

Data Management Plan

Project Name FWO Fundamental Research - DMP - Cuypers (11K8122N) - Data Management Plan

Grant Title 11K8122N

Principal Investigator / Researcher Marie-Lynn Cuypers

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Institution KU Leuven

1. General Information

Name applicant

Cuypers Marie-Lynn

FWO Project Number & Title

11K8122N

Advancing DNA-based antibody therapeutics through evaluation and characterization of *in vivo* expression and complex antibody formats

Affiliation

- KU Leuven

2. Data description

Will you generate/collect new data and/or make use of existing data?

- Generate new data

Describe in detail the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a table (see example) or as a data flow and per WP or objective of the project. If you reuse existing data, specify the source of these data. Distinguish data types (the kind of content) from data formats (the technical format).

Workpackage 1

Origin of Data	Type of data	Format	Volume	How Created
Plasmid maps	Textual (DNA sequence)	Genbank file	10MB	DNA sequence of trasgene of interest in the vector for <i>in vivo</i> transgene expression
Blood Sample Analysis	Numerical (Antibody Concentrations)	Excel files, Graphpad files	50MB	Blood is withdrawn from mice, plasma is extracted by centrifugation, plasma is analysed in ELISA assays
Tissue Sample Analysis	Numerical (DNA/RNA concentration)	Excel files, Graphpad files	50MB	Muscles are isolated from mice, processed for DNA/RNA extraction, total DNA and RNA samples are analyzed with (RT)qPCR
Tissue Sample Analysis	Textual (NGS data - methylation data)	BAM files, Excel files	10GB	Extracted DNA from muscle tissue undergoes bisulfite conversion, PCR amplification, followed by Illumina Next-Generation Sequencing
Tissue Sample Analysis	Microscopy Image	Tiff files	100MB	Immunohistochemical staining is performed on cryosections of the muscles isolated from mice
Tissue Sample Analysis	Confocal Microscopy Image	Leice Image File	50GB	RNA scope assay is performed on cryosections of the muscles isolated from mice and visualized with a confocal microscope

Workpackage 2

Origin of data	Type of data	Format	Volume	How Created
Antibody Construct	Textual (DNA sequence)	Genbank File	50MB	Combination of the different building blocks to form bispecific/trispecific antibodies
Blood Sample Analysis	Numerical (Antibody Concentrations)	Excel Files, Graphpad Files	50MB	Blood is withdrawn from mice, plasma is extracted by centrifugation, plasma is analysed in ELISA assays
Blood Sample Analysis	Numerical (A β -levels)	Excel Files, Graphpad Files	50MB	Blood is withdrawn from mice, plasma is extracted by centrifugation, plasma is analysed for A β -levels
Tissue Sample Analysis	Numerical (Antibody Concentrations)	Excel Files, Graphpad Files	50MB	Brains are isolated from mice and homogenized, brain homogenate is analysed in ELISA assays
Tissue Sample Analysis	Numerical (A β -levels)	Excel Files, Graphpad Files	50MB	Brains are isolated from mice and homogenized, brain homogenate is analysed for A β -levels

3. Legal and ethical issues

Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to your file in KU Leuven's Register of Data Processing for Research and Public Service Purposes (PRET application). Be aware that registering the fact that you process personal data is a legal obligation.

- No

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, add the reference to the formal approval by the relevant ethical review committee(s)

- Yes

Animal experiments will be performed as part of this project. All animal experiments to be performed in the laboratory have been approved by the Ethical committee for Animal Experimentation (ECD) at KU Leuven, and are outlined in ECD project #P157/2017 (Innovatie in intramusculaire gentransfer: Expressie van therapeutische antilichamen en nanobodies via DNA en RNA vectoren). The ECD is valid until September 2022, after which a new ECD project will be submitted for approval.

Does your work possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?

- No

Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions are in place?

- No

4. Documentation and metadata

What documentation will be provided to enable reuse of the data collected/generated in this project?

Protocols and details related to data collection and processing will be recorded in the Electronic Lab Notebook and transcribed to Word or Excel files by the PhD student (Marie-Lynn Cuypers). Data folders containing raw and processed data will be hierarchically organized and labeled based on the source of the data, the type of experiment, the date of data generation, and the different experimental conditions analyzed. Data analysis methods and particularities (including metadata) will be described in text documents and Excel files included in these folders. All files will be stored on the secured network drives of the KU Leuven or in the Electronic Lab Notebook with sharing possibilities.

Will a metadata standard be used? If so, describe in detail which standard will be used. If no, state in detail which metadata will be created to make the data easy/easier to find and reuse.

- No

Text documents and Excel files stored in the Electronic Lab Notebook will contain guidelines describing data collection/analysis methods and all relevant metadata (including experimental conditions, computational analysis and the parameters used for the calculations) to ensure the reusability of the data and the reproducibility of any further data generation.

5. Data storage and backup during the FWO project

Where will the data be stored?

Generated data are digitalized and archived on secured network drives and cloud storage (OneDrive) of the KU Leuven, where automatic backups are performed, during and after the project. Additional backups can be made on external hard drives or secured cloud applications. Data are accessible in the Electronic Lab Notebook (ELN), which can be accessed anywhere and anytime online via a web browser. The ELN cloud is hosted in multiple ISO-certified data centers with high availability and full redundancy. Data are backed up in real-time and are periodically archived to an off-site encrypted vault. Access is restricted to researchers that are involved in the project. Non-digitalized data, are stored in the Laboratory for at least 5 years after conclusion of the project.

How is backup of the data provided?

The data will be stored on network drives, cloud storage and in the electronic lab notebook with automatic back-up procedures.

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely. If no or insufficient storage or backup capacities are available then explain how this will be taken care of.

- Yes

OneDrive Cloud Storage: 2000GB

Electronic Lab Notebook: 10GB (can be upgraded)

KU Leuven Network Drive: 1TB

What are the expected costs for data storage and back up during the project? How will these costs be covered?

The OneDrive storage is free of charge. The cost for storage of data at the KU Leuven network drivers (J-Drive) is €52/year/100GB. The Electronic Lab Notebook license costs €155/year/user. These costs are covered by a general budget from the Laboratory of Therapeutic and Diagnostic Antibodies.

Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Access is restricted to researchers that are involved in the project. Upon completion of the project, the supervisor assures continuity in the data preservation.

6. Data preservation after the FWO project

Which data will be retained for the expected 5 year period after the end of the project? In case only a selection of the data can/will be preserved, clearly state the reasons for this (legal or contractual restrictions, physical preservation issues, ...).

All data will be retained for at least 5 years after the end of the project.

Where will the data be archived (= stored for the longer term)?

Digital data will be stored on the L-Drive of the KU Leuven or in the Electronic Lab Notebook.

Physical samples originating from animals and stock solutions of plasmids etc. will be stored at the appropriate long term storage temperature.

What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?

The cost for storage of data at the KU Leuven network drivers (J-Drive) is €52/year/100GB. These costs are covered by a general budget from the Laboratory of Therapeutic and Diagnostic Antibodies.

7. Data sharing and reuse

Are there any factors restricting or preventing the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

- No

All data will be generated and collected within the Laboratory of Prof. Paul Declerck and Prof. Maarten Dewilde. Data may be shared externally upon reasonable requests from collaborating scientists, which will be reviewed and approved on a case-by-case basis by the project lead (Prof. Maarten Dewilde).

Which data will be made available after the end of the project?

All relevant results will be published in peer-reviewed scientific journals. Raw data will be stored in Electronic Lab Notebook and on shared network drives which are backed-up on a regular basis.

Where/how will the data be made available for reuse?

- Upon request by mail

Raw data will only be made available upon reasonable request by email to the promoter (Prof. Maarten Dewilde).

When will the data be made available?

- Upon publication of the research results

Data will be available under the format of publications. Raw data can be requested by email upon publication of the research results.

Who will be able to access the data and under what conditions?

Everyone will be able to access raw data which are described in publications. In case access is requested to non-disclosed information a confidentiality agreement (CDA) will need to be implemented. Materials will be shared under material transfer agreements (MTA).

What are the expected costs for data sharing? How will the costs be covered?

Beside possible publication costs (covered by the FWO bench fee), no costs are expected to share the data.

8. Responsibilities**Who will be responsible for data documentation & metadata?**

The PhD researcher (Marie-Lynn Cuypers) is the designated responsible person for the proper data documentation and metadata of the PhD project.

Who will be responsible for data storage & back up during the project?

The PhD researcher (Marie-Lynn Cuypers) is the designated responsible person for the proper storage and preservation of the generated data in this PhD project.

Who will be responsible for ensuring data preservation and reuse ?

During the project the PhD student (Marie-Lynn Cuypers) is responsible. The PI (Professor Maarten Dewilde) will ensure data preservation and reuse after the completion of the PhD project.

Who bears the end responsibility for updating & implementing this DMP?

The PhD student (Marie-Lynn Cuypers) together with the PI (professor Maarten Dewilde) bears the end responsibility of updating & implementing this DMP.