DMP title

Project Name My plan (FWO DMP) - DMP title

Project Identifier 18B4222N

Principal Investigator / Researcher Ilse Degreef

Project Data Contact 016338843, ilse.degreef@uzleuven.be

Description Dupuytren under the microscope. A translational project to investigate and validate a novel surgical technique un Dupuytren disease: microfasciectomy. The role of the nerves and the skin will be evaluated and novel treatment options and algorythms to improve safety and efficiency will be introduced within this research project.

Institution KU Leuven

1. General Information

Name applicant

Ilse Degreef

FWO Project Number & Title

FWO Project number: 18B4222N

FWO Project title: Dupuytren under the microscope

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).

Origin	Type of data	Format	Volume
WP1Q1 Technical report microfasciectomy	Textual document Images	.docx/.pdf .jpeg	1GB
WP1Q2 Systematic review: research data from published articles	Textual document Spreadsheets Statistical data (SPSS)	.docx/.pdf .xls/.csv .SPS/.dat	1GB
WP1Q3 Retrospective cohort study: captured via eletronic patient record in online klinisch werkstation (KWS) and UZ Leuven Activity center care program	Textual document Spreadsheets Statistical data (SPSS)	.docx/.pdf .xls/.csv .SPS/.dat	1GB
WP1Q4 Technical innovation: surgical instruments, new surgical technique	Physical data (surgical instrument) Textual data Images	.docx/.pdf .jpeg	1GB
WP2Q1-3 prospective study: captured via electronic patient record in KWS	Textual document Spreadsheets Statistical data (SPSS) Images Physical data (biopsies)	.docx/.pdf .xls/.csv .SPS/.dat .jpeg	5GB
WP2Q4 RCT: captured via electronic patient record in KWS	Textual document Spreadsheets Statistical data (SPSS) Databases (REDCap)	.docx/.pdf .xls/.csv .SPS/.dat .sql	5GB
WP3Q1-3 Prospective cohort studies: captured via electronic patient record in KWS	Textual document Spreadsheets Statistical data (SPSS) Images Physical data (biopsies)	.docx/.pdf .xls/.csv .SPS/.dat .jpeg	10GB

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.

- Yes

Privacy Registry Reference: Compliance Monitoring Tool.

Short description of the kind of personal data that will be used: Data will be pseudonymised and will be stored securely through file data KU Leuven.

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

Ethical approval for the studies has not been requested, but will be done through the PRET application.

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?

- Yes

The PI has currently no intention to claim restrictions for the data that will be created.

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?

1. Study protocols will be written for all clinical studies
2. A codebook with explanation of concepts, variables, and abbreviations will be generated
3. Raw data will be collected through KWS and UZ Leuven activity center care program

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.

- Yes

- REDCap
- RDR repository
- Controlled vocabulaires

5. Data storage and backup during the FWO project

Where will the data be stored?

All data will be stored securely at the File Storage KU Leuven. This storage is located in the central KU Leuven data centers and is offered via the SMB protocol. Data-at-rest encription is standard.

Biopsies will be preserved at the UZ Leuven biobank.

How is backup of the data provided?

File storage KU Leuven has a mirror option.

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

There is no hard limit for maximum storage size

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

Costs:

- up to 100GB 50,53 euro per year
- 50,53 euro per year
- From year 2: calculated based on data storage used

The allocated budget will be used to cover the costs.

Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?
Data will be pseudonymized and securely stored at File Data KU Leuven via SMB protocol with standard data-at-rest encryption.

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 10 years after the last publication of the data.

Where will the data be archived (= stored for the longer term)?
All digital data will be archived at the institutional data repository of the KU Leuven (RDR)
Biopsies will be preserved at the UZ Leuven biobank.

What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?
50GB per year is free per researcher

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)?

- Yes. Specify:

If participants decide to withdraw from the clinical study and request that their data will be destroyed.

Which data will be made available after the end of the project?
The full dataset will be deposited in a cvs format in KU Leuven RDR under a CC-BY license.

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

- In a restricted access repository

Upon request by e-mail

When will the data be made available?

- Immediately after the end of the project

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

- Before publishing: only researchers
- After publishing: everyone upon request by e-mail

What are the expected costs for data sharing? How will the costs be covered?
There are no expected costs.

8. Responsibilities

Who will be responsible for data documentation & metadata?
The PI will be responsible for data documentation and metadata

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

Who will be responsible for ensuring data preservation and reuse ?
The PI will be responsible for ensuring data preservation and reuse

Who bears the end responsibility for updating & implementing this DMP?
The PI bears the end responsibility of updating & implementing this DMP.