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## Biomechanical modeling and 3D high frame rate imaging to support ultrasound shear wave elastography for assessing stiffness in cardiac remodeling

*A Data Management Plan created using DMPonline.be*

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### Project abstract:

Cardiac remodeling refers to changes in structure and function of the heart in response to cardiac disease or injury. A key parameter in the remodeling process is myocardial stiffness, which currently cannot be measured non-invasively in clinical practice. For this purpose, ultrasound shear wave elastography has shown tremendous potential, but the main question remains whether the technique is able to distinguish intrinsic stiffening (possibly non-reversible) from functional stiffening (reversible). To interpret shear wave elastography measurements with respect to its mechanical confounders, this project aims to further advance the finite element model developed in my junior FWO postdoc by accounting for the effects of contractility, viscoelasticity and a realistic natural wave excitation source (realistic cardiac morphology). Complementary to these simulations, we will perform 3D shear wave elastography measurements in healthy volunteers and patients with varying degrees of stenosis to get better insights into the natural wave physics, and subsequently put forward the preferred imaging technology (2D/3D) with optimized settings for robust and reliable results. Based on the experiments and modeling results, a new measurement protocol (with new metrics) will be proposed to pinpoint intrinsic stiffness changes. This protocol will be tested in vivo to assess its feasibility, sensitivity and robustness for myocardial stiffness assessment.

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## FWO DMP (Flemish Standard DMP)

### 1. 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.

|                                |   |               |                     | 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        |
| Ultrasound data                | Bmode and SWE data of research ULAOP scanner                                | New           | Digital             | Experimental          | Raw data: .uop, .rff256 and .uos<br>Processed data: .mat, .png and .gif         | <5TB                           | NA                     |
| Ultrasound data                | Bmode and SWE data of clinical GE scanner                                   | New           | Digital             | Experimental          | Raw data: .DICOM and .h5<br>Processed data: .mat, .png/.fig, .gif               | <5TB                           | NA                     |
| Structural simulations         | Simulated SWE data  | New           | Digital             | Simulation data       | Set-up: .inp, .f, .sh<br>Results: .odb<br>Post-processed: .mat, .png/.fig, .gif | <5TB                           | NA                     |
| Postprocessing scripts         | Scripts for analyzing experimental and simulated data                       | New           | Digital             | Software              | .m, .py   | <1GB                           | NA                     |
| Presentations and publications | Reports, overview results, conference abstracts/presentations, publications | New           | Digital             | Observational         | .docx, .pptx, .pdf  | <100GB                         | NA                     |

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)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes, human subject data

Ultrasound data of the GE ultrasound scanner contains human subject data. Ultrasound data of the ULA-OP ultrasound scanner can contain human subject data.

Relevant ethical approval number are S66757 and S66094.

**Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.**

- Yes

Ultrasound data of the GE ultrasound scanner contains personal data. Ultrasound data of the ULA-OP ultrasound scanner can contain personal data.

Relevant ethical approval number are S66757 and S66094.

**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

The simulation data might potentially result in the development of new post-processing algorithms. If this would happen, we will contact LRD.

**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 in the comment section to what data they relate and what restrictions are in place.**

- No

**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 in the comment section to what data they relate and which restrictions will be asserted.**

- No

## 2. 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).**

Data will be organized in a folder, with the following organization:

- input: subfolder containing the files used to create the data and a README.txt-file explaining how to use the files.
- data: subfolder containing the large data
- analysis scripts: subfolder containing the scripts to get the analysis data (small in size) from the large data in the data-folder. Each script will contain a header explaining the function of the script.
- analysis: subfolder containing the post-processed data in images, movies etc. (typically small in data size)
- README.txt: file explaining the folder structure

In case of simulation data, the folder data can be removed after 5y to save space, as the files in the input-folder will allow to regenerate all data.

**Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.**

- Yes

The choice of metadata standard is not yet decided at this stage of the research. We will update our DMP once it is decided.

### 3. Data storage & back-up during the research project

#### Where will the data be stored?

- Personal laptop (upto 1TB), Onedrive (upto 2 TB) and external harddrives (upto 2TB) for daily use
- Experimental data will be saved on the UZ Gasthuisberg hospital server (yearly fee of 200eur/TB)
- Simulation data will be saved on UGent network drive at bioMMeda-IBiTech lab (default capacity is 2TB, but more space can be provided)
- Publications are stored at KUL's liris and UGent's academic bibliography and repository

#### How will the data be backed up?

Automatic back-up is provided by the UZ Leuven server and UGent ICT department.

I will also make regular personal back-ups on external hard drives.

**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

The storage capacity depends on the UZ Leuven server depends on the size of the data (annual fee of 200eur/TB).

For the UGent data, a default capacity of 2 TB is foreseen on the UGent network drive, but more can be requested if needed.

#### How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Access to data is governed by the access rights management system of the responsible instance (UZ hospital server/UGent server), limiting access to individuals directly associated with the study. Furthermore, the UZ hospital servers can only be accessed from a computer connected to the UZ net (within the hospital). For access to the UGent server, one can connect via a network cable (UGentNet) or via athena.ugent.be (protected by 2-factor authentication).

Onedrive is a personal drive, protected with 2-factor authentication. The personal laptop and external hard-drives are password-protected.

Sensitive data (human data) will be stored at the UZ hospital server of Leuven, which is maximally protected.

#### What are the expected costs for data storage and backup during the research project? How will these costs be covered?

The expected cost for storage on the UZ Leuven servers is about 1000 EUR in total, considering a max of 2 TB over the course of 3 years (200 EUR/TB). This cost will be covered using the bench fee of the project.

### 4. 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...).**

All data generated during the project will be retained for at least 5 years after the end of the project.

For simulation data, we will not store the simulation data itself, but only the files needed to redo the simulation (much smaller in size than the

actual data).

**Where will these data be archived (stored and curated for the long-term)?**

- Experimental data:
  - Human data: for the first 5 years after the end of the project, the data will remain stored on the UZ Leuven server. After that, the responsible needs to decide if further storage is necessary.
  - Non-human data will be archived at KU Leuven RDR or Large Volume Storage or online repositories (e.g. Zenodo).
- Simulation data will be archived on the UGent network server or on online repositories (e.g. Zenodo).

**What are the expected costs for data preservation during the expected retention period? How will these costs be covered?**

The main cost would be associated with storage of the human data, as this needs to be stored securely. Here, we foresee a total of 2000 EUR (2 TB at a cost of 400 EUR/year). This cost will be covered by the research group.

**5. Data sharing and reuse**

**Will the data (or part of the data) be made available for reuse after/during the project? In the comment section please explain per dataset or data type which data will be made available.**

- Yes, in an Open Access repository
- Yes, in a restricted access repository (after approval, institutional access only, ...)

**If access is restricted, please specify who will be able to access the data and under what conditions.**

Depending on the outcome of the project, it might be that part of the data is patentable. In this case, part of the data, will be restricted until the patent is filed.

**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 in the comment section per dataset or data type where appropriate.**

- Yes, Privacy aspects
- Yes, Intellectual Property Rights

We can only share non-sensitive data, i.e. non-human experimental data or simulation data.

If part of the data is patentable, we can also share data after the patent is filed.

**Where will the data be made available? If already known, please provide a repository per dataset or data type.**

KU Leuven RDR or online repositories.

**When will the data be made available?**

Upon publication of research results

**Which data usage licenses are you going to provide? If none, please explain why.**

- CC BY 4.0 for the non-sensitive non-patentable data
- Patent license for the non-sensitive patentable data

**Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.**

- Yes

**What are the expected costs for data sharing? How will these costs be covered?**

The expected costs are yet to be determined, depending on data size.

At the KU Leuven RDR, every researcher can store 50GB per year for free. Also, online platforms like Zenodo allow to store 50 GB per record for free.

## **6. Responsibilities**

**Who will manage data documentation and metadata during the research project?**

Annette Caenen

**Who will manage data storage and backup during the research project?**

Annette Caenen

**Who will manage data preservation and sharing?**

Annette Caenen

**Who will update and implement this DMP?**

Annette Caenen