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	Charlotte Van Edom (0000-0003-2830-624X)
Contributor name(s) (+ ORCID) & roles	Prof. dr. Thomas Vanassche: supervisor Prof. dr. Bart Meyns: co-supervisor
Project number [1] & title	11P6X24N - Exploring the contact pathway (inhibition) during mechanical circulatory support in critically ill: the start of a new era on ICU?
Funder(s) GrantID [2]	FWO 11P6X24N
Affiliation(s)	■ 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	The use of mechanical circulatory support (MCS) devices to support patients with reduced cardiac output has increased dramatically over the last decade. Importantly, bleeding and thrombotic complications remain the Achilles' heel of these patients. This precarious haemostatic balance results from the combination of a pro-coagulant state, due to contact pathway activation by the plastic material from the device with our without critical illness, together with several factors aggravating the bleeding risk, such as the need for anticoagulation and induced coagulation abnormalities. This project focusses on anticoagulation during MCS by assessing current practices and exploring new approaches in the field in order to reduce morbidity and mortality in this population. We will compare current anticoagulant practices within European MCS-centres via an international survey and study the correlation between coagulant tests in this setting, as well as potential causes of discrepancies. Furthermore, we will retrospectively and prospectively study the usage of DOACs (apixaban) in the setting of MCS.

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
1. International survey results	Results from the international survey on antithrombotic practices during percutaneous mechanical	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software	Excel file	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	NA

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

	circulatory support in critically ill adults.			☐ Other:			
2. Anti-Xa and APTT data	Demographics and laboratory parameters from cardiogenic shock patients supported with Impella™	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:	Excel file	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	NA
3. Apixaban in LVAD patients (retrospective)	Demographics, outcomes and laboratory parameters from LVAD patients anticoagulated with apixaban	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:	Excel file	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	NA
4. Apixaban in LVAD patients (prospective)	Demographics, outcomes and laboratory parameters from LVAD patients anticoagulated with apixaban	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:	Excel file	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	NA
5. Apixaban in LVAD	Experimental data from extended	☒ Generate new data ☐ Reuse existing	☒ Digital (as blood samples	☐ Audiovisual ☐ Images ☐ Sound	Excel file	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB	NA

patients	coagulation testing results from LVAD patients anticoagulated with apixaban	data	will be destroyed) ☐ Physical	☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:		☐ < 5 TB ☐ > 5 TB ☐ NA	

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 analyzed 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.	NA
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: S66716 for dataset 1, S69031 for dataset 3. EC application is under preparation for datasets 4 & 5. ☐ 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: S66716 for dataset 1, S69031 for dataset 3. Patient characteristics and lab results will be collected as will be described in detail in the EC request. Anonymized data will be used wherever possible. If re-identification is required, pseudonymized data will be used only where needed. Awaiting EC S-number: EC application is under preparation for datasets 4 & 5.
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:

3. Documentation and Metadata

[4] See Glossary Flemish Standard Data Management Plan

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*.	In capturing data, I ensure clarity and usability by employing comprehensive documentation methods. I gather all relevant information during research, annotating within software like Excel. README files accompany the data, providing context on its generation and research project affiliation. I craft detailed codebooks, guiding users on interpreting and analysing the data. In-file documentation, such as subtabs, further aids understanding. I maintain a well-organized folder structure, storing all documentation alongside the dataset.
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? *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: Methodology, protocol, information on ethical committee approval and all study-related data will be kept in a secure drive. This information is only accessible to the investigator and will only be shared with team members by using secure file sharing when needed. Digital information of study results (lab test results) will be stored on a secure drive.
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)
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:

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*	On the short-term, data will be securely stored on the OneDrive for Business (MS). On the medium and longer term, data will be stored on the Teams site with multifactor authentication with KU Leuven Authenticator app.
What are the expected costs for data storage and backup during the research project? How will these costs be covered?	The existing storage and backup facilities of the university should suffice for this project without additional charge.

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)

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): University central server, OneDrive with automatic back-up procedures, conform KU Leuven RDM policy.
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	Centralized KU Leuven online storage solution will suffice for completion of this project via the KU Leuven OneDrive.

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: Published data will remain available as part of the published work and as part of the required data for validation/auditing. More data can be made available upon request after permission of the principal investigator and after evaluation of the data request proposal. Only anonymised data can be made available.
If access is restricted, please specify who will be able to access the data and under what conditions.	Upon reasonable request, anonymous data can be made available for research collaborations, through a data sharing agreement. Requests will be evaluated by the principal investigator.
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): Data availability will be chosen depending on publication strategy.

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): Data usage license will be discussed with LRD if applicable before any license is granted. Data sharing agreements will be evaluated after consulting LRD.
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?	If specific costs would arise from sharing material, the coverage of these costs will be part of the data transfer agreement and will be negotiated in collaboration with LRD as part of the DTA.

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	Principal Investigator (Thomas Vanassche) has final responsibility, researchers who generate the data will be responsible for the immediate storage.

Who will manage data storage and backup during the research project?	Principal Investigator (Thomas Vanassche)
Who will manage data preservation and sharing?	Principal Investigator (Thomas Vanassche)
Who will update and implement this DMP?	Principal Investigator (Thomas Vanassche)