Understanding thrombo-inflammation: the key to safer antithrombotic therapy?

A Data Management Plan created using DMPonline.be

Creator: Thomas Vanassche

Affiliation: KU Leuven (KUL)

Funder: Fonds voor Wetenschappelijk Onderzoek - Research Foundation Flanders (FWO)

Template: FWO DMP (Flemish Standard DMP)

Grant number / **URL:** 1843423N

ID: 198228

Start date: 01-10-2022

End date: 30-09-2027

Project abstract:

Cardiovascular diseases kill over 17 million people each year, and 85% of these deaths are due to thrombosis, the formation of blood clots in arteries or veins. Thrombosis is the main cause of death and disability and costs over 200 billion € per year in the EU. This burden is expected to increase over the next decade.

Anticoagulants can help to treat and prevent thrombosis, but have important limitations. Since they increase the risk of bleeding, many patients at the highest need for protection are left without treatment. Furthermore, current drugs don’t prevent the underlying vascular changes that cause increased blood clotting. There is an urgent unmet need for better use of current anticoagulants as well as for safer and more effective novel therapies.

The contact pathway links coagulation with the innate immune system, but is not required for protection against bleeding. Drugs that target the contact pathway could provide safer anticoagulation and are in various stages of clinical development. Understanding the role of the contact pathway in specific disease populations is urgently needed to determine who will benefit most from these treatments and to help their clinical translation.

Increasing evidence points to an overarching role for thrombo- inflammation in both atherosclerosis and thrombosis. Targeting the shared cause of vascular disease and thrombosis offers perspectives for more effective therapies to counter the enormous burden of cardiovascular disease.

Last modified: 30-03-2023

Understanding thrombo-inflammation: the key to safer antithrombotic therapy? Application DMP

Questionnaire

Describe the datatypes (surveys, sequences, manuscripts, objects …) the research will collect and/or generate and /or (re)use. (use up to 700 characters)

Question not answered.

Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)

Question not answered.

What's the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)

Question not answered.

Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)

Question not answered.

Which other issues related to the data management are relevant to mention? (use up to 700 characters)

Question not answered.

Understanding thrombo-inflammation: the key to safer antithrombotic therapy?
DPIA

DPIA

Have you performed a DPIA for the personal data processing activities for this project?

Question not answered.

Understanding thrombo-inflammation: the key to safer antithrombotic therapy?
GDPR

GDPR

Have you registered personal data processing activities for this project?

Question not answered.

Understanding thrombo-inflammation: the key to safer antithrombotic therapy?
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
FLEMENGHO	patient cohort, existing database from prospective epidemiological research. Request for data extraction of specified parameters - only data output for study request will be used	Reuse existing data	*Digital*	Observational	*.xml, other*	<1GB	
ICFs	Patient informed consent files	New	Physical				2 boxes 3 binders
Labtests CP	Clinical patient information and results of laboratory tests	New	*Digital*	*Experimental, non-interventional (diagnostic tests)*	*.xml for tabular data*	<1GB	
APS data	Clinical patient information and results of laboratory tests	New	*Digital*	*Experimental, non-interventional (diagnostic tests)*	*.xml for tabular data*	<1GB	
Valve data	results of laboratory tests	New	*Digital*	*Experimental*	*.xml for tabular data*	<1GB	
Animal NET data	in vivo data	New	*Digital*	Experimental	.csv or xml	<1GB	

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:

FLEMENGHO database is available for research collaborations upon request: https://flemengho.eu/en/secundair-gebruik/

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
- Yes, animal data

As part of this project, data from patients will be collected prospectively. Prior to the initiation of this part of the study, an ethics committee file will be submitted.

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

Patient characteristics and lab results will be collected as will be described in detail in the EC request. Anonimized data will be used wherever possible. If re-identification is required, psudonymised data will be used only where needed.

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).

Methodology, protocol, information on ethical committee approval and all study-related data will be kept in a secure drive. This information is only accessible to the investigator and will only be shared with team members by using secure file sharing when needed.
Informed consents will be safely stored at the dedicated secure storing facility behind lock at the clinical study coordination center BLV.

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.

- No

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

Where will the data be stored?

Methodology, protocol, information on ethical committee approval and all study-related data will be kept in a secure drive. This information is only accessible to the investigator and will only be shared with team members by using secure file sharing when needed.
Digital information of study results (lab test results) will be stored on a secure drive.
Informed consents will be safely stored at the dedicated secure storing facility behind lock at the clinical study coordination center BLV.

How will the data be backed up?

Automatic backup is provided via the personal KULeuven OneDrive

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 KULeuven OneDrive capacity is sufficient for this project (2TB)

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

Data will be stored in a secure environment with only access by the PI and - if needed - to authorized personnel.

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

The existing storage and backup facilities of the university should suffice for this project without additional charge. Storage of physical documents will be done in the existing secured long-term document storage facility of the clinical study department.

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 stored for five years after the end of the project for possibility of reuse, as part of preliminary research for future projects, and for regulatory / control reasons.

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

university central server, OneDrive with automatic back-up procedures, conform KULeuven RDM policy

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

centralized KULeuven online storage solution will suffice for completion of this project via the KULeuven OneDrive. If additional storage costs will arise, they can be budgeted through research funds.

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 a restricted access repository (after approval, institutional access only, …)

Published data will remain available as part of the published work and as part of the required data for validation/auditing.
More data can be made available upon request after permission of the principal investigator and after evaluation of the data request proposal. Only anonymised data can be made available.

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

Upon reasonable request, anonymous data can be made available for research collaborations, through a data sharing agreement. Requests will be evaluated by the principal investigator.

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.

- No

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

will be chosen depending on publication strategy

When will the data be made available?

after publication of the research results

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

data usage licence will be discussed with LRD if applicable before any licence is granted. Data sharing agreements will be evaluated after consulting LRD.

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?

If specific costs would arise from sharing material, the coverage of these costs will be part of the data transfer agreement and will be negotiated in collaboration with LRD as part of the DTA.

6. Responsibilities

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

Principal Investigator (Thomas Vanassche) has final responsibility, researchers who generate the data will be responsible for the immediate storage

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

Principal Investigator (Thomas Vanassche)

Who will manage data preservation and sharing?

Principal Investigator (Thomas Vanassche)

Who will update and implement this DMP?

Principal Investigator (Thomas Vanassche)