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	Jens-Uwe Voigt (0000-0002-0575-1888)
Contributor name(s) (+ ORCID) & roles	Co-PI: Jürgen Duchenne (0000-0003-0221-5753) Co-PI: Annette Caenen (0000-0002-4747-6482) Co-PI: Gabor Voros (0000-0003-3077-0914)
Project number [1] & title	FWO senior research project G0A3F24N ***Assessing myocardial stiffness in presence of a left bundle branch block using active shear waves and ultra-high frame rate echocardiography***
Funder(s) GrantID [2]	?
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	Heart failure is often associated with a left bundle branch block (LBBB) conduction delay, causing left ventricular remodelling with a thin and dysfunctional septal wall. LBBB is associated with improved outcome after cardiac resynchronization therapy (CRT), as it can compensate for the conduction delay and may reverse the remodelling. Myocardial scar detection in CRT candidates is essential, as it affects the response to CRT. Scar assessment is however difficult, as current methods are inapplicable due to contraindications or inaccuracies. Therefore, this project explores the use of ultrasound shear wave imaging as non-invasive, widely available tool for evaluating myocardial stiffness in the presence of LBBB. We hypothesize that shear wave measurements can differentiate a non-viable scarred septum from a remodelled but viable septum in LBBB. The objectives of this project are two-fold. From a technological point-of-view, this project will further optimize the available imaging sequence and post-processing pipeline to increase the success rate of the technique, which is necessary to move the tool forward towards the clinics. From a clinical point-of-view, this project will use shear wave imaging to assess the long-term effects of remodelling and reverse-remodelling in animals and patients to better understand the interaction of scar and LBBB on cardiac function and to potentially provide a clinically useful criterion for better selection of CRT candidates.

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
Echo and MRI images	Echo and MRI images taken at experiments and during patient visits	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☒ Images ☐ Sound ☐ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	DICOM	☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☒ < 5 TB ☐ > 5 TB ☐ NA	
High frame rate echo images	Echo images with high frame rate taken at experiments and during patient visits	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☒ Images ☐ Sound ☐ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	SRD	☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☒ < 5 TB ☐ > 5 TB ☐ NA	
Data export and analysis files	Excel and other spreadsheet files, as well as statistical	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical	XLSX, CSV, TXT, XML, SAV	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB	

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

	output			☐ Textual ☐ Model ☐ Software ☐ Other:		☐ > 5 TB ☐ NA	
Informed consent forms	Informed consent forms of participants	☒ Generate new data ☐ Reuse existing data	☐ Digital ☒ Physical	☐ Audiovisual ☐ Images ☐ Sound ☐ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:		☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	Paper
Labchart data	Invasive pressure(-volume) data acquired during the animal experiments	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	ADICHT	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	
Medical data	Exports from ECG's and pacemaker read-outs	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:	PDF	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 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 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.	N/A
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: Human studies: EC S-number: S66757; S66350; S68574 Animal studies: EC P-number: P129/2023 All data will be acquired in either animals or humans.
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: EC S-number: S66757; S66350; S68574 All datasets acquired in patients will be based upon personal data.

[4] See Glossary Flemish Standard Data Management Plan

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: N/A
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: N/A
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: N/A

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*.	Digital data: All raw digital files will be labelled in a structured manner. Data from specific animals will be labelled with their unique Santinel number. Data from specific patients will be labelled with an unique identifier: e.g. patient 1 will be labelled SWE_CRT_001, with SWE_CRT acting as a study identifier and 001 as a patient identifier. A TXT or Microsoft Word file with a clear description of what a specific folder contains will be saved in each specific folder. Written data: Any written documentation on study design, data analysis, variable details and all information necessary for a secondary analyst to use the data accurately and effectively will gathered in notebooks which will be labelled with the investigators' name, title of the project and book number.
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: N/A If no, please specify (where appropriate per dataset or data type) which metadata will be created: Medical images: All images used in our study will be saved in the conventionally-used DICOM format which contains metadata in the file header. This header contains key technical attributes of each specific file. In addition, each animal/patient will have a specific folder carrying the specific animal/patient code with all images. Other medical data: Metadata of other medical data include e.g. naming and headers of PDF files with the ECG and pacemaker read-outs will be labelled with the animals'/patients' specific code. Numeric data: Metadata of numeric data (both raw and processed) include e.g. any headers of CSV, XLS, TXT, SAV files used throughout the study. These will be created manually in a descriptive and structured manner.

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: Medical images: All raw imaging data from patients is stored automatically on the hospitals' clinical servers. These are automatically back-upped. In addition, a copy will be stored on the server of our research group, which are also located within the hospital in Leuven and which are automatically back-upped on a daily basis. The server access subject to the access management of the university/hospital. Medical images from the animal experiments and other medical and numeric data will also be stored on the server of our research group. Everyday working files: Processed data, such as Excel sheets, CSV files etcetera will be stored on the personal virtual hard disks of the respective co-worker which are automatically back-upped on a daily basis. Data on Paper: All written data on paper will be digitized and stored on the server described above. Originals will be kept in a locked cabinet for future reference only when required for legal reasons.
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) The server system of the hospital provides an automatic back-up.

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: Space on the UZ Leuven server is provided by the hospital. Hard disks are provided by the lab. If there isn't sufficient space, additional space can be requested.
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*	Access to data stored on the hospital servers is subject to the access rights management of the hospital. Access will be restricted to persons directly related to the study. The KU Leuven Onedrive is a personal drive, protected with two-factor authentication. The external hard drives and paper files containing study related information will be locked in a separate cabinet within the Medical Imaging Research Center with access for the persons directly related to the study.
What are the expected costs for data storage and backup during the research project? How will these costs be covered?	Data storage capacity including backup on hospital servers is available for a yearly fee of 200 EUR/TB. We expect a total of close to 2 TB, in the end. Given the gradually increasing demands over the three years of the project, we foresee ca. 1000 EUR in total covered by internal funding.

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): All digital data will be stored for 5 years after the end of the study on the UZ Leuven server, which is backed-up daily. After 5 years, given the high cost of the storage and back-up, the data will be stored for long-term on external hard drives. Each hard drive will contain a README-file specifying which data is saved on the drive. Physical data (ICF etc.) will remain stored in files in a cabinet in the lab for 25 years.
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	For the storage of the digital data (± 2TB) for 5 years on the UZ Leuven server, a total cost of ±2000 EUR (200 EUR/TB) is foreseen. This will be covered with internal funding. For the long-term storage of the data on external disks, disks will be purchased. A disk of 2TB costs on average 150 EUR. Also this will be covered with internal funding.

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: All datasets could be made available.
If access is restricted, please specify who will be able to access the data and under what conditions.	Data will be made available for other research groups, upon reasonable request and after publication of research results. Appropriate credit should be given to our research group.
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: N/A
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?	None. Potential costs for data sharing will be billed to the requesting investigator.

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	The responsibility for data storage lies with the academic staff linked to the study, more specifically the assigned PhD-students, under supervision of the PI and Co-PI's. Data backup is automatically provided by the hospital.
Who will manage data storage and backup during the research project?	The responsibility for data storage and back-up lies with the academic staff linked to the study, under supervision of the PI and Co-PI's.
Who will manage data preservation and sharing?	The responsibility for data storage and back-up lies with the academic staff linked to the study, under supervision of the PI and Co-PI's.
Who will update and implement this DMP?	The PI and Co-PI's bear the end responsibility of updating & implementing this DMP.