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	**Vandenbriele Christophe, ORCID: 0000-0001-5151-6400**
Contributor name(s) (+ ORCID) & roles	**Charlotte Van Edom (ORCID: 0000-0003-2830-624X) – PhD student linked to this project**
Project number[1] & title	1803923N - Mechanical Circulatory Support in critically ill cardiogenic shock patients: a complex process of Thrombosis and Hemostasis.
Funder(s) GrantID[2]	1803923N
Affiliation(s)	☐ **KU Leuven** ☐ Universiteit Antwerpen ☐ Universiteit Gent ☐ Universiteit Hasselt ☐ Vrije Universiteit Brussel ☐ Other: Provide ROR[3] identifier when possible:
Please provide a short project description	Although coagulopathy is the most important cause of morbidity/mortality in mechanical circulatory support-patients, its management is still poorly studied and anticoagulation management in critically ill MCS-patients remains an open research field without answers to the most basic questions: how should we monitor anticoagulants, which anticoagulation target should we aim for and which anticoagulant to use. This project aims to elucidate these important questions through a strong international collaboration with various high-output MCS-centers and through experts in the field. We rely on research going from the bench (ex vivo micro-axial flow pump loops, ex vivo platelet research) to bed-side (confirmation of our retrospective study results in a prospective, randomized study set-up).

[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/

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
Observational data – WP1	Anti-Xa study (intermediate vs. Therapeutic)	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☒ Observational ☐ Experimental ☐ Compiled/ aggregated data ☐ Simulation data ☐ Software ☐ Other ☐ NA	☐ .por ☒ .xml Redcap database	☐ < 100 MB ☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	
Experimental data – WP2	Platelet aggregation studies (mocked loop systems, in the presence of SAPT or DAPT)	☒ Generate new data ☐ Reuse existing data	☒ Digital ☒ Physical	☐ Observational ☒ Experimental ☐ Compiled/ aggregated data ☐ Simulation data ☐ Software	☐ .por ☒ .xml ☒ .xl ☐ other: ☐ NA	☒ < 100 MB ☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB	Lab notebook, securely stored inside the hospital walls and after a closed door

[4].

				☐ Other ☐ NA		☐ > 50 TB ☐ NA	
Observational data – WP3	aPTT vs anti-Xa data in patients on mechanical circulatory support	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☒ Observational ☐ Experimental ☐ Compiled/ aggregated data ☐ Simulation data ☐ Software ☐ Other ☐ NA	☐ .por ☒ .xml RedCap Database and Excel (pseudomized data only)	☒ < 100 MB ☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	
Observational data – WP4	FXI/FXII pathway experiment in MCS	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☒ Observational ☐ Experimental ☐ Compiled/ aggregated data ☐ Simulation data ☐ Software ☐ Other ☐ NA	☐ .por ☒ .xml Redcap Database	☒ < 100 MB ☐ < 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).*	
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.	No existing data will be reused
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, there are no issues concerning research data as indicated in the ethics questionnaire of the application form. If yes, please describe:

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

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: - 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:
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).	All persons collaborating on a particular project will also have access to the (shared, but secure) folder of this project. This folder will be located on KU Leuven's (secure) servers. These folders will include (and only these folders) video, photos, data files, etc, obtained from the study. Experimental data will never be kept on publicly accessible media. The folder will be password protected and only accessible to selected individuals. The PI will act as the administrator of these data folders. Written data (data logs) will only be available to those individuals participating in the project and will always be kept within the walls of KU Leuven under lock and key. The PI will have access to these data logs at all times.
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?	All collected clinical data (medical history, hospital stay, ...) will be stored in the patients electronical medical files at the clinical site (UZ Leuven) and will be transferred on an electronical CRF created by our clinical trial center. (REDCap) Each patient will have an assigned code based on the center and the subgroup classification that will identify the patient for the PI only. The PI will create an investigator file in accordance with the EC/GCP requirements. All basic research data that will be generated within this project, will be written down in a lab book according to a mutual method we are using in the lab.
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.*	Storage during research: Documentation and processed data will be deposited in REDCap. Storage capacity can be extended accordingly. Daily backups of the database are foreseen. All historical data are stored in the system. Manuscripts will be published and archived in public repositories. Other electronic files (text, images, spreadsheets,...) will be stored on KU Leuven servers, with hourly onsite backup and mirroring. Storage after research: data will be available in REDCap for at least 5 years. Idem for manuscripts, other electronic files and basic research images/samples.
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: 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]	Digital data will only be available through the secure servers of KU Leuven / UZ Leuven. Data will not be released to the public. Any email traffic will only be through the university's secured servers. Written data (logbook, data manual, ...) will only remain within the walls of the university and will always be kept behind a closed door. Samples will be stored in the KU Leuven biobank according to the rules set by the university.
What are the expected costs for data storage and backup during the research project? How will these costs be covered?	No additional charges provided. Data will be stored on UZ Leuven / KU Leuven data servers that offer sufficient capacity to their employees at no additional cost.

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...).	Datasets collected in the context of clinical research (WP 1, 3 and 4), which fall under the scope of the Belgian Law of 7 May 2004, will be archived for 25 years, in agreement with UZ Leuven policy and the European Regulation 536/2014 on clinical trials of medicinal products for human use.

Where will these data be archived (stored and curated for the long-term)?	Documentation and processed data will be deposited in REDCap and on the KU Leuven servers. Storage capacity can be extended accordingly. All historical data are stored in the system. Storage after research: data will be available in REDCap for at least 5 years. Idem for manuscripts, other electronic files and basic research images/samples.
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	No additional costs foreseen;

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.	Data will only be made available afterwards upont the request of editors/reviewers.
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.	To be discussed

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 publications of research results
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]	At this point, no data from the project will be shared or be reused. This might change throughout the ongoing project.
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:
What are the expected costs for data sharing? How will these costs be covered?	Not applicable

[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?	This data documentation and metadata will be managed during the research project by the PI (Christophe Vandenbriele) and his PhD-student (Charlotte Van Edom)
Who will manage data storage and backup during the research project?	Data storage will be managed during the research project bij the PI (Christophe Vandenbriele) and his PhD-student (Charlotte Van Edom) through the KU Leuven and UZ Leuven protected data servers. No data will be stored outside of the protected servers.
Who will manage data preservation and sharing?	Data preservation and sharting will be managed by the PI (Christophe Vandenbriele) and his PhD-student (Charlotte Van Edom)
Who will update and implement this DMP?	The PI: Christophe Vandenbriele