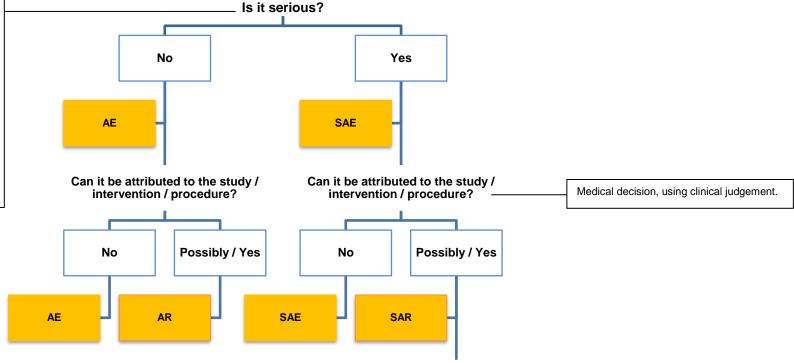**NIHR** | National Institute for Health Research

Decision Tree for Adverse Event Reporting – 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

Yes

AE

SAE

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

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

Medical decision, using clinical judgement.

No

Possibly / Yes

No

Possibly / Yes

AE

AR

SAE

SAR

Is it consistent with the reference safety information?

Refer to the Reference Safety Information for this specific study.

Yes

No

SAR

SUSAR

CTIMP Acronyms

AE — Adverse Event

AR — Adverse Reaction

SAE — Serious Adverse Event

SAR — Serious Adverse Reaction

SUSAR — Suspected Unexpected Serious Adverse Reaction