Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Clinical Trial Safety Reporting Form (SSI/USM)

How to complete this form:

- This form is for reporting Significant Safety Issues/Urgent Safety Measure (SSI/USM) for medicines, biologicals and devices
- This form is to be completed by sponsors and submitted to the TGA within the timeframe outlined in the Australian clinical trial handbook
- Complete all fields

For further guidance on requirements of submission of a safety issue, including Suspected Unexpected Serious Adverse Reactions (SUSAR) and/or Unanticipated Serious Adverse Device Effects (USADE), please see the Australian clinical trial handbook.

Investigational product (IP) represents Investigational Medicinal Products (IMP) and Investigational Medical Devices (IMD)

Report type

Tick all that apply

☐ Initial report

☐ Follow-up report. The initial report was submitted on Click or tap to enter a date.

☐ Significant safety issue (SSI) defined as *a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.*

(Note: SSIs that involve a local SUSAR and/or USADE are subject to further reporting requirements, please see Australian clinical trial handbook | Therapeutic Goods Administration (TGA),)

☐ Urgent safety measure (USM) defined as a *measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.*

International context

Has this safety issue been identified internationally? Yes ☐ No ☐

If yes, please provide further information	

Australian context

List all Australian clinical trials impacted by this report. Please add extra rows as required.

Reference	Protocol Number	Clinical trial notification (CTN)/Clinical trial approval (CTA) Number	Investigational Product (IP)	Medicine, biological or medical device	Australian Sponsor as per CTN/CTA	Number of Australian participants enrolled (S – screened, R – randomised)	Is the IP registered/ listed on the Australian Register of Therapeutic Goods (ARTG)

Reporter

☐ The Australian Sponsor (as per CTN/CTA)

☐ Other party. Confirm reporter's name, contact details and relationship to the Australian sponsor.

Communication

☐ The Principal Investigator(s) has(ve) been notified of the safety issue

☐ The approving HREC(s) has(ve) been notified of this safety issue

Reporting timelines

Time and Date – Date and time of sponsor's first awareness of the safety issue

Date: Click or tap to enter a date. **Time:** **Not Known** ☐

Date the decision was made to implement reported SSI/USM

Date: Click or tap to enter a date. **Time:** **Not Known** ☐ **N/A** ☐

TGA submission due date Click or tap to enter a date.

*Significant safety issues that meet the definition of an urgent safety measure should be notified **within 72 hours**, and all other significant safety issues should be notified **within 15 calendar days** of the sponsor instigating or being made aware of the issue.*

Have you submitted this report within required timeframes? Yes ☐ No ☐

No. justification for a delayed submission:

Source

☐ Sponsor Data Safety Monitory Committee/Board - Pharmacovigilance

☐ Sponsor - Investigator

☐ Overseas Regulator: enter regulator's name and country

☐ Another source: describe the source of the report

Report details

Brief description

Include for all initial reports:

- *supporting evidence*
- *scope - does it apply to one IMP only*
- *further action planned*
- *Independent Data Monitoring Committee – were any actions taken/recommended?*

☐ No ☐ Yes (specify below)

For USM provide the following information:

- *Reason for the USM*
- *Measures taken*
- *Further actions planned*

For SSI "temporary halt of trial" provide the following information:

- *Reasons for the halt*
- *Scope of the halt*
- *Measures taken*
- *Further actions planned*
- *Notification of the trial restarting (when applicable), include evidence that it is safe to restart*

For SSI "early termination of trial" provide the following information:

- *Reasons for early termination*
- *Measures taken*
- *Further actions planned*

For all other SSIs provide the following information:

- *Details of the SSI*
- *Further actions planned*

For follow-up reports provide the following information:

- *What has changed since the initial / previous follow-up report.*

Sponsor assessment outcome and action plan

Include:

- *risk and impact assessment*
- *actions completed*
- *actions planned*
- *planned follow-up reports, if applicable*
- *Is this report final for the reported SSI/USM?*

Actions taken by other regulators

Include:

- *Has an overseas regulator halted the trial? If so, will the sponsor be halting the trial in Australia?*
- *links to any relevant regulator safety assessments or published meeting outcomes*
- *If a clinical trial has been halted, please advise if/when it is planned to resume*

Outcome of issue assessment

(Tick all that apply)

☐ Sponsor intends to update the Company Core Datasheet, Australian Product Information, and/or Consumer Medicine Information

Specify the changes

☐ Sponsor is considering other actions

Describe the actions

Attachments

(Tick all that apply)

☐ Safety Memorandum

☐ Dear Investigator Letter

☐ Safety issue assessment report

☐ HREC notification/decision or requests relating to this report

☐ Decision to halt the study

☐ Other documents – specified below

Report submission

I confirm that:

All relevant fields are completed ☐

QC was conducted to verify that all reported data points are accurate ☐

TGA will be notified of the recommencement of the trial if halted ☐

Name			
Position			
Signature		Date	
Email		Phone	

Please submit the form and all attachments to clinical.trials@health.gov.au