PHARMACOVIGILANCE:
MedDRA CODING SERIOUS ADVERSE EVENTS

DOCUMENT NO.:	**PV004 v4.0**
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ISSUE DATE:	**07 MAR 2024**
EFFECTIVE DATE:	**21 MAR 2024**

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 In order to facilitate the presentation, comparison and sharing of safety data, adverse event information associated with the use of pharmaceutical products need to be classified according to the standardised medical terminology MedDRA (Medical Dictionary for Regulatory Activities).

1.3 The Developmental Safety Update Report (DSUR) contains line listings of all study Serious Adverse Events (SAE), Serious Adverse Reactions (SAR) and Suspected Unexpected Serious Adverse Reactions (SUSAR) received during the period of the DSUR. The DSUR line listings must be MedDRA coded in a consistent and methodical manner.

1.4 The stated diagnosis of all SARs and SUSARs need to be MedDRA coded and cross referenced with the Reference Safety Information (RSI) approved by the relevant competent authorities at the time of the event, for that investigational medicinal product.

2 PURPOSE

2.1 The purpose of the Standard Operating Procedure (SOP) is to describe the procedures for MedDRA coding serious adverse event information for DSUR line listings, SAR and SUSAR reports

2.2 This SOP does not cover MedDRA coding for EudraCT results. These will be covered by the specific study protocol and by any relevant agreements.

3 SCOPE

3.1 This SOP will apply to ACCORD staff responsible for MedDRA coding serious adverse events for studies sponsored by NHSL and/or UoE.

3.2 This SOP does not provide a procedure or instruction on how to code with MedDRA. Further information can be found at www.meddra.org (see 5.1.1).

4 RESPONSIBILITIES

4.1 Individuals carrying out MedDRA coding must ensure they are adequately trained to perform MedDRA duties (see 5.1.1).

4.2 For MedDRA coding events for tabulation in DSURs, it is the responsibility of a member of the Pharmacovigilance (PhV) team or designee to:

- Generate a line listing from the ACCORD PhV database(s) in a spreadsheet format (e.g. Excel).
- Save the line listing in the designated section of the electronic study folder on SharePoint.

4.3 It is the responsibility the PhV team or designee performing the MedDRA coding for the DSUR line listing to:

- Add the line listing header template (PV004-T01)
- Indicate their name as the MedDRA coder
- Indicate the version of MedDRA being used
- Create additional columns for System Organ Class (SOC) and Preferred Term (PT).
- Provide a PT and SOC term from within MedDRA for the Diagnosis terms (event or symptom).
- Save the completed MedDRA coded line listing in the designated section of the electronic study folder on SharePoint
- Ensure that another trained MedDRA coder is assigned to perform a Quality Control (QC) check.

4.4 It is the responsibility of the assigned member of the PhV team or designee performing the QC check to QC each MedDRA coded line listing to ensure the correct SOC and PT have been allocated.

4.5 The PhV team member or designee in receipt of a SAR or SUSAR must code the diagnosis in the safety report, and check that the PTs comprising an 'expected' event are consistent with those listed in the relevant RSI. This check should be confirmed on the SAE summary sheet (PV001-F01) as part of the QC sign off.

5 PROCEDURE

5.1 MedDRA Training

5.1.1 In order to facilitate the implementation and correct use of MedDRA, individuals performing MedDRA coding duties must receive MedDRA specific training as agreed by their line manager. This can be in the form of face-face training or by attending online webinars, both provided by the MedDRA Maintenance and

Support Services Organisation (MSSO). All training will be documented in staff training records.

5.2 Line Listings

5.2.1 A member of the PhV team or designee will generate a line listing from the ACCORD PhV database(s) in a spreadsheet format (e.g. excel). Once the SAE line listing has been generated the spreadsheet can be amended to include the minimal dataset:

- Study name
- Participants ID
- Initial received date
- Latest received date
- Diagnosis
- Description of SAE
- Date of Onset or Date of Event
- Outcome

5.2.2 The line listing header template (PV004-T01) will then be added to the spreadsheet, to facilitate version documentation and QC checks of the sheet prior to finalisation.

5.2.3 Additional columns should be created to capture the SOC and PT term pairs for each medical event (for example any diagnosis, condition, medical/surgical procedure etc.) detailed in the SAE diagnosis.

5.2.4 The member of staff performing the MedDRA coding will document the version of MedDRA being used and the date of coding in the line listing header. The same version of MedDRA should be used to code serious adverse events throughout the duration of the trial.

5.2.5 The name of the individuals coding and performing QC for all the events will be documented in the line listing header along with the date the QC task was carried out.

5.3 Coding all SAE Events

5.3.1 Each serious adverse event should be coded using the online web-based browser for MedDRA. Log-in details are held by from the PhV Team. The MedDRA version used should be the version documented in previous coding spreadsheets for the study in question or, at the time of first coding for the study, the most up-to-date version of MedDRA available at that time.

5.3.2 The staff member will MedDRA code the SAE diagnosis of each individual SAE captured in the line listing.

5.3.3 Only the exact information provided in the SAE diagnosis should be coded. All elements detailed in the diagnosis that can be coded in MedDRA should be coded.

5.3.4 If there is uncertainty over a medical event term detailed in the SAE Diagnosis, e.g. it cannot be found in the MedDRA database, then clarification should be sought from the research team.

5.3.5 For DSUR reporting purposes, only new SAE events reported to the sponsor or existing SAE events updated within the previous DSUR year will be MedDRA coded.

5.3.6 Investigators wishing to use MedDRA code data from the ACCORD safety databases for additional analyses should be made aware of the ACCORD coding practices detailed in this SOP, and should be advised to critically appraise the coding data provided to them, in advance of any analysis.

5.4 QC of all Coded Events

5.4.1 Once all SAE events have been fully MedDRA coded, the line listing document should be passed to another MedDRA trained member of staff to provide a full QC of all events and coded terms (SOC & PT).

5.4.2 During QC, if any queries should arise, these can be highlighted and discussed with the original coder. All queries can then be addressed in discussion between the initial coder and QC coder. Unresolved disagreements can be addressed by another trained member of the UoE Governance team.

5.4.3 The finalised (coded and QC'd) document should be version controlled and include the date of coding. The initial coder and QC coder will sign / date the document and file a copy in the study specific electronic folder on SharePoint and where applicable the Sponsor File or Trial Master File.

5.5 Coding Safety Report Diagnosis

5.5.1 On receipt of a SAR or SUSAR report form the documented diagnosis will be coded to PT level within the MedDRA dictionary. The PT term will be documented on the SAE summary sheet PV001-F01.

5.5.2 The PT term documented should be cross referenced with the approved RSI for the relevant IMP. If the PT matches a term in the RSI, then the event is expected. If the PT does not match the RSI, then the event is unexpected and will be considered a potential SUSAR.

5.5.3 The MedDRA version used should again be the version documented in previous coding spreadsheets for the study in question or, at the time of first

coding for the study, the most up-to-date version of MedDRA available at that time.

6 REFERENCES AND RELATED DOCUMENTS

- MedDRA Web Based Browser - https://tools.meddra.org/wbb/
- MedDRA - https://www.meddra.org/ - Training materials, reference documents and support links can be found here.
- PV004-T01 Line Listing Header template
- PV001-F01 SAE Initial Summary Sheet

7 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	28 MAR 2018	New SOP
2.0	24 JUL 2020	Clarification of use of RSI version approved by competent authorities; introduction of line listing header template to facilitate adherence to ALCOA; clarification of MedDRA version used for coding; sundry minor updates.
3.0	09 JUN 2023	Clarification on PhV Team responsibilities.
4.0	21 MAR 2024	Update of section 4.3, 5.2.3, 5.3.2 and 5.3.3 to reflect that only diagnosis terms will be MedDRA coded instead of the whole event description, removal of the MedDRA coding of outcome of Death. Update of Section 5.2.1 to add Initial Received Date" and "Latest Received Date" in the list of mandatory information on the Listing.

8 APPROVALS

Sign	Date
Camille Bach AUTHOR: Camille Bach, Pharmacovigilance Manager, UoE, ACCORD	Mar 6, 2024
Maria Hogg APPROVED: Maria Hogg, Pharmacovigilance Officer, UoE, ACCORD	Mar 6, 2024

 AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	Mar 7, 2024

PV004 Pharmacovigilance MedDRA Coding SAEs for DSURs v4.0

Final Audit Report 2024-03-07

Created:	2024-03-06 (Greenwich Mean Time)
By:	Gavin Robertson (v1grobe9@exseed.ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAGJGEVRAHg_kWBJSdB1_FFZkXAzcIdHyf

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Document created by Gavin Robertson (v1grobe9@exseed.ed.ac.uk)
2024-03-06 - 08:31:08 GMT- IP address: 90.251.187.219

Document emailed to Camille Bach (Camille.Bach@ed.ac.uk) for signature
2024-03-06 - 08:33:13 GMT

Document emailed to Maria Hogg (Maria.Hogg@ed.ac.uk) for signature
2024-03-06 - 08:33:13 GMT

Document emailed to Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk) for signature
2024-03-06 - 08:33:13 GMT

Email viewed by Camille Bach (Camille.Bach@ed.ac.uk)
2024-03-06 - 08:34:57 GMT- IP address: 104.47.11.126

Document e-signed by Camille Bach (Camille.Bach@ed.ac.uk)
Signature Date: 2024-03-06 - 08:36:17 GMT - Time Source: server- IP address: 192.41.114.226

Email viewed by Maria Hogg (Maria.Hogg@ed.ac.uk)
2024-03-06 - 09:13:31 GMT- IP address: 104.47.11.126

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Email viewed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
2024-03-07 - 08:08:07 GMT- IP address: 104.47.2.254

Document e-signed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
Signature Date: 2024-03-07 - 08:08:21 GMT - Time Source: server- IP address: 62.253.82.233

Agreement completed.

2024-03-07 - 08:08:21 GMT