OPSTAMET: Regulatory-grade properties of tissues for 'in silico medicine' through optimized and standardized mechanical testing

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 experiments							
1.1 mechanical data	raw + processed test data (geometrical + mechanical test itself)	N	D	I,N, T	.txt, .csv, .bmp	<100GB (long-term) <1TB (short term)	0
1.2 parameter fitting	parameter fitting code + resulting parameters	N+E	D	N,T	.mat	<1GB	0
2. Data from FE-simulations							
2.1 Abaqus files for test optimization	Data to run and process FE simulations used during the test-optimization process. This contains user materials, models and output files	N+E	D	N,T,M	.for, .cae, .inp, .odb, .py, .csv	<100GB (long-term) <1TB (short - term)	0
2.1 Abaqus files for uptake in silico health	Data to run and process FE simulations used during the uptake in silico health. This contains user materials, models and output files	N+E	D	N,T,M	.for, .cae, .inp, .odb, .py, .csv	<100GB (long-term) <1TB (short - term)	0
3. General computing code							
3.1 calibration material framework	Everything required to run the framework	N	D	N,T, SO		<100GB	0
3.2 Code to upload the mechanical data	Everything for the tools used to upload the mechanical test data from all participating institutes	N	D	N,T,SO		<1GB	0
3.3 Analysis script and code	All general computing code to process and analyze the results	N	D	N, SO	.mat, .py	<100GB	0
5. Publications	Articles, reviewer comments, revision letters	N	D	I, T	tex, pdf, docx, jpg, png	<1GB	0
6. Project applications		N	D	T	.tex, .pdf, .docx	<1GB	0
7. Presentations	Progress reports, conference presentations and posters	N	D	T, I	.pptx	<1GB	0

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:

Part of the code were generated in the past by STB, these will be taken from Gitlab

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, animal data (Provide ECD reference number below)

Although this project uses animal data, the required samples will come from the slaughterhouse, not requiring ethical approval.

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).

- No

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

There are multiple parts that have the potential to be valorized.

1. Calibration materials & framework to create them
2. Database with regulatory grade parameters
3. Model for in-silico simulations of biological tissues taking into account uncertainty quantification.

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

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.

- No

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
    - Test protocols: SOPs and specific protocols of the performed mechanical tests
    - 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.
    - 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
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.

In every case a readme-file is generated to make clear where everything stands

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
    - Data related to identification of the tested tissue/animal/patient. For our biological samples, metadata is created upon registration at FIBEr (KU Leuven core facility for biomechanical experimentation), 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's 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
    - Abaqus and LS-Dyna 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, roughly according to the template found here: https://cornell.app.box.com/v/ReadmeTemplate

Furthermore the standards that are created within the Soft Tissue Biomechanics group & FIBEr will be followed.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- ManGO
- Shared network drive (J-drive)
- OneDrive (KU Leuven)
- Sharepoint online
- Other (specify below)

Mechanical test data will be stored at FIBEr's ManGo storage.
Computer code will be saved on Gitlab
non-sensitive raw images will be stored at Google Cloud Storage
Other data will be stored on the J-drive (data used for collaboration within the KU Leuven), OneDrive (data mostly used by the researcher itself), Sharepoint online (Data used for collaboration with people outside of the KU Leuven)

How will the data be backed up?

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

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 data is securely stored on KU Leuven servers and only accessible by members of the research unit through authentication.

- 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 the moderator.
- J-drives:
  - FIBEr: access for FIBEr 'developers' and supporting personnel. Access granted on an individual basis by SET-IT support
  - STB: read/write access for all STB members (managed through a 'mechgroup' by NeleFamaey)
  - ADAPT: read/write access for all ADAPT members (managed through a 'mechgroup' by Nele Famaey)
  - IMPACT: read/write access for all IMPAct members (managed through a 'mechgroup' by Nele Famaey)
- I-drive: accessible only to the researcher
- K-drive: STB: read/write access for all STB members (managed through a 'mechgroup' by Nele Famaey)
- NAS: accessible only through FIBEr-desktops and SET-ME-B12011, SET-ME-B12010 or BMe VCL. Access to the latter is managed through a 'mechgroup' by Nele Famaey.
- Google Cloud Storage: accessible through this link: https://drive.google.com/drive/u/4/folders/1nU-17JHI1Q8Y4KfPiUewh2CyqBeTJ4Zl, login is required via the FIBEr biomech account (fiber-nas@biomech.be). The password can be found on https://gitlab.mech.kuleuven.be/BioMech/credentials/wikis/FIBEr-Archive, which is only accessible to FIBEr developers.
- The git repository is currently accessible to STB members only. Access rights are granted on an individual basis to involved master students.

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 cold storage: < 35€ / TB / year,
- KU Leuven RDR: 50GB for free
- K-drive: approximately 130 euro /TB/year
- J-drive: approximately 580 euro /TB/year

These costs will be covered with funding from the project

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). Biological samples are destroyed after mechanical testing and can in any case not be retained due to preservation issues.

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

- Other (specify below)
- Large Volume Storage (longterm for large volumes)
- Shared network drive (J-drive)

All mechanical test data is stored in the FIBEr database and stays there for at least 5 years after the project/publication.
During the project the data will be stored on the J-drive afterwards the data can be placed to MANGO or the K-drive.
If the data is part of a database than it will become archived on KU Leuven RDR.
Programming code will be archived on Gitlab

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,
KU Leuven RDR: 50GB for free
K-drive: approximately 130 euro /TB/year
J-drive: approximately 580 euro /TB/year

These costs will be covered with funding from the project

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)

All datasets with the exception of the biological samples are available for future use after publication, e.g. scientific results (in scientific peer-reviewed journal papers), standard operation protocols for mechanical testing.
Links will be provided as supplementary material to published journal papers.

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

Members of the research unit have access to the data via the shared drives. The scientific community has access to part of the data via a Mendely repository under the
following conditions of use: CC BY, in which appropriate credit must be given to the author and indication of changes must be made, and CC BY-NC, which adds a non-commercial term to the CC BY license.

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.

- No

Where will the data be made available?

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

- KU Leuven RDR (Research Data Repository)
- Other (specify below)

When will the data be made available?

- Upon publication of research results

Which data usage licenses are you going to provide?

If none, please explain why.

- CC-BY 4.0 (data)

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.

- Yes, a PID will be added upon deposit in a data repository

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

Costs for open access publications can be up to €3000 per publication. Sharing large datasets via data repositories can also be costly. Costs for open access publications and possibly for data sharing via repositories (if not free in use) will be covered by the budget of the project.

Responsibilities

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

The PhD & PD researchers are responsible for data documentation and metadata.

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

The PhD & PD researchers are responsible for data storage and back up during the project.

Who will manage data preservation and sharing?

The PhD & PD researchers are responsible for ensuring data preservation and sharing via the shared storage drive during the project. After the project, the PI will be in charge of this.

Who will update and implement this DMP?

The PhD & PD researchers are responsible for updating & implementing this DMP during the project. After the project, the PI will bear the end responsibility of updating & implementing this DMP.