Data Entry Guidelines

<<Study Name/Acronym>>

**Database URL:**

**Effective Date:**

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| **Authorship History** | | |
| **Author Name and Designation** | **Version No** | **Date** |
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| **Review Schedule** |
| This document will be subject to formal review **<<insert appropriate review frequency here – at minimum must be yearly>>** from **<<insert effective date>>.** This document is also subject to interim reviews as and when appropriate. All revision history must be documented in the tables below. |

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| **Document Review History** | | |
| **Version No** | **Date** | **Summary of Revisions** |
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| **Approval** | | | |
| **Name and Project Role** | **Version No** | **Date Approved** | **Signature** |
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*All text in italic green is for guidance purposes only and should be deleted from the final version. This template is for guidance only and should be altered as appropriate.*

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| **Purpose of Document** |
| This document provides instructions for entering study data onto the electronic database provided for this study. This document applies to all study staff at ECTU who are responsible for data entry for the study.  The data conventions and study specific instructions will be implemented at the point of data entry.  This is not a training document. Database training should be provided by the Trial Manager or designee. |

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| **Data Entry Information and Responsibilities**  **Specify the data that will be entered by ECTU staff and who will complete this** | |
| **Description of Data/CRF** | **To be entered by** |
| *Specify Name of CRF (e.g. Baseline CRF, 30-Day Follow-up Questionnaire)* | *Specify who will enter the applicable CRF (e.g. Data Management team, Trial Manager/TMSO)* |

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| **Data Conventions**  **Note – any annotations or corrections made to a pCRF will be made in ink and will be dated and initialled.** | |
| *The conventions below commonly apply to questionnaire data that is completed by the participant (in ink on paper source). These may not be suitable for other types of data entered. Conventions can be added, deleted or altered to suit study requirements as required. If no conventions can be applied to the source data, this section can be deleted.* | |
| 1. **Illegible Data** | Data that cannot be deciphered (e.g. due to handwriting) will not be entered on the database.  The paper source will be annotated to state this. |
| 1. **Extraneous Data** | Extraneous comments on the paper source will generally be ignored but may be further discussed with the Trial Manager at the discretion of data entry personnel. |
| 1. **Missing Data (Unknown or Not Completed Data)** | If an answer has not been completed but the paper source has been annotated with ‘Not Known’ (or similar), the answer should be left blank on the database and the resultant query (if applicable) updated with an appropriate comment (e.g Not known or not completed by pt).  *Missing data may be generally acceptable in some cases (e.g. in participant questionnaires) and queries may not apply. This should be verified with the Trial Manager*. |
| 1. **Multiple Answers** | The following conventions can be applied to multiple choice questions and annotated on the paper source:   1. For multiple choice questions where only one answer is required but two have been given, the least favourable/worst case scenario answer will be applied and entered on the database. 2. For multiple choice questions where only one answer is required but more than two have been given, all answers should be disregarded and not entered on the database as it is not possible to ascertain a correct answer. The pCRF will be annotated to state the data has not been entered on the database due to multiple answers. |
| 1. **Numerical Answers** | The following conventions can be applied to numerical answer questions:   1. Where a single number/unit answer is required (e.g. 1 per day) but a range is given (1-2 per day), the higher numerical answer will be applied (e.g. 2 per day) and entered on the database. This will be annotated on the paper source.   *This rule may not apply to all studies. There may be instances where the lower number is the least favourable/worst case scenario and should be selected (e.g. hours of exercise). This should be discussed with the Trial Manager prior to study start.*   1. Where a single number/unit answer is required but ‘None’ or ‘Zero’ or ‘N/A’ (or similar) has been given, this can be entered as 0 on the database. 2. Where a single number/unit answer is required but the field is left blank, this should *not* be assumed to be a ‘0’ or ‘None’ answer. This should be left blank on the database and the resultant query (if applicable) should be updated with an appropriate comment (e.g. not answered by pt) 3. Where a single number answer is required and is expected to be within a specified range (e.g. a rating between 1-10) but the answer given is outwith the expected range, this will not be entered on the database. The pCRF will be annotated to state this |
| 1. **Dates** | The following conventions can be applied to dates and annotated on the paper source:   1. If a ‘Completion Date’ (or similar) has been left blank, the date the paper source was received at ECTU will be applied and entered on the database 2. If a ‘Completion Date’ (or similar) has been completed as the Date of Birth, the date the paper source was received at ECTU will be applied and entered on the database 3. If a ‘Completion Date’ (or similar) has been completed with an obvious error (e.g. dated after paper source was received at ECTU or was issued to pt, dated with incorrect year), a correction can be made if possible or the date paper source was received at ECTU will be applied and entered on the database. 4. If a ‘Completion Date’ (or similar) has been partially completed (and partial dates are not applicable on the database), a correction can be made if possible (e.g. year is missing) or the date the paper source was received at ECTU will be applied and entered on the database   *In some cases, data completion may be time-sensitive. Ensure that the above conventions do not affect this adversely when agreeing with the Trial Manager and Trial Statistician.* |
| 1. **Yes/No Answers** | Some Yes/No questions may include a sub-question depending on the answer given. For example:  Has the participant been admitted to hospital within the last six months? – Yes or No  If Yes, please specify length of admission in days  The following conventions can be applied to questions with a Yes or No answer and annotated on the paper source:   1. If the initial question has been answered No but the length of admission has been specified, the initial question can be changed to Yes. 2. If the initial question has been answered No but the length of admission is specified as 0 the initial question will remain as No. The length of admission will not be entered onto the database. 3. If both Yes and No have been answered, this will not be entered onto the database. The paper source will be annotated to say the data has not been entered due to ambiguity. |

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| **Data Conventions Applied**  **Complete the conventions applicable to the data** | |
| **Description of Data/CRF** | **Conventions Applied** |
| *e.g. EQ5D5L Questionnaire (Baseline, 3-Month Follow-up, 6-Month Follow-UP)* | *e.g. a, b, c, d, e and f* |
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| **Study Specific Instructions**  **Specify any instructions in addition to the data conventions above**  **Note – any annotations or corrections made to a paper source should be made in ink and should be dated and initialled.** | | | |
| **Description of Data/CRF** | **Datapoint** | **Description** | **Resolution** |
| *e.g. Random Glucose blood results downloaded from app (in excel spreadsheet)* | *e.g. Sample Date and Time* | *e.g. The data is downloaded directly from the app. The Sample Date provided is in American format MM/DD/YYYY and the Sample Time is provided in HH:MM:SS format* | *e.g. The Sample Date can only be entered onto the database using UK/European format, DD/MM/YYYY and the Sample Time can only be entered onto the database using HH:MM format.*  *The Sample Date on the source data will therefore be converted to the correct format at the point of data entry and the Sample Time will be entered without the seconds included.* |
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| **Template Revision History** | | | |
| **Version No** | **Effective Date** | **Revised By (Name and Designation)** | **Summary of Revisions** |
| 1.0 | 27-Mar-2018 | Lynsey Milne (Data Management and QA Project Co-ordinator) | * Initial creation * Template version set at 1.0 |
| 2.0 | 21-Aug-2020 | Lynsey Milne (Assistant Data Manager) | * Updated due to review of ECTU\_SOP\_DM\_01. Overall simplification of document |
| 3.0 | 15-June-2023 | Lynsey Milne (Data Manager) | * Minor wording changes to wording throughout. Extra instructional text added |