

ECTU Data Management Plan

Study Title: {Study Name/Acronym}

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| **Review Schedule** |
| This document must be reviewed at a minimum every **<<insert appropriate review frequency here>>** from **<<insert effective date>>**. This document may also be reviewed and/or updated between formal reviews, where required. Revisions to the DMP must be documented in the Document History section below. |

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| **Document History** | | | |
| **Version No** | **Date** | **Author Name and Role** | **Summary of Revisions** |
| 1.0 | DD-MMM-YYYY |  | * Initial Creation * Study Specific Version set to v1.0 |

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| --- | --- | --- | --- |
| **Approval** | | | |
| **Name and Project Role** | **Signature** | **Date Approved** | **Version Approved** |
| Data Manager |  |  |  |
| Trial Monitor |  |  |  |
| Trial Manager |  |  |  |
| Trial Statistician |  |  |  |

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

**\*Text in red must be adapted as applicable for the study specific DMP**

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| **Introduction** |

The purpose of this document is to describe the data management activity for the **STUDY NAME/ACRONYM** study.

This DMP defines the data management activities and processes for this study so it is managed and maintained in accordance with the appropriate regulatory requirements, ECTU SOPs, sponsor SOPs, study protocol, and GCP requirements. This DMP also describes the documentation that is produced to support the study specific data management activities.

Data management processes are described from study initiation through to database lock and archiving, and identify and define the study personnel and roles involved in CRF design, data collection, and data handling.

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| **Study Description** |

*Please provide a short description of the study including type of study (e.g. multi-centred,open labelled, randomised study across xx sites within the UK) and brief description of the primary objective. Include any other applicable information (e.g. any sub-study information) as may be appropriate*

A detailed description of the study design, duration, and objectives is described in the study protocol. Study timelines and key milestones are available from the Trial Manager or designee.

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| **Personnel and Responsibilities** |

*Please describe the key personnel involved in the study below. Add or remove roles where applicable. The Chief Investigator must always be included. Role description can be altered to suit the study*

|  |  |  |
| --- | --- | --- |
| **Role** | **Name** | **Email** |
| Chief Investigator |  |  |
| Trial Statistician |  |  |
| Unblinded Statistician\* |  |  |
| Trial Manager |  |  |
| Senior Software Developer *(remove if REDCap database)* |  |  |
| Data Manager |  |  |
| Trial Monitor |  |  |

\*Two statisticians are allocated to the trial with the Trial Statistician remaining blinded to the aggregate data by treatment. The Unblinded Statistician will have access to all data

*Please complete the table below detailing the personnel responsible for the tasks listed. The responsibilities detailed in this template are based on normal practice and may be amended where appropriate for the study.*

*\*If the trial is ACCORD sponsored and has been risk assessed, the sponsor must review the CRF prior to initial release. The sponsor must also review completed testing documentation prior to initial release. Please refer to the ACCORD website and current ACCORD SOPs and policies for further information*

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| **Activity** | **Trial Team** | **TM Team** | **DM&P Team** | **Statistician** | **Sponsor** |
| CRF Design |  |  |  |  |  |
| Database Development |  |  |  |  |  |
| Testing and Validation |  |  |  |  |  |
| Query and Missing Data Management |  |  |  |  |  |
| Data Cleaning |  |  |  |  |  |
| Monitoring |  |  |  |  |  |
| Data Export |  |  |  |  |  |
| Database Lock |  |  |  |  |  |
| Data Analysis and Reporting |  |  |  |  |  |
| Archiving |  |  |  |  |  |

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| **CRF Design and Development** |

*Please use the guidance text below if the study is using an eCRF and is subject to CSV review by ACCORD (as detailed in POL007 Computer System Validation). This commonly applies to CTIMPs and other studies where a risk-assessment has deemed this necessary. Additional detail regarding CRF design and development must be specified where applicable to the study.*

Study data will be collected via direct entry to an eCRF.A **bespoke/REDCap** eCRF has been developed by ECTU for this purpose, as per ECTU Data Management and IT SOPs and in accordance with Sponsor requirements as detailed in the relevant SOPs and Policies relating to this process. The eCRF was designed, reviewed, and approved by the Data Manager/Assistant Data Manager (delete as applicable), Trial Manager or designee, Senior Software Developer *(remove Senior Software Developer if a REDCap eCRF)*, Trial Statistician or designee and Trial Monitor. The database specification documentation (including Training and Description document, Validation Plan and Validation Document) was prepared by the Data Manager/Assistant Data Manager/Senior Software Developer *(delete as applicable)* and signed by the Trial Manager or designee. Final approval of the CRF prior to initial release is granted by the Trial Manager or designee and Sponsor representative (as per ACCORD Policy POL007).

Amendments to the live eCRF will follow the ECTU Data Management and IT additional requirements process and the process defined in ACCORD SOP CR013. Changes to the dataset must be reviewed and approved by the Trial Manager or designee, Trial Statistician or designee and Trial Monitor. Minor administrative changes (e.g. spelling, formatting) that do not impact on how the data is collected do not require formal approval by the Trial Statistician or designee. Final approval of the eCRF prior to initial release is granted by the Trial Manager or designee and Sponsor representative (as per ACCORD Policy POL007).

*Please use the guidance text below if the study is using an eCRF and is ACCORD sponsored but not subject to CSV review by ACCORD (as detailed in POL007 Computer System Validation. This commonly applies to non-CTIMPs and studies not subject to a risk-assessment . Additional detail regarding eCRF design and development must be specified where applicable to the study.*

Study data will be collected via direct entry to an eCRF.A **bespoke/REDCap** eCRF has been developed by ECTU for this purpose, as per ECTU Data Management and IT SOPs and in accordance with Sponsor requirements as detailed in the relevant SOPs and Policies relating to this process. The eCRF was designed, reviewed, and approved by the Data Manager/Assistant Data Manager *(delete as applicable)*, Trial Manager or designee, Senior Software Developer *(remove Senior Software Developer if a REDCap eCRF)*, and Trial Statistician or designee. The database specification documentation (including Training and Description document, Validation Plan and Validation Document) was prepared by the Data Manager/Senior Software Developer (delete as applicable) and signed by the Trial Manager or designee.

Amendments to the live eCRF will follow the ECTU Data Management and IT additional requirements process. Changes to the dataset must be reviewed and approved by the Trial Manager or designee and Trial Statistician or designee. Minor administrative changes (e.g. spelling, formatting) that do not impact on how the data is collected do not require formal approval by the Trial Statistician or designee. Final approval of the eCRF prior to initial release is granted by the Trial Manager or designee.

*Please use the guidance text below if the study is using a pCRF and is ACCORD sponsored and subject to combined risk-assessment. This is most commonly applicable to CTIMPs. Additional detail regarding pCRF design and development must be specified where applicable to the study.*

Study data will be collected via a pCRF and then entered onto the study database provided by ECTU. The pCRF has been developed by *(specify who has developed the pCRF)* in accordance with ACCORD SOP CR013. The pCRF was reviewed, and approved by the Data Manager/Assistant Data Manager, Trial Manager or designee, Senior Software and Trial Statistician or designee and Trial Monitor *(amend list as appropriate but Trial Statistician and Trial Monitor must always review the pCRF).*

Amendments to the pCRF must be implemented according to ACCORD SOP CR013. Changes to the dataset must be reviewed and approved by the Trial Manager or designee, Trial Statistician or designee and Trial Monitor. Minor administrative changes (e.g. spelling, formatting) that do not impact on how the data is collected do not require formal approval by the Trial Statistician or designee.

The pCRF has been used as the basis for the design specification for the **bespoke/REDCap** database for this purpose, as per ECTU Data Management and IT SOPs and in accordance with Sponsor requirements as detailed in the relevant SOPs and Policies relating to this process. The database was designed, reviewed, and approved by the Data Manager/Assistant Data Manager (delete as applicable), Trial Manager or designee, Senior Software Developer *(remove Senior Software Developer if a REDCap eCRF)*, Trial Statistician or designee and Trial Monitor. The database specification documentation (including Training and Description document, Validation Plan and Validation Document) was prepared by the Data Manager/Assistant Data Manager/Senior Software Developer *(delete as applicable)* and signed by the Trial Manager or designee. Final approval of the CRF prior to initial release is granted by the Trial Manager or designee and Sponsor representative (as per ACCORD Policy POL007)

Amendments to the live database following an approved change to the pCRF will follow the ECTU Data Management and IT additional requirements process. Changes to the dataset must be reviewed and approved by the Trial Manager or designee, Trial Statistician or designee and Trial Monitor. Minor administrative changes (e.g. spelling, formatting) that do not impact on how the data is collected do not require formal approval by the Trial Statistician or designee. Final approval of the CRF prior to initial release is granted by the Trial Manager or designee and Sponsor representative (as per ACCORD Policy POL007).

*Please use the guidance text below if the study is using a pCRF and is ACCORD sponsored and not subject to combined risk-assessment. This is most commonly applicable to non-CTIMPs. Additional detail regarding pCRF design and development must be specified where applicable to the study.*

Study data will be collected via a pCRF and then entered onto the study database provided by ECTU. The pCRF has been developed by *(specify who has developed the pCRF)* in accordance with ACCORD SOP CR013. The pCRF was reviewed, and approved by the Data Manager/Assistant Data Manager, Trial Manager or designee, Senior Software and Trial Statistician or designee *(amend list as appropriate but Trial Statistician and Trial Monitor must always review the pCRF).*

Amendments to the pCRF must be implemented according to ACCORD SOP CR013. Changes to the dataset must be reviewed and approved by the Trial Manager or designee, Trial Statistician or designee. Minor administrative changes (e.g. spelling, formatting) that do not impact on how the data is collected do not require formal approval by the Trial Statistician or designee.

The pCRF has been used as the basis for the design specification for the **bespoke/REDCap** database for this purpose, as per ECTU Data Management and IT SOPs and in accordance with Sponsor requirements as detailed in the relevant SOPs and Policies relating to this process. The database was designed, reviewed, and approved by the Data Manager/Assistant Data Manager (delete as applicable), Trial Manager or designee, Senior Software Developer *(remove Senior Software Developer if a REDCap eCRF)*, Trial Statistician or designee and Trial Monitor. The database specification documentation (including Training and Description document, Validation Plan and Validation Document) was prepared by the Data Manager/Assistant Data Manager/Senior Software Developer *(delete as applicable)* and signed by the Trial Manager or designee. Final approval of the CRF prior to initial release is granted by the Trial Manager or designee.

Amendments to the live database following an approved change to the pCRF will follow the ECTU Data Management and IT additional requirements process. Changes to the dataset must be reviewed and approved by the Trial Manager or designee, Trial Statistician or designee. Minor administrative changes (e.g. spelling, formatting) that do not impact on how the data is collected do not require formal approval by the Trial Statistician or designee. Final approval of the CRF prior to initial release is granted by the Trial Manager or designee.

*If the study is not ACCORD sponsored, please detail below the CRF design and development process. This must align with the sponsor SOPs and include detail regarding initial development of the CRF, database specification development, and the amendment process.*

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| **Randomisation** |

*Please provide a description of the trial randomisation system, including details of where the randomisation procedure is defined. Provide a description of who has prepared the randomisation lists, where applicable, and who has approved the randomisation procedure. If this process is defined in supporting documentation, please reference the appropriate documentation.*

*If the study does not require any randomisation, use the text below:*

No randomisation is required for this study. *Provide a brief description of the study mechanism* e.g. *participants will be allocated to a study arm based on screening and eligibility criteria for each arm*

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| **Data Workflow and Data Entry** |

*Please provide a detailed description of the CRF workflow and data entry processes for the study. The following points must be detailed in the DMP, where applicable to the study. If some, or all, of this information is described in supporting documentation, please reference the appropriate document.*

* *Detail the types of data collected and how this data is generated*
* *Specify the methods/tools used to capture and record data for the study. Specify where different data sources are used and how each data source will allow CRF completion (e.g. Site staff enter data from source documents on to the study eCRF. Participant questionnaires will be sent by post to participants two weeks in advance of the 6-month and 12-month follow up visits for completion by participants on paper. Paper questionnaires returned to ECTU will be entered by ECTU staff)*
* *Specify the location of the source data or reference the study source data plan*
* *If the eCRF is the source for any data, this must be detailed in the protocol and in the DMP*
* *Describe study specific data entry conventions applicable to the study or refer to the location of the other data handling guidance where appropriate. If data will be entered by ECTU staff, please refer to the ECTU Data Entry Procedures SOP.*
* *Describe timelines for data entry, e.g. data is expected to be entered within one week of the CRF due date*

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| **Training and User Access** |

Initial database training will be provided at each site’s SIV. Ongoing database training (post-SIV) for new study staff at site is delegated to the local PI. All users must review the training material and access the training system before access to the live database is provided.

*The following text applies to studies using a REDCap database:*

In order to access the study database within the REDCap platform, prospective users must first be granted access by the ECTU REDCap Administrators. The Trial Manager or designee will request a REDCap log-in for prospective users before they can be granted access to the study databases (training and live database applications). Requests are made via email [redcap.ectu@ed.ac.uk](mailto:redcap.ectu@ed.ac.uk) with the name and email address of the prospective user. All users will be assigned a unique username and access to the system is role based and password controlled.

Once access to REDCap has been granted, an email will be sent automatically by the REDCap system to the user advising them to log-in and set a password. The ECTU REDCap Administrator will confirm the access has been granted via email to the Trial Manager or designee who requested the access.

The Trial Manager or designee will be responsible for granting access to the study databases (training and live) thereafter. Prospective users must complete a User Access Form and return signed and dated to the Trial Manager or designee. Once approved, access will be granted to the live system. For ACCORD-sponsored studies subject to combined risk assessment, access to the live study database should not be granted until Sponsor Authorisation to Open Trial Site (SATO) is given.

Sites will be instructed to contact the Trial Office if user details change or to remove access when no longer working on the study. The Data Management team will review the user list periodically (approximately every 6 months) and liaise with the Trial Manager or designee to remove user access where appropriate.

*The following text applies to studies using a bespoke database:*

The Trial Manager or designee will be responsible for granting access to the study databases (training and live) thereafter. Prospective users must complete a User Access Form and return signed and dated to the Trial Manager or designee. Once approved, access will be granted to the live system. For ACCORD-sponsored studies subject to combined risk assessment, access to the live study database should not be granted until Sponsor Authorisation to Open Trial Site (SATO) is given.

*The following text applies to both bespoke and REDCap databases:*

All users will be assigned a unique username and access to the system is role based and password controlled.

Sites will be instructed to contact the Trial Office if user details change or to remove access when no longer working on the study. The Trial Manager or designee will review the user list periodically (approximately every 6 months) and liaise with sites to remove user access where appropriate.

An overview of the user roles and their associated access rights are described in Appendix B. Read-only access to the live system will be granted to the ACCORD study monitor and ACCORD QA Coordinator *(delete if not applicable*). Additional read only access for Inspectors/Auditors can be granted on request by contacting the Data Management Team.

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| **Data Quality** |

*NOTE: Text regarding queries may differ according to the study requirements. The text below are standard examples but can be changed as necessary.*

*Text if using a REDCap database:*

Where required, the REDCap database programmer will implement a series of Data Quality Rules to assist in identifying missing or non-conformant data. At a minimum and where possible, these will be applied to all data relating to the primary and secondary outcomes/endpoints and safety data.

These rules can be set to execute in real-time so that the user is alerted to the non-conformance at the point of data entry. Where this is applicable, these will be defined in the validation documentation for the feature they are implemented on.

Other Data Quality Rules can be implemented and executed on an ad-hoc basis by the ECTU Data Management team to identify discrepancies. A manual query will then be added to the database in order to resolve the issue with the site team.

Quality rules will be implemented for the following key data fields:

*Specify where quality rules will be implemented as example below:*

* *All fields relating to the Primary Objectives and Secondary Objectives*
* *All fields relating to the Primary Endpoints, Secondary Endpoints and Safety Endpoints*

*Text if using a bespoke database:*

Data validation checks (“automated data queries”) will be defined for the study to ensure the data entered is complete, plausible, and consistent. At a minimum and where possible, these will be applied to all data relating to the primary and secondary outcomes/endpoints and safety data.

Automated data queries will alert users to missing or non-conformant data, data outside of pre-defined ranges, and data that is inconsistent as defined in the specification. An automated data query is raised when an eCRF page is saved by the user and will be automatically and immediately available for review by users. Manual queries can be raised by those with the correct access rights (see Appendix B: User Roles)

Where an automated data query is applicable, this will be defined in the validation documentation for the feature they are implemented on.

*NOTE: For some studies, some primary and secondary outcome data may not be available until the end of trial and may not be directly entered onto the study database (e.g. lab results that are batch-processed and the results uploaded to the study database in source format). Where this is applicable it should be stated in section 6. Any data quality checks should be considered as part of data cleaning at end of study and specified in the Data Cleaning Plan. Where this applies, please ensure this is stated above.*

*If a third party is responsible for the collection and monitoring of any primary and secondary data (e.g. questionnaire data that is collected by a team external to ECTU), please ensure this is stated in section 6.*

Queries and Missing Data will be managed by the Data Management team/Trial Management team *(delete as applicable)* in accordance with the ECTU Central Office SOP ECTU\_DM\_06. Query and Missing Data Management Study-specific Query and Missing Data Guidelines will be provided to describe the process in further detail. This will be in place within 6 months of the first participant being recruited to the study.

*The following text should be used if Data Quality Control (QC) checks will not be completed by ECTU (to be adapted for study):*

No additional Data Quality Control (QC) Checks will be completed by ECTU for this study as per the criteria set out in ECTU Central Office SOP ECTU\_DM\_05 Data Quality.

*The following text should be used if Data Quality Control (QC) checks will be completed by ECTU (to be adapted for study):*

Data Quality Control (QC) Checks will be completed by the ECTU Data Management team/Trial Management team *(delete as applicable)* criteria set out in ECTU Central Office SOP ECTU\_DM\_05 Data Quality. A Data Quality Control (QC) Check Plan will be provided by the Data Management team/Trial Management team *(delete as applicable)* detailing the scope and schedule of the checks.

The quality and completeness of data entered by sites will be monitored via the query procedures detailed above.

*The text below relates to Data Cleaning performed at the end of study prior to final analysis. If any interim analysis is planned, include a description of the responsibilities relating to this in addition to this text.*

The Data Management team will be responsible for Data Cleaning of the study data and final reconciliation of the Pharmacovigilance (PV) data at the end of trial prior to database lock and final analysis.

A Data Cleaning Plan will be provided for this when appropriate (when the end of study timelines have been established).

For PV data the Data Management team will request a line listing of safety events from the ACCORD Pharmacovigilance Manager, or designee. The safety events listed will be reconciled with the data in the eCRF to ensure theses have been included within the eCRF where applicable (see protocol section XX for details of AEs recorded in the eCRF). This reconciliation will be documented on the Data Cleaning Log. Any discrepancies will be raised with the ACCORD Pharmacovigilance Manager and/or with the study site followed up to resolution.

The Trial Management team will be responsible for the final reconciliation of non-compliances (deviations and violations) at the end of trial prior to database lock and final analysis.

For non-compliances the Trial Management team will request a list of deviations and violations from the ACCORD QA team. The non-compliances listed will be reconciled with the non-compliance information held in the TMF. This reconciliation will be documented by adding an additional column to the line listing. A tick will be inserted to indicate correct entries. The date that the reconciliation was performed will also be included. Documentation of reconciliation should be filed in the TMF. Any discrepancies identified will be raised with the ACCORD QA Co-Ordinator, or designee, and followed up to resolution.

The Trial Management team is responsible for any data cleaning and data reconciliation required prior to DMC/TSC as applicable during the trial.

*The following text applies if the study is monitored:*

This study is monitored by a representative from ACCORD. The study specific Monitoring Plan and SDV Plan describe the monitoring and source data verification activity in detail.

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| **Reports** |

*Please describe the reports required for the study. A list of common reports have been listed below. Please amend this list as required.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Report Name** | **Description** | **Report Used by** | **Frequency** |
| *Add report here* | *Add description here* | *Add detail here* | *Add frequency here* |

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| **Data Transfer** |

*Text if data linkage is included in the study:*

Data Linkage is planned for this study (as detailed in section xx of the study protocol). Appropriate participant identifiers are collected on the study database to facilitate this. *If transfer details for data linkage is known, include here.*

*Please use the section below if Data Transfers are planned for the study (not including planned data linkage at the end of study)*

The table below specifies the Data Transfer arrangements currently in place for the study. Further information on this can be obtained from the Trial Manager or designee *(or include reference document if available)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description of Data** | **Sender Details** | **Recipient Details** | **Frequency of Transfer** | **Reason for Transfer** |
| *e.g. CSV file of all biomarker blood results collected from participants at Baseline, 1-Year and 2-Year Visit* | *e.g. QMRI Labs, RIE* | *e.g. ECTU* | *e.g. Single transfer after LPLV* | *e.g. Data to be uploaded to study database for analysis* |
|  |  |  |  |  |

*Please use the section below if Data Transfers are not planned for the study:*

No Data Transfers are currently planned for the study.

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| **Coding** |

*If coding is applicable, use the following text:*

The coding of adverse events will be performed by an appropriately trained and delegated member of the study team. This will be entered onto the study database in the MedDRA code fields included for this purpose.

Training materials for MedDRA coding are available from ACCORD.

MedDRA coding will be performed, at a minimum, at the end of the study prior to database lock.

*If there are any additional coding requirements, please details these here.*

*If no coding is required, use the following text:*

No coding of events or data is required for the study.

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| **Database Lock and Archiving** |

The study database will be locked before final analysis. Database lock procedures will be performed according to ECTU SOPs. All study data will be stored and archived according to ECTU and Sponsor SOPs.

For database lock for final analysis to occur all site close out visits must be complete (as per ACCORD Policy POL012 Data Management) *(to be altered as required in case of different SOP or Sponsor)*, all data queries resolved and reconciliation of PV and non-compliance data complete.

Following the end of trial, the Trial Manager or designee is responsible for ensuring that all study data and files are archived as per ACCORD SOP GS005 *(to be altered as required in case of different SOP or Sponsor)*, and ECTU SOPs. The archiving period is a minimum of XX years as per the study protocol. After this time period has elapsed no data will be destroyed without authorisation from the Sponsor

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| **Appendix A: Abbreviations and Definitions** | | |
| *To be altered as required* | | |
| **AE** | Adverse Event | |
| **CI** | Chief Investigator | |
| **CRF** | Case Report Form | |
| **DM** | Data Manager/Data Management | |
| **DM&P** | Data Management and Programming Team | |
| **DMP** | Data Management Plan | |
| **eCRF** | Electronic Case Report Form | |
| **LPLV** | Last Participant, Last Visit | |
| **MedDRA** | Medical Dictionary for Regulatory Activities | |
| **pCRF** | Paper Case Report Form | |
| **PDF** | Portable Document Format | |
| **QC** | Quality Control | |
| **SAE** | Serious Adverse Event | |
| **SIV** | Site Initiation Visit | |
| **SDV** | Source Data Verification | |
| **SOP** | Standard Operating Procedure | |
| **TM** | Trial Manager/Trial Management | |
| **TMF** | Trial Master File | |

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| **Appendix B: User Roles** |

*Please amend the table to below to include specific roles for the study. Please also include any additional information on the specific roles if necessary*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Administrator** | **Trial Office** | **Site Researcher** | **Site PI** | **Monitor** | **Statistician** | **Unblinded Statistician** | ***Specify Role*** |
| Add/edit users to the REDCap platform (*to be deleted if bespoke database)* | X |  |  |  |  |  |  |  |
| Add/edit users to the study database | X |  |  |  |  |  |  |  |
| Add participants | X |  |  |  |  |  |  |  |
| Add / edit data | X |  |  |  |  |  |  |  |
| Open data query | X |  |  |  |  |  |  |  |
| View data query | X |  |  |  |  |  |  |  |
| Respond to data query | X |  |  |  |  |  |  |  |
| Close data query | X |  |  |  |  |  |  |  |
| Data Export | X |  |  |  |  |  |  |  |
| Randomisation via API token (to be deleted if bespoke database) | X |  |  |  |  |  |  |  |
| ***Specify task*** |  |  |  |  |  |  |  |  |

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| **Appendix C: Related Documentation** |
| *Please add or delete documentation related to this Data Management Plan. The description must detail where the document is located, e.g. filed in the TMF and electronically on the ECTU shared drive* |

|  |  |
| --- | --- |
| **Document Name** | **Description** |
| Protocol / Project Summary | * Description of the project objectives, design, and organisation * Filed in the TMF and electronically on the ECTU shared drive |
| Database Specification | * Initial description of the project data fields, field validation, logic checks, and automated data queries * Filed in the data management folder and electronically on the ECTU shared drive |
| Validation Documentation | * Consists of the validation plan and validation document * Description of the validation plan, including data field validation, logic checks, and automated data queries * Evidence of each feature’s validation, including a description of whether the feature has passed or failed and the reason for failure * Signed documentation filed in the data management folder * Word versions for editing filed electronically on the ECTU shared drive |
| Query and Missing Data Guidelines | * Description of instructions for generating query and missing data reports for distribution to sites * Description of the guidance on handling unresolved queries, generating manual queries, and missing data * Filed in the data management folder and electronically on the ECTU shared drive |
| Data Entry Guidelines | * Description of the ECTU data entry process where pCRF data is entered at ECTU * Filed in the TMF and electronically on the ECTU shared drive |
| Data Quality Control (QC) Check Plan | * Description of the ECTU QC check process * Filed in the TMF and electronically on the ECTU shared drive |
| Data Cleaning Plan | * Description of the ECTU Data Cleaning process * Filed in the TMF and electronically on the ECTU shared drive |
| Monitoring Plan | * Description of the monitoring requirements and responsibilities * Filed in the TMF and electronically on the ECTU shared drive |
| SDV Plan | * Description of the source data verification activity by the sponsor monitors * Filed in the TMF and electronically on the ECTU shared drive |

<<<<<<<<<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 | 25-Nov-2016 | Michelle Steven (Data Manager) | * Initial creation * Template version set at 1.0 |
| 2.0 | 15-Feb-2017 | Michelle Steven (Data Manager) | * Removal of duplicate standards * Formatting changes and minor corrections to grammar and spelling |
| 3.0 | 01-Jun-2017 | Michelle Steven (Data Manager) | * Additional duplicate standards removed * Formatting changes |
| 4.0 | 06-April-2018 | Michelle Steven (Data Manager) | * Formatting changes * Addition of ‘Associated Documentation’ section listing documents related to data management processes held elsewhere in ECTU * CRF List and Source Data Plan sections removed * Standards amended and moved within template to more appropriate sections * Renamed template to align with new DM template numbering |
| 5.0 | 07-Oct-2018 | Michelle Steven (Data Manager) | * Extensive revision following process review * Extensive formatting changes * Addition of standard text for consistency across DMPs * Addition of further sections to describe data management activity (data transfer, database lock and archiving, randomisation) |
| 6.0 | 15-Jun-2023 | Lynsey Milne (Data Manager), Christopher White (Assistant Data Manager) | * Extensive revision at scheduled review to reflect implementation of ACCORD POL012 Data Management |
| 6.0 | 20 Jan 2025 | Tanya Tharakan (QA Manager) | * Email Ref: Lynsey Milne (20Jan25) Minor edit to Headers of pages 12-13 to match the preceding pages. Header removed from pg14 as this is not study specific, and contains template revision history. Version number and review date remains the same. |
| 7.0 | 19 May 2025 | Lynsey Milne (Data Manager) | * Minor wording changes in section 4 to specify study database build in accordance with Sponsor SOPs and Policies * Additional text in section 8 to clarify implementation of queries on primary and secondary outcome/endpoint and safety data. Additional note included for end of study data and third-party data management |