18F-PSMA-1007 PET/MR imaging, quantification and radiomics in the primary staging of prostate cancer and response prediction after neoadjuvant hormonal therapy

A Data Management Plan created using DMPonline.be

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Project abstract:

In men, prostate cancer (PCa) is the most frequent cancer diagnosis in Belgium. A high biochemical recurrence rate up to 50% is seen in PCa patients after curative treatment. Disease-extent needs to be assessed accurately at diagnosis of PCa to allow correct triage to the most optimal first line of treatment. Current staging consists of pelvic multiparameteric magnetic resonance imaging (MRI), abdominopelvic computed tomography (CT) and bone scintigraphy. These imaging modalities have a low sensitivity for the detection of pelvic lymph node (pLN) metastases (˂40%) and distant metastases (59%). Therefore, extended pLN dissection remains the only reliable way of detecting occult pLN metastases, but the oncological benefit of pLN dissection has not been proven and there is a non-negligible morbidity risk. So, there is clearly a large need for an accurate non-invasive diagnostic test such as 18F-PSMA-1007 positron emission tomography/MRI (PET/MRI). In this project we will (1) investigate the diagnostic accuracy of 18F-PSMA-1007 PET/MRI in PCa staging (2) determine which imaging-biomarkers can aid in patient stratification in PCa staging (3) identify which radiomic features can predict tumor response in patients receiving neoadjuvant hormonal treatment prior to curative treatment. The use of 18F-PSMA-1007 PET/MRI can lead to better PCa staging and optimal use of predictive imaging-biomarkers. These factors directly benefit patients and can result in less futile treatments.

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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

DPIA

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?

Question not answered.

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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	
WP1: kinetic modeling of the 18F-PSMA-1007 tracer + WP3: diagnostic accuracy of 18F-PSMA-1007 PET/MRI	Radiopharmaceutical synthesis (production logs)	generate new data	digital and physical	observational	.pdf	<100 MB	<300 paper sheets
WP1: kinetic modeling of the 18F-PSMA-1007 tracer + WP3: diagnostic accuracy of 18F-PSMA-1007 PET/MRI	Trial documents	generate new data	digital and physical	observational	.pdf	<100 MB	<300 paper sheets
WP1: kinetic modeling of the 18F-PSMA-1007 tracer + WP3: diagnostic accuracy of 18F-PSMA-1007 PET/MRI	Demographic & clinical data (source: electronic patient records UZ Leuven (KWS)) and scan characteristics	generate new data	digital	observational	.cvs, .pdf	<100 MB	N/A
WP1: kinetic modeling of the 18F-PSMA-1007 tracer + WP3: diagnostic accuracy of 18F-PSMA-1007 PET/MRI	human imaging data: 18F-PSMA-1007 PET/MRI data collected from performing 18F-PSMA-1007 PET/MRI scans	generate new data	digital	observational	PET, MRI, listmode RAW & DICOM format	<5 TB	N/A
WP2: 18F-PSMA-1007 PET radiomics	Demographic & clinical data and scan characteristics	reuse existing data	digital	observational	.cvs, .pdf	<100 MB	N/A
WP2: 18F-PSMA-1007 PET radiomics	18F-PSMA-1007 PET data collected from performing 18F-PSMA-1007 PET scans	reuse existing data	digital	observational	DICOM	<5 TB	N/A
WP1: kinetic modeling of the 18F-PSMA-1007 tracer + WP2: 18F-PSMA-1007 PET radiomics + WP3: diagnostic accuracy of 18F-PSMA-1007 PET/MRI	Image analysis and processing	generate new data	digital	observational	DICOM, .csv	<1 TB	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:

For WP2 (18F-PSMA-1007 PET radiomics), data will be used from this study: Devos G, Tosco L, Baldewijns M, Gevaert T, Goffin K, Petit V, Mai C, Laenen A, Raskin Y, Van Haute C, Goeman L, De Meerleer G, Berghen C, Devlies W, Claessens F, Van Poppel H, Everaerts W, Joniau S. ARNEO: A Randomized Phase II Trial of Neoadjuvant Degarelix with or Without Apalutamide Prior to Radical Prostatectomy for High-risk Prostate Cancer. Eur Urol. 2022 Sep 24:S0302-2838(22)02638-0. doi: 10.1016/j.eururo.2022.09.009.

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, human subject data

For WP1 and WP3: ethical approval was obtained via UZ Leuven - ethics number s59428
For WP2: ethical approval was obtained via UZ Leuven - ethics number s58827

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

WP1 and WP3 (Data will be managed in compliance with the UZ Leuven General Data Protection Regulation (GDPR) policy - ethics number UZ Leuven s59428):
- Trial documents
- Demographic & clinical data
- Human imaging data and image analysis

WP2 (Data will be managed in compliance with the UZ Leuven General Data Protection Regulation (GDPR) policy - ethics number UZ Leuven s58827):
- Demographic & clinical data
- Human imaging data and image analysis

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).

We will create a separate folder for WP1, WP2 and WP3 that contains the following information:
Electronic lab notebook in word:
- involved researchers
- ethical approval (reference number & institution)
- short overview of study course and protocol
- detailed methodology used to collect, analyze and store the data
- short written information on data cleaning process and steps

READ ME file in excel for each produced datafile:
- short description of the file and definitions of the variables

Folder with study documents:
- ethical application and approval
- informed consent example
- complete study protocol

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

Metadata standards are not yet used within our group. We ensure the standardization and possibility to reinterpret and reuse data when necessary and permitted via the methods written in the

previous question.
In addition, the data primarily produced by WP1, WP2, WP3 will be imaging data in DICOM files (PET and MRI). These data contain metadata (acquisition parameters) within the DICOM, which can be accessed at all times.

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

Where will the data be stored?

- Radiopharmaceutical synthesis: data stored according to GMP production license (paper & ABU UZ Leuven servers)
- Human imaging data: stored in UZ Leuven PACS
- Trial documents: paper storage according to Good Clinical Practice (GCP)
- Clinical data: KWS UZ Leuven and shared network drive via UZ Leuven

How will the data be backed up?

The backup of the fileservers is based on snapshot technology. The backup of the file servers is a fully automated and a fully monitored process using snapshot and snapmirror. The backup is performed in 2 layers:
a. On the local disk system

- Every hour, a snapshot is taken.
- Every night, an extra shapshot is taken.
- Every week, an extra shapshot is taken.
- The default retention period is:
    - one week (hourly)
    - two weeks (nightly)
    - 18 weeks (weekly)

The end user can use his own Windows PC to restore files to an older version using the “previous versions” function.
b. On a remote disk system

- Every night, the whole local disk system (with all his hourly, nightly and weekly snapshots) is synchronised with a remote copy, also on disk by snapmirror. Snapmirror copies the complete data of the source inclusive all the snapshots.

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 necessary funding for storage and backup for the contracted service has been foreseen.

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

Digital data will be stored in a restricted network share N-drive, which can only be accessed by the involved researchers. Access to code files with pseudonyms is controlled by a data manager (with the PI as a back-up). All other researchers who participate in the project have access to the pseudonymised data only.

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

The department of Nuclear Medicine and Molecular Imaging provides our research group with an N-drive and PACS backup system. As such, costs will be covered by the department.

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 and physical data will be stored for 25 years according to CTC recommendations for clinical trials with medicinal products for human use and for clinical experiments on humans.

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

Paper files will be stored at the department of nuclear medicine and will be scanned and stored in a study-specific, secured folder on the hospital network. Scans will be stored on the PACS archive.

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

It is foreseen that the costs for data preservation will be covered by the department of nuclear medicine and molecular imaging.

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 a restricted access repository (after approval, institutional access only, …)

All digital data will be made available in a restricted access repository.

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

Scientific researchers will have to motivate why they want access to the data:

- What topic are you studying?
- How is the data linked to your research domain?
- Why do you think you need this data?
- Which question/problem will the data help with?
- What do you expect the data to provide you with?

We will always ask to give credit to the original data creators when the data it is being used by other researchers.

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, Privacy aspects

We work with human data. When sharing our data, we will restrict acces and pseudonymize the data.

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

Via RDR, the KU Leuven institutional repository.

When will the data be made available?

Upon publication of research results.

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

Data from the project that can be shared will be made available under a creative commons attribution license (cc-by 4.0), so that users have to give credit to the original data creators.

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

WP2: Devos G, Tosco L, Baldewijns M, Gevaert T, Goffin K, Petit V, Mai C, Laenen A, Raskin Y, Van Haute C, Goeman L, De Meerleer G, Berghen C, Devlies W, Claessens F, Van Poppel H, Everaerts W, Joniau S. ARNEO: A Randomized Phase II Trial of Neoadjuvant Degarelix with or Without Apalutamide Prior to Radical Prostatectomy for High-risk Prostate Cancer. Eur Urol. 2022 Sep 24:S0302-2838(22)02638-0. doi: 10.1016/j.eururo.2022.09.009. Epub ahead of print. PMID: 36167599.

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

RDR is free for KU Leuven personnel, hence, no costs are expected for data sharing.

6. Responsibilities

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

The PhD researcher (Niloefar Ahmadi Bidakhvidi) will be responsible for data documentation; metadata, under supervision of the PI (Karolien Goffin).

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

Data management, storage and back up will be performed by the PhD researcher (Niloefar Ahmadi Bidakhvidi), under supervision of the PI (Karolien Goffin).

Who will manage data preservation and sharing?

The PI (Karolien Goffin) will be responsible for ensuring data preservation and sharing.

Who will update and implement this DMP?

The PhD researcher (Niloefar Ahmadi Bidakhvidi) will be responsible for updating this DMP. The PI (Karolien Goffin) bears the end responsibility for updating and implementing this DMP.