FWO DMP Template - Flemish Standard Data Management Plan

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	Kaat Beunen (0000-0003-3557-0022)
Contributor name(s) (+ ORCID) & roles	Prof. dr. Katrien Benhalima (0000-0002-3325-0263): promotor Prof. dr. Chantal Mathieu (0000-0002-4055-5233): co-promotor Prof. dr. Pieter Gillard (0000-0001-9111-4561): co-promotor
Project number[1] & title	S64308: Closed-loop insulin delivery in pregnant women with type 1 diabetes (the CRISTAL study)
Funder(s) GrantID[2]	1S07723N
Affiliation(s)	☒ KU Leuven ☐ Universiteit Antwerpen ☐ Universiteit Gent ☐ Universiteit Hasselt ☐ Vrije Universiteit Brussel ☐ Other: Provide ROR[3] identifier when possible:

[1] "Project number" refers to the institutional project number. This question is optional since not every institution has an internal project number different from the GrantID. 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.

[3] Research Organization Registry Community. https://ror.org/

Please provide a short project description	Type 1 diabetes (T1D) during pregnancy is associated with an increased risk of maternal and neonatal complications such as preeclampsia, preterm delivery and congenital malformations. The risk for complications remains high, even with increased use of continuous glucose monitoring (CGM) and subcutaneous insulin infusion technologies (e.g. insulin pumps), highlighting the importance of achieving near-normal glycaemic control in pregnancy. With the CRISTAL study, my PhD project, we aim to investigate whether use of an artificial pancreas (closed-loop insulin delivery system) can improve glycaemic control in pregnancy and as such contribute to fewer pregnancy complications. There are currently no data from randomized controlled trials (RCT) evaluating commercially available closed-loop systems in pregnancy. In my project, safety, efficacy, feasibility, and cost-effectiveness of the 780G closed-loop system will be compared to usual standard of care therapy in an open-label RCT in pregnant women with T1D. We plan to include 92 participants with 12 large Belgian and Dutch hospitals. Half of all participants will be assigned to the 780G and the other half will continue with their current treatment. Participants can be included in the study up to 12 weeks of pregnancy. Follow-up is planned until delivery. Innovative markers to better predict glycaemic control and pregnancy outcomes will be evaluated by analysing CGM metrics and novel biomarkers from maternal and cord blood samples.

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[4].

				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
Primary source documents	Paper worksheets that are completed by study staff locally containing data on clinical examinations, patient-reported outcomes, health-economic aspects...	☒ Generate new data ☐ Reuse existing data	☐ Digital ☒ Physical	☐ Observational ☐ Experimental ☐ Compiled/ aggregated data ☐ Simulation data ☐ Software ☐ Other ☒ NA	☐ .por ☐ .xml ☐ .tab ☐ .csv ☐ .pdf ☐ .txt ☐ .rtf ☐ .dwg ☐ .tab ☐ .gml ☐ other: ☒ NA	☐ < 100 MB ☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☒ NA	Several pages
Electronic Case Report Form (eCRF): the Research Electronic Data Capture	The eCRF serves as a digital database for all obtained research data. All research results, often primarily collected on	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☒ Observational ☐ Experimental ☐ Compiled/ aggregated data ☐ Simulation data ☒ Software ☐ Other	☐ .por ☐ .xml ☐ .tab ☒ .csv ☒ .pdf ☐ .txt ☐ .rtf ☐ .dwg	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB	NA

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

(REDCap) web application	paper worksheets, are eventually collected in this database.			☐ NA	☐ .tab ☐ .gml ☐ other: ☐ NA	☐ NA	
Surveys	These are completed by participants online in REDCap by means of a tablet, laptop, or smartphone. Results automatically load into the REDCap database.	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☒ Observational ☐ Experimental ☐ Compiled/ aggregated data ☐ Simulation data ☒ Software ☐ Other ☐ NA	☐ .por ☐ .xml ☐ .tab ☒ .csv ☒ .pdf ☐ .txt ☐ .rtf ☐ .dwg ☐ .tab ☐ .gml ☐ other: ☐ NA	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	NA
Data of diabetes treatment devices	Data of diabetes treatment devices including the 780G insulin pump (investigational device), (blinded) continuous glucose monitoring systems and other diabetes technologies	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☒ Observational ☐ Experimental ☐ Compiled/ aggregated data ☐ Simulation data ☒ Software ☐ Other ☐ NA	☐ .por ☐ .xml ☐ .tab ☒ .csv ☒ .pdf ☐ .txt ☐ .rtf ☐ .dwg ☐ .tab ☐ .gml ☐ other: ☐ NA	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	NA

	which collect important treatment data.						
Blood samples	At screening and the study visits, one encoded sample for central analysis of HbA1c is collected and two encoded samples for future analyses of novel biomarkers and metabolomics are collected. At delivery, one encoded sample for measurement of C-peptide and two encoded samples for future analyses of new biomarkers and metabolomics are collected.	☒ Generate new data ☐ Reuse existing data	☐ Digital ☒ Physical	☐ Observational ☐ Experimental ☐ Compiled/ aggregated data ☐ Simulation data ☐ Software ☐ Other ☒ NA	☐ .por ☐ .xml ☐ .tab ☐ .csv ☐ .pdf ☐ .txt ☐ .rtf ☐ .dwg ☐ .tab ☐ .gml ☐ other: ☒ NA	☐ < 100 MB ☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☒ NA	Max. 1932 blood samples

Guidance: *Data can be digital or physical (for example biobank, biological samples, …). Data type: Data are often grouped by type (observational, experimental etc.), format and/or collection/generation method.* *Examples of data types: observational (e.g. survey results, sensor readings, sensory observations); experimental (e.g. microscopy, spectroscopy, chromatograms, gene sequences); compiled/aggregated data[5] (e.g. text & data mining, derived variables, 3D modelling); simulation data (e.g. climate models); software, etc.* *Examples of data formats: tabular data (.por,. spss, structured text or mark-up file XML, .tab, .csv), textual data (.rtf, .xml, .txt), geospatial data (.dwg,. GML, ..), image data, audio data, video data, documentation & computational script.* *digital data volume: Please estimate the upper limit of the volume of the data per dataset or data type.* *physical volume: Please estimate the physical volume of the research materials (for example the number of relevant biological samples that need to be stored and preserved during the project and/or after).*	
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

[5] These data are generated by combining multiple existing datasets.

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, please describe these issues further and refer to specific datasets or data types when appropriate.	☒ Yes, human subject data ☐ Yes, animal data ☐ Yes, dual use ☐ No If yes, please describe: Data will be processed in accordance with the European General Data Protection Regulation (AVG/GDPR) and Belgian Law (Belgian Law 30 Jul 2018) on the protection of natural persons with regard to the processing of personal data. As the responsible entity of the research, UZ Leuven is the controller of personal data that is processed in the context of the research. Participation in the study means that the physician investigator collects data and uses it for medical publications. The researcher has a duty to treat the collected data confidentially, which means that a participant's name will never be published in the context of a publication or a conference. Study data will always be numbered before transfer to third parties. This number (link between the participant and associated data) will be kept securely by the research team. The researcher is therefore the only person who can establish a link between number and participant. The transferred personal data does not include a combination of elements that allow to identify the patient. A coding procedure is also used for the blood samples, just as for medical data. Samples are therefore only provided with an identification code in the context of this clinical study. The researcher is responsible for ensuring the pseudonymization of the blood samples and the traceability of these blood samples. Under strict conditions, direct access to the medical record may be granted to authorized personnel of the sponsor or of its representative(s), to regulatory authorities or to other persons authorized by law to verify that the study is being performed correctly. Access is only granted to check the quality of the collected data. All persons who are allowed to inspect the medical file are bound by professional secrecy. Therefore, consent to participate in this study also means that encrypted medical data can be used for purposes described in this information form and that it is transferred to the above persons and/or institutions. Processing of personal data is necessary in order to be able to realize the scientific research purposes as described. Conducting academic research is one of UZ Leuven's statutory assignments. As a university

	hospital affiliated with KU Leuven, UZ Leuven must support science and education in the public interest. UZ Leuven wants to clarify the necessity of processing as part of scientific research and as a task of general interest, as the legal basis for processing data by UZ Leuven in the context of this research. In addition, UZ Leuven is subject to specific legal obligations that govern the processing of your data which may be necessary in the context of safety reporting (such as, for example, reporting adverse reactions to supervisory authorities). For data protection legislation, we follow the European GDPR regulations. Ethical approval number of the CRISTAL study project is S64308 (Belgian registration number: B3222020000272; Dutch registration number NL78535.000.21), first approved by the Ethics committee Research UZ/KU Leuven on 18/12/2020. This project is supported and monitored by the Clinical Trial Center of UZ Leuven. All obtained data will be entered and managed in the REDCap web application.
Will you process personal data[6]? If so, briefly describe the kind of personal data you will use. Please refer to specific datasets or data types when appropriate. If available, add the reference to your file in your host institution's privacy register.	☒ Yes ☐ No If yes: - Short description of the kind of personal data that will be used: Encoded data will be collected at study visits, from medical records and applicable software programs (related to diabetes treatment). Per participating site, there is a secure key file stored on a secure server containing patient identifiers (link between the participant and associated data), being the only file with patient identifiers accessible to local researchers. Kind of personal data that will be processed: person's name, address, e-mail, ID number, personal or work phone number, health data (data of clinical examinations, treatment, complications, laboratory results), demographic data, patient-reported data, and health-economic data. - Privacy Registry Reference: EC S-number of the CRISTAL study is S64308.

[6] See Glossary Flemish Standard Data Management Plan

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	
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).	The approved study protocol and data dictionaries will be used along with the data to keep it understandable and (re)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: Data dictionaries will be used to make the data easier to find and (re)use

4. Data Storage & Back-up during the Research Project	
Where will the data be stored?	Research data will be stored for a period of 15 years after the study is finished, according to local guidelines, at Merak NV (Steenhoevestraat 6, 2800 Mechelen). Our research group has long-standing experience with Merak NV for secure and long-term storage of data. All locked eCRFs will be downloaded from REDCap in PDF format (1 PDF file per patient) and these PDF files will then be stored on a USB stick (1 stick per site) which will be archived in the ISF with other research data at Merak NV. Digital data will be stored at the UZ Leuven server, department of Endocrinology, private sharepoint.

How will the data be backed up?
 	
What storage and backup procedures will be in place to prevent data loss? Describe the locations, storage media and procedures that will be used for storing and backing up digital and non-digital data during research.[7]
 	
Refer to institution-specific policies regarding backup procedures when appropriate.
	All obtained data will be stored at the REDCap web application. This will also serve as a back-up of the database. In addition, data is initially collected on primary source documents, i.e. paper (fill-in) worksheets, which will be archived at Merak NV for 15 years after the study is finished.
	
	In UZL REDCap, data is backed up as follows:
	• The web server backup regime is specified below:
	  ○ An hourly backup, the last 6 versions of which are saved
	  ○ A daily backup, the last 7 versions of which are saved
	  ○ A weekly backup, the last 6 versions of which are saved
	• The database backup regime is specified below:
	  ○ A nightly cold backup of all databases
	  ○ One month's storage of the nightly cold backups
	• Data restore, upon request

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 yes, please specify concisely: Primary source documents with data of local participants are stored locally at each site in secure rooms. Within one week after a study visit took place, data is transferred to REDCap in order to have a secure backup of all the data. Insufficient storage or backup capacities are not expected. If no, please specify:

[7] Source: Ghent University Generic DMP Evaluation Rubric: https://osf.io/2z5g3/

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.* [7]	REDCap is a modern, secure software application for building and managing online clinical research databases and survey forms. REDCap has the required safeguards for research data security and privacy (compliant with HIPAA). The REDCap system provides an intuitive interface for users to enter data and have real time validation rules (with automated data type and range checks) at the time of entry. These systems offer easy data manipulation with audit trails for reporting, monitoring and querying patient records. Every action by a user in REDCap is recorded and can be reviewed afterwards. In addition, access to REDCap should be requested by the data manager for all study staff (by means of the access request form). Thereafter, the data management department of the clinical trial center of UZ Leuven should evaluate the access to the CRISTAL project. Access can only be granted after a successful test is taken (score >80%). In REDCap, data access groups are created in REDCap for every participating site in a way that the study staff associated with that site only can access study-specific data for his/her own research site. Our research group has long-standing experience with Merak NV for secure and long-term storage of data. Research documents are stored in optimal conditions in secure storage facilities.
What are the expected costs for data storage and backup during the research project? How will these costs be covered?	Primary source documents are filed locally in binders provided by the sponsor, UZ Leuven. Costs of binders and printed paper worksheets are covered by the study budget. Use of the eCRF (REDCap) costs €80 per year for the general research project. Therefore, a cost of €240 is expected. This is also covered by the study 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...).	All data will at least be retained for 10 years. Collected blood samples will be stored in the biobank of UZ/KU Leuven (on -80°C) for no longer than 10 years according to blood sampling storage guidelines. We plan to store research data for a period of 15 years after the study is finished at Merak NV.
Where will these data be archived (stored and curated for the long-term)?	Research data will be stored and curated for a period of 15 years after the study is finished at Merak NV (Steenhoevestraat 6, 2800 Mechelen). Our research group has long-standing experience with Merak NV for secure and long-term storage of data. Digital data will be stored and curated on the REDCap web application and the UZ Leuven server, department of Endocrinology, private sharepoint.
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	Archiving of one box (with f.e. binders) is €250 for 25 years at Merak NV. The costs will be covered by the study budget.

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, in an Open Access repository ☐ Yes, in a restricted access repository (after approval, institutional access only, …) ☐ No (closed access) ☒ Other, please specify: During the project, research data will not be openly available. Only in the context of a master thesis, research data will be made available as embargoed data. After the project, data will be made available upon publication of the research results (in an open access journal).
If access is restricted, please specify who will be able to access the data and under what conditions.	Access to the CRISTAL study project in REDCap will only be applicable for study staff that completed a role-specifc test with a score >80%. The following roles are applicable: The coordinating investigator: - may create new (subject) records in REDCap for his/her own research site, can add, edit, organize project-wide reports, stats, charts and data dashboards - can execute data quality rules - can open and respond to data queries - has access to logging (i.e. audit trail) and calendar - can view, enter, edit and validate actual study-specific data for his/her own research site - authorized to review/validate site-specific medical data such as lab results, (S)AEs etc. - approves/signs completed eCRF records - authorized to lock/unlock own site's records via eSignature. The principal investigator(s) and investigator(s): - may create new (subject) records in REDCap for his/her own research site - can add, edit, organize site-

	specific reports, stats, charts and data dashboards - can execute data quality rules - can open and respond to data queries - has access to logging (i.e. audit trail) and calendar - can view, enter, edit and validate actual site-specific study data - authorized to review/validate site-specific medical data such as lab results, (S)AEs etc. - approves/signs completed eCRF records - authorized to lock/unlock own site's records via eSignature Other study staff: - may create new (subject) records in REDCap for the research site he/she is affiliated with - can view, enter and edit actual site-specific study data - can open and respond to data queries - has access to logging (i.e. audit trail) and calendar I will be the data manager of the project which means that I: - can add, edit, organize site-specific reports, stats, charts and data dashboards - can execute data quality rules - can open, close and respond to data queries - has access to logging (i.e. audit trail) and calendar - cannot enter or manipulate actual study data collected within the eCRF The monitor/auditor of the study: - can add, edit, organize project-wide and site-specific reports, stats, charts and data dashboards, as relevant to the agreed scope of monitoring/auditing activities - has access to logging (i.e. audit trail) and calendar - cannot enter or manipulate actual study data within the production database (i.e. has data viewing rights only) - can open, close and respond to data queries - is assigned to project/site-specific user groups, as needed to execute the agreed scope of monitoring/auditing activities The statistician: - can add, edit, organize project-wide and site-specific reports, stats, charts and data dashboards - can

	execute data quality rules - cannot enter or manipulate actual study data within the production database (i.e. has data viewing rights only)
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 will the data be made available? If already known, please provide a repository per dataset or data type.	Participation in the study means that data is collected and will be used for medical publications. However, data will always be used in a pseudonymized (encoded) way. It is currently unknown in which medical journals research results will be published although we opt for high-quality journals within the topic.
When will the data be made available? *This could be a specific date (dd/mm/yyyy) or an indication such as 'upon publication of research results'.*	Upon publication of research results

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.* *EXAMPLE ANSWER: E.G. "DATA FROM THE PROJECT THAT CAN BE SHARED WILL BE MADE AVAILABLE UNDER A CREATIVE COMMONS ATTRIBUTION LICENSE (CC-BY 4.0), SO THAT USERS HAVE TO GIVE CREDIT TO THE ORIGINAL DATA CREATORS."* [8]	Currently unknown.
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 ☒ No If yes:
What are the expected costs for data sharing? How will these costs be covered?	Data sharing in the context of publications in (open access) medical journals is covered by the study budget.

7. Responsibilities

[8] Source: Ghent University Generic DMP Evaluation Rubric: https://osf.io/2z5g3/

Who will manage data documentation and metadata during the research project?	During the research project, every local principle investigator or a delegate is responsible for storage of locally obtained research data in the participating site (i.e. primary source documents and the eCRF): prof. K Benhalima (UZ Leuven), prof. B Lapauw (UZ Gent), dr. N Van Wilder (UZ Brussel), dr. D Lee (AZ Imelda), prof. F Nobels (OLVZ), dr. Y Taes (AZ St. Jan), dr. G Vanhaverbeke (AZ Groeninge), dr. D Ballaux (Vitaz), dr. X Aers (AZ Delta), dr. J Cuypers (AZ Turnhout), dr. V Preumont (UCL St. Luc) and dr. S Siegelaar (Amsterdam UMC). I am the data manager of the eCRF (REDCap) for all participating sites.
Who will manage data storage and backup during the research project?	The coordinating investigator of the project is prof. dr. Katrien Benhalima. Together with the data manager, she is the main responsible for the management of data storage and backup during the research project.
Who will manage data preservation and sharing?	The coordinating investigator is the main responsible for the management of data preservation and sharing.
Who will update and implement this DMP?	This DMP will be updated and implemented by the data manager of the project.