**Sponsor Safety Reporting Plan**

**Glasgow Clinical Trials Unit Pharmacovigilance Office**

**Study:**

**Study Short Title: (if applicable)**

**EudraCT No.:**

**Sponsor Ref No:**

**REC No.:**

**CTA No:**

**CTA Date:**

**Effective Date: Enter date of sign off**

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DELETE ALL TEXT IN RED FOR FINAL VERSION

1. **Study personnel and contacts**
   1. **Pharmacovigilance Office**

**Amend as appropriate for study.**

**Insert contact details including address, telephone and email**

**Pharmacovigilance manager:**

**Pharmacovigilance Administrator**

**Pharmacovigilance eCRF developer**

**Trial data manager:**

* 1. **Study Team**

**Amend as appropriate for study.**

**Insert contact details including address, telephone and email**

**Chief Investigator:**

**Co Investigators:**

**Study Coordinator:**

**Project Manager:**

* 1. **Sponsor Representatives**

**Amend as appropriate for study.**

**Insert contact details including address, telephone and email**

**Research Coordinator:**

**Lead Monitor**

**R+I Pharmacy Contact(s)**

**R+I Governance Manager**

**Pharmacovigilance and Safety Manager**

* 1. **REC Details**

**Approving research ethics committee:**

**Contact email addess:**

1. **Overview**

**The aim of this document is to describe the roles, responsibilities and activities of the Glasgow Clinical Trials Unit Pharmacovigilance (PV) Office for the <Add study title> study sponsored by NHS Greater Glasgow & Clyde or co-sponsored with the University of Glasgow (amend as appropriate). All procedures and applications used will be subject to systems validation and will be in accordance with ICH Guideline for Good Clinical Practice. Appropriate quality assurance and quality control measures will be implemented.**

1. **Study Details**
   1. **Title**

**Insert title of study**

* 1. **Type of study**

**Insert study type i.e. open label, single blind, double blind**

1. **Organisation**
   1. **Sponsor**

**NHS Greater Glasgow and Clyde or Co-sponsored with the University of Glasgow (amend as appropriate)**

* 1. **Pharmacovigilance Office**

**The Pharmacovigilance (PV) Office is located within the Glasgow Clinical Trials Unit, Robertson Centre for Biostatistics, University of Glasgow, Glasgow, G12 8QQ.**

* 1. **Project Coordinating Centre**

**Provide details of project coordinating centre if applicable. If international study included details of Country Coordinating Centres**

**Or**

**Remove this section if not applicable**

1. **Data Sources**

**The PV Office will be responsible for accumulating, reviewing and reporting on Serious Adverse Event (SAE) data from a number of primary and secondary sources.**

* 1. **Primary Data Sources**

**The primary sources of data arise from: (amend as appropriate for the study)**

1. **Initial Paper SAE form.**
2. **Initial Verbal report to Pharmacovigilance Office, followed up by written or electronic report.**
3. **eCRF in built reporting procedures.**
   1. **Secondary Data Sources**

**Secondary sources of data arise from:**

1. **SAE Follow-Up report.**
2. **Responses to SAE Queries**
3. **Coding of SAEs (DSURS and SUSARS) and Concomitant Medications (SUSARs only)**
4. **Trial pharmacovigilance** 
   1. **Reference safety information used for trial IMP(s)**

**Indicate for each trial IMP whether the RSI is an IB or an SmPC.**

* 1. **Safety data collection period**

**Document the duration of safety reporting with justification. i.e. where a trial has a substantial number of screening tests that are trial specific or where there is a run in period then SAEs should be collected from consent otherwise collect from randomization.**

**Similarly SAEs should not be collected from day x until the date treatment stopped +30 days. There should be a documented decision for the date SAE collection stops. This may be the time from stopping until the drug is cleared (usually considered 5 half-lives) but this may be complicated by the IMP having long lasting biological effects. Justification for the choice of end date should be provided.**

**If treatment breaks are allowed or treatment is intermittent what does this mean for SAE data collection? This should be documented (and in the protocol) and justified.**

* 1. **Expectedness of life threatening and fatal events**

**Normal process is as follows:**

**For IB: Not expected.**

**For SmPC: Fatal events not expected, life threatening events can be expected (but the benefit/risk ratio may be unfavourable in which case would still be considered unexpected). Fatal events can be considered expected if the SmPC states that fatal events are expected.**

**For example: For a patient with asthma or heart failure with a requirement for ongoing treatment generally life threatening or fatal events would not be considered expected. For an acute MI/stroke trial life threatening or fatal events would likely be considered expected. For cancer trials generally life threatening events would be considered expected but fatal events may only be considered expected if second/third line.**

* 1. **Adverse events of special interest**

**Outline the process for the collection of adverse events of special interest i.e. if collected as SAEs or as more detailed AE. Detail reasons for collection and how they will be monitored i.e. DMEC or statistical methods. If AESIs collected as SAEs detail if they will be included in the DSUR. Similarly if collected as ARs detail if they will be included in the DSUR.**

* 1. **Adaptations to SAE data collection**

**General assumption that all SAEs are collected for a trial from the date of randomization/consent to the date a participant stops treatment plus a suitable number of day as detailed in section 6.2.**

**Where a trial is risk adapted then an explanation and justification for that risk adaptation should be included here. For example: End points may be excluded from expedited reporting, or may be excluded from SAE reporting entirely but collected in a different manner. For a phase IV trial may wish to collect limited number of SARs i.e. only those that are of interest and SUSARs.**

**Document where SAE would be collected where risk adaptation is in place and what processes are in place to monitor that data if required.**

* 1. **Collection of deaths, overdoses etc as SAEs**

**General assumption that such events are NOT collected as SAEs, but may be required for some trial. For example: chemotherapy used in more frail population may want to collect deaths occurring within 30 days of treatment.**

1. **SAE processing and reporting**

**Each SAE form received will be processed as per guideline 55.001g PV Office Processing for Clinical Trials of Investigational Medicinal Products**

* 1. **Study Specific Pharmacovigilance Office Processes**

**(amend accordingly if a study specific form or eCRF is used)**

**Optional: In addition to the checks detailed within guideline 55.001G the following additional checks should take place during the processing of each SAE.**

**OUTLINE RELEVANT CHECKS**

**OR**

**Remove this section if not applicable**

* 1. **Study specific review of Serious Adverse Events by the Chief Investigator**

**Document the process for the review of SAEs by the chief investigator. This should be discussed at the trial risk assessment and is dependent on the phase of the trial, the relative risk of the trial, and the IMP involved.**

**At a minimum all SAEs should be reviewed in real time by the CI for a phase I trial and all events assessed as SARs by the reporting investigator should be reviewed by the CI in real time for a phase IIa trial. For phase IIb and above CI review of events should be risk assessed**

* 1. **Study Specific arrangements for assessment of expectedness**

**Detail if applicable if not applicable then remove this section**

* 1. **Pregnancy Forms**

**Add details as per Protocol.**

**Pregnancy forms will be scanned and saved to the study folder. Paper Pregnancy forms will be filed with the SAE forms.**

1. **SUSAR review and reporting**
   1. **Unblinding process for SUSAR reporting REMOVE IF NOT RELEVANT**

**For blinded CTIMPs insert details of the study specific process to be followed to unblind the treatment allocation of any potential SUSARs. This process will be determined by the sponsor risk assessment process and the study specific unblinding process. Amend suggested text below as appropriate for the study.**

Only cases occurring in participants on the active drug (unless excipients in the placebo are deemed attributable) will be considered SUSARs which require reporting to the REC & MHRA within the specified timelines

**Following confirmation of a potential SUSAR by the CI, the treatment allocation for the participant will be unblinded by Sponsor PV Office personnel (or other sponsor representative) to facilitate appropriate reporting to the MHRA and REC.**

**Unblinding for SUSAR reporting will be carried out via the xxx Study Unblinding IVRS system using the procedure documented in the xxx Study Unblinding Worksheet.**

**A copy of the worksheet can be found in the paper and electronic TRUST study folders.**

**Unblinding IVRS Number for UK:** xxx

**The completed worksheet documenting the treatment allocation will be stored securely with the paper SAE forms. The documents will be stored separately from other study documents with access restricted to sponsor PV office.**

**If the patient is found to be in the treatment group, a SUSAR report will be submitted to the MHRA and to the REC as detailed in 9.7 above.**

**If the patient is found to have received placebo an assessment will be made as to whether the reaction could have been caused by the placebo. This assessment will be made by the designated reviewer:**

**(Add name and contact details)**

**If the event is not considered to be related to the placebo it is not a SUSAR and no regulatory reporting is required. If the event is considered related to the placebo and the designated reviewer believes the event to be unrelated the event should be reported as a SUSAR as per below**

* 1. **Expediting Reports of SUSARs to MHRA/Research Ethics Committee**

**If the event is considered to be related to the IMP/placebo and is unexpected as per the RSI a SUSAR report will be submitted to the MHRA and REC as per guidelines 55.001b and 55.001c**

* 1. **Informing country coordinating centre of SUSARs**

**Amend as appropriate for an international CTIMP in line with the terms of any agreements/contracts (Delete section if Non-CTIMP)**

**Remove if not applicable**

**Or**

**In order to facilitate the reporting of any SUSARs in the trial to the regulatory authority in the other collaborating countries an unblinded report will be provided to the country coordinators.**

**For blinded trials only: The accompanying email will highlight that the report contains “unblinded” information and should only be accessed by the individual(s) who will carry out the regulatory reporting.**

* 1. **Informing Investigators of SUSARs**

**CTIMP studies only-amend** depending on study specific arrangements **as appropriate.-Delete section if Non-CTIMP**

**For blinded trials: SUSAR reporting to participating investigators will be blinded.** **No detail of the treatment allocation will be included in this report.**

**For open label trials:** The PV office will forward a copy of a report of any event identified by the CI as SUSAR with an accompanying cover letter to the CI/Project Manager for onward distribution to co-investigators.

**IMPs used in multiple trials sponsored by NHS GG&C or co-sponsored with the University of Glasgow: Describe the process by which SUSARs will be disseminated amongst investigator across all trials.**

* 1. **Study Specific Requirements**

**Insert section if there are any study specific requirements e.g. forwarding of SAEs to Pharmaceutical company/IDMC/other country sponsor**

**OR**

**Not applicable**

1. **Coding**
   1. **Medical Conditions**

**Data sources: Serious Adverse Events**

**Medical History recorded on SAE forms**

**Drug Indications recorded on SAE forms.**

**For all Serious Adverse Events reported, only the diagnosis will be coded using the MedDRA dictionary or ICD-10 (delete as appropriate) assisted by the auto-encoding system or manually coded according to the coding guidelines.**

**For SUSARS: Diagnosis, Medical History and Drug Indication will be coded automatically when the event is entered in to the MHRA eSUSAR system.**

* 1. **Drugs**

**Data sources: Drugs recorded on SAE forms**

**For SUSARS: Drugs will be coded automatically when the event is entered in to the MHRA eSUSAR system.**

1. **Quality** 
   1. **Quality Control**

**Quality control will be carried out on an ongoing basis as per Guideline 18.008B. PV Office –QC process**

* 1. **Quality Assurance**

**All processes will be carried out in line with Glasgow Clinical Trial Units Standard Operating Procedures. This will include the clinical review of all SAEs before data lock.**

**Add as appropriate**

**Or**

**Not applicable**

1. **Related Documents**

**SOP 55.001 Pharmacovigilance in Clinical Trials of Investigational Medicinal Products (Glasgow Clinical Trials Unit)**

**Guideline 55.001B** [**PV Office – Expediting SUSARs**](https://www.glasgowctu.org/media/1734/guideline55001b_v30.pdf)

**Guideline 55.001C** [**PV Office – Submitting SUSAR Reports to MHRA via eSUSAR**](https://www.glasgowctu.org/media/1735/guideline55001c_v50.pdf)

**All Standard Operating Procedures are available via the Glasgow Clinical Trials Unit website:** [www.glasgowctu.org](http://www.glasgowctu.org)**.**