DMP title

Project Name My plan (FWO DMP) - DMP title
Grant Title 1SD2322N
Principal Investigator / Researcher Eline Verscheure
Description In this project, I will map the environmental contamination and unintended internal exposure to antineoplastic agents in a home setting. If I find contamination at patients' homes and internal exposure in healthcare workers and family members, I will evaluate the genotoxic and epigenetic effects.
Institution KU Leuven

1. General Information

Name applicant

Eline Verscheure

FWO Project Number & Title

1SD2322N - Assessment of effects after unintended exposure to cytostatic drugs

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).

How created	Type of data	Format	Volume
Data from analysis of biological samples or environmental samples after sample preparation and analysis with e.g. UPLC-MS/MS + method development	Numerical	txt, xlsx	t.b.d.
Questionnaires	Qualitative data, nummerical data	docx, xlsx	t.b.d. (+/- 90 kB per questionnaire)
Effects assessment in blood: CBMN assay	Numerical	xlsx	t.b.d.
Effects: DNA-adducts + method development - UPLC-MS/MS	Numerical	txt, xlsx	t.b.d.
Effects: 8-OHdG +method development - ELISA	Numerical	csv, xlsx	t.b.d.
Effects: global DNA/RNA methylation + method development - UPLC-MS/MS	Numerical	txt, xlsx	t.b.d.
Effects: gene specific DNA methylation + method development-pyrosequencing	Numerical	.PYRO, csv, pyrogram will be exported as pdf	1 MB (csv)/10-25 MB pyrorun

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: G-2021-3987

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

-Information on exposure and effects thereof from biological samples (epigenetic changes, DNA-adducts, chromosomal aberrations).

-Questionnaire information (e.g. name, zip-code, sex, date of birth, BMI, coffee/alcohol intake, physical activity, diet, smoking, contact information, eductaion cleaning procedures, knowledge on antineoplastic agents, use of personal protective equipment, if familymembers share spaces with patients at home, use of medication, medical conditions, etc.).

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

PRET application:G-2021-3987
File was submitted to ethical committee, but not ethical approval obtained yet.

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?

Detailed protocols for each experiment will be noted down in a paper or electronic lab notebook (.docx). After validation of the methods, the final protocols will be documented as SOPs. Processed data will be stored in folders for each type of experiment (biological monitoring, environmental montoring, CBMN assay etc.), in spreadsheets with resuls (.csv, .xls). The questionnaires and informed consent forms will be documented as Word document, signed hardcopies (printed paper). The patient identifier record (name of subject and unique number) are stored in an Excel file, but not at the same location as the questionnaires and informed consents. The patient identifier record will be stored at a password protected network under supervision of the PI.

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

Generated and processed data will be stored in separate folders at OneDrive for each experiment to make sure the data can be easily found and reused. These folders with documents (.xls, .csv, .docx) will contain guidelines on how to generate and process data and will include metadata (experimental conditions, sample keys, etc.) to ensure reusability and reproducibility of data.

5. Data storage and backup during the FWO project

Where will the data be stored?

Coded data will be stored at the personal OneDrive of the researcher and the shared drive of the lab. The coding list containing the identity of the participants will only be accessible to the doctoral researcher an the PI. This list will be stored as an excel sheet at a non-shared drive, protected with a personal password.

How is backup of the data provided?

Data will first be stored on OneDrive (synchronized). Backups will be made to the shared drive of the lab. The KU Leuven servers are backed up automatically.

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

Suffcient storage and backup capacity is provided on the KU Leuven servers and networks. OneDrive provides 2 TB which should be sufficient for the generated and processed data.

What are the expected costs for data storage and back up during the project? How

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

I do not expect costs for data storage and back up during the project, storage space provided by KU Leuven is free of charge.

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

We will collect sensitive personal data in our project by use of questionnaires. All samples will be pseudonymized. The coding list containing the identity of the participants will only be accessible to the doctoral researcher an the PI. This list will be stored as an excel sheet at a non-shared drive, protected with a personal password. By initially storing data on a personal OneDrive, only the researcher has access to the pseudonymized 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 stored until the end of the project. All data will be retained for at least 5 years after the end of the project, conform FWO policy.

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

All data wil be stored on the shared drive of the lab for at least 10 years, according to 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?

Samples will be stored at -80°C or -20°C, electricity costs for the freezers are included in the general lab costs. Storage at KU Leuven servers is free of charge, so no additonal costs for data preservation are expected.

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

(Only pseudonymised data will be shared).

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

Results of the project and their interpretation will be made available through publication of journal papers in peer-reviewed academic journals. All pseudonymized data can be made available upon resonable request after the end of the project.

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?

During the project only the involved researcher and PI will have access to the data. After publication, pseudonymised data will be available for research purposes.

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

No costs are expected, storage at KU Leuven servers is free of charge, as well as the use of Belnet FileSender.

8. Responsibilities

Who will be responsible for data documentation & metadata?

The researcher will be responsible for data documentation and metadata.

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

The researcher is responsible for data storage adn 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.