

ECTU Data Management Handover Log

Study Title: {Study Name/Acronym}

\*Guidance text in green must be removed from the study specific copy

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| **Introduction** |

The purpose of this document is to provide an overview of the Data Management procedures for the **STUDY NAME/ACRONYM** study and is used to document all handover activities between the current Data Manager/Assistant Data Manager/Data Management Support Officer (delete as applicable) to the new Data Manager/Assistant Data Manager/Data Management Support Officer (delete as applicable)

This document will be maintained by the current Data Manager throughout the handover period. Handover is completed upon agreed sign-off of this document by both parties.

The table below details handover meeting conducted during this process (add new line for each meeting):

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| **Handover Meeting Details** | |
| **Meeting Date** | **Meeting Content** |
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| **Study Information** |

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| **Study Details** | |
| **Current Status** | In Setup  Recruiting  In Follow-up  Data Cleaning  Close Out/Database Lock  Closed  Temporary Halt |
| **Timelines** | Expected SATO:  LPLV:  Data Cleaning Start & End Dates:  Expected Database Lock: |
| **DM Study Activities (Data Management & Database)** | DM and DB  DM Only  DB Only |
| **Database Type** | REDCap  Bespoke |
| **Database URL(s) or Project Name(s)** *For bespoke provide URL(s) or for REDCap provide project names* | Live:  Training: |
| **Shared Drive Location** | Detail the text location of the shared drive folders |
| **Additional Key Information** |  |

Please describe the key personnel involved in the study below. Add or remove roles where applicable and specify if roles are external from ECTU e.g. Trial Manager (External).

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| **Study Contact Details** | | |
| **Role** | **Name** | **Email** |
| **Chief Investigator** |  |  |
| **Trial Statistician(s)** |  |  |
| **Trial Management Team** |  |  |
| **Senior Software Developer** *(remove if REDCap database and no API randomisation)* |  |  |
| **Previous Data Management Team** |  | *Only include if DM team member still working within ECTU* |
| **Trial Monitor**  *(remove if non-monitored study)* |  |  |

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| **Data Management Procedures Documentation** |

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| **Task/Document Name** | | **Delegated to ECTU DM?** | **Status** | **Most Recent Approval Date and Expected Review Date** | **Location on drive** |
| **Data Management Plan** | | Yes  No | Live  Draft  Pending (Not yet drafted)  N/A |  |  |
| **Query and Missing Data Guidelines:** | | Yes  No | Live  Draft  Pending (Not yet drafted)  N/A |  |  |
| **Data Entry Guidelines:** | | Yes  No | Live  Draft  Pending (Not yet drafted)  N/A |  |  |
| **QC Check Plan:** | | Yes  No | Live  Draft  Pending (Not yet drafted)  N/A |  |  |
| **Data Cleaning Plan:** | | Yes  No | Live  Draft  Pending (Not yet drafted)  N/A |  |  |
|  |  | | | |  |
| ***Query Contact List Location:*** | |  |  | |  |

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| **Database (REDCap Only)** |

This table provides a brief overview to guide you. For detailed information, please refer to the study specific files.

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| **Database Functionality & Requirements** | |
| **Multiple Study Arms:** | Yes  No  **If Yes, provide details:** |
| **Surveys:** | Yes  No  **If Yes, provide details:** |
| **Alerts:** | Yes  No  **If Yes, provide details:** |
| **Form Display Logic:** | Yes  No  **If Yes, provide details:** |
| **SMS Messaging:** | Yes  No  **If Yes, provide details:** |
| **Data Uploads:** | Yes  No  **If Yes, provide details:** |
| **Other** | Yes  No  **If Yes, provide details:** |

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| **Study Specific Details** |

Sections to be added/removed as required

|  |  |
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| **Study-specific Details** | |
| **Query and Missing CRF** | Provide details on how the queries and missing CRF checks are completed, and the frequency at which they are done.  Include here any requirements outwith the usual query runs, study specific considerations, difficulties, and/or future work required. |
| **Adding Users and User Rights** | Provide details on who is responsible for allocating user rights to the study database |
| **Upcoming Database Changes** | Specify if no outstanding change requests are applicable  Provide details of any potential updates that may be required in the future |
| **Data Cleaning Details** | Specify when planning for this should be expected |
| **QC Check Details** | Provide brief details of QC checking requirements if applicable |
| **Ongoing or predicted future Issues** |  |
| **Other Useful Information** |  |

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| **Handover Sign-Off** |

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| All handover is now complete and responsibility for the Data Management activities for the <<Study Name/Acronym>> passes to the new DM/ADM/DMSO as of the date below | | |
| **Current DM/ADM/DMSO Name** | **Signature** | **Date** |
|  |  |  |
| **New DM/ADM/DMSO Name** | **Signature** | **Date** |
|  |  |  |

<<<<<<<<<For template control only. Remove this page from study specific version>>>>>>>>

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| **Template Revision History** | | | |
| **Version No** | **Effective Date** | **Revised By (Name and Designation)** | **Summary of Revisions** |
| 1.0 | 21Mar25 | Lynsey Milne, Data Manager | * Initial creation/new document * Template version set at 1.0 |