

STANDARD OPERATING PROCEDURE (SOP)

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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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This document is effective from the date of the approval signature and will be reviewed in three years, or earlier if required.

Document History

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1. PURPOSE

The purpose of this SOP is to define a standardised and controlled process for the identification, generation, assignment, communication, response, review, resolution and closure of data queries within OpenClinica. The SOP is intended to ensure that discrepancies, omissions and inconsistencies in clinical trial data are identified and appropriately investigated and resolved in a timely manner, while maintaining data integrity, traceability and an appropriate audit trail.

The purpose of query management is to ensure that clinical trial data are accurate, complete, consistent, traceable, and fit for analysis, while ensuring that queries are managed consistently and in accordance with the protocol, Data Management Plan, Data Validation Plan, and applicable regulatory and institutional requirements.

The SOP also establishes roles and responsibilities, query management timelines, escalation requirements and oversight processes to support effective data cleaning and ensure that clinical trial data are of sufficient quality for database lock and analysis.

1.1. Quality Improvement

This SOP improves the quality of clinical trial data by establishing a standardised, controlled and documented process for managing data queries, and in turn, increasing the quality of data for statistical analysis.

2. BACKGROUND

Accurate, complete and reliable data are essential for the quality and integrity of clinical trials. Data queries provide a controlled mechanism for identifying, investigating and resolving discrepancies, omissions, inconsistencies or potential errors in clinical trial data.

Effective query management is an integral component of clinical trial data cleaning and validation. It supports data quality, maintains traceability of data review activities and enables monitoring of outstanding or recurring issues. Query management is particularly important during final data review and prior to database lock.

OpenClinica provides functionality to support query management arising from automated validation checks, manual data review, source data review, monitoring, medical review, data reconciliation and other data management activities. Queries should be clear, specific and raised in a timely manner, with responses appropriately reviewed and documented before resolution and closure.

This SOP defines the standardised process and responsibilities for managing queries in OpenClinica, from identification and generation through to response, review, resolution and closure, in accordance with applicable study procedures, regulatory requirements and Good Clinical Practice (GCP).

3. SCOPE

This SOP applies to all clinical trials sponsored by the Murdoch Children's Research Institute (MCRI) and is applicable to all MCRI researchers involved in clinical trials, including Sponsor-Investigators, Statisticians, Database Programmers/Developers, Data Managers, Clinical Trial Managers/Trial Coordinators, Clinical Trial Assistants, Data Assistants and those holding Honorary positions within MCRI.

This SOP applies to clinical trials using OpenClinica as an Electronic Data Capture (EDC) system where queries are raised to clarify, correct, or confirm clinical trial data.

It applies to queries arising from:

- automated edit checks and validation rules
- manual data review
- review of source data or Case Report Forms (CRFs)
- cross-form or cross-visit inconsistencies
- missing or incomplete data
- external data reconciliation
- laboratory, imaging, safety, or other external data
- protocol or eligibility review
- medical review
- data listings and data review reports; and
- other data quality activities identified during the conduct or close-out of the trial.

4. RESPONSIBILITY

Reviewing, cleaning and validating data is the responsibility of the research project team. The following is the responsibility matrix for data validation activities:

Function	Activities and Responsibilities	Scope
Data Manager Data Management Team	• Establishing and maintaining the query management process • Ensuring queries are raised consistently and appropriately • Reviewing queries for clarity, relevance, and appropriateness • Monitoring query status and time to completion • Reviewing query responses • Closing queries when adequately resolved • Escalating overdue or unresolved queries as appropriate • Maintaining query management metrics and reports • Ensuring query activities are appropriately documented and traceable; and • Performing final query reconciliation prior to database lock.	Trial Coordinating Centre (Sponsor)

Function	Activities and Responsibilities	Scope
Clinical Trial Manager Study Team	- Supporting identification and review of data discrepancies - Ensuring clinically significant issues are appropriately escalated - Supporting participating trial sites in resolving outstanding queries - Monitoring site performance where required; and - Participating in final query review and database lock activities.	Trial Coordinating Centre (Sponsor)
Trial Monitor	- Identifying and communicating data discrepancies - Supporting query resolution; and - Escalating outstanding or recurring issues in accordance with the study monitoring plan.	Trial Coordinating Centre (Sponsor)
Medical Monitor/Clinical Reviewer	Where applicable, the Medical Monitor or designated clinical reviewer is responsible for reviewing and resolving medically complex or clinically significant queries within their area of responsibility.	Trial Coordinating Centre (Sponsor)
Sponsor-Investigator	- Overseeing that participating trial site responses to clinically relevant queries are accurate and supported by source documentation - Ensuring that required corrections are made by appropriately authorised personnel - Ensuring unresolved clinically significant issues are appropriately addressed before database lock; and - Overall oversight and review of data collected.	Trial Coordinating Centre (Sponsor)
Participating Trial Site Team Site Data Manager	- Reviewing and addressing data clarification requests/queries in relation to their site's data - Investigating queries against source documentation and other available information - Providing accurate and timely responses - Correcting data where appropriate - Documenting the reason for changes where required; and - Escalating issues to the Site Principal Investigator or appropriate clinician where required.	Participating Trial Site Team
Site Principal Investigator	- Reviewing queries assigned to their site - Investigating queries against source documentation and other available information - Providing accurate and timely responses - Correcting data where appropriate - Documenting the reason for changes where required - Ensuring responses are provided only by	Participating Trial Site Team

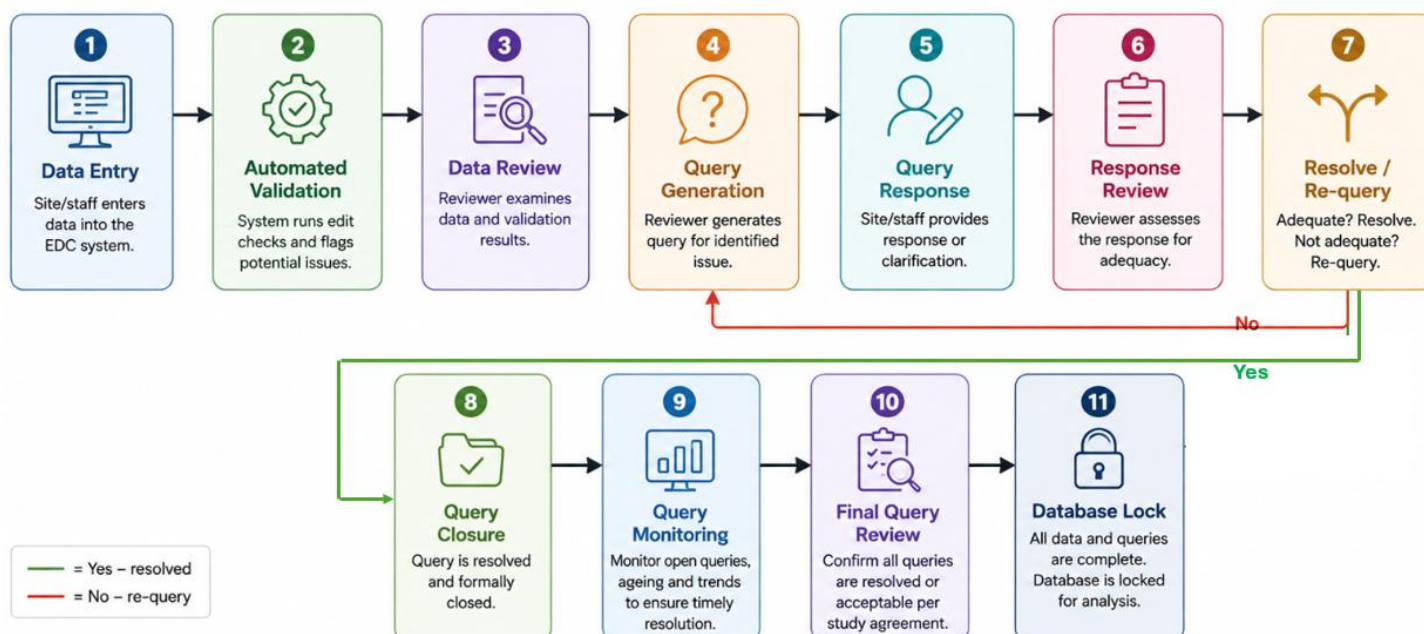
Function	Activities and Responsibilities	Scope
	appropriately authorised personnel; - Ensuring responses are accurate and clear - Escalating issues to the Sponsor-Investigator, Medical Monitor or Clinical Trial Manager, where required; and - Providing Site PI data attestation (i.e. sign-off of CRFs).	

5. RELATED DOCUMENTS

- [MCTC195 Template | Data Management Plan](#)
- [MCTC238 SOP | Data Cleaning and Validation](#)
- [MCTC241 Form | Completion of Data Cleaning Activities](#)
- [MCTC216 Form | eCRF Data Review and Sign Off by PI](#)
- [MCTC231 SOP | CRF Design and Development](#)
- [MCTC232 Guidance | CRF Design and Development](#)
- MCTC245 SOP | Database Lock

6. PROCEDURE

6.1.Workflow



6.2. Principles of Query Management

There are 5 basic components in the query management process:

1. Identification of a (possible) inconsistency or uncertainty (i.e. data issue)
2. Query generation and assignment
3. Responding to queries
4. Updating the data (if applicable)
5. Review of query responses, closing or re-raising a query

In OpenClinica, the Queries Page is the central location for reviewing all notes — queries, annotations, and reasons for changes in data — entered within a study or site. Notes can be sorted or filtered by Query ID, Participant ID, Note Type, Resolution Status, Days Open, Assigned User, CRF, and other columns.

The Queries page includes two sections:

Query Summary Table	The Query Summary Table displays a count of all query resolution statuses and their totals for the queries shown in the Queries Table.
Queries Table	The Queries Table lists all queries, annotations, and reasons for change recorded in the study. You can filter the table to display only specific note types (for example, queries only, annotations only, or reasons for change only), or any combination of the three. The table can also be printed or downloaded for offline review.

More information on managing queries in OpenClinica can be found here:

<https://docs.openclinica.com/oc4/using-openclinica-as-a-data-manager/queries/>

6.3. Identification of Data Issues

- Potential data issues may be identified through automated edit checks, manual data review, monitoring, source data review, medical review, external data reconciliation or other data management activities
- An error or discrepancy can also be identified by a member of the study team through the team's own adopted quality control activities
- The person identifying the issue should determine whether a query is required in accordance with the study's Data Management Plan and Data Validation Plan.

6.4. Query Generation

OpenClinica has an internal system to raise, log and track queries. It is recommended that all projects using OpenClinica use the internal system to manage their queries.

- A discrepancy should be reviewed to determine whether a query is required
- Should an error be found, or clarification deemed necessary, a query can be raised.
- This query should describe the question being posed about an issue with a particular data point. All queries should be logged, describing who raised them and when.
- Queries should:
 - Clearly identify the data or issue requiring clarification
 - Be short and concise and sufficiently specific to facilitate resolution
 - Request only the information required to resolve the issue
 - Avoid leading the site towards a particular response (e.g. write 'Please recheck this value on the source and confirm' rather than to ask "Should this value = 5")
 - Be written in professional and neutral language
 - Keep consistency between similar questions. Templates can be useful for recurring queries
 - Reference relevant information where appropriate; and
 - Protect participant confidentiality.
- Queries should not request information that is unnecessary for resolution of the identified issue.
- Queries should be issued using the appropriate OpenClinica query functionality. The authorised user should:
 - Navigate to the relevant participant, event, form, and data item
 - Review the data and associated context
 - Create a query against the relevant data item or form, as appropriate
 - Enter a clear description of the discrepancy or required clarification
 - Assign the query to the appropriate recipient/user
 - Confirm that the query has been issued successfully
 - Monitor the query through the appropriate OpenClinica query/status functionality.
- Where the OpenClinica configuration supports different query types or statuses, these should be used consistently in accordance with the study-specific Data Management Plan.

6.5. Query Assignment

- Queries should be assigned to the appropriate study/site personnel responsible for reviewing and resolving the issue.
- The responsible user should be clearly identifiable, and query status should be monitored until resolution.

6.6. Query Response

The participating trial site team should review each query against source documentation and available clinical information and respond to any queries raised within a timely manner (generally 5 business days).

- Any questions raised in the query should be responded to, and where needed extra clarification should be given. If anything is unclear, the trial site team can ask for further clarification in their response.
- Queries should be responded to in OpenClinica, enabling ease of tracking, review and close-out of queries.

The participating trial site team should:

- Review and directly address the query
- Verify the accuracy of the information against source documentation, where applicable, and provide sufficient clarification
- Correct the data where needed
- Avoid entering unnecessary personal or sensitive information into query text
- Provide an explanatory response where the data are correct or cannot be changed
- Be entered by appropriately authorised personnel; and
- Submit the response within the study-defined timeframe.

Data should only be changed when supported by appropriate source documentation or other authorised evidence.

6.7. Correcting/Updating Data (if applicable)

After responding to the query, the data can be updated where needed by authorised participating trial site team members.

- All correction and/or updates to data must be completed by authorised data entry/collection staff
- Updates in the data should be logged either in the electronic audit trail, or another logging system (e.g. On paper documents, the change should be signed and dated)
- OpenClinica requires a general explanation to be entered when any saved data form is updated but changes specific to each data query should also be referenced by the person updating the data in the query response.

6.8. Review of Query Responses

The Data Manager or other appropriately authorised reviewer should assess whether the response adequately addresses the query.

The Data Manager (or reviewer) should determine whether:

- The query has been adequately answered
- The underlying data have been corrected where required
- The response is consistent with other trial data
- Supporting information is adequate
- The query requires further clarification; and

- The issue has been satisfactorily resolved.

If the response is satisfactory, the query may be closed in OpenClinica.

If the response is insufficient, the query should be reissued or otherwise managed in accordance with the study-specific query workflow.

6.9. Re-Querying

In cases where the query response is incomplete, unclear or does not adequately address the identified issue, the query must be re-issued or additional clarification requested.

The reissued query should clearly state what additional information or action is required.

Repeated or unresolved queries should be monitored and escalated where appropriate., or to identify potential training, process, or systemic issues.

6.10. Closing/Resolving Queries

Queries should only be closed after a final review by authorised personnel from the Data Management Team or Central Trial Coordinating Team, who can confirm the issue has been appropriately addressed. Note that the personnel will need to have either a Data Manager or Monitor role in OpenClinica to close an open query.

The query record should provide sufficient information to demonstrate:

- The issue identified
- The response provided
- Any resulting data correction and/or updates; and
- The basis for resolution and closure.

6.11. Query Escalation

Queries should be escalated to the Sponsor-Investigator and/or Data Management Team when they:

- Remain unresolved beyond the defined timeframe
- Require repeated follow-up
- May affect participant safety or eligibility
- May materially affect study endpoints or analysis
- Indicate a systemic or recurring data issue; or
- Remain unresolved at the time of final data review.

Escalation should follow the study-specific escalation pathway.

6.12. Query Monitoring and Reporting

The Data Manager should periodically review query metrics, including:

- Number of open queries (per site and overall)
- Number of closed queries (per site and overall)
- Outstanding and overdue queries (per site and overall)
- Average time to query resolution
- Queries per CRF/visit
- Queries by participant
- Recurring or systemic issues; and
- Queries remaining at key study milestones, including database lock.

Query metrics must be reviewed as part of ongoing data quality oversight.

6.13. Final Query Review

Prior to database lock, the Data Manager (or authorised delegates) should perform a final review of outstanding queries to confirm that:

- Critical and important queries have been resolved
- Appropriate responses have been reviewed
- Required data corrections have been completed
- Unresolved queries have been assessed and documented
- Any accepted known issues have been appropriately documented; and
- Query records are complete and appropriately closed.

The final query review should be documented in accordance with the study's database lock procedures.

6.14. Documentation and Audit Trail

Query management activities must be performed within OpenClinica. Query records and associated data changes must be maintained in accordance with the study's Data Management Plan and Data Validation Plan. OpenClinica's audit trail and query history must be retained as part of the electronic trial records.

Research Teams must not delete, overwrite or otherwise circumvent query or audit trail information.

6.15. Database Lock Requirements

Before database lock, the Data Manager should confirm that the query management process has been completed in accordance with the approved Data Management Plan, the Statistical Analysis Plan (where applicable) and database lock requirements.

Any remaining unresolved queries or known data issues must be documented using [MCTC241 Form | Completion of Data Cleaning Activities](#), assessed for their impact on the study and formally accepted by the appropriate study personnel before database lock.

6.16. Deviations from this SOP

Any deviation from this SOP shall be documented, assessed for impact and managed in accordance with the applicable deviation/CAPA procedure.

Significant deviations affecting data integrity, participant safety or the validity of the trial data shall be escalated to the Sponsor.

7. GLOSSARY

Automated Query

A query generated through an automated validation or edit check when entered data do not meet predefined conditions.

Case Report Form (CRF)

A form that collects and contains Study Event information for a Study Participant.

A Case Report Form (CRF) is a crucial paper or electronic document used in clinical research to systematically record all protocol-required information for each participant in a study. CRFs serve as the primary data collection tool, ensuring consistent, accurate, and complete data for analysis, which helps evaluate the efficacy and safety of medical interventions and answer specific research questions. They are vital for regulatory compliance and the overall success of a clinical trial, capturing details such as demographics, vital signs, and treatment outcomes for each individual participant.

Central Trial Coordinating Team

A group of MCRI researchers (at the Sponsor-level) organised to coordinate the planning, development, operations and conduct of an MCRI-sponsored, Investigator-Initiated, clinical trial.

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'.

Closed Query

A query that has been reviewed and formally closed by an appropriately authorised user in OpenClinica.

Data Query

A documented request for clarification or correction of a data item or set of data items.

Database Lock

The formal process by which a clinical trial database is placed into a controlled, read-only state after all required data cleaning, review, validation, query resolution and reconciliation activities have been completed and the dataset has been determined to be complete and fit for statistical analysis. Following database lock, changes to the clinical trial data are restricted and may only be made through a predefined, documented and authorised process.

Manual Query

A query generated by a study team member following manual review of clinical trial data.

OpenClinica

OpenClinica is a cloud-hosted, open-source software platform used for electronic data capture (EDC) and clinical data management (CDM) in clinical trials. It helps researchers design and manage clinical studies, capture patient and operational data electronically via eCRFs, and ensure regulatory compliance through features like audit trails and edit checks. OpenClinica supports various aspects of a trial, including patient-reported outcomes (ePRO), randomization, supply chain management, and reporting, with solutions designed to be flexible and user-friendly.

Query Response

The information provided by the responsible user in response to a query.

Re-query

A subsequent query raised when the original response does not adequately resolve the identified issue.

Site PI Data Sign-Off

A documented confirmation by the Site Principal Investigator that the clinical trial data submitted by their site have been reviewed and, to the extent applicable, are accurate, complete and consistent with the source records, protocol and applicable trial requirements, and that any outstanding data issues have been appropriately addressed or documented.

Source Data

Information contained in original records or certified copies of original records from which clinical trial data are derived.

8. REFERENCES

- [OpenClinica Documentation and Training Site: Section 5.2 Queries \(Data Manager\)](#)
- [OpenClinica Documentation and Training Site: Section 8.3 Source Data Verification](#)
- [NHMRC Australian Code for the Responsible Conduct of research \(2018\)](#)
- [NHMRC National Statement on Ethical Conduct in Human Research \(2025\)](#)
- [TGA Integrated Addendum to ICH E6 \(R1\): Guideline for Good Clinical Practice ICH E6 \(R3\) 2016 – Annotated with TGA comments](#)
- [ICH E8 \(R1\) | General Considerations for Clinical Studies](#)
- [ICH E9 | Statistical Principles for Clinical Trials](#)

9. COLLABORATORS

Name / Role	Department / Group	Affiliation
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