Receipt, Onward Reporting and Follow-Up of Safety Reporting for Regulated Medical Device Studies

Document No.:	PV005 v4.0
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Issue Date:	31 JUL 2025
Effective Date:	14 AUG 2025

1 Introduction

1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

1.2 Legislation that applies in Great Britain: Medical devices are regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which gave effect in UK law to the directives listed below:

Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
Directive 93/42/EEC on medical devices (EU MDD)
Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)

Legislation that applies for Northern Ireland: The EU Medical Devices Regulation (Regulation 2017/745) (EU MDR) and the In Vitro Diagnostic Medical Devices Regulation (Regulation 2017/746) (EU IVDR) applies in Northern Ireland as well as EU member states.

1.3 The UoE is responsible for pharmacovigilance (PhV) and safety reporting for studies sponsored by UoE and/or NHSL.

1.4 Adverse Event (AE) and device deficiency identification, recording and reporting procedures relating to trials involving medical devices, where safety reporting is

specified in the protocol, will comply with the requirements of the UK MDR 2002, the EU IVDR and EU MDR (where applicable) and with Good Clinical Practice (GCP).

2 Purpose

2.1 To describe the procedure for handling safety reporting of events occurring in NHSL/UoE sponsored Clinical Investigations of Medical Devices (CIMDs) that fall under the UK MDR 2002, EU MDR and EU IVDR.

3 Scope

3.1 This SOP also applies to the ACCORD Pharmacovigilance Team or designee staff involved in safety reporting for all relevant studies sponsored by UoE and/or NHSL.

4 Responsibilities

4.1 It is the responsibility of a PhV Officer, or designee, to:

- Confirm receipt of safety reports;
- Enter the Serious Adverse Event (SAE) into the PhV database;
- Onward report the event as per the study protocol, regulatory, and contractual obligations;
- Request and track follow-up information;
- File the completed SAE in the Trial Master File (TMF) or Sponsor File.
- Maintain the TARA PhV Database Tracker (for received SAE reports and SAEs reported that require Follow-up) on the ACCORD SharePoint.

4.2 It is the responsibility of the PhV Manager, or designee (someone who didn't perform the report data-entry into the PhV Database), to perform Quality Control (QC) checks of each safety report and corresponding PhV database entry.

4.3 It is the responsibility of the PhV Manager, or designee, to:

- Ensure all SAEs and other reportable events are reported to the relevant Competent Authority (CA) when required.
- Ensure all USADEs (Unexpected Serious Adverse Device Effect) are reported to the relevant Research Ethics Committee (REC)
- Ensure all SAEs are notified to appropriate parties as per any contractual obligations (e.g. device manufacturer).

5 Procedure

5.1 Receipt of SAE Reports

5.1.1 On receipt of a SAE report, the PhV Officer or designee, will review the information provided in the relevant form (CR012-T01 SAE CIMD Form).

5.1.2 A SAE CIMD Summary Sheet (PV005-F01) will be completed for each SAE by the PhV Officer, or designee.

5.1.3 A receipt should be e-mailed to the sender by the PhV Officer or designee within 1 working day.

5.1.4 If any of the data is missing, unclear, invalid or otherwise requires follow up, the PhV Officer or designee, should request the required data or clarifications in writing (e-mail) or by telephone, this include clarification about events that might have been reported in error as per protocol.

5.1.5 The PhV Officer or designee will save initial, follow-up, and final electronic copies of the SAE in the appropriate study folder on the ACCORD SharePoint.

5.1.6 SAEs will be entered into the ACCORD PhV database by the PhV Officer or designee, within 5 working days of first receiving the report.

5.1.7 All SAEs received by the PhV team will be captured in the TARA PhV Database Tracker on SharePoint by the PhV Officer or designee. The Tracker will be checked by the PhV Manager, or designee, and completed once QC of the report is performed. QC cannot be performed by the member of the PhV team responsible for SAE data entry.

5.1.8 The Pharmacovigilance Manager, or designee, will ensure all sites are informed that an USADE has been reported for that study. If the study is being co-ordinated by a unit/group/individual, responsibility for informing all sites of an USADE may be delegated to them. The Sponsor should be copied into the correspondence to all sites.

5.1.9 For multicentre studies, where relevant and specified in the study protocol and/or study specific procedure, the ACCORD PhV team will onward report SAEs, as required, to the CI/Trial Manager within agreed timelines.

5.2 Expedited Reporting of SAEs to the Competent Authority (CA)

5.2.1 The reporting of SAEs to the Medicines and Healthcare products Regulatory Agency (MHRA) will not be required for medical devices that are UKCA / CE / CE UKNI marked for the purpose that is under investigation.

5.2.2 Any SAEs which indicate an imminent risk of death, serious injury or serious illness and that requires prompt remedial action for other patients/subject, users or other persons or a new finding to it - will be reported immediately, but not later than 2 calendar days after the Sponsor becoming aware of a new reportable event or of new information in relation to an already reported event.

5.2.3 Any other SAEs or new information in relation to an already reported event will be reported immediately, but not later than 7 calendar days after the sponsor becoming aware.

5.2.4 In order to report SAEs to the CA, the report will be made using the cumulative SAE reporting form located in the Pharmacovigilance folder on the ACCORD SharePoint:

- MEDDEV 2.7/3 SAE reporting table or MDCG 2020-10/2 SAE reporting table for studies with sites in Great Britain and studies with sites both in Great Britain and Northern Ireland.
- MDCG 2020-10/2 SAE reporting table for studies with sites in Northern Ireland but no sites in Great Britain.

5.2.5 Only one reporting form should be used per trial. This report should be cumulative and should be updated for each new event (and follow-up) and sent to the CA.

5.2.6 Any new event or updated information added to the reporting form should be highlighted and the status column amended as below:

a= added a new reportable event
m= modified already
u=unchanged

5.2.7 In addition to the reporting of individual serious adverse events, quarterly summary reports of all serious adverse events should also be provided to the MHRA. The template provided by the MHRA will be used.

The table should contain information on SAEs for the entire duration of the trial, not just those which have occurred during the specific quarter. The ACCORD PhV Manager

or designee will have an oversight of this SAE summary prior to submission to MHRA but the redaction and submission of this summary is the Investigator's responsibility.

SAE reporting rules for Great Britain:

This section concerns clinical investigations with sites in Great Britain, and clinical investigations with sites in both Great Britain and Northern Ireland.

All SAEs, whether initially considered to be device/procedure related or not, involving a device under clinical investigation within Great Britain should be reported to the MHRA. In addition to SAEs, the following reportable events will also be reported to the MHRA:

- Any Investigational Medical Device Deficiency that might have led to a SAE if:
    1. Suitable action had not been taken or
    2. Intervention had not been made or
    3. If circumstances had been less fortunate
- New findings/updates in relation to already reported events.

This includes all serious adverse events, irrespective of whether the device has been assessed as having a causal relationship, and reportable events as mentioned above occurring in third countries in which a clinical investigation is performed under the same clinical investigation plan.

SAE reporting rules for Northern Ireland:

This section concerns clinical investigations with sites in Northern Ireland (but no sites in Great Britain).

The following SAEs involving a device under clinical investigation within Northern Ireland should be reported to the MHRA without delay:
(a) any SAE that has a causal relationship with the investigational device, the comparator or the investigation procedure or where such causal relationship is reasonably possible;
(b) any device deficiency that might have led to a SAE if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
(c) any new findings in relation to any event referred to in points (a) and (b).

5.2.8 The completed cumulative spreadsheet should be submitted to the MHRA via the MORE Portal

5.2.9 The PhV Manager, or designee, will save a copy of the cumulative report that was sent to the MHRA in the TMF or Sponsor File and electronic file for that study on SharePoint, if appropriate.

5.3 Expedited Reporting of SAEs to the REC

5.3.1 Only reports of SAEs that are:

- related to the study (ie they resulted from administration of any of the research procedures) and
- unexpected (ie not listed in the protocol as an expected occurrence)

should be reported to the relevant REC within 15 calendar days of the Sponsor becoming aware of the event. For medical devices this means the USADEs should be reported.

5.3.2 The PhV Manager, or designee, will e-mail the report form along with the covering REC non-CTIMP Safety Report Form (https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/) to the relevant REC. Any comments from the CI (Chief Investigator) should be added to the covering reporting form, if appropriate. Any relevant follow-up information will be submitted to the REC and MHRA as appropriate.

5.3.3 Reports of double-blind trials will be unblinded by ACCORD PhV Team before USADEs are reported to the REC.

5.4 Follow-Up of SAEs

5.4.1 When communication with sites between Monitoring Visits reveals information relevant to the outcome of the trial or relating to participant safety, or any other issue which requires additional documentation these data will be documented in a Contact Report. Contact Report Forms (CM002-T02) will be prepared and signed by the Clinical Trials Monitor, or designee, reviewed by the Senior Clinical Trials Monitor or designee where required, and filed in the TMF and/or Sponsor File.

5.5 QC checking and filing of SAEs

5.5.1 The PhV Manager, or designee will QC check all SAE forms received by ACCORD and the subsequent data entry onto the PhV database. QC cannot be performed by the member of the PhV team responsible for SAE data entry.

5.5.2 QC checks will be performed in batches approximately 3-4 weeks apart.

5.5.3 The PhV Manager, or designee responsible of the QC, will document any discrepancies into the PhV Database and on the TARA PhV Database Tracker on SharePoint.

5.5.4 The PhV Officer, or designee, responsible for SAE data entry into the PhV database will address the discrepancies and return the SAE form to the PhV Manager, or designee, for QC.

5.5.5 The PhV Manager, or designee, will document the completion of the QC process on the PhV Database and on the SAE CIMD summary sheet (PV005-F01).

5.5.6 Once all QC / follow-up queries have been answered satisfactorily, the SAE report is considered fully completed and the QC of the report in the database is completed, the PhV Officer or designee will print the report for filing and sign the SAE CIMD summary sheet (PV005-F01). This signature confirms that all the queries have been addressed.

5.5.7 When the QC check is complete and the SAE form is complete, the e-mailed completed SAE form and signed SAE CIMD summary sheet (PV005-F01) will be filed in the TMF or Sponsor File, as appropriate, by the PhV Officer, or designee.

5.5.8 If there is more than one SAE for a participant, then they will be filed in 'date of onset' order, from newest to oldest (i.e. the most recent on top).

5.6 Reporting device deficiencies to the Sponsor

5.6.1 Device deficiencies will be documented on CR012-T02 Medical Device Deficiency Form.

5.6.2 On receipt of device deficiency reports, the PhV Officer, or designee, will assess the report to ensure the correct assessment has been made. In the case of the event meeting SAE, SADE, USADE criteria or in case of a device deficiency that might have led to an SAE, the PhV Officer or designee, will ensure that all the correct reporting procedures have been followed.

5.6.3 The PhV Officer or designee, will send an email to confirm receipt of the Device deficiency report within 1 working day. If this email is not received within 1 working day of sending the report to ACCORD, the Investigator must email ACCORD on safety@accord.scot to check that the report has been received by ACCORD.

5.6.4 Device Deficiencies will be entered into the ACCORD PhV database by the Pharmacovigilance Officer, or designee, within 5 working days of first receiving the report.

5.6.5 The Investigator is responsible for reporting device deficiencies to the relevant NHS Medical Physics department, if applicable.

5.6.6 Device deficiency reports emailed to ACCORD and any follow-up information and correspondence will be kept by the Investigator in the ISF and by the Sponsor in the Sponsor File or TMF if held.

5.6.7 For multicentre studies, where relevant and specified in the study protocol and/or study specific procedure, the ACCORD PhV team will report device deficiency reports, as required, to the CI/Trial Manager within agreed timelines.

5.6.8 If there is a contractual obligation, as specified in the study protocol and/or study specific procedure, the ACCORD PhV team will report device deficiencies, as required, to the third party within the agreed timelines.

6 References and Related Documents

- ISO 14155:2020 (Clinical investigations of medical devices for human subjects – Good Clinical Practice)
- Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which, prior to the end of the transition period, gave effect in UK law to the directives listed below:
  - Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
  - Directive 93/42/EEC on medical devices (EU MDD)
  - Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)
- EU Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC',
- EU Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- MEDDEV 2.7/3 Revision 3 – Guideline on medical devices
- PV005-F01 SAE CIMD Summary Sheet

- CR012-T01 SAE CIMD Form
- CR012-T02 Medical Device Deficiency Form

7 Document History

Version Number	Effective Date	Reason for Change
1.0	31 JAN 2020	New SOP
2.0	08 JUN 2023	Updated throughout to align with EU MDR, EU IVDR and UK MDR 2002. Definitions updated and moved to appendix 1. Document updated to reflect the PV team. Mentions to fax removed and CR012-F01 discontinued. Device Deficiency reporting timelines added. Requirement for PhV team to enter Device Deficiencies added to 5.6.4. Addition of the quarterly summary submission (5.2.7). PV005-F02 updated to include SAE. Removal of the use of the PV001-F02 QC form. QC procedure updated following switch to the TARA PhV Database
3.0	21-Nov-2024	Update of Summary Sheet process – creation of "SAE CIMD Summary Sheet" that combine "PV005-F01 SAE CIMD initial summary sheet" and "PV005-F02 SAE CIMD FU summary sheet" – update of PV005-F01 (now v2.0) PV005-F02 is now obsolete Update to reflect that only completed SAE forms will be printed.
4.0	14 AUG 2025	Update following internal audit of Nov2024: - addition in 5.1.4 that clarification will be requested from site if the SAE is suspected to have been reported by error as per protocol. Update of section 5.2.4 about the cumulative forms that have to be used. Update of 5.2.7 to clarify that MHRA template will be used for the quarterly report of SAE to the MHRA and addition of reportable events as per MHRA guideline.

		References: addition of MEDDEV 2.7/3 as this is the document the MHRA is referring to for reportable events. Minor typo and clarification added. PV005-F01 (now v3.0) updated to align with new ACCORD branding. Clarification about the info to be captured added.

8 Approvals

Sign	Date
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Sweta Rath APPROVED: Sweta Rath, Pharmacovigilance Officer, UoE, ACCORD	30-Jul-2025
L. Mackenzie AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	31-Jul-2025

PV005 Receipt Onward Reporting And Follow-Up ... v4.0

Final Audit Report 2025-07-31

Created:	2025-07-30 (British Summer Time)
By:	Roisin Ellis (v1relli8@exseed.ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAADAgPooLLadUH2oEVOa9pfQ2WDWuC1Muv

"PV005 Receipt Onward Reporting And Follow-Up ... v4.0" History

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Agreement completed.

2025-07-31 - 8:32:03 AM GMT+1