Safety Reporting for Clinical Trials

Externally Sponsored Trials

Reporting adverse events

Unless otherwise stipulated in your approval letter, for externally-sponsored clinical trials conducted at Metro North HHS, the NHMRC guidance document applies to safety monitoring and reporting for clinical trials involving therapeutic products NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods.

What should be reported to the HREC?

- Urgent Safety Measures (USMs) instigated by the Site or Sponsor within 72 hours of becoming aware of the event
- All other Significant Safety Issues (SSIs) should be notified within 15 calendar days of the sponsor instigating or being made aware of the issue
- An annual safety report including a clear summary of the evolving safety profile of the trial
- Investigator Brochure amendments
- Data Safety Monitoring Board (DSMB) reports

What should be reported to the RGO?

- Urgent Safety Measures (USMs) instigated by the Site or Sponsor within 72 hours of becoming aware of the event
- Suspected Unexpected Serious Adverse Reactions (SUSARs) or Unanticipated Serious Adverse Device Effects (USADEs) arising from the local site, within 72 hours of becoming aware of the event or change in status from SAE to SUSAR
- All other SSI that result in temporary halt, amendment or early termination of a trial within 72 hours of becoming aware of the event
- An annual safety report including a clear summary of the evolving safety profile of the trial
- Investigator Brochure amendments
- Data Safety Monitoring Board (DSMB) reports

What should NOT be reported to the HREC or RGO?

- Single Serious Adverse Events (SAEs), Serious Adverse Reactions (SARs) and Adverse Events (AEs) that do not affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.
- External SUSARs or device/non-therapeutic good equivalents
- Six monthly line listings

Summary tables

Definitions

Table 1 Definitions

Term	Definition
Annual Safety Report	Summary of all newly available safety information relevant to a trial that is received over a 12-month period (the Executive Summary of safety information produced for international regulators, such as the Development Safety Update Report (DSUR) may serve as the Annual Safety Report).
Investigational Brochure (IB)	Compilation of the clinical and non-clinical data on the investigational product(s) that are relevant to the study of the product(s) in human participants.
Product Information (PI)	The approved Australian summary of the scientific information relevant to the safe and effective use of a prescription medicine. If the conditions of use differ from those authorised, the PI should be supplemented with a summary of relevant clinical and non-clinical data that supports the use of the product in the trial.
Significant Safety Issue (SSI)	A safety issue that could adversely affect the safety of participants or materially impact on the ethical acceptability or conduct of the trial.
SAE – Serious Adverse Event **SAR – Serious Adverse Reaction** ***persistent or significant disability or incapacity, or is a congenital anomaly or birth defect SUSAR***	Any adverse event/adverse reaction that results in death, is life threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	An adverse reaction that is both serious and unexpected.
Urgent Safety Measure (USM)	A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety. Note: This type of significant safety issue can be instigated by either the investigator or sponsor and can be implemented before seeking approval from HREC's or institutions.

Further information

Please visit the MNHHS Research website

https://metronorth.health.qld.gov.au/research/ethics-and-governance/post-approval-reporting

Contact Us

Please visit the MNHHS Research website

https://metronorth.health.qld.gov.au/research/contact

Table 2: Investigator Reporting – flow and timing of safety reports for clinical trials

	Individual SAEs (except those identified in the Protocol as not requiring reporting)	Congenital Anomaly/birth defect from participant/partner pregnancy	Individual SAE's deemed SUSARs/USADEs by the investigator, arising from the Local Site	Urgent Safety Measures (USM) instigated by the Site	Other Urgent Safety Measures instigated by the Sponsor	All other SSI (including, temporary halt/early termination of a trial)	Annual Sponsor Safety Report
Sponsor	Within 24 hours of becoming aware of the event.	Within 24 hours of becoming aware of the event.		Within 24 hours of becoming aware of the event.			
To RGO			Within 72 hours of becoming aware of the event.	Within 72 hours of becoming aware of the event.	Within 72 hours of becoming aware of the event.	No later than 15 calendar days of the Sponsor becoming aware of the issue.	Annual Basis

Table 3: Sponsor Reporting – flow and timing of safety reports for clinical trials

	SUSARs/USADEs (occurring in Australian Participants)		Significant Safety Issues (SSI)		Annual Safety Report
	Fatal/Life Threatening SUSARs	**All Other SUSARs**	**Urgent Safety Measure**	**All other SSI (including, temporary halt/early termination of a trial)**	//
To Investigators			Without undue delay and no later than 72 hours of the Sponsor becoming aware of the issue	No later than 15 calendar days of the Sponsor becoming aware of the issue.	Annual basis
To TGA	Immediately but no later than 7 calendar days after being aware; follow up information within a further 8 calendar days	15 calendar days after being made aware of the case	Without undue delay and no later than 72 hours of the Sponsor becoming aware of the issue	No later than 15 calendar days of the Sponsor becoming aware of the issue.	Annual basis
To HREC			Without undue delay and no later than 72 hours of the Sponsor becoming aware of the issue	No later than 15 calendar days of the Sponsor becoming aware of the issue.	Annual basis