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.

**CTIMP Acronyms**

- AE: Adverse Event
- AR: Adverse Reaction
- SAE: Serious Adverse Event
- SAR: Serious Adverse Reaction
- SUSAR: Suspected Unexpected Serious Adverse Reaction

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**Decision Tree for Adverse Event Reporting – CTIMPs**

**You have identified an Adverse Event**

- **Is it serious?**
  - **No**
    - AE
  - **Yes**
    - SAE

- **Can it be attributed to the study / intervention / procedure?**
  - **No**
    - AE
  - **Possibly / Yes**
    - AR

- **Can it be attributed to the study / intervention / procedure?**
  - **No**
    - SAE
  - **Possibly / Yes**
    - SAR

- **Is it consistent with the reference safety information?**
  - **Yes**
    - SAR
  - **No**
    - SUSAR

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Medical decision, using clinical judgement.

Refer to the Reference Safety Information for this specific study.
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.

**Decision Tree for Adverse Event Reporting – NON CTIMPS**

You have identified an Adverse Event

**Is it serious?**

- **No**
  - Adverse event
  - Can it be attributed to the study / intervention / procedure?
    - **No**
      - Adverse event
    - **Possibly / Yes**
      - Related Event

- **Yes**
  - Serious Adverse Event
  - Can it be attributed to the study / intervention / procedure?
    - **No**
      - Serious Adverse Event
    - **Possibly / Yes**
      - Serious Related Event

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

- **Yes**
  - Serious Related Event
- **No**
  - Unexpected Serious Related Event
**Decision Tree for Adverse Event Reporting – MEDICAL DEVICES**

**You have identified an Adverse Event**

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

**Is it serious?**

- **No**
  - **AE**
  - Can it be attributed to the study / intervention / procedure?
    - **No**
      - **AE**
    - **Possibly / Yes**
      - **ADE**
  - **SAE**
    - Can it be attributed to the study / intervention / procedure?
      - **No**
        - **SAE**
      - **Possibly / Yes**
        - **SADE**

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

- **No**
- **Possibly / Yes**

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

- **Yes**
  - **ASADE**
- **No**
  - **USADE**

**Medical Device Acronyms**

- **AE** Adverse Event
- **ADE** Adverse Device Effect
- **SAE** Serious Adverse Event
- **ASADE** Anticipated Serious Adverse Device Effect
- **ASADE** Unanticipated Serious Adverse Device Effect

**Medical decision, using clinical judgement.**

Refer to the Reference Safety Information for this specific study.
NIHR National Institute for Health Research

Decision Tree for Adverse Event Reporting – ALL STUDIES

You have identified an Adverse Event

Is it Serious?

No

AE (all)

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

No

AE (all)

Related Event

AR (CTIMPs)

ADE (Medical Devices)

Yes

SAE (all)

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

No

SAE (all)

Serious Related

SAR (CTIMP)

ADE (Medical Devices)

Yes

SAE (all)

Serious Related

SAR (CTIMP)

ADE (Medical Devices)

Is it consistent with the available information?

Yes

SAR (CTIMP)

Unexpected Serious Related Event

SUSAR (CTIMP)

No

Serious Related Event

SAR (CTIMP)

Unexpected Serious Related Event

SUSAR (CTIMP)

Medical Device Acronyms

AE Adverse Event
AR Adverse Reaction
SAR Serious Adverse Reaction
SUSAR Suspected Unexpected Serious Adverse Reaction

CTIMP Acronyms

AE Adverse Event
AR Adverse Reaction
SAE Serious Adverse Event
SUSAR Suspected Unexpected Serious Adverse Reaction

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

Clinical judgement

Must be medical decision in CTIMPs and Medical Devices

Refer to the Reference Safety Information (or equivalent) for this specific study.

Health and Care Research Wales safety reporting decision trees v1.0. Last reviewed Jan 2023. Adapted, with thanks, from the NIHR original document.