ARTISTE - Autonomous Robotic Suturing for fetal surgery

A Data Management Plan created using DMPonline.be

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Template: FWO DMP (Flemish Standard DMP)

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Project abstract:

Single-Port Access surgery (SPA) demonstrates significant potential as an alternative to traditional multi-port Minimally Invasive Surgery (MIS). In contrast to conventional MIS, SPA employs a single incision or a natural orifice to reach the surgical site. SPA is particularly well-suited for treating Open Spina Bifida (OSB), which necessitates strict limitations on port diameter (10 mm O.D.). In OSB repair, suturing is widely regarded as the most demanding and time-intensive task. The ARTISTE project endeavors to address this highly challenging task by using KUL's macro-micro robotic system, along with the application of artificial intelligence (AI) and augmented reality (AR) techniques. The project will commence by exploring multi-sensor fusion to ensure reliable and accurate multi-arm instrument proprioception, followed by path planning and AR/VR visualization for in-utero suturing. Ultimately, the project aims to demonstrate the autonomous suturing capabilities of the macro-micro system under environmental contact. If receiving approval from ethical committee, the autonomous suturing demonstration will be carried out in collaboration with the clinical partner on two or three pregnant sheep.

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ARTISTE - Autonomous Robotic Suturing for fetal surgery 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 physical data
Dataset Name	Description	New or reused	Digital or Physical	Digital Data Type		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:	Compiled/aggregated dataSimulation data	from the following options: • .por,	Please choose from the following options: • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • NA	
Hysteresis_micro	Hysteresis date collected from the micro part of the macro- micro multi- arm robot for fetal surgery	Generate new data	Digital	Experimental	.csv and .bag (Rosbag file)	< 100 MB	
characterization_macro	The data collected during the characterization of the macro part of the macro-micro multi-arm robot.	Generate new data	Digital	Experimental	.csv	< 100 MB	
input_output_behavior_sheath_robot	The dataset includes the input-output behavior, including hysteresis effects, collected from a catheter sheath robot.	Generate new data	Digital	Experimental	.csv and .txt	< 100 MB	
Trajectory_following	Data collected during the trajectory- following experiment with the multi- arm robot.	Generate new data	Digital	Experimental	.csv	< 100 MB	
input_output_behavior_sheath_robot_2023	The dataset includes the input-output behavior, including hysteresis effects, collected from a old version of the catheter sheath robot in 2023.	Reuse existing data	Digital	Experimental	.csv	< 100 MB	

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:

We will be reusing a dataset previously collected by our team, which characterizes the input-output behavior of a catheter sheath robot. This dataset is crucial for testing novel deep learning algorithms with potential applications in the ARTISTE project.

Source of Reused Dataset: https://data.4tu.nl/private_datasets/nxjyapcAoN-59A6PtnHZPOXagFLWwfglB8x-A6uKRMs

Purpose: The data is used to develop and refine deep learning algorithms that improve the functionality and accuracy of robotic systems, critical for advancements in the ARTISTE 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.

No

Our project does not involve any experiments on humans or animals, and we do not foresee the engagement of any such activities before the project concludes on October 31, 2024.

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

Our project does not involve the processing of personal data. We have no plans to conduct experiments or studies that handle personal data in a way that could identify individuals.

In future stages of the project, we may conduct user studies to evaluate performance. However, these studies are designed to collect only non-identifiable data related to user performance. No personal identifiers or sensitive personal information will be collected, ensuring that individual participants cannot be traced or identified through the data. This approach aligns with privacy protection standards and ensures compliance with relevant data protection regulations.

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

Our project's dataset holds potential for commercial valorization, particularly if the deep learning algorithms and the robotic systems involved are protected through patents or software copyrights. This dataset could be crucial for fine-tuning these technologies, enhancing their commercial applications. We plan to consult KU Leuven's Intellectual Property unit to ensure compliance with IP regulations and to explore potential IP protections. Additionally, we will coordinate with Leuven Research & Development (LRD) before disseminating any data, to properly navigate the pathways for technology transfer and commercial exploitation. This strategic approach will help secure intellectual property rights and facilitate commercial opportunities for our research outcomes.

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

For this project, which is funded by KU Leuven without the involvement of collaborators or third-party agreements, we do not anticipate any restrictions related to the exploitation or dissemination of the data we use or reuse. The absence of external collaborators and third-party contracts simplifies the legal landscape, allowing us to manage and share our data freely under the guidelines established by KU Leuven and applicable open data policies.

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

Given the current scope and nature of our project, we do not foresee any issues regarding intellectual property rights and ownership of the data we plan to use or reuse. All data collected is anticipated to be generated internally by our research team.

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).

To maintain the usability and comprehension of our data, rigorous documentation practices aligned with FAIR principles are implemented:

- 1. Comprehensive Documentation: Methodological details and analytical procedures are documented within README.txt files for each dataset, where data collection methods and processing steps are clearly described.
- 2. Repository Standards and FAIR Compliance: Data are deposited in KU Leuven RDR, accompanied by detailed metadata using controlled vocabularies to ensure that the data is findable, accessible, interoperable, and reusable.
- 3. Accessible and Interoperable Metadata: Metadata linked to scientific publications are kept openly available to enhance transparency, with standardized terms and formats ensuring compatibility and ease of use across various research platforms and studies.

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

Metadata for the research data will be meticulously structured, involving detailed documentation through designated metadata elements or fields. This ensures that the data is not only machine-readable but also actionable and interpretable. The following measures will be taken:

- 1. Include essential details like the title, creator/author, date of publication, date of data collection, and version of the dataset.
- 2. Document subject and keywords, geographical and temporal coverage, methodology, and data quality. Also include technical details such as file format, data structure, and accessibility (how to access the data, including URLs or identifiers like DOIs).
- 3. Provide rights and permissions, email of the corresponding author, and recommended citation to ensure users understand how to correctly use and cite the dataset.

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

Where will the data be stored?

During the research project and up to 5 years or more after the project, data will be stored on the researcher's University PC, synced with the OneDrive account associated with KU Leuven or stored on a folder on a shared drive of the department. This dual-location storage ensures real-time backup and accessibility. Upon completion of the project, the data and insofar compatible with the instructions from the tech transfer office, will be transferred to an open-access data repository to facilitate widespread dissemination and enhance scientific exchange. Examples of potential repositories include KU Leuven RDR, Figshare, Zenodo, and the Open Science Framework, which are renowned for their accessibility and reliability in the academic community.

How will the data be backed up?

To safeguard against data loss, a rigorous backup strategy will be implemented throughout the duration of the research. Data will be regularly backed up in two layers: first, locally on the researcher's University PC; second, remotely via the OneDrive account of KU Leuven, ensuring cloud storage benefits such as disaster recovery and remote access. This approach not only secures the integrity of the data but also ensures that there are multiple data recovery points in the event of hardware failure or other forms of data loss.

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

Based on the current assessment, there is sufficient storage and backup capacity for the project. The researcher's University PC has been checked to ensure adequate space is available for the project's needs. Additionally, the KU Leuven OneDrive account provides 2TB of cloud storage, of which only approximately 5% is currently utilized. This substantial available capacity confirms that the planned backup strategy is feasible and will support the project's data management requirements effectively.

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

To ensure that the data are securely stored and protected from unauthorized access or modification, the following security measures will be implemented:

- I. Network Security: Regular security assessments and updates will be conducted to ensure that network defenses are current and effective against potential cyber threats.
- II. Computer Systems and File Security: 1) Access controls will be strictly enforced. Only designated research team members will have access rights to the data files, and permissions will be set to limit access to read-only wherever possible to prevent unauthorized modifications. 2) Multi-factor authentication (MFA) will be enabled for access to the OneDrive account to provide an additional layer of security beyond username and password.

These combined measures provide a robust framework for securing sensitive data throughout the research project, mitigating risks related to unauthorized data access or loss.

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

The expected costs for data storage and backup during the research project are minimal, as the University PC already has sufficient storage and the KU Leuven OneDrive account provides 2TB of cloud storage, of which only about 5% is currently used, thus incurring no additional cost. The only potential expenditure might be the purchase of an external hard drive for extra backup security, typically ranging from 50 to 150 euros. These costs, minimal as they are, will be covered by the research project's budget, ensuring that all data management requirements are met efficiently and economically.

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 collected during the project will be retained for at least 5 years following its conclusion, in accordance with KU Leuven's Research Data Management (RDM) policy. This retention timeframe ensures sufficient duration for data verification, reanalysis, and potential follow-up studies within academic and research contexts.

The data will be securely stored in digital form, utilizing both local and cloud storage solutions to maintain data integrity and accessibility. In cases where data cannot be preserved for the full five-year period due to legal, contractual, or privacy concerns, specific reasons will be clearly documented. All decisions regarding the retention and deletion of data will adhere to institutional policies and legal requirements, ensuring responsible data management throughout the project lifecycle.

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

For long-term archiving and curation, the research data from this project will be uploaded to the KU Leuven Research Data Repository (RDR). In this repository, the dataset will be carefully documented with detailed metadata to ensure clarity and comprehensibility. Additionally, a permanent identifier will be assigned to the dataset, enhancing its discoverability, making it easily citable, and facilitating its availability for reuse by other researchers. This approach not only aligns with best practices for data management but also supports the principles of open science by ensuring that the data is accessible and maintained securely within a trusted institutional framework.

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

The expected costs for data preservation during the retention period are negligible. KU Leuven Research Data Repository (RDR) offers 50 GB per year per researcher at no additional cost. Considering that the dataset generated during this project is anticipated to be less than 10 GB, this allocation is more than sufficient to meet our storage needs without incurring extra expenses. This provision by KU Leuven ensures that the data can be securely stored, maintained, and made accessible for the required retention period without financial burden, thereby supporting the project's data management strategy efficiently and economically.

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 an Open Access repository

The data generated during the project that does not contain personal information will be made available for reuse after and during the project period. This data will be deposited in the KU Leuven Research Data Repository (RDR), where it will be openly accessible for other researchers to use and build upon. Each dataset or data type will be made available according to its nature and any relevant considerations.

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

For this project, the dataset will be publicly accessible once it is stored in the KU Leuven Research Data Repository (RDR). Upon depositing the data, it will be assigned a Digital Object Identifier (DOI), which not only facilitates easy sharing but also enhances the dataset's visibility and citability. This DOI ensures that the dataset can be reliably located and referenced by other researchers within the scientific community, promoting transparency and collaboration.

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

As currently assessed, there are no factors that restrict or prevent the sharing of data collected and generated in this project. The project has been designed with the intention of full transparency and openness, ensuring all generated datasets can be freely accessed and reused by the academic community and beyond.

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

The data generated during this project will primarily be made available through the KU Leuven Research Data Repository (RDR). This repository is ideal for our needs as it not only ensures long-term preservation and accessibility but also provides a DOI for each dataset, enhancing the findability and citability of our data.

Additionally, datasets may also be submitted as supplementary materials alongside the publication manuscripts. This method allows datasets to be stored in publishers' repositories, directly linking them with the corresponding research articles for greater accessibility and context. Such dual hosting ensures that the data remains closely associated with published findings, facilitating validation and further exploration by other researchers.

When will the data be made available?

The data will be made available in alignment with key project milestones to ensure appropriate dissemination and use. Specifically, the data will be released as follows:

- 1. Upon Publication of Research Results: Datasets integral to specific publications will be made available concurrently with the publication itself. This ensures that the data supporting the research findings is accessible to readers and reviewers at the time of publication, enhancing transparency and facilitating peer verification and further study.
- 2. After Project Completion: Additional data collected during the project that may not be directly linked to specific publications or translation efforts will be made available after the project has officially concluded. This allows for comprehensive finalization and review of all data to ensure accuracy and completeness before it is shared.

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

For this project, we will apply the Creative Commons Attribution-NonCommercial (CC BY-NC) license to our data. This license allows others to remix, adapt, and build upon the data non-commercially, as long as they credit us and indicate if changes were made. Using the CC BY-NC ensures that the data is accessible for academic and educational purposes while restricting commercial use, aligning with our goal to promote wide dissemination without commercial exploitation.

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

Each dataset generated from this project will be assigned a DOI upon uploading and review in the KU Leuven Research Data Repository. The DOI ensures that each dataset is uniquely identifiable, easily citable, and readily accessible. This step is crucial for enhancing the visibility and usability of the data, facilitating academic sharing and ensuring that contributors receive proper credit in subsequent reuses of the data.

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

The expected costs for data sharing in this project are minimal, given that our datasets are small. Depositing these smaller datasets in data repositories, such as the KU Leuven Research Data Repository, is typically covered by the repository itself, which means there is no direct cost to us for data deposition.

6. Responsibilities

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

Dr. Di Wu, Xiaohang Zhang and Prof. Emmanuel Vander Poorten,

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

Dr. Di Wu, Xiaohang Zhang, and Prof. Emmanuel Vander Poorten

Who will manage data preservation and sharing?

Dr. Di Wu, Prof. Emmanuel Vander Poorten and Xiaohang Zhang

Who will update and implement this DMP?

Dr. Di Wu and Prof. Emmanuel Vander Poorten

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