FWO DMP Template - Flemish Standard Data Management Plan

Version KU Leuven

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	**Yannick Hoffert, 0000-0002-1631-9484**
Contributor name(s) (+ ORCID) & roles	
Project number [1] & title	1SHAA24N, Model-informed precision dosing of tacrolimus in solid organ transplant recipients
Funder(s) GrantID [2]	
Affiliation(s)	x KU Leuven ☐ Universiteit Antwerpen ☐ Universiteit Gent ☐ Universiteit Hasselt ☐ Vrije Universiteit Brussel ☐ Other: ROR identifier KU Leuven: 05f950310

[1] "Project number" refers to the institutional project number. This question is optional. 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.

Please provide a short project description	Tacrolimus is a cornerstone immunosuppressive drug used after solid organ transplantation. However, its variable blood exposure and narrow therapeutic window put patients at risk of graft rejection (underexposure) and organ injury/malignancy (overexposure). While therapeutic drug monitoring is routinely used to tailor individual tacrolimus dosing based on blood concentrations, there is a lack of evidence-based exposure targets and accurate dosing algorithms. By building pharmacometrics models to large real-world datasets, the applicant will characterize exposure-response relations (pharmacodynamics) of tacrolimus in patients with liver transplants to enable rational identification of exposure targets. He will also investigate the dose-exposure relation (pharmacokinetics) of tacrolimus in the unexplored context of bowel transplantation. Furthermore, he will study multi-model and machine-learning algorithms to enhance the predictive performance of pharmacokinetics models for patients with bowel, liver, kidney, heart, and lung transplants. After retrospective evaluation, a selected algorithm will be integrated into a model-informed precision dosing software tool to guide safe and effective tacrolimus dosing for every patient. The tool will be validated in a pilot trial, aiming to improve treatment outcomes of liver and bowel transplant recipients. This study presents a unique and innovative approach to address an important clinical need in transplantation medicine.

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 [3].

				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
		☒ Generate new data ☒ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☐ Textual ☒ Model ☒ Software ☐ Other:	.xls for observational and experimental patient information .mod for population models .csv for simulation files .R for R code for data processing (including exploratory data analysis, and data visualization)	☐ < 1 GB ☐ < 100 GB ☒ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	

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

GUIDANCE: *The data description forms the basis of your entire DMP, so make sure it is detailed and complete. It includes digital and physical data and encompasses the whole spectrum ranging from raw data to processed and analysed data including analysis scripts and code. Physical data are all materials that need proper management because they are valuable, difficult to replace and/or ethical issues are associated. Materials that are not considered data in an RDM context include your own manuscripts, theses and presentations; documentation is an integral part of your datasets and should described under documentation/metadata.* *RDM Guidance on data*	
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.	WP1 (S65900), WP2 (S64409), WP3 (S53364), WP4 (S51577/S63978), WP5 (S67234)
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: ☐ Yes, animal data; provide ECD reference number: ☐ Yes, dual use; provide approval number: ☒ No Additional information:
Will you process personal data[4]? 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) ☐ No Additional information: S-number as provided earlier
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:

[4] See Glossary Flemish Standard Data Management Plan

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:

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). *RDM guidance on documentation and metadata*.	1. Regarding extracted patient information, an explanation for each observed patient information (demographics, lab measurements, disease characteristics etc) will be provided. A ReadMe file of the data structure will be written. 2. Regarding the model files, the annotation will be provided following each line of the model code to explain the meaning and function of the code. A ReadMe file will be provided to illustrate the dataset used to build the model, the object (drug concentration/effect) that is being modeled, and the problem that the model aims to solve. 3. Regarding the model-derived simulation files, a ReadMe file will be provided to illustrate the model used to simulate the files as well as the information presented in the simulation file. 4. Regarding the generated R code for data individualization, the annotation will be provided following each line of the R code to explain the meaning and function of the code.

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: Metadata will be generated following the relevant international standard in biomedical science. 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? *Consult the interactive KU Leuven storage guide to find the most suitable storage solution for your data.*	☐ Shared network drive (J-drive) ☐ Personal network drive (I-drive) ☒ OneDrive (KU Leuven) ☐ Sharepoint online ☐ Sharepoint on-premis ☐ Large Volume Storage ☐ Digital Vault ☐ Other:
How will the data be backed up? *WHAT STORAGE AND BACKUP PROCEDURES WILL BE IN PLACE TO PREVENT DATA LOSS?*	☐ Standard back-up provided by KU Leuven ICTS for my storage solution ☒ Personal back-ups I make (specify) ☒ Other (specify) KU Leuven provides free storage and backup capacity of 2 TB on OneDrive for Business for this project.

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 no, please specify: There is no additional cost expected. KU Leuven provides free storage and backup capacity of 2 TB on OneDrive for Business for this project.
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.* *Guidance on security for research data*	Sensitive data will never be allowed to be carried on unprotected personal devices. We ensure that the processing of personal data will be fully compliant with the European Regulation 2016/679 (the General Data Protection Regulation, or "GDPR", in force from 25 May 2018), which covers the protection of personal data.
What are the expected costs for data storage and backup during the research project? How will these costs be covered?	There is no cost expected for data preservation during the retention period of 5 years. KU Leuven offers free online storage of 2 TB on OneDrive for Business for every employee. All relevant data will be stored under the OneDrive for Business account of the promoter (Prof. Erwin Dreesen)

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...). *Guidance on data preservation*	☒ All data will be preserved for 10 years according to KU Leuven RDM policy ☐ All data will be preserved for 25 years according to CTC recommendations for clinical trials with medicinal products for human use and for clinical experiments on humans ☐ Certain data cannot be kept for 10 years (explain) For each WP : the dataset file(s), R script(s), final model file(s), and .lst file(s) of the final model(s).
Where will these data be archived (stored and curated for the long-term)? *Dedicated data repositories are often the best place to preserve your data. Data not suitable for preservation in a repository can be stored using a KU Leuven storage solution, consult the interactive KU Leuven storage guide.*	☐ KU Leuven RDR ☐ Large Volume Storage (longterm for large volumes) ☐ Shared network drive (J-drive) ☒ Other (specifiy): All relevant data will be kept on OneDrive for Business for five years after the end of the research, conform the KU Leuven RDM policy.
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	There is no cost expected for data preservation during the retention period of 5 years. KU Leuven offers free online storage of 2 TB on OneDrive for Business for every employee. All relevant data will be stored under the OneDrive for Business account of the promoter (Prof. Erwin Dreesen)

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, as open data ☐ Yes, as embargoed data (temporary restriction) ☒ Yes, as restricted data (upon approval, or 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.	All data will be made available in a restricted access repository upon request and by institutional access 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:
Where will the data be made available? If already known, please provide a repository per dataset or data type.	☒ KU Leuven RDR ☐ Other data repository (specify) ☐ Other (specify)

When will the data be made available?	☒ Upon publication of research results ☐ Specific date (specify) ☐ Other (specify)
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.* *Check the RDR guidance on licences for data and software sources code or consult the License selector tool to help you choose.*	☐ CC-BY 4.0 (data) ☒ Data Transfer Agreement (restricted data) ☐ MIT licence (code) ☐ GNU GPL-3.0 (code) ☐ Other (specify)
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, a PID will be added upon deposit in a data repository ☐ My dataset already has a PID ☐ No
What are the expected costs for data sharing? How will these costs be covered?	There is no cost for sharing the data within KU Leuven. The cost of sharing data with external parties needs to be covered by the external parties.

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	The PhD student Yannick Hoffert himself

Who will manage data storage and backup during the research project?	The PhD student Yannick Hoffert himself
Who will manage data preservation and sharing?	The promoter of this research project (prof. Dreesen)
Who will update and implement this DMP?	The PhD student Yannick Hoffert himself