Guideline number	**Guideline 55.001B**	Version	**4.0**
Title	**PV Office – Expediting SUSARs**		

Purpose of document:

To outline the process for expediting reports of Suspected Unexpected Serious Adverse Reactions (SUSARs) to the necessary regulatory authorities.

Personnel:
PV Administrator
PV and Safety Manager and delegated Sponsor representatives

Background
SUSARs require expedited reporting to the regulatory authorities (MHRA) and the relevant Ethics Committee (REC). Other safety issues also qualify for expedited reporting where they may materially alter the current benefit-risk assessment of an investigational medicinal product or that are sufficient to consider changes in the investigational administration or in the overall conduct of the trial.

The MHRA require expedited reporting of all UK-relevant **SUSARs.** The MHRA's definition of 'UK-relevant' includes reports of the following:

- SUSARs originating in the UK
- SUSARs originating outside the UK where the sponsor has an ongoing trial in the UK involving the same IMP.

Where NHS GGC sponsor (or co-Sponsor with the University of Glasgow) a trial with sites outside the United Kingdom there is a requirement for the reporting of SUSARs to the competent authorities within each country. For sites within the EU there is also a requirement for reporting of events to the EudraVigilance platform. The PV office must ensure that all SUSARs occurring in countries other than the UK are reported to the relevant competent authority. In general expedited reporting to CAs outside the UK will be delegated to the local coordinating centre within each participating country. The reporting processes should be documented within the PV plan.

The main REC (i.e. the REC which approved the trial) should be sent expedited reports of all SUSARs occurring in the UK in the trial for which the main REC gave a favourable opinion.

Where NHS GGC sponsor (or co-Sponsor with the University of Glasgow) a trial with sites outside the United Kingdom there may be a requirement for the reporting of SUSARs to the local REC equivalent. The PV office must ensure that all SUSARs occurring in countries other than the UK are reported to the relevant REC equivalent, if applicable. In general expedited reporting to RECs outside the UK will be delegated to the local coordinating centre within each participating country. The reporting processes should be documented within the PV plan.

The regulations set time limits for reporting:

Fatal or Life Threatening SUSARs: not later than 7 days after the sponsor for Pharmacovigilance had information that the case fulfilled the criteria for fatal or life-threatening SUSAR and any follow-up information with a further 8 days.

All other SUSARs: not later than 15 days after the sponsor for Pharmacovigilance had information that the case fulfilled the criteria for a SUSAR.

Guideline notes

1. When a SUSAR is received it will be processed as per the SAE Processing Guidelines.
2. Email notification of the SUSAR will be sent to the Chief Investigator who will be asked to review the event and confirm that it fulfils SUSAR criteria.
3. The minimum criteria for reporting of a SUSAR to the regulatory authorities are:
    - A suspected investigational medicinal product
    - An identifiable subject (e.g. participant number)
    - An adverse event assessed as serious and unexpected, for which there is a reasonable causal relationship
    - An identifiable reporting source

And when available and applicable:

- A EudraCT number or a local study reference number.
- A unique case identification (i.e. sponsor's case identification number)
- Treatment assignment after unblinding and validation (or not) of the suspect causes.

4. If the opinion of the CI or Sponsor PV and Safety Manager (or their delegates) is that the Serious Adverse Event fulfils the criteria for a SUSAR, the report will be reported in an expedited manner to the relevant authorities.

5. The PV and Safety Manager or the PV administrators will enter the SUSAR onto the MHRA's ICSR database, as per the User Guidance.

6. A full report in pdf format will be downloaded for forwarding with the appropriate covering form to the relevant REC. The REC contact details will be included in the PV Plan for the trial.

7. The pdf report will be saved in the relevant study folder and a copy will be filed with the original SAE report and all related correspondence in the PV filestore

   Note: The Causality assessment made by the investigator cannot be downgraded. The causality assessment can, however, be upgraded by the sponsor. In the case of a difference of opinion on causality, both assessments will be recorded, and where an event has been assessed by one party as related to IMP this will be used for expedited reporting purposes.

Guideline signatories

Prepared by Signature	Marc Jones Date
Approved by Signature	Caroline Watson Date

Document history

Version	Date	Description
1.0	02/09/2010	Version 1.0 creation
2.0	29/11/13	Additional background information added Guideline No. allocated
3.0	15/07/2016	Reviewed and released as part of SOPs reorganisation process. Guideline has moved to SOP category 55 NHS GG&C Sponsor Pharmacovigilance and renumbered (previously 18.001B). 'Prepared by' changed to Caroline Watson, 'Approved by' changed to Julie Brittenden.
4.0	09/06/2023	Updated to reflect changes to reporting systems and Brexit changes