ECTU Central Office WPD_DM_W1: Preparing for and Completing Data Quality Control (QC) Checks

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	27-Mar-2018	• Initial Creation/New document
2.0	21-Aug-2020	• Updated at scheduled review • Document moved to new template • Alteration to Introduction, referencing ECTU_DM_XX Data Quality Assurance • Extensive changes throughout document with clearer guidelines and timeframes regarding error resolution and Data Quality Check Final Report sign-off
3.0	26 Aug 2024	• Updated to new WPD template • Document title changed from ‘Data Quality Checks • Minor changes throughout document • Removed reference to Data Quality Assurance document

The user of this document is responsible for ensuring it is the current version.

1. INTRODUCTION

Data Quality Control (QC) Checks, along with Query and Missing Data Management and Data Cleaning, are part of the ECTU Data Management Procedures developed to ensure data quality and accuracy.

The procedure determining when Data Quality Control (QC) Checks can be completed for a study is specified in ECTU Central Office SOP _DM_05 Data Quality Control (QC) Checks.

This Working Practice Document (WPD) describes the process for preparing, completing and documenting QC Checks.

2. INSTRUCTIONS and GUIDANCE

2.1 Creating and Maintaining a Data Quality Control Check Plan

2.1.1 The Data Quality Control (QC) Check Plan will be written using the template DM006 Data Quality Control Check Plan.

2.1.2 The scope and content of the QC Check must be agreed with the Trial Manager or designee. The Data Quality Control (QC) Check Plan will include the following:

- **The method of data entry**

- **Is a TSC and/or DMC in place to oversee the study?**
  Where possible, the schedule of the QC Checks should be planned so checks are completed before committees meet. The schedule for this will be stated in the charter.

- **Is there a Sponsor Monitoring and Source Data Verification Plan in place?**
  These should be checked prior to agreeing to the scope of the QC Checks to avoid duplication of checks (for example, if the Study Monitor will conduct a check on the Primary Outcome Data, this should not be repeated in ECTU QC Check). Additionally, the scope of a QC Check performed by ECTU is limited to the study data and should not include any compliance checks performed as part of Monitoring and SDV activities.

- **Type and Details of Check**
  Specify the type of QC Check (see section 2.1.3 for further details) Once the type of check is agreed, specify what type of data will be checked and the level of QC checking required.

- **Proposed QC Check Schedule**
  Standard QC Checks should be completed at least every six months (depending on the duration of the study). The study specific QC Check Plan must specify the QC check schedule. The exact dates of QC checks are not required in the QC Check Plan. However, there must be a plan in place to allow the QC checker to arrange and prepare for QC checks in advance.

2.1.3 There are three types of QC Check: Data Entry Check, Primary Outcome Check, Other Critical Data Check:

- **Data Entry Check**
  A Data Entry Check can be completed on any dataset but most commonly on data transcribed from a pCRF/ data collection sheet or other paper source onto the database. Data uploads should also be taken into consideration, if applicable.

- **Primary Outcome Check**
  This is a check performed on data points relating to the Primary Outcome only.

- **Other Critical Data Check**
  This is a discretionary check that may be completed on data deemed high-risk (for example, high volumes of blood results entered at one time that may be prone to data entry errors) or to Safety Endpoint Data.

2.1.4 The QC Check Plan will specify the types of checks required and specify the details of what will be included in the check. The following are general standards that are used in ECTU but the exact criteria will depend on the nature of the study:

- **Data Entry Check**
  100% of selected data (for example, all follow-up questionnaires, all data entered, all Baseline Visit data) entered on the database for 5-10% of participants consented/randomised to the study.

- **Primary Outcome Check**
  100% of Primary Outcome data entered on the database for a minimum of 5-10% of participants consented/randomised to the trial.

- **Other Critical Data Check**
  100% of applicable data (for example, Troponin Results at Baseline Visit) entered on the database for 5-10% of participants consented/randomised to the study.

2.1.5 The QC Check Plan will also specify how participants will be selected for inclusion in the QC Check (for example, applicable participant numbers will be selected at random by the QC Checker)

2.1.6 The QC Check Plan will be approved by the Data Manager, Assistant Data Manager or designee. The approved QC Check Plan will be emailed to the trial inbox.

2.1.7 All study-specific Data Quality Control (QC) Check Plans 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.

2.1.8 Regularly scheduled QC checks are known as ‘Standard QC Checks’. If an additional QC check is required, for example if a high error rate is identified at a regularly

scheduled QC check or if requested by the Trial Manager or designee following identification of an issue at site, an Additional Data Quality Control (QC) Check Plan will be developed.

2.1.9 An Additional Data Quality Control (QC) Check Plan will be documented using the template DM006 Data Quality Check Plan. The sections that are not applicable for an Additional QC Check Plan are indicated on the template and should be deleted as required.

2.2 Preparing for and completing the QC Check

2.2.1 Before the check can be performed ensure the following has been completed:

- An approved Data Quality Control (QC) Check Plan is in place
- Identify or obtain the necessary participant numbers required for the study (it may be necessary to request a random list of applicable participants from the database programmer)
- Complete the QC Check Details and Datapoint Calculations sections of the template DM011 QC Check Overview.

2.2.2 A QC Check Overview will be completed for each check using template DM011 QC Check Overview. The following sections are completed:

- **QC Check Details (completed prior to check)**
  - Study Name
  - Standard/Additional QC Check Plan Version No and Date
  - Date of QC Check
  - QC Check Completed By (Name and Designation)
  - All participant numbers and all CRFs checked should be listed

- **Datapoint Calculations (completed prior to check)**
  - CRF Name
  - CRF Version No and Name (if applicable)
  - Minimum Datapoints
  - Maximum Datapoints
  - Average Datapoints (rounded to the nearest whole number)

  In order to calculate the error rate percentage at the end of the check, the number of datapoints for each CRF must be calculated. As the number of datapoints per each CRF can be dependent on the answers given, the average number of datapoints will be used for each.
  If only selected datapoints within the CRF are included in the check and the datapoint calculations, this should be stated in this section.

- **Errors (completed during QC Check)**
  - Study No/Participant No (as applicable)
  - CRF Name

- Data Entered By (if known)
- Description of Error
- No of Datapoints
- Action taken/required
- Comments

Each error identified in the check will be documented in this section and will include a description of the error (for example, Systolic Blood Pressure is 125 on CRF but is entered as 128 on database) and the remedial action that has been taken or is required (for example, Please review result and correct on CRF or database as appropriate).

- **Total Errors (completed after QC Check)**
  Once the check is complete, the number of datapoints will be totalled to give the total number of errors.

2.3 Correction of Errors

2.3.1 All errors will be followed up to resolution by the QC Checker.

2.3.2 Errors on data entered by ECTU

Where the data has been entered by ECTU staff, errors identified during the QC Check can be corrected at the time of the QC Check. This should be documented as the action taken for the error. Error corrections of this nature should only be undertaken if the error is unambiguous (for example, a patient-reported response on a questionnaire, a blood result documented on a verified lab report, an expected response as documented in the study Data Entry Guidelines or a clear data entry error). If the error is unclear, it should be referred back to the person who completed the data entry for further clarification.

2.3.3 Errors on data entered at site

As much as possible, manual queries will be raised on the study database to advise sites of any errors to correct. These will be sent to site as part of the regular query and missing data procedures. The site should provide a response confirming the remedial action taken before the query is closed at ECTU. Where this is done, this should be documented in the actions taken for the error on the DM011 QC Check Overview document, with the date the manual query was raised and the date it was closed stated.

Alternatively, queries can be sent to site via email with instruction to resolve. This should be documented in the actions taken for the error on the DM011 QC Check Overview document. All emails should be retained with the rest of the QC Check documentation.

2.4 Error Rates

2.4.1 The acceptable total % error rate threshold is 5%. The Trial Manager or designee will be informed of the error rate and will be provided with a copy of the DM011 QC Check Overview in order to review the errors identified. A draft copy of the Data Quality

Control (QC) Check Final Report will also be provided, detailing the error rates per CRF.

2.4.2 If the total % error rate is above this threshold, or if errors are identified that indicate another underlying issue (for example, site training issue, issue with the CRF design), further action (such as a repeat QC Check) may be required, this will be discussed with the Trial Manager or designee. Any further action required should be documented on the Data Quality Control (QC) Check Final Report.

2.5 Data Quality Control (QC) Check Final Report

2.5.1 The QC Checker will complete the Data Quality Control (QC) Check Final report using template DM007 Data Quality Control (QC) Check Final Report.

2.5.2 The Data Quality Control (QC) Check Final Report will be completed after the QC Check is complete and the total % error rate has been calculated.

2.5.3 If required, as detailed in section 2.4.1 above, a draft copy will be provided to the Trial Manager or designee. Any concerns should be highlighted and further actions discussed. It is not necessary to finalise the report at this time.

2.5.4 The Data Quality Check Final Report will be approved by the QC Checker, with oversight from the Trial Manager, within 3-months of the QC Check date to allow time for all errors to be resolved by sites if required.

2.5.5 If errors cannot be resolved within this timeframe, this should be escalated to the Trial Manager and documented on the report. The QC Checker will continue to follow-up the outstanding errors to resolution.

2.5.6 All completed documentation for the QC Checks will be filed in the TMF.

3. RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- ECTU Central Office SOP ECTU_DM_10 Data Quality Control (QC) Checks
- ECTU Central Office SOP ECTU_SOP_DM_07 Data Management Version Control and Document Review

Templates (on ECTU Shared Drive)

- DM011 QC Check Overview
- DM006 Data Quality Control Check Plan.
- DM007 Data Quality Control (QC) Check Final Report

ACCORD

- POL012 Data Management Policy

ECTU_WPD_DM_W1 Preparing for and Completing Data QC Checks v3.0

Final Audit Report 2024-08-12

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