Data management plan

RDM F01 Data management plan v3.2

*For requirements, explanation of the topics, definitions and abbreviations, see*location AMC: [*SOP RDM001 Research data management*](http://intranet.amc.nl/web/file?uuid=af259bc9-3a21-43da-9f66-cd6613394815&owner=70eb19ba-5a0c-4929-8478-6e880c82e612&contentid=12975)location VUmc: [*SOP RDM001 Research data management*](http://intranet.vumc.nl/afdelingen-themas-1/datamanagement/procedures-en-templates.htm)

**Study:**

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| Protocol / Study number |  |
| Summary of the project |  |
| Type of study | WMO compliant  not WMO compliant |
| Co-ordinating PI / executive researcher |  |
| Department |  |
| Responsible for completion of the  data management plan | *Include e-mail address* |
| Other persons involved in data management | *Specify name and role* |
| Funding body and grant number |  |
| Partner organization(s) | *Partners that use the data, or whose data are used* |
| Consulted data management expert | *Specify name and function* |
|  |  |
| Data management plan version / date |  |
| Signature |  |

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| **Phase 1: Study preparation** | |
| **Privacy and security safeguards** | |
| **1.2\*** | The data set is anonymous and cannot be linked to a human subject  The data set is encoded; subjects can be identified through a subject identification log  The data set is directly identifiable  Data are de-identified during the study  *Explain why the selected level of identifiability is chosen and describe how and in what phase of the study data are de-identified:*… |
| **1.3 1.4 1.5 1.6** | A Data Protection Impact Assessment (DPIA) has been performed  The data acquisition has been registered  An informed consent procedure has been set up that describes the data set, time span of data retention, information on sharing data or making data available for future follow-up research; *provide document name and location: …* |
|  | Additional information: |
| **Data acquisition** | |
| **General** | |
| **1.10** | *Specify the data acquisition per type of data. Include a description of the terminology standard, classification or existing data definitions that has been applied in the data set:*  Reuse of existing data: specify…  Use of measured data: specify…  Data collection: specify… |
| **1.11** | Different data files are merged, using the same PIN |
|  | Additional information: |
| **Reuse of existing data**  Not applicable | |
| **1.12** | *Specify the source that is used to acquire data:* … |
| **1.13** | The reuse of data is covered by the subject’s informed consent |
| **1.14** | Contractual arrangements are in place for reuse of data from an external party; *provide document name and location: …* |
|  | Additional information: |
| **Measured data**  Not applicable | |
| **1.16** | The system that generates the measured data are hosted by the Amsterdam UMC or by an Amsterdam UMC partner, *namely: …*  The system that generates the measured data is hosted by a non-Amsterdam UMC partner, *namely: …*  Contractual arrangements are in place for use of measured data from an external party |
| **1.17** | A description of the generated data is available; *provide document name and location: …* |
| **1.18** | All users are trained in the system and this has been documented; *provide document name and location: …* |
|  | Additional information: |
| **Data collection**  Not applicable | |
| **1.20 1.21** | The data collection system is hosted by the Amsterdam UMC or by an Amsterdam UMC partner, *namely: …*  The data collection system is hosted by a non-Amsterdam UMC partner, *namely: …*  Contractual arrangements are in place for data collection through an external party |
| **1.22** | A data definition (data dictionary) is available; *provide document name and location: …* |
| **1.23** | Checks on completeness, correctness and consistency are incorporated in the data collection system and have been documented; *provide document name and location: …* |
| **1.24** | The system for data collection has been tested; test findings and final approval are documented; *provide document name and location: …* |
| **1.25** | Access to the data collection system is managed by the coordinating PI. User roles and authorizations are documented; *provide document name and location: …* |
| **1.27** | Users are trained in the data collection system; this is documented; *provide document name and location: …* |
|  | Additional information: |

\* ***1.2*** *refers to* ***topic 1.2*** *in the SOP Research Data Management where this guideline is presented. Not all topics in the SOP are listed in this DMP and several SOP topics may be covered under one DMP item.*

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| **Data storage** | |
| **1.29** | *Specify where the data are stored:*  On the department’s G-drive (location AMC) or M-drive (location VUmc) or on the personal H-drive (location AMC) or N-drive (location VUmc); *specify the path: …*  The folder and file structure with the corresponding access rights are documented; *provide document name and location: …*  On a (database) server that falls under a central backup regime; *specify server name: …*  On a (database) server of an Amsterdam UMC -partner, *namely*: …  Externally, *namely:* …  Contractual arrangements are in place for manual data collection through an external party; *provide document name and location: …* |
| **1.30** | The size of the data is … gigabyte during data collection and … gigabyte when archiving the project  Budget is allocated for storage and archiving |
| **1.31** | The coordinating PI keeps track of authorizations and documentation |
|  | Additional information: |
| **Subject identification log**  Not applicable | |
| **1.32 1.33** | The subject identification log(s) is/are kept separate from other study related dataset; *provide document name and location: …* |
|  | Additional information: |
| **Data sharing**  Not applicable | |
| **1.34** | For the collaboration with the research partners, written agreements on data management, privacy and intellectual properties are made |
|  | Additional information: |

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| **Phase 2: Data collection** | |
| **General** | |
| **2.1** | A site signature and delegation log is kept of all people involved in the data collection; *provide document name and location: …* |
| **2.3** | *If applicable:* a procedure for deblinding is in place and have been documented; *provide document name and location: …* |
|  | Additional information: |
| **Reuse of existing data / use of measured data**  Not applicable | |
| **2.6** | The reused existing data or the raw, measured data are stored as read-only file and a new file is created for further processing |
|  | Additional information: |
| **Externally acquired data**  Not applicable | |
| **2.8** | Procedures and responsibilities for the external data acquisition are defined; *specify: …* |
| **2.9** | Contractual arrangements for the external acquisition of data are made; *provide document name and location: …* |
|  | Additional information: |
| **Quality control** | |
| **2.12 2.13 2.14** | Procedures for data collection are documented; *provide document name and location: …*  Checks on completeness, correctness and consistency are applied and documented; *provide document name and location: …*  Completion of multicentre data collection is signed off by the local coordinating PI  Other quality control procedures, *specify:* … |
|  | Additional information: |

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| **Change control**  Not applicable | |
| **2.15** | *How are changes to the* ***data*** *handled?*  Documentation on the paper data collection tool (pCRF, questionnaire)  Audit trail or ‘track changes’ functionality in the applied system  Other change control, *specify:* …………and *provide document name and location: …* |
| **2.16** | *How are changes to the* ***design*** *of the data collection handled?*  By creating a new version  Audit trail or ‘track changes’ functionality in the system  Other change control procedures, *specify:* ………  All changes in the design are also documented; *provide document name and location: …* |
|  | Additional information: |

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| **Phase 3: Processing & statistical analysis** | |
| **Locking a data collection**  Not applicable | |
| **3.1**  **3.2** | *Describe how the data collection system is locked:*  Using the locking functionality in the system  Other, *specify:* …  Approval has been documented; *provide document name and location: …* |
|  | Additional information: |
| **Export to the data processing and statistical environment**  Not applicable | |
| **3.3 3.4** | The software system(s) including version number, and format(s), applied for processing and statistical analysis, are: …  The data are stored in a generic and machine actionable format, specify… |
|  | Additional information: |
| **Data processing and statistical analysis**  Not applicable | |
| **3.5** | The acquired data are stored as read-only file and a new file is created for further processing and statistical analysis |
| **3.6** | All data processing and analysis is programmed in syntax or script files |
| **3.7** | Descriptive comments are added to the syntax or script files |
| **3.8** | Syntax or script files are placed under version control |
| **3.9** | Data corrections in this phase are made in the original source  Data corrections in this phase are programmed in syntax or script files |
|  | Additional information: |
| **Sharing data for processing or statistical analysis**  Not applicable | |
| **3.11** | Sharing data with external parties is covered in the informed consent procedure |
| **3.13** | Data are transferred in a secure way; *specify: …* |
|  | Additional information: |

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| **Phase 4: Writing & publishing** | |
| **Filing**  Not applicable | |
| **4.1** | For each publication a structured subfolder has been created |
|  | Additional information: |
| **Accessibility of the data set** | |
| **4.2** | A persistent identifier (e.g. DOI, Handle) has been be created |
|  | Additional information: |

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| **Phase 5: Archiving & open data** | |
| **Open data**  Not applicable | |
| **5.1** | Reusing data is covered in the informed consent procedure |
| **5.2** | The research data will be publicly accessible without any restriction  Conditions for reuse apply and have been documented; *provide document name and location: …*  Conditions for reuse have been verified by Legal Research Support or by IXA |
| **5.3** | Once the project has ended, my data will be accessible  Immediately  After an embargo period, *specify duration and reason:* … |
| **5.4** | *Which data will be published?*  The raw, pre-processed data  The processed data  Other: *…*  *Location of the data:*  The digital archive (location specified in 5.13)  Other: *…* |
| **5.5** | The data collection can be found through an online (metadata) catalogue or web portal, *specify*: *…*  The data collection can be found through an repository or archive, *specify*: *…*  This catalogue / web portal or repository / archive has a Data Seal of Approval  This catalogue / web portal or repository / archive creates a Persistent Identifier (e.g. a DOI or Handle), *specify: …*  I have not chosen a catalogue / web portal or repository / archive, explain why not …. |
| **5.6** | *What descriptive documentation is provided about the study****?*** …  Study protocol  Data dictionary  Statistical Analysis Plan  Data validation and derivation plan  Data Management Plan  Other: *…* |
| **5.7** | *What descriptive documentation is provided about the* ***data****, including processing and analysis?*  Documentation on study procedures, *specify:* …  Documentation on data definitions, *specify:* …  Syntaxes or scripts  Software or hardware  Other: *…* |
|  | Additional information: |
| **Transfer to an external party**  Not applicable | |
| **5.8** | Agreements on data transfer are made; *provide document name and location: …* |
| **5.9** | A copy of the data and documentation is kept in Amsterdam UMC  All data transfers have been documented; *provide document location: …* |
| **5.10** | Data are transferred in a secure way; *specify: …* |
|  | Additional information: |
| **Digital archiving** | |
| **5.11** | Digital data will be preserved for … years |
| **5.12** | Sufficient budget is available for archiving during the retention period (see also 1.31) |
| **5.13** | Specify the location of the digital archive: *…* |
| **5.14** | A subject identification log is archived and kept separate from other study related data. This does not conflict with the subject’s informed consent |
|  | Additional information: |
| **Paper archiving**  Not applicable | |
| **5.15** | Specify the physical location of the paper archive: *…* |
| **5.16** | Paper documentation will be preserved for … years |
|  | Additional information: |