UMC Utrecht

Data Management Plan Template

Versie	Datum
1.0	Juni 2017

Introduction

The aim of a Data Management Plan is to ensure that good scientific practice is followed according to the FAIR principles; data should be made 'Findable, Accessible, Interoperable and Re-usable'. The Data Management Plan is an integral part of the research protocol and describes a standardized way how research data are collected, how data are used and stored during research and how you made data accessible for others after the research has been completed.

Please find the link to Data Management Plan Template.

(Use the Chrome browser to open the link)

The principle investigator or the researcher is required to use this template to describe their datamanagement plans, unless the funder/sponsor/executer requires a different template. If there is information missing in this template, please add the missing information in your appendix.

Before completing this Data Management Plan form, it is mandatory to get approval from your data manager. For advice and support please contact the Data Manager of your division or department.

0. Instructions

Please read before filling out this Data Management Plan form for research involving human subjects.

The aim of a Data Management Plan is to ensure that good scientific practice is followed according to the FAIR principles; data should be made 'Findable, Accessible, Interoperable and Re-usable'. This document describes a standardized way how research data are collected, how data are used and stored during research and how you made data accessible for others after the research has been completed.

Researchers are compliant with the requirements of the policy "Data Management van Mensgebonden onderzoek" by using standard UMC Utrecht IT products and services and by using this template. The Data Management Plan is an integral part of the research protocol. The principle investigator or the researcher is required to use this template to describe their datamanagement plans, unless the funder/sponsor/executer requires a different template. If there is information missing in this template, please add the missing information in your appendix.

The Data Management Plan for your study can only be accessed via this link you received by email. Please store this link!

The Data Management Plan template contains several chapters which can be filled out randomly. During the process it is possible to save answers and continue at a later time (use the button 'Close'). After completing a chapter the form can be submitted (use the button 'Submit') and the filled forms have to be separately exported in pdf format (use the button 'Download)'.

Please be noticed when the form is submitted it is no longer possible to make changes.

Before completing this Data Management Plan form, it is mandatory to get approval from your data manager. For advice and support please contact the Data Manager of your division or department.

Data Management Plan approved by
Name of DM that has given approval ……

1. General information

In order to be able to review your DMP, please provide some general information about your research project. You can copy paste from other documents (e.g., Research Proposal/Protocol).

1.1 Short description of your research

……

1.2 Kind of study (multiple answers possible)

- WMO
- Non-WMO
- Biobank
- Non-biobank
- Monocentre
- Multicenter
- Prospective
- Retrospective

1.3 Name of sponsor (verrichter)

……

1.4 Name and function of PI

……

1.5 Name and function of researcher(s)

……

1.6 Name of Data Manager

……

1.7 Funding body(ies) and grand number

……

1.8 Partner Organization(s)

……

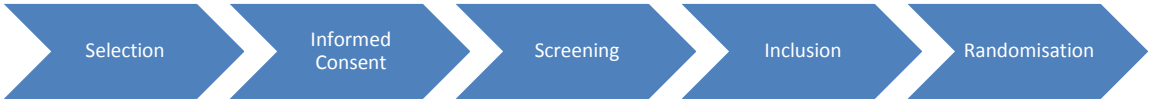
1.9 Duration of the study

……

2. Selection and inclusion of subjects

In this section, describe which data and systems you need to select and include your subjects.

In many research projects, there is a difference between selection and inclusion. First, potential participants are selected based on known characteristics and informed consent is registered. After selection, sometimes more detailed information is needed to determine the in- and exclusion criteria. This is called screening. Based on this information, the participants who are eligible for the study are included by the researcher. After inclusion, you can randomize the subjects if needed for your study.



From a data perspective, different data sources are needed for Selection and Screening. Both are addressed in this chapter.

Selection of study population

2.1 What type of subjects will be selected for your study? (multiple answers are possible)

- ○ Healthy participants
- ○ Patients from UMC Utrecht only
- ○ Patients from other organizations (including other hospitals, general practitioners, etc.), please describe the organization ……
- ○ Other, namely ……

2.2 Which in- and exclusion criteria are used to select potential subjects the study?
(copy paste from research proposal)
……

2.3 Which data do you need to select the subjects, and from which source is this data derived?
……

2.4 How many subjects do you expect to select in your study?
(copy paste from research proposal)
……

2.5 In case you want to use privacy sensitive data from patients for selection, who will carry out the selection of eligible subjects?

- ○ A clinician responsible for the population, or someone who is authorized by the responsible clinician to carry out this task on his/her behalf
- ○ Somebody without clinical responsibility for the population who is not authorized by the responsible clinician to carry out this task on his/her behalf. We made sure the following conditions are met:

- There is informed consent of the patient to use his/her privacy sensitive data (broad consent) **or,**
- The amount of work to obtain informed consent to use his/her privacy sensitive data for selection is disproportionate **and** the research study serves the public interest **and** there is a notification in the electronic patient record of this patient that his/her data are used for research

- Not applicable, I don't use privacy sensitive data from patients
- Unknown, please check with your data manager or research quality coordinator

2.6 In case you want to reuse data already collected for research purposes in order to select eligible subjects, are you allowed to use the data?

- Yes, I have approval from the Principal Investigator responsible for data you want to reuse.
- Not applicable, I don't use data already collected in a previous research project
- Unknown, please check with your data manager or research quality coordinator

Informed consent

2.7 In case you have planned to obtain informed consent from the study participants, how do you register the data from the signed informed consent forms?

- The informed consent process will be recorded in the electronic patient file (HiX) with a custom made questionnaire
- I will register the details in my own database
- Informed consent will be recorded in another tool, namely……
- No, please describe why no consent will be asked from the study participants, ……..

Screening

2.8 After selection, participants are screened because more detailed information is needed to include them as subjects in the study

- Yes, please answer the following questions
- No, please go the next chapter

2.9 Which criteria must potential subjects meet to be included for the study?

(copy paste from research proposal)

……

2.10 What type of data do you need to include the subjects, and from which source is this data derived?

……

……..

2.11 How many subjects do you expect to include for you study?

(copy paste from research proposal)

……

2.12 In case you want to use privacy sensitive data from patients for screening, who will carry out the screening of eligible subjects?

- A clinician responsible for the population, or someone who is authorized by the responsible clinician to carry out this task on his/her behalf

- Somebody without clinical responsibility for the population and he/she is not authorized by the responsible clinician to carry out this task on his/her behalf. I made sure the following conditions are met:
  - There is informed consent of the patient to use his/her privacy sensitive data (broad consent) **or,**
  - The amount of work to obtain informed consent to use his/her privacy sensitive data for selection is disproportionate **and** the research study serves the public interest **and** there is a notification in the electronic patient record of this patient that his/her data are used for research
- Not applicable, I don't use privacy sensitive data from patients
- Unknown, please check with your data manager or research quality coordinator

Inclusion

2.13 How do you register inclusion of study participants?

- Study inclusion process will be recorded in the electronic patient file (HiX)
- Study inclusion will be recorded in another tool, namely……..
- No, please describe why no study inclusion is registered, ……

Randomization

2.14 Will you use randomization to define the study population?

- No
- Yes

2.14.1 What type?

Simple

- Block
- Minimization

2.14.2 Which groups?

……

2.14.3 Number of subjects per group?

……

2.14.5 Which strata?

……

2.14.6 Which system?

- Randomization module Julius Centre (Random)
- ALEA
- Other, namely……

3. Data Collection & Data Access

When you collect data for your research project, you usually follow the process below. First you gain access to the source data. Secondly, you capture the data and thirdly you combine your source data in your research database. Chapter 4 is about preparation and analysis of your data.

Please describe in this section which source data you use and how you transfer the source data to your research data base. This involves technical aspects as well as privacy/legal aspects.

Codebook and datamodel

3.1 Did you describe the data that will be collected and stored in your research database?
- Yes, I prepared a codebook of my research database; please attach the codebook to this document
- No, I still have to do this. Please finish your codebook before start of the study.

3.2 Is there a description of the source data available?
- Yes, data description is available on Research Data Platform
- Yes, please attach the data description to this document
- No

Source Data

3.3 Which source data do you need? (multiple options possible)
- New research data collected with a Case Report Form. *Please fill out section 3.2.1.*
- Medical Devices (*For a definition of medical devices, see the data management policy on Connect, section "definitions".) Please fill out section 3.2.2*
- Data derived from biomaterial. *Please fill out section 3.2.3*
- Data stored in a research database or dataset. *Please fill out section 3.2.4*
- UMC Utrecht Health Care Data. *Please fill out section 3.2.5*
- External data. *Please fill out section 3.2.6*
- Other, namely……

3.3.1 New Research data collected with Case Report Forms

A Case Report Form (CRF) is a printed, optical or electronic document designed to collect the data that is described in the protocol for each trial subject.

Which CRF will be used? (multiple answers possible)	○ HIX (including patient portal) ○ NetQ ○ Open Clinica ○ Research Online 2 ○ Research Online for Researchers ○ Other, namely ……..
Do you use a pre-existing Case Report Form template?	○ No, I will design a Case Report Form specific for the proposed study ○ Yes, the name and ID (if known) of the Case Report Form is …….. ○ Unknown, please check with your data manager or research quality coordinator
Who will fill out the Case Report Forms? (multiple answers possible)	○ Patient or study participant ○ Medical doctor ○ Researcher ○ Research nurse /research assistant ○ Other, namely……..

How will the subjects be registered in the CRF?
(multiple answers are possible)
	○ Patient number
	  ○ Automatic linkage with HIX
	  ○ Manual entry of patient number in the database
	○ Study number
	  ○ The study number is generated automatically by the eCRF
	  ○ Manual entry of study number into the database
	  ○ I will create a list with the link between HIX patient number and study number
	○ BSN
	  ○ Automatic linkage with HIX
	  ○ Manual entry of BSN in the database
	○ Other, namely ……..

In what file formats will the data be extracted?	○ Database
	  ○ SQL/MySQL/Oracle etc
	  ○ Other, namely……
	○ File:
	  ○ .sas7bdat (SAS)
	  ○ .sav (SPSS)
	  ○ .accdb (Access)
	  ○ .txt
	  ○ .csv
	  ○ .xls
	  ○ .pdf
	  ○ Other, namely ……..

How will you be able to get access the collected data?	○ Data will be accessible for the researcher on the

	Research Data Platform in a separate datamart for this study ○ Data will be accessible for the data manager on Research Data Platform and will be extracted by the data manager for the purpose of this study ○ Datasets will be created by Julius Centrum data managers ○ Data will be accessible for the researcher from the application itself ○ Other, namely ……..

3.3.2 Collecting data with Medical Devices

Please describe in this section how you will collect and process data generated by a medical device.
For a definition of medical devices, see the *data management policy on Connect*, section "definitions".

For more information about medical devices and the procedures you need to follow to use them please go to:
https://richtlijn.mijnumc.nl/JCI/Documentatie/Paginas/Introductieprocedure-Medische-Technologie.aspx
https://richtlijn.mijnumc.nl/JCI/Documentatie/Paginas/Introductieprocedure-proef%2c-zicht%2c-leen-van-Medische-Technologie.aspx

Has the medical device passed the introduction procedure for medical devices?	○ Yes, registration number of the existing device is …….. ○ No, registration is pending (new device) ○ No
What type of medical device will you use?	○ Device ○ Disposable ○ Implant ○ Reusable tools ○ Software
Describe the medical device you will use	
What is the estimated size of the data, and what will be the expected growth rate?	

How is the data generated by the device?	○ Database
	  ○ Stand-alone database
	  ○ Clinical assistant database (MBOS, DICOM)
	○ File
	  ○ sas7bdat (SAS)
	  ○ .sav (SPSS)
	  ○ .accdb (Access)
	  ○ .txt
	  ○ .csv
	  ○ .xls
	  ○ .pdf
	  ○ .avi
	  ○ .wav
	  ○ .jpeg
	○ View in HiX
	○ Other, namely……

What type of data will be collected?	○ Quantitative information ○ Text ○ Video ○ Audio ○ Graphs /Images ○ Other, namely……..
How will you be able to get access to the collected data?	○ Data will be accessible for the researcher on the Research Data Platform in a separate datamart for the purpose of this study ○ Data will be accessible for the data manager on Research Data Platform and will be extracted by the data manager for the purpose of this study ○ Datasets will be created by Julius Centrum data managers ○ Data will be accessible for the researcher from the application itself ○ Other, namely……..

How will the subjects be identified in the data? (multiple answers are possible)	○ Patient number
	  ○ Automatic linkage with HIX
	  ○ Manual entry of patient number in the database
	○ Study number
	  ○ The study number is generated automatically by the eCRF
	  ○ Manual entry of study number into the database
	  ○ I will create a list with the link between HIX patient number and study number
	○ BSN
	  ○ Automatic linkage with HIX
	  ○ Manual entry of BSN in the database
	○ Other, namely ……

Do you have permission from the data owner to use the data from the medical device for your study? (for example, permission from the department of Cardiology for use of ECG data)	○ Yes ○ No, approval from data owner needed ○ Unknown, please check with your research quality coordinator

From a privacy point of view, are you allowed to use the data from the medical device?	○ Yes, I need identifiable data and:
	  ○ there is informed consent from the participant to use this data OR
	  ○ there is permission of the responsible clinician
	○ Yes, I will use anonymous data
	○ No
	○ Unknown, please contact your data manager or research quality coordinator

3.3.3. Data derived from analysis of biomaterial.

When data is derived from analysis of biomaterial, the process below is roughly followed. Sometimes, the first 2 steps are skipped because you can use material that is already collected. In this section, please explain how you will collect the data as result of your analysis, and how you will link the results with the samples and participants in the study.

For what purpose do you will collect biomaterial?	○ I will collect samples specific for the proposed study ○ I will use collected samples from a previous study ○ I will use 'restmateriaal'
Where is or will the biomaterial (be) stored after collection?	○ Central biobank in UMC Utrecht ○ Local biobank in UMC Utrecht ○ Biobank outside UMC Utrecht, please describe organization where the samples are stored …….. ○ Other, namely ……
Which device do you use to analyze your samples?	

How is the data generated by the device?	○ Database
	  ○ Stand-alone database
	○ File
	  ○ sas7bdat (SAS)
	  ○ .sav (SPSS)
	  ○ .accdb (Access)
	  ○ .txt
	  ○ .csv
	  ○ .xls
	  ○ .pdf
	  ○ .avi
	  ○ .wav
	  ○ .jpeg
	○ View in HiX
	○ Other, namely……

How can you link the samples to the subjects after you receive the samples prior to analysis?	○ Biobank number
	  ○ The study number is generated automatically
	  ○ Manual entry of study number into the database
	  ○ I will create a list with the link between HiX patient number and study number
	○ Patient number
	  ○ Automatic linkage with HiX (HL7)
	  ○ Manual entry of patient number in the database
	○ Study number
	  ○ The study number is generated automatically
	  ○ Manual entry of study number into the database
	  ○ I will create a list with the link between HiX

	patient number and study number ○ BSN ○ Automatic linkage with HiX (HL7) ○ Manual entry of BSN in the database ○ Other, namely ……..
How can you link the results to the samples after analysis?	○ Biobank number ○ The study number is generated automatically ○ Manual entry of study number into the database ○ I will create a list with the link between HiX patient number and study number ○ Patient number ○ Automatic linkage with HiX (HL7) ○ Manual entry of patient number in the database ○ Study number ○ The study number is generated automatically ○ Manual entry of study number into the database ○ I will create a list with the link between HiX patient number and study number ○ BSN ○ Automatic linkage with HiX (HL7) ○ Manual entry of BSN in the database ○ Other, namely ……
Do you have permission to use the result data?	○ Yes ○ No, approval from data owner needed ○ Unknown, please check with your research quality coordinator
From a privacy point of view, are you allowed to use the result data ?	○ Yes, I need identifiable data and: ○ there is informed consent from the participant to use this data OR ○ there is permission of the responsible clinician ○ Yes, I will use anonymous data ○ No ○ Unknown, please contact your data manager or research quality coordinator
How will you be able to get access to the collected data?	○ Data will be accessible for the researcher on the Research Data Platform in a separate datamart for the purpose of this study ○ Data will be accessible for the data manager on Research Data Platform and will be extracted by the data manager for the purpose of this study ○ Datasets will be created by Julius Centrum data managers ○ Data will be accessible for the researcher from the application itself ○ Other, namely ……..

3.3.4 Data stored in a research database or dataset

Describe the type of data you will use for your study	

How will the subjects be identified in the data?	○ Patient number
	  ○ Automatic linkage with HIX
	  ○ Manual entry of patient number in the database
	○ Study number
	  ○ The study number is generated automatically
	  ○ Manual entry of study number into the database
	  ○ I will create a list with the link between HIX patient number and study number
	○ BSN
	  ○ Automatic linkage with HIX
	  ○ Manual entry of BSN in the database
	○ Other, namely ……

What type of data is collected?	○ Quantitative information ○ Text ○ Video ○ Audio ○ Graphs /Images ○ Other, namely……

In what file formats will the data be generated?	○ Database
	  ○ Stand-alone database
	○ File
	  ○ sas7bdat (SAS)
	  ○ .sav (SPSS)
	  ○ .accdb (Access)
	  ○ .txt
	  ○ .csv
	  ○ .xls
	  ○ .pdf
	  ○ .avi
	  ○ .wav
	  ○ .jpeg
	  ○ Other, namely……

What is the size of the data?	
Do you have permission from the PI of the study that collected the data to use this data?	○ No, please contact the PI ○ Yes, please attach agreement of the PI
How will you be able to get access to the collected data?	○ Data will be accessible for the researcher on the Research Data Platform in a separate datamart for this study ○ Data will be accessible for the data manager on Research Data Platform and will be extracted by the data manager for the purpose of this study. ○ Datasets will be created by Julius Centrum data managers ○ Data will be accessible for the researcher from the

	application itself ○ Data will be accessible for the researcher from a dataset created by the data manager or researcher ○ Other, namely ……

3.3.5 Use of UMC Utrecht health care data

From which healthcare information system(s) do you use data? Data description is available on Research Data Platform.	○ EPD (including patient portal) ○ EPD Radiotherapie ○ 4KP (Anstat) ○ MetaVision (PDMS) ○ GLIMS ○ HELIX ○ EPD other sites than UMCU ○ Paper medical files ○ Other, namely ……
Describe the data you will use	

How will the subjects be identified in the data?	○ Patient number
	  ○ Automatic linkage with HIX
	  ○ Manual entry of patient number in the database
	○ Study number
	  ○ The study number is generated automatically
	  ○ Manual entry of study number into the database
	  ○ I will create a list with the link between HiX patient number and study number
	○ BSN
	  ○ Automatic linkage with HiX (HL7)
	  ○ Manual entry of BSN in the database
	○ Other, namely ……

What type of data will be collected?	○ Quantitative information ○ Text ○ Video ○ Audio ○ Graphs /Images ○ Other, namely……

In what file formats will the data be generated?	○ Database
	  ○ Stand-alone database
	  ○ Clinical assistant database (MBOS, DICOM)
	○ File
	  ○ sas7bdat (SAS)
	  ○ .sav (SPSS)
	  ○ .accdb (Access)
	  ○ .txt
	  ○ .csv

	○ .xls ○ .pdf ○ .avi ○ .wav ○ .jpeg ○ View in HiX ○ Other, namely……
What is the estimated size of the data, and what will be the expected growth rate?	
Do you have permission to use the data from the health care information system(s)?	○ Yes ○ No, approval from data owner needed ○ Unknown, please check with your research quality coordinator
From a privacy point of view, are you authorized to use the data from the health care information system(s)?	○ Yes, I need identifiable data and: ○ there is informed consent from the participant to use this data OR ○ there is permission of the responsible clinician ○ Yes, I will use anonymous data ○ No ○ Unknown, please contact your data manager or research quality coordinator
How will you be able to access the collected data?	○ Data will be accessible for the researcher on the Research Data Platform in a separate datamart for this study ○ Data will be accessible for the data manager on Research Data Platform and will be extracted by the data manager for the purpose of this study. ○ Datasets will be created by Julius Centrum data managers ○ Data will be accessible for the researcher from the application itself ○ Other, namely ……

3.3.6 Use of external data

External data is data generated, collected or stored by another organization outside the UMC Utrecht, for example GBA or CBS.

Describe the data you will use for the purposed study	
From which institute do you use data?	○ Municipal administration ○ (Gemeentelijke Basis Adminisatratie persoonsgegevens; GBA) ○ Statistics Netherlands ○ (Centraal Bureau voor de Statistiek; CBS) ○ Nationwide network and registry of histo- and cytopathology ○ (Pathologisch Anatomisch Landelijk Geautomatiseerd Archief; PALGA) ○ Netherlands Comprehensive Cancer Organisation (Integraal Kankercentrum Nederland; IKNL)

	○ Julius General Practitioners Network ○ (Julius Huisartsen Netwerk; JHN) ○ Nederlandse Orgaantransplantatie Registratie; NOTR ○ National Institute of Health and the Environment (Rijksintituut voor Volksgezondheid en Milieu; RIVM) ○ Other hospital than UMC Utrecht, namely ……. ○ University, namely …….. ○ Organisation outside the Netherlands, namely …….. ○ Other, namely ……
Describe the data you will use for the purposed study	
What type of data will be collected?	○ Quantitative information ○ Text ○ Video ○ Audio ○ Graphs /Images ○ Other, namely……

In what file formats will the data be generated?	○ Database
	  ○ Stand-alone database
	  ○ Clinical assistant database (MBOS, DICOM)
	○ File
	  ○ sas7bdat (SAS)
	  ○ .sav (SPSS)
	  ○ .accdb (Access)
	  ○ .txt
	  ○ .csv
	  ○ .xls
	  ○ .pdf
	  ○ .avi
	  ○ .wav
	  ○ .jpeg
	○ View in HiX
	○ Other, namely……

What is the estimated size of the data, and what will be the expected growth rate?	
How will you link the external data to the subjects?	○ Anonymous participant/patient number ○ Study number ○ BSN ○ Name, address, residence ○ Birth date ○ Other, namely …
How will the data be transferred?	○ Secure File Share ○ Secure e-mail ○ Safe USB stick ○ DVD ○ Other, namely ……..
Who will receive the data from the institute?	○ PI ○ Researcher ○ Study data manager

	○ Data manager from Julius Center ○ Data manager from Research ICT ○ Other, namely ……..
Who will link the data to your subjects?	○ Record linkage performed by the external institute ○ Record linkage performed by study data manager or researcher ○ Record linkage performed by data manager Julius Center ○ Record linkage performed by data manager Research ICT ○ Record linkage by a Third Trusted Party (e.g. Mondriaan, Surf) ○ Other, namely …….. ○ Not applicable, I don't need to link the data
Does the person or institute who will perform the record linkage have permission to access identifiable data?	○ Yes, there is informed consent from the participant to link the data ○ No ○ Unknown, please contact your data manager or research quality coordinator
How will you be able to access the collected data?	○ Data will be accessible for the researcher on the Research Data Platform in a separate datamart for this study ○ Data will be accessible for the data manager on Research Data Platform and will be extracted by the data manager for the purpose of this study. ○ Datasets will be created by Julius Centrum data managers ○ Data will be accessible for the researcher from the application itself ○ Other, namely ……..
From a legal perspective, are you compliant with the checklist for external data from UMC Utrecht Legal department?	○ Yes, I filled out the checklist ○ No, ○ Not sure, I will contact the Legal Department

4. Data validation & preparation & analysis

In this section you are asked to describe how to validate the collected dataset(s), what steps you will undertake to prepare the data for analysis, including joining and linking of different data sources and the requirements you have in terms of software and processing power for analysis.

Data Validation

The purpose of data validation is to check if there are any differences between the data visible in the source system (source data) and the data visible in the dataset(s) you received (raw data).

4.1 **Have you planned to check the quality of the raw data with the source data?** For example, if you receive a dataset containing EPD data, have you planned to check this data with the data visible in the source system?

- ○ Yes, this will be performed by the monitor and I have a monitoring plan. Please go to the next section and attach the monitoring plan.
- ○ Yes, please answer de questions below.
- ○ No, please contact your datamanager for advice and support

Which methodology do you use to check the quality of the raw data?	○ 10% check ○ Data check normality ○ Check outliers ○ Other, namely ……
Who will perform data quality checks?	○ Researcher ○ Study datamanager ○ Data manager within department ○ Data manager from Julius Centre ○ Automatic data quality checks in the eCRF tool ○ Other, namely…… ○ NA, because……
Is the person who will perform the quality checks authorized for the source system?	○ No ○ Yes ○ Maybe/don't know

In which programs are raw data opened and edited? You may select multiple options.	○ SAS EG ○ SAS BASE ○ SPSS ○ R ○ Openclinica ○ NetQ ○ MS EXCEL ○ MS Access ○ Other, namely……
In order to be able to reproduce your findings, all changes derived from quality checks need to be documented and saved. In which file format are any changes derived from data quality checks saved? You may select multiple options.	○ Text document ○ Excel document ○ Queries ○ Other, namely……

Data Preparation

The purpose of data preparation is to make the datasets ready for analysis.

4.2 Do you need to combine data from different raw datasets in order to create a dataset that can be used for analysis?

- ○ Yes
- ○ No, please go to the next section

Who will link the different raw data sets?	○ Researcher ○ Study datamanager ○ Datamanager within department ○ Datamanager from Julius Centre ○ Research Data Platform ○ Thrusted Third Party (TTP) (Mondriaan, ZorgTTP) ○ Other, namely…… ○ NA
How will the different raw data sets be linked?	○ Anonymous participant/patient number ○ Study number ○ BSN ○ Name, address, residence ○ Birt date ○ Other, namely ……
In case you are linking the raw datasets on an anonymous participant/patient number or study number, is the result table still anonymous?	○ Yes, persons are not traceable ○ No, with the combined data from different datasets it is possible to identify a person although there is no personal identifiable data such as name or BSN.
In order to be able to reproduce your findings, all actions needed to join the different datasets need to be documented and saved. In which file format are the	○ Text document ○ Excel document ○ Queries

steps taken to join datasets saved?	○ Other, namely……

Data analysis

Data analysis is performed on a 'frozen' data set. When you have collected all your data and prepared for analysis, you can freeze the dataset. After freezing the set, it is not possible to add or change anything.

Describe how the data analysis will be performed *You may copy the description of the statistical analysis from the METC protocol.*	
Which tools or software are used to perform the data analysis. You may select multiple options.	○ SAS EG ○ SAS BASE ○ SPSS ○ R ○ MS EXCEL ○ MS Access ○ STATA ○ Other, namely……
In order to be able to reproduce your findings, all steps taken in the analysis need to be documented and saved. In which file format are the steps taken to join datasets saved? You may select multiple options.	○ Text document ○ Excel document ○ Queries ○ Other, namely……
Do you expect to use High Performance Computing for your analysis?	○ Yes ○ No ○ Maybe

5. Data storage

Please check and describe how you will store your data during the study.

How do you store the research data during the study? (multiple answers possible)	○ Yes, I use the UMCU map structure on the Research network disc of my division ○ The data is stored on my own H disc ○ The data is stored utside the UMC Utrecht ○ The data is stored on my own hard drive ○ Other, please describe……..
Where will the research data be stored during the study (paper)?	○ Within the UMC Utrecht in a locked room or cabinet ○ Outside the UMC Utrecht in a secured place ○ Other, please specify……..
Is personal data stored separately from research data?	○ Yes, personal data and the key table linking research data to personal data are stored in a different map or physical place ○ No, research data contains personal identifiable data.

6. Data sharing

Please check and describe how you will share your data with researchers in your team during the study.

Data sharing during the study

6.1 Will the personal data of the study participants be shared among the participating centers?

- Yes, the organizing center receives personal data form the local center(s)
- No, the data stays in the local center

6.2 Who will get access to the personal data of the study participants? (multiple answers possible)

- Research Nurse
- Research Analyst
- Doctor
- Nurse
- Principal Investigator
- Data Manager
- Researcher
- Other……

6.3 From a privacy point of view, are you authorized to share the personal data with the persons listed above

- Yes
- No, approval from data owner needed
- Unknown, please check with your data manager or research quality coordinator

6.4 Who will get access to the research data?(multiple answers possible)

- Research Nurse
- Research Analyst
- Data Manager
- Researcher
- Doctor
- Nurse
- Principal Investigator
- Other……

6.5 Do you share the data outside the UMC Utrecht?

- No
- Yes, and I have checked with the Legal department that all needed data sharing contracts are in place
- Yes, but there are no official documents or data sharing contracts signed

6.6 What type of facilities do you use to send/share data to other researchers in the team?

- Email
- Secure email
- Surf Drive
- Network disc
- USB / external harddisk
- Multiple centers will have access to the eCRF tool
- Other, namely ……

Data sharing after closing the study

Please check and describe how you will share your data with researchers in your team after the study.

Is Open Access of your data mandatory from the funding body?

- Yes, where did you share your data? ……
- No

If Open Access is not mandatory, are you willing to share your data?

- Yes
- No, please motivate why ……

7.Data Archiving & Reuse of data

Please describe how you will archive your study data and how the data can be reused for future research.

7.1 Have you planned to archive your data when the study has ended?

- Yes, please answer the next questions
- No, please contact your data manager for advice and support

7.2 Where will you archive your data?

- I use the UMCU directory structure on the Research network disc of my division.
- On my own H disc
- Outside the UMC Utrecht
- On my own hard drive
- Data collected on paper will be digitalized according the policy 'Digitalisering van mensgebonden onderzoeksdossiers'
- Other, please describe……

7.3 Will your data be findable in an existing data catalogue?

- No
- Yes, I plan to register my dataset with DTL, GWAS or another external catalogue
- Yes, I use a predefined directory structure on my division network disc

7.4 If you don't have a data model or codebook, how do you ensure the data can be understood and reused by other researchers?

……

8. Costs for data management

Please specify the costs for every aspect of data management described in this data management plan:

Data management aspect	*Specification of the expenses*	*Organization charging costs*	*Are the costs an estimation or do you have an offer from the organization providing the service?*
Collecting data with CRFs	***Hosting costs***		
	Software Licenses		
	Configuration of questionnaires		
	Data extraction		
Collecting data with medical devices	***Data modelling***		
	Data extraction		
Collecting data from biomaterial	***Data modelling***		
	Data extraction		
Use of preexisting research data	***Costs for reuse of the data***		
Use of UMC Utrecht health care data	***Data modeling***		
	Data extraction		
Use of external data	***Data extraction***		
Data validation, preparation and analysis	***Costs for gaining access to the source system***		
	Costs for carrying out the validation (if you don't do this yourself)		
	Costs for data preparation (including costs for TTP in case you need them)		
	Costs for processing power (for example, for use of the High Performance Computing facility)		
Data Storage	***Storage costs***		
Data Sharing	***Licenses for data sharing applications***		
Archiving and Reuse	***Storage costs for archiving***		