GENERATION OF PURIFIED BIOMIMETIC NANOPARTICLES TO STIMULATE THERAPEUTIC DELIVERY TO TUMOR CELLS

A Data Management Plan created using DMPonline.be

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Project abstract:

To date, nanoparticle delivery to solid tumors in general, and the specific delivery to cancer cells has remained very low, as most nanoparticles are rapidly sequestered from the blood. To overcome this problem, scientists have looked at the concept of biomimetics, where engineered nanomaterials are surrounded by membranes isolated from natural cells in order to trick the immune system and delay nanoparticle clearance. Here, we aim to improve on the current biomimetics technology by using a novel in-house developed purification scheme that generates highly purified populations of nanoparticles coated with biological membranes. To enhance delivery, we will test the use of macrophage membranes to avoid immune cell recognition and chimeric antigen receptor (CAR)-natural killer (NK) cell membranes to specifically target the cancer cells. By making fusion membranes and further combining these biomimetic nanoparticles with pharmacological agents that stimulate tumor targeting (transcytosis induction and vessel normalization), we will perform an in-depth study of nanoparticle biodistribution. The improved tumor cell targeting will then be demonstrated by the targeted delivery of a therapeutic gene that will drive anti-cancer immune responses. This project will pave the way for enhanced delivery of nanoformulations to solid tumors (primary and metastatic nodules) and in doing so, can drive an entirely new field of targeted drug delivery using nanomaterials.

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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	
FLECT/IVIS	whole body in vivo imaging	New data	Digital	Experimental	DICOM	< 1TB	
ImageStream	image-based flow cytometry	New data	Digital	Experimental	.cif, .rif	< 5TB	
Intravital	Intravital microscopy	New data	Digital	Experimental	OME-tiff	< 5TB	
IHC	Immunohistochemistry	New data	Digital	Experimental	OME-tiff	< 1TB	
IHC2	Immunohistochemistry2	New data	Physical	Experimental		NA	400 tissue slides
tissues	collected tissue samples	New data	Physical	Experimental		frozen samples	100 tissue samples
cells	engineered cells	New data	Physical	Experimental		frozen samples	50 1,5mL vials
NP data	TEM, DLS, zeta-potential on nanoparticle properties	New data	Digital	Experimental	OME-tiff	< 100GB	
NP data2	numerical data	New data	Digital	Experimental	.csv, .xls	< 1GB	
reports	presentations and discussions on results	New data	Digital	Compiled/aggregated data	.docx; .pptx; .pdf	< 100 GB	

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:

NA

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

Datasets on FLECT/IVIS, intravital, IHC as well as tissues and cells will be obtained from animal experiments. These data sets will only be generated in the second year of the project and a project is being prepared to be submitted to the KULeuven animal ethics committee by the end of this month.

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

NA

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 data on the cells, but also the tissues samples, FLECT/IVIS, intravital and IHC are all linked to the generation of a novel method through which we can optimize nanoparticle delivery and which we may want to patent. During the runtime of the project, we will only share the data with members of the team that are actively involved in the project; using password-protected data folders specifically for this project where only active team members will be allowed access to seeing the data.

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

NA

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

NA

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).

For every set of images/data, a separate .xls file will be created linking the particular images, organised in folder to the exact experiment and listing the experimental details, date/time and people involved.
A second .xls file will be generated that will contain processed (numerical data) of analyzed images which will be linked to the first .xls file (i.e., tab sheet with list of source files interpreted).
A full overview of all data sets will be kept in a dedicated .xls file which will list all experiments performed with indication of date/time and where to find the source material and processed data. Reports are kept together with the above (in a shared storage place / folder).

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

DataCite; as we plan on applying for possible patent(s), we do not aim to deposit it on a public repository as long as the patent has not been approved, and after liaising with LRD.

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

Where will the data be stored?

All data will be stored in a project-dedicated L-drive (large volume storage servers, provided to all KULeuven researchers).

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

- Yes

Additional space (per 5TB) can be purchased through KULeuven ICTS for <€600/year.

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

The L-drive will only be accessible to team members working on this specific project. This includes the PI, the lab manager and the student(s) working on this specific project.

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

This will be approximately €1200/year, which will be paid for as part of the consumables money budgeted into the project.

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 data will be preserved for 10 years according to KU Leuven RDM policy

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

KULeuven K-drives for large volume storage (long-term for large volumes)

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

The costs will be approximately €1200/year. As most of the data are imaging-based, the data will be placed along with other imaging data of the C-More facility in a dedicated folder, only accessible for memvbers that have been involved in the original project. The costs for these will then be paid for by overheads and income generated by C-More-mediated services to external (industrial) partners.

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.

- No (closed access)

This will depend largely on our interactions with LRD and the patent application. At this moment, we do not plan to share the data during the project.

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

Only active team members involved in this project will have read access. This means only the PI, the lab manager and the PhD student(s) who contribute to this project.

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

NA

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

Depending on the outcome of the patent application, and LRD advice, we will not make the data available. Any data not relevant to the patent after discussion with LRD would be made available through KU Leuven RDR.

When will the data be made available?

Provisionally: upon granting of the patent

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

Data Transfer Agreement (restricted data)

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

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?

NA

6. Responsibilities

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

lab manager (Dr. Carla Rios Luci) and PI (Stefaan Soenen)

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

KU Leuven ICTS automatic backup.

Who will manage data preservation and sharing?

Stefaan Soenen

Who will update and implement this DMP?

Stefaan Soenen

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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)

Question not answered.

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)

Question not answered.

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)

Question not answered.

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)

Question not answered.

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

Question not answered.

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DPIA

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

Question not answered.

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GDPR

GDPR

Have you registered personal data processing activities for this project?

- Not applicable