Plan Overview

A Data Management Plan created using DMPonline.be

Title: Shaping ‘good’ genomic care: the implementation of next-generation sequencing technologies in clinical care practices in Europe, the U.S. and South Africa

Creator: Janneke Kuiper

Principal Investigator: n.n., Janneke Kuiper

Data Manager: n.n., Janneke Kuiper

Project Administrator: n.n., Janneke Kuiper

Affiliation: KU Leuven (KUL)

Funder: Fonds voor Wetenschappelijk Onderzoek - Research Foundation Flanders (FWO)

Template: FWO DMP (Flemish Standard DMP)

Principal Investigator: n.n. n.n., Janneke Kuiper

Data Manager: n.n. n.n., Janneke Kuiper

Project abstract:

Expanding and deepening my PhD research on the introduction of next-generation sequencing (NGS) in diagnostic practice in the Netherlands and Belgium, this project will analyse and compare the shaping of NGS practices in the EU, U.S. and South Africa by investigating both the on-the-ground NGS practices and the sociocultural context of these local settings. Going beyond a linear conception of technology implementation, this project takes a sociological approach to understand how NGS is made to ‘work’ in the clinic whilst considering the cultural, political, and economic power relations it is embedded in. The project will analyse how NGS care takes shape in practice by focusing on key moments of decision-making, communication patterns, and standardisation and localisation across these three research sites with their distinct care practices, values, moralities, interests, and cultures (of care). This practice-based approach allows the proposed research to assess the influence of the local on the global and vice versa. Through a combination of literature review, document analysis and multi-sited qualitative fieldwork, this project will provide insight into the politics of care involved in shaping ‘good’ genomic care and show how this impacts the care that is offered to patients in the genetics clinics and broader perceptions of care.

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Shaping ‘good’ genomic care: the implementation of next-generation sequencing technologies in clinical care practices in Europe, the U.S. and South Africa

Application DMP

Questionnaire

The questions in this section should only be answered if you are currently applying for FWO funding.
Are you preparing an application for funding?

- No

Shaping ‘good’ genomic care: the implementation of next-generation sequencing technologies in clinical care practices in Europe, the U.S. and South Africa

DPIA

DPIA

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

- Not applicable

Shaping ‘good’ genomic care: the implementation of next-generation sequencing technologies in clinical care practices in Europe, the U.S. and South Africa

GDPR

GDPR

Have you registered personal data processing activities for this project?

- Yes

Shaping ‘good’ genomic care: the implementation of next-generation sequencing technologies in clinical care practices in Europe, the U.S. and South Africa

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
		Please choose from the following options: • Generate new data • Reuse existing data	*Please choose from the following options:* • Digital • Physical	*Please choose from the following options:* • Observational • Experimental • Compiled/aggregated data • Simulation data • Software • Other • NA	*Please choose from the following options:* • .por, .xml, .tab, .csv,.pdf, .txt, .rtf, .dwg, .gml, … • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
R1	PhD Interview healthcare professionals EU	Reuse existing data	Digital	Observational	.pdf, .txt	<100MB	
R2	PhD Interview parents of patients EU	Reuse existing data	Digital	Observational	.pdf, .txt	<100MB	
R3	PhD Observations multidisciplinary team meetings	Reuse existing data	Digital	Observational	.pdf, .txt	<100MB	
R4	PhD Observations clinical consultations	Reuse existing data	Digital	Observational	.pdf, .txt	<100MB	
R5	PhD Fieldnotes	Reuse existing data	Digital	Observational	.pdf, .txt	<100MB	
R6	PhD Demographics clinical consultations	Reuse existing data	Digital	Observational	.cvs	<1MB	
I1	Interview key stakeholders NGS care EU	Generate new data	Digital	Observational	wav, .mp3, .pdf, .txt	<100GB	
I2	Interviews healthcare prof. + key stakeholders NGS care US	Generate new data	Digital	Observational	wav, .mp3, .pdf, .txt	<100GB	
I3	Interviews healthcare prof. + key stakeholders NGS care South Africa	Generate new data	Digital	Observational	wav, .mp3, .pdf, .txt	<100GB	
W1	Workshop EU implementation NGS	Generate new data	Digital	Observational	wav, .mp3, .pdf, .txt	<100GB	
O1	Observations clinical consultations US	Generate new data	Digital	Observational	wav, .mp3, .pdf, .txt	<100GB	
O2	Observations clinical consultations South Africa	Generate new data	Digital	Observational	wav, .mp3, .pdf, .txt	<100GB	
D1	Demographics clinical consultations US	Generate new data	Digital and physical	Observational	.cvs	<1MB	
D2	Demographics clinical consultations South Africa	Generate new data	Digital	Observational	wav, .mp3, .pdf, .txt	<100GB	
O3	Observations multidisciplinary team meetings US	Generate new data	Digital	Observational	wav, .mp3, .pdf, .txt	<100GB	
O4	Observations Multidisciplinary Team Meetings South Africa	Generate new data	Digital	Observational	wav, .mp3, .pdf, .txt	<100GB	
N1	Fieldnotes US	Generate new data	Digital and physical	Observational	.pdf, .txt	<100GB	
N2	Fieldnotes South Africa	Generate new data	Digital and physical	Observational	.pdf, .txt	<100GB	

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:

Reuse of processed observational data (pseudonymized transcripts and fieldnotes + demographical data) gathered during the PhD research of Janneke Kuiper (Kuiper, J., Van Hoyweghen, I., Borry, P., & Vears, D. (2024). Handling technology with care: The introduction of next-generation sequencing in diagnostic clinical practice).

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.

- No

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

- name and surname
- e-mail address
- gender
- age
- occupation and professional activities
- level of education (ordinal scale)
- mother tongue
- country of birth
- country of birth father
- country of birth mother
- family and household composition
- data concerning physical and/or mental health
- health: diagnosis, symptoms, medical history
- audio-recordings

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).

All relevant information on methodology, protocols and coding will be stored in text files (.txt, .pdf).

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.

- No

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

Where will the data be stored?

During the project, I will use the range of storage solutions provided by KU Leuven for the digital data gathered: a KUL-managed computer (password protected), laptop file storage, secure KUL network drives (I-/J-drive).

How will the data be backed up?

Standard back-up provided by KU Leuven ICTS for my storage solution.

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 data size will not exceed what has been provided through KU Leuven's data storage services which are free to its employees.

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

2 factor authentification

S1A and S1B: Storage at the One drive cloud service provided by the Faculty of Arts (2 TB storage free of charge). This storage space is safe and automatically backed-up, and allows for extra protection of sensitive data, such as Multi Factor Authentication and Conditional Access functions, so that the historical researcher alone can access the data before anonymisation. The data will be anonymised with Cubase, distorting the voice and bleeping any identifiable information.

As soon after collecting the data on the laptop file storage, the data will be stored on secure KU Leuven drives (I-/J-drive), which are incorporated within the secured KU Leuven environment, password-protected (including smartphone-based multi-factor identification) and only accessible by registered collaborating researchers. Only the PI can request access to the network drive for study personnel.

The audio-files will be pseudonymized during transcription, the audio recording with identifiable information (voice, names) will be destroyed after transcript validation.The transcriptions of the interviews will be pseudonymised by giving the research participants and their organizations fictive names and, if necessary, by not stating their precise professional titles or other information that could make them recognizable. This personal information will be removed from the data set and the 'key' will be stored separately in a password-protected file. No identifying information is accessible to third parties.

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

No additional costs are expected, as the data size will not exceed what has been provided through KU Leuven's data storage services which are free to its employees.

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...).

The minimum preservation term of 5 years after the end of the project will be applied to all processed data (audio files will be deleted after transcription and subsequent validation of the transcripts).

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

Previously mentioned data will be saved on the shared J:drive: this KU Leuven network drive is incorporated within the secured KU Leuven environment, is password-protected (including smartphone-based multi-factor identification) and is only accessible by registered collaborating researchers. Only the PI can request access to the network drive for study personnel.

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

No additional costs are expected, this data storage service is offered by KULeuven to its employees.

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, …)

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

Access will be granted only to researchers who submitted a request via email to Janneke Kuiper (researcher) and received approval. If access is allowed, pseudonymised data will be shared using a secured email-program.

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
- Yes, Ethical aspects

All datasets may contain personal and sensitive information, so we have an ethical and legal obligation to protect (and not share) some of the data (e.g transcripts and audio recordings). When a participant indicates in the informed consent letter not to share the data, we will respect this restriction.

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

The data will not be made available in a repository, but on a peer-to-peer basis.

When will the data be made available?

Upon publication of research results.

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

A Data Transfer Agreement (restricted data) will be used.

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.

- No

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

Therer are no costs involved in data sharing.

6. Responsibilities

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

Janneke Kuiper

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

Janneke Kuiper

Who will manage data preservation and sharing?

Janneke Kuiper

Who will update and implement this DMP?

Janneke Kuiper