Plan Overview

A Data Management Plan created using DMPonline.be

Title: Strengthening FIBEr's competitive position in the medical device industry

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Principal Investigator: Nele Famaey

Data Manager: Nic Vermeeren, Matijs Loeckx, Kimberly Crevits

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Template: KU Leuven BOF-IOF

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Project abstract:

Within this project, FIBEr, KU Leuven Core Facility for Biomechanical Experimentation will strengthen its position as a testing laboratory for the mechanical evaluation of medical devices. Medical devices are evaluated using in vitro bench tests, animal and/or clinical trials, and by using computational models. FIBEr offers services for each of these methods, thereby focusing on mechanocompatibility, i.e. the mechanical match between the medical device and the surrounding tissue. During this project we will further expand our portfolio for academic and industrial customers by focusing on 1) implementing the ISO17025 for certified testing, 2) gaining expertise in fatigue testing of orthopedic and cardiovascular devices, and 3) developing a set-up to study in vitro biodegradability of implants.

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Strengthening FIBEr's competitive position in the medical device industry

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.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		*Indicate: **N**(ew data) or **E**(xisting data)*	Indicate: **D**(igital) or **P**(hysical)	Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
1. Data from the experiment							
1.1. Clinical data	Data regarding general health and biometric parameters of animal/patient	E	D	N	csv	< 1GB	
1.2. Geometrical data	Medical scans (CT, MRI, US), microCT data, pictures of the tissue samples	N	D	I	tiff, dicom	> 5 TB	
1.3. Histological data	Histological slices, accompanying images, accompanying quantitative data (e.g. sample thickness, constituent fraction)	N	D, P	I	physical slices, tiff, csv	< 100GB	
1.4. Mechanical data	Raw data of the mechanical experiments	N	D	N	csv, xlsx, txt	< 1TB	
2. Data from parameter optimization							
2.1. Parameter fitting code	Matlab and python code that has as input the raw data of the mechanical experiments, and as output the material parameters of a certain constitutive model Abaqus model used for inverse parameter fitting	N, E	D	SO	py, m	< 100 GB	
2.2. Resulting material parameters	Output from parameter fitting code	N	D	N	txt	< 1 GB	
3. Data from FE simulations							
3.1. Abaqus files	Data to run and process FE simulations. This contains user materials, models and output files	N	D	SO	for, cae, inp, odb, py, csv	< 1 TB	
4. General computing code	All general computing code to process and analyze the results	N, E	D	SO	m, py	< 100 GB	
5. Operational files	General files for daily operations in and out of the lab. This includes quality system certification documentation.	N, E	D	T	MS office	< 1TB	

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:

We intend to reuse existing data. In case of human data, we will always check whether the original informed consent allows reuse of the data, or whether there are any restrictions on reuse.

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 below)
- Yes, animal data (Provide ECD reference number below)
- Yes, dual use (Provide approval number below)

Yes, ethical approval is obtained on a per study basis.

Will you process personal data? 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)

All data leaving the University Hospital is pseudonymized. This is done using a Matlab script. The patient key must be introduced and will be used to name the pseudonymized files. The directory of the original CT scan images must be introduced as well. The resulting new pseudonymized files will be stored in the current Matlab working directory. In this way, the patient name, birth date, address and ID will be removed.
cfr. https://admin.kuleuven.be/privacy/en/intranet/researchers

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

FIBEr performs experiments for industrial clients. The data that is shared differs per project. Usually the raw mechanical test data is shared (1.4 in first question), and a report is created (in word or ppt and shared in pdf format).

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or Data transfer agreements, Research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Depending on the contract, certain restriction may apply on the data that is specifically part of a project with industry. A standard terms & conditions document specifies the default settings, cfr the next question.

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 in the comment section to what data they relate and which restrictions will be asserted.

- Yes

For mechanical tests performed at FIBEr, terms and conditions were agreed upon with LRD, in brief: Data related to mechanical tests of native biological tissue is the IP of FIBEr. Data related to mechanical tests of tissues that have undergone a certain intervention for which the materials or technique is the property of an external partner, and the tests are performed in

collaboration with this partner, is the IP of the partner, but available for use by FIBEr.
Test protocols: SOPs and specific protocols of the performed mechanical tests. There can be IP in the newly developed testing protocols. If developed entirely by members of the STB group, IP remains at KU Leuven. If external partners are involved, IP issues are dealt with on a per project basis.
Data processing & simulation software & accompanying files: IP belongs to the entity that created or maintains the code, usually FIBEr.

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).

1. Documentation from experiments
- Data related to identification of the tested sample
- Test protocols: SOPs and specific protocols of the performed mechanical tests on a certain sample
- Manuals: manuals for operating the testing devices, performing the scans, histology, etc.
- Logbook and pictures of experiments
2. Documentation from parameter optimization
- Parameter fitting code is properly annotated and contains a readme-file to describe its content.
- Resulting material parameters are always accompanied by a report of the parameter fitting run, indicating settings of the parameter fitting code.
- Version management of the scripts is done by Gitlab KU Leuven
3. Data from FE simulations
- All generated models are accompanied with a readme-file or contain a header to describe their content, author(s) and last modification date
- The simulation software automatically generate metadata for every simulation, according to their own standards
4. General computing code
- All generated processing and analysis code is accompanied with a readme-file and contains a header to describe its content, author(s) and last modification date.
- Version management of the scripts is done by Gitlab KU Leuven.

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.

- Yes

1. Metadata from experiments
- For all samples, identification metadata is created upon registration at FIBEr, according to predefined fields, which is then safely stored in the FIBEr database. (The FIBEr database is accessible to FIBEr users; registration and KU Leuven login required.)
- Specific protocol that was used to perform the mechanical test on a certain tissue. For our testing protocols, the FIBEr template is used, provided and reviewed by a member of the FIBEr team.
2. Metadata from parameter optimization
- Resulting parameters are always accompanied by a report of the parameter fitting run, indicating settings of the parameter fitting code.
- Any in-house developed code is properly annotated and accompanied by a readme-file.
3. Metadata from FE simulations
- The simulation software automatically generate metadata for every simulation, according to their own standards.
- Any in-house developed code is properly annotated and accompanied by a readme-file.
4. Metadata of general computing code
- Any in-house developed code is properly annotated and accompanied by a readme-file.
Data is uploaded to ManGO using a custom data acquisition and uploader. A predefined metadata schema is required to be filled out prior to uploading.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- ManGO
- Sharepoint online
- Other (specify below)

NAS buffer storage for temporary storage during data processing, located within the FIBEr lab and hosted by SET-IT.
Git repository for code development.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution

All data are stored on the university's central servers with automated back-up procedures.

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

All storage solutions have user management procedures in place only admins can perform.
FIBEr database is accessible to FIBEr users (registration and KU Leuven login required). Users have write-once rights (through the FIBEr uploader interface or the FIBEr apps webpage), data cannot be removed or modified except by an admin.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

KU Leuven charges a fixed price per TB on the different storage locations, whereby the average usage is charged on a yearly basis.
ManGO: ~ 35€ / TB / year
These cost are billed to the users of FIBEr based on how much space they require.

Data Preservation after the end of the Research Project

Which data will be retained for 10 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...).

- Certain data cannot be kept for 10 years (explain below)

All datasets will be retained for 5 years after the end of the project (and for publications, until 5 years after the work has been published). After this period, the data is handed over the respective PIs.
Biological samples are destroyed after mechanical testing and can't be retained due to preservation issues.

Where will these data be archived (stored and curated for the long-term)?

- Other (specify below)

ManGO cold storage

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

ManGO cold storage: < 35€ / TB / year,

These cost are billed to the users of FIBEr based on how much space they require.

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.

- Yes, as open data
- Yes, as restricted data (upon approval, or institutional access only)
- No (closed access)

Academic projects have their own data sharing protocol in place on a per study basis.
Data sharing for industrial projects is defined in the project's contract.

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

See previous question.

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, intellectual property rights

If applicable, restrictions are contractually agreed upon.

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- Other (specify below)

Academic projects have their own data sharing protocol in place on a per study basis.
Data sharing for industrial projects is generally done through Belnet Filesender.

When will the data be made available?

- Other (specify below)

Depends on project.

Which data usage licenses are you going to provide?

If none, please explain why.

- Other (specify below)

Academic projects have their own data sharing protocol in place on a per study basis.

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

Academic projects have their own data sharing protocol in place on a per study basis.

What are the expected costs for data sharing? How will these costs be covered?

Academic projects have their own data sharing protocol in place on a per study basis.

For industrial clients the cost shall be included in the quotation

Responsibilities

Who will manage data documentation and metadata during the research project?

FIBEr staff: kimberly Crevits, Nic Vermeeren, Thomas Overbergh & Heleen Fehervary

Who will manage data storage and backup during the research project?

The lab manager, Kimberly Crevits.

Who will manage data preservation and sharing?

The lab manager, Kimberly Crevits.

Who will update and implement this DMP?

FIBEr staff