ECTU Central Office WPD ECTU_DM_W1: Data Quality Checks

Version No:	2.0
Effective Date:	21 Aug 2020

Authorship and Approval			
Name and Designation	Author/Reviewer/ Approval	Date	Signature
Lynsey Milne, Assistant Data Manager	v2.0 Author	06 Aug 2020	See retained approval email dated 06 Aug 2020
Tony Wackett, Assistant Data Manager	v2.0 Reviewer	06 Aug 2020	See retained approval email dated 06 Aug 2020
Michelle Steven, Data Manager	v2.0 Approval	06 Aug 2020	See retained approval email dated 06 Aug 2020

Document Revision History		
Version No	Date	Summary of Revisions
1.0	27th March 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

1. INTRODUCTION

Data Quality Checks (QC Checks), along with Monitoring and Source Data Verification, are performed to ensure that the study data is accurate and robust prior to analysis.
Where this activity has been delegated to the Data Management team, QC Checks form part of data quality procedure outlined in ECTU Central Office SOP ECTU_DM_05 Data Quality
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 Check Plan

2.1.1 The Data Quality Check Plan will be written using the template DM006 Data Quality Check Plan.

2.1.2 The scope and content of the QC Check must be discussed and agreed with the Trial Manager. DM006 Data Quality Check Plan must be used to facilitate this discussion:

- The method of data entry
  Data entered from pCRF by ECTU data management or trial management staff will require regular QC checks. Any additional checks are at the discretion of the Data Management team.

- 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.

- Is there a Sponsor Monitoring and Source Data Verification Plan in place?
  These should be checked prior to agreeing the scope of the QC Checks as the sponsor may have delegated some checking responsibilities to ECTU. Any conflicts with checks carried out by the Sponsor should also be avoided (e.g. if the Monitor will check the Primary Outcome Data, this should not be repeated in the ECTU QC Check).

- Type and Details of Check
  Specify the type of QC Check (see section 2.1.2 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.

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

- Data Entry Check
  This is a check performed on data points using a comparison of data completed on a pCRF or other source data to data entered onto the database.

- Primary Outcome Check
  This is a check performed on data points using a comparison of data completed on a pCRF or other data source for data relating to the Primary Outcome

- Other Critical Data Check
  This is a discretionary check that may be performed if the Primary Outcome Check cannot be checked (e.g. scan data). It may also be performed for other data that is deemed high-risk (e.g. high volumes of blood results entered at one time that may be prone to data entry errors) or to Secondary Outcome data.

2.1.3 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 be depend on the study:

- Data Entry Check
  100% of selected data (e.g. 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 all participants consented/randomised to the trial. It is recommended that if it is possible to QC Check the Primary Outcome data, that all applicable data is checked.

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

2.1.4 The QC Check Plan will also specify how participant numbers will be selected for inclusion in the QC Check (e.g. applicable participant numbers will be selected at random).

2.1.5 The QC Check Plan will be approved by the Trial Manager and the Data Manager/Assistant Data Manager responsible for the checks.

2.1.6 All study-specific Data Quality Check Plans 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.

2.1.7 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 following identification of an issue at site, an Additional QC Check Plan will be developed.

2.1.8 An Additional 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 completed, ensure the following has been completed:

- An approved QC Check Plan is in place
- Obtain the necessary participant numbers required for the study (it may be necessary to request a random list of applicable participants from the IT programmer for the study)
- 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, QC Check Plan Version No and Date, Date of QC Check, QC Check Completed by. All participant numbers and all CRFs checked should be listed.

- Datapoint Calculations (completed prior to QC Check)
  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. The minimum, maximum and average datapoints (rounded to the nearest whole number) should be stated.
  The Name and Version No of each CRF used to calculate the datapoints will be stated. The current version will be used in the calculations.
  If any datapoints on a CRF are excluded from the QC Check and the calculations (e.g. scan data that it not included in the QC Check or blood results that will be batch-processed at the end of trial and so are not available to check), this should be noted in this section.

- Errors (completed during QC Check)
  Each error identified in the check will be documented in this section. The Participant No, the CRF where the error was identified, who entered the data, a detailed description of the error (e.g. Systolic Blood Pressure is 125 on CRF but is entered as 128 on database), the no of datapoints that are incorrect and the remedial action that has been taken or is required (e.g. 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 The Data Management team will be responsible for following all errors up to resolution.

2.3.2 Errors on data entered by ECTU

Where the data has been entered by ECTU, errors identified during the QC Check can be corrected at the time. 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 (e.g. 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).

2.3.3 Errors on data entered at site

If possible and appropriate to do so, 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 reports. 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, with the date the manual query was raised and the date it was closed stated.
Alternatively, the QC Check Overview can be sent to the site via email with instruction to complete the Comments section with the remedial action taken and to return to ECTU when this is completed.

2.4 Error Rates

2.4.1 The results and error rate will be discussed with the Trial Manager once the QC Check is complete.
The acceptable total % error rate threshold is 5%. If the total % error rate is above this threshold, or if errors are identified that indicate another underlying issue (e.g. 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. Any further action required should be documented on the Data Quality Check Final Report.

2.5 Data Quality Check Final Report

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

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

2.5.3 At this stage, the QC Check should be discussed with the Trial Manager, giving feedback of the types of errors and the total % error rate. 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 Trial Manager and QC Checker 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 by the time the report is to be approved, this should be escalated to the Trial Manager and documented on the report.

2.5.6 Once approved, the Data Quality Check Final Report and QC Check Overview documents will be retained in the Data Management Master File.

3. RELEVANT DOCUMENTS AND REFERENCES

SOP and WPD

- ECTU Central Office SOP ECTU_DM_05 Data Quality
- 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

- DM011 QC Check Overview
- DM006 Data Quality Check Plan
- DM007 Data Quality Check Final Report

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