Adverse Event Flowchart - Identifying

NO

**AE?**

Any untoward medical occurrence in a clinical trial participant, which does not necessarily have a causal relationship with an IMP.

**AR?**

Any untoward and unintended response to an IMP which is related to any dose administered to that participant.

**SAE or SAR?** Any AE or AR that at any dose:

* Results in death of the clinical trial participant
* Is life-threatening
* Requires hospitalisation or prolongation of existing hospitalisation
* Results in persistent or significant disability or incapacity
* Consists of congenital anomaly or birth defect
* Other significant medical event

NO

**Is the SAE/SAR likely to be related to the IMP or NIMP?**

Possibly, probably or definitely related to the IMP/NIMP should be reported as being related to the IMP/NIMP.

**AE/AR**

YES

**Is the SAR expected?** Expected SARs are listed in the summary of product characteristics, investigator’s brochure or trial protocol.

**SAE**

**SUSAR**

**SAR**

NO

YES

**SAR**

YES