Standard Operating Procedure CCTU/SOP068

Document Title Review of SAE Line Listing by Academic Research Leads for Cambridge Sponsored CTIMPs

1. Scope

This SOP applies to the Cambridge Clinical Trials Unit Regulatory Team and Academic Research Leads within CUH/CPFT.

2. Purpose

To ensure that SAE line area specialists appropriately review listings of adverse events in order to assess potential trends across trials and IMPs. To ensure there is appropriate onward reporting of identified trends to the sponsor via the CCTU and the dissemination of key messages and trends in departmental meetings

3. Definitions and Abbreviations

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

3.1. Definitions

Term	Definition
Cambridge Sponsored	Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH); or the University of Cambridge (UoC); or jointly by CUH and UoC. Or Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) or CPFT jointly with the University of Cambridge
Serious Adverse Event (SAE)	Any AE or effect that at any dose that: -Results in death -Is life threatening -Requires hospitalisation or prolongation of existing hospitalisation -Results in persistent or significant disability/incapacity -Is a congenital anomaly/birth defect -Is 'an other' important medical event
Pharmacovigilance	Pharmacovigilance is the on-going monitoring of the safety profile, combined with the on-going assessment and evaluation of the risk-benefit of medicines. This process is important to identify adverse reactions, identify previously unrecognised adverse reactions and changes in patterns of known adverse reactions. Pharmacovigilance is the key activity to prevent harm to the trial participant and patients by ensuring that medicines put onto the market are safe.

3.2. Abbreviations

Abbreviation	Meaning
ARL	Academic Research Leads
CCTU	Cambridge Clinical Trials Unit
CPFT	Cambridgeshire and Peterborough NHS Foundation Trust
CTC	Clinical Trials Coordinator
CTIMP	Clinical Trial of an Investigational Medicinal Product
PV	Pharmacovigilance
PVO	Pharmacovigilance Officer
SAE	Serious Adverse Event

4. Undertaken by

The CCTU Pharmacovigilance team and designee(s) involved in the PV management of Cambridge Sponsored CTIMPs.

5. Items Required

Current Divisional Directorates and Clinical Departments with Academic research leads document available on the shared drive. (Restricted access)

6. Summary of Significant Changes

Listing format

Shared Pharmacovigilance mailbox cuh.cctupv@nhs.net

7. Method

The following sections provide a description of the processes to be followed when implementing this document's procedures.

7.1. SAE line listings

The Pharmacovigilance team will produce line listings of new SAEs reported by trial every quarter, with exception of the last quarter of the year, which will be an annual cumulative line listing.

All new SAEs for that quarter or year (for annual listing) will be extracted from the PV database and formatted into a one page line listing containing:

- SAE event database number
- Trial SAE reference number
- Date received by Sponsor
- Date of SAE onset
- SAE, SAR and SUSAR classification
- SAE term
- IMPs name

- IMP causality assessment
- Seriousness criteria
- Reporter site name
- Resolution date
- Outcome

7.2. Academic research leads review

All SAE line listings are sent to the ARLs of the relevant clinical department quarterly by email copying in the CI. The current list of ARLs is available on the shared drive.

Academic Research Leads are required to:

- Acknowledge receipt of the line listings in a timely matter, normally within 10 days
- Compare with previous reports and feedback any trends or concerns to the CCTU PV Team cuh.cctupv@nhs.net
- Discuss the line listings for trends at their departmental meetings
- Provide confirmation to the CCTU Pharmacovigilance team that the line listings have been disseminated either by email or meeting minutes within one month of line listing receipt

7.2.1. Filing of SAE line listings review

- Printed copies of the emails and line listings are filed by the PVOs in the Line Listings Review File
- Confirmation of the line listings review and dissemination will also be retained
- A copy of the annual line listing will be provided to the relevant trial team/ CTC for inclusion in the TMF.

7.3. Escalation of trends or any other important safety issues

- Any trends or issues identified by the CCTU PV Team must be notified the Regulatory Quality Manager
- The Regulatory Quality manager will escalate to the Sponsor within 2 working days of notification

8. Monitoring Compliance with and the Effectiveness of this Document

a. Process for Monitoring Compliance and Effectiveness

As part of routine monitoring visits, audit and inspection

b. Standards/Key Performance Indicators

This process forms part of a quality management system and is reviewed according to CCTU procedures. Standard Operating Procedures are reviewed every two years.

9. References

The Institute of Clinical Research, Abbreviations used in Clinical Trials.

MHRA, Good Clinical Practice "Grey Guide"

MHRA, Good Pharmacovigilance Practice guide "Purple Guide"

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')

10. Associated Documents

NA

11. Equality and Diversity Statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

12. Disclaimer

It is the user's responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

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