Amsterdam Public Health

Amsterdam UMC · VU VRIJE UNIVERSITEIT AMSTERDAM · UNIVERSITY OF AMSTERDAM

Quantitative research preparation – **Data Management Plan**	Set-up & Conduct– Methods & Data Collection	
	VERSION	3.0

Aim
To ensure data management that adheres to the FAIR (Findable, Accessible, Interoperable, Reusable) principles.

Requirements
A data management plan according to the FAIR principles, with incorporation of data management considerations to meet requirements from relevant regulations and guidelines (e.g. AVG/GDPR, WMO, NFU guidelines) codes of conduct, and, where applicable, funder's requirements.

Responsibilities
Executing researcher:
- Make an appointment with a research data management consultant for a consultation about making a data management plan. Write a draft plan prior to the appointment.

Project leaders:
- To make sure the executing researcher contacts a data manager.

Research assistant: N.a.

How To
Data management plays an increasingly important role in doing scientific research involving human subjects (both 'WMO' and 'non WMO'). From subsidizing agencies, scientific journals, laws and regulations (including privacy) and from the point of view of scientific integrity, increasingly high demands are placed on the responsible handling of research data during all phases of the research process. FAIR data (Findable, Accessible, Interoperable, Reusable) is the keyword.

More and more funders also demand a so-called data management plan (DMP) in case of an approved grant application. A DMP must define how your data management is/will be organized and what choices have been made/are still pending during all phases of the research process. This plan should preferably be drawn up in cooperation with or with advice from a data management expert within the own organization. A data management plan is required for all projects within Amsterdam UMC, to help ensure high quality datasets.

For advice on making a data management plan a consultation appointment with a data management consultant is recommended. Amsterdam UMC employees can make an appointment with the central (Research) Data Management department (VUmc: datamanagement@vumc.nl, AMC and combined projects: rdm@amsterdamumc.nl). Standard Operation Procedures and templates for Data Management can be found here for VUmc and for AMC researchers information can be found here. For VU employees support is available from the UBVU. It is advisable to make an appointment at least 4 months before the data collection starts, so things can be properly regaled.

During a research data management consultation it is also possible to make appointments regarding the possible outsourcing of work to the (VUmc) Data Management department. Consultations are always free of charge. More intensive operational tasks like creating a database or making a custom web application for collecting data will be invoiced by the Data Management department, and should therefore be covered by project finances. This will need to be taken into consideration in the project budget/grant application.

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Depending on the funding agency, a variety of DMP templates are available and mandatory. Most often, Amsterdam UMC researchers can use the [Amsterdam UMC template](#), which is also highly recommended to ensure all medical research DMP requirements are addressed.

The ultimate goal of a DMP is to make clear how that data will be reusable and verifiable and will be permanently stored in an accessible archive (repository) after finishing the project. Therefore, it is necessary that all steps are described to that ensure that these data will be complete, clean, consistent and well documented.

It is important to think carefully and systematically about themes like:
- appropriate data collection (including appropriate tools and computer programs to achieve this)
- privacy issues in data processing
- managing dataflow
- data cleaning
- data documentation
- meta-data schemes for the description of the data collection
- meta-data schemes to link your datasets to other datasets
- sustainable file formats
- any import and export of data
- replication packages
- long term archiving and publishing data

Audit questions
1. Has an early appointment been made with the Data Management department or your own data manager associated with your research group?
    a. If not: What are the reasons?
2. Has a copy of the information plan been stored?
3. Has the advice described in the information plan been followed?

LINKS

	Link
AMC SOPs	http://intranet.amc.nl/web/organisatie/domeinen/research/clinical-research-unit-cru/cru-home/sops-1.htm
AmsterdamUMC-Vumc RDM	https://intranet.vumc.nl/afdelingen-themas-1/datamanagement/research-datamanagement-procedures-en-templates.htm
AVG	https://wetten.overheid.nl/BWBR0040940/2020-01-01/0/
GDPR	https://eur-lex.europa.eu/eli/reg/2016/679/oj
WMO	https://wetten.overheid.nl/BWBR0009408/2020-01-01
NFU guideline	https://www.nfu.nl/themas/randvoorwaarden-wetenschappelijk-onderzoek/klinisch-onderzoek
Code of Conduct	https://www.amsterdamumc.org/research/integrity.htm

DOCUMENT HISTORY

Version	Status	Date	Name
3.0	Revision	06APR2021	Elize Vlainic, Dr. Wouter van Ballegooijen
2.1	Added AMC SOP Data Management link	06SEP2018	EMGO
2.0	Revision format	12MAY2015	EMGO
1.3	English translation	01JAN2010	EMGO
1.2	Support from the Data Management department developed further and realised and need for a paperless office emphasised	27MAY2009	EMGO
1.1	Support from D&S described more extensively and updated	19OCT2006	EMGO

DOCUMENT APPROVAL

Role	Name	Date
Project Leader	Dr. Seta Jahfari	24MAY2021