Adverse Event Flowchart - Reporting

SUSARs will be reported by ACCORD on behalf of the investigator to the MHRA and main REC (if required) within 7 days for life threatening or fatal SUSARs and within 15 days for all other SUSARs.

**Serious Adverse Reaction (SAR). All SARs must be reported on an SAE Form and emailed to** [**Safety@ACCORD.scot**](mailto:Safety@ACCORD.scot) **within 24 hours of becoming aware of the event.**

**SUSAR. This must be reported on an SAE Form and should be emailed to** [**Safety@ACCORD.scot**](mailto:Safety@ACCORD.scot) **with 24 hours of becoming aware of the event.**

Adverse Event (AE). This does not require expedited reporting. Record on CRF/AE log only.

**Serious Adverse Event (SAE). All SAEs must be reported on an SAE Form and emailed to** [**Safety@ACCORD.scot;**](mailto:Safety@ACCORD.scot;)**within 24 hours of becoming aware of the event.**

YES

YES

YES

NO

Is the event expected (i.e. is it listed in the summary of product characteristics)?

Related to IMP? For trials involving NIMPs, is the event related to an interaction between the IMP and NIMP, or is the event linked to either the IMP or NIMP and cannot be clearly attributed to either one of these?

NO

**Serious Adverse Event (SAE), as above.**

**From time participant is consented**:

AE observed (as defined in ACCORD SOP CR005).

NO

Is it serious (according to seriousness criteria described in ACCORD SOP CR005?)