

**General information**

|  |  |
| --- | --- |
| **Sponsor** | xxxxx |
| **Coordinating Investigator or Project Lead** | xxxxx |

**DMP Prepared by**

|  |  |
| --- | --- |
| **Name & Function** | xxxxx |
| **Signature & Date** | xxxxx |

|  |
| --- |
| **NOTE:*** **This is an example. Adapt the Data Management Plan where applicable.**
* **At least the yellow marked text xxxxx or dd/mm/yyyy should be completed or might be adapted**
* **When the DMP is final , then best remove all yellow marks, italic grey instructions and this note**
 |

**PRE-STUDY PHASE**

**1. Study setup**

|  |
| --- |
| **1.1 General information** |
| *Section that describes the aim and purpose of the DMP*The Data Management Plan (DMP) describes the lifecycle for the data of this project/study. It provides information on what and how research data will be collected, processed, retained and shared; on the standards applied and on the measures to ensure data integrity, quality, confidentiality and security. |

|  |
| --- |
| **1.2 Study design**  |
| Section that describes a résumé of the study, type of data collected, with an overview of the data handling in the various study visits and activities. By preference it will hold flowcharts and a schematic overview of the visit schedule and related procedures.Résumé to be copied from the study protocol and pasted here |

|  |
| --- |
| **1.3 Communication** |
| *Section that describes**briefly the communication of Data Management(DM) within the study/project, with clarification of the focal points for DM at the sponsor and the sites.* The central Data Manager at the Sponsor institute will be the main contact for data management of the project/study. The site Data Manager (s) will be the main contact for data management at the site(s).Data management issues will be reported at TMG or specific DM meetings where regular feedback can be made to the rest of the team members. |

|  |
| --- |
| **1. 4 Documentation** |
| *Section that describes**briefly documentation handling of DM within the study/project*During the project/study all study-related electronic data management documentation will be stored at xxxxx (sponsor institute/server/folder(s) Printed documents will be retained at xxxxx (sponsor institute/department/room/closet). |

|  |
| --- |
| **1.5 Timelines** |

Table that list all essential milestones and timelines of DM within the study/project

|  |  |
| --- | --- |
| **Milestone** | **Estimated Date** |
| eCRF/database creation  | dd/mm/yyyyy |
| Validation and launch of the eCRF/database | dd/mm/yyyyy |
| DM training | dd/mm/yyyyy |
| First patient first visit (FPFV) | dd/mm/yyyyy |
| Last patient last visit (LPLV) | dd/mm/yyyyy |
| Database lock | dd/mm/yyyyy |
| Data Sharing  | dd/mm/yyyyy |

Create, adapt or delete rows if needed

|  |
| --- |
| **1.6 Study roles and responsibilities** |

*Table that lists all essential stakeholders of the study/project. Adapt where applicable.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Study role** | **Name** | **Location (institute/site)** | **Responsibility** |
| Coordinating Investigator | xxxxx | Sponsor | Overall project coordiination |
| Project Coordinator | xxxxx | Sponsor | Day to day coordination |
| Monitor | xxxxx | Sponsor | Site Monitoring |
| Central Data Manager | xxxxx | Sponsor | Overall DM  |
| Data reviewer 1 | xxxxx | Sponsor | Data validation/Querying |
| Data reviewer 2 | xxxxx | Sponsor | Data Validation/Querying |
| Medical Coder | xxxxx | Sponsor | Standardizing AEs |
| Study Statistician | xxxxx | Sponsor | Statistical analysis |
| Laboratory manager | xxxxx | Central Lab | Lab procedures |
| Laboratory technician | xxxxx | Central Lab | Lab procedures |
| Principal Investigator 1 | xxxxx | Site1 | Site 1 Coordination |
| Principal Investigator 2 | xxxxx | Site2 | Site 2 Coordination |
| Principal Investigator 3 | xxxxx | Site3 | Site 3 Coordination |
| Study nurse 1 | xxxxx | Site1 | Study procedures/Data capture |
| Study nurse 2 | xxxxx | Site2 | Study procedures/Data capture |
| Study nurse 3 | xxxxx | Site3 | Study procedures/Data capture |
| Hospital Pharmacist 1 | xxxxx | Site1 | Storage/dispensing |
| Hospital Pharmacist 2 | xxxxx | Site2 | Storage/dispensing |
| Hospital Pharmacist 3 | xxxxx | Site3 | Storage/dispensing |
| Site data manager 1 | xxxxx | Site1 | Site 1 DM coordination |
| Site data entry clerk 1 | xxxxx | Site1 | Site 1 Data entry |
| Site data manager 2 | xxxxx | Site2 | Site 2 DM coordination |
| Site data entry clerk 2 | xxxxx | Site2 | Site 2 Data entry |
| Site data manager 3 | xxxxx | Site3 | Site 3 DM coordination |
| Site data entry clerk 3 | xxxxx | Site3 | Site 3 Data entry |
| ... |  |  |  |

Create, adapt or delete rows if needed

|  |
| --- |
|  **1.7 Confidentiality of study participant data** |
|  *Section that refers to essential principles and measures with regard to privacy and confidentiality of the study/project data*Personal and medical information from the trial will be kept confidential, in line with the requirements of the European General Data Protection Regulation 2016/679, and with applicable requirements in the study country(ies). Name and contact data for each participant will be kept separate and limited to the clinical staff at the respective site(s) only. Instead, name and contact data will be replaced by a specific study subject identification code (=pseudonym). These pseudonymized data will be used for further trial handling and reporting. For data sharing purposes and to avoid re-identification of study participants, these pseudonymized data will be converted further into anonymized data (amongst others by replacing the study subject identification code with a new code; by generalizing and randomizing of specific variables). All paper documents and electronic files needed for data management will be restricted to authorized study staff, both at the sponsor and at the sites. Controlled access to study computers, servers, study binders, study offices and server locations will be encouraged by a Standard Operating Procedure on security and by specific measures at the sites and sponsor (locked cabinets and rooms, badge control where possible). |

|  |
| --- |
| **2. Source Document/CRF Design (Data collection design)** |
| *Section on designing data collection tools or paper Case Report Forms (CFRs) for accurate and appropriate capture of data** *Data collection tool meeting the regulatory requirements*
* *Data collection tool meeting standards (e.g. CDASH)*
* *User friendliness of completion*
* *User friendliness for data entry*
* *Meeting the needs of the protocol*

*Section that refers to the SOP-WP3-02-CRF Design*A CRF template was designed based on the study protocol. This document serves as the basis for the eCRF design (see section 3). A copy of the template is stored at xxxxx (sponsor institute/server/folder(s).  |

|  |
| --- |
| **3. Database/eCRF design** |
| *Describes more in detail the software or system used, with its various features & functionalities**Section that refers to the SOP-WP3-16-Database (DB)/ eCRF Design* Study data will be captured in electronic Case Report Forms (eCRFs). The eCRF will be designed with REDCap software by the study Data Manager, based on a paper template drafted in collaboration with the Coordinating Investigator, Project Coordinator and Statistician.Data capture will be performed offline using the REDCap Mobile App installed on tablets in combination with REDCap online for entry and data resolution workflow (data queries).Sponsor team members will use REDCap online for system and data management (set up and design, control user rights, view data, lock records, queries, create and execute data quality rules, etc.).**3.1 REDCap software**REDCap (Research Electronic Data Capture) is a secure web-based application designed to support data capture for research studies. REDCap provides: 1) an intuitive interface for data entry (with data validation); 2) a security system that prevents unauthorized access to the data; 3) a built-in audit trail that automatically logs all user activity; 4) data exports to CSV/Excel and common statistical packages (SPSS, SAS, R, Stata); 5) flexible user rights for managing user privileges and creating user roles; and 6) advanced features, such as branching logic, calculated fields, e-signatures, record lock/unlocking, data import tool, login settings, data resolution workflow, data quality rulesREDCap is developed and maintained by a team at Vanderbilt University and licensed by the xxxxx sponsor Institute. The application and data are housed on servers provided by the xxxxx sponsor Institute. These servers are located within the xxxxx sponsor institute’s secure data center. The data center is physically secured through limited badge access. Local support for REDCap is provided by xxxxx sponsor Institute (department or persons).**3.2 Mobile app**The REDCap mobile app is an app that can be installed on a tablet or mobile device so that data may then be collected in an offline fashion on that device, after which it may then be synced back to a project on the REDCap server. The app is most useful when data collection will be performed where there is no internet service (e.g. no Wi-Fi or cellular service) or where there is unreliable internet service. Once the mobile project is set up on the device, the user can collect data (which is stored locally on the device), and then at some point sync that data back to the project on the REDCap server. |

|  |
| --- |
| **4. Database/System Validation** |
| *Describes in general the validation of the database or implemented system for performing data collection/entry, data management and data handling**This section focuses on two primary areas of responsibility:** *Validation of the software itself, meaning the responsibility of a data management organization to prospectively validate a (clinical) data management application that was purchased and installed for the purpose of performing data management tasks*
* *Validation of the system set-up for this particular study.*

*Section that refers to the SOP-WP3-17-System Validation, SOP WP3-22-Site Database Deployment, SOP WP3-23-Site Systems Upgrade and SOP WP3-24-Change Management.*The validation process will provide documented proof that the data collection tool meets the predefined specifications and quality. Validation tests are performed to demonstrate that the system meets the established requirements.REDCap version used: REDCap LTS 8.10.4, Mobile App v4.0.9**Validation documentation REDCap*** Change Control Form: sponsor institutional registration nr (if applicable)
* Criticality Assessment: sponsor institutional registration nr (if applicable)
* Validation Plan: sponsor institutional registration nr (if applicable)User Requirement Specifications: sponsor institutional registration nr (if applicable)
* Installation Qualification: sponsor institutional registration nr (if applicable)
* Operational Qualification: sponsor institutional registration nr (if applicable)
* Validation Report: sponsor institutional registration nr (if applicable)

The validation report concluded that there were no constraints for release. The REDCap software was released for use on dd/mm/yyyy. **Validation documentation for Project/study xxxxxx*** Change Control Form : sponsor institutional registration nr (if applicable)
* Test Report-A Mobile App: sponsor institutional registration nr (if applicable)
* Test Report-B Online: sponsor institutional registration nr (if applicable)

Test Reports will be drafted to document the qualification tests for the study eCRF. The Test Reports will be split in two parts; one for the Mobile App and one for REDCap Online (for laboratory and data management).Any changes to the system during the study will be tested and version control will be tracked in a Change Control Log.The test report concluded that there were no constraints for release. The REDCap project /study specific eCRF/database was released for use on dd/mm/yyyy. The Validation documentation is available at xxxxx (sponsor institute/server folder/subfolder) and/or xxxxx (sponsor institute/room/binder). |

|  |
| --- |
| **5 Database/Data Security** |
| *Section that describes the security measures taken to the data in the database/system** *Physical and technical safeguards*
* *Definition of access levels for users*
* *Authorization and withdrawal of database users (listing of these users)*

*Section that refers to the SOP-WP3-18-Information Security Policy***5.1 General**The following physical and technical safeguards and security measures are in place:All data collected in the eCRFs will be pseudonymized; a unique study specific code will be assigned to each study participant. Any information that could lead to the identification of the participant will not be included in the study data electronic file.Access to the online project is restricted by username and password and is granted/revoked by the system administrator. All users will be assigned to a specific user role. Each user role enables the user to use certain functions (e.g. View & Edit, Read Only, Lock/Unlock Records …). A list of all users with their names and their user roles will be kept at the xxxxx (sponsor institute/server folder/subfolder) and/or xxxxx (sponsor institute/room/binder).Login settings are enforced: * Auto logout time is set at 30 minutes.
* Number of failed login attempts before user is locked out is set at 5.
* Amount of time user will be locked out after having failed login attempts exceeding the set limit is 15 minutes.

Limited access to the rooms where the server and all study data are located. **5.2 Mobile app**Transmission: Data is transmitted securely to and from the REDCap server via SSL (https) Device's Hard Drive: The database is encrypted on the mobile device's hard drive using SQLCipher (public key/private key encryption). This prevents someone from breaking into the file in the event of a stolen device.Application: A login with a 6-digit pin is required to access the application. Five login attempts are allowed before lockout, and a 15-minute lockout period is initiated. When the application is sent to the background or is cloaked with a screen saver, the pin is required again to access the application if a user is logged on. Similar log in attempt rules and lockout rules apply when the user reenters the application.Logs: Project logs for activity on the REDCap Mobile App are stored in the database’s Mobile App File Archive. These can be transmitted to the server (for one given project) via the Send Project Logs button on the Project menu. These logs record data creation, modifications, and uploads; renaming, deletion, and viewing of records; and downloads of project instruments and records.**5.3 ICF and identification log**Informed Consent Forms (ICFs) and identification logs are managed securely at the study site and only accessible to site staff. |

|  |
| --- |
| **6. Database backup** |
| *Section that describes the safeguarding of the dataset during a project** *Creation of backup copies of a database*
* *Implementation of a backup version when original is lost*

*Section that refers to the SOP-WP3-19-Data Backup & Disaster Recovery*A timely backup of data will be provided at the server, computer and/or database level. This will be performed following the procedure SOP Backup, Restore and Contingency Planning provided by the Sponsor. |

|  |
| --- |
| **7. DM Training** |
| *Section that describes all appropriate training for study staff in Data Management.** *Training confirmation form*
* *Template for user guidelines*
* *Periodic Training Plan*

*Section that refers to the SOP-WP3-03-DM/IT Training & Capacity Building*All site personnel involved in eCRF handling (Site investigators, Data Managers, Data Entry clerks, Nurses) and all data Monitors will receive a training + user guidelines before the use of the eCRF. All other users will receive user guidelines. In addition, other DM or IT or relevant study procedures might be clarified during the training.The site personnel will be trained on site by the Data Manager or Monitor before the start of the study. Training Confirmation form(s) will be used to document the training. listing who was trained, when , by whom and with a short description of the training contents. |

**STUDY CONDUCT PHASE**

|  |
| --- |
| **8. Data Capture/Entry** |
| *Section that describes the process of entering data into the data capture system or database** *Target times for entry and verification*
* *Type of verification (double data entry, etc)*
* *Data entry conventions and guidelines*
* *Functions/roles involved*

*Section that refers to the SOP-WP3-06-Data Collection & Entry*All available clinical data specified in the study protocol will be entered in eCRFs using the REDCap mobile app installed on tablets, or online via laptop/desktop.Data will be entered in the mobile app in real-time or should be entered online as soon as the data become available. Data entry will be done following the data entry guidelines specified for the study. This document will be distributed on paper and electronically at the study site. Study staff entering data in the eCRF will be trained and the training will be documented in a training log. Only users with View & Edit rights can enter/modify data. All data entries and modifications will be tracked by electronic audit trail.Data entry must be performed on a regular basis. If not done regularly, the site will be informed by the Project Coordinator, Data Manager or Monitor to check up on the delay. |

###

|  |
| --- |
| **9. Data Review** |
| *Section that describes the process of verifying the accuracy, consistency and completeness of data entered into the database** *Manual checking procedures*
* *Automatic checking procedures (edit checks)*
* *Discrepancy handling*

*Section that refers to the SOP-WP3-07-Data Validation & Review*The Data Validation Plan (DVP) explains how the data collected during this study will be verified and cleaned before statistical analysis.Data review will be performed by the Data Reviewer, Monitor and the Data Manager where applicable. Data review includes the following tasks: * Checking completeness, accurateness and consistency of data
* Raising manual queries if needed
* Checking the site’s responses to all warnings and queries
* Checking if warnings and queries are reviewed by the site on a regular basis
* Coding of all AE’s and Medical History (see more in section 12. Coding)
* SAE reconciliation (see more in section 13. SAE reconciliation)

Cooperation with Monitors:The Data Monitor(s) will visit the site on a regular basis to, amongst others, check the accuracy of the data entered in the eCRF by verifying with the source documents available on site (= Source Document Verification, or SDV).Monitoring is done in accordance with the Monitoring Plan. Findings on DM and data quality will be recorded in the Monitoring Visit Report. Corrective actions will be followed up by the Monitor (or Data Reviewer or Data Manager, if applicable). |

|  |
| --- |
| **10. Data Tracking** |
| *Section that describes the reception and tracking of data** *Tracking sheet or system*
* *Data flow diagram*
* *Monitoring and reporting on data flow: completing vs missing data*

*Section that refers to the SOP-WP3-10-Data Tracking*REDCap has various tools to track data: * Status icons (Incomplete, Unverified, Complete, Mixed)
* Dashboard (Search)
* Data Reports
 |

|  |
| --- |
| **11. Data/Medical Coding** |
| *Section that describes the coding data items in a clear and consistent manner** *Details of in-house coding conventions*
* *Details of (or referral to) external coding conventions (WHO, MedDRA,...)*
* *Details of tasks and responsibilities (Medical coder)*

*Section that refers to the SOP-WP3-08-Data Coding and Medical Coding*Medical Coding is the process of matching a recorded medical condition against a medical dictionary. The purpose is to avoid that medical conditions, differently written or synonyms, would be counted as different medical conditions.In this study, the MedDRA dictionary version XXXXX will be used.During and at the end of the study, the Data Reviewer, Data Manager or Statistician will extract data related to the Adverse Events and Medical History eForms from the study database. Medical conditions that cannot be matched automatically with the MedDRA dictionary will be listed for manual coding by the study Medical Coder. |

|  |
| --- |
| **12. SAE Reconciliation** |
| *Section that describes the process of cross checking related data of serious adverse events (SAE), between the data management system (study database) and the safety system (SAE Reports).** *Description of procedure and timelines*
* *Details of tasks and responsibilities*
* *Checklist template*

*Section that refers to the SOP-WP3-09-SAE Reconciliation*SAE reconciliation is the process of reconciling the study database with the safety database to ensure the data is consistent.SAE reconciliation includes:* Cross checking SAE data from the eCRF (study database) with the SAE reports and safety database
* SAE-reconciliation is the process done by the Data Reviewer and/or Data Manager (if applicable)
* The process is documented by using a SAE reconciliation checklist.
 |

|  |
| --- |
| **13. Data Storage** |
| *Section that describes the storage /retention of data:* * *Electronic storing system*
* *Paper retention*

**Documentation** Essential (electronic) documents related to the study will be stored in a (electronic) Trial Master File, or (e)TMF.The trial master file shall consist of essential documents, which enable both the conduct of a clinical trial and the quality of the data produced to be evaluated. Those documents shall show whether the investigator and the sponsor have complied with the principles and guidelines of good clinical practice and with the applicable requirements.At the sponsor site, the (e)TMF will be retained at xxxxx (sponsor institute/server folder/subfolder) and/or xxxxx (sponsor institute/room/binder).The study site will also store essential electronic documentation on their server or other digital media (DVD, USB stick, …).Physical and technical safeguards are put in place (see also section 5. Data security).**REDCap data**REDCap stores its data and all system and project information in various relational database tables (i.e. utilizing foreign keys and indexes) within a single MySQL database, which is an open source RDBMS (relational database management system).All data in the study REDCap MySQL database are stored and protected at the sponsor institutional servers and cannot be accessed by unauthorized users. Physical access to the server room is only for authorized persons with a personal badge. The REDCap Mobile App employs encryption-at-rest on the mobile device’s hard drive so that all important data and information stored on the device is properly protected from unauthorized or malicious users. |

|  |
| --- |
| **14. Data Transfer** |
| *Section that describes the transferring of data between stakeholders of a study/project.** *Considering confidentiality and appropriate measures*
* *Agree timelines of transfer*
* *Specifications of the format*
* *Description of the transfer process*

*Section that refers to the SOP-WP3-11-Data Transfer*Sensitive data should not be stored or shared by means of unprotected cloud-based platforms or unprotected e-mail. When transferring files with sensitive data over the internet, this should be done by secured (encrypted) file transfer. The following methods are encouraged:* + - Encryption
* Sensitive data (personal data, [coded] study databases etc.) must be encrypted by using E-Mail encryption and/or WinZip file encryption or other means of encryption. When using Outlook, then use options ‘Encrypt only’.
* FTP server
* The File Transfer Protocol (FTP) is a standard network protocol used for the transfer of computer files between a client and server on a computer network.
 |

|  |
| --- |
| **15. IT Support** |
| *Section that describes the IT Support and Documenting interventions by IT while supporting hard- or software** *Description of the problem + stakeholders*
* *Description of impact of actions on the study data*
* *Description of the solution and actions to be taken*

*Section that refers to the SOP-WP3-20-IT & DM Support*During the study conduct phase, the Data Manager will act as the first line helpdesk to resolve any database issues or respond to other data related questions. If needed, second line support will be provided by the study IT collaborators. Critical issues which impact the study will be documented.  |

|  |
| --- |
| **16. Database Lock/Unlock** |
| *Section that describes the following:* *Locking the database to ensure security on completion of data entry and discrepancy resolution. Unlocking for authorized changes to a locked dataset.* * When to lock and unlock (quality checklist, acceptable error rate, reason for unlocking)
* Authorizations for locking and unlocking + template of approval form

*Section that refers to the SOP-WP3-12-Database Lock / Unlock*The Data Manager will ensure locking of the database after checking/performing the following: * + - Completion of eCRFs of all recruited patients
		- Assessment of double patient eCRFs
		- Blank or wrongly created eCRFs
		- Resolution of all queries
		- Medical coding
		- SAE reconciliation
		- Final quality checks by the statistician
		- Removal of access rights to the database for data entry and site personnel
		- Approval and signature for Database Lock

Documentation of the study Database lock will be performed with a Database Lock Checklist and a Database Lock Approval form. If applicable, database unlock will also be documented. The overall procedure, with details and timelines of Database Lock are best discussed by meeting the Coordinating Investigator, Project coordinator and Study statistician. The meeting minutes should be stored at the sponsor TMF. |

**POST STUDY PHASE**

|  |
| --- |
| **17. Archiving** |
| *Section that describes the archiving of project data to ensure security and confidentiality of the data , to allow comprehensive reconstruction of the completed work and to ensure regulatory requirements for retention DM Plan.* *Electronic archiving system: database; program* *Reference data (normal ranges, coding)* *Timing and length of archiving* *Submission and retrieval procedure**Section that refers to the SOP-WP3-13-Archiving*The essential study documents are those documents which individually and collectively permit to assess the conduct of the trial, the quality of the data produced and the compliance with GCP standards and applicable regulatory requirements. After completion of the study, source data, ICFs and a copy of the CRFs will be kept on site, and the study master file will remain available for internal audits and/or inspections of regulatory authorities for a period of 15 years, unless differently requested by (inter)national authorities. (Note : The European Regulation EU No 536/2014 for clinical trials specifies a period of 25 years)The study archives at the sponsor will be available at xxxxx (sponsor institute/server folder/subfolder) and/or xxxxx (sponsor institute/room/binder). The sites should best provide the location of their study archives to the sponsor. |

|  |
| --- |
| **18. Data Management Report** |
| *Section describing of a ‘final report on the DM activities of the study, with in particular quality issues and deviations of the DM plan.** *Reporting data processing details*
* *Reporting on quality efforts and issues*
* *List of unsolved discrepancies and edit checks*

*Section that refers to the SOP-WP3-14-Data Management Report*After study completion, a Data Management Report will be made to detail how the data in this study was handled and how it deviated from the Data Management Plan. All relevant changes (e.g. Lost to follow up numbers) , technological problems and quality issues (e.g unresolved queries) will be listed. Deviations which have impact on the analysis of the study/project should be communicated and documented to the Coordinating Investigator, Project coordinator and Statistician before analysis. |

|  |
| --- |
| **19. Data Sharing** |
| *Section that describes the sharing of data, in particular to inform, to facilitate collaboration and to ensure regulatory , funder or publisher requirements.* * *type of data & system used*
* *Security and confidentiality measurements*
* *Agreements (what data; when; process. format)*
* *Description of metadata*

*Section that refers to the SOP-WP3-15-Data Sharing*The participant-level study data will be available for sharing within reasonable time after the study and according to the Sponsor Data Sharing policy, FAIR principles, the PANDORA – ALERRT Data Sharing PrinciplesData sharing for secondary research will also be included in the Informed Consent Form. The study data will be anonymized and supported by metadata and documentation, such as the study protocol, annotated CRFs (questions with question codes) and the Statistical Analytical Plan. Researchers can request the Sponsor for access to the anonymized data for well-defined research or secondary analyses via a controlled access procedure. |

**Revision history**

|  |  |
| --- | --- |
| **Version n° & Date** | Description |
| **V0.1 dd/mm/yyyy** | Draft |
| **V1.0 dd/mm/yyyy** | Final |

**Approved by**

|  |  |
| --- | --- |
| **Project Lead\*****Name & Function** | xxxxx |
| **Signature & Date** | Xxxxx  **dd/mm/yyyy** |

\*Adapt ( Coordinating Investigator and/or PI) and create a row more if needed