Instructions are in red/explanatory text in blue.

Delete all coloured text from the completed document.

|  |  |
| --- | --- |
| **Study:** | EudraCT number for drug trials or REC number for non-drug trials |
| **Protocol short name:** |  |
| **Protocol version and date:** |  |

Signature **list**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Role** | **Name** | **Signature** | **Date** |
| Written by | Data manager |  |  |  |
| Reviewed by |  |  |  |  |
| Approved by |  |  |  |  |

****Document history****

|  |  |  |
| --- | --- | --- |
| **Version number** | **Version date** | **Summary of revisions made:** |
| **Draft version 0.1** |  |  |
| **Final version 1.0** |  |  |

Distribution list

|  |  |  |
| --- | --- | --- |
| **Role** | **Name** | **Address (department, telephone, fax, e-mail)** |
| Sponsor |  |  |
| Monitor |  |  |
| Project team |  |  |
| Investigator |  |  |
|  |  |  |

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List of abbreviations   
Edit accordingly what is used in this document.

| **Abbreviation/ term** | **Explanation** |
| --- | --- |
| aCRF | Annotated Case Report Form  An annotated CRF is generally defined as a blank CRF with markings, or annotations, that coordinate each datapoint in the form with its corresponding dataset name. Essentially, an annotated CRF communicates where the data collected for each Question is stored in the database. |
| ATC | Anatomical Therapeutic Chemical (ATC) classification system |
| DB | Database  A structured set of data held in a computer. |
| DEA | Data Entry Application  An application to input data or information into the computer. |
| DEI | Data Entry Instructions |
| DM | Data Management/Data Manager |
| DMD | Data Management Documentation |
| DMP | Data Management Plan |
| DMR | Data Management Report |
| eCRF | Electronic Case Report Form  An electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject. |
| EDCS | Electronic Data Capture System  An electronic data capture system (EDCS) is a computerized system designed for the collection of clinical data in electronic format for use mainly in human clinical trials.  In this document, the term is used for data entered from paper CRFs to an electronic system. |
| EDMS | Electronic Data Management System  A software system for organizing and storing different kinds of documents. |
| IMP | Investigational Medicinal Product |
| ITT | Intention To Treat population  Intention-to-treat analysis is a comparison of the treatment groups that includes all patients as originally allocated after randomization. |
| MedDRA | Medical Dictionary for Regulatory Activities |
| MO/MM | Medical Officer/Medical monitor  A representative of a drug sponsor who has medical authority to evaluate the safety aspects of a clinical trial. |
| PP | Per Protocol population  Per-protocol analysis is a comparison of treatment groups that includes only those patients who completed the treatment originally allocated. |
| PROM | Patient Reported Outcome Measures  Patient reported outcome measures (PROMs) are questionnaires patients complete on their health and quality of life. |
| SAE | Serious Adverse Event |
| SUSAR | Suspected Unexpected Serious Adverse Reactions |
| TLF | Tables / listings/ figures |
| TMF | Trial Master File |
| UAT | User Acceptance Testing  User acceptance testing (UAT) is the last phase of the software testing process. During UAT, actual software users test the software to make sure it can handle required tasks in real-world scenarios, according to specifications. |

# INTRODUCTION

This data management report describes the data handling processes which were used to ensure the accurate and reliable delivery of study data for analysis and reporting.

# PROJECT PERSONNEL

All data management personnel that were involved in this study is listed in Data Management Personnel Log (DMPL) version X.X.

# DOCUMENTATION

## Data management files

Document any deviation from the Data Management Plan (DMP).

## Protocol

The final version of the clinical study protocol was insert version number dated DDMMMYYYY and amended as follows:

|  |  |
| --- | --- |
| Amendment number | Version date |
|  |  |
|  |  |

## Database specification document

The final version of the database specification lists all the automatic and manual checks.

# ELECTRONIC DATE MANAGEMENT SYSTEMS

## DEA security

Document any deviation from the DMP.

# DEA DESIGN

## Case Report Form (CRF) and Patient Reported Outcome Measures (PROM)

|  |  |
| --- | --- |
| for eCRF | An electronic CRF (eCRF) developed using the following electronic EDCS: Insert the system name and version number (e.g.Viedoc®/ Telenor Form ®) was used for this study. |
| for paper CRF | A paper CRF was used for this study.  A database with a DEA for handling of all data recorded on paper CRFs was created by the data manager in the following electronic data management system (EDMS) |
| For PROM | Patient reported outcomes were collected using:  Insert the names of any questionnaires and / or system name for electronic PROM and version number |

## Annotated CRF

The following versions of the annotated CRF are filed in the TMF.

|  |  |
| --- | --- |
| **Version number** | **Version date** |
| 0.1 |  |
| 1.0 |  |

## Testing

|  |  |
| --- | --- |
| For eCRF | The eCRF was tested by entering test data into all fields on each unique page and continuous pages in the system and documented in the user acceptance testing (UAT) document version x.x. Calculations of insert derived data name performed by the system were verified for accuracy and precision.  PDF prints of the data generated during testing of the eCRF is filed in the TMF  Copies of the annotated PDF prints of the CRF (archival copies) used for the QC check to confirm that system was ready for release are filed in the TMF. |
| For paper CRF | The DEA (for paper CRFs) was tested using two CRFs populated with test data, one without obvious errors and one with a large number of errors (using subject number which are not going to exist in the study e.g. 99998 and 99999). The testing was documented in the UAT document version x.x.  The annotated QC check listings of the data from the test subjects are filed in the TMF. |
| For both paper and eCRF | An export from the DEA to datasets suitable for statistical analyses was performed. The data manager and/or study statistician checked that the exported datasets contained all critical information. Critical information per patient was defined as: change as appropriate   * Date of informed consent * Dates of patient specific milestones (e.g. randomisation, start of treatment, end of treatment, end of study) * Reasons for early study termination * All necessary information required to calculate and analyse the primary endpoint(s) (including covariates) * All necessary information required to calculate and analyse key secondary endpoints (if any) * All protocol defined requirement for reporting serious adverse events (SAEs) * Other key safety endpoints * Other key baseline variables |

## Approval

The DEA approval form (version insert version number) was first approved on insert date.

## DEA updates

All database updates and the changes are recorded in the DEA change log, which is filed in the TMF.

For example, the following versions of the DEA were used:

|  |  |  |
| --- | --- | --- |
| **CRF/DEA change log** | | |
| **Version number** | **Version date** | **Summary of revisions:** |
| 1.0 | DDMMMYYYY | Start version of DEA |
| 1.1 | DDMMMYYYY | Addition of a new variable: XXXX |
| 1.2 | DDMMMYYYY | XXXXXXX |
| 2.0 | DDMMMYYYY | Required by protocol amendment X |
| 2.1 | DDMMMYYYY | Addition of new forms/visits: XXXXX |

## DEA Security

Document any deviation from the DMP.

# RANDOMISATION

Document any deviation from the DMP.

Not applicable.

# DATA ENTRY

Document any deviation from the DMP.

## Self-evident corrections

For paper CRF

All the self-evident corrections were listed and the listing was signed by the principal investigator / national coordinating investigator before the database was locked. The signed listings are filed in the TMF.

Not applicable.

## Derived data

The following parameters were derived from source data:

* Corrected QT interval
* Creatinine clearance
* BMI
* FEV1

State the formulae which was used and how the calculation was validated.

# DATA QUALITY CONTROL

Document all data quality control steps that have been performed during the project. Any deviation should be reported here.

## Data verification

Document any deviation from the DMP.

Automated edit checks defined in the database specification document were completed and no discrepancies resulted.

Manual verification (proof reading) of the database against paper CRF was done for a random sample of 10% of the patients.

The error rate was XXXX

Data entry reports and other documentation of verification are filed in the TMF.

Or

Not applicable

## Data validation

Document any deviation from the DMP.

QC of closed queries was performed for 10% of all the closed queries.

The observed error rate was: XXXX

The following discrepancies were still present but were not deemed to adversely affect the results of the study:

At a data review meeting held on DDMMMYYYY, the following tables/listing/figures (TLFs) were reviewed:

# RECONCILIATION OF SERIOUS ADVERSE EVENTS (SAE)

Listings of all SAE were prepared and the following data points were checked:

Event term, start and stop date, outcome etc.

The observed error rate was specify

# DATA FROM EXTERNAL SOURCES

The following external data was imported into the database:

The accuracy and completeness of imported data was checked by specify the checks and the documentation of the checks is filed in the TMF.

# CODING

The following items were coded using the specified coding dictionaries (include all versions of the coding dictionary used):

|  |  |
| --- | --- |
| Data items | Coding dictionary |
| Diagnoses | ICD version xx.x,  ICD version xx.x  or  DSM version xx.x,  DSM version xx.x |
| Adverse Events | MedDRA version xx.x,  MedDRA version xx.x  or  CTCAE v.xx,  CTCAE v.xx  or  any other appropriate coding system |
| Concomitant medication | WHO DDD ATC version DDMMMYYYY,  WHO DDD ATC version DDMMMYYYY |

Listings of the coded items including coding dictionary version were provided to insert name(s) member of research team for their review and approval.

The annotated listings are filed in the TMF.

# INTERIM ANALYSIS/DATA MONITORING COMMITTEE

Document any deviation from the DMP and describe the data which was submitted for any planned interim analyses/analysis/DMC meetings and the date.

# DATABASE LOCK

The database was locked on DDMMMYYYY.

Document the allocation to the different study populations and any deviation from the DMP.

## Database unlock

If the database was unlocked to correct errors, the process should be described here or state that the database was not unlocked and thereafter relocked.

# UNBLINDING

The following code file for merging with the database was generated on the DDMMMYYYY.

Not applicable, no randomisation was performed for this study.

# DATABASE EXPORT

The following clinical datasets were delivered to the NCI/PI:

* xxxx.csv/xxxx.xlsx
* xxxx.csv/xxxx.xlsx
* xxxx.csv/xxxx.xlsx

The data were be uploaded to insert path/ url as specify file type(s) files on the DDMMMYYYY.

# AUDIT

Not applicable.

An audit was conducted on DDMMMYYYY and the audit certificate is filed in the TMF.

# ARCHIVING

All documentation has been filed in the TMF and will be retained until DDMMMYYYY.