STANDARD OPERATING PROCEDURE (SOP)

Title: Case Report Form (CRF) Design and Development

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Reviewed and Approval

This reviewer agrees with the technical content of the document and that this document is approved for implementation at the Melbourne Children's.

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Document History

Revision	Modified by	Effective Date [DD/MMM/YYYY]	Description of Change
1.0	Laura Galletta	04/SEP/2026	New Issue

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1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure to be followed when designing and developing Case Report Forms (CRFs) for use within a clinical trial.

Case Report Forms can be in either paper and/or electronic format. This SOP focuses on electronic CRF (eCRF) design and development.

1.1. Quality Improvement

The design of the CRF and its completion has a direct impact on the quality of the data collected during a clinical trial. A well designed CRF will:

- ensure that no essential data is missed
- ensure that data queries are kept to a minimum
- aid in data management and data verification; and
- assist with statistical analysis and reporting.

2. BACKGROUND

Protocol-required data can come from a number of different sources such as interactive response technologies (IRTs), clinical outcome assessments (COAs), patient-reported outcomes (PROs), wearable devices, and central laboratory data. A key component of protocol data sources are case report forms, defined in ICH-GCP E6 (R3) as "a data acquisition tool designed to record protocol-required information to be reported by the investigator to the sponsor on each trial participant". CRFs will:

1. Record key elements of protocol data such as eligibility, demographics, administration of investigational product, and other endpoint data
2. Act as a "glue" for other trial data, such as recording date and time of samples taken at bedside that are subsequently centrally analysed
3. Fulfil reporting requirements such as participant safety through adverse event CRFs and protocol compliance through deviation CRFs.

The purpose of a CRF is to provide a standard, consistent, timely and structured way of capturing data in accordance with the clinical trial protocol, which will allow for efficient and complete data processing, analysis and reporting of trial endpoints. In addition, the CRF allows the Sponsor-Investigator to verify that the protocol is being followed.

3. SCOPE

This SOP applies to all clinical trials sponsored by the Murdoch Children's Research Institute (MCRI).

Where clinical research is sponsored by another institution, this procedure should be followed as far as possible, and in line with the contractual agreement between MCRI and the other institution, if data management services are provided by MCRI.

This SOP is applicable to all MCRI researchers involved in clinical trials, including Sponsor-Investigators, Statisticians, Database Programmers/Developers, Data Managers, Clinical Trial Managers, Trial Coordinators and those holding Honorary positions, and describes the activities and best practice in the design and development of CRFs.

4. RESPONSIBILITY

Ultimately, it is the responsibility of the Sponsor-Investigator to ensure that the processes outlined in this SOP are followed. However, all staff covered by this SOP are directly responsible for implementing the procedures set out in this SOP, in accordance with their role and delegated duties.

Sponsor:

Holds the overall responsibility for CRF design. The sponsor may delegate this task to the Sponsor-Investigator for MCRI-sponsored clinical trials; this will be detailed in the Sponsorship Letter of Approval. The Sponsor-Investigator must sign the final approved version of the CRF and any subsequent amended CRFs. The Sponsor-Investigator will also need to approve the Data Management Plan (DMP) and Data Validation Plan (DVP).

Sponsor-Investigator (or delegate):

The Sponsor-Investigator must design the CRF and ensure it has undergone sufficient review by the appropriate personnel, including the trial statistician, clinical trial manager and/or data manager.

The Sponsor-Investigator is also responsible for conducting a review on the final draft of the CRF to ensure completeness, accuracy, reliability, and consistent intended performance. The Sponsor must ensure that any appropriate training has been conducted, that any related documentation is reviewed, and sign the change control form following any amendments that requires changes to the CRF design. The documentation for the release process of updated CRFs must be filed in the TMF.

Clinical Trial Managers/Data Managers:

Clinical Trial Managers/Data Managers are responsible for creating a DMP and DVP, and for performing validation of the CRF to demonstrate that it is fit for purpose. This should include comprehensive User Acceptance Testing (UAT). Compliance with the validation plan will ensure that sufficient testing has been conducted prior to the database going live. Any related documentation, such as CRF Completion Guidelines, must also be created to instruct other users.

Statistician:

The assigned statistician must review the CRF to determine that:

1. All required data is being collected to undertake the analyses of the protocol endpoints
2. The data being collected is in an appropriate format; and
3. The data being collected is in an assessable format.

5. PROCEDURE

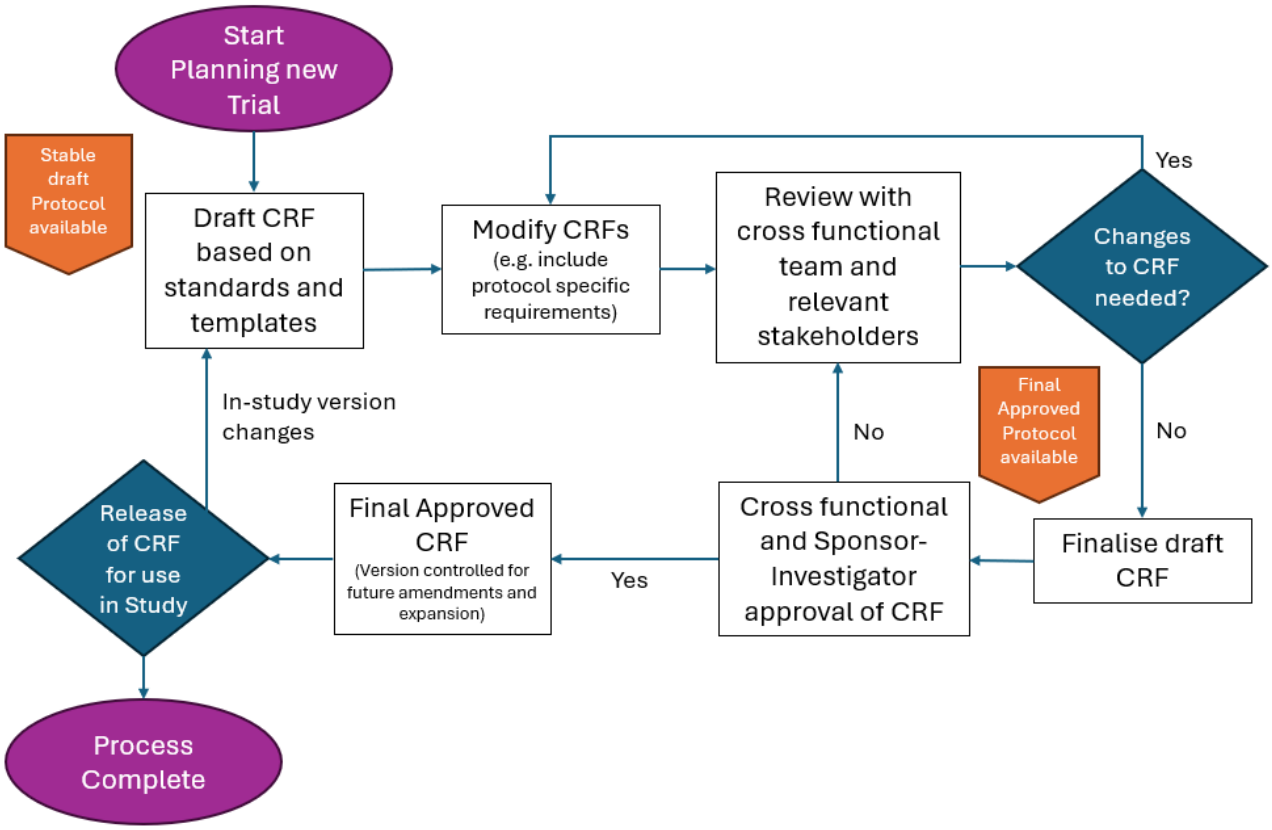
For general principles relating to CRF design and development, it is recommended that this SOP be used in conjunction with the following guidance document: MCTC232 | Guidance | Case Report Form (CRF) Design and Development. This document provides further guidance on how the requirements in this SOP can be fulfilled.

Once the protocol has been finalised (or is close to completion) the Sponsor-Investigator (or delegate) will draft the CRF in line with the protocol. The designing of the CRF must be based on the protocol requirements and the statistical analysis of the trial data.

The draft CRF will be reviewed by cross-functional team members and relevant stakeholders to ensure that all CRFs are performing as expected and that the required data is being collected to perform the statistical analysis of the trial.

It is the responsibility of the Sponsor-Investigator to provide documented approval for final version of the CRF prior to release.

5.1. Workflow



5.2. Format of CRF

The first step in designing a CRF is to determine whether a paper form or an eCRF will be used.

Where regulations or clinical trial complexities dictate that the project's CRF be established in a compliant, validated application, it is recommended that researchers use the OpenClinica electronic data capture tool.

For less complex clinical trials, researchers are recommended to use REDCap.

Paper CRFs may occasionally be a pragmatic choice in scenarios where use of an eCRF is difficult or impractical, but this is not recommended. The use of an eCRF is always encouraged over paper-based systems because they:

- Streamline clinical trials through real-time data validation, enhanced security and remote accessibility
- Enable data sharing across multiple sites/collaborators
- Ensure any updates to the CRF will be available to all sites simultaneously
- Can be built to detect any irregularities in the data, facilitating accurate and reliable data collection
- Allow for centralised and/or remote monitoring.

5.3. Data Acquisition Tool Selection

It is highly recommended that researchers use the electronic data acquisition tools available at MCRI. MCRI provides researchers with the following electronic data acquisition tools:

Data Acquisition Tool	Purpose	Benefit	Compliant with Regulations	Recommended Use
REDCap	Secure web application for building and managing online surveys and databases.	Free licence. Database programming experience not essential.	No - not compliant, although is capable of meeting strict regulatory requirements such as FDA 21 CFR Part 11, HIPAA, GCP and GDPR*. Note: REDCap eConsent does not meet regulatory requirements.	Low-risk, national, clinical trials.
OpenClinica	Secure web-based electronic data capture platform used to collect, manage, clean, store, and retrieve clinical trials data.	Validated and compliant tool meeting all local and international regulatory & data protection regulations. Increased data quality. Note: yearly licence fee applicable.	Yes - with all major global regulatory standards, including: FDA 21 CFR Part 11, HIPAA, GDPR, and GCP guidelines.	High-risk, complex, multi-site clinical trials, including APTs, International trials, trials regulated by the FDA and CTN trials.

Data Acquisition Tool	Purpose	Benefit	Compliant with Regulations	Recommended Use
Paper CRFs	Capture data as per protocol on paper.	Cost effective, no database programming experience required.	Yes – provided they follow strict guidelines for data integrity, security, and trial reconstruction.	Low-risk, single-site, non-CTN trials, where use of REDCap or other eCRF is not feasible.

REDCap **itself is not inherently compliant out-of-the-box. Compliance depends entirely on how Institutional IT Departments configure the software and how research team build the study. MCRI does not maintain a compliant REDCap environment.*

REDCap:

Research Teams can request a REDCap user account via: https://redcap.link/mcri-redcap-access-request

Assistance can be requested via the MCRI REDCap Helpdesk: https://redcap.mcri.edu.au/community/post.php?type=question&space=9

The MCRI REDCap Administrators provide generic training and advice to research teams but will not build the database. This responsibility lies with the Sponsor-Investigator (or delegate), including ensuring that an appropriate level of UAT of the eCRF has been completed prior to use.

OpenClinica:

Research Teams should contact OpenClinica@mcri.edu.au to request an OpenClinica user account and for assistance with the use of OpenClinica for clinical trials. The MCRI OpenClinica Administrators provide generic training and advice to research teams but will not build the database. This responsibility lies with the Sponsor-Investigator (or delegate), including ensuring that an appropriate level of User Acceptance Testing (UAT) of the eCRF has been completed prior to use.

5.4. Data Sources

Identifying all data sources in a clinical trial is critical to ensure patient safety, maintain scientific integrity, and support regulatory compliance. Researchers are encouraged to map and track all sources of data; some examples include data from:

- Electronic Medical Records (EMR)
- Mobile health apps/Wearables/devices data
- Laboratory & Imaging Systems data
- Central Laboratory results
- Biospecimen sample collection
- Patient-reported outcomes (PROs)/Patient diaries
- Data/results from independent SAE reviews
- Registries linked to a clinical trial

Identifying, mapping and tracking data sources establishes the traceability and validity required for evidence-based medicine. Developing and maintaining a Data Flow Diagram (DFD) will assist in this process. A DFD in clinical trials is a visual map that traces how information moves throughout a study. It illustrates the complete lifecycle of clinical data, from initial capture at the patient level to processing, review, storage, and final archiving, mapping the exact paths between stakeholders, devices, and databases.

5.5. CRF Design Procedure

- The Sponsor-Investigator (or delegate) will decide on the data acquisition tool that will be used to format the CRF (i.e., REDCap or OpenClinica)
- The Sponsor-Investigator (or delegate) will design/develop the CRF based on the requirements of the protocol and the statistical analysis of the data. A defined list of critical data items may help when developing the CRF. Refer to MCTC232 Guidance | CRF Design & Development.
- The Sponsor-Investigator (or delegate) will engage with experts (for example, the trial statistician, clinical trial manager/trial coordinator, database programmer, and/or co-investigators) on developing the CRF. The Sponsor-Investigator will ensure their expert advice is incorporated, and the Sponsor-Investigator (or delegate) will ensure evidence of their engagement is filed in the TMF
- The Sponsor-Investigator (or delegate) will ensure gathering of any other data is kept to a minimum (i.e., collect only what you need and not more) and is appropriate for the project, e.g., participant identifiers, visit dates, intervention information
- The Sponsor-Investigator (or delegate) is responsible for identifying all sources of data and for developing and maintaining a DFD
- Where additional data are planned to be collected (e.g., central laboratory data, central imaging data, patient-reported outcomes, etc.), the Sponsor-Investigator (or delegate) will ensure that the trial's DMP captures the requirement and source of this additional data collection, and a record of these activities are captured within the appropriate CRF
- Where the CRF contains identifiable participant data, the Sponsor-Investigator (or delegate) will ensure the Participant Information and Consent Form (PICF) contains adequate detail to appropriately inform the participant about how their data will be processed and stored. The Sponsor-Investigator (or delegate) is also responsible for ensuring any highly sensitive or personal data collected and processed for the trial is collected and processed in accordance with all relevant Institutional, local, national, and international data protection regulations
- The Sponsor-Investigator (or delegate) will ensure CRFs are finalised in a timely fashion to allow for real-time data collection, e.g., CRF sections relating to participant recruitment are finalised before recruitment commences
- The Sponsor-Investigator (or delegate) will ensure that the CRF follows a standardised, chronological order to allow for easy completion and facilitation of data management

and validation practices, statistical analysis, and reporting of the project. This will also help to minimise data queries returned to sites

- The Sponsor-Investigator (or delegate) will ensure that the terminology used in the CRF matches those used in the protocol and other key trial-related documents, particularly in the categorisation and coding of adverse events. Use of standard nomenclature is advised (e.g., MedDRA/CTCAE terminology for adverse events, SNOMED CT for clinical terms, ICD-10 for diagnoses, WHODrug.
- Where possible, variable naming in the eCRF should follow a recognised terminology standard (e.g. CDASH). This will assist with future data sharing, anonymisation practices, and interoperability of the dataset
- The Sponsor-Investigator (or delegate) will ensure that the design of the CRF allows for the site Principal Investigator (PI; or delegate) to confirm the observations recorded in the CRF. For eCRFs, this can be in the form of an electronic signature being applied via the PI's specific user account
- The Sponsor-Investigator (or delegate) will identify in the protocol (or in a separate document) where sections of the CRF will be used as source data. Refer to Melbourne Children's Clinical Trial (drug or device intervention) or Clinical Trial (non-drug, non-biological, non-device intervention) Protocol Templates
- Where trial participants are expected to complete questionnaires, the Sponsor-Investigator (or delegate) will ensure the questionnaires are approved by the Human Research Ethics Committee (HREC). Where validated questionnaires are available, the Sponsor-Investigator (or delegate) will use them in accordance with their licences/permissions. Where questionnaires are being created specifically for the project, the Sponsor-Investigator (or delegate) will ensure the language used within them is at a suitable level for the participant population
- At minimum, the Sponsor-Investigator (no delegation allowed) will approve the final version of any CRFs containing items required for the statistical analysis of the data. The Sponsor-Investigator may delegate approval of the final version of any other CRFs to appropriately trained personnel.
    - It is expected that the trial statistician will also review and approve the CRFs.
    - The Sponsor-Investigator (or delegate) will file evidence of any CRF approvals in the TMF.

5.6. General Principles and Guidance on CRF Design

Further guidance can be found in the MCTC232 Guidance | CRF Design & Development.

5.7. CRF User Acceptance Testing (UAT), Validation, and Approval

CRF user acceptance testing (UAT), validation, and approval are vital because they establish the foundation of data integrity. By thoroughly testing and formally approving the forms before patient enrolment commences, researchers ensure data is collected and recorded accurately, complies with the study protocol, and meets strict global regulatory standards.

- All CRFs should be thoroughly tested and approved prior to the database being released for use. Refer to MCTC235 SOP | User Acceptance Testing (UAT).
- Validation documents needed to sufficiently document validation activities include a risk assessment, data protection impact assessment (DPIA), validation plan, validation report, CRF Completion Guidelines, and a change control form.
- Note that the UAT and validation process should be performed across as many forms as possible to demonstrate that the CRF is fit for its intended purpose, operating as expected, and that appropriate data is being collected.
- Multiple users including the Sponsor-Investigator must be involved in the testing process. If it is not possible for the Sponsor-Investigator to validate part of the CRF, there must be confirmation of validation oversight from the Sponsor-Investigator, via email or signature.
- Evidence of completed UAT and a validation report should be signed by the Sponsor-Investigator, Statistician, Data Manager/s and Clinical Trial Manager. All UAT and validation documentation must be filed in the TMF.

5.8. CRF Release

The CRF release process should be documented by the Sponsor-Investigator (or delegate) in the TMF. The final approved CRF must be filed in the TMF and signed by the Sponsor-Investigator to confirm the release of each version. Alternatively, this approval and release can be documented on a Database Approval Form.

5.9. CRF Implementation and Training

- The Sponsor-Investigator (or delegate) will inform the participating trial site of the CRF to be used.
- Each member of participating trial site team should receive training on the CRF, as required. It is the responsibility of the Sponsor-Investigator (or delegate) to ensure that participating trial site staff are appropriately trained and have been delegated the duty to enter data into the CRF. Signature and Delegation Logs must have evidence of this responsibility delegated to trial site staff.

- Protocol training and CRF completion training can be embedded as part of the standard Site Initiation Visit (SIV) and site start-up training.
- Protocol training and CRF completion training must be documented in a training log and filed in the TMF and ISF.

5.10. CRF Amendments

- When amendments are needed to the approved CRF, the Sponsor-Investigator (or delegate) will document the necessary changes on a change control form. Refer to SOP | REDCap Project Change Control (Clinical Trials) or MCTC233 SOP | OpenClinica Change Management for OpenClinica users.
- The Sponsor-Investigator (or delegate) will keep a record of the changes made to the CRF template and document the rationale/justification for any changes to data items. The change control form should be completed and signed by the Sponsor-Investigator (or delegate). Refer to MCTC234 Template | CRF Change Version Log.
- There must be an audit trail for each amendment of the CRF, including version numbers of CRFs.
- The final amended CRF must undergo UAT prior to going live, with evidence of UAT filed in the TMF. The evidence must include any UAT failures as well as the rectification.
- The Sponsor-Investigator (or delegate, when applicable) will approve the final changes before implementing these changes to the live CRF. This approval must be documented and filed within the TMF.
- It is expected that there is also documented evidence of the statistician's approval, where any changes to the CRF relate to items required for the statistical analysis of the data.
- Once the amended CRF is approved, the Sponsor-Investigator (or delegate) will repeat the steps for CRF implementation (refer to Section 5.9 above).
- All documentation, decisions and/or communication must be filed in the TMF.

6. LIST OF EXPECTED OUTPUTS

- ☐ Trial-specific CRFs containing the items required to report on the trial objectives and analysis plan
- ☐ Documented evidence of completed user acceptance testing (UAT) of CRFs
- ☐ Documented evidence within the TMF confirming the Sponsor-Investigator and Statistician's approval of the CRFs, and for any subsequent amendments where changes relate to items required for the statistical analysis of the data
- ☐ Documented evidence that sites have been informed about the CRFs or subsequent amendments before use
- ☐ Evidence of training provided to participating trial site staff on the CRFs and subsequent amendments
- ☐ A record/log of any changes made to the CRF and, where required, the rationale for any changes to data items.

7. COLLABORATORS

Name / Role	Department / Group	Affiliation
Luke Stevens	*Clinical Epidemiology & Biostatistics Unit (CEBU)*	*MCRI*
Richard Hall	*Melbourne Children's Trial Centre (MCTC)*	*MCRI*
Billy McMahon	*Cancer Therapies*	*MCRI*

8. RELATED DOCUMENTS

- MCTC195 Template | Data Management Plan
- MCTC232 Guidance | CRF Design and Development
- SOP | REDCap Project Change Control (Clinical Trials)
- MCTC233 SOP | OpenClinica Change Management
- MCTC234 Template | CRF Change Control Log
- MCTC235 SOP | User Acceptance Testing (UAT)
- MCTC236 Template | UAT Testing Log Template
- MCTC076 Guidance | Electronic File Naming Conventions
- MCRI Data Governance Framework
- MCRI Data Management Policy

9. GLOSSARY

Case Report Form (CRF)
Data collection tool used to record all the protocol required information to be reported to the sponsor on each research/trial participant. The CRF may be paper or electronic.

Clinical Trial
The World Health Organization (WHO) definition for a clinical trial is: 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.

CRF Completion Guidelines
CRF completion guidelines are study-specific documents that provide step-by-step instructions for investigators to accurately and consistently fill out Case Report Forms (CRFs) for clinical trials. They are essential for ensuring data quality and integrity by clarifying how to record data, handle missing information, and follow specific rules outlined in the study protocol.

CTCAE (Common Terminology Criteria for Adverse Events)
CTCAE is a standardized grading system developed by the U.S. National Cancer Institute (NCI) to describe the severity of adverse events in cancer therapy. It provides a set of criteria with severity grades from 1 (mild) to 5 (death) to help clinicians, researchers, and regulators consistently document and analyse side effects.

Data Flow Diagram (DFD)
Data Flow Diagram (DFD) is a visual map that traces how information moves throughout a clinical trial. It illustrates the complete lifecycle of clinical data—from initial capture at the patient level to processing, review, storage, and final archiving—mapping the exact paths between stakeholders, devices, and databases.

Data Protection Impact Assessment (DPIA)
A DPIA is a systematic risk assessment process that helps organisations identify, assess, and mitigate risks associated with processing personal data. It is a requirement under laws like the EU's General Data Protection Regulation (GDPR) when processing is likely to result in a high risk to the rights and freedoms of individuals. A DPIA is conducted before data collection and processing begins and includes a description of the processing, an assessment of the risks, and the measures to address those risks.

Essential Documents
Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. These documents serve to demonstrate the compliance of the Investigator, Sponsor and monitor with the standards of Good Clinical Practice (GCP) and with all applicable regulatory requirements. Filing essential documents at the Sponsor site and participating trial sites also assists with the successful management of the trial.

Good Clinical Practice (GCP)
A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

International Conference on Harmonisation (ICH)
The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration.

ICD-10
ICD-10 is the 10th Revision of the International Statistical Classification of Diseases and Related Health Problems, a global standard for classifying diseases, injuries, and causes of death developed by the World Health Organization (WHO). It is an alphanumeric coding system used worldwide for health statistics, population health monitoring, and health service planning. Variations like the ICD-10-CM (Clinical Modification) are used in the United States for medical billing and diagnoses, while versions like the ICD-10-AM/ACHI/ACS are used in Australia for classifying admitted patient care.

Investigator

A person responsible for the conduct of the clinical trial at a trial site. There are four types of Investigator roles used to describe Investigators with different levels of responsibility for the conduct of clinical trials. These are described below.

Associate Investigator

Any individual member of the clinical trial team designated and supervised by the Principal Investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). May also be referred to as sub-investigator.

Coordinating Principal Investigator (CPI)

If a study is conducted at more than one study site, the Principal Investigator taking the additional responsibility for coordination of the study across all sites in a region is known as the Coordinating Principal Investigator (CPI). This role applies to externally sponsored studies where the Sponsor may be a collaborative research group, commercial Sponsor or an institution. The Principal Investigator at each site will retain responsibility for the conduct of the study at their site.

Principal Investigator (PI)

The PI is the person responsible, individually or as a leader of the clinical trial team at a site, for the conduct of a clinical trial at that site. As such, the PI supports a culture of responsible clinical trial conduct in their health service organisation in their field of practice and, is responsible for adequately supervising his or her clinical trial team.

The PI must conduct the clinical trial in accordance with the approved clinical trial protocol and ensure adequate clinical cover is provided for the trial and ensure compliance with the trial protocol.

Sponsor-Investigator

An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a participant. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

Investigator-Initiated Trial (IIT)

A clinical trial which is initiated and organised by an Investigator i.e. an individual rather than a collaborative group, company, or organisation. In these cases, the Investigator will take on the role of the trial sponsor and will then be responsible for the extensive GCP, and regulatory requirements associated with both the management and conduct of the trial.

Investigator Site File (ISF)
Filing repository controlled by the site Principal Investigator. It is held at the trial site and contains all the essential documents necessary for the site trial team to conduct the trial as well as the essential documents that individually and collectively permit evaluation of the conduct of the trial at the site and the quality of the data produced.

MedDRA
The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) developed MedDRA, a rich and highly specific standardised medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans. MedDRA is available to all for use in the registration, documentation and safety monitoring of medical products both before and after a product has been authorised for sale. Products covered by the scope of MedDRA include pharmaceuticals, biologics, vaccines and drug-device combination products.

Melbourne Children's
The campus encompassing all staff from The Royal Children's Hospital, Murdoch Children's Research Institute and Department of Paediatrics University of Melbourne who initiate or carry out research under one or more of these institutional affiliations.

Melbourne Children's Trials Centre (MCTC)
Melbourne Children's Trials Centre (MCTC) is a collaboration between the Royal Children's Hospital, The Murdoch Children's Research Institute, The Royal Children's Hospital Foundation and The University of Melbourne. This Centre brings together expertise in research, clinical practice, and education and incorporates anyone who initiates or carries out research under one or more of these institutional affiliations.

Murdoch Children's Research Institute (MCRI)
An Australian paediatric medical research institute located in Melbourne, Victoria, affiliated with the Royal Children's Hospital and the University of Melbourne. The institute has six research themes: cellular biology, clinical sciences, genetics, infection and immunity, population health, and data science.

Protocol
A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial.

Quality Control (QC)
The operational techniques and activities undertaken to verify that the requirements for quality of the trial-related activities have been fulfilled.

SNOMED CT (Systematized Nomenclature of Medicine--Clinical Terms)
SNOMED-CT is a comprehensive, multilingual clinical healthcare terminology used to standardize clinical documentation and facilitate the electronic exchange of health information. It includes codes, terms, synonyms, and definitions for concepts in human and non-human medicine and

can be mapped to other coding systems, such as ICD-10-CM. The terminology is a global standard for electronic health records (EHRs) that helps improve the quality and continuity of patient care.

Source Data

Source data is the original recording of an item of data. "All information in original records and certified copies of original records or clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial." (Section 1.51, Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA Comments).

Source Document

Source documents are documents which contain source data. When data is entered directly into your electronic Case Report Forms (data collection forms) or database, the Case Report Form/database becomes your source document for that information.

Sponsor

An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. For investigator-initiated trials, MCRI or RCH will act as the Sponsor but delegate many sponsor responsibilities to the Coordinating Principal Investigator. In this case the CPI has the role of both Sponsor and Investigator and hence the MCTC has adopted the term **Sponsor-Investigator** to reflect the dual role of the CPI in investigator-initiated trials.

Trial Master File (TMF)

Filing repository controlled by the Sponsor/Sponsor-Investigator. It is the collection of essential documents that allows evaluation of Sponsor responsibilities for the conduct of the clinical trial, the integrity of the trial data, and the compliance of the trial with Good Clinical Practice (GCP).

User Acceptance Testing (UAT)

User acceptance testing (UAT) is the final phase of software testing where real end-users test a product to ensure it meets their needs and functions correctly in a real-world scenario before deployment. It validates that the software aligns with business requirements and is user-friendly, unlike earlier testing phases that focus on technical specifications. This helps minimise risks and ensures the product is ready for release.

WHODrug

WHODrug is a global, validated dictionary of medicinal product information that is maintained by the Uppsala Monitoring Centre (UMC), the WHO Collaborating Centre for International Drug Monitoring. It contains information on a wide range of products, including drugs, vaccines, and herbal remedies, and is used by the biopharmaceutical industry for drug coding, patient safety, clinical trials, and pharmacovigilance.

10. REFERENCES, LEGISLATIONS AND STANDARDS

- Australian Commission on Safety and Quality in Health Care. The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials. Sydney: ACSQHC; 2022
- NHMRC Australian Code for the Responsible Conduct of research (2018)
- NHMRC National Statement on Ethical Conduct in Human Research (2025)
- ICH-GCP (http://www.ich.org/); in particular ICH-GCP R6 (E3).
- TGA Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice ICH E6 (2) 2016 – Annotated with TGA comments available at: https://www.tga.gov.au/publication/note-guidance-good-clinical-practice
- Data Protection Act 2018: https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted
- For electronic data capture, FDA 21 CFR Part 11 establishes and defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable, and equivalent to paper records.
- MCRI's Data Governance Framework defines minimum standards for Data Management and Data Governance practices when collecting and handling data.

DOCUMENT END