

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	Hannah Van Belle - https://orcid.org/0000-0001-8897-4229
Contributor name(s) (+ ORCID) & roles	Alexander Van De Bruaene - https://orcid.org/0000-0002-0469-8640 : promotor Kim Martinod - https://orcid.org/0000-0002-1026-6107 : co-promotor Sophie Pierard - https://orcid.org/0000-0003-0078-9788 : co-promotor Louise Coats - https://orcid.org/0000-0003-3422-5497 : co-promotor
Project number ¹ & title	Inflammation, Fibrosis and Thrombosis in Fontan circulatory failure: the INFINETx study
Funder(s) GrantID ²	Fonds voor Wetenschappelijk Onderzoek - Research Foundation Flanders (FWO) – 1115525N
Affiliation(s)	<input type="checkbox"/> KU Leuven <input type="checkbox"/> Universiteit Antwerpen <input type="checkbox"/> Universiteit Gent <input type="checkbox"/> Universiteit Hasselt <input type="checkbox"/> Vrije Universiteit Brussel <input type="checkbox"/> 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	<p>INFINETx is a prospective case-control multicentre translational study which aims for a better understanding of the pathophysiology of Fontan circulatory failure in patients born with a functionally univentricular heart. We hypothesize that the hemodynamic changes in a Fontan circulation induce a state of sterile inflammation, contributing to the development of fibrosis and thrombosis. We will study the role of inflammation with a focus on neutrophils as well as the renin angiotensin aldosterone system (RAAS) in the sequential development of fibrosis, diastolic dysfunction, decreased exercise capacity, heart failure, heart failure hospitalization and death. We will also examine markers of thrombosis and prothrombotic changes in neutrophils in Fontan patients and their association with thrombo-embolic events and mortality as hard endpoints. We also aim to validate shear wave elastography as a non-invasive measure of myocardial stiffness by comparison with fibrosis visualized by magnetic resonance imaging (MRI) and invasive pressure measurements when available. Lastly, we will characterize end-organ damage in Fontan patients by relating albuminuria with RAAS hormonal levels and the severity of Fontan circulatory failure on the one hand, thereby setting the stage for future clinical trials with SGLT2 inhibitors, and by assessing the reliability of spleen stiffness as a non-invasive measure of portal hypertension in Fontan associated liver disease on the other.</p>
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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 data⁴.

				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
		<input type="checkbox"/> Generate new data <input type="checkbox"/> Reuse existing data	<input type="checkbox"/> Digital <input type="checkbox"/> Physical	<input type="checkbox"/> Observational <input type="checkbox"/> Experimental <input type="checkbox"/> Compiled/aggregated data <input type="checkbox"/> Simulation data <input type="checkbox"/> Software <input type="checkbox"/> Other <input type="checkbox"/> NA	<input type="checkbox"/> .por <input type="checkbox"/> .xml <input type="checkbox"/> .tab <input type="checkbox"/> .csv <input type="checkbox"/> .pdf <input type="checkbox"/> .txt <input type="checkbox"/> .rtf <input type="checkbox"/> .dwg <input type="checkbox"/> .tab <input type="checkbox"/> .gml <input type="checkbox"/> other: <input type="checkbox"/> NA	<input type="checkbox"/> < 100 MB <input type="checkbox"/> < 1 GB <input type="checkbox"/> < 100 GB <input type="checkbox"/> < 1 TB <input type="checkbox"/> < 5 TB <input type="checkbox"/> < 10 TB <input type="checkbox"/> < 50 TB <input type="checkbox"/> > 50 TB <input type="checkbox"/> NA	
Patient data	Demographics, medical history, history taking and physical examination,	Reuse existing data (medical history, clinical follow-up, events/outcome collected during	Digital	Observational and experimental	Data is primarily stored in the KWS electronic medical database (EMD). The data	<100 MB	NA

⁴ Add rows for each dataset you want to describe.

	outcome data (events during follow-up)	routine clinical practice) and generate new data (history taking and physical examination at baseline)			relevant to our research is stored in Redcap eCRF (.csv)		
Informed consent form (ICF)	Signed ICF	New	Physical	NA	NA	NA	3 folders of paper
Biobank sample storage form	Form tracking the amount and nature of stored samples in KUL Biobank	New	Physical	NA	NA	NA	1 folder of paper
Electrocardiogram	ECG: raw data and trace	New	Digital	Observational	.xlsx (raw data) .png (trace)	<100MB	NA
Echocardiography + HFR SWE	Echocardiography and high frame rate shear wave images taken at baseline visit	New	Digital	Observational and experimental (some additional images to clinical standards)	.dcm (DICOM)	<5TB	NA
Labchart data	Invasive pressure measurement	New	Digital	Observational	.adicht	<100GB	NA

	data						
Cardiopulmonary exercise test (CPET)	Table with gas exchange measurements and 9-panel graphs	New	Digital and physical (when printed)	Observational	.pdf	<100MB	2 folders of paper
Cardiac MRI	Magnetic resonance imaging: report from radiologist in KWS (EMD), relevant information is being stored in redcap	New	Digital	Observational and experimental (MRI is clinically indicated in route follow-up, results are also used for research purposes)	.csv	<100 MB	NA
Liver echography	Report from radiologist in KWS, relevant information is being stored in redcap	New	Digital	Observational	.csv	<100MB	NA
Liver and spleen stiffness measurement (Fibroscan)	Report from KWS, relevant information is being stored in redcap eCRF	New	Digital	Observational	.csv	<100MB	NA

Blood draw	<ol style="list-style-type: none"> 1. Clinical lab analysis 2. Plasma preparation and storage at -80°C in aliquots of 1.5 ml 3. Neutrophil isolation and storage at -80°C 	<ol style="list-style-type: none"> 1. New 2. New 3. New 	<ol style="list-style-type: none"> 1. Digital 2. Physical 3. Physical 	Experimental	<ol style="list-style-type: none"> 1. .csv, .xlsx 2. NA 3. NA 	<ol style="list-style-type: none"> 1. <100MB 2. NA 3. NA 	<ol style="list-style-type: none"> 1. NA 2. 3 freezer drawers in Biobank (~6ml per included person, 5 to 8 aliquots) 3. 1 freezer drawer in Biobank (1 aliquot in 1 on 3 participants)
Urine sample	Urine sample is sent to clinical lab for analysis, after which it is discarded. Relevant results are stored in the eCRF in Redcap	New	Digital	Experimental	.csv	<100MB	NA
Tissue samples	Cryopreserved tissue samples are stored at -20°C	New	Physical	Experimental	NA	NA	1 drawer in -20°C freezer (Biobank)
Confocal microscopy	Imaging files from confocal microscope	New	Digital	Experimental	.jpg .tiff	<100 GB	NA

ELISA	Results from ELISA tests on stored plasma <ul style="list-style-type: none"> - Raw ELISA readout files - Standard curve plotting output files - Output figures (Graphpad Prism) 	New	Digital	Experimental	.csv .xslm .prism, .png, .pdf	<100MB	NA
RNA sequencing data	Bulk RNA sequencing from stored neutrophils <ul style="list-style-type: none"> - Raw sequencing data files - Scripts for analysis - Output figures 	New	Digital	Experimental	<ul style="list-style-type: none"> - .fastq, .bam, .tsv, .count - .bash, .R, .rds - .xml, .csv, .txt, .xlsx, .png, .pdf 	<1TB	NA
Protocols	Word documents and notes in lab	New	Digital and paper	Experimental	.docx	<100MB	1 A4 laboratory notebook

	notebook						
Data analysis, presentations and manuscript preparation	Analysis in Excel and statistical programs (SPSS, GraphPad Prism) and text in word or pdf	New	Digital	Experimental	.xlsx .prism, .sav .jpg, .tiff .docx, .pdf, .ppt	<1GB	

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 DATA⁵ (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.	<p>Patient data: demographics and medical history. Securely stored in KWS (electronic medical database). Relevant information reused in redcap eCRF (.csv).</p> <p>Publicly available genetic reference databases such as Genome Browser, Gene Cards, Human Protein Atlas, Ensembl. Publicly available databases of chromatin accessibility, such as ATACdb. Publicly available ChIPseq data.</p>
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⁵ These data are generated by combining multiple existing datasets.

<p>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.</p>	<p><input checked="" type="checkbox"/> Yes, human subject data <input type="checkbox"/> Yes, animal data <input type="checkbox"/> Yes, dual use <input type="checkbox"/> No</p> <p>If yes, please describe (additional information): Yes. Approval from the Ethics Committee of UZ Leuven Hospitals has already been obtained (S67430). Datasets: all datasets are linked to/derived from human subject data.</p>
<p>Will you process personal data⁶? 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.</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes:</p> <ul style="list-style-type: none"> - Short description of the kind of personal data that will be used: <ul style="list-style-type: none"> ○ Demographics (.csv (redcap eCRF)) ○ Medical history (.csv (redcap eCRF)) ○ History taking/symptoms (.csv (redcap eCRF)) ○ Findings from physical examination (.csv (redcap eCRF)) ○ Results from technical exams done in clinic: ECG ((.csv (redcap eCRF), .png, .xlsx), spirometry (.csv (redcap eCRF)), echocardiography (including high frame rate imaging, (.csv (redcap eCRF), .dcm), cardiopulmonary exercise test (.csv (redcap eCRF), .pdf), cardiac MRI (.csv (redcap eCRF)), liver ultrasounds (.csv (redcap eCRF)), liver- and spleen transient elastography (.csv (redcap eCRF)) ○ Results from processing of blood and urine sample (.csv (redcap eCRF)) - All data derive from human subjects. - Privacy Registry Reference: NA. The study has been approved by the ethics committee of UZ Leuven (S67430).

⁶ See Glossary Flemish Standard Data Management Plan

<p>Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, ...)?</p> <p>If so, please comment per dataset or data type where appropriate.</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p>If yes, please comment:</p>
<p>Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/Data transfer agreements, research collaboration agreements)?</p> <p>If so, please explain to what data they relate and what restrictions are in place.</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p>There is a collaboration in place with UCL with material and data transfer agreement. This however does not restrict exploitation or dissemination of the data.</p>
<p>Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use?</p> <p>If so, please explain to what data they relate and which restrictions will be asserted.</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p>If yes, please explain:</p>

3. Documentation and Metadata

<p>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).</p>	<p>All patients and healthy volunteers are assigned a unique code when included in the study. This code is then used as identifier when analysing the research data.</p> <p>Patient information stored in digital files (eCRF in redcap) are classified by pseudonym. Raw data is also stored in folders per individual (by pseudonym). This is all done by a single researcher (HVB).</p> <p>Meta-data for the echocardiographic images (date, identifier) is included in the .dicom file that can be read by the EchoPac software. Meta-data for the labchart files is also included in the file itself (date, stage in protocol), and can be read via the software.</p> <p>Experimental protocols are written in a detailed manner in order to be understandable for future users, and stored digitally (.docx) to be able to share them in the future.</p> <p>These protocols stored in a secured UZ Leuven Onedrive, with regular backups, and will also be shared on a shared KUL drive upon study completion (maintained by KUL ICTS, routine backups).</p> <p>Manuscripts and supplementary materials will be made publicly available by upload to Lirias. However, not all patient data can be publicly shared to due privacy issues.</p> <p>Physical data: folders are labelled (i.e. informed consents patients/controls, sample storage forms... with the study number (S67430)). The Lab notebook is named and experiments dated and titled with protocol enclosed. After completion of the study the folders will be stored in the secured desk of the PI for the required duration.</p>
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<p>Will a metadata standard be used to make it easier to find and reuse the data?</p> <p>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.</p> <p><i>REPOSITORIES COULD ASK TO DELIVER METADATA IN A CERTAIN FORMAT, WITH SPECIFIED ONTOLOGIES AND VOCABULARIES, I.E. STANDARD LISTS WITH UNIQUE IDENTIFIERS.</i></p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p>If yes, please specify (where appropriate per dataset or data type) which metadata standard will be used:</p> <p>If no, please specify (where appropriate per dataset or data type) which metadata will be created:</p> <p>DIGITAL DATA:</p> <p>Patient data: patient data will be stored in an electronic case report form (eCRF in Redcap) labelled with the patient's specific code. The eCRF is organized first by pseudonym, then by visit and further by exam (e.g. medical history, baseline characteristics, ECG, ultrasound...). Within these files, subheaders are used. All the variables included in the eCRF have a clarifying header describing the variable and units used.</p> <p>Raw data: every individual has a folder in which the raw data is stored. Raw data is always labeled with the pseudonym and date of generation.</p> <ul style="list-style-type: none"> - ECG: trace and raw data (pseudonym + ECG + trace (.png) or raw data (.xlsx) - Labchart: pseudonym + date (.adicht). Details about the protocol are included in the .adicht file itself. - Medical images: All images used in our study will be saved in the conventionally-used DICOM format which contains metadata in the file header. This header contains key technical attributes of each specific file. <p>Numeric data: Metadata of numeric data (both raw and processed) e.g. any headers of XLS, TXT, CSV files used throughout the study, will be created manually in a descriptive and structured manner. Patient's specific codes will be used when analyzing data.</p> <p>Documentation including experimental protocols and parameters (concentrations or titers measured, number of cells counted,...) will be recorded in physical laboratory books and stored into Word or Excel files, which also contain the necessary metadata (user, date,...) and parameters (cell count, concentrations...) regarding the experiment.</p>
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	<p>PHYSICAL DATA</p> <p>Protocols cfr supra. Folders are labelled by study number and content.</p> <p>Biological samples (plasma, neutrophils) stored in the biobank are retrievable with the help of an excel sheet in which each aliquot is recorded (place in box, shelf and freezer).</p>
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4. Data Storage & Back-up during the Research Project	
Where will the data be stored?	<ul style="list-style-type: none"> - Patient data: eCRF in redcap - Echocardiography images: KWS (electronic medical database with regular backups) - Protocols: UZ Leuven OneDrive (automatic daily back up).
<p>How will the data be backed up?</p> <p><i>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</i></p> <p><i>REFER TO INSTITUTION-SPECIFIC POLICIES REGARDING BACKUP PROCEDURES WHEN APPROPRIATE.</i></p>	<ul style="list-style-type: none"> - Redcap: automatic (institutional) - Raw data: is primarily stored in the KWS electronic medical database, from which the source data can always be retrieved if necessary (automatic back up, institutional). The images will be transferred to a large volume cloud-based storage with automatic back up (e.g. KUL L-Drive) where they will be saved for as long needed during and after the project. - Protocols: automatic back-up on OneDrive cloud (institutional). - Physical <ul style="list-style-type: none"> o Folders: Storage in locked desk. o Biological samples: storage in -80°C freezer, which is equipped with an alarm system to prevent damage in the case of dysfunction.

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

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.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, please specify concisely: Enough storage capacity in Redcap, UZ Leuven OneDrive and KU Leuven drives. Storage capacity can be increased if necessary. Enough freezer space and desk space for physical data. Back up is ensured by our institution (daily automatic backup saved on the UZ Leuven server). If no, please specify: NA
How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons? <i>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</i>	The eCRFs in Redcap can only be accessed by people that have been given access by our research group and are trained in the use of Redcap. Double authentication is used (hospital-level security). The OneDrive is personal to the grant holder and secured by double authentication. The KUL drives are also secured by double authentication. Desks are always locked when left unattended. If data has to be transferred it will be done either directly to the secured systems or via Belnet filesender.
What are the expected costs for data storage and backup during the research project? How will these costs be covered?	Redcap: 80€/year UZ Leuven OneDrive: free (personnel) KUL L Drive (5TB): 569.2€/year These costs are covered by the Single Ventricle Research fund grant which covers the consumables of the project.

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...).	<p>Data will be stored for at least five years in agreement with the classical retention policies.</p> <p>Urine samples are being discarded after analysis.</p> <p>Plasma samples and tissue sections may have been used before the end of the 5- year term, remaining material will be stored up to 5 years. However, all related electronic documentation on these data will be saved.</p>
Where will these data be archived (stored and curated for the long-term)?	<p>Redcap serves as data storage and archive tool for the collected patient data during the legally required duration.</p> <p>Echocardiography images and other raw data will be stored on a large volume drive such as KU Leuven L-drives.</p> <p>Biological samples will be stored in the Biobank for the required period of time (if not used by experiments (e.g. ELISA, RNAseq) by the end of the study) and paperwork will be stored in the desk of the PI who is a staff member in the UZ Leuven clinic.</p>
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	<p>Redcap: 80€/year</p> <p>KUL L Drive (5TB): 569.2€/year</p> <p>Costs of biobank: not known yet (contract negotiations ongoing)</p> <p>These costs during the project are covered by the Single Ventricle Research fund grant which covers the consumables of the project.</p> <p>Long-term data storage and costs will be managed and evaluated by the principal investigator responsible for this project, Prof. Van De Bruaene.</p>

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/#INFO-EU-REPO-ACCESSRIGHTS](https://wiki.surfnet.nl/display/STANDARDS/INFO-EU-REPO/#INFO-EU-REPO-ACCESSRIGHTS)

- ☒ Yes, in an Open Access repository
- ☒ Yes, in a restricted access repository (after approval, institutional access only, ...)
- ☐ No (closed access)
- ☐ Other, please specify:

Data related to publications will be shared publicly in the supplementary materials of the journal and in the KUL repository (Lirias).

Access to patient data is restricted, but all data will be made available upon reasonable request if data handling is done in accordance to the ethical guidelines.

If access is restricted, please specify who will be able to access the data and under what conditions.

The PI is responsible for evaluating if the request to access data is reasonable and decides under which conditions the data is transferred and reused.

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:

As this is a small patient group which is being extensively phenotyped, even pseudonymised data can be traced back to the individual. The data is very sensitive as it contains medical/clinical data and events. Therefore, the data access is restricted to people with a legitimate right for access upon request after approval by the PI.

<p>Where will the data be made available? If already known, please provide a repository per dataset or data type.</p>	<p>All data is stored in Redcap. At the end of the study, the data will be extracted to an excel sheet for further analysis.</p>
<p>When will the data be made available?</p> <p><i>THIS COULD BE A SPECIFIC DATE (DD/MM/YYYY) OR AN INDICATION SUCH AS 'UPON PUBLICATION OF RESEARCH RESULTS'.</i></p>	<p>Data in published manuscripts will be made available in supplementary materials and more detailed data upon request (by email) to Prof. Van De Bruaene. The manuscript (accepted version) and supplementary materials will also be deposited in the KUL repository (Lirias). Remaining data collected during the study can be made available upon reasonable request.</p>
<p>Which data usage licenses are you going to provide? If none, please explain why.</p> <p><i>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.</i></p> <p><i>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</i></p>	<p>As advised by the KU Leuven RDM helpdesk and the license selector tool, we will use the Creative Commons Attribution-ShareAlike (CC BY-SA-4.0) license. This license allows others to use, copy, distribute, and modify the data for any purpose, as long as the original source is properly attributed and any modifications are distributed under the same license terms.</p>

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

<p>Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, please provide it here.</p> <p><i>INDICATE WHETHER YOU INTEND TO ADD A PERSISTENT AND UNIQUE IDENTIFIER IN ORDER TO IDENTIFY AND RETRIEVE THE DATA.</i></p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p>If yes:</p>
<p>What are the expected costs for data sharing? How will these costs be covered?</p>	<p>No costs expected. E.g. Belnet filesender is free.</p>

7. Responsibilities

Who will manage data documentation and metadata during the research project?	PhD researcher Hannah Van Belle will be responsible for the management of data documentation and metadata, with oversight by PI Prof. Van De Bruaene.
Who will manage data storage and backup during the research project?	PhD researcher Hannah Van Belle will be responsible for the data storage and backup during the research project, with oversight by PI Prof. Van De Bruaene.
Who will manage data preservation and sharing?	PI Prof. Alexander Van De Bruaene is responsible for the preservation of the data during and after the end of the research project, and for the data sharing.
Who will update and implement this DMP?	This initial version of the DMP will be adjusted throughout the project by the PhD researcher Hannah Van Belle. The PI bears the end responsibility of monitoring the updating & implementing this DMP.