IMMOBONE - Immunomodulation for bone tissue engineering

A Data Management Plan created using DMPonline.be

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Project abstract:

Tissue engineering (TE) refers to the branch of regenerative medicine that develops artificial grafts to replace or repair human tissues. Different TE strategies might either recapitulate tissue function outside the body or rely on endogenous regeneration. In both cases, a TE graft must integrate with the host after implantation. The translation of TE grafts to the clinical practice is still limited and requires novel insights into their therapeutic mechanisms of action.

The IMMOBONE project aims to generate novel evidence at the single-cell level of the host response to TE grafts and boost the graft-driven regeneration capacity. The project will build on a tibial defect model in mice, where the immune and the regenerative responses to the implantation of a hydrogel and an organoid-based graft will be characterized up to the single-cell level. The applicant will rationally define the most influential T cell subset for a regenerative response and functionalize the hydrogel-based graft to activate this specific cell type.

IMMOBONE is conceived to broaden the applicant's expertise in osteoimmunology, material sciences and bioinformatics, while enhancing his experimental and computational skill set. The applicant's background makes him uniquely suited to bridge the knowledge of the two supervisors involved. If successful, IMMOBONE will make the applicant an independent scientist and will contribute to the use of immunoengineering as an integral part of regenerative medicine.

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Application DMP

Questionnaire

Describe the datatypes (surveys, sequences, manuscripts, objects …) the research will collect and/or generate and /or (re)use. (use up to 700 characters)

New data generated:
a- Experimental immunohistochemistry, Immunofluorescence microscopy, histology and microCT images
microCT; size unknown; TIF/JPEG
Histology; Immunohistochemistry; Immunofluorescence; 10 MB/file; TIF/JPEG
b- Single-cell transcriptomic datasets (<1TB; table, .csv)
c- Numerical scripts for scientific programming (<100MB, Python and R programming languages)
d- Numerical outputs of postprocessing analyses (10MB/file, tables, .csv and plots, .svg)
e- Experimental protocols (<100MB, text, .txt) and lab notebooks (<100MB, Excel, .xlsx)
The expected total volume of data is below 5TB.

Existing data reused:
a- Transcriptomic datasets from the literature and in-house skeletal atlas (table, .csv)
b- Open-source packages for scientific computing (Python and R programming languages)

Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)

1. The electronic versions of the lab notebooks and personal electronic folders are maintained on all storage platforms. Prof Geris is responsible for data preservation after project completion.
2. Upon generation, standard electronic data will be stored on the 'drive' available on the user's computer and connected to the KU Leuven central storage infrastructure. Larger datasets (eg. microCT) will be stored on the Large Volume Storage of the KU Leuven ICTS. All documentaion stored on KU Leuven servers is backed-up on a dialy basis and overall data preservation conforms to an existing Disaster Recovery Plan.

   Long term storage is offered by the KU Leuven for large quantities of data not subject to much change and will be used to retain data after project completion.

What's the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)

Electronic data will be retained for the duration of the project and at least five years after completion. No deviation from the principle of preservation of data is envisioned.

Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)

The research activity will comply with the principles outlined by the the GDPR regulation (Regulation (EU) 2016/679) on the protection of individuals for the processing of personal data, and on the movement of such data. Personal data related to osteoprogenitor cell donors will be limited to patient age, sex and the presence of congenital defects with an impact on the musculoskeletal system (in accordance with ethics committee approval). It will only be disclosed to the researcher on a need-to-know basis, and only accessible on password protected computer systems. Subject data will be appropriately coded and identifiable by a unique identifier (pseudonymisation).

Which other issues related to the data management are relevant to mention? (use up to 700 characters)

- Data back-up: Electronic data is backed up on the ICTS data centre through automatic backups using "snapshot" technology and online storage of incremental data changes. When a file is stored, there is an immediate replication to the second ICTS data centre. ICTS can get the disaster copy active (online) within the hour.

- Storage costs: Storage and back-up of electronic data during and after the project are 125€/TB/year. They are covered by the host group and the central budget or the Prometheus platform it is part of.

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DPIA

DPIA

Have you performed a DPIA for the personal data processing activities for this project?

- Not applicable

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GDPR

GDPR

Have you registered personal data processing activities for this project?

- Not applicable

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FWO DMP (Flemish Standard DMP)

1. 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.

				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
		Please choose from the following options: • Generate new data • Reuse existing data	*Please choose from the following options:* • Digital • Physical	*Please choose from the following options:* • Observational • Experimental • Compiled/aggregated data • Simulation data • Software • Other • NA	*Please choose from the following options:* • .por, .xml, .tab, .cvs,.pdf, .txt, .rtf, .dwg, .gml, … • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
Microscopy images	Experimental immunohistochemistry, histology and Immunofluorescence images taken in brightfield or confocal microscopes	Generate new data	Digital Physical	Experimental	.tif .jpeg	<100GB	Tissue slides will be stored at room temperature, and they will take approximately 5 boxes.
microCT images	Experimental microcomputed tomography images	Generate new data	Digital	Experimental	.tif .jpeg	<1TB	
Single-cell transcriptomic datasets	Gene expression level of individual cells by simultaneously measuring the mRNA concentration of thousands of genes	Generate new data	Digital	Experimental	.fastq	<1TB	
Single-cell transcriptomic datasets	Gene expression level of individual cells by simultaneously measuring the mRNA concentration of thousands of genes	Reuse existing data	Digital	Experimental	.hdf5	<1TB	
Python and R scripts	Numerical scripts for scientific programming	Generate new data	Digital	Software	.py .ipynb .R	<100MB	

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:

An integrated single-cell atlas of the skeleton from development through adulthood
https://doi.org/10.1101/2022.03.14.484345

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes, animal data
- Yes, human subject data

All experiments involving informed consent and samples of human origin will be reviewed by the Ethics Committee of the Faculty of Medicine of KU Leuven (presided by Prof. Dr. Minne Casteels). For its review, the Committee is guided by the following international agreements and directives:
• the Helsinki Declaration on the Ethical Principles for Research involving Human Subjects adopted by the World Medical Association,
• the Universal Declaration on Bioethics and Human Rights adopted by UNESCO,
• the Good Clinical Practice (GCP) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001).
• the Charter of Fundamental Rights of the European Union (2000/C 364/01)
• the Convention of the Council of Europe on 'Human Rights and Biomedicine' (April 4, 1997)
• the directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004

All experiments involving research on small laboratory animals will be reviewed by the Ethics Committee of the Animal Research Facilities of the KU Leuven (presided by Prof. An Zwijsen). For its review, the Committee is guided by:
• the application of the 'three R's rule' (reduction, replacement, and refinement)
• the directive 2010/63/EU
• the Amsterdam protocol on animal protection and welfare.
For animal experiments, to comply with the ethical regulations concerning research with animals, a complete Ethical Committee Dossier (ECD), describing in detail all animal research procedures, the number of animals and animal species in this proposal and including all information concerning compliance with the 'three R's rule', will be submitted for review by the Ethical Committee of the Animal Research Facilities upon acceptance of the grant. Obtaining animals for the proposed studies will be always conditional on the approval and the ordering procedure

will be monitored by members of the Ethical Committee. An ECD file describing experiments similar as those described in this proposal has already been approved (in the context of Prof. Geris's ERC Starting and Consolidator Grants). In addition, KU Leuven has official authorization for housing/breeding rodents from the national government (LA2210515 and LA1210238). The following procedures will be described in the ECD need approval by the Ethical Committee before starting the experiments: (a) collection of tissues or RNA (euthanized mice), (b) orthotopic implantation of tissue construct using internal or external fixation devices (anaesthetized mice).

Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes

The applicant will comply with the principles outlined by the the GDPR regulation (Regulation (EU) 2016/679) on the protection of individuals for the processing of personal data, and on the movement of such data. Personal data related to osteoprogenitor cell donors will be limited to patient age, sex and the presence of congenital defects with an impact on the musculoskeletal system (in accordance with ethics committee approval). It will only be disclosed to the researcher on a need-to-know basis, and only accessible on password protected computer systems. Subject data will be appropriately coded and identifiable by a unique identifier (pseudonymisation).

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.

- No

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 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

2. 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).

Experiments are tracked using Benchlin, a cloud-based software platform providing electronic lab notebooks. Each experiment is assigned a documenting workflow where daily activities are tracked. Such documenting workflows are regularly exported in .html formats and stored in the Large Volume Storage of the KU Leuven ICTS.
Protocols are also created on Benchling and attached to the experiment documenting workflows. The procotols are regularly exported in .html formats and stored regularly in the Large Volume Storage of the KU Leuven ICTS.
Scripts for data analysis are all written in Python or R. Scripts are stored in Jupyter Notebooks (.ipynb format), where each single step of the analysis is also documented.

Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.

- No

There are no standards for metadata for most of the experiments carried out in this project. For this reason, all relevant experimental information for reproducibility will be collected and store it with the data: cell lines, culture conditions, instrument settings, experimental conditions (time points, control groups) and analysis software information will be included at the minimum.

3. Data storage & back-up during the research project

Where will the data be stored?

All experimental data will be stored in an electronic lab book with the chronological reporting of all related experiments. Results will be reported in electronic books that include a cross reference to the electronic lab book. All data, experimental lab books and reports are stored electronically on the personal KU Leuven One Drive for daily back-up and they are moved to the Large Volume Storage of the KU Leuven ICTS on a monthly basis. Larger and RAW data files (microCT images, RNA sequencing data) are directly stored on the Large Volume Storage of the KU Leuven ICTS.

How will the data be backed up?

Daily back-up of newly generated data is guaranteed with the KU Leuven One Drive service, while the the Large Volume Storage of the KU Leuven ICTS secures daily backup of the large files/datasets directly uploaded there.

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

The OneDrive has a limitation in storage capacity (2TB) which will be sufficient for the electronic lab notebooks, small datasets and experiment reports generated in this project. The reserach groups provides sufficient data storage for all larger data files in the Large Volume Storage of the KU Leuven ICTS.

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

Data stored in the KU Leuven One Drive is not accessible by any other person except the reseracher. Data files in the Large Volume Storage of the KU Leuven ICTS are only accessible by lab members via a two-step authentication system.

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

The KU Leuven OneDrive comes without charge, and will be enough for storing data/lab notebooks and reports for the entire duration of the project. The cost of the Large Volume Storage of the KU Leuven ICTS is covered by Prof. Geris.

4. 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 digital data generated during the project (Microscopy and microCT images, single-cell transcriptomic datasets, Python and R scripts) as well as the tissues slides will be stored for at least five years after the ending of the project.

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

The data will be stored in the Large Volume Storage of the KU Leuven ICTS. Tissue slides will be stored at the Skeletal Biology and Engineering Research Center of KU Leuven.

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

Prof. Geris will cover the cost of the Large Volume Storage of the KU Leuven ICTS as well as the cost for storing the tissue slides at the Skeletal Biology and Engineering Research Center of KU Leuven.

5. Data sharing and reuse

Will the data (or part of the data) be made available for reuse after/during the project? In the comment section please explain per dataset or data type which data will be made available.

- Yes, in an Open Access repository

Single-cell transcriptomic datasets, Python and R scripts will be deposited in Zenodo (CERN Data Center), which is a repository compliant with the OpenAIRE guidelines and located on European territory. Zenodo assigns uploads to the applicant's account and the portal of the funding agency,
thus increasing the visibility of both.
In addition, Python and R scripts will be uploaded on GitHub, which is a standard hosting service to share scripts in the scientific community.

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

Microscopy and microCT images will be accessible by all members of Prof. Geris' group.

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 in the comment section 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.

Single-cell transcriptomic datasets, Python and R scripts will be available in Zenodo (CERN Data Center).
Python and R scripts will also be available on GitHub.

When will the data be made available?

The data will be made available upon acceptance for publication of the related research papers.

Which data usage licenses are you going to provide? If none, please explain why.

There is no license associated to the use of single-cell transcriptomic datasets.
Python and R scripts wil be licensed under MIT license.

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.

- Yes

DOI will be provided upon acceptance for publication of the related research papers.

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

Both Zenodo and GitHub have no cost for uploading data.

6. Responsibilities

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

Gabriele Nasello

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

Gabriele Nasello

Who will manage data preservation and sharing?

Gabriele Nasello

Who will update and implement this DMP?

Gabriele Nasello