Glasgow Clinical Trials Unit
Guideline 55.001A
Version 4.0

PV Office – Preparation of Sponsor Safety Reporting Plan, Glasgow Clinical Trials Unit (GCTU) Pharmacovigilance (PV) Office

Purpose of document:

The purpose of this guideline is to outline the process for the development of a study specific Sponsor Safety Reporting Plan for each CTIMP and Clinical Investigations sponsored by NHS GGC or Co-sponsored with the University of Glasgow.

Personnel:
Pharmacovigilance Administrator
Pharmacovigilance and Safety Manager
R&I Research Governance Manager

Background:

A study specific Sponsor Safety Reporting Plan will be prepared for each CTIMP sponsored or co-sponsored by NHS GGC, and clinical investigations of non CE marked medical devices. The Sponsor Safety Reporting Plan documents GCTU PV Office activities within the study and contains study specific information e.g. contact details, any risk adapted modifications to the reporting requirements, detailed information regarding the assignment of expectedness etc.

During the set up phase of the study the Pharmacovigilance and Safety Manager will prepare a draft plan using the Sponsor Safety Reporting Plan template (Form 55.001A). This will be modified with reference to the study protocol, the risk assessment, and any study agreements or contracts.

Content of PV Plan
The following sections will be included when applicable:

Title page
1. Study personnel and contacts
2. Overview
3. Study Details
4. Organisation
5. Data Sources
6. Trial pharmacovigilance
7. SAE processing and reporting
8. SUSAR review and reporting
9. Coding
10. Quality
11. Related Documents

Draft Sponsor Safety Reporting Plans will be reviewed by the CI, the R&I Research Governance Manager, and the trial pharmacist where applicable. Draft Plans will also be circulated to the trial management group for review but their sign off is not required.

Sponsor Safety Reporting plans will be approved by the R&I Research Governance Manager and may be updated as required throughout the course of the trial.

Filing
Copies of the plan will be filed in:

Study Pharmacovigilance File (electronic and paper)
CI Site File

Related Documents:
Form 55.001A-GCTU Sponsor Safety Reporting Plan Template

Document Details:

Prepared by: Marc Jones Signed: …… Date: / /

Approved by: Caroline Watson Signed: …… Date: / /

Document History:

Version	Details	Date
1.0	Initial creation	29/11/2013
2.0	Change of Title, change to review process, index updated, addition of filing information	21/09/2015
3.0	Reviewed and released as part of SOPs reorganisation process. Guideline has moved to SOP category 55 NHS GG&C Sponsor Pharmacovigilance and renumbered (previously 18.001A). 'Prepared by' changed to Caroline Watson, 'Approved by' changed to Julie Brittenden.	15/07/2016
4.0	Updated in line with amendments to Form 55.001A and following discussions by the Sponsor PV Group	26/04/2021