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	**Steven Simoens (0000-0002-9512-2005)**
Contributor name(s) (+ ORCID) & roles	**Isabelle Huys, co-supervisor** **Walter Van Dyck, co-supervisor**
Project number[1] & title	How to create sustainable market access to advanced therapies?
Funder(s) GrantID[2]	G0A8Y24N
Affiliation(s)	■ KU Leuven ☐ Universiteit Antwerpen ☐ Universiteit Gent ☐ Universiteit Hasselt ☐ Vrije Universiteit Brussel ☐ Other: Provide ROR[3] identifier when possible: 05f950310

[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	Advanced therapies are groundbreaking medicines that may cure diseases. However, there is still uncertainty about their long-term impact on patient health and their high price threatens to make them unaffordable. How can we ensure patient access to advanced therapies? This project will address four key challenges. First, advanced therapies are developed by pharmaceutical companies and by academic institutions. However, we do not currently know how these ways of developing advanced therapies affect R&D, innovation, competition and patient access. Second, the project will explore methods to deal with the uncertain long-term impact on patient health of advanced therapies. Additionally, it will test how evidence on how an advanced therapy performs in daily clinical practice can be used to inform the decision about its reimbursement. Also, a study will investigate how the decision whether to reimburse an advanced therapy can be based on its broad impact on society. Third, the project will calculate the total cost of upcoming advanced therapies and examine how this can be spread over multiple years. Furthermore, it will focus on approaches to reimburse valuable, but affordable products. A fourth part of the project will look at opportunities and propose actions for multiple European countries to work together and support sustainable patient access to advanced therapies.

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
ATMP academic development	Literature review, interview and roundtable results	☒ 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: .mp3/.mp4/NVP/.xls ☐ NA	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	
ATMP pipeline & budget impact	Pipeline & budget impact model results	☒ Generate new data ☒ Reuse existing data	☒ Digital ☐ Physical	☐ Observational ☐ Experimental ☒ Compiled/ aggregated data	☐ .por ☐ .xml ☐ .tab ☐ .csv	☒ < 100 MB ☐ < 1 GB ☐ < 100 GB ☐ < 1 TB	

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

				☒ Simulation data ☐ Software ☐ Other ☐ NA	☐ .pdf ☐ .txt ☐ .rtf ☐ .dwg ☐ .tab ☐ .gml ☒ other: .xls ☐ NA	☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	
ATMP cost-effectiveness & affordability	Literature review & survey results	☒ 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: .qsf/.xls ☐ NA	☒ < 100 MB ☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	
ATMP spread payments	Literature review results & simulation model results of spread payments	☒ 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	☐ < 100 MB ☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB	

					☐ .dwg ☐ .tab ☐ .gml ☒ other: .xls ☐ NA	☐ > 50 TB ☐ NA	
ATMP clinical uncertainties	Literature review & focus group discussion results	☒ 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: .mp3/.mp4/NVP/.xls ☐ NA	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	
ATMP economic evaluation	Literature review, simulation model & interview results	☒ 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	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB	

					☐ .tab ☐ .gml ☐ other: .xls/.mp3/.mp4/NVP ☐ NA	☐ NA	
ATMP broad value assessment	Literature review, document analysis & focus group discussion results	☒ 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: .mp3/.mp4/NVP/.xls ☐ NA	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	
ATMP international collaboration	Literature review, interview & survey results	☒ 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	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB	

					☐ .dwg ☐ .tab ☐ .gml ☒ other: .mp3/.mp4 /NVP/.qsf/.xls ☐ NA	☐ > 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.	-Peer-reviewed and grey literature -Clinical trial databases, such as EudraCT (EU Drug Regulating Authorities Clinical Trials; https://eudract.ema.europa.eu), ClinicalTrials.gov, ICTRP (International Clinical Trials Registry Platform of the World Health Organization; https://www.who.int/clinical-trials-registry-platform), Catapult clinical trials database (https://ct.catapult.org.uk/resources/clinical-trials-database), American Society of Gene & Cell Therapy database (https://asgct.org/), and the Gene Therapy Clinical Trials Worldwide database (https://www.genetherapynet.com/clinical-trials.html)
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 This project does not carry out experiments on humans, but elicits the opinion of different stakeholders (such as health care payers, health technology assessment bodies, pharmaceutical companies, academics and patient organisations) about sustainable market access to advanced therapies. For those studies involving these stakeholders, an application will be submitted to the research ethics committee of KU Leuven. If yes, please describe:

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: Personal data to be collected relate to an individual's professional life and include an individual's name, phone number, e-mail address, professional address, professional occupation, employer. These data are used only with a view to contacting individuals in the context of the studies (except for data about professional occupation, which will be aggregated into broad categories and reported in articles to be published in the scientific literature). - Privacy Registry Reference:
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:

[6] See Glossary Flemish Standard Data Management Plan

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:

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).	Research methods and practices will be fully documented and described in detail in the study protocols to be submitted to the research ethics committee of KU Leuven and in the articles to be published in the scientific literature. For each study, a separate folder (and sub-folders, if relevant) will be created that includes such files as the study protocol, information letter, invitation to participate in the study, informed consent form, reporting template and data collection form, interview/expert panel guide, ethical approval document, audio and Nvivo files, relevant published scientific articles, endnote files. For each study, a README.txt file will be created including general information, project information, file overview and storage information.
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 no, please specify (where appropriate per dataset or data type) which metadata will be created: No metadata will be created.

4. Data Storage & Back-up during the Research Project	
Where will the data be stored?	The time-stamped master copy of the data will be kept on our research unit central storage facility. Copies can be made and kept on personal devices. Since the project team involves members from different institutions, we will use Sharepoint to facilitate collaboration and information exchange.
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.*	The data will be backed up on the university's central servers.
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: Sufficient storage capacity is available on our research unit central storage facility, on Sharepoint, and on the university's central servers. 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]	Data can be accessed by project team members only and are stored on platforms to which unauthorized persons don't have access.
What are the expected costs for data storage and backup during the research project? How will these costs be covered?	There are no additional expected costs for data storage and back up related to the project. If such costs would be incurred, they will be covered by the FWO allocated project budget.

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 data will be retained for at least ten years after the end of the project.
Where will these data be archived (stored and curated for the long-term)?	The data will be archived on the university's central servers (with automatic back-up procedures).

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	There are no additional expected costs for data preservation related to the project. If such costs would be incurred, they will be covered by the FWO allocated project budget.

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:
If access is restricted, please specify who will be able to access the data and under what conditions.	Project team members only
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: Data on the opinions of stakeholders can only be used in the context of the project studies, given that this condition will be included in the informed consent form with a view to be able to recruit participants.
Where will the data be made available? If already known, please provide a repository per dataset or data type.	Not applicable

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'.*	Not applicable
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]	Not applicable
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.*	Not applicable
What are the expected costs for data sharing? How will these costs be covered?	No expected costs for data sharing.

[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?	The project team members.
Who will manage data storage and backup during the research project?	The project team members.
Who will manage data preservation and sharing?	The project grant holder, Prof. Steven Simoens.
Who will update and implement this DMP?	The project grant holder, Prof. Steven Simoens.