Identifying, Recording and Reporting Adverse Events and Urgent Safety Measures for Clinical Trials of Investigational Medicinal Products

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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 The World Health Organisation defines pharmacovigilance (PhV) as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem."

1.3 Adverse Event (AE) and other safety event identification, recording and reporting procedures will comply with the requirements of the Medicines for Human Use (Clinical Trial) Regulations 2004/1031 as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 and Good Clinical Practice (GCP).

1.4 Where NHSL and/or UoE agree to co-sponsor a Clinical Trial of an Investigational Medicinal Product (CTIMP) with another organisation the responsibility for PhV must be agreed between all co-sponsoring organisations before the trial commences and should be clearly documented in a clinical trial agreement or equivalent.

2 Purpose

2.1 To describe the procedure for identifying, recording and reporting AEs (including adverse reactions, serious adverse events/reactions, and unexpected serious adverse reactions) urgent safety measures (USMs) and other safety events occurring in CTIMPs that are sponsored or co-sponsored by NHSL and/or the UoE.

3 Scope

3.1 This SOP applies to clinical researchers conducting CTIMPs sponsored by NHSL and/or UoE. This SOP is also applicable to ACCORD members of staff responsible for PhV following ACCORD SOP PV001.

4 Responsibilities

4.1 ACCORD will be responsible for PhV for CTIMPs that are sponsored by NHSL and/or UoE. This responsibility may not be delegated to the Investigators.

4.2 The Principal Investigator (PI) will be responsible for identifying and recording AEs, USMs, and other safety events as detailed in this procedure. They will also be responsible for reporting those events to the Sponsor when required (see section 5.10). The execution of PI tasks may be designated to suitably qualified personnel at location using a delegation log. Designation of tasks does not, however, transfer *responsibility* for those tasks to the designee.

5 Procedure

5.1 Definitions

5.1.1 Reference Safety Information (RSI)

The RSI is a list of expected Serious Adverse Reactions (SARs) which are classified using preferred terms (PTs) according to the Medical Dictionary for Regulatory Activities (MedDRA). It is used for the assessment of the expectedness of all 'suspected' serious adverse reactions (SARs) that occur in clinical trials.

5.1.2 Onset date

Date of the first signs and/or symptoms of the event.

5.1.3 Adverse Event (AE)

Any untoward medical occurrence in a clinical trial participant, which does not necessarily have a causal relationship with an Investigational Medicinal Product (IMP).

5.1.4 Adverse Reaction (AR)

Any untoward and unintended response to an IMP which is related to any dose administered to that participant. The definition covers also all events linked to medication errors and uses outside what is foreseen in the protocol, including misuse and abuse of the product.

5.1.5 Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR)

Any AE or AR that at any dose:

- results in death of the clinical trial participant
- is life-threatening*
- requires inpatient hospitalisation^ or prolongation of existing inpatient hospitalisation
- results in persistent or significant disability or incapacity
- consists of a congenital anomaly or birth defect
- results in any other significant medical event not meeting the criteria above

* Life-threatening in the definition of an SAE or SAR refers to an event where the participant was at risk of death at the time of the event. It does not refer to an event which hypothetically might have caused death if it were more severe.

^ Any hospitalisation that was planned prior to randomisation will not meet SAE criteria. Hospitalisation for elective treatment of a pre-existing condition that did not worsen from baseline is generally not considered an SAE.

5.1.6 Suspected Unexpected Serious Adverse Reaction (SUSAR)

A Suspected Unexpected Serious Adverse Reaction (SUSAR) is any AR that is classified as serious (5.1.5), is suspected to be caused by an IMP, and is not consistent with the RSI found, for example, in the Summary of Product Characteristics (SPC) or Investigator's Brochure (IB) for that IMP.

NB: Fatal and life-threatening SARs should usually be considered unexpected even if previous fatal and life-threatening SARs have occurred. Fatal SARs can only be considered expected for IMPs with a Marketing Authorisation (MA) when it is clearly stated in the table or list of ARs in Section 4.8 of the SPC, that the IMP can cause these fatal SARs. Thus, the RSI of a product that has not received an MA should never include fatal SARs.

5.2 Identifying and Recording AEs and SAEs

5.2.1 The decision on what AE data to record will be the result of an assessment of the risk associated with the study before the clinical trial is undertaken.

5.2.2 The protocol will define:

- When AEs or SAEs will be identified

- What events are not to be identified, recorded, notified and/or reported as AEs, SAEs, SARs or SUSARs

5.2.3 AE and SAE data will be recorded by the PI or a member of the study team designated to do so, on the Case Report Forms (CRF) and/or SAE report forms (CR005-T01 or CR005-T04). PIs or designees will record all AEs in the AE log (CR005-T05) unless otherwise defined in the protocol. AE details will be entered into the AE log in a timely fashion. The PI or designee will record each untoward medical occurrence identified as a separate adverse event. If there are subsequent additional relevant medical occurrences, these events should also be recorded as separate adverse events. Where any adverse event recorded meets the seriousness criteria, the event will be submitted to the Sponsor as a separate SAE.

5.2.4 AEs and SAEs should be recorded from the time the participant signs the consent form to take part in the trial, unless otherwise specified in the protocol.

5.2.5 AEs or SAEs may also be identified by support departments, for example, clinical biochemistry, haematology, or radiology. Where notification of abnormal values or measurements would not occur as standard clinical practice, the procedure for notifying the PI of such adverse events must be clearly documented in the protocol or trial specific procedures.

5.2.6 Template CR005-T03 (Adverse Events Flowchart - Identifying) can be used by PIs and designees to aid AE identification and classification.

5.3 Assessment of AEs

5.3.1 Each AE must be assessed for seriousness, causality, severity and expectedness by the PI or another suitably qualified physician in the trial team who is trained in recording and reporting AEs and who has been designated this role on the delegation log by the PI.

5.3.2 During PI absences appropriately qualified, experienced and trained location staff may report SAEs if they have been designated this task on the delegation log by the PI.

5.4 Assessment of Seriousness

5.4.1 The PI or designee will make an assessment of seriousness (as defined in section 5.1.5).

5.5 Assessment of Causality

5.5.1 For randomised double blind studies, the event will be assessed for causality as though the trial participant was taking the IMP.

5.5.2 The PI or designee will make an assessment of whether the AE is likely to be related to the IMP according to the following definitions:

- Unrelated: where an event is not considered to be related to the IMP.
- Possibly Related: The nature of the event, the underlying medical condition, concomitant medication or temporal relationship make it possible that the AE has a causal relationship to the study drug.

5.5.3 In studies using a Non-Investigational Medicinal Product (NIMP), the PI or designee must also consider whether the AE might be caused by either the IMP or the NIMP, or whether the AE is likely to be related to an interaction between the IMP and the NIMP, even if it cannot be clearly attributed to either one of these.

5.5.4 Any AE that is considered to be related to the IMP or the NIMP or to an interaction between the IMP and NIMP, even if it cannot be clearly attributed to either one of these, is described as an Adverse Reaction (AR).

5.5.5 Where there are two different assessments of causality (e.g. by PI and CI: Chief Investigator), the causality assessment by the PI or designee cannot be downgraded. In the case of a difference of opinion, both assessments are recorded and the 'worst case' assessment is used for reporting purposes.

5.6 Assessment of Expectedness

5.6.1 If the AE is judged to be related to the IMP, the PI or designee will make an assessment of expectedness based on knowledge of the reaction and the list of MedDRA Preferred Terms (PTs) in the RSI (usually listed in the IB or SPC). The event will be classed as either:

- Expected: the reaction is consistent with the adverse reactions of the study drug listed in the RSI. Or:
- Unexpected: the reaction is not consistent with adverse reactions listed in the RSI*.

The MHRA (Medicines and Healthcare products Regulatory Agency) approved version of the RSI at the time of onset of the event (onset date as described in 5.1.2) should be

used to assess the expectedness of a SAR and confirm if the event in question is a SUSAR.

*For consistency of assessing expectedness the same version of the RSI contained in the SPC or IB should be used throughout a DSUR reporting period.

5.6.2 A SAR may be described as 'unexpected' by the PI or designee, if it has occurred with greater severity than was anticipated. PIs/designees should note this in the 'additional information' section of the SAE form.

5.6.3 Reports which add significant information on the specificity, increase of occurrence, or severity of a known, already documented SAR constitute unexpected events.

5.6.4 Any SAR that is considered to be unexpected is described as a SUSAR.

5.7 Assessment of Severity

5.7.1 The PI or designee will make an assessment of severity for each AE according to the following categories:

- Mild: an event that is easily tolerated by the trial participant, causing minimal discomfort and not interfering with everyday activities.
- Moderate: an event that is sufficiently discomforting to interfere with normal everyday activities.
- Severe: an event that prevents normal everyday activities.

5.7.2 The term 'severe' used to describe the intensity of an event should not be confused with the term 'serious', as defined in section 5.1.5, which is a regulatory definition based on trial participant/event outcome action criteria. For example, a headache may be severe but not serious, while a minor stroke may be serious but is not severe.

5.8 Parent-Child Information

5.8.1 Events where a foetus/neonate/child suffers an SAE as a result of a medication taken by the parent require a parent-child report to be completed (CR005-T04).

5.8.2 In these instances, the foetus/neonate/child is classified as the participant and all sections of the parent-child report should describe the SAE as it applies to the child rather than the parent. A separate report for the parent should be generated only if the parent also suffers an SAE.

5.9 Completion of SAE form

5.9.1 SAE, SAR and SUSAR reports must be as complete as possible at the time of initial reporting to ACCORD. However, completion of reports should not take priority over the submission of reports as per required timelines (see section 5.10).

5.9.2 If any of the required information is not available at the time of reporting, the PI must ensure that any missing information is emailed to ACCORD as soon as this becomes available. It should be indicated on the report that this information is follow-up information of a previously reported event. See section 5.10 for reporting and 5.16 for details regarding follow-up.

5.9.3 If reports are received by ACCORD with identifiable data, the data will immediately be scored through by ACCORD and the sender informed of this breach in confidentiality. Where appropriate, ACCORD will communicate actions to be taken regarding the data breach.

5.10 Reporting SAEs/SARs/SUSARs to the Sponsor (ACCORD)

5.10.1 Any AE that is assessed as an SAE, SAR or SUSAR is subject to expedited reporting requirements.

The protocol will define and justify which SAEs will not be subject to expedited reporting to the Sponsor.

5.10.2 The PI is responsible for reporting SAEs to ACCORD within 24 hours of becoming aware of the event. The PI may delegate this task to an appropriately qualified member of the trial team.

5.10.3 Each separate SAE, SAR or SUSAR report will be emailed as an individual .pdf file to Safety@ACCORD.scot; using Template report CR005-T01 or CR005-T04. Reports will be complete as far as possible and will be signed and dated by the PI or suitably qualified clinician listed on the delegation log.

5.10.4 SAE, SAR and SUSAR reporting to ACCORD should maintain the blind unless it is considered necessary to break the blind in the interest of trial participant safety.

5.10.5 The PhV Officer, or designee, will send an email to confirm receipt of the SAE, SAR or SUSAR report within 1 working day. If this email is not received within 1 working day

of sending the report to ACCORD, the PI or appropriately qualified delegate must email ACCORD to check that the report has been received by ACCORD.

5.10.6 Once an SAE, SAR or SUSAR report is received by ACCORD it will be entered onto the ACCORD PhV Database by the PhV Officer, or designee.

5.10.7 All SAE, SAR and SUSAR reports emailed to ACCORD and any follow-up information and correspondence will be retained in the Investigator Site File (ISF) and also retained by the Sponsor in the Trial Master File (TMF) or Sponsor File, as applicable. See also 5.16 for further details regarding follow-up.

5.10.8 For multicentre studies, ACCORD will report SAEs, as required and defined in the protocol, to the CI/Trial Manager within agreed timelines.

5.10.9 If there is a contractual obligation, ACCORD will report any SAEs or SUSARs as required to third parties within the agreed timelines.

Template CR005-T02 (Adverse Event Flowchart - Reporting) illustrates the reporting procedure and can be used by investigators to clarify AE reporting requirements.

5.11 Reporting of SUSARs for blinded studies involving placebos or comparator drugs

5.11.1 Comparator drugs and placebos, when used in a CTIMP, must be considered as Investigational Medicinal Products (IMPs) for the purposes of safety reporting. Therefore, SUSARs associated with a comparator product will follow the same reporting requirements as indicated above for a test drug, and SARs reported for a comparator drug will be assessed against that drug's RSI in the same way as is done for a test drug.

5.11.2 If, following unblinding, a participant is revealed to have taken a placebo, it will not be deemed necessary to report the event as a SUSAR, unless the PI considers that the event may be related to a component of the placebo.

5.11.3 The reporting deadlines for SUSARs attributable to comparator drugs remain the same as the timelines for test drugs (see section 5.10).

5.12 **Expedited Reporting of SUSARs**

5.12.1 ACCORD is responsible for reporting of SUSARs to the Research Ethics Committee (REC) (if required) and Competent Authority(ies) (CA).

5.12.2 In the UK, there is no requirement to send a notification to the main REC, the MHRA will liaise with the REC if deemed appropriate.

5.12.3 For International studies: The procedure for reporting relevant events onwards to CAs and RECs will be included in any agreements between international groups performing the study.

5.12.4 SUSARs include events possibly related to:
- The IMP, comparators or placebo (when the PI considers that the event may be related to a component of the placebo)
- The IMP/comparators or NIMP (where it is not possible to distinguish between Medicinal Products in terms of causality of possibly related effects…)
- An interaction between IMP/comparators and NIMP

5.12.5 Fatal or life threatening SUSARs will be reported as soon as possible but no later than 7 calendar days after ACCORD is first aware of the reaction. Any additional relevant information will be submitted within 8 days of the initial report. All other SUSARs will be reported within 15 calendar days after ACCORD is first aware of the reaction. If significant new information on an already reported case is received by ACCORD, this information will be reported as a follow-up report within 15 days of ACCORD receiving this information

5.12.6 For blinded studies, the blind will be broken by ACCORD before SUSARs are reported to the REC (if applicable) and CA.

5.12.7 SUSARs reported for participants who, subsequent to blind break, were known to be receiving placebo, WILL NOT be reported to the CA unless the PI considers that the event may be related to a component of the placebo.

The trial team WILL NOT be informed of the unblinding result.

5.12.8 In order to maintain the blind, the trial team will only be informed that unblinding procedures were followed, and that potential SUSARs would have been reported when necessary to the CA.

5.12.9 SUSAR reports will be sent to the MHRA electronically via the ICSR Submissions website (https://icsrsubmissions.mhra.gov.uk/login).

5.12.10 Any relevant follow-up information will be submitted to the MHRA as appropriate.

5.12.11 ACCORD will inform the Chief Investigator (CI) and Trial manager (TM) of all 'potential' SUSARs and any other arising safety information, this include SUSARs occurring in other trials sponsored by ACCORD and using the same IMP. For multicentre studies, the CI and TM will then inform all locations that a 'potential' SUSAR has been reported to the Sponsor. A basic description of the event will be provided, but the locations will remain blinded. The Sponsor should be copied into the correspondence to all locations.

5.13 Urgent Safety Measures (USMs)

5.13.1 If a safety issue is identified during a clinical trial, PIs must act immediately to protect participants from any immediate threat to their health and safety. PIs may implement a deviation from or change to the protocol to eliminate an immediate hazard to trial participants without prior approval from the REC and the MHRA. This action comprises a USM. The PI must inform the CI and the Sponsor immediately when a USM is implemented. The CI, acting on behalf of the Sponsor, must contact the Clinical Trial Unit at the MHRA (ideally within 24 hours and no later than 3 days after the measures are taken) and discuss the issue with a medical assessor immediately (+44 (0) 20 3080 6456).

5.13.2 The CI must then notify the MHRA in writing within 7 days of implementation of measures. Notification is usually by email (clintrialhelpline@mhra.gov.uk). For trials which have gone through the Combined Review process, the USM written notification should be submitted via the Integrated Research Application System (IRAS) system. Written notification in the form of a substantial modification is also required and must be submitted to the MHRA, the REC and ACCORD. The substantial modification covering the changes made as part of the USM should be submitted within approximately two weeks of notification to the MHRA.

5.13.3 Notification of a USM should be delivered by:

- Sending an email to clintrialhelpline@mhra.gov.uk marked urgent safety measure or submitting the report via IRAS; and
- Emailing ACCORD at safety@accord.scot marked urgent safety measure; and

- Sending an email to the relevant main REC (required only for studies NOT submitted via Combined Review. For studies submitted via Combined Review, the urgent safety measure (USM) notification should be submitted in IRAS. No additional notification is required to the REC), marked urgent safety measure; and
- Sending an email to the relevant NHS R&D offices, marked urgent safety measure.

5.13.4 A copy of the notification and receipt must be filed in the ISF and in the TMF or Sponsor File.

5.13.5 Form CR010-F01 (Protocol Violation Reporting Form) will be completed by the PI and "urgent safety measure" will be indicated in accordance with SOP CR010 (Management of Protocol Deviations and Violations) and emailed to QA@accord.scot. The QA Manager, or designee, will ensure the information is forwarded to the sponsor's representative to assess if the risk/benefit balance of the study has been altered and if it is appropriate for NHSL/UoE to continue as the sponsor.

5.14 Expedited Reporting of Other Events

5.14.1 The following safety issues will also be reported to ACCORD in an expedited fashion, using the same methods (as described in section 5.10).

- An increase in the rate of occurrence or a qualitative change of expected SAR, which is judged to be clinically important.
- Post-study SUSARs that occur after the trial participant has completed a clinical trial and are notified by the PI to the sponsor (to be reported to the MHRA like regular SUSAR as mentioned in section 5.12).
- SARs occurring to a participant after the treatment of that participant has ended if the investigator becomes aware of them,
- New events related to the trial or the development of the IMPs and likely to affect the safety of the participants.
- Recommendations of the DMC where relevant for the safety of the trial participants.
- Any reaction due to a NIMP that is likely to affect the safety of trial participants.
- In the case of advanced therapy investigational medicinal products, relevant safety information regarding the procurement or the donor
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5.14.2 With the exception of post-study SUSARs, the above mentioned events are not to be reported to the MHRA as SUSAR, but they might require other action, such as Urgent Safety Measures. A copy of the report and any follow-up information and correspondence will be kept in the TMF or Sponsor File.

5.15 Pregnancy Reporting

5.15.1 Pregnancy is not considered to be an AE or SAE, however the PI must collect pregnancy information for any female study participants or female partners of male study participants who become pregnant while participating in a study.

5.15.2 Any pregnancy that occurs in a trial participant or their partner during a study should be followed to outcome. In some circumstances, it may be necessary to monitor the development of the newborn for an appropriate period post-delivery in accordance with the study protocol.

5.15.3 The PI will record the information on Form CR005-F02 (Pregnancy Notification Form) and send this to the ACCORD office (details found in section 5.9) within 14 days of being made aware of the pregnancy.

5.16 Follow-Up

5.16.1 After recording and reporting safety events, it is the responsibility of the PI to follow-up the affected participant(s) until resolution of the event or death of the participant(s).

5.16.2 If the outcome of an initial report of an event is one of the following outcome options:

- Condition still present and unchanged
- Condition deteriorated
- Condition improving

Then the PI must follow-up with the participant(s). Unless otherwise defined in the protocol, a safety report will not be considered complete until the outcome is:

- Completely recovered (including date of recovery)
- Recovered with sequelae (including date of recovery)
- Death (including date of death)

5.16.3 In the case of parent-child reports where the seriousness criteria have been assessed as "Congenital anomaly/birth defect", the PI must follow-up the event and provide the sponsor with any relevant updated information until the trial has ended.

5.16.4 All new information/follow-up information must be initialled and dated on the follow-up reports.

5.16.5 If the diagnosis or event description has changed as a result of follow-up, then expectedness should be reassessed by the location PI.

5.16.6 Follow-up reports should be submitted to the sponsor (ACCORD) as per section 5.10. If required, the Follow-Up Sign Off Sheet (CR005-T06) should be completed alongside the original SAE form.

5.16.7 If, after follow up, resolution of an event cannot be established, an explanation should be recorded on the CRF or AE log or additional information section of SAE form. Participant will be considered lost to Follow-up.

5.17 External Contracting of SAE, SAR and SUSAR Reporting

5.17.1 Expedited reporting may be contracted to an external facility for individual studies. Study specific expedited reporting will be detailed in the protocol.

5.18 Requests for SAE Line Listings

5.18.1 Requests for SAE line listings for specific trials can be made by the trial team (e.g. CI, Trial Manager, statistician) to the ACCORD office via safety@accord.scot.

5.18.2 A minimum of 2 weeks notice should be given by the requestor to ACCORD for the generation of a trial-specific line listing.

5.18.3 The request should detail the trial name and the reporting period required.

5.19 Data Monitoring Committee Meetings

5.19.1 Line listings, unless stated otherwise in the Data Monitoring Committee (DMC) Charter, will be reported by the CI, or designee, to the DMC and/or the Trial Management Group (TMG) and/or the Trial Steering Committee (TSC) as appropriate. Listings may be requested for this purpose as detailed in 5.18.

6 References and Related Documents

- The Medicines for Human Use (Clinical Trials) Regulations, (SI 2004 No. 1031) as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

- European Commission Guidance Document 'Detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use', ("CT-3"), (2011/C 172/01)
- National Institute for Health Research Clinical Trials Toolkit, Oct2024
- MHRA Guidance - Clinical trials for medicines: collection, verification, & reporting of safety events – updated 01-Oct-2025
- CR005-T01 SAE / SAR / SUSAR report
- CR005-T02 Adverse Event Flowchart – Reporting
- CR005-T03 Adverse Event Flowchart – Identifying
- CR005-T04 Parent-Child SAE report
- CR005-T05 CTIMP Adverse Event Log
- CR005-T06 Follow-Up Sign Off Sheet
- CR005-F02 Pregnancy Notification Form
- CR010 Management of Protocol and GCP Deviations and Violations
- PV001 Pharmacovigilance: Receipt, Onward Reporting and Follow-Up of Safety Reports

7 Document History

Version Number	Effective Date	Reason for Change
1.0	22 MAR 2011	N/A
2.0	14 SEPT 2011	Amend reporting forms and clarify procedures
3.0	20 FEB 2014	Amended procedure to follow ACCORD internal procedures, modified fax cover sheet and reporting forms
4.0	13 MAR 2017	Amended procedures to align with ACCORD internal procedures associated with PV001. SOP now captures procedures for the assessment of AEs in PI absences and which version of the RSI to use when assessing SUSARs. Updated information regarding the reporting of USMs added. ACCORD contact details have been updated throughout the SOP. Updated all associated forms and templates. CR005-W01 made obsolete. Relocation of the AE Log (CR005-T05) from CR007 to CR005.
5.0	21 MAR 2018	Addition of CR005-T06 CTIMP SAE Follow-Up Sign Off Sheet. CR005-T01 updated.

6.0	10 JUNE 2020	Clarification on fatal and life-threatening SARs (always considered unexpected unless RSI states that the IMP can cause fatal SARs). Inclusion of definition on Reference Safety Information (RSI). Clarification that MHRA-approved version of RSI must be used to assess expectedness of SARs. Clarification of respective roles of PI and CI in safety reporting. Several minor changes in wording.
7.0	08 JUN 2023	Addition of "onset date" description Update to include PhV Manager and PhV Officer responsibilities. Removal of fax mentions. Update of 5.13 – USM following the combined review process becoming effective Update of the SUSAR submission to include ICSR submission website and remove the eSUSAR portal as this will not be used after 01-Oct-2022 Update of the SUSAR submission rules to REC to include the trials submitted via Combined Review Removal of CR005-F01 Cover Sheet and Return Receipt Update of 5.2.3 to clarify that SAE should be reported with one SAE per SAE form. Addition of 5.9.3 on action to take if identifiable data are provided. CR005-F02 (now v8.0), CR005-T01 (now v6.0) and CR005-T04 (now v3.0) have been updated with minor administrative changes.
8.0	17 JUL 2025	SOP and associated documents CR005-T01, CR005-T02, CR005-T03, CR005-T04, CR005-T05, CR005-T06 and CR005-F02 updated to align with new ACCORD branding. Update of 5.12.2, 5.13.4 and 5.14.3 as no REC notification is required for studies submitted via Combined Review.

		Addition of 5.16.9 to clarify lost to follow-up situations. Update of 5.12.3 to clarify the MHRA timeline for reporting SUSAR. Update of 1.2, PhV definition according to the WHO. References: removal of the European Commission Guidance as it now obsolete and not applying to the UK. CR005-T01 (now v8.0) updated previously to indicate definitions and clarification for the capture of Diagnosis, Causality and Expectedness. CR005-T02 (now v4.0) updated to remove mention of fax. CR005-T04 (now v4.0) updated to make it easier to complete, following the template of CR005-T01
9.0	28 APR 2026	Updated to align with new Clinical Trial Regulations and ICH-GCP (R3). 5.1.4 Definition of AR - covers events linked to medication errors, misuses and abuses. 5.1.5 Definition of SAE - addition of clarification about hospitalisation 5.6.3 Addition of clarification about SARs that should be treated like SUSARs. 5.12 Removal of the mention to submit SUSAR to REC. 5.12.5 Clarification of the timeline to report SUSAR FU info to the CA. 5.12.11 Clarification and update that ACCORD will inform CI of all SUSARs, and CI/TM will inform locations if appropriate. 5.13 Update of the USM timeline 5.14 Update of the Expedited reporting of other events. CR005-T01 SAE form updated to include a question for blind trials about the event being possibly related to the placebo or not. CR005-T02 AE flowchart updated to remove mention of REC submission.

		CR002-T05 AE log updated to clarify that MedDRA coding is mandatory for all trials addition of a column to say if IMP received prior to AE or not and to add IMP name.

8 Approvals

Sign	Date
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CR005 Identifying Recording and Reporting AEs and USMs for CTIMPs v9.0

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Signature Date: 2026-02-13 - 2:25:19 PM GMT - Time Source: server- IP address: 81.109.241.151

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