

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 drug-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 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

Parties using this SOP must visit www.accord.scot to guarantee adherence to the latest version.

- 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 site 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.

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. Any hospitalisation that is planned post randomisation, will meet the SAE criteria.

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 Reference Safety Information (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) in the European Union (EU) 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 in the EU 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 site 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 Reference Safety Information (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 reference safety information (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 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 every day 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, 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 to the Research Ethics Committee and the Competent Authority

- 5.12.1 ACCORD is responsible for reporting of SUSARs to the Research Ethics Committee (REC) and Competent Authority(ies) (CA). SUSARs include events possibly related to:
- The IMP or comparators
 - 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
- 5.12.2 Fatal or life threatening SUSARs will be reported within 7 calendar days after ACCORD is first aware of the reaction. All other SUSARs will be reported within 15 calendar days after ACCORD is first aware of the reaction.
- 5.12.3 For blinded studies, the blind will be broken by ACCORD before SUSARs are reported to the REC and CA.
- 5.12.4 SUSARs reported for participants who, subsequent to blind break, were known to be receiving placebo, WILL NOT be reported to the REC and CA.
- The trial team WILL NOT be informed of the unblinding result.**
- 5.12.5 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 where necessary to the REC and CA.

- 5.12.6 SUSAR reports will be sent to the MHRA electronically via the ICSR Submissions website (<https://icsrsubmissions.mhra.gov.uk/login>).
- 5.12.7 SUSAR reports will be sent to the REC with the Health Research Authority (HRA) Safety Report Form. For CTIMPs submitted via combined review: MHRA will liaise with the REC if deemed appropriate. There is no requirement to email the REC.
- 5.12.8 Any relevant follow-up information will be submitted to the REC and MHRA as appropriate.
- 5.12.9 In multicentre studies, ACCORD will inform other sites that a 'potential' SUSAR has been reported to the Sponsor. The PhV Manager, or designee, will inform all sites in a study that a potential SUSAR has been reported for that study. If the study is being coordinated by a unit/group/individual, responsibility for informing all sites of a SUSAR may be delegated to them. A basic description of the event will be provided, but the sites will remain blinded.

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 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 3 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 amendment is also required and must be submitted to the MHRA, the REC and ACCORD. The substantial amendment 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, 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).
1. An increase in the rate of occurrence or a qualitative change of expected SAR, which is judged to be clinically important.
 2. Post-study SUSARs that occur after the trial participant has completed a clinical trial and are notified by the PI to the sponsor.
 3. New events related to the trial or the development of the IMPs and likely to affect the safety of the participants.
 4. Recommendations of the DMC where relevant for the safety of the trial participants.
 5. Any reaction due to a NIMP that is likely to affect the safety of trial participants.
- 5.14.2 The PhV Manager, or designee, is responsible for informing the main REC and MHRA of these safety issues within the same timelines as described in section 5.12. A copy of the letter 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 has 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 site PI.

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

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
- 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, 2012
- European Commission Guidance Document 'Guidance documents applying to clinical trials - guidance on investigational medicinal products (IMPs) and 'non investigational medicinal products' (NIMPs)(Volume 10, Clinical Trials), Rev. 1, March 2011
- MHRA Guidance - Clinical trials for medicines: manage your authorisation, report safety issues – updated 08-Nov-2022
- 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 CTIMP SAE 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

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		<p>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</p> <p>Update of the SUSAR submission rules to REC to include the trials submitted via Combined Review</p> <p>Removal of CR005-F01 Cover Sheet and Return Receipt</p> <p>Update of 5.2.3 to clarify that SAE should be reported with one SAE per SAE form.</p> <p>Addition of 5.9.3 on action to take if identifiable data are provided.</p> <p>CR005-F02 (now v8.0), CR005-T01 (now v6.0) and CR005-T04 (now v3.0) have been updated with minor administrative changes.</p>
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8 APPROVALS

Sign	Date
<p><i>Camille Bach</i></p> <p>AUTHOR: Camille Bach, Pharmacovigilance Manager, UoE, ACCORD</p>	<p>May 23, 2023</p>
<p><i>Maria Potter</i></p> <p>APPROVED: Maria Potter, Pharmacovigilance Officer, UoE, ACCORD</p>	<p>May 24, 2023</p>
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CR005 Identifying Recording and Reporting AEs and USMs for CTIMPs v7.0

Final Audit Report

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