Query and Missing Data Guidelines (ECTU REDCap Database)

**<<Study Name/Acronym>>**

**Database URL:**

**Effective Date:**

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| **Authorship History** |
| **Author Name and Designation** | **Version No** | **Date**  |
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| **Review Schedule**  |
| This document will be subject to formal review **<<insert appropriate time period>>** from **<<insert effective date>>.** This document is also subject to interim reviews as and when appropriate. All revision history must be documented in the tables below. |

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| **Document Review History** |
| **Version No**  | **Date**  | **Summary of Revisions** |
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| **Approval** |
| **Name and Designation** | **Version No** | **Date Approved** | **Signature**  |
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*All text in italic green is for guidance purposes only and should be deleted from the final version. This template is for guidance only and should be altered as appropriate.*

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| **Purpose of Document**  |
| This document provides instructions for generating queries and any relevant data management reports for further action. It also provides guidance on handling unresolved queries, generating further ad hoc queries, and missing data.The procedure for completing a query run is detailed in ECTU Central Office ECTU\_DM\_06 Query and Missing Data Management. |

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| **General Information** |
| **Query Accessibility** | Queries are added to the database based on the executable Data Quality Rules and/or from any bespoke reports created to identify missing data and/or data discrepancies.Queries are displayed on the Data Resolution Dashboard via the Resolve Issues application on the database. |
| **Responsibilities** | *Specify who will be responsible for the query runs and how often (e.g. DM Team) and that the TM will maintain oversight of this.* *Specify when query runs will be begin (e.g. only sites that have recruited a participant)* |
| **Notifications to Site** | Sites will be notified of any outstanding queries via email to a designated site contact. They will be advised to check the Data Resolution Dashboard to address these on the database *(also specify if report of this is attached. NOTE: Reports sent to site must be in an uneditable format)* |
| **Contacts** | *State where Query Contact List or alternative is held. Specify if trial email address is to be copied into all query emails.* |
| **Saving Instructions** | *Specify where the csv or excel copies of the reports will be saved.* Reports will be saved with the following naming conventions:Query Report DDMMMYYYY |
| **Blank Reports** | If the generated report shows no outstanding queries or missing CRFs, the report will be saved in the location stated above with the following naming convention:Query Report DDMMMYYYY blank |

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| **Query Management** |
| The Data Resolution Dashboard should be reviewed for any site responses, discrepancies or potential query closures. Once all necessary reviews have been completed, the sites can be notified of their outstanding queries. |
| **Entering a query comment** | * It may be necessary to enter a comment on the query if further explanation of the query is required or if the site response provided is insufficient.
* Query comments will be entered at the discretion of the query checker unless stated in the Study Specific Instructions section.
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| **Closing a query** | * A Query will be closed if it has been confirmed that the data entered is correct or if the data cannot be obtained (any exceptions to this are detailed in the Study Specific Instructions section).
* The query checker will ensure that an appropriate comment is entered stating the reason the query has been closed.
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| **Generating additional queries** | * It may be necessary to generate additional queries if there is a data discrepancy identified that has not been picked up by the Data Quality Rules programmed into the database (e.g. an incorrect date or time that is obviously incorrect but is still within the logical parameters allowed on the database). NOTE: *Manual queries may be added as per procedure as part of a QC Check for the study. These will be reviewed and updated or closed by the QC Checker*. If manual queries are required frequently as part of the query management process, this will be discussed with the Trial Manager or designee as a database update may be required.
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| **Missing CRF Management** |
| **Missing Data Timeframes** |
| **CRF** | **Due By Date**  | **Completion Timeframe**  | **Action Required and Missed Date**  |
| *Specify CRF Name/Timepoint (e.g. Baseline Blood Results)* | *Specify when the CRF is due to be completed by and will appear on the Missing CRF Report if not (e.g. 30 Days after Randomisation)* | *Specify timeframe for CRF to be completed (e.g. +/- 14 Days after Due By Date)* | *Specify what action will be taken when CRF is identified as missing (e.g. If the data is not completed by the specified Due By Date, but is still within the completion timeframe, a query will be added to the database to remind site the visit is due. Specify when the data will be regarded as permanently missed and will no longer be followed-up with site/participant (e.g. If data is not completed by the latest applicable date in the Completion Timeframe)* |
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| **Study Specific Instructions**  |
| **CRF** | **Query Text** | **Example Response** | **Action Required** |
| *Specify CRF Name/Timepoint (e.g. Baseline Blood Results)* | *Specify query text as on database (e.g. Cholesterol is Missing)* | *Specify example response (e.g. Not documented on CRF, not taken at visit)* | *Give brief description of required action to take (e.g. Cholesterol level from previous 6-months can be used for study. Please check participant hospital notes for available result)* |
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| **Template Revision History** |
| **Version No** | **Effective Date** | **Revised By (Name and Designation)** | **Summary of Revisions**  |
| 1.0 | 15-June-2023 | Lynsey Milne (Data Manager) | * Initial Creation
* Template version set to 1.0
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