FWO_1830522N_TVanuytsel

Project Name DMP_1830522N_TVanuytsel - FWO_1830522N_TVanuytsel
Project Identifier 1830522N
Grant Title 1830522N
Principal Investigator / Researcher Tim Vanuytsel
Institution KU Leuven

1. General Information

Name applicant
Tim Vanuytsel

FWO Project Number & Title
1830522N: The central role of the duodenal microenvironment in functional dyspepsia.

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).

WP1: In-depth characterization of duodenal mucosal immune activation in functional dyspepsia

+

WP3: Anti-inflammatory treatments in FD

	Type of data	Format	Volume	How created
1	Symptom questionnaires Quality of Life questionnaires Food frequency questionnaires	.xls .txt	1-100MB 5-500kB	Questionnaires are filled out on paper and are transferred into an Excel file Online questionnaires are filled out using the Qualtrics platform. Data can be extracted as .txt files which are converted into .xls files.
2	Personal data: sex, age, weight, length, medication, allergies, co-morbidities	.xls	1-5MB	The data are filled out on paper by the patient and transferred into an Excel file.

3	Flow cytometry	.fcs .wsp	5-30MB 1-10MB	Flow cytometry data are saved from FACS Diva software as .fcs (3.0) files, which are processed in FlowJo software as a workspace (.wsp) per experiment The physical samples are discarded after the analysis since no further experiments can be done using these cells.
4	Gene expression data (RT-PCR)	.txt .xls .png	1-10kB 1-100MB 50-100kB	Samples with reaction mix are transferred into 96 well plates, analyzed in a light-cycler PCR machine. The machine generates a .txt file with the Ct values, which is then transferred to an .xls file for further processing. Graphical overviews of PCR efficiency are saved as .png files The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Tim Vanuytsel.
5	Protein expression data (Mesoscale protein assay)	.txt .xls	1-10kB 1-100MB	Samples are analyzed in a multiplexing imager. A .txt file with the spectrophotometry results is generated and then transferred to an .xls file for further processing. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Tim Vanuytsel.

6	Immunofluorescence microscopy images	.tif .czi	5-20MB 10-50MB	Widefield immunofluorescence images acquired with an Olympus microscope are saved as .tif files using Adobe Photoshop. Processing in ImageJ software renders new .tif files. Confocal immunofluorescence images acquired with an LSM880 Zeiss microscope are saved as .czi files using Zeiss Black software. Processing in ImageJ software renders .tif files. The physical samples (paraffin blocks with sample embedded and tissue slides) will be stored in the cold room of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Tim Vanuytsel

WP2: The link between duodenal inflammation and neuronal activation in FD
+
WP3: Anti-inflammatory treatments in FD

	Type of data	Format	Volume	How created
1	Neuronal imaging movies	.pst .inf .vws .txt .pxp .xls	40-60MB 1-100bytes 50-250MB 1-25kB 0.1-5GB 10-100MB	Live fluorescence microscopy image series generated using a calcium imaging technique are saved as outlook data files (.pst) in TillVision software with supporting technical metadata (.inf). Additional metadata are stored as .vws and .txt files. After analysis by Igor software, workspace files are saved as .pxp files, with results summarized in .xls files. The physical samples are discarded after analysis since the tissue is not suitable for further analysis anymore.
2	Immunofluorescence microscopy images	.tif	5-20MB	Widefield immunofluorescence images acquired with an Olympus microscope are saved as .tif files using Adobe Photoshop. Processing in ImageJ software renders new .tif files. The physical samples (paraffin blocks with sample embedded and tissue slides) will be stored in the cold room of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Tim Vanuytsel
3	fMRI brain imaging data	bids dicom	75-80 GB	These data were acquired during a previous clinical study of my group (S60953 and S60984) but not processed yet. The analysis of these data is part of the current FWO project; (f)MRI data were acquired in listmode raw and DICOM format and stored in Brain Imaging Data Structure (BIDS) file format (https://bids.neuroimaging.io/). The volume of structural MRI raw data averages 30 MB per subject and fMRI raw data 1.2 GB per task scan.

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: GDPR questionnaire of studies S64807 - S64847

Short description of the kind of personal data that will be used:

The data below will be used as pseudononimized data. The file containing the link between the unique study number and the patient ID (as used in the electronic patient file) and the name of the patient is password protected and stored on the secured server of the UZ Leuven. This file also contains the contact details including E-mail and telephone number.

Data collected as pseudonimized data:

Age, sex, weight, length, medication, allergies, co-morbidities, medical history, symptom severity and frequency, food intake.

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

Reference to ethical committee approval (including GDPR questionnaire): S64807 - S64847

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?

We refer to the data mentioned in section 2 using the same numbers:

WP1: In-depth characterization of duodenal mucosal immune activation in functional dyspepsia

+

WP3: Anti-inflammatory treatments in FD

1-2: Questionnaire and personal data

The general study protocol, including detailed information on the type and time of filling out the questionnaires, is stored on KULeuven OneDrive. SOPs for the informed consent procedure and calculation of the summary scores of the questionnaires is also available on KULeuven OneDrive.

3: Flow cytometry

Standard metadata according to guidelines (MIFlowCyt) are collected and include the overview of the experiment, flow sample/specimen details, instrument details and data analysis details. Furthermore the data and time of the experiment are also included. SOPs for the flow cytometry protocols are available on KULeuven OneDrive.

4: Gene expression data

A .txt file is generated by the LightCycler machine including the date and time of the experiment, the name of the samples in each location of the plate and the fluorophore used (standard SYBR-green). Graphical representation of efficiency of the reaction are generated as .png files.

SOPs for the processing of RNA samples, cDNA production and RT-PCR protocol are available on KULeuven OneDrive.

5: Protein expression data

A .txt file is generated by the multiplex machine including the date and time of the experiment, title of the plate, the analyzed proteins and the name of the samples in each location of the plate.

SOPs for the protein extraction and processing using the MesoScale technology are available on KULeuven OneDrive.

6: Immunofluorescence microscopy data

A .txt file is generated including the date and time of the experiment, exposure time (ms),

wavelength (Ex and Em).
SOPs for the immunofluoresence staining and image generation is stored on KULeuven OneDrive.

WP2: The link between duodenal inflammation and neuronal activation in FD
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WP3: Anti-inflammatory treatments in FD
1: Neuronal imaging movies
Supporting technical metadata are generated as .inf, .vws and .txt files, including date and start time of experiment, exposure time, monochromator wavelength, monochromator wavelength increment, image type, horizontal and vertical binning factor, chip window x- and y position, chip window width and height.

SOPs for live calcium imaging are stored on KULeuven OneDrive.

2: Immunofluorescence microscopy data
A .txt file is generated including the date and time of the experiment, exposure time (ms), wavelength (Ex and Em).
SOPs for the immunofluoresence staining and image generation is stored on KULeuven OneDrive.
3: fMRI brain imaging data
The study design and research procedures of these previously generated data was extensively document, including the settings of data collection, equipment details and settings, sampling methodology, specification of the raw data file names (which measures they refer to), information that describes the variable codes (referring to type and time of specific measurements) and used analyses methods, as well as any other information necessary for a secondary analyst to use the data accurately and effectively. The experimental and data analysis metadata are stored in a structed manner alongside our research data in .csv, .docx, .xslx or .txt files (e.g. “README” files for each distinct dataset). The metadata related to the machine settings, time and date of the experiments are stored in the BIDS file format.

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

Where possible, metadata standards will be used - e.g. in case of the flow cytometry data the MIFlowCyt standard will be used as detailed in the previous question - or if unavailable, the experimental and data analysis metadata will be stored in a structed manner alongside our research data in .csv, .docx, .xslx or .txt files (e.g. “README” files for each distinct dataset), based on commonly used terminology in the field of neuroimaging, biomedicine and biostatistics. For the (f)MRI data, metadata are included in the BIDS file format.

5. Data storage and backup during the FWO project
Where will the data be stored?
All experimental data are transferred via the KU Leuven server to a personal computer where data are immediately uploaded to KU Leuven OneDrive where the master copy of the data is stored. Only working templates are saved locally in FACS Diva software (Flow cytometry) or TillVision software (Neuronal imaging).
The pseudonimization link containing the link between the unique study number and the patient ID (as used in the electronic patient file) and the name of the patient is password protected and stored on the secured server of the UZ Leuven.
Data in paper format (informed consent forms, payment forms, inclusion/exclusion criteria forms) will be stored separately in a key-locked cabinet in a restricted room of the research group).
Biological data (blood samples and derivatives) will be stored in the KU Leuven Biobank.

How is backup of the data provided?
The data are stored on KULeuven One Drive with automatic daily 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

The available storage space of the OneDrive is sufficient for the amount of data specified above. If needed (not anticipated), this can be extended flexibly if needed. Storage for biological samples is guaranteed by dedicated freezer space at a PI-owned freezer in the KU Leuven Biobank.

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

The KULeuven OneDrive is free of charge.

The freezer to store the biological samples has already been purchased by the PI and is located in the biobank at no cost.

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

Since we will be working with sensitive personal data that will only be anonymised at the end of the project, the data will be stored in the UZ Leuven secure environment for private data.

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, ...).

Biological samples will be destroyed after 5 years because of the degradation of the samples. Some samples will be destroyed immediately after analysis: flow cytometry samples and neuronal imaging samples.

The obtained data will be anonimized at the end of the project and stored for at least 10 years as detailed below.

The anonimized data will also be presented in PhD theses and research papers.

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

The data will be stored on the university's central servers (with automatic back-up procedures) for at least 10 years, conform the KU Leuven RDM policy.

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

The costs to archive the digital data are estimated at 156,60 EUR/TB/year and will be paid from the current project.

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

Anonimized data can be made available for further analyses in line with the terms of the ICFs and following advice from the relevant local ethics committees.

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

The anonimized data sets can be shared within the research unit or shared upon request.

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

- Upon request by mail

Data will be available on request after signing a data sharing agreement.

When will the data be made available?

- Upon publication of the research results

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

The anonimised data will be available upon reasonable request by email after publication of the

data and after signing a data sharing agreement.

What are the expected costs for data sharing? How will the costs be covered?
Data sharing is free of charge.

8. Responsibilities

Who will be responsible for data documentation & metadata?
The researcher working on this project: Matthias Ceulemans.

Who will be responsible for data storage & back up during the project?
The researcher working on this project: Matthias Ceulemans.

Who will be responsible for ensuring data preservation and reuse ?
The PI: Tim Vanuytsel.

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