Query and Missing Data Guidelines (ECTU Bespoke 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 query and missing data reports on the study database and distributing these for further action. It also provides guidance on handling unresolved queries, generating manual 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** | |
| **Report Availability and Accessibility** | *Specify the reports that have been built onto the study database for this purpose (e.g. Data Query Report, Missing CRF Report)*  *Specify how these can be accessed (location on database and user role required to access).* |
| **Responsibilities** | *Specify who will be responsible for generating the reports and how often (e.g. DM Team) and that the TM will maintain oversight of this.*  *Specify when reports will be generated (e.g. only sites that have recruited a participant)* |
| **Notifications to Site** | *Specify how the site will be notified of any queries (e.g. pdf report emailed to site contact. NOTE – reports sent to site must be sent 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 pdf copies of the reports will be saved.* Reports will be saved with the following naming conventions:  Query Report DDMMMYYYY  Missing CRF 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  Missing CRF Report DDMMMYYYY blank  *Depending on the study, saving blank Missing CRF Reports may not be appropriate. This should be assessed per study* |

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| **Query Management** | |
| When the report has been generated initially it should be reviewed for any site responses, discrepancies or potential query closures. Once all necessary reviews have been completed, a new report can be generated to reflect the updates. | |
| **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. |
| **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 (either by ECTU or by site) stating the reason the query has been closed. |
| **Generating a manual query** | * It may be necessary to generate a manual query if there is a data discrepancy identified that has not been picked up by the automated system 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). These will commonly be identified manually during a query review. * 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. |
| **Editing a query report** | * It may be necessary to edit a Query Report before it can be sent to site. This may involve removing an invalid query (pending a database fix to correct the issue) or in order to separate out queries that have to be sent to different contacts to resolve (if this is the case, this will be detailed in the Study Specific Instructions section). * A Query Report can only be edited in Excel or Word format. The report should be exported to this format initially to make the edits before saving as a pdf to send to sites. * Query Reports will be edited at the discretion of the query checker as and when required. |

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| **Missing CRF Management** | | | | |
| **Missing Data Timeframes** | | | | |
| **CRF** | **Due By Date** | | **Completion Timeframe** | **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 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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| **Editing a missing CRF report** | | * It may be necessary to edit a Missing CRF Report before it can be sent to site. This may involve removing a missing CRF which has passed the completion timeframe and is known to be permanently missed. * A missing CRF Report can only be edited in Excel or Word format. The report should be exported to this format initially to make the edits before saving as a pdf to send to sites. | | |

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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 | 27-March-2018 | Lynsey Milne (Data Management and QA Project Co-ordinator) | * Initial Creation * Template version set at 1.0 |
| 2.0 | 21-Aug-2020 | Lynsey Milne (Assistant Data Manager) | * Updated due to interim review of ECTU\_SOP\_DM\_01. Overall simplification of document |
| 3.0 | 15-June-2023 | Lynsey Milne (Data Manager) | * Title of document changed – guidelines for bespoke databases only |