Office for Research

SOP-RTM-08

TRIAL DATA ENTRY AND QUERY RESOLUTION

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1. PURPOSE:

The purpose of this SOP is to outline the procedure for managing trial data entry into Case Report Forms (CRFs), both paper and electronic CRFs, and procedures for data query resolution for clinical trials at Epworth HealthCare (Epworth).

2. BACKGROUND

Documentation plays a vital role in clinical research and trials. It validates how authentic the research data was collected and verify the result of data**.** The most important purpose of source documentation in a clinical trial is to reconstruct the trial as it happened. It should enable an independent observer to reconfirm the data.

Accurate and timely data entry allow timely trial monitoring and safety reviews.

3. SCOPE:

All clinical trials conducted at Epworth.

4. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons or parties engaged in the research activity at Epworth.

5. RESPONSIBILITIES:

The sponsor is responsible for:

- Providing data collection forms, systems monitoring and communicating queries and resolution of queries.
- Ensuring the systems comply with Good Clinical Practice (GCP)[1] and applicable regulatory requirements

The Principal Investigator (PI) is responsible for ensuring data entry and management of query resolution in a clinical trial is conducted in accordance with this SOP. The PI can delegate at his/her discretion certain trial duties to suitably qualified individuals. Delegation of trial activities must be recorded on the delegation log. The PI remains responsible for any delegated activity.

6. DEFINITIONS

Source documents - Original documents, data, and records[1].

7. PROCEDURE:

7.1 Data Entry

a. Most of the clinical trials at Epworth use remote data capture (RDC) or electronic data capture (EDC). The Sponsor may provide commercially developed EDC systems for a specific trial.

b. The data entered by Epworth clinical research staff in the CRFs is derived from source documents such as study specific worksheets, electronic medical records, laboratory reports and imaging/ scan reports. For more details on source document management please refer to SOP-RTM-07 *Source Document Management*.

c. Epworth clinical research staff assigned to data entry on the Delegation Log must ensure that they have adequate training on CRF data entry, and all such training should be documented in the training log, or with a certificate of completion, for the respective trial. Data entry should be performed as per CRF Completion Guidelines provided by the Sponsor for respective trials.

d. Data from source documents should be transcribed into the CRFs in a timely manner or as prescribed by the contract with the Sponsor.

e. Data entered into the CRFs must be anonymised and the participant's identity must remain confidential. In order to ensure participant safety, the trial participant should only be identified in the CRF by means of the allocated participant number and/or initials (if applicable).

f. Access to CRFs must be restricted only to designated users who have been identified to perform this activity in the Delegation Log. Users will access CRFs through their trial accounts which are password protected.

5.2 Query Resolution

- Data queries can be either automatic or generated by a Sponsor or study monitor after data verification. Pop-up queries or query icons should be checked frequently and a response provided within the required trial timelines.
- Queries in the CRF should reflect a full audit trail of queries raised and resolved, such that it can be retrieved and reported.
- If a query is unclear, or if more information is required, the study monitor should be contacted for further clarification.
- Once all data are verified and clean, the Sponsor will lock the participant data entered into the CRFs. The PI will review and approve the entered data by signing the specific field in the CRF.

5.3 Protection of Electronic Data / eCRFs

- A unique, confidential user ID and password will be issued by the Sponsor or system service provider to each designated EDC user. The EDC user must ensure he/she has received a user ID and password before the trial starts.

- For security reasons, the EDC users should not disclose their user ID/password to anyone else for any purpose.
- When a member of the trial team, leaves a trial, the Sponsor should be notified to ensure their access to the CRF is removed.

8. REFERENCES:

1. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) https://www.tga.gov.au/publication/note-guidance-good-clinical-practice

9. RELATED DOCUMENTS:

7.1 Related Forms and Templates

N/A

7.2 Related SOPs

- SOP-RTM-07 Source Document Management

10. VERSION CONTROL

Document History			
Version	**Date**	**Summary of Changes**	**Author**
1.0	26/4/2019	N/A - First Issue	Helen Christensen
2.0	19/6/2024	Update header format and template. Update title to 'Trial Data Entry and Query Resolution'. Add sections 2. Background and 5. Responsibilities Update Section 4. Applicability, to include archiving of paper or other physical records. Section 7. Procedure, move responsibilities described to section 5. Responsibilities Remove reference to SOP-Glossary-of-Terms Update format of version control history table.	Sarah Rickard

11. APPENDIX

N/A