https://dmponline.be/plans/207761/overviewLumiSense – Intraluminal intra-operative sensing-based planning for improved catheter navigation

A Data Management Plan created using DMPonline.be

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Template: KU Leuven BOF-IOF

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Project abstract:

Brain stroke is the second leading cause of death and the third leading cause of disability and death combined in the world. In the case of acute ischemic stroke, Mechanical Thrombectomy (MT) has become the first line of treatment. During these interventions, flexible instruments are manoeuvred across stiff obstacles in order to remove a blood clot from an occluded vessel and restore blood supply to the brain. Interventionists typically rely on 2D X-ray fluoroscopy for intra-operative visual guidance, which besides causing numerous health concerns due to prolonged radiation exposure, it also limits scene awareness as interventionists must mentally relate 2D information to a 3D representation of the blood vessels while performing safety-critical interventions. Through the development of a series of key enabling technologies, KU Leuven's Robot Assisted Surgery (RAS) group has developed a radiation-free guidance system for safer and improved catheter navigation. By solely relying on intra-operative sensing, the system facilitates 3D local visualization of inherent 3D structures (guidewires/catheters and surrounding vascular network). However, information is only provided for a short planning horizon and having a further understanding of the patient's anatomy might prove useful when trying to detect occlusions. As such, LumiSense aims to develop a multimodal visual guidance framework that exploits both radiation-free pre-operative and intra-operative imaging. In addition to benefits for patients, the technology creates a safer and more female-friendly work environment.

Last modified: 30-05-2024

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	
cto_ivus	IVUS images taken during PCI from CTO patients. Images collected during a previous project involving the group.	E	D	I	DICOM, json and tif/tiff	<100GB	NA
emt_free_shape_sensing	Analysis of shape sensing algorithms without reliance on electromagnetic tracking	N	D	N	bag	<100GB	NA
pre_clinical_validation	Validation of the LumiSense platform in realistic conditions.	N	D	N	bag	<100GB	NA
LumiSense_platform	Software platform encompassing all the algorithms developed during or prior, if relevant, to the project.	N	D	SO	Python, C++	<1GB	NA

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:

The existing data that is planned to be reused refers to the cto_pci dataset. This data is not public and presents no restrictions within the use of this project. Moreover, it was collected during a previous project of the group and it is stored in the shared network drive (J:) of KU Leuven, to which only authorised members have access to.

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)

Ethical approval (ECD) has already been requested for the collection of validation data in realistic scenarios (number P011/2023 - Reuse animals). For additional experiments involving animal data, if envisioned and essential, ethical approval (ECD) will be requested once the respective protocols are finalized.

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

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 datasets “emt_free_shape_sensing” and “pre_clinical_validation”, and the software “LumiSense_platform” will allow for the evaluation of technology transfer and possibly intellectual property to a spin-off venture.

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

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

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).

Quantitative data will be stored in .bag files.
The .bag file structure allows to name variables (curvature, position, etc).
Each .bag file will be accompanied by a post-processing Python script.
Documentation will be provided about the contents of the .bag files, such as units of measurement, and the physical meaning of the data.
Source code (Python and C++) will be adequately commented and accompanied by a README.me file and other documentation detailing the structure of the project, as well as instructions of usage.

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.

- No

Metadata on the datasets will be created by the post-processing scripts in .csv format. Metadata will contain information about aspects such as the study number, good/successful and bad/unsuccessful results/experiments, and conclusions taken from the researchers.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Shared network drive (J-drive)
- OneDrive (KU Leuven)

How will the data be backed up?

- Personal back-ups I make (specify below)
- Standard back-up provided by KU Leuven ICTS for my storage solution

External hard drives backups.

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?

Access to shared drives (OneDrive or J-drive) will only be granted to persons involved in the project.

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

There are no expected additional costs for data storage.

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)?

- Shared network drive (J-drive)

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

N/A

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.

- Yes, as restricted data (upon approval, or institutional access only)

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

Data will be made accessible to people that continue (parts of) the research and after approval from the members involved in 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 per dataset or data type where appropriate.

- Yes, intellectual property rights

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- KU Leuven RDR (Research Data Repository)

When will the data be made available?

- Other (specify below)

Data will be made available after associated patent(s) have been filed, and after approval from the members involved in the project.

Which data usage licenses are you going to provide?

If none, please explain why.

- Data Transfer Agreement (restricted data)
- MIT licence (code)
- GNU GPL-3.0 (code)

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.

- No

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

N/A

Responsibilities

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

Wim-Alexander Beckers, Beatriz Farola Barata, Gianni Borghesan

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

Wim-Alexander Beckers, Beatriz Farola Barata, Gianni Borghesan

Who will manage data preservation and sharing?

Beatriz Farola Barata, Gianni Borghesan

Who will update and implement this DMP?

Beatriz Farola Barata, Gianni Borghesan