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Title	**Sponsor safety data**		

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SOP category	NHS GG&C Sponsor Pharmacovigilance
Staff category	

Staff Category	R	A	C	I
R&I Pharmacovigilance	X			
R&I Research Governance Manager		X		
R&I Innovation Lead			X	
Sponsor Research Co-Ordinators			X	
Project Managers			X	
Industry Collaboration Project Manager			X	
R&I Pharmacy			X	
R&I Monitoring			X	
Chief Investigator				X
Principal Investigator				X

1. Scope

This procedure applies to NHSGGC staff with Sponsor responsibilities.

Chief Investigators (CIs) will be provided with a copy (marked as an uncontrolled copy) of this SOP for their information. The CI and Project Manager are responsible through training for ensuring that local PIs understand how to complete pharmacovigilance forms.

2. Purpose

The purpose of this SOP is to describe how safety data is captured and reports are provided for studies sponsored by the NHS Greater Glasgow and Clyde and/or co-sponsored with the University of Glasgow to ensure that sponsor safety reporting responsibilities are fulfilled.

3. Procedures

This SOP describes the procedure for Sponsored/Co-Sponsored Studies supported by the Sponsor Pharmacovigilance (PV) Office(s).

3.1. Study Types

There are three principal study types that require the collection of safety data and these are as follows:

- Clinical trials of investigational medicinal products (CTIMPs)
- Clinical investigations of a medical device (CIMD)
- All other research involving a study specific intervention (non CTIMP)

Each of these study types have broadly similar goals with respect to data collection but differ in specific requirements.

3.1.1. CTIMPS

Sponsor responsibilities for CTIMP pharmacovigilance are documented within the CT3 guidance and include the requirement to:

- Keep detailed records of all adverse events reported by study investigators as defined within the trial protocol
- Report suspected unexpected serious adverse reactions (SUSARs) to the Competent Authority (MHRA) and the Research Ethics Committee (REC) within specified timelines – See Section 3.3.1
- Assess the expectedness of reported SARs against the reference safety information
- Inform investigators of SUSARs
- Provide annual development safety reports (DSUR) detailing serious adverse reactions and events to the appropriate competent authorities and a safety report – See Section 3.3.3

3.1.2. CIMDs

Sponsor responsibilities for CIMD safety reporting are documented within MEDDEV 2.7/3 and within the UK Medical Devices Regulations 2002 and include the requirement to:

- Keep detailed records of all adverse events reported by study investigators as defined within the trial protocol
- Keep detailed records of all device deficiencies reported by users or study investigators as defined within the study protocol
- Report all SAEs and device deficiencies that may have resulted in SAEs to the MHRA within specified timelines – See Section 3.3.2
- Report all unexpected serious adverse device effects (USADEs) to the REC within specified timelines - See Section 3.3.2
- Provide quarterly reports detailing aggregate safety data to the MHRA - See Section 3.3.4

3.1.3. Non CTIMPS

Sponsor responsibilities for safety reporting in non CTIMPs are documented within the UK policy framework for health and social care research and, in general, are risk adapted on a per study basis. In general most non CTIMPs are low risk interventions that do not require full safety reporting as per CTIMPs and CIMDs. There may be higher risk interventions of novel surgery, novel radiotherapy, or complex psychological and sociological interventions that are to be studied. In general the following requirements will be met:

- Keep detailed records of all related and unexpected serious adverse events (RUSAEs) reported by investigators and any other serious adverse events as detailed within the study protocol
- Ensure that all. RUSAEs are reported to the REC, either directly by the Sponsor or via the Chief Investigator and trial team

3.2. Capturing Safety Data

Safety data can be captured in the following ways:

3.2.1. SAE and device deficiency Capture

Primary Data Sources

1. Reporting of SAEs or device deficiencies via eCRF in-built reporting procedures
2. Initial verbal report to the PV Office, followed up by written or electronic report
3. For non CTIMPS only: Initial paper SAE form emailed by the investigator or their designee to the PV Office

Secondary Data Sources

1. SAE or device deficiency follow-up report
2. Responses to SAE queries

3.2.2. Sponsor Serious Adverse Event Forms

For CTIMPs and CIMDs the Sponsor will provide the CI and trial teams with eCRF reporting capabilities for SAEs and device deficiencies. This will be agreed prior to regulatory green light. A generic GCTU form or an adapted version of this form will be provided to all sites in case of eCRF failure by the project manager as part of the TMF and may also be found at https://www.glasgowctu.org/Home/00-safety-reporting/

3.3. Reporting Pharmacovigilance Data

3.3.1. SUSAR Reports (CTIMPs only)

As detailed in SOP 55.001 the PV Office will obtain information from the trial eCRF or SAE report, and send the SUSAR to:

- MHRA (via the ICRS system)
- REC (in the form of a copy of the ICRS form)

Electronic copies of the unblinded data are kept within the PV Office filestore and access to this data is controlled at a user access level. The PV Manager retains copies of unblinded SUSARs within a locked cabinet or locked drawer within the Sponsor office. This is not accessible to Sponsor staff other than the PV manager. Should the PV manager be unavailable and access to unblinded SUSARs be required then the PV Office must be contacted in the first instance to provide this information. Any request for access to unblinded SUSAR data must be justified and adequately documented.

3.3.2. SAE and Device Deficiency Reports (CIMDs only)

As fully detailed in SOP 55.007 the PV Office will obtain information from the study eCRF SAE or device deficiency forms, extract the relevant data and send the SAEs and device deficiencies to:

- MHRA (via the MORE system)

Any USADE will be sent to the REC in the form of a completed non CTIMP safety report form

3.3.3. Development Safety Update Report (DSUR) (CTIMPs only)

- Information from each individual trial eCRF is used to complete the DSUR (refer to SOP 55.002)
- Generated by a third party and e-mailed to central pharmacovigilance system

Where DSURs contain unblinded data the final version of the DSUR will not be distributed outside of the PV office other than to the Competent Authority and REC. Copies will be retained electronically by the PV Office and PV manager, and the PV manager will hold paper copies of the DSUR. Access to these documents is controlled at the user access level for electronic records, and for paper records by the documents being kept in locked cabinets or drawers.

3.3.4. Quarterly safety reports (CIMDs only)

- Information from each individual study eCRF is used to complete the line listings and relevant data for reporting to the MHRA as per current guidance

Where quarterly reports contain unblinded data they will not be distributed outside of the PV office other than to the MHRA. Copies will be retained electronically by the PV Office and PV manager. Access to these documents is controlled at the user access level for electronic records, and for paper records by the documents being kept in locked cabinets or drawers.

3.3.5. Related and Unexpected Serious Adverse Events (non CTIMPs only)

As detailed in SOP 55.004 the PV Office will obtain information from the trial eCRF or SAE report, and send the RUSAE to the approving REC via the Non-CTIMP safety report to REC form (https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/)

A copy of the completed form will be kept within the PV Office filestore and access to this data is controlled at a user access level. On very rare occasions non CTIMPs may be blinded, in this case SAEs will be stored as per section 3.3.1.

3.3.6. Management Reports

The PV and Safety Manager will routinely review data collated in the central database and will be responsible for the production of management reports, either per trial, per type of SAE (e.g. SARs, SUSARs, RUSAEs, device deficiencies etc.), per drug or device, or any other report requested by appropriate NHSGGC committees.

3.4. Safety Reporting System

Safety data for Sponsored/Co-Sponsored CTIMPS are entered in study-specific eCRFs. These eCRFs are developed and maintained by the appropriate data management centre.

The Sponsor and PV Office can access each study-specific eCRF via the relevant URL.

Access to unblinded data via the eCRF is controlled at a user access level and is not available to staff other than those designated as requiring access to unblinded data. Access to unblinded data must be fully justified.

Each eCRF is a secure web-based electronic system which incorporates a system for the remote capture of SAE information. This allows users to enter SAEs or DDs directly into the eCRF.

The system facilitates the production of:

- A .pdf report of each SAE or DD entered in to the system
- Automatic email notifications to sponsor PV Office facilitating timely review of the event
- Automatic email notifications to other agreed personnel e.g. Chief Investigator, Sponsor depending on trial specific requirements
- Line listings and SAE summaries required for annual safety report/Development Safety Update Reports
- Provision of data to populate the Eudravigilance database for SUSAR reporting

4. Referenced documents

- SOP 55.002 - Preparation and submission of the Development Safety Update Report
- European Commission: Communication from the Commission— Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3') http://ec.europa.eu/health/files/eudralex/vol-10/2011_c172_01/2011_c172_01_en.pdf
- MEDDEV 2.7/3. Clinical Investigations: Serious Adverse Event Reporting Under Directives 90/385/EEC and 93/42/EEC
- The Medical Device Regulations 2002: https://www.legislation.gov.uk/uksi/2002/618/contents/made
- The UK Policy Framework for Health and Social Care: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/
- https://www.hra.nhs.uk/documents/2466/Non_CTIMP_Safety_Report_Form_Accessible_September_2020_AA.odt
- https://assets.publishing.service.gov.uk/media/65a6564996a5ec00137319e5/QSR_template.pdf

5. Related documents

- Form 55.015A – SAE Processing Form
- SOP 55.004 - Safety Reporting Requirements for Research Other Than Clinical Trials of Investigational Medicinal Products and non CE Marked Medical Devices
- SOP 55.007 - Safety Reporting in Clinical Trials of Medical Devices of Non CE Marked Medical Devices or CE Marked Devices Used Outside of their Intended Purpose (Sponsored and Hosted Clinical Investigations)
- Guideline 55.001A - PV Office – Preparation of Sponsor Safety Reporting Plan, Glasgow Clinical Trials Unit (GCTU) Pharmacovigilance (PV) Office
- Guideline 55.001B - PV Office – Expediting SUSARS
- Guideline 55.001C - PV Office – PV Office – Submitting SUSAR reports to MHRA via ICSR
- Guideline 55.001F - PV Office – Pharmacovigilance File
- Guideline 55.001G - PV Office Processing for Clinical Trials of Investigational Medicinal Products
- Guideline 55.007A - PV Office Processing for Clinical Investigations of Non CE Marked medical Devices:

6. Document History

Version	Date	Description
1.0	15/07/2016	Release of first version
2.0	19/12/2018	Updated to capture changes to the SAE reporting systems.
3.0	10/07/2020	Updated to capture storage and access to unblended data.
4.0	07/06/2024	Updated to include all safety data types and update legislation and collection of safety data.