Adverse Event

See Adverse Event Topic under Patient Care for the full discussion

Defining and explaining Adverse Event and Adverse Event Reporting from a Clinical Research perspective has been done many times. The objective here is to provide a brief summary and to point to other available resources.

In Clinical Research the term "Adverse Event" has a wider sense than is used in Clinical Care. Put very simply in Clinical Research anything untoward that happens to a subject while they are on a trial could be a direct or indirect consequence of the study drug and is therefore an Adverse Event. Rashes, Headaches, Tachycardia, etc are all easily understood and are also recognised as Adverse Events in Clinical Research and Clinical Care. Slips and falls are clearly Clinical Research Adverse Events because the study drug may be affecting coordination or balance, they may or may not be regarded as Adverse Events in Clinical Care depending on the clinician's view point. Death in a road traffic accident, or Seriously inappropriate social behaviour, or Self harm etc may be a result of a Study Drug and are Adverse Events that have to be reported for Clinical Research but they are unlikely to be seen as Adverse Events from a Clinical Care perspective.

Other Resources of Interest

Detail	Link or Content
FHIR Spec	R4 Ballot Content for AdverseEvent Resource
TransCelerate Mapping Team (DRAFT - to be reviewed 28-Feb)	Any untoward or unintended sign, symptom, result, disease, or other medical occurrence (including an abnormal laboratory or ECG finding) in a clinical trial participant or associated person, with a temporal association with the use of a medical product, procedure, or other therapy, or in conjunction with a research study, regardless of causal relationship. EXAMPLE(S): death, back pain, headache, pulmonary embolism, heart attack, car accident.
Spreadsheet from 2012 S&I Framework PH group	
V3 ballot package has a description of ICSR requirements	HL7 V3 ICSR Storyboards

BRIDG AE Subdomain: Spreadsheet of all elements used in the subdomain	
ICH E2B	A description of the data elements defined for pharmaceutical product adverse event reporting by the International Conference on Harmonization
Medical Devices Post Market Surveillance (Global Harmonization Taskforce	
Pharmacovigilance of Veterinary Medicinal Products (VICH)