FWO DMP Template - Flemish Standard Data Management Plan

Project supervisors (from application round 2018 onwards) and fellows (from application round 2020 onwards) will, upon being awarded their project or fellowship, be invited to develop their answers to the data management related questions into a DMP. The FWO expects a **completed DMP no later than 6 months after the official start date** of the project or fellowship. The DMP should not be submitted to FWO but to the research co-ordination office of the host institute; FWO may request the DMP in a random check.

At the end of the project, the **final version of the DMP** has to be added to the final report of the project; this should be submitted to FWO by the supervisor-spokesperson through FWO's e-portal. This DMP may of course have been updated since its first version. The DMP is an element in the final evaluation of the project by the relevant expert panel. Both the DMP submitted within the first 6 months after the start date and the final DMP may use this template.

The DMP template used by the Research Foundation Flanders (FWO) corresponds with the Flemish Standard Data Management Plan. This Flemish Standard DMP was developed by the Flemish Research Data Network (FRDN) Task Force DMP which comprises representatives of all Flemish funders and research institutions. This is a standardized DMP template based on the previous FWO template that contains the core requirements for data management planning. To increase understanding and facilitate completion of the DMP, a standardized **glossary** of definitions and abbreviations is available via the following link.

1. General Project Information	
Name Grant Holder & ORCID	**Zilke Claessens (0000-0003-2895-1599)**
Contributor name(s) (+ ORCID) & roles	**Prof. Isabelle Huys (0000-0002-4738-8298), promotor** **Dr. Liese Barbier (0000-0003-1786-2080), co-promotor** **Francesco Pignatti, co-promotor**
Project number[1] & title	1S52123N, Policy recommendations for a pharmaceutical R&D and evaluation framework that is driven by unmet medical needs
Funder(s) GrantID[2]	Fonds voor Wetenschappelijk Onderzoek - Research Foundation Flanders (FWO)
Affiliation(s)	■ KU Leuven ☐ Universiteit Antwerpen ☐ Universiteit Gent ☐ Universiteit Hasselt ☐ Vrije Universiteit Brussel ☐ Other: Provide ROR[3] identifier when possible:

[1] "Project number" refers to the institutional project number. This question is optional since not every institution has an internal project number different from the GrantID. Applicants can only provide one project number.

[2] Funder(s) GrantID refers to the number of the DMP at the funder(s), here one can specify multiple GrantIDs if multiple funding sources were used.

[3] Research Organization Registry Community. https://ror.org/

Please provide a short project description	The concept of unmet medical needs is been used in, and beyond, regulatory and market access practices, determining the eligibility of innovative therapeutics in pathways for accelerated market access. These pathways are developed to speed up market access for products meeting the most pressing needs but what are the highest needs? No generally accepted understanding or definition of the unmet medical need concept is available. This complicates its application in guiding decision-making and impeding a clear signal for drug developers. Therefore, this project aims To align stakeholders' understanding of the concept of unmet medical needs and contribute to a drug evaluation framework that drives and supports the industry to meet the most pressing unmet medical needs.

2. 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[4].

				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
CTG documents	Database of all CTG documents to be assessed during the project.	☐ Generate new data ☒ Reuse existing data	☒ Digital ☐ Physical	☐ Observational ☐ Experimental ☐ Compiled/ aggregated data ☐ Simulation data ☐ Software ☒ Other ☐ NA	☐ .por ☐ .xml ☐ .tab ☐ .csv ☒ .pdf ☐ .txt ☐ .rtf ☐ .dwg ☐ .tab ☐ .gml ☐ other: ☐ NA	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	70 documents
EPAR documents	Database of all EPAR documents assessed in the project.	☐ Generate new data ☒ Reuse existing data	☒ Digital ☐ Physical	☐ Observational ☐ Experimental ☐ Compiled/ aggregated data ☐ Simulation data ☐ Software ☒ Other ☐ NA	☐ .por ☐ .xml ☐ .tab ☐ .csv ☒ .pdf ☐ .txt ☐ .rtf ☐ .dwg ☐ .tab	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	70 documents

[4] Add rows for each dataset you want to describe.

					☐ .gml ☐ other: ☐ NA		
Availability of medicines in Belgium	Data set of all medicines authorized by EMA between 2015-2020, with respective availability rates and times to availability in Belgium	☐ Generate new data ☒ Reuse existing data	☒ Digital ☐ Physical	☐ Observational ☐ Experimental ☒ Compiled/ aggregated data ☐ Simulation data ☐ Software ☐ Other ☐ NA	☐ .por ☒ .xml ☐ .tab ☐ .csv ☐ .pdf ☐ .txt ☐ .rtf ☐ .dwg ☐ .tab ☐ .gml ☐ other: ☐ NA	☒ < 100 MB ☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	324 products
Unmet medical need survey results	Data set of all survey results obtained from the public discrete choice experiment, for use within the research group only	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☒ Observational ☐ Experimental ☐ Compiled/ aggregated data ☐ Simulation data ☐ Software ☐ Other ☐ NA	☐ .por ☒ .xml ☐ .tab ☐ .csv ☐ .pdf ☐ .txt ☐ .rtf ☐ .dwg ☐ .tab ☐ .gml ☐ other: ☐ NA	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	700 participants
					☐ .por	☐ < 100 MB	

					☐ .xml ☐ .tab ☐ .csv ☐ .pdf ☐ .txt ☐ .rtf ☐ .dwg ☐ .tab ☐ .gml ☐ other: ☐ NA	☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	

GUIDANCE:

DATA CAN BE DIGITAL OR PHYSICAL (FOR EXAMPLE BIOBANK, BIOLOGICAL SAMPLES, …). DATA TYPE: DATA ARE OFTEN GROUPED BY TYPE (OBSERVATIONAL, EXPERIMENTAL ETC.), FORMAT AND/OR COLLECTION/GENERATION METHOD.

EXAMPLES OF DATA TYPES: OBSERVATIONAL (E.G. SURVEY RESULTS, SENSOR READINGS, SENSORY OBSERVATIONS); EXPERIMENTAL (E.G. MICROSCOPY, SPECTROSCOPY, CHROMATOGRAMS, GENE SEQUENCES); COMPILED/AGGREGATED DATA[5] (E.G. TEXT & DATA MINING, DERIVED VARIABLES, 3D MODELLING); SIMULATION DATA (E.G. CLIMATE MODELS); SOFTWARE, ETC.

EXAMPLES OF DATA FORMATS: TABULAR DATA (.POR,. SPSS, STRUCTURED TEXT OR MARK-UP FILE XML, .TAB, .CSV), TEXTUAL DATA (.RTF, .XML, .TXT), GEOSPATIAL DATA (.DWG,. GML, ..), IMAGE DATA, AUDIO DATA, VIDEO DATA, DOCUMENTATION & COMPUTATIONAL SCRIPT.

DIGITAL DATA VOLUME: PLEASE ESTIMATE THE UPPER LIMIT OF THE VOLUME OF THE DATA PER DATASET OR DATA TYPE.

PHYSICAL VOLUME: PLEASE ESTIMATE THE PHYSICAL VOLUME OF THE RESEARCH MATERIALS (FOR EXAMPLE THE NUMBER OF RELEVANT BIOLOGICAL SAMPLES THAT NEED TO BE STORED AND PRESERVED DURING THE PROJECT AND/OR AFTER).

[5] These data are generated by combining multiple existing datasets.

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.	CTG documents: non-public documents made available upon request by the RIZIV/INAMI EPAR documents: obtained from EMA website Availability of medicines in Belgium: data obtained from EMA website and responsible Belgian authorities (RIZIV/INAMI, FAGG) via website and upon request
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, please describe these issues further and refer to specific datasets or data types when appropriate.	☒ Yes, human subject data ☐ Yes, animal data ☐ Yes, dual use ☐ No During different studies, human participants will be involved and human subject data will be gathered. Before we start with each study, we will complete the PRET questionnaire about GDPR and data handling. Furthermore, we will apply for ethical committee approval if needed. All data will be stored on the online secured, safe platform of KU Leuven, Sharepoint. Only the researchers involved in a study (dependent on each study, these can be different) will get access to the study documents on the Sharepoint. In each protocol that we will submit to the ethical committee, we will mention which researcher(s) will get access to the study documents on the Sharepoint. As such, we will also have ethical committee approval for sharing our research/personal data with certain researchers. Furthermore, informed consent will always be gathered of participants before collecting personal data. This data will further be handled as also indicated in the informed consent form. Personal data will minimally be pseudonomized. If possible, we will always make the data files anonymous.

Will you process personal data[6]? If so, briefly describe the kind of personal data you will use. Please refer to specific datasets or data types when appropriate. If available, add the reference to your file in your host institution's privacy register.	☒ Yes ☐ No If yes: - Short description of the kind of personal data that will be used: age, health state, gender, socio-economic relevant data - Privacy Registry Reference: not yet available but PRET and ethical committee from the UZ Leuven clearance will be obtained prior to the start of every study.
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 ☒ No If yes, please comment:
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 to what data they relate and what restrictions are in place.	☐ Yes ☒ No If yes, please explain:
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 to what data they relate and which restrictions will be asserted.	☐ Yes ☒ No If yes, please explain:

[6] See Glossary Flemish Standard Data Management Plan

3. 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).	The data is extracted to excel documents and dated. The documents and datasets are saved on a secured KU Leuven drive, accessible by the PI of the project.
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. *REPOSITORIES COULD ASK TO DELIVER METADATA IN A CERTAIN FORMAT, WITH SPECIFIED ONTOLOGIES AND VOCABULARIES, I.E. STANDARD LISTS WITH UNIQUE IDENTIFIERS.*	☐ Yes ☒ No If yes, please specify (where appropriate per dataset or data type) which metadata standard will be used: If no, please specify (where appropriate per dataset or data type) which metadata will be created:

4. Data Storage & Back-up during the Research Project

Where will the data be stored?	During and after the research, all data will be stored on the online secured, safe platform of KU Leuven, Sharepoint. This platform has enough storage to keep all the data that will be gathered during this PhD project. A backup will be stored on the KU Leuven internal server.
How will the data be backed up? *WHAT STORAGE AND BACKUP PROCEDURES WILL BE IN PLACE TO PREVENT DATA LOSS? DESCRIBE THE LOCATIONS, STORAGE MEDIA AND PROCEDURES THAT WILL BE USED FOR STORING AND BACKING UP DIGITAL AND NON-DIGITAL DATA DURING RESEARCH.*[7] *REFER TO INSTITUTION-SPECIFIC POLICIES REGARDING BACKUP PROCEDURES WHEN APPROPRIATE.*	A backup will be stored on the KU Leuven internal server. Backup occurs automatically, as the folders are synched.
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 ☐ No If yes, please specify concisely: The storage of Sharepoint is 5GB, but this is expendable in blocks of 5GB. Only small datasets will be gathered during this project. However, if needed, Sharepoint can be expended, ensuring me that enough space is available to collect alle the data. If no, please specify:

[7] Source: Ghent University Generic DMP Evaluation Rubric: https://osf.io/2z5g3/

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons? *CLEARLY DESCRIBE THE MEASURES (IN TERMS OF PHYSICAL SECURITY, NETWORK SECURITY, AND SECURITY OF COMPUTER SYSTEMS AND FILES) THAT WILL BE TAKEN TO ENSURE THAT STORED AND TRANSFERRED DATA ARE SAFE.* [7]	During the project's data collection phase (i.e. before data is made open) all data is stored on a secure, 2 factor authentication protected KU Leven One Drive server. namely Sharepoint. Backup copes are made on the KU Leuven internal server, which is also password protected. Backup occurs automatically, as the folders are synched. The Excel file that contains the names and contact details of all (potential) interviewees is further protected with a password.
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 FWO bench fee.

5. 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...).	All obtained/generated databases will be stored in accordance to the ethical clearance obtained from the ethical committee of UZ Leuven, there are no restrictions. Only recordings of participants in qualitative research will be deleted upon transcription this in accordance with ethical guidelines.

Where will these data be archived (stored and curated for the long-term)?	On a secured KUL server, only accessible to researchers involved in this project.
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	No expected additional costs.

6. 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. *NOTE THAT 'AVAILABLE' DOES NOT NECESSARILY MEAN THAT THE DATA SET BECOMES OPENLY AVAILABLE, CONDITIONS FOR ACCESS AND USE MAY APPLY. AVAILABILITY IN THIS QUESTION THUS ENTAILS BOTH OPEN & RESTRICTED ACCESS. FOR MORE INFORMATION: HTTPS://WIKI.SURFNET.NL/DISPLAY/STANDARDS/INFO-EU-REPO/#INFOEUREPO-ACCESSRIGHTS*	☐ Yes, in an Open Access repository ☒ Yes, in a restricted access repository (after approval, institutional access only, …) ☐ No (closed access) ☐ Other, please specify: - CTG documents: No (non-public documents, obtained upon request) - EPAR documents: yes - Availability of medicines in Belgium: No (confidential information) - UMN survey: yes, in an Open Access repository (only aggregated results) - UMN interviews: no (confidential information) Personal data will remain closed, as it can identify patients, and is irrelevant to others. All datasets that do not contain personal information can be made available after publication. Reuse of datasets will be limited as all results will first be published and secondary analysis are not possible.
If access is restricted, please specify who will be able to access the data and under what conditions.	Restrictions to data access will be made as I am working with personal data. Only researchers within the KU Leuven/UZ Leuven involved in a specific study that need to have access to certain files will get permissions. This will be clearly indicated in the PRET and EC application. If researchers outside the KU Leuven/UZ Leuven want to have access to the files with personal data, a data sharing agreement wil be made by LRD.

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 ☐ Yes, aspects of dual use ☐ Yes, other ☐ No If yes, please specify: - CTG documents: Yes, other: confidential governmental information - Availability of medicines in Belgium: yes, other: confidential governmental information - UMN survey: yes, privacy aspects (only aggregated, non-confidential data will be shared) - UMN interviews: yes, privacy aspects In this PhD project, we will work with personal data and human participants. Before we start with each study, we will complete the PRET questionnaire about GDPR and data handling. Furthermore, we will apply for ethical committee approval if needed. All data will be stored on the online secured, safe platform of KU Leuven, Sharepoint. Only the researchers involved in a study (dependent on each study, these can be different) will get access to the study documents on the Sharepoint. In each protocol that we will submit to the ethical committee, we will mention which researcher(s) will get access to the study documents on the Sharepoint. As such, we will also have ethical committee approval for sharing our research/personal data with certain researchers. If possible, data will be made anonymous. However, for interviews, this will not be possible, and data will be pseudonymized.
Where will the data be made available? If already known, please provide a repository per dataset or data type.	Data will be deposited in the KU Leuven's Research Data Repository. This means that it will remain accessible after the life of the project, even after my own association with KU Leuven ends. All documentation and published results will be available through Lirias, the KU Leuven repository. Lirias also provides a gateway to materials stored on the Research Data Repository. I have investigated the conditions for use of the KU Leuven research Data Repository and an satisfied that it is suitable for this project.

When will the data be made available? *This could be a specific date (dd/mm/yyyy) or an indication such as 'upon publication of research results'.*	Upon completion and publication of the study
Which data usage licenses are you going to provide? If none, please explain why. *A data usage license indicates whether the data can be reused or not and under what conditions. If no licence is granted, the data are in a grey zone and cannot be legally reused. Do note that you may only release data under a licence chosen by yourself if it does not already fall under another licence that might prohibit that.* *Example Answer: E.g. "Data from the project that can be shared will be made available under a Creative Commons Attribution license (CC-BY 4.0), so that users have to give credit to the original data creators."* [8]	The data will be licensed under Creative Commons Attribution Non-Commercial ShareAlike 4.0 International. This will allow others to use the data for non-commercial purposes, as long as they acknowledge the source and distribute contributions under the same license.
Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, please provide it here. *Indicate whether you intend to add a persistent and unique identifier in order to identify and retrieve the data.*	☒ Yes ☐ No If yes: In Sharepoint, a unique ID number will be added to each file.
What are the expected costs for data sharing? How will these costs be covered?	No expected cost

[8] Source: Ghent University Generic DMP Evaluation Rubric: https://osf.io/2z5g3/

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	PhD researcher (Zilke Claessens) and Isabelle Huys (supervisor)
Who will manage data storage and backup during the research project?	PhD researcher (Zilke Claessens) and Isabelle Huys (supervisor)
Who will manage data preservation and sharing?	PhD researcher (Zilke Claessens) and Isabelle Huys (supervisor)
Who will update and implement this DMP?	PhD researcher (Zilke Claessens) and Isabelle Huys (supervisor)