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	Laurine Wouters (0000-0002-1841-6720)
Contributor name(s) (+ ORCID) & roles	PI: Prof. MD. Jens-Uwe Voigt (0000-0002-0575-1888) Co-PI: Prof. Jan D'hooge (0000-0002-2346-142X) Co-PI: Dr. Jürgen Duchenne (0000-0003-0221-5753)
Project number [1] & title	11PP524N - Cardiac shear wave elastography: a non-invasive approach to evaluate myocardial stiffness
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	Cardiac shear wave elastography (SWE) is a novel and non-invasive technique to evaluate myocardial stiffness. It is based on the detection of shear waves that travel through the heart after for example mitral or aortic valve closure (MVC, AVC). The speed of these shear waves is directly dependent on myocardial stiffness. Since myocardial stiffness is dependent on both intrinsic properties and loading conditions of the heart, SWE could be valuable for evaluating processes that result in altered intrinsic myocardial properties, such as scarring and fibrosis. With this project, we aim to explore the ability of SWE to evaluate myocardial fibrosis and scar burden in two cardiac pathologies: left bundle branch block (LBBB) and aortic stenosis (AS). In both pathologies, fibrosis and scar burden play an essential role in disease progression and prognosis. Therefore, detection of changes in intrinsic myocardial properties with SWE might help to monitor patients, determine the right point in time for an intervention or select suitable candidates for a therapy. Furthermore, as myocardial stiffness is also dependent on loading, it is relevant to determine whether an increased stiffness is the result of changes in the intrinsic properties of the myocardium or alterations in loading. Therefore, as a second part of this project, we aim the determine the effect of altered loading conditions on shear wave measurements.

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 images	Echo images taken during study 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	
HFR images	Echo images acquired at a high frame rate (±1000 fps)	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☒ Images ☐ Sound ☐ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	SRD-files	☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☒ < 5 TB ☐ > 5 TB ☐ NA	
Data analysis files	Excel files for data analysis	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical	XLSX-files	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB	

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

				☐ Textual ☐ Model ☐ Software ☐ Other:		☐ > 5 TB ☐ NA	
ICF	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
Finapres data	Continuous blood pressure measurement data	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	XML/CSV	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	
Labchart data	Invasive pressure measurement data	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	ADICHT-files	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	
Questionnaires	Questionnaires in CRT study	☒ Generate new data ☐ Reuse existing	☐ Digital ☒ Physical	☐ Audiovisual ☐ Images ☐ Sound		☐ < 1 GB	paper

		data		☐ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:		☐ < 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.	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: ☐ Yes, animal data; provide ECD reference number: ☐ Yes, dual use; provide approval number: ☐ No Additional information: EC S-number: S66757; S66350; S68574 Datasets: all datasets contain human subject data

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 Datasets: all datasets contain personal data
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:

[4] 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). *RDM guidance on documentation and metadata*.	All patients are assigned a unique code when they are added to the study database. This code will then be used as identifier when analyzing research data. Digital data: All digital files will be labelled and stored in a structured manner, e.g. each study has its own digital folder with subfolders containing raw and analysed patient data. Data from specific patients will be labelled with an unique identifier: e.g. patient 1 will be labelled SWE_AS_001, with SWE_AS acting as a study identifier and 001 as a patient identifier. A TXT or Microsoft Word file (README file) with a clear description of what a specific folder contains will be saved in each specific folder. Physical data: Physical data will be stored in different folders, organized for each study. In the beginning of each folder, a written paper is added that contains info on what is stored in this specific map.

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: 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 patient will have a specific folder carrying the specific patient code with all images. Other medical data: Metadata of other medical data e.g. questionnaires, ICF etc. will be labelled with the patients' specific code. Numeric data: Metadata of numeric data (both raw and processed) e.g. any headers of XLS, TXT, CSV files used throughout the study, will be created manually in a descriptive and structured manner. Patient's specific codes will be used when analyzing data.

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: High frame rate ultrasound images will be stored on external hard drives, given the large size of the data. The drives are locked in cabinets in the lab and are only accessible for people involved in the study. A back-up of the high frame rate images will be made on the UZ Leuven hospital's server (not the J-drive of KU Leuven) immediately after a patient is added. These servers are backed-up daily and only accessible with permission. Conventional echo images (not high frame rate) are stored on KWS, a digital platform where medical data of patients can be stored and accessed upon request. This platform is backed-up daily and medical data can be stored there without extra cost (echo images are part of the medical record of the patients).
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 ☒ Other (specify): Standard back-up provided by UZ Leuven server and KWS platform

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 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. 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*	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 one drive 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 four 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 (questionnaires, 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: Datasets: all datasets
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:
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-student Laurine Wouters, under supervision of the PI. 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.
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.
Who will update and implement this DMP?	The PI bears the end responsibility of updating & implementing this DMP.