Safety reporting

AE: Adverse Event
SAE: Serious Adverse Event
SSI: Significant Safety Issue

SUSAR: Suspected Unexpected Serious Adverse Reaction
USADE: Unexpected Serious Adverse Reaction
USM: Urgent Safety Matter

Adapted from ACTEC resources

Sponsor will Keep records of all **AEs /device deficiencies** reported to them by PI & maintain up-to-date line listings

Sponsor is responsible to report to 3 parties

[Days = Calendar days]

TGA
clinical.trials@health.gov.au

- **Australian SUSAR/USADE** *Death/life threatening* ≤ 7 days (follow up: further ≤ 8 days)
- **SSI** ≤ 15 days
- **USM** ≤ 72 hours *(strongly recommend ≤ 24 hrs)*
- **Other Australian SUSAR/USADE** ≤ 15 days

PI

- **SSI** ≤ 15 days
- **IB** update as required
- **USM** ≤ 72 hours
- **SUSAR/USADE line listings** *(only if required by global sponsor)*

HREC

- **SSI** ≤ 15 days
- **IB** update as required
- **USM** ≤ 72 hours *(strongly recommend ≤ 24 hrs)*
- **Annual Safety Report** Annually or per global reporting cycle

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