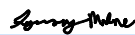





## ECTU Central Office SOP\_DM\_10: Data Quality Control (QC) Checks

Version No:	1.0
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Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
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1.0	01 Jul 2024	<ul style="list-style-type: none"> <li>Initial Creation/New Document</li> </ul>

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## 1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for assessing when Data Quality Control (QC) Checks are appropriate and the procedure for completing and documenting these checks for studies within ECTU.

## 2.0 SCOPE

This SOP applies to all studies where data management has been delegated to the ECTU Data Management Team.

## 3.0 RESPONSIBILITIES

Delegation of this task to ECTU Data Management Team will be established at the start of study as per ECTU Central Office SOP ECTU\_DM\_01 Data Management Procedures.

The ECTU Data Management Team is responsible for assessing the study for the suitability of Data Quality Control (QC) Checks against the criteria specified in this SOP, and where appropriate, for completing and documenting the QC Check

## 4.0 PROCEDURE

### 4.1 Data Quality Control (QC) Checks

**4.1.1** A QC Check consists primarily of a visual check of study data entered onto the database compared to the pCRF or other paper source document (where applicable) but may also include defined logic checks to verify the accuracy of the data entered.

**4.1.2** QC Checks are separate from any monitoring and source data verification checks that may be completed by the study monitor. QC Checks are completed on the study data entered on the study database and do not include compliance checks (for example, checking of consent forms). Where a Monitoring and/or SDV Plan is in place for the study, this will be reviewed during the development of the QC check plan by the Data Management Team to ensure there is no duplication of checks performed by the study monitor and the designated DMP team member at ECTU.

**4.1.3** The ECTU Data Management team will be responsible for determining whether QC Checks can be completed for a specific study, as well as determining the scope and frequency of the checks. This will be agreed with the Trial Manager or designee.

**4.1.4** All Data Quality Control (QC) Check requirements will be documented in the Data Management Plan (DMP).

### 4.2 Determining when Data Quality Control (QC) Checks are required

**4.2.1** QC Checks are mandatory for any data that is entered onto the study database from pCRF or other paper source by ECTU staff.

**4.2.2** QC Checks are also mandatory for any data that is uploaded to the study database (via CSV file or similar) and populates specific fields in the dataset. This does not

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apply when the file is uploaded and does not populate specific fields in the dataset but is instead used in its original format (for example, SAE, deviation and violation listings from the Sponsor).

**4.2.3** For studies where data is entered onto the database by site staff as an eCRF or where data is entered by site staff from a pCRF or other paper source, QC Checks are not mandatory but will be considered by the study DM during the development of the DMP. If a practical scope and method of completing the checks can be identified, priority consideration should be given to the Primary Outcome Data. The following should be considered:

- Assess the types of data collected and how, and if this is entered onto the study database. Not all data can be checked or will be held on the study database (for example, scan data which may be held and analysed on a separate platform or survey responses entered directly by the participant).
- If data is entered by site staff from a pCRF or other paper source,
  - whether ECTU staff can visit the site to access the data and complete the check. There is very narrow scope for checks to be completed under this circumstance and will be dependent on adequate funding and resourcing for this within the team. It may also not be feasible for multi-centre studies as site visits outwith Lothian are not feasible and so consistent checking is not possible.
  - whether anonymised data can be sent to ECTU from the site to complete the check. It may be possible for some data to be provided (for example, participant questionnaires) but this will be dependent on resource at the site. For multi-centre studies it may not be possible to adopt this consistently at all sites.
- Whether it is possible to complete a QC Check via a defined logic check. This may include checking data for obvious outliers (for example, numerical values above or below a defined range or obvious date errors) or verifying data accuracy through different fields (for example, the same data may be entered in different fields for different purposes, allowing a comparison check for accuracy). This option would be most suited to data completed via an eCRF (where the eCRF is regarded as the source data). However, depending on the nature of the study, it may not always be possible to identify a suitable way of checking this data.

**4.2.4** If it is determined that QC Checks are applicable for the study, the delegated team who will complete the checks will provide a Data Quality Control (QC) Check plan specifying the scope of the QC Checks as agreed and the proposed schedule for completion. This document will also be referenced in the DMP.

**4.2.5** Guidance on developing a QC Check Plan and preparing for, completing and documenting QC Checks is described in ECTU Central Office WPD ECTU\_DM\_W1 Preparing for and Completing Data Quality Control (QC) Checks.

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**4.2.6** If it is determined that QC Checks are not applicable, this will be documented in the DMP, briefly outlining the reasons for no additional checks.

## **5.0 RELEVANT DOCUMENTS AND REFERENCES**

### **[On ECTU Website](#)**

- ECTU Central Office SOP ECTU\_DM\_01 Data Management Procedures.
- ECTU Central Office WPD\_DM\_W1 Preparing for and Completing Data Quality Control (QC) Checks

### **Templates** (on ECTU Shared Drive)

- DM006\_Data Quality Control Check Plan

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# ECTU\_SOP\_DM\_10 Data Quality Control (QC) Checks v1.0


Final Audit Report

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