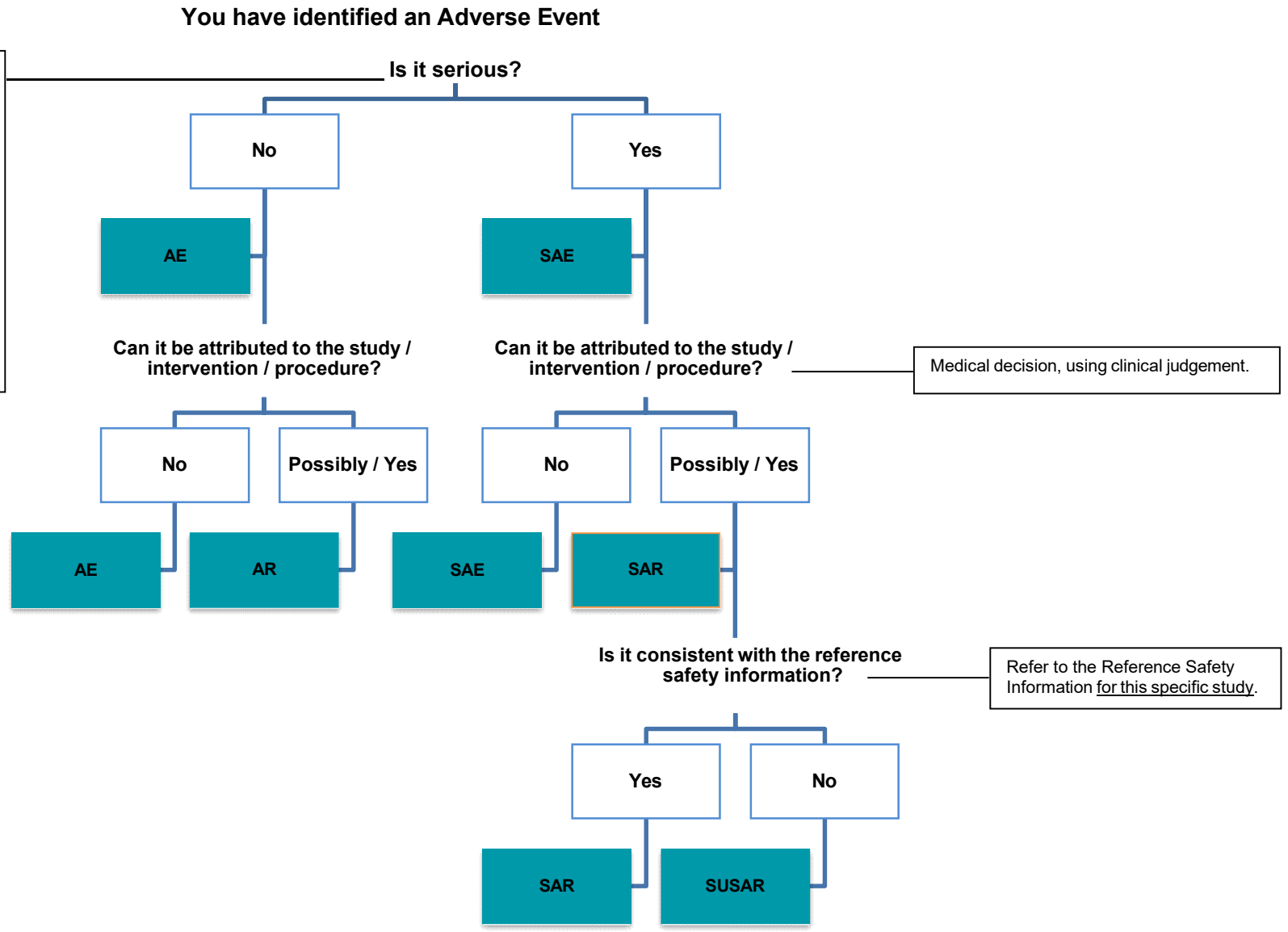
Decision Tree for Adverse Event Reporting – CTIMPs

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

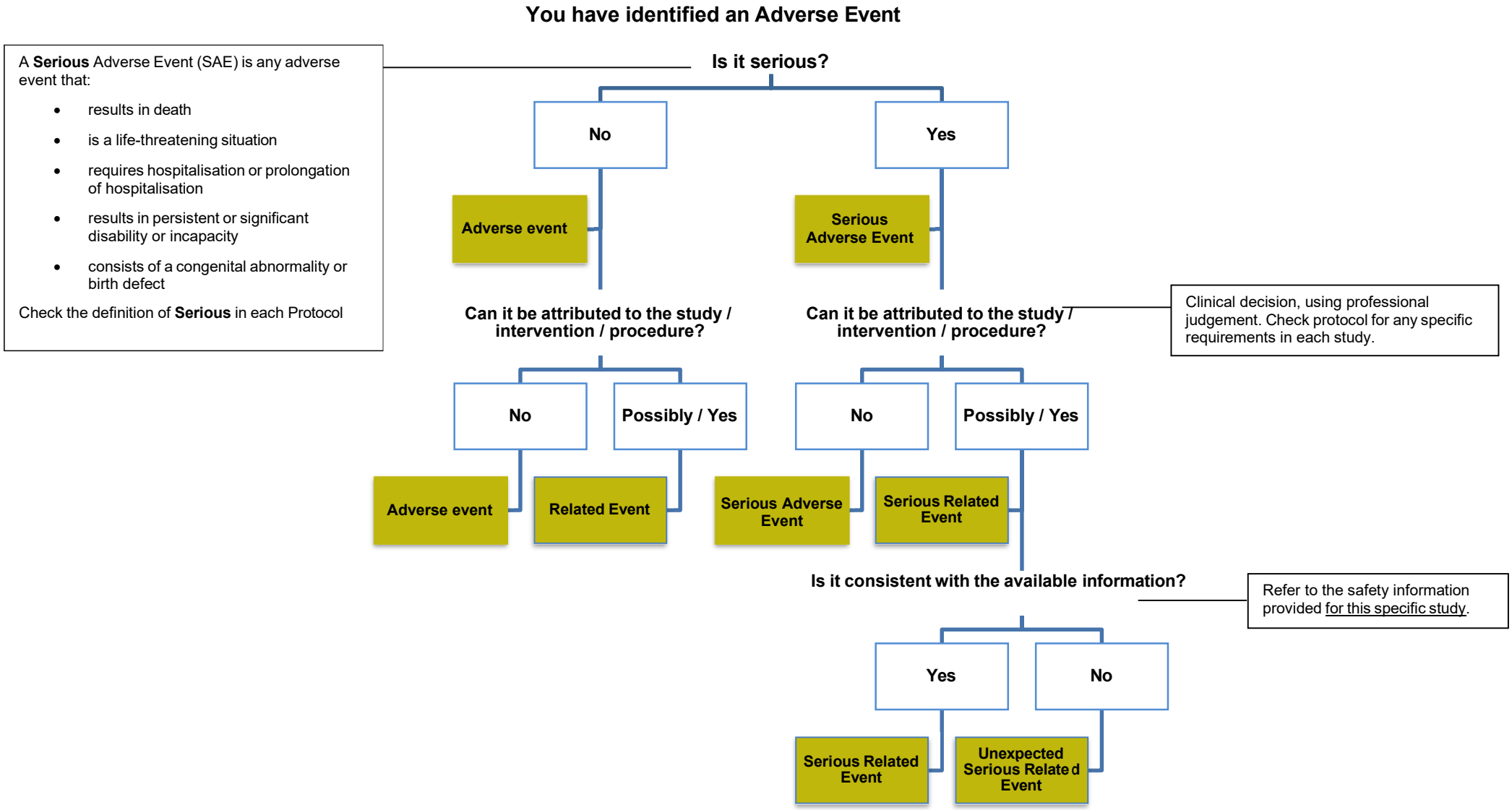
Check the definition of **Serious** in each Protocol



CTIMP Acronyms

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

Decision Tree for Adverse Event Reporting – NON CTIMPS



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**
- **Yes** → **SAE**

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

- **No** → **AE**
- **Possibly / Yes** → **ADE**

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

Medical decision, using clinical judgement.

- **No** → **SAE**
- **Possibly / Yes** → **SADE**

Is it consistent with the available information?

Refer to the Reference Safety Information for this specific study.

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

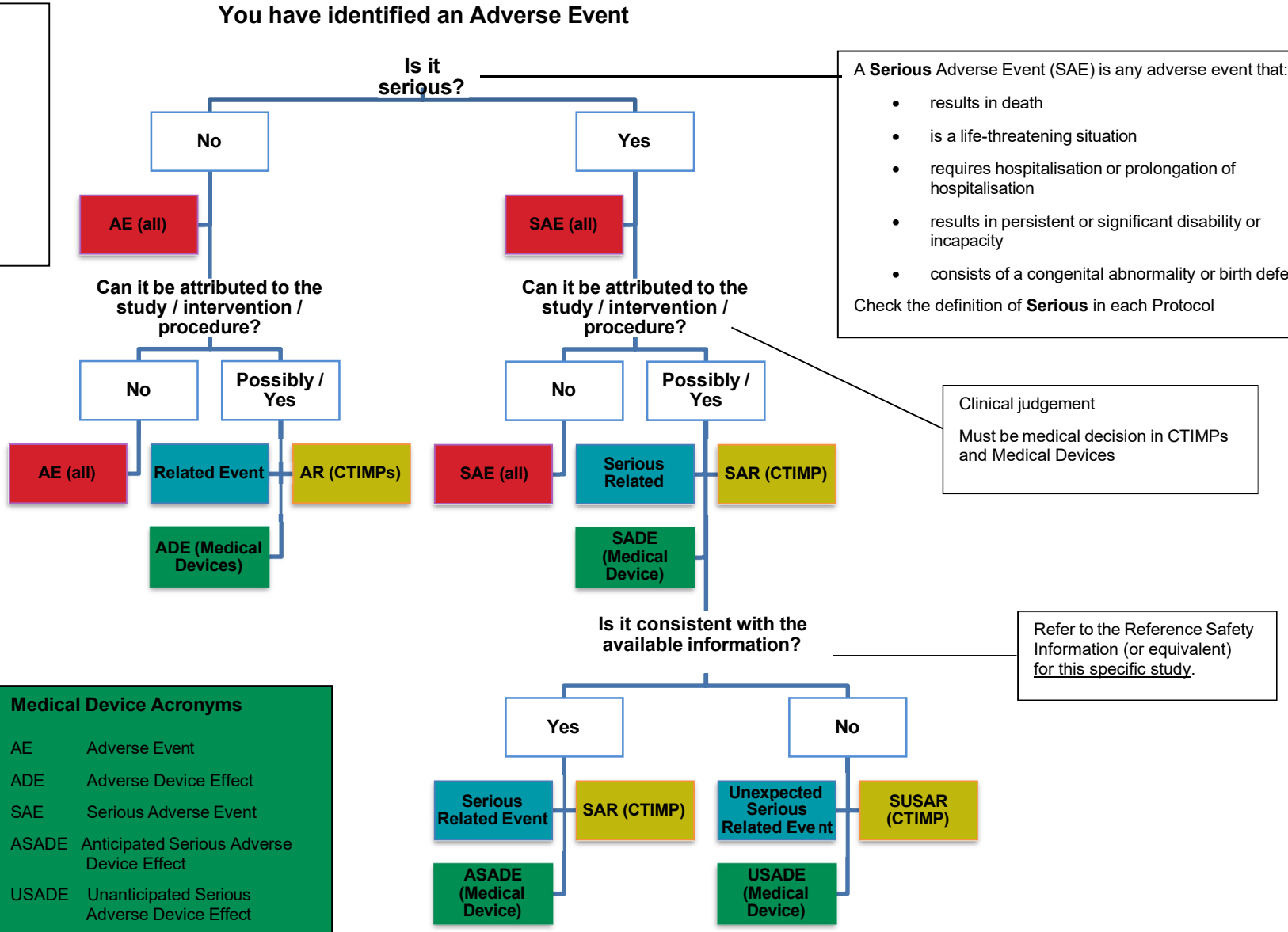
Medical Device Acronyms

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

Decision Tree for Adverse Event Reporting – ALL STUDIES

KEY

- Applies to all clinical research studies
- Clinical Trials of Investigational Medicinal Products (CTIMPs) only
- Clinical Investigations of Medical Devices only
- Other interventional studies (non-CTIMPs) only



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.

CTIMP Acronyms

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

Medical Device Acronyms

AE	Adverse Event
ADE	Adverse Device Effect
SAE	Serious Adverse Event
ASADE	Anticipated Serious Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect