

ECTU Central Office SOP_DM_06: Query and Missing Data Management

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	21 Aug 2020	Initial creation.
2.0	19 Feb 2024	Transfer to new template v3.0 Extensive revision to include different requirements in relation to bespoke and REDCap databases including implementation of queries on the database and management throughout the study.
3.0	07 Sep 2026	Further clarification on management of Missing CRFs Query run deviation procedure added Minor wording/numbering changes throughout

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1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedures for the regular management of data queries and missing CRFs on a study database.

2.0 SCOPE

This SOP applies to all studies where the ECTU Data Management Team will be responsible for query and missing data management throughout the life-cycle of a study. This includes management of queries and missing data via bespoke and REDCap databases provided by ECTU.

3.0 RESPONSIBILITIES

Delegation of this task to the ECTU Data Management Team will be established at the start of the study as per ECTU Central Office SOP ECTU_DM_01 Data Management Procedures.

All query and missing data management requirements will be referenced in the Data Management Plan (DMP).

Where the ECTU Data Management team are delegated this task, the designated Data Manager, Assistant Data Manager or designee will be responsible for implementing and maintaining the Query and Missing Data Guidelines.

The Trial Manager or designee is responsible for providing training to site staff regarding resolution of data queries if required, as well as approving the data queries and missing CRF procedures as detailed in the Query and Missing Data Guidelines.

4.0 PROCEDURE

4.1 Query and Missing Data Management on an ECTU bespoke database

4.1.1 Where a study uses a bespoke database built by the ECTU Programming team, a query specification is provided as part of the overall database specification during the database build phase. The specification will include which data fields will require a query and under which circumstances that query should trigger (the query behaviour). Queries are validated as part of the database build.

4.1.2 It will also be possible to add a manual query to a bespoke database. This function will be limited to certain user roles and can be used for additional queries that are not part of the automated system. These are usually identified by Trial Office staff during the query or other review processes.

4.1.3 In addition to the individual queries, the bespoke database will also include a Data Query Report (or similar) which will collate all queries into a single report that can be used to monitor and manage the outstanding queries at sites. The Data Query Report includes a list of all queries on individual fields within each CRF on the database.

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- 4.1.4** The Data Query Report will include a set of filters that allow a bespoke report to be generated per site as a minimum requirement. Other filters may be added as per the study requirements (for example, filter by CRF, exclude closed queries etc.)
- 4.1.5** Where possible, a Missing CRF Report should also be included at the specification and database build phase. This will be used to identify where entire CRFs have not been completed within the timeframe specified in the protocol. Alternative methods to a Missing CRF Report (e.g. automated queries) may be used depending on the study.
- 4.1.6** Query and missing data is managed on the bespoke databases by generating the Data Query Report and/or Missing CRF Report (where applicable), as standard on a monthly basis, to identify the outstanding queries on data that has been entered.
- 4.1.7** Data Query Reports and Missing CRF Reports will usually be generated on a site-by-site basis but may be generated by CRF depending on the study requirements.
- 4.1.8** Upon generating the Data Query Report, it will be reviewed for updates. Queries may be updated with a response or closed by the assigned user role depending on the update. Details on query closures and responses will be included in the study-specific Query and Missing Data Guidelines.
- 4.1.9** If a Missing CRF Report is available, this will also be generated and reviewed for any issues. The Missing CRF report itself may be sent to sites to prompt the completion of the CRF. It may be necessary to edit this report before it is sent to site. Alternatively, the Data Manager Assistant Data Manager or designee may review the Missing CRF Report and add manual queries to the database to prompt completion of the CRF. In this case, these will be included as part of the Query Report and the Missing CRF Report does not need to be sent to site. The Missing CRF Report should still be retained and edited to specify where queries have been added to the database. All management methods relating to Missing CRFs will be stated in the Query and Missing Data Guidelines
- 4.1.10** Once the final Data Query and/or Missing CRF Reports have been generated for a site, these will be saved in pdf format in the Data Management section of the study folder on the ECTU DataStore Section 9 for full-service studies, and 3 for partial service under the new folder structure. The reports will be named clearly and will include the date (for example, Query Report 06Sep2022, Missing CRF Report 06Sep2022).
- 4.1.11** In the event that a Data Query Report is generated and is blank (i.e. no queries are outstanding for that particular site), the report will be saved as above (in section 4.1.10) indicating in the name that the report is blank (e.g. Query Report 06Sep2022 blank). Blank Missing CRF Reports can be saved in the same fashion if it is appropriate to do so, however as a Missing CRF Report may be blank for quite some time (in the case of studies with long follow-up periods), this should be decided on a study-by-study basis and will be specified in the Query and Missing Data Guidelines.
- 4.1.12** As Data Query Reports and Missing CRF Reports may be large files, these will not be printed and kept in paper format. All reports generated will be retained as specified above and all details of query resolution will be saved in the query response section and/or audit trail on the bespoke database. A file note will be provided by the ECTU

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Data Management team for inclusion in the Data Management section of the TMF indicating where details of the query and missing data reports and any resolution can be found. A template version of this file note is available for this purpose DM016 File NoteQuery Report and Email Notification.

- 4.1.13** If there are queries and/or missing data outstanding for a particular site, the reports will then be sent (in pdf/uneditable format) to designated query contacts at site via email advising them to address these on the database (see section 4.3). Blank reports will not be sent to sites.

4.2 Query and Missing Data Management on an ECTU REDCap database

- 4.2.1** Where a study uses a REDCap database built by the ECTU Data Management team, the basis of any query and missing data management will be implemented via Data Quality Rules and Reports programmed into the database by the Data Manager, Assistant Data Manager or designee.
- 4.2.2** Data Quality Rules are not queries but are programmed rules used to identify missing or non-conformant data. Executing these rules within the database highlights where these discrepancies can be found and a manual query can then be added if required in order to resolve the issue with site.
- 4.2.3** Data Quality Rules can be set to execute in real-time. This means that an alert will appear on screen at the time of data entry if the rule is triggered (for example, a rule can be written to identify when a future date is entered. If a future date is entered in the applicable field, once the page is saved an alert will appear on screen). It may not always be appropriate to use rules that execute in real-time (for example, for complex rules). If these are implemented, these should be validated as part of the database build.
- 4.2.4** Bespoke reports can also be created to monitor data where applicable. The report can include any fields within the database, and should be discussed with the software developer to determine if implementation is possible and appropriate.
- 4.2.5** Once the Data Quality Rules and Reports have been implemented on the study database, these will be executed and checked regularly, as standard on a monthly basis. Manual queries will then be added to the database as required, based on any discrepancies highlighted.
- 4.2.6** Manual queries will then appear in the 'Resolve Issues' in the Applications section of the study REDCap database. The Data Resolution Dashboard will display all open queries and can be filtered according to site for ongoing management and review. Site users are only able to see open queries that pertain to their site.
- 4.2.7** The Data Resolution Dashboard should be reviewed for updates and responses to existing queries. Queries may be updated with a response or closed depending on the update. Details on query closures and responses will be included in the study-specific Query and Missing Data Guidelines.

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- 4.2.8** Once all new queries have been added and any updates have been made, the Data Resolution Dashboard should be exported and saved (as csv or excel) file as per the instructions in section 4.1.10. Sections 4.1.11, 4.1.12 and 4.1.13 in relation to blank reports and printing reports also apply here.
- 4.2.9** Where queries are outstanding for a site, the designated query contact will be informed via the monthly reports emailed by the Data Manager, Assistant Data Manager or designee that they have queries to address (as per section 4.3). The sites will be advised to check the Data Resolution Dashboard for a list of the outstanding queries. The exported Data Resolution Dashboard can also be sent to site if required, however this may not be suitable for every study. If a report is sent to site this must be sent in a format that cannot be edited by the site (for example, in pdf format or a locked csv/excel spreadsheet).
- 4.2.10** A Data Quality Rule execution may highlight a discrepancy that does not require further follow-up with site (for example, this may have been implemented by the Data Manager as means of monitoring data completion rather than highlighting potential specific errors). In this case, a manual query will not be required and the Data Manager, Assistant Data Manager or designee will verify the data in Data Quality section of the database with an appropriate explanation comment. This will then exclude this discrepancy when the Data Quality Rule is executed again. These exclusions are retained as part of the audit trail on the database.
- 4.3 Frequency of query runs and notifications to site contacts**
- 4.3.1** A query run is the generation of Data Query Reports and Missing CRF Reports (where applicable) on bespoke databases or the execution of Data Quality Rules and Report checks on REDCap databases.
- 4.3.2** The standard frequency that a query run will be completed is monthly. An increased frequency is not routinely practiced but may be considered at the discretion of the Data Manager, Assistant Data Manager or designee. A decreased frequency is not recommended. Monthly query runs are recorded by saving the reports as detailed in sections 4.1.10 and 4.1.11 and retention of the notification email as detailed in section 4.3.6 and 4.3.7.
- 4.3.3** Once the frequency of the query runs has been established, the Data Manager, Assistant Data Manager or designee is responsible for scheduling and completing these within their own work calendar. Where there is occasion for the query run to be missed as per the agreed schedule for any reason, this will only be considered a deviation when three consecutive query runs have been missed. The Data Manager, Assistant Data Manager or designee is responsible for informing the relevant stakeholders when appropriate and will liaise with the Trial Manager to ensure the appropriate deviation paperwork is completed should this occur.
- 4.3.4** A query run will begin at each site once at least one participant has been recruited and added to the study database. It is not necessary to complete a query run for unopened sites or sites that have not begun recruitment.

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4.3.5 The Trial Manager or designee will advise of the appropriate designated query contact or contacts at each site. A Query Contact list will be implemented and maintained by the ECTU Data Management team for this purpose, using template DM009 Query Contact List. The contact list can be found in the DM section of the study specific folder on DataStore. The Query Contact list is a living document that will be continuously updated throughout the trial. The study-specific version is not subject to version control.

4.3.6 The query and missing data notification (as stated in sections 4.1.13 and 4.2.9 (if applicable)) will be sent to the designated site via email. The notification email will be sent from the ECTU DM generic email address (dm.ect@ed.ac.uk). The study-specific email address (if applicable) or Trial Manager or designee will be copied into the notification email.

4.3.7 The notification email will be retained with the ECTU DM generic email inbox in a study specific folder sorted by site. A copy will also be saved in pdf format alongside the query and/or missing CRF reports for the site in DataStore.

4.4 Query Responses and Resolution

4.4.1 Queries will generally be resolved directly on the study database (either bespoke or REDCap) Query resolution is defined as:

- Completion of missing data
- Correction/ deletion of a data discrepancy
- Confirmation that data entered is correct
- Confirmation that data is missing and cannot be obtained

4.4.2 For bespoke databases, completion of data or correcting a discrepancy will normally cause the query to disappear automatically. This then requires no further action and the details of the correction or addition will be retained in the audit trail on the database.

4.4.3 For REDCap, all resolved queries will be closed manually by the Data Manager, Assistant Data Manager or designee. Closed queries remain accessible on the study database.

4.4.4 For queries where data is confirmed as correct or confirmed as missing, this will be stated in the query response or comment field. These queries, and queries that have been added manually (to either a bespoke or REDCap database) will not close automatically. These will be closed manually once the response has been reviewed and accepted. Closed queries remain accessible on the study database.

4.4.5 The Trial Manager or designee will provide training to the site user on how to enter a comment or response on a query as part of the database training

4.5 Query and Missing Data Guidelines

4.5.1 Query and Missing Data Guidelines will be implemented and maintained for all studies where the ECTU Data Management Team are responsible for the query process.

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4.5.2 The following templates will be used to complete the Query and Missing Data Guidelines

- DM008 Query and Missing Data Guidelines (ECTU Bespoke Database)
- DM017 Query and Missing Data Guidelines (ECTU REDCap Database)

4.5.3 The Query and Missing Data Guidelines will specify the following:

- Availability of any reports for queries or missing data (where applicable)
- The frequency of the query runs, who will complete these when these are applicable
- How notifications will be sent to sites and location of the Query Contact List
- Where any reports will be saved including procedure for blank reports (no queries)
- General query and missing data management instructions
- Study-specific query and missing data management instructions

4.5.4 The Query and Missing Data Guidelines will be approved by the Trial Manager or designee and Data Manager, Assistant Data Manager or designee, documenting agreement and approval of the data query and missing CRF procedures. Guidelines will be held in the study specific folder on DataStore. A signed copy will also be sent to the trial team for their retention.

4.5.5 Approved Query and Missing Data Guidelines will be in place within six months of the first participant recruited to establish the initial procedure followed. The guidelines may be further updated with specific instructions as required.

4.6 Study Document Version Control and Review

4.6.1 All study-specific Data Entry Guidelines and Query and Missing Data Guidelines produced by the Data Management team will be subject to version control and regular reviews. This procedure is detailed in ECTU Central Office SOP ECTU_SOP_DM_07 Data Management Document Version Control and Review.

5.0 RELEVANT DOCUMENTS AND REFERENCES

[ECTU Website:](#)

- ECTU_SOP_DM_01 Data Management Procedures
- ECTU_SOP_DM_07 Data Management Document Version Control and Review
- DM008_Query and Missing Data Guidelines_BESPOKE
- DM009_Query Contact List
- DM016_File Note_Query Report and Email Notification
- DM017_Query and Missing Data Guidelines_REDCAP

ECTU_SOP_DM_06 Query and Missing Data Management v3.0 and associated documents

Final Audit Report

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