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	**Jan Gunst, ORCID 0000-0003-2470-6393**
Contributor name(s) (+ ORCID) & roles	
Project number [1] & title	Toward facilitating recovery of critically ill patients by metabolic interventions and exploiting fasting-induced repair pathways: Recover-fast
Funder(s) GrantID [2]	Research Foundation – Flanders (FWO), 1842724N
Affiliation(s)	KU Leuven ROR identifier KU Leuven: 05f950310
Please provide a short project description	In the next 5 years, I will elucidate the ideal blood glucose target in critically ill patients, and translate the mechanistic insights of protection by fasting into a clinically applicable, fasting-mimicking intervention. A first part focuses on the ideal glucose target in adult critically ill patients, which is highly debated, especially since recent feeding strategies have shifted to less aggressive feeding in the early phase, which lowers the degree of stress hyperglycemia. I am the principal investigator of the multicenter TGC-fast RCT (N=9230), which randomized patients who do not receive early parenteral nutrition -the current feeding standard- to tight vs. liberal glucose control. The impact on acute clinical outcome has recently been published (Gunst J. et al. NEJM 2023). In brief, tight glucose control did not impact mortality, but associated with less morbidity. In this project, I will investigate the impact of tight glucose control in the absence of early parenteral nutrition on acute and long-term functional outcome and healthcare costs, study whether any impact depends on the preadmission level of glucose control, and study whether stress hyperglycemia independently associates with long-term diabetes. A second part focuses on developing and validating fasting-mimicking strategies. My previous research put forward fasting-induced autophagy and ketogenesis as protective. I will study a potential role of ketones in mediating outcome in the TGC-fast RCT, and I will study two promising, novel fasting-mimicking strategies in animal and patient studies, to design a proof-of-concept RCT in patients, with the ultimate aim of improving patient care.

[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.

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
WP1	TGC-fast (effect on muscle weakness)	☒ Generate new data ☒ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:	.pdf, .readme files, .xlsx, .csv, .fmp, .jmp	☒ < 1 GB (new data) ☒ < 100 GB (existing data) ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	
WP2	TGC-fast (long-term functional outcome)	☒ Generate new data ☒ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:	.pdf, .readme files, .xlsx, .csv, .fmp, .jmp	☒ < 1 GB (new data) ☒ < 100 GB (existing data) ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	
WP3	TGC-fast (costs)	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical	.pdf, .readme files, .xlsx, .csv, .fmp, .jmp	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB	

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

				☒ Textual ☐ Model ☐ Software ☐ Other:		☐ > 5 TB ☐ NA	
WP4	TGC-fast-ketones	☒ Generate new data ☒ Reuse existing data	☒ Digital ☒ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:	.pdf, .readme files, .xlsx, .csv, .fmp, .jmp	☒ < 1 GB (new data) ☒ < 100 GB (existing data) ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	Measurements on 10000 stored blood samples already stored/available in biobank; storage volume approximately 2-3 ml per sample
WP5	TGC-fast (HbA1c)	☒ Generate new data ☒ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:	.pdf, .readme files, .xlsx, .csv, .fmp, .jmp	☒ < 1 GB (new data) ☒ < 100 GB (existing data) ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	
WP6	Long-term diabetes	☒ Generate new data ☒ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:	.pdf, .readme files, .xlsx, .csv, .fmp, .jmp	☒ < 1 GB (new data) ☒ < 100 GB (existing data) ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	

WP7	KETOCARE	☒ Generate new data ☐ Reuse existing data	☒ Digital ☒ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:	.pdf, .readme files, .xlsx, .csv, .fmp, .jmp	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	Blood and urine samples will be collected: 28 samples per patient x 16 patients = 448 tubes of 2-3ml. If necessary, depending on the results, the experiment may be repeated once or twice with a higher dose.
WP8	FM-drug – mice	☒ Generate new data ☐ Reuse existing data	☒ Digital ☒ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:	.pdf, .readme files, .xlsx, .csv, .fmp, .jmp	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	Pilot study: 1 blood and urine sample of 12 mice. Proof-of-concept study: 1 blood, urine, heart, kidney, liver and muscle sample of 30 mice. Total: 204 tubes for biological samples (tube volume approximately 1.5 ml).
WP9	FM – patient	☒ Generate new data	☒ Digital ☒ Physical	☐ Audiovisual ☐ Images ☐ Sound	.pdf, .readme files, .xlsx, .csv, .fmp, .jmp	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB	Daily blood and urine samples will be collected.

		☐ Reuse existing data		☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:		☐ < 5 TB ☐ > 5 TB ☐ NA	Estimating a median ICU stay of 7 days, this will result in 560 blood and 560 urine samples (of 2-3ml each).
WP10	POC – patient	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☒ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:	.pdf, .readme files, .xlsx, .csv, .fmp, .jmp	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	

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.	The reused data have been collected by myself (TGC-Fast) and by our research group (EPaNIC). Data are stored on UZ Leuven servers, and biological samples are stored in the biobank. The analyses for which existing data (or biological samples) will be (re)used (or analyzed for the first time) are prespecified secondary analyses and mechanistic studies of patients included in the TGC-Fast and EPaNIC RCTs, for which ethical approval and informed consent have been obtained.

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: S61145 (WP1-6), ML4190 (WP6), S67928 (WP7) ☒ Yes, animal data; provide ECD reference number: P163-2022 (WP8) ☐ Yes, dual use; provide approval number: ☐ No Additional information: As outlined in the submitted project, the last work packages (WP9-10) are conditional to the results of the first work packages. Before start of WP9-10, EC approval will be obtained.
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: S61145 (WP1-6), ML4190 (WP6), S67928 (WP7). As outlined in the submitted project, the last work packages (WP9-10) are conditional to the results of the first work packages. Before start of WP9-10, EC approval will be obtained.
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: The LOGIC-Insulin software has been patent-protected (invention by KU Leuven researchers; patent owned by KU Leuven). If the project confirms beneficial effects of tight glucose control on outcome in a cost-effective way (WPs 1-6), this could spark commercial interest. KU Leuven also holds a patent/patent application for ketone administration to critically ill patients (WP7±10).
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:

[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:

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 data are stored in a structured Filemaker database. All characteristics can be queried to retrieve specific participants or samples. Data can be exported as Excel files that are analyzed most often in JMP. The full study protocols describe data collection and definition of variables. Standing operating procedures are in place to describe data collection. For individual data elements requiring explanation, a definition is provided as info label in the structured database. All these documents are stored electronically in the structured study master file. We will keep a separate registry documenting the names and locations for raw and processed data exports as used for every step in the project.
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 All characteristics can be used as metadata in the structured Filemaker CRF to retrieve specific participants or samples. Metadata of experimental laboratory measurements will be provided as readme, word or excel files, containing all settings and technical descriptions of the experiment and data.

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) for WP8 ☐ Personal network drive (I-drive) ☐ OneDrive (KU Leuven) ☐ Sharepoint online ☐ Sharepoint on-premis ☐ Large Volume Storage ☐ Digital Vault ☐ Other: shared network drive UZ Leuven server (WPs 1-7 and 9-10)
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): Standard back-up provided by UZ Leuven IT
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 The storage volume made available by UZ/KU Leuven is appropriate for storage. Standard back-up is provided.

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 databases are user ID/password protected, with logged access control at network, directory and database level. Biological samples are stored in a registered biobank, only accessible to authorized people, with a log record of all sample handlings. The databases are stored on secure servers within UZ/KU Leuven, maintained by the IT department and maximally protected by firewalls and login procedures with daily backups. The biobank has standard procedures to protect adequate storage.
What are the expected costs for data storage and backup during the research project? How will these costs be covered?	None. If there would be costs associated for data storage, these costs will be covered by budgets of the laboratory of intensive care medicine.

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 (WP8) ☒ 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 (WP1-7, WP9-10) ☐ 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 for WP7 ☐ Large Volume Storage (longterm for large volumes) ☒ Shared network drive (J-drive) for WP8 ☒ Other (specify): UZ Leuven servers (WPs 1-7 and 9-10)
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	None. Data preservation on UZ Leuven servers is currently free of costs. The expected costs for data preservation on KU Leuven RDR are expected not to exceed the limit of 50 GB per year. If the dataset would exceed this limit, costs for data preservation will be paid by budgets of the laboratory of intensive care medicine.

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.	For all WPs, data sharing will be considered only on a collaborative basis with the PI, after evaluation of the proposed study protocol and statistical analysis plan.

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: The clinical databases contain sensitive and personal information. Although the data are pseudonymized, theoretically, it could be possible to identify a patient based on a combination of demographic characteristics and admission date/diagnosis. Therefore, it is important to only share those data that are necessary to answer a specific research question. For data obtained during clinical studies (WP1-7, WP9-10), study questions that fall outside the original study question are subject to ethical approval. Hence, as data sharing would occur in the context of a new study question, ethical approval would be needed.
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). For WP7, data will be deposited in the KU Leuven RDR. The clinical data will not be made available unconditionally in the public space, due to ethical and privacy restrictions.
When will the data be made available?	☐ Upon publication of research results ☐ Specific date (specify): ☒ Other (specify): Data sharing will be considered only on a collaborative basis with the PI, after evaluation of the proposed study protocol and statistical analysis plan.

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?	No costs are expected. If any occur, they will be covered by the requesting parties.

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	The clinical trial assistants and PhD students assistants affiliated with the project will manage data documentation and metadata, under supervision of the PI (Jan Gunst).
Who will manage data storage and backup during the research project?	For clinical studies (WP1-7, WP9-10), the database manager (Liese Mebis) will manage data storage and backup, under supervision of the PI. For animal studies (WP8), the PhD student affiliated with the project will manage data storage and backup, under supervision of the PI.

Who will manage data preservation and sharing?	The PI will manage data preservation and sharing, in collaboration with the database manager.
Who will update and implement this DMP?	The PI will update and implement this DMP, in collaboration with the database manager.