Beyond inflammation: addressing disease impact in rheumatoid arthritis

A Data Management Plan created using DMPonline.be

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Project abstract:

4-year PhD project, with FWO-Strategic Basic research fellowship funding, focusing on optimization of pharmacological and non-pharmacological care strategies aiming to reduce patient-reported disease impact in rheumatoid arthritis. The non-pharmacological part of the project aims to identify persistent problems unrelated to active inflammatory disease ("unmet needs") in patients with rheumatoid arthritis that impact patients' lives (qualitative study project), investigate optimal management strategies for unmet needs (literature studies, systematic literature review, Delphi experiment), and finally design a pilot trial testing the implementation of a new care model addressing unmet needs. The pharmacological part of the project aims to investigate the optimal treatment strategy with the drug rituximab in patients with rheumatoid arthritis in terms of optimal reduction in patient-reported disease impact, in a multicentric superiority randomized controlled trial (RITUXERA).

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FWO DMP (Flemish Standard DMP)

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	
S68348_DiscordanceScore	Discordance Score calculation sheet for selection of participants of qualitative research project (S68348)	Generate new data	Digital	Experimental	.xlsx	<100MB	NA
S68348_RAID	Rheumatoid Arthritis Impact of Disease (RAID) questionnaires completed by participants of qualitative study (S68348)	Generate new data	Physical	NA	NA	NA	+- 20 pages of completed questionnaires
S68348_Audiotapes	Audiotapes and back up audiotapes of interviewed participants of qualitative study (S68348)	Generate new data	Digital	Experimental	.m4a	<100GB	NA
S68348_Transcripts	Transcribed interviews of participants of qualitative study (S68348)	Generate new data	Digital	Experimental	.docx	<1GB	NA
S68348_Coding	Coding of interview transcripts in NVivo (S68348)	Generate new data	Digital	Software	Other: NVivo qualitative data analysis software	<100GB	NA

S67309_eCRF_online	Completed eCRFs of participants of RCT RITUXERA (S67309) in REDCap	Generate new data	Digital	Software	Other: Research Electronic Data Capture (REDCap)	<100GB	NA
S67309_eCRF_exported	Completed eCRFs of participants of RCT RITUXERA (S67309) exported from REDCap	Generate new data	Digital	Experimental	.xlsx	<100GB	NA
S67309_statisticalanalysis	Statistical analysis of data from RITUXERA (S67309)	Generate new data	Digital	Software	Other: R (R-Project for Statistical Computing)	<100GB	NA
SystematicReview_Screening	Screening process for inclusion in systematic review (unspecified intervention for unmet need in rheumatoid arthritis)	Generate new data	Digital	Software	Other: Rayyan	<1GB	NA
SystematicReview_Analysis	Overview of relevant information (study characteristics and results) of included articles for systematic review (unspecified intervention for unmet need in rheumatoid arthritis)	Generate new data	Digital	Compiled data	.xlsx	<100GB	NA
Delphi	Information gathered from Delphi panel focusing on optimal care strategies for unmeet needs in rheumatoid arthritis	Generate new data	Digital	Other	.docx	<1GB	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:

Existing data from published randomized controlled trials (found using medical literature databases like MEDLINE, Embase, Cochrane, Web of Science and CINAHL) will be extracted for a systematic literature review on the effect of a well-defined intervention (yet to be specified) for a specific unmet need in patients with rheumatoid arthritis (yet to be specified). (Corresponding to datasets SystematicReview_Screening and SystematicReview_Analysis)

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

In this research project, human subject data will be collected:

- Personal data:
  - In a qualitative study (datasets S68348_Audiotapes, S68348_Transcripts and S68348_Codes)
  - In a randomized controlled trial (datasets S67309_eCRF_online and S67309_eCRF_exported)
- Health-related (medical) data:
  - In a qualitative study (datasets S68348_DiscordanceScore, S68348_RAID, S68348_Audiotapes, S68348_Transcripts and S68348_Codes)
  - In a randomized controlled trial (datasets S67309_eCRF_online, S67309_eCRF_exported and S67309_statisticalanalysis)

Ethical approval was obtained for:

- The qualitative study (S68348): reference B3222023001310
- The RCT RITUXERA (S67309): EU CT reference: 2023-506638-59-01

NB. Patients will be referred to in data sets by pseudonymisation.

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 will be processed in a qualitative study, a randomized controlled trial and a Delphi experiment.
Personal data includes:

- Participating patients' name and surname (potentially): dataset S68348_Audiotapes
- Participating patients' sex, age and other relevant demographical data (including educational level and work status): datasets S68348_Audiotapes, S68348_Transcripts, S68348_Codes, S67309_eCRF_online and S67309_eCRF_exported
- Participating patients' family situation (marital status, children): datasets S68348_Audiotapes, S68348_Transcripts, S68348_Codes)
- Participating health care professionals' demographical data (age, sex, profession and specific expertise): dataset Delphi_Input

In all aforementioned datasets, with the exception of dataset S68348_Audiotapes, data of participants will be pseudonymised.
Dataset S68348_Audiotapes will be irreversibly destroyed upon completion of qualitative data analysis for the qualitative study.
As mentioned above, ethical approval was already obtained for the qualitative study (reference B3222023001310) and the randomized controlled trial (EU CT reference: 2023-506638-59-01).

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

Not applicable, as all data will not be available for commercial purposes in any capacity.

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

Not applicable, as I will not be working on data created outside of the research group.

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

Not applicable.

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).

Dataset	Accompanying information
S68348_DiscordanceScore	Accompanied by an additional .pdf file containing user manuals on discordance score calculations and relevant journal references.
S68348_RAID	Accompanied by an additional .pdf file containing user manuals on RAID score calculations and relevant journal references.
S68348_Audiotapes	No additional accompanying information deemed necessary.
S68348_Transcripts	An additional .docx file will accompany all transcripts, in which information is provided on the timing and place of every interview, behavioural cues and body language information, as well as information regarding the interviewer and the observer.
S68348_Coding	No additional accompanying information deemed necessary.
S67309_eCRF_online	Data dictionaries are incorporated within the REDCap software, providing information on coding of REDCap field names and values of drop-down list/radiobutton answers.
S67309_eCRF_exported	Data dictionaries will be exported from REDCap software in a .xslx file, providing information on underlying meaning of coding of REDCap field names and values of drop-down list/radiobutton answers. Furthermore, additional .xslx files will provide information on the timing of the study visits and pseudonymized patients IDs.
S67309_statisticalanalysis	Information on performed statistical analyses will be exported from R analysis software (Rfile). Furthermore, .txt files will accompany these files for further explanations.
SystematicReview_Screening	No additional accompanying information deemed necessary.
SystematicReview_Analysis	Accompanied by additional .docx files containing information on the search strategy (detailed per medical database, including date of search, etc.).
Delphi_Input	Accompanied by additional .docx file providing information on time and place of Delphi rounds, as well as pseudonymized parrticipant IDs.

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

Metadata will accompany the data sets as stated above.

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

Where will the data be stored?

Data will be stored on:

- The PhD researcher's work laptop (storage capacity of 500 GB), secured with password and biometric security.
- KU Leuven SharePoint (storage capacity of 5 TB, password protected), enabling sharing of data within authorized members within the research group. Monthly storage of new data.
- UZ / KULeuven environment (uz \ data \ Rheumatology), accessible to members of the research group via a password- protected personal computer.
- Statistical data will additionally be stored online (R software, password protected).
- Electronic case report forms will additionally be stored online (REDCap software, password protected).
- Systematic review screening processes will additionally be stored online (Rayyan software, password protected)
- Qualitative data analysis will additionally be stored online (NVivo software, password protected)
- Literature referencing will additionally be stored online (Endnote and Mendeley software, password protected)

How will the data be backed up?

The same data will be stored in several different ways, as specified in the previous question.
In addition, the PhD researcher's work laptop is automatically backed up every hour on a password secured 2TB external hard disk drive.

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

- PhD researcher's work laptop: 500 GB
- External hard disk drive: 2TB
- KU Leuven SharePoint: 5TB

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

- All data is either stored on the PhD researcher's work laptop, secured biometrically and by password), a password secured external hard disk drive, KU Leuven SharePoint and the password-protected UZ / KULeuven environment (uz \ data \ Rheumatology).
- Digital data stored on the PhD researcher's work laptop (.xlsx, .pdf, .docx, ...) is additionally secured by an additional password in order to open and/or modify files.
- Physical data will be stored on the research site in a secured place only accessible by authorized members within the research group.

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

NVivo cost: 80 EUR for one academic year, which is considered to be sufficient to complete all analyses and export all results. Costs were covered by the PhD researcher's FWO bench fee.
REDCap cost: 80 EUR per year: 1 year for development and 3 year trial duration = 320 eur, covered by supervisor's research budget. After trial completion, all data will be exported from REDCap.
UZ/KU Leuven environment and KU Leuven SharePoint are available for free.
No additional costs are expected.

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...).

In accordance with the KU Leuven RDM policy, data corresponding to the qualitative research project (i.e. datasets S68348_DiscordanceScore, S68348_RAID, S68348_Transcripts and S68348_Coding (exported from NVivo in a .docx file), a systematic literature review (i.e. datasets SystematicReview_Screening and SystematicReview_Analysis), and the Delphi experiment (i.e. dataset Delphi_Input) will be preserved for a minimum of 10 years.
In accordance with the CTC recommendations for clinical trials with medicinal products for human use and for clinical experiments on humans, data corresponding to the RCT (i.e. datasets S67309_eCRF_exported and S67309_statisticalanalysis) will be preserved for at least 25 years.

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

Original data will remain stored in the electronic medical patient files (KWS UZ Leuven) for an undetermined amount of time.
The aforementioned data sets will remain stored in the UZ / KULeuven environment (uz \ data \ Rheumatology), KU Leuven SharePoint and at the work computer of the PhD student, all environments being password-protected. An external hard disk drive containing a back up of all data will be stored in a secure UZ Leuven environment.

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

No additional costs are expected.

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.

- No (closed access)

Data will only be made available during and after the project to authorized members of the research group through the UZ / KULeuven environment (uz \ data \ Rheumatology) or via KU Leuven SharePoint, or through access of data backed up on an external hard disk drive. As stated below, if in the future data would be shared to external researchers (thus for research purposes only) after completion of the project, a data transfer agreement shall be drawn up. However, at present there are no plans to share data with external researchers.

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

Access will only be provided to authorized members within the research group (Skeletal Biology and Engineering Research Center, KU Leuven).

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.

- No

Not applicable.

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

As stated above, pseudonymized data will be available in UZ / KULeuven environment (uz \ data \ Rheumatology) accessible via a password-protected personal computer, KU Leuven SharePoint or via an external hard disk drive upon request via e-mail. Only authorized members within the research team will be considered for data access.

When will the data be made available?

Data are already available for authorized members within the research group during the research project.

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

All data collected is covered by regulations on clinical trials, with the research group owning the data. Should in the future data be shared with third parties for research purposes (after completion of the project), a data transfer agreement should be drawn up. At present, however, there are no plans to share data with external researchers.

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?

No additional costs are expected for data sharing.

6. Responsibilities

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

The PhD researcher (Elias De Meyst) and Johan Joly (designated responsible person in the research group)

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

The PhD researcher (Elias De Meyst) and Johan Joly (designated responsible person in the research group)

Who will manage data preservation and sharing?

The PhD researcher (Elias De Meyst) and supervisor (Prof. Dr. Patrick Verschueren) and Johan Joly (designated responsible person in the research group)

Who will update and implement this DMP?

The PhD researcher (Elias De Meyst)