related Event

AR (CTIMPs)

**Can it be attributed to the** **study?**

No

Possibly/Yes

SAE (all)

Serious Related Event

SAR (CTIMP)

**Is it consistent with the available information?**

Yes

No

Serious Related Event

SAR (CTIMP)

SUSAR (CTIMP)

Unexpected Serious Related Event

**KEY**

 Definition for CTIMPs and non-CTIMPs

 Definition for non-CTIMPs only

 Definition for CTIMPs only

**CTIMP Acronyms**

AE Adverse Event

AR Adverse Reaction

SAE Serious Adverse Event

SAR Serious Adverse Reaction

SUSAR Suspected Unexpected

 Serious Adverse Reaction

**Is it serious?**