Unraveling the relation between endurance exercise and atrial fibrillation by examining atrial remodelling, autonomic tone, inflammation and genetic predisposition
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
CRM	Continuous rhythm monitoring to assess arrhythmia and ANS	• Generate new data	• Digital	• Experimental	• Tabular data: .por, .xml, .tab, .csv, pdf	• <100GB	
Imaging	TTE and CMR to assess atrial remodeling	• Generate new data	• Digital	• Experimental	• Tabular data: .por, .xml, .tab, .csv, pdf • Raw image data	• <1TB	
Genetics	SNP's, PRS	• Generate new data	• Digital	• Experimental	• Tabular data: .por, .xml, .tab, .csv, pdf	• <100GB	
Inflammation	Proteomics	• Generate new data	• Digital	• Experimental	• Tabular data: .por, .xml, .tab, .csv, pdf	• <100GB	

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

Amendment to Master@Heart protocol approved by Ethics Committee Research UZ/KU Leuven 14-03-2025.

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

Following data will be collected: questionnaires and clinical examination, blood samples for biochemistry and genotyping, imaging including echocardiography and cardiac MRI, ECG and holter-monitoring. REDCap will be used as electronic CRFs (eCRF). The researchers will enter the pseudonymised information required by the protocol into REDCap.

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.

- No

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).

REDCap will be used as electronic CRF (eCRF). The researchers will enter the pseudonymized information required by the protocol into REDCap. All data fields will be completed where appropriate. Accompanying information for each data field is stored in REDCap.
As data are entered, automated cross-check programs will search for any data discrepancies in the eCRF. Appropriate error

messages will be generated, allowing for the modification or verification of the entered 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

Instrument-specific metadata standards will be used for rhythm monitoring and imaging (TTE, CMR) modalities.

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

Where will the data be stored?

Storage during research: Documentation and processed data will be deposited in REDCap. Storage capacity can be extended accordingly. Daily backups of the database are performed. All historical data are stored in the system. Manuscripts will be published and archived in public repositories. Other electronic files will be stored on KU Leuven servers, with hourly onsite backup and mirroring. Genetic data are stored on servers of the Genomics core. 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 and genetic sequences.

How will the data be backed up?

As I will be using institutional storage platforms, back-up is automatically provided.

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

cfr. supra: capacity can be extended if necessary

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

Data will be securely stored either the REDCap platform or KU Leuven servers. Both are password protected and not accessible to any third parties.
Data will be coded/pseudonymised, meaning that there continues to be a link between the data and the individual who provided it. The research team is obligated to protect the data from disclosure outside the research team according to the terms of the research protocol and the informed consent document. The subject's name or other identifiers are stored separately from their research data and replaced with a unique code to create a new identity for the subject.

Note that no new inclusions are planned, therefore this pseudonymisation process has already taken place for the current Master@Heart cohort.

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

REDCap: Yearly €90 fee. PI personal budget.
KULeuven servers: none.

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...).

Data will be available in REDCap and KU Leuven servers for at least 5 years. Idem for manuscripts, other electronic files and basic research images/samples and genetic sequences.

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

REDCap and KU Leuven servers

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

REDCap: Yearly €90 fee. PI personal budget.
KULeuven servers: none.

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.

- No (closed access)

Data sharing is not applicable seeing as we are working with clinical human data and this was not included in our informed consent.

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

NA

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, Ethical aspects

Data sharing is not applicable seeing as we are working with clinical human data and this was not included in our informed consent.

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

NA

When will the data be made available?

NA

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

NA

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.

- No

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

NA

6. Responsibilities

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

Jarne De Paepe

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

Jarne De Paepe

Who will manage data preservation and sharing?

Prof. Dr. Tomas Robyns

Who will update and implement this DMP?

Prof. Dr. Tomas Robyns