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	**Lies Langouche – ORCID ID 0000-0002-8564-6809**
Contributor name(s) (+ ORCID) & roles	**Jan Gunst - ORCID ID 0000-0003-2470-6393** **Michael Casaer - ORCID ID 0000-0002-7087-0795**
Project number [1] & title	Toward individualized nutrition in critically ill patients: from unraveling and identifying metabolic dysregulation to therapeutic interventions
Funder(s) GrantID [2]	G029525N
Affiliation(s)	x KU Leuven ☐ Universiteit Antwerpen ☐ Universiteit Gent ☐ Universiteit Hasselt ☐ Vrije Universiteit Brussel ☐ Other: ROR identifier KU Leuven: 05f950310

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[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 | Critical illness is any acute life-threatening condition for which the body requires intensive mechanical organ replacing therapy or pharmacological support to prevent imminent death. The initial cause of critically illness can be major trauma, surgery, severe infection, extensive burns or exacerbation of a chronic illness. Over 10% of patients develop protracted critical illness and remain dependent on life support for a prolonged period of time (several days to weeks to months). These patients often suffer from complications that are rather provoked by their ongoing critical illness than the original indication for admission. The metabolic pathways involved in the delayed recovery or the development of detrimental complications of protracted critical illness remain poorly understood. Better identification and understanding might thus lead to major clinical progress. We want to investigate whether a hampered switch from carbohydrate to lipid metabolism in nutrient restricted conditions during critical illness might contribute to compromised clinical outcomes. We hypothesize that carnitine deficiencies contribute to such impaired metabolic switch and to the phenotype of prolonged critical illness. We aim to enhance specific nutritional metabolic pathways in order to improve outcome and to identify improvement of metabolic homeostasis through novel "ready-to-feed" indicators. |

				2. Research Data Summary			
				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	Animal study: The impact of parenteral nutrition infusion on phosphate redistribution in septic mice.	☒ Generate new data ☐ Reuse existing data	☒ Digital ☒ Physical	☒ Audiovisual ☒ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☒ Software ☐ Other:	pdf, txt, xlsx, csv, jmp, tiff, jpeg, ppt, doc pdf, png, svg, jmp, sas, R, RMD files	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	Tissue and plasma samples
WP2	Patient study: The impact of intermittent nutrient provision on phosphate redistribution in prolonged critically ill patients.	☒ Generate new data ☒ Reuse existing data	☒ Digital ☒ Physical	☒ Audiovisual ☒ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☒ Software ☐ Other:	pdf, txt, xlsx, csv, jmp, tiff, jpeg, ppt, doc pdf, png, svg, jmp, sas, R, RMD files	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	
WP3	Patient study: The occurrence of early and late (relative) hypophosphatemia and associated caloric intake in	☒ Generate new data ☒ Reuse existing data	☒ Digital ☒ Physical	☒ Audiovisual ☒ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☒ Software ☐ Other:	pdf, txt, xlsx, csv, jmp, tiff, jpeg, ppt, doc pdf, png, svg, jmp, sas, R, RMD files	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	

	relation to outcome.					
WP4	Patient study: Occurrence and impact of (relative) carnitine deficiency in the context of early enhanced feeding.	☒ Generate new data ☐ Reuse existing data	☒ Digital ☒ Physical	☒ Audiovisual ☒ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☒ Software ☐ Other:	pdf, txt, xlsx, csv, jmp, tiff, jpeg, ppt, doc pdf, png, svg, jmp, sas, R, RMD files	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA
WP5	Patient study: Impact of intermittent nutrition provision on (relative) carnitine deficiency in prolonged critically ill patients.	☒ Generate new data ☒ Reuse existing data	☒ Digital ☒ Physical	☒ Audiovisual ☒ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☒ Software ☐ Other:	pdf, txt, xlsx, csv, jmp, tiff, jpeg, ppt, doc pdf, png, svg, jmp, sas, R, RMD files	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA
WP6	Patient study: Association between carnitine deficiency and the development of muscle weakness.	☒ Generate new data ☒ Reuse existing data	☒ Digital ☒ Physical	☒ Audiovisual ☒ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☒ Software ☐ Other:	pdf, txt, xlsx, csv, jmp, tiff, jpeg, ppt, doc pdf, png, svg, jmp, sas, R, RMD files	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA

WP7	Animal study: impact of carnitine supplementation with standard PN.	☒ Generate new data ☐ Reuse existing data	☒ Digital ☒ Physical	☒ Audiovisual ☒ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☒ Software ☐ Other:	pdf, txt, xlsx, csv, jmp, tiff, jpeg, ppt, doc pdf, png, svg, jmp, sas, R, RMD files	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	Tissue and plasma samples
WP8	Animal study: impact of LCT-rich PN with differential glucose availability.	☒ Generate new data ☐ Reuse existing data	☒ Digital ☒ Physical	☒ Audiovisual ☒ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☒ Software ☐ Other	pdf, txt, xlsx, csv, jmp, tiff, jpeg, ppt, doc pdf, png, svg, jmp, sas, R, RMD files	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	Tissue and plasma samples
WP9	Animal study: Impact of an MCT- vs. LCT-rich PN	☒ Generate new data ☐ Reuse existing data	☒ Digital ☒ Physical	☒ Audiovisual ☒ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☒ Software ☐ Other	pdf, txt, xlsx, csv, jmp, tiff, jpeg, ppt, doc pdf, png, svg, jmp, sas, R, RMD files	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	Tissue and plasma samples

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.	WP2 and 5: secondary analysis of the ICU-FM1 study - doi: 10.1186/s13054-020-02987-3 W4: secondary analysis of the EPaNIC trial - doi: 10.1056/NEJMoa1102662. WP6: secondary analysis of the CROSS study – ISRCTN17621057
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: WP2 and 5 - S59328 WP3 - S68847 WP4 – S50404 WP6 – S58533 ☒ Yes, animal data; provide ECD reference number: WP1: to be requested WP7: to be requested WP8: CMM-P077/2023 WP9:to be requested ☐ Yes, dual use; provide approval number: ☐ No Additional information:
Will you process personal data[3]? 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):see above for numbers ☐ No Additional information:

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:
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

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[3] See Glossary Flemish Standard Data Management Plan

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.*	Data is stored in structured databases. All characteristics can be queried to retrieve specific participants or samples. Data can be exported as Excel files or csv files. 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. As soon as robust and conclusive data analyses will be achieved, data will be deposited in the Research Data Repository (RDR) of KU Leuven (https://rdr.kuleuven.be/) and will be available to the community upon reasonable request. Data will get a persistent DOI identifier upon deposit in the repository, and metadata including keywords will be added in the repository.
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: Data will be deposited in a format that can be accessible for everyone, and that is widely used as a standard in our scientific discipline. Mostly csv, txt and pdf file formats will be released to the KULeuven RDR. We will use SI units and standard vocabularies where possible.

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
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*	Study databases are protected, accessible only with restricted user ID and password. Access control is set at network, directory and database level.
What are the expected costs for data storage and backup during the research project? How will these costs be covered?	According to our plans, there will be no cost to make data and research outputs FAIR in this project, as repositories and other resources are provided by free, open access platforms. Data preservation on UZ Leuven servers is currently free of costs. Data preservation on KULeuven servers will be paid by other 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 ☒ 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):
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	No costs are expected. If any occur, they will be covered by the requesting parties.

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: 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.
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, 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. The animal databases contain research data that might generate novel IP. Data sharing will be considered only on a collaborative basis with the PI, after evaluation of the proposed study protocol and statistical analysis plan.
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)
When will the data be made available?	☒ Upon publication of research results ☐ Specific date (specify) ☐ Other (specify) Restricted, 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 researchers 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?	The researchers 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.
Who will update and implement this DMP?	The PI will update and implement this DMP.