**DATA MANAGEMENT PLAN**

Title:*Insert full study title here*

Short title: *Insert acronym/short title*

Date/version of Data Management Plan:

*Delete the text in yellow once the plan is complete.*

***Introduction:*** *The use of this template is* ***not*** *mandatory, but should be used as guidance for example in connection with JRMO SOP 38d*

*The purpose of this Data Management Plan (DMP) is to define and provide instructions regarding the conduct of data management processes and the flow of data from source data to data release for analysis.*

*A DMP is recommended for large, long-running, multi-centre trials; and is especially useful in cases where the trial requires deviations from or amendments to current SOPs. However, for clarity of trial management processes, data flow and responsibilities it is recommended to put a proportionate DMP in place also for smaller, single-centre trials, based on a risk-assessment approach. Not all headings of this template are necessarily needed for all trials and additions of other headings should be introduced when necessary.*

*The scope of this DMP is not to define CRF design, data base design, data base validation and testing, plan of data analysis, data base security. These processes should be defined and detailed in other SOPs.*

*This DMP will detail trial specific processes or will just refer to SOPs if those are followed without any specifics.*

*The DMP will describe:*

1. *CRF work flow*
2. *Data entry*
3. *Data cleaning – data query process - quality checks*
4. *Definition and location of source data*
5. *Database lock*
6. *Data release*
7. *Reports*
8. *Transferring/downloading data/coding/PV data base reconciliation*
9. *Location of data and plan for data archiving*

* *Responsible individuals/groups (Appendix 1)*
* *Definitions – Abbreviations (Appendix 2)*
* *Applicable SOPs and other documents (Appendix 3)*
* *Required documentation to be produced (Appendix 4*

*The red text in each section is guidance delete once plan is complete*

*Use Arial size 11 font*

1. **CRF Workflow**

* *Study specific handling/logistics for delivering CRFs to sites;*
* *Completion of CRFs; amendment and implementation process for CRFs*
* *When and how are CRFs delivered to data clerk for data entry, etc.*
* *Filing and archiving of paper CRFs*

1. **Data Entry**

* *When, how, by whom will data be entered; Study specific entry guidelines.*
* *Specify any data which is collected, but not entered into the actual trial database (e.g. Sponsor SAE form data)*

1. **Data Cleaning, data query process, quality checks**
   * *By whom, when and how?*
   * *Edit check specifications (can reference data validation plan)*
   * *Data management regarding self-evident corrections )*
   * *Handling guidelines for queries and chasing of CRFs*
   * *Query process/flow and tracking including process for editing data*
   * *Different levels and steps of quality check- i.e. checks of data from source do CRF (SDV); check of data from CRF to database (quality check of data entry); check before data lock for completeness, accuracy;*
   * *Define percentage of SDV, CRF data entry checks;*
   * *Any specific monitoring*
2. **Definition and Location of source data**

*Detail here what is considered source data and if any source data is directly entered into CRF pages; specific actual location of source data*

1. **Data base lock**

*Data lock procedures should ensure that the data set used for analysis is clearly identified. This should be retained separately from the live database to allow reproducible analyses. It is a controlled procedure that freezes the data in a particular format, securing the study data and preventing further changes. There is a requirement to ensure all the study data have been received, verified, fully coded, and cleaned for analysis with all queries resolved before locking the database for further analyses*

* + *By whom, when and how?*
  + *Give details in case deviation from the relevant SOP – any specifics*
  + *When can a database be unlocked?*

1. **Data release**

*Details of when data can be released, by whom data release can be requested, and relevant SOPs/Guidance*

1. **Reports**

*Timing and frequency of planned reports where interim data downloads are necessary (e.g. for DMECs, interim analysis, or other justified purposes). List of standard reports and frequency of reports.*

1. **Transferring/Downloading Data/Coding/PV database reconciliation**

*Details of any requirements and arrangements in this trial where data will be downloaded / transferred directly into the trial database as electronic data set from another source – for example laboratory systems etc. Add details if any specific coding will take place (when and by whom) before data is entered into database; reconciliation between the Sponsor PV database and the SAE/SAR records in the trial database. d*

1. **Location of data and plan for data archiving**

*Include here whether any of the data (source or CRF data) will be located outside the normal database, TMF/ISF e.g. in hospital systems/specialist software packages or in a standalone file.*

*Details of relevant SOPs to be followed; can include any specific study closeout checklist or database audit plan; details of format, how and where data will be archived (if known; otherwise just “ archiving method to be decided and agreed at a later date* i*n accordance with sponsor requirements.”).*

**Appendix 1 - Responsibilities and scope of work**

|  |  |  |
| --- | --- | --- |
| **Team Member** | **Role** | **Contact Details** |
|  | Data entry |  |
|  | Quality checks |  |
|  | Data lock |  |
|  | Data release |  |
|  | Reports |  |
|  | Etc.….. |  |

**Appendix 2 – Definitions – examples only - amend as required**

|  |  |
| --- | --- |
| **Term** | **Definition** |
| *CI* | *Chief Investigator* |
| *CTC* | *Clinical Trials Coordinator* |
| *CTIMP* | *Clinical Trial of an Investigational Medicinal Product* |
| *DM* | *Data Manager* |
| *CRF* | *Case Report Form* |
| *PI* | *Principal Investigator* |
| *Validations* | *Edit checks which are programmed into the data entry system* |
| *DE* | *Data Entry* |
| *AE* | *Adverse Event* |
| *DMP* | *Data Management Plan* |
| *SAE* | *Serious Adverse Event* |

**Appendix 3 - Applicable SOPs and guidelines**

*Add current table listing all relevant data management SOPs*

**Appendix 4 - Required documentation to be produced**

*If applicable - Add here list of any specific logs/signature/forms needed*