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| Luxembourg Institute of Health |  | Author: |  | Version 1.0 April 16h, 2019 |

Data Management Plan

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# Approval Page

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| The DMP documents the processes and procedures employed by organizations to promote consistent, efficient and effective data management practices for each individual study. A primary goal of the DMP is to communicate to all stakeholders the necessary knowledge to create and maintain a high-quality database ready for analysis. For each new study, clinical data management (CDM) personnel should compose a detailed DMP based on the protocol, work scope, contract, analysis plans, dataflows, case report forms (CRFs), other supporting documents, and data management standards and practices. The entire DMP should be drafted and approved by all responsible parties prior to commencement of the work it describes. The clinical data manager should ensure the DMP is kept current, including proper version control, and that all parties involved agree with the content. Upon conclusion of the study, the DMP should be archived with all other pertinent study documentation.  The DMP should be created during the setup phase of each study and should contain information relating to all aspects of data management activities to be performed. The DMP should be considered a living document throughout the life cycle of a study, capturing any changes impacting data management made to the protocol or processes being used. |

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| **Study Name** |  |
| Data Manager Name |  |
| Total Number of Reviewers |  |
| Date of the Last Approval |  |

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| **Reviewer Name** | **Job Function** | **Date of Approval** | **Signature** |
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Date: Data Manager Signature:

# Protocol Summary

Short synopsis of the study protocol, visit schedule, or critical data analysis variables. A list of major protocol revisions and associated version numbers should be maintained.

|  |
| --- |
| **Synopsis** |
| Reference document (Full Protocol): XXX.pdf |
| **Description of study synopsis** |

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| --- |
| **Visit schedule** |
| Reference document: XXX.pdf – PAGE X |
| **Description of study visit schedule** |

List of critical data analysis variables.

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| **Variable Name** | **Variable Label** | **Dataset** |
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| Reference documents: XXX.pdf and XXX.docx | | |

List of major protocol revisions and associated version numbers.

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| --- | --- | --- |
| **Protocol/Amendment Name** | **Version** | **Date of Release** |
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# Dictionary and Coding Management

**Medical coding dictionaries1** used for the study.

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| **Dictionary Name** | **Version** | **Reference Document\*** |
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\* Document providing instructions for how to handle dictionary updates or changes and define all quality control measures, validation methods, and user acceptance testing (UAT) for the dictionary

**Auto-Encoding** or Study-Specific Conventions used.

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| **Variable Name** | **Original Value** | **Auto-Encoding or Study-Specific Convention** |
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| Reference document: | | |

# Definitions and Acronyms

**List of acronyms** that are specific to the protocol and DMP, and definitions of terms that may be misinterpreted or misunderstood.

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| --- | --- |
| **Acronym/Term** | **Definition** |
| DMP | data management plan |
| SOPs | standard operating procedures |
| CRFs | case report forms |
| UAT | user acceptance testing |
| AE/SAE | adverse event /serious adverse event |
| EDC | electronic data capture |
| CDMS | clinical data management system |
| QA/QC | quality assurance / quality control |
| DSMB | data safety monitoring board |
| LIH | Luxembourg Institute of Health |
| PI | Principal Investigator |
| CIEC | Clinical and Epidemiological Investigation Center |
| CCMS | Competence Center for Methodology and Statistics |
| CHL | Centre Hospitalier de Luxembourg |
| HRS | Hôpitaux Robert Schuman |
| LNS | Laboratoire National de Santé |
| IBBL | Integrated BioBank of Luxembourg |
| AUC | Area Under Curve |
| GDPR | General Data Protection Regulation |
| CRA | Clinical Research Associate |
| GCP | Good Clinical Practices |
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| Reference document: | |

# Personnel/Role Identification/Training

Key personnel with roles and responsibilities for the associated protocol and study activities. Or reference to external documents or related SOPs containing this information.

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| **Key Personnel Name** | **Role/Responsibility** |
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| Reference document (related to project-specific training requirements for various roles and functions): | |

# Timelines

Listing of expected completion targets for all deliverables. For example, database validation could be targeted for completion a specified number of weeks from the time the protocol is finalized.

|  |  |
| --- | --- |
| **Milestone** | **Date/Timeline** |
| Protocol finalization |  |
| CRF development |  |
| Database design and UAT |  |
| Data validation, programming and UAT |  |
| First patient first visit |  |
| Last patient last visit |  |
| Last CRF/data element received/entered |  |
| Last query/discrepancy form received/completed |  |
| Final SAE reconciliation completed |  |
| Medical coding completed and approved |  |
| Interim analysis, when applicable |  |
| Database audit |  |
| Database lock |  |
| Study data and documentation archiving |  |
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# Case Report Form

Detailed description of the CRF design process.

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| **CRF design process** |
| Reference document: |
| **The first version of XXX was developed by Clinical Data Manager on XX-XX-2020. Several intermediate versions were proposed by X unit, and the final version was validated on XX-XX-2020.** |

General guidelines for CRF completion, as well as protocol-specific guidelines.

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| **CRF Completion Guidelines** |
| Reference document: |
|  |

Process description for managing changes to the CRF design. Changes to CRFs may also involve metadata changes.

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| **CRF design changes managing** |
| Reference document: |
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# Database Design, Creation and Maintenance

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| **Database Creation** |
| Reference document (Data Validation Plan): OP-DMS-002 - Creation of the Study Database and OP-DMS-003 - Edit check development |
| **Database X will be created by clinical data manager, using X software.** |
| **System holding the data** |
| Reference document: |
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| **Table naming conventions** |
| Reference document: |
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# Database Archive

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| **Specific information regarding procedures for archiving the electronic records.** |
| Reference document: |
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# Database Roles and Privileges

List of profiles for available database roles within the system being used to support the study.

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| **Persons Involved in the Study** | **Database Role Assigned** |
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| Reference document (where the roles and the associated privileges are described): | |

# Database Security

Description of the security of networked equipment and servers as well as security features of the electronic records within the clinical data management system (CDMS).

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| **Maintenance of User Roles and Access** |
| Reference document: XX.pdf |
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| **Database Backup** |
| Reference document: PRO IT-905.02.pdf |
| **This procedure describes the necessary actions to make backup copies of data, systems appliances and databases in order to prevent or minimize the risk of data loss and secure business continuity. This procedure encompasses the rules and frequency of the backup copy and periodical tests of the copies made.** |

# Database Entry and Processing

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| **Data Entry Guidelines2** |
| Reference document: Manuel-Utilisateur-CSEntry-8.0.100.pdf |
| **Data will be first collected by clinical nurse from LIH in paper CRF directly on different sites (hospital, laboratories), and in second time, the same clinical nurse will enter the data in eCRF on Ennov Clinical platform. If needed, the Clinical Data Manager will raise the queries including discrepancies and missing data. Monitor will go on site for Source Data Verifications (% of monitored data will be specified in Monitoring plan). Once all queries resolved, investigators will be able to access the platform, to control and to sign the data.** |
| **Data Discrepancy Conventions** |
| Reference document: |
| **We will not have any specific conventions in classifying and processing of data discrepancies.** |

**Data Receipt**. Specify the type of receipt (paper CRF or EDC), the expected frequency of data receipt, and how data receipt will be tracked (e.g. by post vs by e-mail). This also refers to data transfers from any third-party vendors.

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| **Site/Third-party Vendor** | **Type of Receipt** | **Expected Frequency** | **Tracking Type** |
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| **Data Processing** |
| Reference document: |
| **Description of how the data will be processed upon receipt at the organization (either electronic or paper-based data).** |

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| **Data Entry** |
| Reference document: |
| **Clinical nurse from LIH will enter the data in X platform, and we will have X data entry.** |

**Self-Evident Corrections** list -- changes to data or resolution of a query that can easily and obviously be made on the basis of other existing information on the CRF without sending a query to the investigative site. Identify authorized data management personnel who will make these corrections to the data as necessary.

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| **DM personnel** | **Variable Name** | **Dataset** | **Original Value** | **Corrected Value** |
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| Reference document: | | | | |

**Data Reconciliation**. Provide details about the data fields and external databases requiring reconciliation per the study protocol.

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| **Site/Third-party Vendor** | **Variable to Reconciliate** | **Frequency of Reconciliation** |
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| Reference document: | | |

**Database Lock criteria3**. Provide details who will be responsible for database lock, and processes that will be employed in locking the database.

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| **Person responsible** | **Process Employed in Locking** | **Condition Required** |
|  | Each CRF will be locked individually | If monitoring done, if no open queries, if investigator signed |
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| Reference document: | | |

# Data Validation and UAT

**Validation test procedures4** ensuring integrity of study-specific components such as programming/algorithms, data entry/EDC screens, online logic/data-checking routines, security, backups, and archiving.

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| **Validation Test Procedure Name** | **UAT Date** | **Reference Document** |
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| Reference document: | | |

**Manual Review Specifications**—Description of all types of manual review specifications. Some aspects of these checks may be identified electronically depending on the features of the CDMS utilized. Other manual reviews (e.g., medical history, adverse events, concomitant medications reports, header information) may be generated via the CDMS.

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| **Type of Manual Review Specification** | **Variable Manually Reviewed** | **Dataset** |
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| Reference document: | | |

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| **Discrepancy Management** |
| Reference document: |
| **Description of the query process in detail, including how data clarification forms for paper studies or electronic queries for EDC studies are to be raised, tracked and handled when resolved, the annotation of any working copy CRFs and the documentation to be filed or retained. If different statuses are used for discrepancies, they should be defined.** |

**Electronic data discrepancy management**—Define and describe processes to resolve electronic data discrepancies for the dataset or module being checked. These processes should include presentation of information which may include the CRF module, variable description, name of the edit check, processes for the use of test cases, a description of the edit check, an output message that would translate to a data query, other associated variables in the case of cross-checking data, and processes for documentation of these testing and validation activities.

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| **Variable** | **Associated Variable(s)** | **Output Message** | **Validation Process** |
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| Reference document: | | | |

# SAE Data Reconciliation

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| **SAE reconciliation plan** |
| Reference document: |
| **Description of the protocol specific SAE reconciliation plan.** |

# Quality Assurance/Control Processes

**SOP compliance checklist** indicating which SOPs are applicable to the study. Document in the comments section of the SOP compliance checklist any justification for opting out of all or part of the SOPs.

|  |  |  |
| --- | --- | --- |
| **SOP Name** | **Applicable to the Study** | **Comments** |
| **Data Privacy** | YesNo |  |
| **Data Management Plan** | YesNo |  |
| **Project Management for CDM** | YesNo |  |
| **Vendor Selection and Management** | YesNo |  |
| **DM Standards in Clinical Research** | YesNo |  |
| **Design and Dvp of Data Collection Instr.** | YesNo |  |
| **Edit Check Design Principles** | YesNo |  |
| **EDC Concepts and Study Start-up** | YesNo |  |
| **EDC Study Conduct** | YesNo |  |
| **EDC Study Closeout** | YesNo |  |
| **CRF Completion Guidelines** | YesNo |  |
| **CRF Printing and Vendor Selection** | YesNo |  |
| **DB Validation Programming and Stds** | YesNo |  |
| **Laboratory Data Handling** | YesNo |  |
| **External Data Transfers** | YesNo |  |
| **Patient-Reported Outcomes** | YesNo |  |
| **CDM Presentation at Investigator Mtgs** | YesNo |  |
| **Training** | YesNo |  |
| **Metrics in Clinical Data Mgmt** | YesNo |  |
| **Assuring Data Quality** | YesNo |  |
| **Measuring Data Quality** | YesNo |  |
| **Data Storage** | YesNo |  |
| **Data Entry Processes** | YesNo |  |
| **Medical Coding Dictionary Mgmt & Maint** | YesNo |  |
| **Safety Data Mgmt and Reporting** | YesNo |  |
| **SAE Data Reconciliation** | YesNo |  |
| **Database Closure** | YesNo |  |
| **Clinical Data Archiving** | YesNo |  |
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| **Level of checks** | | |
| Reference document: | | |
| **We will put in place the strongest level of QC checking, especially all inclusion exclusion criterias, safety data, and all protocol end points.** | | |

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| **Frequency of quality control checks** |
| Reference document: |
| **After every new patient will be entered in the Studz database, queries will be raised and sent for corrections.** |

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| **QC check documentation processes** |
| Reference document: |
| **Define the means by which QC checks are documented and how this documentation is maintained throughout the course of the study.** |

# External Data Transfers

Description of the data type (e.g., safety lab data), the entity providing or receiving the data and any applicable agreements, the format, the frequency of transfers, and contact information for all those involved with the data transfer. Good practice is to have an established data transfer plan and to conduct a test data transfer prior to the need for a live transfer.

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| **Variable** | **Format** | **Method** | **Provider** | **Frequency** | **QC** |
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| Reference document: | | | | | |

# Audit Plans

Description of the on-site interim and final study database audit and corrective action plans.

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| --- | --- | --- | --- |
| **Site** | **Audit Type** | **Date** | **Comments** |
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# Metrics

Description of the metrics that will be used for the study.

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| **Variable Name** | **Metric Definition** | **Measure** |
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| Reference document: | | |

# Reports

List of available reports for dissemination throughout the life of the study. For each report, specify the target audience, content of the report, level of detail provided, date of data extraction, frequency of generation and the mechanism used for distribution (e.g., e-mail, posting electronically).

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| --- | --- | --- | --- | --- | --- | --- |
| **Name** | **Audience** | **Content** | **Level** | **Date** | **Frequency** | **Distribution** |
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| Reference document: | | | | | | |

# Communications

Description of the types of communications or correspondence used in the study.

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| --- | --- | --- | --- | --- |
| **Medium\*** | **Frequency** | **Date** | **Escalating Process** | **Reference Document** |
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\* Medium (e.g., face-to-face vs. conference call vs. Web conference)

# Other Processes

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| **DSMB requirements** |
| Reference document: |
| **Description of any requirements pertaining to DSMB meetings that may occur during the course of the study. What preparation is expected to be performed prior to these meetings? Will this preparation be treated as a lock in regards to having all data clean and reported upon prior to the meeting? Will the DSMB be focusing on a sample of the data or the complete data set?** |

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| **Business rules** |
| Reference document: |
| **Specify business rules that may have an impact on data handling or data integrity in the DMP. For example, regularly scheduled IT maintenance that limits server access, organization-wide observed holidays or an anticipated change of address during the course of the study may affect data handling.** |

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| **Flowcharts and forms** |
| Reference document: |
| **(e.g., CRFs, source documents, adjudication and query forms)—Include applicable flowcharts or sample forms that may be required by your organization.** |

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| **Problems and resolutions** |
| Reference document: |
| **Document the process of identifying, discussing, resolving and filing problems arising and resolved during the study.** |

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| **Change control processes** |
| Reference document: |
| **Evaluate if other change control processes may be encountered during the course of the study and describe them in the DMP.** |

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| **Blind data review specifications** |
| Reference document: |
| **Description of the expectation from data management if a blind data review will be conducted.** |

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| **Archival and record retention process** |
| Reference document: |
| **Description of when and how the archival process occurs. The processes described revolve around current organizational and governmental regulations. There are certain requirements that must be met according to applicable regulatory and/or sponsor requirements.1 Document the record retention timeframe and communicate this timeframe to site personnel.** |

**References**

1. Please refer to the “Dictionary Management” and “Safety Data Management and Reporting” chapters.
2. Please refer to the “Data Entry and Data Processing” chapter.
3. Please refer to the “EDC Study Closeout” or “Database Closure” chapters.
4. Please refer to the “Database Validation, Programming, and Standards” chapter.

**Chapter Revision History**

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| --- | --- | --- | --- |
| **Version** | **Date** | **Author** | **Reason for version change** |
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