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	**Jef Brebels - http://orcid.org/0000-0002-0920-8305**
Contributor name(s) (+ ORCID) & roles	**Arn Mignon - http://orcid.org/0000-0002-4339-8827 - Supervisor** **Veerle Bloemen - http://orcid.org/0000-0003-0332-2833 - Co-supervisor**
Project number [1] & title	**Development of a double-layered polymer-based tubular construct loaded with enzyme-responsive polymersomes for flexor tendon repair**
Funder(s) GrantID [2]	**1SH1D24N**
Affiliation(s)	KU Leuven ROR identifier KU Leuven: 05f950310
Please provide a short project description	Flexor tendon injuries are a significant problem for patients, healthcare, and society as a whole, due to extended healing times and various postoperative complications such as infections, adhesions, and scar tissue formation. The expression of collagen type III is largely responsible for the latter, diminishing the ultimate strength of the hand. These complications often necessitate re-operation or, in some cases, amputation. Flexor tendons lack the capacity for spontaneous healing, requiring traditional techniques such as suturing or grafting, which fail to provide an adequate long-term solution. In the last decade, researchers have attempted to produce constructs to address these recurrent issues, incorporating active compounds. However, this often results in a burst release and inadequate mechanical strength and thus not providing a combined solution for both the mechanical and biological problems. The proposal is designed to develop a smart polymer-based double-layer fibrous construct that provides an enhanced healing environment for injured flexor tendons. Additionally, by aligning the fibres parallel to the collagen fibrils by melt electrowriting, the aim is to reduce tendon scar tissue. The outer layer will be processed by electrospinning. Spraying of enzyme-responsive polymersomes in between the layers will ensure a controlled release of antimicrobial compounds. The proposal surpasses the current state-of-the-art in the biomedical field of flexor tendon repair.

[1] "Project number" refers to the institutional project number. This question is optional. Applicants can only provide one project number.

[2] Funder(s) GrantID refers to the number of the DMP at the funder(s), here one can specify multiple GrantIDs if multiple funding sources were used.

2. Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data [3].

The project will generate qualitative and quantitative experimental data from material syntheses and their corresponding physico-chemical, mechanical and biological analyses. The spectra and other produced files will be stored on a computer with regular back-ups to an online cloud. A second type of data that will be generated during the project will be numerical (quantitative read-outs and derived parameters) and multimedia files (images from live cell imaging, confocal microscopy). These data will be collected or exported in data objects such as Microsoft Excel spreadsheets (.xlsx) and image files such as .png, .tiff, .jpg and their respective raw image data which can be opened and analyzed with ImageJ, an open-source software. Due to the usage of different experimental set ups, the expected total volume will be up to one TB. A third relevant dataset will include all the research protocols, SOPs, PowerPoint presentations and publications which will be stored primarily as excel, word, PowerPoint and PDF files. The total volume is estimated to amount up to 50 GB. No personal data will be collected, nor will this data be used. All the data will be stored on the personal network drive of the involved researchers with automated regular backups on the OneDrive cloud and physical hard-drives. A summary can be seen in the following table 1.

Table 1. Summary of generated datasets

	Assay	Obtained file	Extension	Storage
Raw	Fourier-Transform Infrared Spectroscopy , Nuclear Magnetic Resonance, Gel Permeation Chromatography, mechanical tests (for instance with a Dynamic Mechanic Analyzer), Spectrophotometric read-outs	Spectra, graphs, datapoints exports	.csv, .txt	150 GB
Raw	Live cell imaging, confocal microscopy, regular microscopy	Image files	.png, .tiff, .jpg	200 GB
Processed	Image analysis, gel fraction, swelling ratio, antimicrobial effect, cell viability, mechanic profile, reaction yield, etc.	ImageJ macros, values exported to Microsoft Excel for analysis, statistical tests and derivation of parameters	.xlsx, .csv, processed images in their original extension	400 GB
Processed	Protocols, SOPs, PowerPoint presentations and publications	excel, word, PowerPoint and PDF	.xlsx, .docx, .pdf, pptx	50 GB

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

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.	No
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: ☐ Yes, animal data; provide ECD reference number: ☐ Yes, dual use; provide approval number: ☒ No Additional information:
Will you process personal data[4]? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).	☐ Yes (provide PRET G-number or EC S-number below) ☒ No Additional information:
Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.	☒ Yes ☐ No If yes, please comment: The potential for IP will be assessed during the research, which would mainly consist of patents. In such case, IP restrictions would be implemented on the related protocols and dissemination would be restricted upon patent protection.

[4] See Glossary Flemish Standard Data Management Plan

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). *RDM guidance on documentation and metadata*.	Descriptive metadata of items will be captured in XML files, the tracking will be managed by linking these to the date of the experiment. Furthermore, for every material protocol, an overview table will be made in excel where to reference the corresponding performed characterization. An electronic file is kept for each experimental set-up and results. These will always be backed-up in the cloud.
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: See above.

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) → Personal mass-storage hard-drive ☐ 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 There are 2 terabytes of space provided to each KU Leuven staff member, which is currently enough for storing research-related data. Big data such as extensive multimedia files will be stored on the personal network drive from KU Leuven. 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*	OneDrive encrypts the files with a unique AES256 key encrypted with a set of master keys stored in Azure Key Vault of Microsoft. OneDrive gives at-rest and in-transit encryption as standard for all users and file types. For the physical hard drive backups, these will be kept at the research location and will only be accessible by the researchers involved in the project. The institutional accounts and equipment are also protected from logging in by username and password complemented by an internal authentication developed by the university. KU Leuven drives are restricted to personnel of KU Leuven.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?	Two TB of storage on the institutional OneDrive is provided to every researcher for free by the university. The hard drives for data transfer can be bought on the project budget in case of need. The back-ups will be kept at the corresponding drive of KU Leuven network.

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) The research project involves the synthesis and improvement of procedures and protocols which are needed for the continuation of the research and will be stored indefinitely. These implementations result in Standard Operating Procedures (SOPs). This project may also re-use or continue from SOPs that have been logged in from former projects into dedicated platforms for data management (i.e., Microsoft Teams). Raw data of the project will also be stored on the personal network drive from KU Leuven.
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): Data of long-term value will be published in the form of research articles in journals with Open Access possibility; for which intermediate data and workflows used for the manuscript will be published alongside with the original data if suitable for the scientific community. The rest of the data will be kept stored on the personal drive of KU Leuven linked to the project and relevant data for future experiments will be kept on the OneDrive platform. Physical and automatic online back-ups performed regularly and will also be kept on the archive network drive from KU Leuven.
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	For storage on external hard drives, the cost is limited to the purchase of these. The storage on the university OneDrive platform and the university drives have no direct additional costs allocated to the research group.

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.	Institutional access 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: Yes, before sharing, the potential of IP will be assessed. If there is, its relevance will be communicated to the technology transfer department, after which all relevant data will be restricted until the filing of a patent. In the meantime, the data will be kept at KU Leuven's Research Data Repository. Once the patent is granted, the data will be published in articles with open access.

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 assessed as relevant for future research will be made available to researchers at the corresponding institute. • In a restricted access repository • Upon request by mail • Other (specify): at KU Leuven's shared drive with possible restrictions due to IP possibilities
When will the data be made available?	☐ Upon publication of research results ☐ Specific date (specify) ☒ Other (specify) • After an embargo period. • Upon publication of the research results • Should there be IP-related issues, an embargo will be established up to the publication of the IP
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?	These costs will be limited to the hard drives for physically transferred data. The data available in the OneDrive platform will not cause additional costs.

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	Arn Mignon (Supervisor)
Who will manage data storage and backup during the research project?	The involved researchers will be responsible for storing and sharing their generated data storage and for the creation of back-ups. Regular online back-ups will automatically be performed by the ICTS of KU Leuven.
Who will manage data preservation and sharing?	The involved researchers will be responsible for their own data preservation. These activities will be supervised by the corresponding PI's.
Who will update and implement this DMP?	The supervisor (Arn Mignon) bears the end responsibility of updating & implementing this DMP.