Gouden-NK: het gebruik van goud-gemedieerde opwarming voor een verbeterde en veilige immunotherapie

A Data Management Plan created using DMPonline.be

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Template: KU Leuven BOF-IOF

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Project abstract:

Triple-negatieve borstkanker (TNBC) is een agressief subtype van borstcarcinoom waarbij recidief en metastasen vrij vaak voorkomen en de algehele overleving laag blijft. Nieuwe behandelingsopties op basis van immunotherapie hebben bij een klein deel van de patiënten veelbelovende resultaten laten zien, maar bij veel anderen is het niet effectief. Een belangrijke reden hiervoor is direct gecorreleerd met een niet-immunogene tumor micro-omgeving (TME). Er bestaan verschillende manieren om de immunogeniciteit van de TME te verbeteren, waaronder adoptieve overdracht van door chimere antigeenreceptor (CAR) gemanipuleerde T- of natural killer (NK)-cellen, inductie van immunogene celdood of inductie van hoge endotheliale venulen (HEV). Al deze methoden lijden echter aan de gevaren van off-target effecten en mogen alleen worden toegepast op de tumor of metastatische locaties. In het huidige project stellen we voor om nanotechnologie te gebruiken om deze problemen te overwinnen door de activering van alle therapieën mogelijk te maken door middel van nabij-infrarood licht (NIR) en hierbij selectief de therapeutische middelen die aanwezig zijn op de tumorplaats te activeren.

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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	
FLECT/IVIS	whole body in vivo imaging	N	D	I	DICOM	<1TB	
ImageStream	image-based flow cytometry	N	D	I	.cif, .rif	<1TB	
intravital	intravital microscopy	N	D	I	OME	<5TB	
IHC	immunohisto-chemistry	N	D	I	OME	<1TB	
tissue samples	collected tissues	N	P	tissues	frozen samples		
cells	engineered cells	N	P	cells	frozen samples		
nanoparticle characterization	TEM, DLS, Z-potential,	N	D	I	OME	<100GB	
nanoparticle characterization	numerical data	N	D	N	.csv, .xls	<1GB	
reports	presentation and discussion of results	N	D	T/N/I	.doc, .pdf, .ppt	<100GB	

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)? 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)

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 bring prepared to be submitted to the KULeuven animal ethics committee by the end of this month.

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

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 therapeutic entity that we would like 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 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

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

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 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

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.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Large Volume Storage

All data will be stored in a project-dedicated L-drive

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?

The L-drive will only be accessible to team members working on this specific project. These members will furthermore only have reading access. For every lab, there will be only 1 member who will have full access to write, read, and edit.

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.

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...).

- 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)?

- Large Volume Storage (longterm 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. The costs for these will then be paid for by overheads and income generated by C-More-mediated services to external (industrial) partners.

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.

- 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. Per lab involved, only 1 member will have full access to manage all datasets belonging to their own 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 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.

- Other (specify below)

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 trough KU Leuven RDR.

When will the data be made available?

- Other (specify below)

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 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?

NA

Responsibilities

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

Lab manager (Dr. Carla Rios Luci)
PIs (Stefaan Soenen, Colinda Scheele)

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, Colinda Scheele