ECTU Central Office SOP ECTU_DM_06: Query and Missing Data Management

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Effective Date: 21 Aug 2020

Authorship and Approval

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<tbody>
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Document Revision History

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<tr>
<th>Version No</th>
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<td>1.0</td>
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1. PURPOSE

This Standard Operating Procedure (SOP) describes the procedures undertaken by the Data Management Team when they are responsible for the regular management of data queries and missing CRFs.

2. SCOPE

This SOP applies to all studies where it has been determined that ECTU Data Management Team will provide query and missing data management support for a study, as per ECTU SOP DM 01 (Section 2). This SOP is applicable to all members of the team assigned to complete these tasks.

This SOP also applies to ECTU Trial Managers, where trial management activities have been delegated to ECTU.

3. PROCEDURE

3.2 Query and Missing Data Procedures

3.2.1 Where data query and missing data management will be provided by the Data Management team, guidelines will be provided using DM008 Query and Missing Data Guidelines Template.

3.2.2 The guidelines will specify the following (detailed instructions are provided on the template):

   General Information
   - Report Availability and Accessibility
   - Notifications to Site
   - Contacts
   - Saving Instructions
   - Blank Reports

   Query Management
   This section specifies the standard practices that the Data Management team will apply when handling queries and generating reports including:
   - Entering a query comment
   - Closing a query
   - Generating a manual query
   - Editing a query report

   Missing CRF Management
   This section specifies the process for following up missing CRFs. It includes instructions for discontinuing follow up, where applicable.

   Study Specific Instructions
   This section provides instructions for handling study specific queries. This is used to document query management instructions relating to specific datapoints on a CRF.

3.2.3 Query and Missing CRF Reports will be sent to site on a monthly basis unless otherwise agreed with the Trial Manager. An increased frequency may be appropriate depending on the study. A reduced frequency is not recommended.

3.2.5 Query and Missing CRF Reports will be sent electronically via email from the shared Data Management email address (dm.ectu@ed.ac.uk). All sent emails must be retained in the study folder within the email inbox.
3.2.4 The Query and Missing Data Guidelines will be approved by the Trial Manager and Data Manager/Assistant Data Manager, documenting agreement and approval of the data query and missing CRF procedures implemented by the Data Management team. The Trial Manager must maintain oversight of the procedure.

3.2.5 Approved Query and Missing Data Guidelines should 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.

3.2.6 The approved Query and Missing Data Guidelines will be retained by the Data Management team in the study-specific data management file.

3.7 Document Version Control and Review

3.7.1 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 Version Control and Document Review.

4. RELEVANT DOCUMENTS AND REFERENCES

SOP and WPD:

- ECTU Central Office SOP ECTU_SOP_DM_01 Data Management Procedures
- ECTU Central Office SOP ECTU_SOP_DM_07 Data Management Version Control and Document Review

Available on the ECTU website - www.ed.ac.uk/usher/edinburgh-clinical-trials/supporting-trials/governance/standard-operating-procedures

Templates:

- DM005 Data Entry Guidelines
- DM008 Query and Missing Data Guidelines

Available from the Data Management Team – dm.ectu@ed.ac.uk