Identifying, Recording and Reporting Adverse Events and Device Deficiencies for Regulated Medical Device Studies

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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 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 identifying, recording, reporting and receipting AEs and other safety events occurring in NHSL/UoE sponsored Clinical Investigations of Medical Devices (CIMDs) that fall under UK MDR 2002, EU MDR and EU IVDR.

3 Scope

3.1 This SOP applies to all clinical researchers undertaking CIMDs that fall under the UK MDR 2002, EU MDR and EU IVDR sponsored by NHSL and/or the UoE.

3.2 This SOP also applies to ACCORD PhV staff involved in safety reporting for all CIMD studies sponsored by UoE and/or NHSL.

4 Responsibilities

4.1 The ACCORD PhV team will be responsible for medical device vigilance for CIMD trials that are sponsored by NHSL and/or UoE. The sponsor may choose to delegate some or all PhV tasks to the Investigator.

4.2 The Investigator will be responsible for identifying and reporting AEs, and Serious Adverse Events (SAEs), Adverse Device Effects (ADEs), Serious Adverse Device Effects (SADEs), Anticipated Serious Adverse Effects (ASADEs) and Unanticipated Serious Adverse Device Effects (USADEs) and device deficiencies as detailed in this procedure. See Appendix 1 for definitions.

5 Procedure

5.1 Identifying and Recording AEs and SAEs

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

5.1.2 The risk analysis plan /protocol will define:

- What AEs or SAEs are not to be recorded, notified and/or reported.
- When AEs or SAEs will be identified.

5.1.3 The protocol will also define how AEs will be identified. Unless otherwise stated in the risk analysis plan/protocol, the Investigator(s) (or a member of the research team with delegated responsibility to do so – such delegation must be captured in the study site delegation log/contracts) will ask research participants at each trial visit about any hospitalisations, consultations with other medical practitioners, disability or incapacity or whether any other adverse events have occurred.

5.1.4 AEs and SAEs should be recorded from the time the participant signs the consent form to take part in the trial, unless otherwise defined in the risk analysis plan/protocol.

5.1.5 AEs may also be identified by support departments e.g. clinical biochemistry, haematology, radiology. Where notification of such abnormal values or measurements would not occur as standard clinical practice, the procedure for notifying the Investigator of such AEs must be clearly documented in the risk analysis plan/protocol.

5.2 Assessment of AEs

5.2.1 Each AE must be assessed for seriousness, causality, severity and expectedness by the Principal Investigator (PI) or another suitably qualified physician in the research team who is trained in recording and reporting AEs and who has been delegated this role. During PI absences, appropriately qualified, experienced and trained site staff may assess causality and report SAEs if they have been delegated this task on the delegation log by the PI.

5.2.2 For randomised double-blind studies, AEs will be assessed as though the trial participant was subjected to the device under investigation.

5.3 Assessment of Seriousness

5.3.1 The Investigator will make an assessment of seriousness (as defined in Appendix 1 – see SAE definition).

5.4 Assessment of Causality

5.4.1 The Investigator will also make an assessment of whether the AE is likely to be related to the device according to the following definitions:

- Unrelated: where an event is not considered to be related to the device.
- 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 device.

5.4.2 Where there are two assessments of causality (e.g. between PI and Chief Investigator (CI)), the causality assessment by the PI 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.

5.5 Assessment of Expectedness

5.5.1 If the AE is judged to be related to the device, the Investigator will make an assessment of expectedness based on knowledge of the event and any relevant product information as documented in the risk analysis plan report/protocol. The event will be classed as either;

- Expected: the reaction is consistent with the effects of the device listed in the risk analysis plan report/protocol/IB (Investigator Brochure).
- Unexpected: the reaction is not consistent with the effects listed in the risk analysis plan report/protocol/IB.

5.6 Assessment of Severity

5.6.1 The Investigator will make an assessment of severity for each AE according to the following categories:

- Mild: an event that is easily tolerated by the research 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.

The term 'severe' used to describe the intensity of an event should not be confused with the term 'serious', as defined in Appendix 1, 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.

5.7 Reporting SAEs/SADEs/ASADEs/USADEs to the Sponsor (UoE/NHSL)

5.7.1 The following events are considered reportable events and require reporting to the Sponsor:

- Any SAE that occurs irrespective of the causality and expectedness
- 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

- Any new findings/updates in relation to already reported events.
- Post-study USADEs that occur after the trial participant has completed a clinical trial should also be notified by the Investigator to the Sponsor.

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

5.7.2 The Investigator is responsible for reporting SAEs to ACCORD within 24 hours of becoming aware of the event.

5.7.3 SAE reports will be emailed as a .pdf file to safety@accord.scot using Template report CR012-T01 (SAE CIMD Form). Reports will be complete as far as possible and will be signed and dated by the Investigator.

5.7.4 The ACCORD PhV team will send an email to confirm receipt of the SAE 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.

5.7.5 Once an SAE report is received by ACCORD it will be entered onto the ACCORD PhV database by the ACCORD PhV team (PV005 Receipt, Onward Reporting And Follow-Up Of Safety Reporting For Regulated Medical Device Studies).

5.7.6 All SAE reports submitted to ACCORD, and any follow-up information and correspondence, will be kept by the Investigator in the Investigator Site File (ISF) and by the Sponsor in the Sponsor File or Trial Master File (TMF) if held.

5.7.7 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.

5.7.8 If there is a contractual obligation, the ACCORD PhV team will onward report any SAEs as required to the third party within the agreed timelines and as detailed in the study protocol and/or study specific procedure and/or contract.

5.7.9 Where applicable, SAEs, SADE or USADEs which occur at site must be reported on the NHS Boards/Trusts electronic incident reporting system (e.g. Datix). Reporting of

incidents must be carried out in accordance with the Boards/Trusts Incident and Accident reporting policy.

5.7.10 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 and that they must take steps to ensure that this does not reoccur, where appropriate.

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

5.8.1 The ACCORD PhV Team is responsible for reporting SAEs, where appropriate, to the CA. The reporting of SAEs to the MHRA (Medicines and Healthcare products Regulatory Agency) will not be required for medical devices that are UKCA / CE / CE UKNI marked for the purpose that is under investigation. The reporting of SAE and quarterly report to the MHRA is not required for devices registered with the MHRA as "Performance Evaluation" ONLY.

5.8.2 Any SAEs which indicate an imminent risk of death, serious injury or serious illness and that require prompt remedial action for other patients/trial participants, 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.

5.8.3 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.

5.8.4 In order to report SAEs to the CA, the ACCORD PhV team will use 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).

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.

5.8.5 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 will 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.

5.8.6 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:

- 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;
- 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;
- Any new findings in relation to any event referred to in points (a) and (b).

5.9 Expedited Reporting of SAEs to the Research Ethics Committee (REC)

5.9.1 Only reports of SAEs that are related to the study (i.e. they resulted from administration of any of the research procedures) and unexpected (i.e. 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.

5.9.2 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 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.

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

5.10 Follow-up of SAEs

5.10.1 After recording and reporting safety events, the Investigator will follow-up with the affected participant(s) until resolution of the event or death of the participant(s).

5.10.2 If the outcome of an initial report of an event is one of the following outcome options, the Investigator must follow-up with the participant(s):

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

5.10.3 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)

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

5.10.5 Follow-up reports will be submitted to the ACCORD PhV team as per section 5.7.3.

5.10.6 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.

5.11 External contracting of SAE, SADE and USADE Reporting

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

5.12 Reporting device deficiencies to the Sponsor

5.12.1 Device deficiencies will be documented on CR012-T02 Medical Device Deficiency Form and will be reported to the Sponsor (details in section 5.7) within 7 days of being made aware of the Device Deficiency for Device Deficiencies that are not linked to a potential SAE and within 24h for Device deficiencies linked to a potential SAE.

5.12.2 On receipt of device deficiency reports, the ACCORD PhV team 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 as SAE, the ACCORD PhV team will ensure that all the correct reporting procedures have been followed.

5.12.3 The ACCORD PhV team 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. Once a device deficiency report is received by ACCORD, it will be entered onto the ACCORD PhV database by the PhV team.

5.12.4 The Investigator will report device deficiencies to the relevant NHS Medical Physics department, if applicable.

5.12.5 Device deficiency reports submitted 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. See 5.10 for further details regarding follow-up.

5.12.6 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.

5.12.7 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.

5.13 Requests for SAE line listings

5.13.1 Requests for SAE line listings for specific trials can be made by the trial team to the ACCORD office via safety@accord.scot

5.13.2 A minimum of 2 weeks' notice should be given by the requester to ACCORD for the generation of a trial specific line listing.

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

5.14 Medical Device Quarantine

5.14.1 If the event is defined as serious i.e. a SAE or device deficiency that could have led to an SADE or USADE the Investigator must quarantine the device as soon as possible e.g. segregating the device from other equipment and labelling as not for use with contact details attached.

5.14.2 Until the CA and Sponsor has been given the opportunity to carry out an investigation, all items (together with relevant packaging materials) will be quarantined. They will not be repaired, discarded, returned to the manufacturer or removed from the site/organisation premises without agreement from the Sponsor.

5.14.3 Medical devices will not be sent to the CA unless this has been specifically requested. Investigators should contact the manufacturer to obtain information relating to the procedure for returning the device, where considered appropriate.

5.14.4 The device will be cleaned and decontaminated where appropriate, securely packaged, and clearly labelled, including the CA or manufacturer reference number if needed. Documentation regarding shipment and receipt of the device, where available, will be retained in the ISF.

5.15 Data Monitoring Committee meetings

5.15.1 Line listings, unless stated 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 5.13.

6 References and Related Documents

- 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)

- 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
- 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
- ISO 14155:2020 (Clinical investigations of medical devices for human subjects – Good Clinical Practice)
- MEDDEV 2.7/3 Revision 3 – Guideline on medical devices
- CR012-T01 SAE CIMD form
- CR012-T02 Medical Device Deficiency Form
- REC non CTIMP Safety Report Form
- GS002 Combined Risk Assessment

7 Document History

Version Number	Effective Date	Reason for Change
1.0	14 SEPT 2011	N/A – new procedure
2.0	02 OCT 2017	Amended procedures to align with ACCORD internal procedures associated with PV001. The definitions at section 5.1 have been updated in line with ISO 14155:2011 and MEDDEV 2.12/1 rev.8. SOP now captures procedures for the assessment of AEs in PI absences. ACCORD contact details have been updated throughout the SOP. SOP now captures procedures for medical device quarantine and reporting device deficiencies to Medical Physics.
3.0	31 JAN 2020	Updated throughout to align with EU Medical Devices Directive (93/42/EEC). Definitions updated in section 5.1. SOP, CR012-T01 and CR012-T02 names updated.
4.0	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 PhV team. Mentions to fax removed and CR012-F01 discontinued. Device Deficiency reporting timelines added to 5.12.1. Requirement for PhV team to enter

		Device Deficiencies added to 5.12.3. Addition of the quarterly summary submission (5.8.5). Addition related to receipt of identifiable information (5.7.10). CR012-T01 and CR012-T02 (both v3.0) updated to remove references to fax. CR012-T02 also now includes reporting timelines.
5.0	14 AUG 2025	SOP and associated documents CR012-T01 and CR012-T02, updated to align with new ACCORD branding. Updates/clarification of the definitions according to UK MDR 2002 and ISO 14155:2020. Update of 5.7.1 clarification about reportable events according to MEDDEV 2.7/3 as this is the document the MHRA is referring to. Update of 5.8.1 to make it clear that SAE and quarterly reports are not needed for studies that are device performance evaluation only. Update of 5.8.4 to clarify that MHRA template will be used for the quarterly report of SAE to the MHRA. Update of 5.8.5 and addition of reportable events as per MHRA guideline. Addition of 5.10.6 to clarify lost to follow-up situations. 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. CR012-T01 (now v4.0) updated to indicate definitions and clarification for the capture of Diagnosis, Causality and Expectedness. Addition of "Device deficiency that might have let to an SAE" as a seriousness criteria. Update of the seriousness criteria to follow ISO 14155:2020 definition of a SAE for a device study. New table format to include more than one device if needed. Addition of

		clarification about the additional info that can be provided. CR012-T02 (now v4.0) updated with new table format to make the capture of info easier. Addition of a question if the device deficiency might have led to an SAE and addition of a comment to complete a SAE form if this is the case.

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

APPENDIX 1: DEFINITIONS

Medical Device

Medical Device definition according to UK MDR 2002

A medical device is defined as any instrument, apparatus, appliance, material or other article whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which:

(a) is intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception, and

(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,

and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device

Medical Device definition according to EU MDR

'Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:
- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices

Investigational medical device

An investigational medical device is a medical device being assessed for safety, effectiveness or performance in a clinical investigation. This includes medical devices already on the market that are being evaluated for new intended uses, new populations, new materials or design changes. This includes medical devices already on the market that are being evaluated within their intended use in a post-market clinical investigation (interventional or non-interventional).

Adverse Event (AE)

Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons whether or not related to the investigational medical device and whether anticipated or unanticipated. This definition includes events related to the investigational device or the comparator. This definition includes events related to the procedures involved. For users or other persons, this definition is restricted to events related to investigational medical devices or comparators.

Serious Adverse Event (SAE)

An adverse event is defined as serious if it led to any of the following:

a. Death,
b. Serious deterioration in health of the subject, users, or other persons that either resulted in;
    - A life threatening illness or injury, or
    - A permanent impairment of body structure or a body function including chronic diseases, or
    - Inpatient or prolonged hospitalisation, or

- medical or surgical intervention to prevent life threatening illness or injury, or permanent impairment to a body structure or a body function,

c. Foetal distress, foetal death or a congenital abnormality or birth defect, including physical or mental impairment.

A planned hospitalisation for a pre-existing condition, or a procedure required by the risk analysis plan/protocol/Clinical Investigation Plan (CIP), without a serious deterioration in health, is not considered a serious adverse event.

Device Deficiency

Is an inadequacy of a medical device with respect to its identity, quality, durability, reliability, usability, safety or performance. Device deficiencies include malfunctions, user errors and inadequacy in the information supplied by the manufacturer including labelling.

Adverse Device Effect (ADE)

An ADE is an adverse event related to the use of an investigational medical device. This includes any adverse event resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, operation, or any malfunction of the investigational medical device.

An ADE includes any event that is a result of a use error or intentional misuse. Use error refers to an act or omission of an act that results in a different device response than intended by the manufacturer or expected by the user. Use error includes the inability of the user to complete a task. An unexpected physiological response of the subject does not in itself constitute a use error.

Serious Adverse Device Effect (SADE)

A SADE is an adverse device effect that has resulted in any of the consequences characteristics of a SAE.

Anticipated Serious Adverse Device Effect (ASADE)

A serious adverse device effect, which by its nature, incidence, severity or outcome has been identified in the current version of the risk analysis report, protocol or CIP.

Unanticipated Serious Adverse Device Effect (USADE)

Serious adverse device effect, which by its nature, incidence, severity or outcome has **not** been identified in the current version of the risk analysis report, protocol or CIP.

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