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	**Xavier Bossuyt (ORCID ID: 0000-0001-6856-8485)**
Contributor name(s) (+ ORCID) & roles	**Nick Geukens – copromotor (0000-0001-5706-1072)** **Maaike Cockx – project manager (0000-0003-0361-5505)**
Project number [1] & title	G0GE523N – ReNewAthero (Self-Antigen expressing mRNA vaccination for atherosclerosis)
Funder(s) GrantID [2]	ERA4HEALTH - CARDINNOV
Affiliation(s)	☐ **KU Leuven** ☐ Universiteit Antwerpen ☐ Universiteit Gent ☐ Universiteit Hasselt ☐ Vrije Universiteit Brussel ☐ **Other: University of Leiden, University of Tel Aviv** 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	Cardiovascular Diseases (CVD) is the leading cause of morbidity and mortality worldwide, primarily caused by major acute cardiovascular events (MACE) such as stroke and myocardial infarction. The main underlying pathology is atherosclerosis, which often remains undetected until rupture of unstable atherosclerotic lesions causes the catastrophic clinical manifestations. Atherosclerosis has classically been treated as a disease driven by dyslipidemia. This, however, ignores the substantial contribution of inflammatory processes to the pathophysiology of this disease. Importantly, mounting evidence suggests atherosclerosis has a strong autoimmune component, opening up new avenues to find therapeutic targets that have previously been overlooked. In the University of Leiden (ULEI), an immunopeptidomics screen of human atherosclerotic plaques revealed a large number of putative autoantigens (n=11) being presented inside the plaque. The role of KU Leuven in this project is to evaluate if these putative autoantigens are CVD-specific. We will do this by developing a multiplex assay on a Luminex platform (available in our laboratory) that will evaluate the presence of autoantibodies to all autoantigens simultaneously in plasma samples of patients with CVD and (disease) controls. The autoantibodies that are most prevalent in CVD and generate the highest signals (~high antibody binding) will be subsequently evaluated for their binding characteristics.

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
		☐ 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	
Methods, SOPs and protocols	Methods, SOPs and protocols for antigen binding to Luminex beads and to FO-SPR fibers	New	Digital	Textual	.docx	< 1 GB	
Raw data from Luminex 200	Raw data results Luminex runs	New	Digital	Numerical	.cvs	< 1 GB	
Raw data	Raw data results	New	Digital	Numerical	.xslx	< 1 GB	

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

from FOx instrument (FO-SPR)	from antibody binding on FO-SPR platform						
Analyzed data Luminex	Analyzed data Luminex	New	Digital	Numerical Images Textual	.xslx .jpg .ppt or .dpcx	< 100 GB	
Analyzed data FO-SPR	Analyzed data FO-SPR	New	Digital	Numerical Images	.xslx .jpg	< 100 GB	

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: S69836 ☐ Yes, animal data; provide ECD reference number: ☒ Yes, dual use; provide approval number: EC DMM approval Ref. no.: D-20240514m ☐ No Additional information:

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: S69836
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: Access Rights to Results and Background needed for the performance of the own work of a Party under the Project and for the duration of the Project shall be granted on a royalty-free basis unless otherwise agreed. Dissemination activities shall be compatible with the protection of intellectual property rights, confidentiality obligations and the legitimate interests of the owner(s) of the respective Results prior notice of any planned publication shall be given to the other Parties concerned at least 45 days before the publication. Any objection to the planned publication shall be made to the Coordinator and to any Party concerned within 30 days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

[4] See Glossary Flemish Standard Data Management Plan

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: - The Parties recognize that for the good governance of the Project, for good intellectual property management, and to facilitate compliance with legal and ethical standards, it is desirable to record any transfers of Human Samples and associated Data between the Parties for the performance of the Project. When one Party (the "Provider") transfers Human Samples and associated Data to another Party (the "Recipient") under the Consortium Plan, a bilateral material transfer agreement shall be concluded between these Parties to specify the conditions of such transfer of Human Samples. - Dissemination activities shall be compatible with the protection of intellectual property rights, confidentiality obligations and the legitimate interests of the owner(s) of the respective Results prior notice of any planned publication shall be given to the other Parties concerned at least 45 days before the publication. Any objection to the planned publication shall be made to the Coordinator and to any Party concerned within 30 days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted

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 experiments of Luminex and FO-SPR will be documented in an Electronic Lab Journal (elab).
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: To our knowledge, there is no formally acknowledged metadata standard specific to our discipline

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:
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):
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: The storage capacities of the server of KU Leuven provide sufficient storage volume for our generated data.
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*	The experiments and results stored in the electronic lab journals are only accessible to the persons involved in the project.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?	The expected costs: €2000 for 3 years storage on J-drive. Costs will be covered by project budget.

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): K-drive of KU Leuven
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	The expected costs: €2000 for 10 years storage on K-drive. Costs will be covered by PharmAbs.

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:
If access is restricted, please specify who will be able to access the data and under what conditions.	Access will be granted upon written request by the creators of the dataset. Commercial reuse is not allowed.

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 necessary, the Parties shall cooperate in order to enable one another to fulfil legal obligations arising under applicable data protection laws (the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and relevant national data protection law applicable to said Party) within the scope of the performance and administration of the Project and of this Consortium Agreement. - The Human Samples and associated Data shall be used by the Recipient for purposes of the Project only. The Recipient will be entirely responsible for the correct use of the Human Samples and associated Data and the Provider shall have no obligations or liability concerning the Human Samples and associated Data or the use, storage and disposal of the Human Samples and associated Data other than using reasonable endeavours to ensure the accuracy of any information that it supplies. The Recipient shall not be entitled to transfer the Human Samples and associated Data to any third party without the Provider's prior written consent. - As to Tel Aviv University, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions are mentioned in the CA.
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): Upon request by mail

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?	**NA**

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	**Maaike Cockx and Xavier Bossuyt**

Who will manage data storage and backup during the research project?	**Maaike Cockx and Xavier Bossuyt**
Who will manage data preservation and sharing?	**Xavier Bossuyt and Nick Geukens**
Who will update and implement this DMP?	**Maaike Cockx**