DEVELOPMENT, VALIDATION, AND VALORIZATION OF A PATIENT PREFERENCE PLATFORM TO INFORM HEALTHCARE DECISION-MAKING

A Data Management Plan created using DMPonline.be

Creators: n.n. n.n., n.n. n.n., Rosanne Janssens

Affiliation: KU Leuven (KUL)

Funder: KU Leuven (KUL)

Template: KU Leuven BOF-IOF

Principal Investigator: n.n. n.n.

Grant number / URL: https://www.kuleuven.be/onderzoek/portaal/#/projecten/3M230020

ID: 200282

Start date: 01-03-2023

End date: 28-02-2026

Project abstract:

Healthcare industry, regulators, health technology assessment bodies, payers, clinicians, and patients are calling for evidence-based approaches for assessing and including patients' preferences and patient evidence into their decisions. Hence, the scientific aims of this C3 project are to develop: i) a science-driven, validated workflow for patient preference studies (PPS), and ii) pathways for implementing patient evidence (incl. from PPS) in decision-making, including via patient decision aids (PtDAs). The valorization objectives are to: i) secure intellectual property rights (copyright, patents) on the digitalized PPS and PtDA workflow and exploit these via (licensing) contracts, ii) exploit our consolidated methodological expertise and validated plug-and play PPS and PtDA digital platform via contract research and European, national and individual grants, and iii) establish a Patient Evidence and Patient Preference Research Center for sustainable PPS innovation, valorization, and stakeholder engagement.

Last modified: 16-06-2023

DEVELOPMENT, VALIDATION, AND VALORIZATION OF A PATIENT PREFERENCE PLATFORM TO INFORM HEALTHCARE DECISION-MAKING

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.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		*Indicate: **N**(ew data) or **E**(xisting data)*	Indicate: **D**(igital) or **P**(hysical)	Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
Audiofiles from patient interviews/focus group discussions	Audiorecordings from the interviews and focus group discussions with patients describing their treatment and healthcare preferences and unmet needs	New and existing	Digital	Sound	MP3/WAV	<100GB	NA
Transcripts from patient interviews/focus group discussions	Textual files (word files) from the interviews and focus group discussions with patients describing their treatment and healthcare preferences and unmet needs	New and existing	Digital	Textual	.docx	<100GB	NA
Excel files containing patient preference and evidence survey data	Excel files containing completed survey data from the patient evidence surveys (including completed electronic consent form)	New and existing	Digital	Textual and quantitative data	.xls	<100GB	NA
Protocols describing patient preference and patient evidence study methods for ethical committee approval (incl. informed consent forms, questions, information sheets)	Word documents describing steps to conduct qualitative and quantitative research for preference study and patient evidence study design and conduct	New and existing	Digital	Textual	.docx	<1GB	NA
Excel files containing participants' answers to the online surveys prior to qualitative interviews/group discussions	Excel files containing completed survey data (including electronic informed consent) prior to participation to the interview/group discussion	New and existing	Digital	Textual and quantitative data	.docx	<100GB	NA
Excel files containing analysis of regulatory and HTA guidelines, publications and reports (i.e. FDA, EMA, KCE, EUnetHTA, NICE, IQWiG)	Excel files containing data for analysis of integration of patient experience data in current guidelines and decision-making frameworks	New and existing	Digital	Textual and quantitative data	.xls	<100GB	NA
Excel files containing analysis of regulatory and HTA documents (e.g., EPARs, postmarketing authorisation documents,CTG/CR and Managed Entry Agreements (MEAs)	Excel files containing data for analysis of integration of patient experience data in past decisions	New and existing	Digital	Textual and quantitative data	.xls	<100GB	NA
Audiofiles from interviews/focus group discussions with stakeholders on implementation ways for patient experience data	Audiorecordings from the interviews and focus group discussions with stakeholders on patient experience data integration in decision-making	New	Digital	Sound	MP3/WAV	<100GB	NA
Transcripts from interviews/focus group discussions with stakeholders on implementation ways for patient experience data	Transcripts from the interviews and focus group discussions with stakeholders on patient experience data integration in decision-making	New	Digital	Textual	.docx	<100GB	NA
NVivo files from interviews/focus group discussions with patients and stakeholders on implementation ways for patient experience data	Analysed textual files from qualitative research with patients and stakeholders involved in medical product decision-making	New	Digital	Textual	.nvpx / .nvp	<100GB	NA
Audiofiles from interviews/focus group discussions with patients and healthcare providers on their needs towards shared decison-making and patient decision aids	Audiorecordings from the interviews and focus group discussions with patients describing their needs towards shared decison-making and patient decision aids	New	Digital	Audio	MP3/WAV	<100GB	NA
Transcripts from patients and healthcare provider interviews/focus group discussions on their needs towards shared decison-making and patient decision aids	Transcripts from the interviews and focus group discussions with patients and healthcare provider interviews/focus group discussions on their needs towards shared decison-making and patient decision aids	New	Digital	Textual	.docx	<100GB	NA
Protocols describing methods for qualitative stakeholder research on patient experience data integration (incl. informed consent forms, questions, information sheets)	Word documents wherein the steps for the qualitative stakeholder research on patient experience data integration is described (incl. informed consent forms, questions, information sheets)	New	Digital	Textual	.docx	<1GB	NA
Protocols describing methods for qualitative stakeholder research on shared decision-making (incl. informed consent forms, questions, information sheets)	Word documents wherein the steps for the qualitative stakeholder research on shared decision-making is described (incl. informed consent forms, questions, information sheets)	New	Digital	Textual	.docx	<1GB	NA
NVivo files from interviews/focus group discussions with patients on their health and treatment preferences and unmet needs	Analysed textual files from qualitative research with patients	New and existing	Digital	Textual	.nvpx	<100GB	NA
Completed informed consent forms from qualitative research with healthcare stakeholders	Completed word and PDF files wherein participants have indicated that they agree to participating in the research	New and existing	Digital	Textual	.docx	<1GB	NA
Regulatory and HTA guidelines, publications and reports (i.e. FDA, EMA, KCE, EUnetHTA, NICE, IQWiG)	Inventory of raw data (unanalysed files) ready for analysis	Existing	Digital	Textual	PDF	<1GB	NA
Regulatory and HTA documents (e.g., EPARs, postmarketing authorisation documents,CTG/CR and Managed Entry Agreements (MEAs)	Inventory of raw data (unanalysed files) ready for analysis	Existing	Digital	Textual	PDF	<1GB	NA
Excel files containing patients and healthcare providers' feedback on the patient decision aid and and related outcome parameters	Excel files that include patients' and healthcare providers' feedback on the patient decision aid	New	Digital	Textual and numerical	.xls	<1GB	NA
Excel files containing patients and healthcare providers' opinions and needs towards treatment decision-making and towards shared decision-making and patient decision aids	Excel files that include patients' and healthcare providers' opinions on treatment decision-making and ways forward	New	Digital	Textual and numerical	.xls	<100GB	NA

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:

- Patient preference and patient evidence studies
  - audiofiles: researchers' laptop and/or smartphone
  - transcripts: researchers' laptop
  - NVivo files: researchers' laptop
  - excel files (preference survey): researchers' laptop
  - protocols: researchers' laptop
  - excel files containing participants' answers prior to participating in qualitative PPS research: researchers' laptop
  - completed consent forms: researchers' laptop
- Patient evidence data implementation studies
  - audiofiles: researchers' laptop
  - transcripts: researchers' laptop
  - NVivo files: researchers' laptop
  - excel files: researchers' laptop
  - protocols: researchers' laptop
  - Regulatory and HTA guidelines, publications and reports (i.e. FDA, EMA, KCE, EUnetHTA, NICE, IQWiG): researchers' laptop
  - Regulatory and HTA documents (e.g., EPARs, postmarketing authorisation documents,CTG/CR and Managed Entry Agreements (MEAs): researchers' laptop
  - completed consent forms: researchers' laptop
- Shared decision-making and patient decision aid studies
  - audiofiles: researchers' laptop
  - transcripts: researchers' laptop
  - NVivo files: researchers' laptop
  - excel files (preference survey): researchers' laptop
  - protocols: researchers' laptop
  - excel files containing patients and healthcare providers' feedback on the patient decision aid and related outcome parameters: researchers' laptop
  - completed informed consent forms: researchers' laptop

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, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- Yes, human subject data (Provide SMEC or EC approval number below)
- EC approval was already obtained for patient preference studies (PPS) and shared decision-making (SDM) studies that were ongoing at the start of the C3 project (inflammatory bowel diseases (IBD), gene therapy, multiple myeloma)
  - Qualitative IBD PPS: S65034
  - Quantitative IBD PPS: 65998
  - Quantitative Duchenne PPS: S66104
  - Observational IBD SDM study: S66833
  - Interview study SDM + survey: S66893
  - Shared decision-making study multiple myeloma: S66580
- EC approval will be obtained for all patient preference and patient evidence studies, stakeholder research on patient evidence implementation and shared decision-making that will be initiated from the start of the C3 project

Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- Yes (Provide PRET G-number or EC S-number below)

Yes:

- Patient preference and patient evidence studies (obtained PRET and EC approvals for ongoing patient evidence studies in inflammatory bowel diseases: qualitative study: S65034, quantitative study: S65998)
  - audiofiles
  - transcripts
  - NVivo files
  - excel files (preference survey)
  - excel files containing participants' answers prior to participating in qualitative PPS research
  - completed consent forms
- Patient evidence data implementation studies
  - audiofiles
  - transcripts
  - NVivo files
  - excel files
  - completed consent forms
- Shared decision-making and patient decision aid studies (obtained PRET and EC approvals for ongoing shared decision-making studies: S66833, S66893, S66580)
  - audiofiles
  - transcripts
  - NVivo files
  - excel files (preference survey)
  - excel files containing patients and healthcare providers' feedback on the patient decision aid and related outcome parameters
  - completed informed consent forms

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.

- Yes
- Patient preference and patient evidence studies:
  - Protocols: intellectual property rights (IPRs; copyrights, patents) - for exploitation via (licensing) contracts
  - Decision-tree for methods selection, and standardized attribute instrument library: intellectual property rights (IPRs; copyrights, patents) - for exploitation via (licensing) contracts
- Patient evidence data implementation studies:

    - Recommendations and implementation pathways: intellectual property rights (IPRs; copyrights, patents) - for exploitation via (licensing) contracts
- Shared decision-making and patient decision aid studies
    - Patient decision aids: intellectual property rights (IPRs; copyrights, patents) - for exploitation via (licensing) contracts
    - Protocols: intellectual property rights (IPRs; copyrights, patents) - for exploitation via (licensing) contracts

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or 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.

- Yes

- Regulatory and HTA guidelines, publications and reports (i.e. FDA, EMA, KCE, EUnetHTA, NICE, IQWiG): no material or data transfer agreements applicable
- HTA documents (e.g., CTG/CR and Managed Entry Agreements (MEAs): access and confidentiality plans to review the reports are already in place and/or will be sought
- Regulatory documents (EPARs, postmarketing authorisation documents) are online / publically available: no material or data transfer agreements applicable

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.

- Yes

Licenses are in place for some of the questionnaires (e.g., EQ-5D) that we will include in our (patient evidence) studies. Whenever needed, we will seek approval for using these. Intellectual property rights (authorship rights) on the (grey) literature for patient evidence (integration) studies and shared decision making studies will be asserted.

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).

Protocols for all studies will be developed and guarded centrally in a sharepoint environment shared within the researchers of the research group ("regulatory sciences"). These protocols will describe accompanying information necessary to keep the data understandable and usable for the researchers involved in the studies now and in the future.

Will a metadata standard be used to make it easier to find and reuse the data?
If so, please specify which metadata standard will be used.

If not, please specify which metadata will be created to make the data easier to find and reuse.

- No

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Personal network drive (I-drive)
- OneDrive (KU Leuven)
- Sharepoint online

- Patient preference and patient evidence studies
    - audiofiles: researchers' laptop (personal network drive and/or OneDrive) and/or smartphone
    - transcripts: researchers' laptop (personal network drive and/or OneDrive)
    - NVivo files: researchers' laptop (personal network drive and/or OneDrive)
    - excel files (preference survey): researchers' laptop (personal network drive and/or OneDrive)
    - protocols: researchers' laptop (personal network drive and/or OneDrive) and Sharepoint online of the regulatory sciences group
    - excel files containing participants' answers prior to participating in qualitative PPS research: researchers' laptop (personal network drive and/or OneDrive)
    - completed consent forms: researchers' laptop (personal network drive and/or OneDrive)
- Patient evidence data implementation studies
    - audiofiles: researchers' laptop (personal network drive and/or OneDrive)
    - transcripts: researchers' laptop (personal network drive and/or OneDrive)
    - NVivo files: researchers' laptop (personal network drive and/or OneDrive)
    - excel files: researchers' laptop (personal network drive and/or OneDrive)
    - protocols: researchers' laptop (personal network drive and/or OneDrive) and Sharepoint online of the regulatory sciences group
    - Regulatory and HTA guidelines, publications and reports (i.e. FDA, EMA, KCE, EUnetHTA, NICE, IQWiG): researchers' laptop (personal network drive and/or OneDrive) and Sharepoint online of the regulatory sciences group
    - Regulatory and HTA documents (e.g., EPARs, postmarketing authorisation documents,CTG/CR and Managed Entry Agreements (MEAs): researchers' laptop (personal network drive and/or OneDrive) and Sharepoint online of the regulatory sciences group
    - completed consent forms: researchers' laptop (personal network drive and/or OneDrive)
- Shared decision-making and patient decision aid studies
    - audiofiles: researchers' laptop (personal network drive and/or OneDrive)
    - transcripts: researchers' laptop (personal network drive and/or OneDrive)
    - NVivo files: researchers' laptop (personal network drive and/or OneDrive)

- excel files (preference survey): researchers' laptop (personal network drive and/or OneDrive)
- protocols: researchers' laptop (personal network drive and/or OneDrive) and Sharepoint online of the regulatory sciences group
- excel files containing patients and healthcare providers' feedback on the patient decision aid and related outcome parameters: researchers' laptop (personal network drive and/or OneDrive)
- completed informed consent forms: researchers' laptop (personal network drive and/or OneDrive)

Personal data from the patient preference and patient evidence studies, patient evidence integration studies, shared decision-making studies will be stored using the storage solution approved in the PRET application.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution
- Personal back-ups I make (specify below)

During and after the research, all data will be stored on the online secured, safe platform of KU Leuven Sharepoint and via the personal network KU Leuven drive. The KU Leuven Sharepoint platform has sufficient storage to keep all the data that will be gathered during this Research Project. A standard back-up is provided by KU Leuven ICTS. In addition, a backup will be stored on the KU Leuven Onedrive. Personal back-ups will be made on the personal network drive (I-drive).

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

During and after the research, all data will be stored on the online secured, safe platform of KU Leuven Sharepoint and via the personal network KU Leuven drive. The KU Leuven Sharepoint platform has sufficient storage to keep all the data that will be gathered during this Research Project. A standard back-up is provided by KU Leuven ICTS. In addition, a backup will be stored on the KU Leuven Onedrive. Personal back-ups will be made on the personal network drive (I-drive). Backup occurs automatically, as the folders are synched.

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

Only the researchers involved in the project will have access to the secured KU Leuven server and as such the data. All researchers will work on a password protected computer of the KU Leuven.

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

As only small datasets will be generated that can be stored (now and after the end of the project) on the online, free of charge platform of KU Leuven, Sharepoint, there will be no costs related to data storage. If deemed needed, extra storage can be bought (5GB for 39,80 euro), which can be paid from the C3 Project funds.

Data Preservation after the end of the Research Project

Which data will be retained for 10 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...).

- Certain data cannot be kept for 10 years (explain below)

All data will be preserved for 10 years (in line with KU Leuven RDM policy), except for the audio recordings of stakeholder interviews and focus group discussions. These will be deleted upon completion of the respective study. The transcripts from the recordings will be preserved for 10 years.

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

- Other (specify below)

All datasets will be stored on the online secured, safe platform of KU Leuven, Sharepoint.

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

As only small datasets will be generated that can be stored on the online, free of charge platform of KU Leuven, Sharepoint, there will be no costs related to data storage.

Data Sharing and Reuse

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

- Other (specify below)

The data sharing possibilities will depend on the type of data gathered within the project. We distinguish between three types:
- Personal data and interview/ focus group discussion transcripts will remain closed, as it can lead to stakeholder identification
- Outcomes with potential for commercial valorization will not be made publicly available
- Datasets that do not contain personal information and have no potential for commercial valorization will be made publicly available at the time of or after scientific publication (made available through a repository/or made available upon request).

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

The data access possibilities will depend on the type of data gathered within the project:
- Personal data and interview/ focus group discussion transcripts: only involved researchers can access this data.
- Outcomes with potential for commercial valorization: only involved researchers can access this data
- Datasets that do not contain personal information and have no potential for commercial valorization: we strive to make these publicly available/no access restrictions (made available through a repository/or made available upon request).

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 per dataset or data type where appropriate.

- Yes, privacy aspects
- Yes, intellectual property rights
- Yes, ethical aspects

The data access and sharing possibilities will depend on the type of data gathered within the project:
- Personal data and interview/ focus group discussion transcripts: only involved researchers can access this data. --> restrictions due to privacy and ethical reasons
- Outcomes with potential for commercial valorization: only involved researchers can access this data --> restrictions due to potential IPR
- Datasets that do not contain personal information and have no potential for commercial valorization: we strive to make these publicly available/no access restrictions (made available through repository/or made available upon request).

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- KU Leuven RDR (Research Data Repository)
- Other (specify below)

Audiofiles and transcripts will be stored on a KU Leuven sharepoint.
Aggregated data resulting from the analysis of the data from audiofiles and transcripts will be made stored on personal protected computers of the researchers and made available via publications, meetings with stakeholders, experts, and conferences.
All data will be stored and made available according to the conditions as approved by the ethics committee.

When will the data be made available?

- Upon publication of research results

Data will be analysed during the project duration, and aggregated results will be made public via scientific publications or conferences after conclusion of each individual study. Data sharing in this sense is not expected to be postponed for IP reasons.

Which data usage licenses are you going to provide?

If none, please explain why.

- CC-BY 4.0 (data)
- Data Transfer Agreement (restricted data)
- Other (specify below)

For data that does not involve software source code, we will use a creative commons licence.
For certain types of data, a data transfer agreement might be needed, to be discussed with LRD.
For software, an appropriate license mechanism will be discussed with LRD.

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- No

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

Data will be shared via scientific publications or conferences. Publication of such data is in most cases associated with publication fees requested by publishers, ranging between 1500 euro - 3500 euro.
Data shared via conferences requires researchers attending these events, which also generates costs, depending on the type of conference and place of the venue and length of stay.
Costs associated with publications and conferences will be covered partly via the C3 budget, partly via other budgets.

Responsibilities

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

- data management roles: The phd, post doctoral researchers as well as ZAP in the research project are responsible for documentation, storage and back up of the data they are generating. The ZAP researchers are responsible for the long term preservation of the data and data sharing also beyond the length of the project itself.
- Name the people responsible: ZAP persons are Isabelle Huys, Martina Vandebroek, Patrick Neven, Séverine Vermeire, Kristiaan Nackaerts, Steven Simoens, Liesbeth De Waele, Tom Adriaenssens, Thomas Vanassche. Research manager is David Geerts. Post-doctoral researchers are Rosanne Janssens and Liese Barbier, PhD researchers are Elise Schoefs, Alice Vanneste, Charlotte Verbeke, Thomas Desmet, Zilke Claessens and new phd researchers to be hired.
- Resources needed for data management: personal protected computers, KU Leuven Sharepoint
- Persons responsible to regularly review and update of the DMP: post-doctoral researchers and C3 PI in collaboration with ZAP researchers
- The DMP will be part of the agenda of the C3 meetings with the whole research team.
- Oversight of research data in project: the DMP will be regularly revised and updated so that an overview can be held on all sorts of new data generated during the project

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

The post-doctoral researchers and C3 PI will manage the data storage and backup during the researchers, in close dialogue with the ZAP of the project and with input and support of the PhD researchers.

Who will manage data preservation and sharing?

Data preservation and sharing during the project will be managed by the post-docs and C3 PI, the PhD researchers in close dialogue with the ZAP.
Data preservation and sharing on the long term beyond the lifespan of the project will be the responsibility of the ZAP of the project. Isabelle Huys can figure as contact person for this aspect.

Who will update and implement this DMP?

The DMP update is part of the agenda of the meetings with the whole research team. Update will be organised by the post-docs and PI, in close dialogue with the ZAP and with input and support of the PhD researchers.