Does patient empowerment foster access to and re-use of data in biomedical research, while allowing for meaningful protection of the fundamental right to data protection of patients?

A Data Management Plan created using DMPonline.be

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Project abstract:

Biomedical research relies on access to and re-use of personal data. The complex legal EU framework and in particular the divergent application of the General Data Protection Regulation, currently challenge the conduct of research. New policy initiatives, such as the European Health Data Space, promise to address the existing complexities and facilitate research, while simultaneously empowering patients by strengthening their control over their personal data. However, the patients' voice is still predominantly missing in the academic debate on these topics, and it is not clear whether patient empowerment could indeed foster research, while allowing for meaningful protection of the fundamental right to data protection. The goal of this project is to elucidate the relationship between patient empowerment and biomedical research in the EU, via a combination of legal and sociomedical research. A mixed methods design will be employed: desk research will be complemented with empirical research (qualitative and quantitative). A discrete choice experiment, semi-structured interviews, and a Delphi study will be conducted with biomedical research stakeholders (patients and patient representatives, academic and commercial sponsors of clinical trials, investigators, physicians, regulators, and ethics committees).

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DPIA

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Have you performed a DPIA for the personal data processing activities for this project?

- Not applicable

Does patient empowerment foster access to and re-use of data in biomedical research, while allowing for meaningful protection of the fundamental right to data protection of patients?

GDPR

GDPR

Have you registered personal data processing activities for this project?

- Not applicable

Does patient empowerment foster access to and re-use of data in biomedical research, while allowing for meaningful protection of the fundamental right to data protection of patients?

FWO DMP (Flemish Standard DMP)

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1. Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

				Only for digital data	Only for digital data	Only for digital data	Only for physical data
Dataset Name	Description	New or reused	Digital or Physical	Digital Data Type	Digital Data format	Digital data volume (MB/GB/TB)	Physical volume
F1	Data obtained through focus groups. The focus groups will be recorded, and subsequently transcribed.	Generate new data	Digital	Observational	.pdf	<100 GB	N/A
S1	Data obtained through online questionnaires	Generate new data	Digital	Observational	.csv	<100 GB	N/A
I1	Data obtained through semi-structured interviews. The interviews will be recorded and subsequently transcribed.	Generate new data	Digital	Observational	.pdf	<100 GB	N/A
S2	Data obtained through a Delphi study, performed through a series of survey questionnaires with open-ended and closed-ended questions.	Generate new data	Digital	Observational	.csv, .pdf	<100 GB	N/A

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

I will not be reusing existing data.

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes, human subject data

I will be conducting non-interventional and low risk studies (in the forms of focus groups, semi-structured interviews, and surveys) with biomedical research experts, patient representatives, and patients. Prior to the conduct of the studies described in my research proposal, I will submit an application for ethical approval to the Ethics Committee Research UZ/KU Leuven. I will also go through a Privacy Review at KU Leuven, and I will follow all additional specific advice of the privacy experts to protect the privacy of my research subjects.

Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes

Personal data for organizing the research (e.g., name, email address) will be collected for datasets F1, I1 and S2. The data will not be included in the analysis and will be stored separately from the research data.

Personal data for research purposes: for all datasets, participants will be asked to provide their demographics (e.g., age, gender, education, country of residence). These data will be pseudonymized.

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/Data transfer agreements/ research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

2. Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g., in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, Codebook.tsv etc. where this information is recorded).

I will use README.txt files for each of the work packages of the envisaged research project. The KU Leuven template will be followed.

Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.

- Yes

I will follow the RDR metadata format and the DDI codebook.

3. Data storage & back-up during the research project

Where will the data be stored?

All data will be stored on the KU Leuven OneDrive for Business, which uses a multifactor authentication system.

How will the data be backed up?

Standard back-up solution provided by KU Leuven ICTS will be used.

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

As KU Leuven personnel, I have access to 2 TB of data storage on KU Leuven's OneDrive for Business. The estimated sizes of the datasets are <100 GB, therefore there is sufficient storage and backup capacity.

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

KU Leuven's OneDrive for Business is of personal nature. Therefore, all files that I have not explicitly shared, are accessible only to myself. In the scope of my envisaged research, only my PI (prof. Isabelle Huys) and collaborating researchers will receive access to the necessary folders an encryption key.

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

KU Leuven's OneDrive for Business is free for KU Leuven staff.

4. Data preservation after the end of the research project

Which data will be retained for at least five years (or longer, in agreement with other retention policies that are applicable) after the end of the project? In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

After the end of the research, all data will be stored and archived on KU Leuven's trusted Research Data Repository. As stipulated by KU Leuven's Research data management policy, all relevant data generated will be retained for a period of minimally 10 years after the end of the project, in a safe, secure and sustainable way for purposes of reproducibility, verification, and potential reuse.

Where will these data be archived (stored and curated for the long-term)?

On KU Leuven's Research Data Repository.

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

Usually, preservation of smaller datasets is free of charge.

5. Data sharing and reuse

Will the data (or part of the data) be made available for reuse after/during the project? In the comment section please explain per dataset or data type which data will be made available.

- Yes, in a restricted access repository (after approval, institutional access only, …)

S1 and S2 will be made available in restricted access repository.

If access is restricted, please specify who will be able to access the data and under what conditions.

Only scientific researchers will be able to access the data from S1 and S2. To do so, they will have to motivate themselves and provide information about their domain of study, specific research questions, what problems the data will be used to solve. All researchers who receive access to the data, will have to provide credit to the original data creators.

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)? Please explain in the comment section per dataset or data type where appropriate.

- Yes, Privacy aspects

Data from F1 and I1 will not be made available due to protection of the privacy and confidentiality of participants.

Where will the data be made available? If already known, please provide a repository per dataset or data type.

On KU Leuven's Research and Data Repository.

When will the data be made available?

Upon publication of research results in scientific journals.

Which data usage licenses are you going to provide? If none, please explain why.

Creative Commons Attribution 4.0 International

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.

- Yes

A DOI will be available through KU Leuven's Research and Data Repository.

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

As KU Leuven RDR is free for KU Leuven staff, no costs for data sharing are expected.

6. Responsibilities

Who will manage data documentation and metadata during the research project?

The postdoctoral fellow awarded the FWO scholarship (Dr. Teodora Lalova-Spinks) will be responsible for managing data documentation and metadata, under the supervision of Prof. Isabelle Huys

Who will manage data storage and backup during the research project?

The postdoctoral fellow awarded the FWO scholarship (Dr. Teodora Lalova-Spinks) will manage data storage and backup, under the supervision of Prof. Isabelle Huys.

Who will manage data preservation and sharing?

The postdoctoral fellow awarded the FWO scholarship (Dr. Teodora Lalova-Spinks) will manage data preservation and sharing, under supervision of Prof. Isabelle Huys.

Who will update and implement this DMP?

The postdoctoral fellow awarded the FWO scholarship (Dr. Teodora Lalova-Spinks), under the supervision of Prof. Isabelle Huys.