TRA-COAT: Development and in vivo validation of a novel resistance-proof triggered release antibiofilm coating for orthopaedic implants and vascular grafts.
DPIA

DPIA

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

- Not applicable

TRA-COAT: Development and in vivo validation of a novel resistance-proof triggered release antibiofilm coating for orthopaedic implants and vascular grafts.

GDPR

GDPR

Have you registered personal data processing activities for this project?

- Not applicable

TRA-COAT: Development and in vivo validation of a novel resistance-proof triggered release antibiofilm coating for orthopaedic implants and vascular grafts.

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, .csv,.pdf, .txt, .rtf, .dwg, .gml, … • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
Documents on existing data	Data related to established synthesis of 2-AI compounds, existing methods of coating adhesion, properties of model substrates, and current antimicrobial and microscopic protocols	Reuse existing data	Digital	Compiles/aggregated data	.docx .pptx	2 GB	
Documents on new data	All documents specifying protocols, test reports, results etc.	Generate new data	Digital	Compiled/aggregated data	.docx .pptx	2 GB	
Images	Images of samples, project activities etc.	Generate new data	Digital	Experimental	.jpg .bmp	10 GB	
Liquid chromatography mass spectrometry	Read-out of the release studies	Generate new data	Digital	Experimental	.xlsx .pzfx .raw		

Microbial cell counts via CFU	Read-out of antibiofilm activity (both in vitro and in vivo) and competition assay	Generate new data	Digital	Experimental	.xlsx .pzfx	<1GB	
Microbial cell counts via flow cytometry	Read-out for evolution assays and biofilm assays (both in vitro and in vivo)	Generate new data	Digital	Experimental	.xit .wsp .fcs	<100GB	
OD measurements	Read-out for MIC assays	Generate new date	Digital	Experimental	.xlsx .pzfx	<100 MB	
Bacterial biomass production	Measurement of biofilm biomass via crystal violet assay and MTT assay	Generate new data	Digital	Experimental	.xlsx .pzfx	<1GB	
Confocal and epifluorescence microscopy images	Microscopic images of bacterial biofilms (in both in vitro and in vivo set-ups) and microscopic images for histological evaluation for fracture healing (rabbit model and sheep model)	Generate new data	Digital	Experimental	.czi .tiff	3-5 TB	
RNA sequencing	RNA-sequencing of treated and untreated bacteria during different stages of biofilm formation	Generate new data	Digital	Experimental	.FASTQ .BAM	<1TB	
Whole genome sequencing	WGS data of the ancestral and selected evolved strains	Generate new data	Digital	Experimental	.FASTQ .BAM	<5TB	
Radiographs of rabbit limbs	1. Radiographs of the operated limb to evaluate osteotomy healing	Generate new data	Digital	Experimental	.dcm .tiff		
Mutant bacterial strains	Deletion mutants deficient in the biofilm-associated process	Generate new data	Physical				~ 10 mutant strains, stored in cryotubes

Evolved bacteria	Evolved bacterial populations and isolated clones from the evolved populations	Generate new data	Physical				~5000-10000 samples, stored in 96-well plate format
Rabbit tissue samples	Soft tissue and bone tissue originating from rabbit fracture model	Generate new data	Physical				~50 samples
Sheep tissue samples	Abcesses originating from the vascular graft model in sheep	Generate new data	Physical				~50 samples
Physical samples of functionalized film coatings	Samples of newly developed antimicrobial coating	Generate new data	Physical				

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 have already published several papers covering the synthesis and antibiofilm activities of 2-aminoimidazoles:

- https://doi.org/10.1021/jm1011148
- https://doi.org/10.1016/j.bmc.2011.04.026
- https://doi.org/10.1039/C3OB42282H
- https://doi.org/10.3390/molecules191016707
- https://doi.org/10.1128/aac.00035-16
- https://doi.org/10.1016/j.ejmech.2017.06.043
- https://doi.org/10.1016/j.bmc.2018.01.005

Additionally, we already have several publications covering the coating protocol and potential of 2-AI coated titanium surfaces:

- https://doi.org/10.3389/fmicb.2021.658521
- https://doi.org/10.1002/jbm.b.34283
- https://doi.org/10.1002/jor.23238

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

Rabbit and sheep experiments are planned in WP4 (year 3)
An application to the animal ethical committee of the KU Leuven will be submitted once the required preliminary data is collected.

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.

- 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

The new preventive coating will be valorized. IP will be protected by copyrights and patent applications.
The new *in situ* biofilm staging assay may be submitted to ASTM as new standardized method.

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

KU Leuven currently has a strong IP position regarding the 2-aminoimidazoles with granted patents with product claims, application claims and a long service life. We expect the new TRA-coating to be patentable due to the new use of boronic acid esters for the triggered release of antimicrobials.

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).

1. The data will be accompanied by a detailed metadata txt file denoting important characteristics (e.g. strain, material, time point,..) necessary for interpretation of the results. The key characteristics will also be denoted in the filename of the data files.
2. A detailed experimental protocol will be added to the directory of the corresponding experimental results. This step-wise description will facilitate potential future reproduction of the experiments.
3. For every deliverable in the project, a general outline txt file will be created. This file provides an overview of all the available data, the design of the experiment and the structure of the data saving.

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.

- Yes

Microscopy data: OME-XML metadata standard
Sequencing data: MIxS metadata standard
Flow cytometry data: MIFlowCyt metadata standard

A metadata template will be constructed in the frame of the project for data types where no general metadata standard is available.

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

Where will the data be stored?

1. Data generated by the different partners will be saved on a collective sharepoint for the data during the project. In view of the size of the raw microscopy and sequencing data, these data will be exempt from the sharepoint.
2. Additionally each partner will store their generated data on the central storage facility of their respective research units with the same structure as the sharepoints.
3. Personal copies can be made and kept on personal devices.

How will the data be backed up?

1. The collective sharepoint is backed up three times per day.
2. The internal back-up of the specific partners is managed according the procedures of their respective research institutions.

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

Sufficient storage space is provided by the respective research institutions

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

1. Viewing and modification rights in sharepoint are granted based on the involvement in the specific work packages.
2. Critical documents, e.g. reports, presentations,... can be (temporarily) locked by the author(s).
3. Sharepoint provides a changelog for detecting and reverting possible unauthorized changes.
4. The internal storage of the partners provides a back-up for the sharepoint and vice versa.
5. Physical data is stored in a secured -80°C freezer at the facility with limited-access.

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

1. The total cost of storage are estimated on ~€3000-€400 per year, mainly for the raw sequencing data (~5TB) and microscopic pictures (~5TB).
2.The costs will be covered by the respective partners using the allocated project budget

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 of the generated data will be stored for minimum 5 years after the end of the project

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

Digital data:

1. Every partner will store their generated data for at least 5 years according to the storage and back-up procedures present at their research institute.
2. The project coordinator will store the total generated data in the research project using the archive network (K:) drives

provided by the KU Leuven

Physical data:
Physical date will be stored in a secured -80°C freezer at the corresponding partner with limited-access.
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What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

The shared network at KU Leuven (used for temporary storage) covers 100GB per research unit. Additional storage on this drive costs approximately 580 euros per TB per year.
Long-term storage on the archive network (K: drives) cost approximately 130 euros per TB per year.
The costs will be covered by the project.

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.

- Other, please specify:

No data produced and/or used in TRACOAT will be made openly available by default. The TRACOAT project is focused on industrial competitiveness. Much of the data, as well as the existing data used for the project, will be of commercial interest for the partners, and it is necessary to exclude it from open access.
However, we still aim to be "as open as possible". Therefore, the consortium expects to eventually publish the most important project results through peer-reviewed publications, with open access to the related experimental data, when all required protection of IPR has been obtained. We will consider the IPR and open access requirements together in the context of the exploitation strategy for each result.

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

Third parties using the data are expected to include the following:

- Licensees and other external collaborators working with TRACOAT partners on commercialisation of results, needing access to project data to support scale up of production, analysis and other technical development activities. Data access covered by bilateral collaboration or license agreements, NDAs etc.
- Researchers interested to perform studies replicating the project results or comparing with data from their own research, e.g. antimicrobial performance of other types of coatings (only for data related to results disseminated in peer-reviewed publications that is made open access)

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.

- Yes, Intellectual Property Rights

There are legal considerations for the sharing of much of the expected research data relating to the eventual commercialisation of the results (see above)

Where will the data be made available? If already known, please provide a repository per dataset or data type.

The sequencing data will be deposited International Nucleotide Sequence Database Collaboration (INSDC)
For other data, trusted repositories will be used and these will be selected jointly by the data owners involved. For instance, KU

Leuven has previously used the Research Data Repository, RDR (KU Leuven's own institutional data repository, https://rdr.kuleuven.be/)

When will the data be made available?

The data will be made available upon publication of the corresponding research results. IPR of the novel coating will be addressed before dissemination.

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

Where data is disseminated with open access, we will use the following license: Attribution-NonCommercial-ShareAlike 4.0 International (CC BY-NC-SA 4.0).

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

All data that is made available by open access, will be uploaded to data repositories that provide a persistent identifier (DOI) for the dataset.

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

No costs are expected.

6. Responsibilities

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

The WP leaders carry the end responsibility for the correct documentation of the data generated in their respective WP

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

Each partner is responsible for correct data storage, i.e. sharepoint and internal, for the duration of the project. The project coordinator is responsible for the coordination of the data storage

Who will manage data preservation and sharing?

The coordinator of the project will collect all the data after the project and ensure correct preservation of the data

Who will update and implement this DMP?

The coordinator, together with the project partners, bears the end responsibility of updating & implementing this DMP.