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	Chantal Mathieu & 0000-0002-4055-5233
Contributor name(s) (+ ORCID) & roles	Conny Gysemans (0000-0003-3559-6089) & co-promotor
	Pierre Lemaitre (0000-0003-0687-8685) & co-promotor
Project number 1 & title	G.0316.25N & Age-related heterogeneity in response to disease-modifying therapies in new-onset type 1
	diabetes
Funder(s) GrantID ²	
Affiliation(s)	
	☐ 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.

Type 1 diabetes (T1D) is the most common chronic metabolic disease in childhood, yet it can occur at any age. Epidemiological data indicate that more than half of the new T1D cases are adults. While there are clear differences in the clinical course of young- compared to adult-onset T1D with a shorter pre-symptomatic period, higher frequencies of autoantibodies, a more aggressive presentation, and faster progression to exogenous insulin, our knowledge on the underlying determinants is limited. In this project, we aim to identify, in young- and adult-onset T1D, distinct biomarkers that would be predictive and prognostic of promising disease-modifying therapies to halt beta cell destruction. We propose a translational approach in which we first will take advantage of the non-obese diabetic (NOD) mouse model and use state-of-the-art multi-omics technologies (i.e., multiparameter flow cytometry, single cell CITE-sequencing, and spatial transcriptomics and proteomics) to discover key age-related pathogenic processes which will be validated in human dataset and bio-samples available via large consortia. Next, we hope to find predictive and prognostic biomarkers of anti-CD3 and low-dose ATG therapies in young- and adult-onset T1D by translating preclinical observations from mice to humans. These findings could revolutionize clinical trial design paving the way to tailor interventions to specific age groups and guide combination therapies and adaptive trial designs.

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.

				ONLY FOR DIGITAL	ONLY FOR DIGITAL	ONLY FOR DIGITAL DATA	ONLY FOR PHYSICAL
				DATA	DATA		DATA
Dataset Name	Description	New or Re-used	Digital or Physical	Digital Data Type	Digital Data Format	Digital Data Volume (MB, GB, TB)	Physical Volume
WP1. Identification of peripheral single cell profiles reflecting pancreas specific changes in newly diabetic NOD mice	droplet-based CITE- sequencing	☑ Generate new data ☑ Reuse existing data	⊠ Digital	□ Audiovisual □ Images □ Sound ☑ Numerical ☑ Textual □ Model ☑ Software □ Other:	.FASTQ .H5 .h5ad .R .RDS .GMT	□ < 1 GB □ < 100 GB ⊠ < 1 TB □ < 5 TB □ > 5 TB □ NA	
	Spatial transcriptomics	☑ Generate new data ☑ Reuse existing data	⊠ Digital	□ Audiovisual □ Images □ Sound ☑ Numerical □ Textual □ Model ☑ Software □ Other:	.FASTQ .R .RDS .h5ad Zarr store .Excel .TIFF	□ < 1 GB □ < 100 GB ⊠ < 1 TB □ < 5 TB □ > 5 TB □ NA	N= number of slides
	Multi-parameter spectral flow cytometry	☑ Generate new data ☑ Reuse existing data	☑ Digital	☐ Audiovisual☐ Images☐ Sound☑ Numerical	.FCS .WSP .EXDAT .Excel	☐ < 1 GB ☑ < 100 GB ☐ < 1 TB ☐ < 5 TB	

	Multiplex immunohistochemistry	☑ Generate new data ☑ Reuse existing data	☑ Digital ☑ Physical		.prism .TIFF .OME.TIFF Zarr store	□ > 5 TB □ NA □ < 1 GB □ < 100 GB ☑ < 1 TB □ < 5 TB □ > 5 TB □ NA	N= number of slides
WP1. Validation of the peripheral single cell profiles identified in NOD mice in humans	Whole blood RNA sequencing data INNODIA samples	☐ Generate new data ☑ Reuse existing data	⊠ Digital	☐ Audiovisual ☐ Images ☐ Sound ☑ Numerical ☑ Textual ☐ Model ☑ Software ☐ Other:	.FASTQ .EPS .RTF .CSV .SAS7BDAT .Excel	□ < 1 GB □ < 100 GB ☑ < 1 TB □ < 5 TB □ > 5 TB □ NA	
	CYTOF mass spectrometry data INNODIA samples	☐ Generate new data ☑ Reuse existing data	☑ Digital	□ Audiovisual □ Images □ Sound ☑ Numerical ☑ Textual □ Model ☑ Software □ Other:	.FCS .Excel .prism	□ < 1 GB □ < 100 GB ⊠ < 1 TB □ < 5 TB □ > 5 TB □ NA	
	Spatial transcriptomics (xenium)	☑ Generate new data	☑ Digital	☐ Audiovisual ☐ Images ☐ Sound ☑ Numerical	.FASTQ.GZ .TIFF	□ < 1 GB □ < 100 GB	N= number of slides

WP2: Identify predictive and prognostic	Multiplex immunohistochemistry (COMET)	☑ Generate new data ☑ Generate new data ☐ Reuse existing	☑ Digital ☑ Physical ☑ Digital ☑ Physical	I Textual □ Model	.JSON .h5ad Zarr store .Excel .TIFF .OME.TIFF Zarr store .doc .excel .prism	<pre></pre>	N= number of slides Storage of serum, plasma and/or tissue in ultra-freezers and
biomarkers of anti-CD3 and low-dose ATG therapies in young- and adult onset type 1 diabetes	Droplet CITE-sequencing	□ Generate new data □ Reuse existing data	⊠ Digital	Numerical Textual Model Software Other: Audiovisual Images Sound Numerical Textual Model Software Other:	.FASTQ .H5 .h5ad .R .RDS .GMT .Excel	□ < 5 TB □ > 5 TB □ > 5 TB □ NA □ < 1 GB □ < 100 GB □ < 1 TB □ < 5 TB □ > 5 TB □ > 5 TB	liquid nitrogen tank (cryotheek)

	Multi-parameter spectral flow cytometry	⊠ Generate new data □ Reuse existing data	⊠ Digital	□ Audiovisual □ Images □ Sound ☑ Numerical ☑ Textual □ Model ☑ Software □ Other:	.FCS .WSP .EXDAT .Excel .prism	□ < 1 GB □ < 100 GB ⊠ < 1 TB □ < 5 TB □ > 5 TB □ NA
WP2: Human validation	Bulk RNA sequencing data AbATE trial	☑ Generate new data☐ Reuse existing data	⊠ Digital	 ☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☒ Software ☐ Other: 	.FASTQ .RTF .CSV .SAS7BDAT .Excel	□ < 1 GB □ < 100 GB □ < 1 TB □ < 5 TB □ > 5 TB □ NA
	Bulk RNA sequencing date TN10 trial	☒ Generate new data☒ Reuse existing data	⊠ Digital	 ☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☒ Software ☐ Other: 	.FASTQ .RTF .CSV .SAS7BDAT .Excel	□ < 1 GB □ < 100 GB □ < 1 TB □ < 5 TB □ > 5 TB □ NA
	Bulk RNA sequencing data MELD-ATG trial	☑ Generate new data☑ Reuse existing data	⊠ Digital	 ☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☒ Software ☐ Other: 	.FASTQ .RTF .CSV .SAS7BDAT .Excel	

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.	Primary data: experimental data (from single-cell omics, from mouse and human samples), and compiled and integrated data (from experimental data generated during this project). Reuse of existing data: human PBMC samples and database of INNODIA consortium on clinical parameters of human samples plus use part of our own previously published data, analyzed in a new different context. These data will be used for publication in high-ranked international peer-reviewed journals and for patent filing in case we find interesting age-associated gene signatures or protein profiles related to disease pathogenesis or therapy outcomes.
Are there any ethical issues concerning the	☑ Yes, human subject data; provide SMEC or EC approval number: S62381; S
creation and/or use of the data	☑ Yes, animal data; provide ECD reference number: 125/
(e.g. experiments on humans or animals, dual	☐ Yes, dual use; provide approval number:
use)? If so, refer to specific datasets or data	□ No
types when appropriate and provide the	Additional information:
relevant ethical approval number.	
Will you process personal data ³ ? If so, please	
refer to specific datasets or data types when	□ No
appropriate and provide the KU Leuven or UZ	Additional information: S60020, S62381, S63466, S68144, S69171
Leuven privacy register number (G or S number).	
Does your work have potential for commercial	⊠ Yes
valorization (e.g. tech transfer, for example spin-	□ No
offs, commercial exploitation,)?	If yes, please comment:
If so, please comment per dataset or data type	Gene signatures related to therapy response of teplizumab and low-dose ATG could be used to file
where appropriate.	patents.

³ See Glossary Flemish Standard Data Management Plan

Do existing 3rd party agreements restrict	⊠ Yes
exploitation or dissemination of the data you	□ No
(re)use (e.g. Material/Data transfer agreements,	If yes, please explain:
research collaboration agreements)?	Part of the human samples were collected within INNODIA and nPOD consortia and have all legal documents
If so, please explain to what data they relate and	in place.
what restrictions are in place.	
Are there any other legal issues, such as	⊠ Yes
intellectual property rights and ownership, to be	□ No
managed related to the data you (re)use?	If yes, please explain: We have access to bulk RNA sequencing data from TN10 trial (not publicly available)
If so, please explain to what data they relate and	but DTA has been finalized between the different parties and IP has been discussed.
which restrictions will be asserted.	

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.

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.

Raw experimental data will be collected per experimental test and will include a README.txt file with a clear description of what the data represent and how they were generated. Each individual file will contain information on the study design, the origin of the samples, and all necessary information for an independent analyst to use or reuse the data. This description will be documented in page-numbered lab notebooks as well as in electronic format. The lab implemented an ELN since January 2025. The lab also uses SOP (.pdf) accompanying the raw experimental data. The lab has a document (.pdf) with overview of all SOP (different versions and updates). Analysed data (e.g.: graphs, tables, texts, power point presentations etc.) will be stored in folders containing the raw and processed data files they are referring to. These folders are organized per project. File formats will be .docx, .pdf, .RData, .jpg, .tiff, .png, .csv, etc. Inclusion of dates will indicate the different version of specific file. Programming languages and code are text-based format and will provide an overview of the necessary packages and libraries in the datasets. Data analysis methods and particularities (including metadata) will be described in text documents and Excel files included in these folders. All files will be stored in the KU Leuven J- or L-drives with sharing possibilities via One Drive (managed by the KU Leuven IT department). Several students working with single-cell omics have followed the VIB course on GitLab in which changes in files are trackable and managed automatically especially code reviews, sharing code snippets etc. are possible.

☐ 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: Text documents and Excel files stored within each experiment folder in the J- and L-drives will respectively contain guidelines describing data collection/analysis methods and all relevant metadata (including experimental conditions, sample keys, computational analysis pipelines and their parameters) to ensure the reusability of the data and the reproducibility of any further data generation. For data on human blood samples the clinical study number will be included; for data on pre-clinical mouse experiments the type of mice will be included.

	4. Data Storage & Back-up during the Research Project
Where will the data be stored?	■ Shared network drive (J-drive)
	☐ Personal network drive (I-drive)
Consult the interactive KU Leuven storage guide to	□ Teams
find the most suitable storage solution for your data.	□ Sharepoint online
	□ Sharepoint on-premis
	■ Large Volume Storage
	□ ManGO
	□ Digital vault
	□ Other:
How will the data be backed up?	☑ Standard back-up provided by KU Leuven ICTS for my storage solution
	□ Personal back-ups I make (specify)
WHAT STORAGE AND BACKUP PROCEDURES WILL BE IN PLACE TO	□ Other (specify)
PREVENT DATA LOSS?	▼ Yes
Is there currently sufficient storage & backup	□ No
capacity during the project? If yes, specify	We have sufficient storage and backup capacity both on J (1.5Tb of which 11.7 Gb free space) and L (10 TB
concisely. If no or insufficient storage or backup capacities are available, then explain how this	of which 2.1 Tb free space) drive. We can easily request for addition storage capacity.
will be taken care of.	or milen 2.2 12 mee space, anner the carreasily request for adams in storage supusity.
will be taken care of.	If no, please specify:
How will you ensure that the data are securely	For paper notebooks: Office doors are always locked when researchers are out of the office. For digital files:
stored and not accessed or modified by	all data on J- and L-drives are stored in password protected drives that are only accessible by people from the
unauthorized persons?	Pls laboratories. dr. Gysemans is responsible for allowing people access to these drives.
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	
Guidance on security for research data	

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

Costs for data storage are incorporated in the requested FWO funding. Our J- fand L-drive have a current capacity of 1.5 TB and of 10 TB respectively. The annual cost of L-drive storage is 569 € per 5 TB of storage space per year. This cost and capacity include the performance of mirror copies of the stored data, for safety backup purposes. We expect that 1 TB will be sufficient to store all data generated as part of the project. These costs will be covered by the budget of the project lead (Prof. dr. Chantal Mathieu).

5. Data Preservation after the end of the Research Project ☑ All data will be preserved for 10 years according to KU Leuven RDM policy Which data will be retained for at least five ☐ All data will be preserved for 25 years according to CTC recommendations for clinical trials with years (or longer, in agreement with other medicinal products for human use and for clinical experiments on humans retention policies that are applicable) after the ☑ Certain data cannot be kept for 10 years (explain) end of the project? In case some data cannot be preserved, clearly state the reasons for this Our university's data management policy expects that relevant research data generated are retained for a (e.g. legal or contractual restrictions, period of minimally 10 years after the end of the project, in a safe, secure & sustainable way for purposes of storage/budget issues, institutional policies...). reproducibility, verification, and potential reuse. However, for biological samples it is not always possible to keep them for 10 years since the long-term stability of some biological samples has not been established. Guidance on data preservation Publication data will be further organized and catalogued on a figure-by-figure basis for future reference to raw datasets used for figure generation. ☐ KU Leuven RDR Where will these data be archived (stored and **■** Large Volume Storage (longterm for large volumes) curated for the long-term)? ■ Shared network drive (J-drive) □ Other (specifiy): 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.

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

Our J- and L-drive have a current capacity of 1.5 Tb and of 10 Tb respectively. The annual cost of L-drive storage is 569 € per 5TB of storage space per year. This cost and capacity include the performance of mirror copies of the stored data, for safety backup purposes. We expect that 1 TB will be sufficient to store all data generated as part of the project. These costs will be covered by the budget of the project lead (Prof. Chantal Mathieu).

6. Data Sharing and Reuse Yes, as open data Will the data (or part of the data) be made Yes, as embargoed data (temporary restriction) available for reuse after/during the project? Yes, as restricted data (upon approval, or institutional access only) Please explain per dataset or data type which □ No (closed access) data will be made available. □ Other, please specify: 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/#INF **OEUREPO-ACCESSRIGHTS** All data will be generated and collected within the Leuven Diabetes lab. Data may be shared externally upon If access is restricted, please specify who will be reasonable requests from collaborating scientists, which will be reviewed and approved on a case-by-case able to access the data and under what basis by the project lead. Single cell omics data are mostly deposited in open access repositories upon conditions. publication.

Are there any factors that restrict or prevent the	☐ Yes, privacy aspects
sharing of (some of) the data (e.g. as defined in	☐ Yes, intellectual property rights
an agreement with a 3rd party, legal	☐ Yes, ethical aspects
restrictions)? Please explain per dataset or data	☐ Yes, aspects of dual use
type where appropriate.	□ Yes, other
type where appropriates	⊠ No
	If yes, please specify:
Where will the data be made available?	☐ KU Leuven RDR
If already known, please provide a repository	□ Other data repository (specify)
per dataset or data type.	□ Other (specify)
	Relevant raw data will at that same moment be made available in well-established open-access data
	repositories.
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	□ CC-BY 4.0 (data)
provide? If none, please explain why.	□ Data Transfer Agreement (restricted data)
	□ MIT licence (code)
A DATA USAGE LICENSE INDICATES WHETHER THE DATA CAN BE	☐ GNU GPL-3.0 (code)
REUSED OR NOT AND UNDER WHAT CONDITIONS. IF NO LICENCE IS	□ Other (specify)
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 <u>License selector</u>	
tool to help you choose.	

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, please provide it here.	 ⊠ Yes, a PID will be added upon deposit in a data repository □ My dataset already has a PID □ No
INDICATE WHETHER YOU INTEND TO ADD A PERSISTENT AND UNIQUE IDENTIFIER IN ORDER TO IDENTIFY AND RETRIEVE THE DATA.	
What are the expected costs for data sharing? How will these costs be covered?	Costs for data sharing will be discussed with collaborators on a case-by-case basis.

	7. Responsibilities
Who will manage data documentation and metadata during the research project?	Students and technicians involved in the project will be responsible for data documentation.
Who will manage data storage and backup during the research project?	Students and technicians will have the daily responsibility of recording all data (i.e., digital, paper, and biological samples). They will also be responsible for the correct and accurate data entry and recording of the metadata
Who will manage data preservation and sharing?	Conny Gysemans is responsible for the storage (J- and L-) drives of the Leuven Diabetes Lab. She will ensure data preservation and reuse.
Who will update and implement this DMP?	The PIs bear the end responsibility of updating & implementing this DMP.