

PV Office – Pharmacovigilance File

Purpose of document:

To outline the process for creating a study Pharmacovigilance (PV) File.

Personnel:

Pharmacovigilance Office
Pharmacovigilance and Safety Manager

Background

The Trial Master File (TMF) (as per SOP 51.016) shall consist of essential documents, which enable both the conduct of a clinical trial and the quality of the data produced to be evaluated according to Article 16 of Directive 2005/28/EC. These documents should be filed in such a way that it will facilitate management of the clinical trial, audit and inspection.

The TMF is considered to be comprised of the Sponsor File, Chief Investigator Site File and Principal Investigator Site File(s).

The Glasgow Clinical Trials Unit Pharmacovigilance Office maintains a PV section of the Sponsor File for each CTIMP.

Guideline notes

1. When a CTIMP sponsored by NHS Greater Glasgow and Clyde (NHS GGC) or co-sponsored with the University of Glasgow becomes active, a PV File will be created.
2. The PV File be created as per Form 51.016D
3. The PV File shall be updated by the PV and Safety Manager on an ongoing basis throughout the lifetime of the trial.
4. The PV File shall be stored within the filing cabinet in the Sponsor PV Office.
5. The PV File will be archived with other Sponsor File documents as per SOP 51.006, Archiving Essential Documents from Clinical Research – Process for Sponsored and Hosted Research.

Document Details:

Prepared by: Marc Jones Signed: Date: / /

Approved by: Chloe Cowan Signed: Date: / /

Document History:

Version	Details	Date
1.0	Version 1.0 creation	02/09/2010
2.0	PV File Index updated. Other minor changes Guideline No. allocated	29/11/2013
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 18.001F). 'Prepared by' changed to Caroline Watson, 'Approved by' changed to Julie Brittenden. Reference to archival SOP corrected.	15/07/2016
4.0	Amended references to the location of the PV file and where SAEs and related correspondence are stored.	19/12/2018

This guideline is a controlled document. The current version can be viewed on the Unit's internet site. Any copy reproduced from the internet site may not, at the time of reading, be the current version.