Blood pTau and GFAP dynamics in confirmed presymptomatic sporadic Alzheimer's Disease

Project Name My plan (FWO DMP) - Blood pTau and GFAP dynamics in confirmed presymptomatic sporadic Alzheimer's Disease

Project Identifier steffi.demeyer@kuleuven.be

Grant Title 11M0522N

Principal Investigator / Researcher Steffi De Meyer

Description The goal of this project is to unravel how blood-based biomarkers change before symptoms of sporadic Alzheimer's Disease set in and how these changes relate to underlying pathology as seen on PET scans and postmortem examination, beyond amyloid. To this end, biomarker levels will be measured in serum samples of five independent cohorts including two academic and three clinical cohorts. Demographic, clinical and imaging data of the academic cohorts have already been collected by collaborating laboratories. For the three clinical cohorts, demographic and clinical data will be retrieved from the patients' medical files. For all five cohorts, these data will then be investigated in relationship to the serum biomarker levels that will be measured during this project.

Institution KU Leuven

1. General Information

Name applicant

Steffi De Meyer

FWO Project Number & Title

Number: 11M0522N

Title: Blood-based GFAP and pTau in confirmed presymptomatic sporadic Alzheimer’s Disease

Affiliation

- KU Leuven

2. Data description

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

- Generate new data
- Reuse existing 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).

Type of data	Format	Volume	How created
Biomarker data	.xls	2 files of max 1 MB	Blood-based immunoassays on the Simoa and Ella platform
Positron emission tomography scans	.nii	250GB	Recorded in list mode, reconstructed into 6x5min frames and converted from original DICOM files
Magnetic Resonance Imaging scans	.nii	20 GB	3D Turbo field echo sequence on a 3 Tesla Philips Achieva system
Cognitive and demographic data of academic cohorts	.accdb	35 KB	In-person interviews with neuropsychologists
Cognitive and demographic data of clinical cohorts	.accdb	35 KB	Retrieved from clinical workstation, in which they were entered after consultation of the patient with a neurologist.
Mass spectrometry data	.raw .mgf .xml .xlsx	1 MB per run	Mass-spectrometry run fenerates .raw files that are converted to .mgf files, .xml files and eventually excel files through run alignment, peak picking and a Mascot search, respectively.
Postmortem data	.accdb	1 KB	Neurofibrillary tangle density and synaptic density scores will be determined by the Laboratory for Neuropathology
Statistical analyses	.R	1 MB	R scripts for statistical analyses will be created using the R terminal

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

Brain imaging data (positron emission tomography scans and magnetic resonance imaging scans) as well as demographic (age, sex, education), genetic (APOE genotype) and clinical information (cognitive tests) of all included subjects. Biomarker information will be generated in serum samples.

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

S51125 Use of demographic, genetic, cognitive and imaging data for research purposes
S65105 obtaining p-tau biomarker data in cohort of cognitively healthy elderly (F-PACK)
S65540 obtaining p-tau biomarker data in cohort of AD patients (COPRA)

S66140 obtaining GFAP biomarker data in cognitively healthy elderly and AD patients

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?

1. For PET and MRI images metadata (pixel size, orientation, scanner settings, data, subject) is stored in the header of the original DICOM image

2. For neuropsychological testing, details on the subject, the interview itself and the informed consent process have been entered in an Excel file

3. For R scripts, README text files will be generated which describe the analyses performed as well as the path(s) where the relevant data is stored.

4. For biomarker data, information about the assay characteristics, the assay and mass spectometry runs and other remarks will be stored per sample in an excel file.

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

Metadata created in the current project is two-fold

- Details about the assay characteristics as well as the runs performed, which will be stored in an excel file
- Details about the statistical analyses performed and path where employed data is stored will be described in a README file

All other metadata has been created in the context of other projects and is already in place

5. Data storage and backup during the FWO project

Where will the data be stored?

1. Imaging, demographic and clinical data, which has already been collected, is stored on the a Secure Sockets Layer virtual private network (SSL VPN) of KU Leuven. SSL VPN is a web-based technology that enables a secure connection to the university network. This security is ensured by authentication at the user level as well as encryption of all received and sent data.

2. Patient data will be retrieved from the highly-secured clinical work station of the hospital and stored in on the university's SSL VPN where they will be assigned study codes for further analyses.

How is backup of the data provided?

The data will be stored on the university's central servers 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

Yes, imaging files, which consititute the largest part of data to be stored, has already been stored on the SSL VPN server paid for by my copromotor. In this project the largest data type are the mass spectrometry files which will be saved on a seperate SSL VPN drive of KU Leuven. In case the storage capacity of this drive transpires to be insufficient, a second drive will be bought.

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

The host laboratory will obtain a subscription to the secure university SSL VPN drives. This has a cost of €51.9 per year. Long term storage of data will be done on a separate K drive, which can be obtained at a 50% discount for €5.69 per year.

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

The sensitive personal data will be stored in the university's SSL VPN, which is a web-based technology that enables a secure connection to the university network. This security is ensured by authentication at the user level as well as encryption of all received and sent data. File transfer to third parties that do not have access to this drive will be performed using Bellnet. All data will be anonomized and study codes will be stored in a separate locked file.

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 subject data generated or used in this study will be collected in a Master Excel database, which will be stored on a SSL VPN along with the raw imaging data and mass spectrometry excel files. Other MS data will be stored on the SyBioMa PC and drives.

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 yearly fee for the use of the university SSL VPN equals €57.59, which will be funded by the host laboratory

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

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

Only published data will be made available upon reasonable request

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

- Upon request by mail

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 data will be deposited on the univerity's SSL VPN. On request published and anonymized data might be shared with third parties for the sole purpose or reproduction of the study.

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

No costs for the host institution

8. Responsibilities

Who will be responsible for data documentation & metadata?

All data generated during this project will be documented by Steffi De Meyer, who will also provide the relevant metadata

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

Storage and back up of the data generated in this project is the responsibility of Steffi De Meyer

Most data employed in the current project has however already been collected. Storage and back

up of that data is the responsibility of the PhD or postdoc student that collected them.

Who will be responsible for ensuring data preservation and reuse ?

Storage and reuse of blood-based data is the responsibility of Dr. Poesen. Clinical, demographic and imaging
data of volunteers is the responsibility of Dr. Vandenberghe for the F-PACK cohort, Dr. Vandenbulcke for the L3D cohort and Dr Thal for the neuropathological cohort.

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

The PI (Koen Poesen) bears the end responsibility of updating & implementing this DMP.