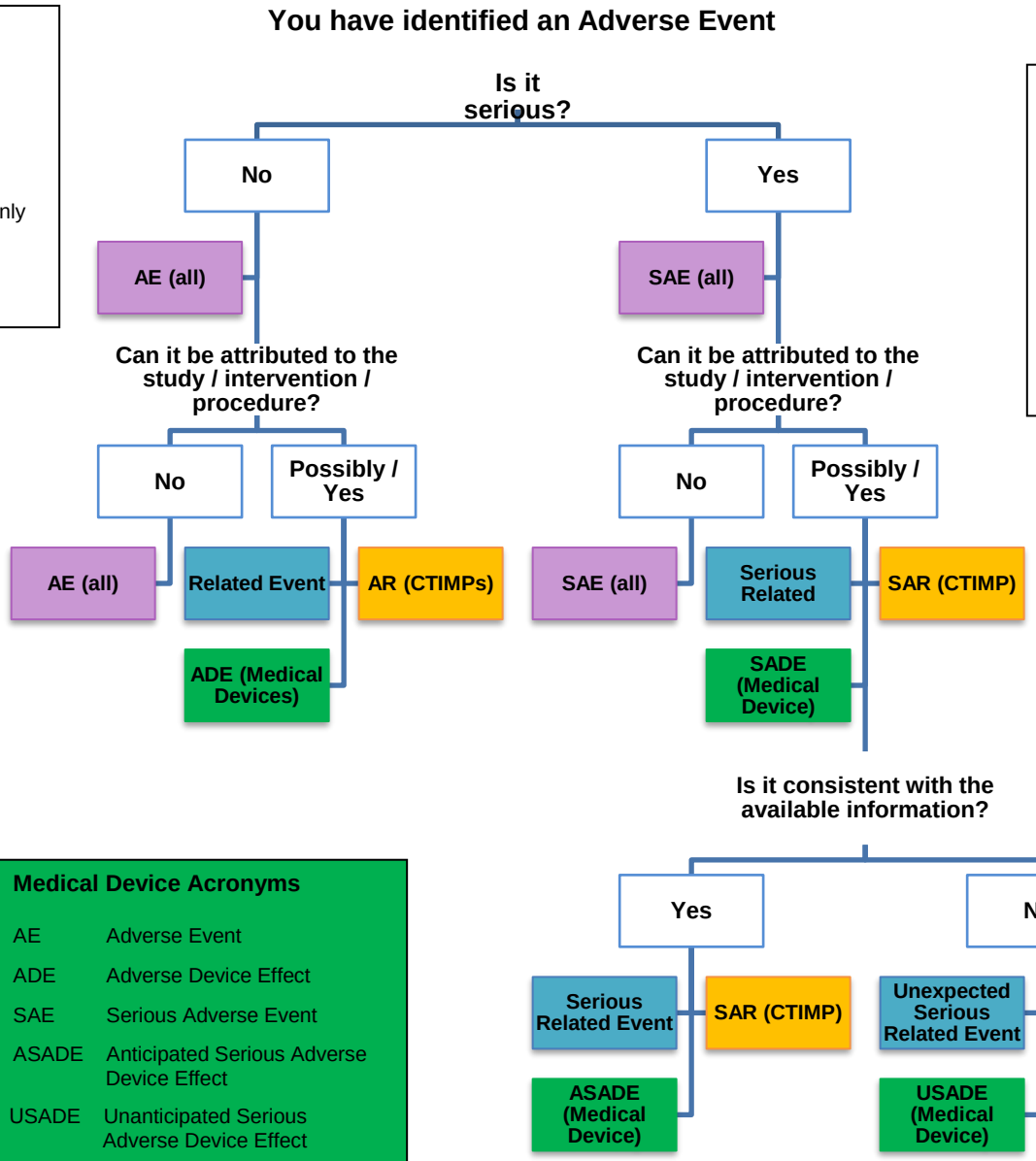
NIHR | National Institute for Health Research

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

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