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	**Pieter Gillard, ORCID: 0000-0001-9111-4561**
Contributor name(s) (+ ORCID) & roles	Margaretha Visser (0000-0003-0216-4028) – PhD; sub-investigator; UZ/KU Leuven; data collection and data analysis Sara Charleer (0000-0003-2100-4927) – PhD; post-Doc UZ/KU Leuven: data collection and data analysis Laura Valgaerts, ORCID: 0009-0002-2501-6554, PhD UZ/KU Leuven: data collection and data analysis
Project number [1] & title	Assessing novel technologies and glucometrics to improve glucose control and quality of life of people with type 1 diabetes
Funder(s) GrantID [2]	
Affiliation(s)	■ KU Leuven ☐ 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.

Please provide a short project description	Type 1 diabetes (T1D) is caused by the destruction of the cells that make insulin. People with T1D need to check blood glucose several times a day and administer the appropriate amount of insulin. Incorrect insulin dosing can lead to very low or chronically high glucose levels which can cause coma or organ damage. Novel technologies such as continuous glucose monitoring (CGM) and hybrid closed loop (HCL) systems offer the opportunity of improved treatment, but better knowledge regarding possible benefits and utility of different devices is needed. I will investigate the impact of different systems on glucose control and quality of life (QOL) of people with T1D and whether using data generated by these CGM systems (glucometrics) can help improving diabetes care. First, I will study long-term beneficial effects of real-time (rt) CGM and its health-economic impact in a pre-specified analysis of the ALERTT1 trial. Second, I will investigate if switching to more advanced systems or insulins impacts glucometrics and QOL. Third, I will collaborate with a group of machine learning experts to develop an artificial intelligence based model using data of patients on rtCGM systems and physical activity trackers. We will assess if this model can help to calculate how much insulin to inject around physical activity. Last, I will study the exact relation between number of insulin producing cells and glucometrics in patients who were autotransplanted with those cells after pancreatectomy.

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
INRANGE – Medtronic 780G database	Data (clinical data, glucose data and questionnaires) , digitalized in SPSS database	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	SPSS Statistics Data Document (.sav)	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	
INRANGE – Tandem database	Data (clinical data, glucose data and questionnaires) collected via eCRF Castor and digitalized in SPSS database	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	SPSS Statistics Data Document (.sav)	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	
GLADE – University Hospitals Leuven	Data (clinical, glucose, and questionnaires) collected via	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical	SPSS Statistics Data Document (.sav)	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB	

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

database	CSV format from proprietary software platforms, and digitalized in SPSS database digitalized in SPSS database			☐ Textual ☐ Model ☐ Software ☐ Other:		☐ > 5 TB ☐ NA	
ALERTT1 - (6-month RCT + 30-month extension) database	Data (clinical data, glucose data and questionnaires) collected via OpenClinica and digitalized in SPSS database	☒ Generate new data ☐ Reuse existing data	☒ Digital ☒ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	SPSS Statistics Data Document (.sav)	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	Multiple folders with original study documents (paper), stored centrally (UZ Leuven) and on-site
ENHANCED1 - database	Data (physical activity data, food intake data, glucose and insulin data) collected via application programming interfaces and digitalized in different databases	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	PostGresDB, MongoDB, and MinIO	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	

ATHLETE1-database	Data collected in ENHANCED1 study	☐ Generate new data ☒ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	PostGresDB, MongoDB, and MinIO	☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	
Transplant-database	All data combined of each study (RESCUE, FUTURE, ALERTT1, INRANGE)	☐ Generate new data ☒ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:	Database (.sav)	☒ < 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.	FOR ATHLETE1-database: Data collected in the ENHANCED1 (NCT05670366) will be reused. FOR Transplant database, data of the following studies will be reused: FUTURE: - NCT02898714 - DOI: 10.2337/dc19-1610 (results until 12 months) - DOI: 10.1089/dia.2022.0452 (results until 24 months) RESCUE: - NCT02601729 - DOI: 10.1210/jc.2017-02498 (results until 12 months) - DOI: 10.2337/dc20-1531 (results until 24 months) INRANGE: - NCT04414280 ALERTT1: - NCT03772600 - DOI: 10.1016/S0140-6736(21)00789-3 (results until 6 months) - DOI: 10.1016/S2213-8587(22)00352-7 (extension phase: results until 24 months)
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: INRANGE Medtronic and Tandem: B322201942115; ALERTT1 B322201838252; ENHANCED-1: B3222022000933; RESCUE: B322201526850; FUTURE: B322201526850 ☐ Yes, animal data; provide ECD reference number: ☐ Yes, dual use; provide approval number: ☐ No Additional information: For retrospective studie no specific EC approval (B-number) is provided. All studies on human data are or will be submitted for ethical approval (see S-number below for all S-numbers)

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). INRANGE Medtronic and Tandem: S63351; ALERTT1 S61830; ENHANCED-1: S64550; RESCUE: S58626; FUTURE: S59342; ATHLETE-1 S66569; GLADE: S66239; TRANSPLANT:S68425; ☐ 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: FOR ALERTT1 there is a contract agreement that pseudonymized data will be transferred to Dexcom FOR TRANSPLANT there will be a contract agreement on the transfer of pseudonymized data to VERTEX

3. Documentation and Metadata

[4] 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*.	SPSS Statistics Data Documents (.sav) contain a description (i.e. variable list, measurement units, scale information) of each variable in order to keep the data understandable and usable. Readme.txt files provide the necessary information to keep the data in database understandable and usable.
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: There is no metadata standard in our field. Project metadata of all databases (.sav) were created manually.

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: All the physical data (informed consent forms, collected data on paper) with personal data of the participants are stored in a safe location in UZLeuven, only accessible by the research team.
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/UZ 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:
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*	Paper data is secured in a safe location where only members of the research team have access. Data stored on the central servers are only accessible by those who have access to these digital folders. Only members of the research team have access.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?	Costs linked to data storage and back-up, if any, will be covered by the research grant. No costs

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): Paper data will be sent to an archive (OASIS: https://www.oasisgroup.be/) Digital data (anonymized) will be stored on the central server of UZ Leuven.

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	Data storage is estimated at €10.000. Costs linked to data storage and back-up will be covered by the research grant.

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.	Anonymous data are shared with centers participating the trials, based on research questions mentioned in an approved protocol by the relevant ethical committees. Selected anonymous data collected in the study and additional documents can be made available to others on the basis of a reasonable request and under a data transfer agreement signed by the institutions.

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: for all databases, sharing of data should follow privacy regulation, legal restrictions and contracts will need to stipulate that intellectual property will remain at KULeuven/UZLeuven
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). Data will be made available if an agreement (approved by EC and CTC) is made with outside parties. It will also specify which data repository will be used or how the data will be shared.
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) Data will be made available if an agreement (approved by EC and CTC) is made with outside parties. It will also specify which data repository will be used or how the data will be shared.
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?	

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	The PhD researchers (Jolien De Meulemeester, Laura Valgaerts, future others) or sub-investigator (Margaretha Visser) will be responsible for managing data documentation and metadata, together with the team of research assistants (Head Hilde Morobe). Ultimately, managing data documentation and metadata is the responsibility of the supervisor (Pieter Gillard).

Who will manage data storage and backup during the research project?	The PhD researchers (Jolien De Meulemeester, Laura Valgaerts, future others) or sub-investigator (Margaretha Visser) will manage data storage and backup during the PhD research, together with the team of research assistants (Head Hilde Morobe). Ultimately, managing data storage and backup is the responsibility of the supervisor (Pieter Gillard).
Who will manage data preservation and sharing?	The PhD researchers (Jolien De Meulemeester, Laura Valgaerts, future others) or sub-investigator (Margaretha Visser) will manage data preservation and sharing, together with the team of research assistants (Head Hilde Morobe). Ultimately, managing data preservation and sharing is the responsibility of the supervisor (Pieter Gillard).
Who will update and implement this DMP?	The PhD researchers (Jolien De Meulemeester, Laura Valgaerts, future others) or sub-investigator (Margaretha Visser) will update and implement this DMP, together with the team of research assistants (Head Hilde Morobe). Ultimately, updating and implementing this DMP is the responsibility of the supervisor (Pieter Gillard).