Generator based therapeutic radiopharmaceutical production for targeting of fibroblast activation protein

A Data Management Plan created using DMPonline.be

Creator: Janke Kleynhans

Affiliation: KU Leuven (KUL)

Funder: Fonds voor Wetenschappelijk Onderzoek - Research Foundation Flanders (FWO)

Template: FWO DMP (Flemish Standard DMP)

Principal Investigator: Janke Kleynhans

Project Administrator: n.n. n.n.

Grant number / URL: 1226524N-7029

ID: 202618

Start date: 01-10-2023

End date: 30-09-2026

Project abstract:

Targeted Radionuclide Therapy (TRNT) is an established, evidence based treatment modality where a radioactive ligand (radiopharmaceutical) is injected intravenously allowing targeted irradiation of a primary tumour and all its metastasis that expresses the molecular target. When a diagnostic radionuclide is used, the radiopharmaceutical can be used for imaging applications. This study aims to develop highly selective radiopharmaceuticals targeting FAP in the TME radiolabelled with the generator-produced radionuclides rhenium-188 (therapeutic) or technetium-99m (diagnostic) to efficiently treat and image highly malignant PDAC, also in less developed countries.

Last modified: 04-04-2024

Generator based therapeutic radiopharmaceutical production for targeting of fibroblast activation protein 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)

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)

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)

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)

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

Generator based therapeutic radiopharmaceutical production for targeting of fibroblast activation protein
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.

Work Package 1: Fundamental Research

				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
Chemical Library of Compounds	Small samples of synthesised compounds and intermediates	New	Physical	N/A	N/A	N/A Inventory on Labguru	Up to 5 Boxes in -80 Freezer
Synthesis methods	Organic Synthesis & Radiolabelling methods	New	Digital	Experimental	N/A	Data on Labguru [Laboratory Management System]	5 Physical Laboratory Notebooks
Analysis methods	Analytical and Radioanalytical Methods	New	Digital	Protocols	N/A	Data on Labguru [Laboratory Management System]	N/A
LC/MS Data	LC/MS analysis for compound characterization	New	Digital	Experimental	.dat .hdx .pdf	< 100 GB Summary on Labguru	N/A
HPLC Data	HPLC & RadioHPLC data for compound purity	New	Digital	Experimental	.std .pdf	< 1 GB Summary on Labguru	N/A
NMR Data	Raw Data + assigned spectra & written report.	New	Digital	Experimental	.precomp .pdf	< 100 GB Summary on Labguru	N/A
Generator records	Certificates of analysis, elution records and radiation protection records	New	Digital	Experimental	N/A	Data on Labguru [Laboratory Management System]	1 Physical Laboratory Notebooks
Cold RP Standards	Samples + Certificates of Analysis	New	Physical	Inventory listed on LabGuru	N/A	Inventory on Labguru	1 Box in -80 Freezer

Work Package 2: In Vivo and In Vitro Evaluation

				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	Physical volume
Cell lines	In vitro cell lines used during experiments	New	Physical	N/A	N/A	Inventory on Labguru	Up to 80 samples in the cryopreservation unit
Growth records	Records of cell growth as well as tumour growth records	New	Digital	Experimental	Excel [.xls] and on Labguru	Data on Labguru [Laboratory Management System]	N/A
Animal welfare records	Records of weekly checks and animal weights	New	Digital	Experimental	Excel [.xls] and on Labguru	Data on Labguru [Laboratory Management System]	N/A
Protocols followed (in vivo and in vitro)	A detailed description of animal studies performed	New	Digital	Protocols	N/A	Data on Labguru [Laboratory Management System]	N/A
Tumour samples	Tumours collected for further analysis and reuse	New	Physical	N/A	N/A	N/A	10 Boxes in -80 Freezer
Assay results	Results and measurements	New	Digital	Experimental	Excel [.xls] and on Labguru	< 1 GB	N/A
Radioactive sample measurements	Perkin Elmer gamma-counter measuring radioactive concentrations	New	Digital	Experimental	.csv; Excel [.xls]	< 1 GB	N/A
Animal scanning data	PET/SPECT and CT data	New	Digital	Experimental	.dcm .img	< 1 TB	N/A
Treatment data & survival data	A detailed description of animal studies performed	New	Digital	Experimental	N/A	Data on Labguru [Laboratory Management System]	N/A
Incucyte generated data	Live cell analysis through fluorescence	New	Digital	Experimental	.ict .pdf	< 1 TB	N/A

Work Package 3: GMP Production

				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	Physical volume
Radiolabelling Protocols	Optimized protocols for quantitative radiolabelling	New	Digital	Protocols	N/A	Data on Labguru [Laboratory Management System]	N/A
Validation of Analytical Methods	Analytical and Radioanalytical Methods that have been validated with different conditions tested	New	Digital	Experimental	N/A	Data on Labguru [Laboratory Management System]	N/A
Protocols for Automated synthesis	Digital protocol designed to operate automated synthesis robot with Trasis interface	New	Digital	Protocols	Script for running automation [.tra]	< 1 GB Stored on Trasis server	N/A

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:

No existing data will be reused during this project.

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

An animal ethics application was approved by the KU Leuven Animal Ethics Committee [P079-2023]. The information on approved animal studies and the management of these protocols (eg. registration of the number of animals used/adaptations to ethics applications) are all stored on the tick@lab animal research facility software of the biomedical sciences group.

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

Not Applicable.

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

Investigating the design of novel radiopharmaceuticals for potential cancer treatment holds significant promise for commercial valorization. While the outcomes of research endeavours are inherently uncertain, the pursuit of innovative solutions in oncology presents opportunities for various forms of commercial exploitation, including but not limited to technology transfer, spin-offs, and eventual commercialization.

To aid this, we work in close collaboration with the unit Intellectuele Eigendom at KU Leuven before we disseminate any data and we are also working on the design of possible radiopharmaceuticals that could be patented. As such, the confidentiality of this project is closely guarded. The data is not shared outside the collaboration with the ICMATE group and all participants have signed a non-disclosure agreement. The results will not be presented or published until the decision is made with regards to future valorization.

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

There are no other issues related to data management that we are currently aware of.

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).

Our laboratory is subscribed [currently for 3 years with a definite extension] to the Labguru online electronic laboratory notebook service. This service allows for the clear documentation of all the procedures followed, the creation of standard protocols, attaching all the result files per experiment and also providing inventory capabilities to ensure that physical samples are recorded properly.
The Labguru electronic software allow for all data to be findable easily by using the filtering function as well as accessible to the whole lab to reuse the data and also follow the protocols. Although LabGuru does allow the sharing of information with collaborators, our group has decided to only share data in-house for members of the Laboratory for Radiopharmaceutical Research.
Except for animal in vivo scanning data (PET, SPECT and CT data), all the data will be linked into LabGuru to the experiments and protocols used to generate the data. This will be done in at least PDF format or similar reports as it is not always easy to link the raw data to LabGuru.

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

These process are all done automatically by the LabGuru software. Data is easily searched, retrieved and reused.

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

Where will the data be stored?

All the data for experiments, protocols and results as well as the final analysed data will be stored on LabGuru. This is a yearly subscription service that is paid for by the internal funds of the Laboratory for Radiopharmaceutical Research. The storage is envisioned to at least outlast the required 5-year storage mandate requested.
Raw data for the analysis (HPLC data, LC/MS data, NMR data and imaging data) are stored on the KU Leuven G drive and backed up to the KU Leuven K Drive every 6 months.
The Incucyte system has 16.4 TB storage capacity and has 4 hard drives. The data is stored in RAID format and is duplicated across different hard drives. Routine data backup is also performed.

How will the data be backed up?

Raw data for the analysis (HPLC data, LC/MS data, NMR data and imaging data) are stored on the KU Leuven G drive and backed up to the KU Leuven K Drive every 6 months.

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

Yes, the LabGuru platform currently has up to 15 GB storage for the combined research of the group and should more space be needed, this can be increased by an upgraded subscription. All the other data are moved to the K Drive of KU Leuven.

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

LabGuru has a mandated two-step authentication system that is mandatory for all users. When you log in, only you can add records to your name, and once added, it cannot be deleted. There is also a feature that allows the verification of your protocols and data by a second user to increase security, readability and management of data.

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

The costs associated with the use of LabGuru is provided by the internal funding of the Laboratory for Radiopharmaceutical Research, KU Leuven.

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 stored for 7 -10 years. This is because the data gathered will also be used for product development and valorization should a feasible product be developed during the research.
However, tissue samples and chemical library samples will only be tested for the shelf-life of individual samples. Chemical library samples are where a small test amount is kept in a -80 degree freezer should additional analysis be necessary. In this case, the sample will be tested at a predefined retest date (e.g. 12 months). If the sample is no longer intact, it will be discarded. Tissue samples will be kept for a maximum of 5 years.

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

The responsibility of long term storage will be undertaken by Prof Frederik Cleeren and this will be stored on the servers of KU Leuven with access provided to the entire research group with permission of Prof Cleeren. The methods and protocols developed will have reuse value for the group.

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

The costs associated with the use of LabGuru is provided by the internal funding of the Laboratory for Radiopharmaceutical Research, 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.

- No (closed access)

The data generated in our lab is kept on LabGuru and the KU Leuven K Drive or our group's Internal J Drive. Laboratory books are kept in the laboratory storage. We will not be sharing our data publically. However, should the experiments become part of peer reviewed scientific publications, we will ensure that the methods are described as such that they are reproducible.

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

Data is restricted to active members of the Laboratory for Radiopharmaceutical Sciences group. Should some property information be shared to collaborators, this happens under strict non-disclosure policies. The access to data is controlled by Prof Guy Bormans and Prof Frederik Cleeren.

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 is always the possibility of valorization of the research being done in our group. As such, intellectual property rights should be strictly guarded.

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

N/A

When will the data be made available?

N/A

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

When data is made public- this will always be in the form of accepted peer reviewed scientific publications. In such an instance the data usage licenses are normally dictated by the specific publisher. Normally this should be through a Creative Commons Attribution (CC-BY) licence, but this is different based on the publisher.

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.

- No

We will not be making datasets publically available.

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

The publication costs for scientific peer-reviewed articles will be covered by my FWO bench fee or the Laboratory for Radiopharmaceutical Research, whatever is applicable.

6. Responsibilities

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

Janke Kleynhans

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

Janke Kleynhans

Who will manage data preservation and sharing?

Prof Frederik Cleeren

Who will update and implement this DMP?

Janke Kleynhans

Generator based therapeutic radiopharmaceutical production for targeting of fibroblast activation protein GDPR

GDPR

Have you registered personal data processing activities for this project?

- Not applicable

Generator based therapeutic radiopharmaceutical production for targeting of fibroblast activation protein DPIA

DPIA

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

- Not applicable