# Document Summary Sheet

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| Document: | Data Quality Plan |
| Purpose: | This DQP template may be used for clinical studies at CTU, unless another template has been agreed upon. |
| Audience/User: | Clinical Data Managers and study teams of clinical studies at CTU |
| Details: | The template should be customised to the protocol, the studies’ special needs / circumstances, and the requirements of the data capture system. Sections may be edited or deleted as needed. |
| Best Practice Recommendations: | * Instructions to the users in red (delete before final).
* Suggested texts in blue (edit and change the colour of the text before final).
* Please note that according to EU regulation 536/2014 the definition of a “clinical study” at CTU is a clinical trial or a non-interventional study.
* **Remove this Tool Summary Sheet prior to the use of this template.**
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Document Revision History:

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| --- | --- | --- |
| **Version Number** | **Version Date** | **Summary of Revisions Made:** |
| **2.1** | 07JUN2024 | **Renamed the title from Data Validation Plan to Data Quality Management, and described the concept** |
| **2.0** | 29NOV2023 | **Final version** |

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| --- |
| **study DESCRIPTION** |
| **EU CT no (ID)/REC No.** |  |
| Study Name |  |
| Study Short Name |  |
| Protocol version and date |  |

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| --- |
| **Version Control** |
| **Version** | **Date** | **Description of major changes (to last version)** |
| Draft version 0.1 | DDMMMYYY | NA |
| Final version 1.0  |   |  |

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| --- |
| **Signature List** |
|  | **Name and Role** | **Date and Signature** |
| **Approved by** | [Name],Cordinating Investigator / Project Leader |  |

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|  | **Name and Role** | **Date and Signature** |
| **Created by** | [Name], Clinical Data Manager |   |

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# Introduction

## Purpose

The purpose of this document is to describe the comprehensive data quality management throughout the lifecycle of the [short name] study. This is to ensure the accuracy, integrity and reliability of the clinical data. It is created by the CDM and signed by the CI or designee before the study goes live and saved in the Clinical Data Management Documentation (CDMD).

# Data Quality MANAGEMENT

Data Quality Management (DQM) is the process of planning, assuring and controlling the quality, validity and integrity of the data throughout the entire lifecycle of the study. The DQM process will be based on a risk assessment, although the main focus should be on the study endpoints and objectives.

The DQM process may be updated based on substantial protocol modification(s) and/or findings from risk assessment meeting(s).

Data Quality Management will be performed according to SOP DM05 Data Validation, SOP DM09 SAE Reconciliation and SOP DM12 Central Monitoring. Any deviations from the plan will be documented in the Data Management Report (DMR).

# Data Validation

Data validation at the subject-level is a critical component of the DQM strategy, focusing on the important individual data-points (i.e. endpoint data, safety data, etc.). Data validation will ensure data accuracy and validity and will be performed according to the SOP DM05 Data Validation and documented in the attached Data Quality Document (DQD). The DQD v1.0 is a document specifying all data checks programmed in the eCRF before the study goes live and these initial checks may be updated. Additional eCRF edit checks and batch processing data checks will be added to the DQD and updated during conduct. Any updates can be initiated by the study team or by the CDM. Before database (DB) lock the final version of the DQD will be reviewed by the CI or designee and sent to TMF for archiving / archived in the eTMF.

Data validation includes the use of query-triggered edit checks, entry restrictions and missing values inside the eCRF and batch processing checks using a statistical software to identify and rectify discrepancies and/or anomalies. A manual check (involves a visual review of the data) for e.g. to identify sensitive data may also be included.

## eCRF edit checks

The purpose of eCRF edit checks is to automatically detect and flag incorrect data entries in real-time.

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### Query-triggering edit checks

These are programmed into the eCRF to prevent the entry of illogical, incorrect or invalid data. Such data will be queried, and the query resolution will be approved by CDM, unless otherwise agreed upon.

### Entry Restrictions

This type of check will trigger error messages upon initial data entry. They include date fields restricted to valid calendar dates and format restrictions e.g. number of decimals.

### Missing values

Missing mandatory fields will automatically be marked red during data entry. A list of all missing values may be found in Viedoc Clinic | Issues | Dropdown menu: Choose “Missing data”.

## Batch processing data checks

The purpose of batch processed data checks are to identify potential issues that may not be immediately apparent at the point of data-entry. These will be performed outside the eCRF (e.g in statistical software programmes such as SAS, R, Excel and/or SPSS) and will be run at various intervals throughout the study, see item 5.

The findings from the batch processed data checks may result in queries in the eCRF or listings delivered directly to the study team. Both require corrective actions from the study team. The query resolution will be approved by CDM.

## Query management

Queries generated from query-triggered edit checks, entry restrictions and missing values require action from the study team during data entry. Queries from the batch processed edit checks will be raised directly in the eCRF by the CDM and require an action from the study team. These queries will be approved or rejected and followed up until resolution.

Queries may also be raised directly in the eCRF by other than the CDM, e.g. monitor(s). The study personell that has generated the queries will be responsible for addressing the resolution of the queries issued by them.

# Centralised monitoring

Centralised monitoring will not be performed in this study.

*or*

Centralised Monitoring (CM) is a remote evaluation of accumulating data, performed during conduct phase to identify risks that have impact on the data e.g. identify irregularities and data trends between sites. Potential irregularities could signify protocol non-compliance, operational inconsistencies, or data fabrication/manipulation.

In Viedoc, Key Risk Indicator metrics and Reports (using R) can be used to identify potential risks during the study. The Reports application in Viedoc can be used, utilising both standard reports available to all studies and custom reports designed specifically for this study. Other statistical software e.g. SAS, SPSS can be used to perform CM.

The CM will be documented in a report (Temp DM12.01 Centralised Monitoring report) and any potential issues should be followed-up by the Coordinating Investigator (CI).

The study monitor will also have access to the Key Risk Indicator metrics and Report application and will able to run these reports prior to, for example, monitoring visits. Any findings made by the study monitor may be included in the Monitoring Report.

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## Key Risk Indicators

If the KRIs are continuously monitored the data does not need to be validated at each time point. Potential risk factors should be identified during the risk assessment process. Elements of CM can be displayed in and exported from Viedoc Reports as Key Risk Indicators (KRI). Key Risk Indicators (KRIs) are metrics used to monitor risks factors. Three different warning thresholds are defined, +/- 1 Standard Deviation (SD), +/- 2 SD, and greater than +/-2 SD.

Update the list according to the study’s needs, and describe more thoroughly the relevant indicators.

CM may include the following standard KRI’s:

|  |  |
| --- | --- |
| KRI | Description |
| # of AE per subject | Calculates the number of AE for each patient (one record per patient, with frequency of AE) |
| Unconfirmed missing items per subject | The same as "Open Queries per subject" (but only for Unconfirmed missing) |
| Closed queries per subject | Calculated as '#Closed queries' / '# of Subjects' |
| eCRF data entry lag (in days) | Fetches the timelapse days for each form. For each form, the difference between the form Initiated Date and the corresponding Event Date is calculated. This is considered as the lapsed time in days from the date of the visit to the date of form initiation.For example, if the Event Date is 01-Feb-2022, but the form was first saved on 10-Feb-2022, the timelapse would be 9 days. |
| Pending forms per subject | Calculates the average number of pending forms for each subject. |
| Signature lag (in days) | Calculates the signature lag (in days) for each form. This is calculated as the number of days between the last edit date and time and signature date and time |
| Drop-out Rate (DOR) % | Calculates the drop out rate |
| Confirmed missing items per subject | Calculated as '#Confirmed missing items'\* / '# of Subjects' |
| Open queries per subject | Calculates the number of queries for each subject. |
| Query response lag (in days) | Calculated as sum of 'Open to Resolved Days'\* or if missing, 'Open to Closed Days'\*/'#Closed queries' (pre-queries and Removed queries are excluded) |
| Overdue events per subject | Calculates the average number of overdue events for each subject |
| Data changes per form | Fetches the number of updates for each form |
| Screen Failure Rate (SFR) % | Calculates the screening failure rate. The screen failure rate is based on the following subject status definition in Viedoc Designer: ScreenFailed - if WithdrawnState = TRUE and EnrolledState != TRUE |

If any additional variables/forms or custom reports are included in the centralised monitoring, please list below.

|  |  |
| --- | --- |
| Other KRIs | Description |
| Enrolment rate | Add definition |
| Protocol Deviation Rate (Out of range Visit Date and Missing Dose Rate may be included) | Compares the number of PDs per subject per site |
| Audit trail review (ATR)\* | The Audit trail review report shows divergences to the normal data entry pattern as well as the general performance |

\*ATR is risk-based and should be seen in context with the “Data changes per form” or other findings from the CM process.

# SAE/AESI reconciliation

There will be no Serious Adverse Event (SAE) reconciliation between the study database and an external database in this study.

*or*

Serious Adverse Event (SAE) and Adverse Events of Special Interest (AESI) reconciliation will be performed between the study database and the safety database at agreed stages during conduct of the study or once, immediately before DB lock.
Necessary actions from the reconciliation outcome when not exact or consistent match will be taken by CDM in collaboration with the Medical Monitor (MM) in the study.

Exact: Items must match exactly

Consistent: Items do not have to match exactly but there must be a justifiable reason for non-exact match and the data must be comparative, not contradictory.

The process will follow SOP DM9 SAE reconciliation, and will be documented in Temp DM09.01 SAE Reconciliation Form and archived in the CDMD folder.

The following variables in the table will define the items to be reconciled.
(Please adjust the table according to the study and delete text in blue)

|  |
| --- |
| **Reconciliation of items** |
| **Study database** | **Safety database** | **Remarks** | **Type of match** |
| Study ID | Study ID |  | Exact |
| Site no. | Site no. |  | Exact |
| Subject ID | Subject ID |  | Exact |
| AE term | AE as reported |  | Consistent |
| Preferred term | Preferred term | Should match on MedDRA Preferred term  | Exact |
| SOC | SOC | System Organ Class  | Exact |
| Date SAE became serious | Date onset SAE | SAE are reported separately and outside the study database, therefore the start date of AE can be before the start date of the SAE report | Exact |
| Severity | Grading of AE according to CTCAE | The most extreme severity | Exact |
| Serious AE? |  | If an AE is reported as SAE, a SAE report must exist | Exact |
| Relation | Relationship to IMP | Relationship to IMP | Exact/Consistent |
| Action | Action taken to IMP (as a result of the event) | None, temporarily interrupted, permanently withdrawn, not applicable or unknown. | Exact/Consistent |
| Outcome | SAE outcome | Outcome may differ.If the outcome is “fatal” a date of death must be provided and consistent in the SAE report and the study database.Follow-up for safety reasons after the subject has left the study may occur. | Consistent |
| Treatment required | Treatment given because of the occurrence of this AE? (as a result of the event) | Procedure, medication or none | Consistent |

# Data Quality timepoints

The data quality controls will be performed with the following frequency during conduct of the study and as frequently as needed before database lock: (check cost estimate)

|  |  |
| --- | --- |
| **Task** | **Frequency** |
| Data validation  | Twice per year |
|
|
| Central monitoroing | Twice per year |
|
|
|
|
| SAE reconciliation | Twice per year |
|
|

# References

Legg inn alle referanser til SOP’er – med versjonsnummer!

The following versions of SOP’s will be used in this study:

|  |  |  |
| --- | --- | --- |
| SOP | Version | Approval date |
| SOP DM05 Data Validation | 2.0 | 29NOV2023 |
| SOP DM09 SAE Reconciliation | 2.0 | 29NOV2023 |
| SOP DM12 Centralised Monitoring | 0 | 18MAR2019 |