Project Acronym:
BRAINSONIC (ENTERPRISES/0223/Sub-Call1/0057)

Project Title:
MRI-guided Focused Ultrasound robotic system for brain tumors.

Deliverable number: 2.2

Data Management Plan

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General information

Executive Summary

This data management plan describes the lifecycle of all research data to be generated during the BRAINSONIC project. The plan explicitly outlines the methodologies to be undertaken to ensure that data generated throughout the project is properly used, as well as the standards that will be applied to ensure the quality of acquired data and guarantee data preservation both during and beyond the project's end date. Moreover, the plan includes all measures to be undertaken by the consortium to warrant that all data is processed in accordance with national and international guidelines. These include techniques to align data with Findable, Accessible, Interoperable and Reusable (FAIR) principles, as well as methods to ensure that collected data are processed and shared in compliance with the General Data Protection Regulations (GDPR) and intellectual property (IP) rights to guarantee the confidentiality and security of exchanged data and prevent inappropriate access by 3rd parties. The data management plan was be periodically updated during the first year of the project as necessary.

1) Data Description and Collection

1.1) Describe how new data will be collected or produced and/or how existing data will be re-used.

1.1.1) Explain the purpose of data collection/generation and its relation to the objectives of the project. Explain the methodologies or software that will be used if new data are collected or produced. Explain how data provenance will be documented.

Data collection:

Data produced or collected in the scope of the BRAINSONIC project were determined in the Work Package (WP) description of the granted research proposal. In this sense, new data will be collected or generated throughout the project duration to completely attain and fulfil the aims and objectives of the project. These data will be analysed and reported in the relevant confidential or publicly available deliverables. Non-confidential outcomes will be disseminated through numerous scientific publications to ensure accessibility to the scientific community and the general public.

Methodology:

Over the course of the project, multiple methodologies incorporating numerous experimental, design, and analytical techniques will be systematically followed using several instrumentation and software platforms to produce a range of raw, processed, or analysed data. In each case raw, processed and analysed data will be separated to achieve data provenance ensuring that all data can always be traced back to its original form. The data to be generated under each project objective over the course of the project's lifetime are listed below.

Objective 1: Development of a Magnetic Resonance Imaging (MRI) -compatible Focused Ultrasound (FUS) Robotic system

Associated WP: WP3

Data:

- 3D Computer Aided Design (CAD) model of robotic system parts; All parts of the robotic system will be individually designed using the Inventor software (Autodesk, San Francisco, California, USA).
- 3D CAD model of robotic system assembly; CAD models of all individual parts of the robotic system will be processed using the Inventor software (Autodesk, USA) creating the 3D design of the assembled robotic system.
- High-resolution figures of the robotic system; CAD models of the assembled robotic system and its individual parts will be analysed with the Inventor software (Autodesk, USA) and extracted as figures (to be included in the generated patent, deliverable and manuscript documents).
- High resolution photos of the manufactured robotic device.

Objective 2: Development of accompanied treatment planning-monitoring software

Associated WP: WP3

Data:

- The treatment planning/monitoring software will be developed in C# (Microsoft Corporation, Washington, USA) under the .NET framework (Microsoft Corporation, USA) with parallel scripts written in Python (Python Software Foundation, Delaware, USA) integrating MR image transfer and MR thermometry tools.
- Codebase (source code files and scripts).
- Screenshots showcasing the various features and functionalities of the software.

***Objective 3*: Development of phantom with tumor mimics**

Associated WP: WP4

Data:

- 3D CAD models of skull and tumor moulds; The associated designs will be produced using the Inventor software (Autodesk, USA).
- MRI data for assessing imaging features of the developed phantoms, e.g., contrast between tumor simulators and surrounding, and optimizing sequence parameters for proper tumor visibility. All associated raw data will be collected within a 3T MRI scanner (Magnetom Vida, Siemens Healthineers, Erlangen, Germany). Data will be directly retrieved from the MRI scanner and extracted from the MRI control computer in a physical format (CD-ROM). Raw MRI data will be analysed with a DICOM software (MicroDicom, MicroDicom Ltd., Sofia, Bulgaria).

***Objective 4*: Evaluation of the MR compatibility, motion accuracy, and heating capabilities of the developed FUS robotic system**

Associated WP: WP5

Data:

- Thermocouple recordings on agar-based phantoms and excised pork tissue; Temperature data will be acquired with thermocouple sensors (5SC-TT-K-30-36, type K insulated beaded wire, Omega Engineering, Norwalk, Connecticut, USA) during sonications executed with the robotic system and recorded with a digital thermometer (HH806AU, Omega Engineering, USA). Captured data will be extracted with a dedicated software (HH800-SW, Omega Engineering, USA) in a tabular form for further analysis with Excel.
- Photos of lesions created with the FUS robotic system on excised pork tissue; Dissected pork tissue samples will be photographed post-sonication to digitally visualise results (formed lesions).
- MRI data for thermal heating performance and evaluation of MRI compatibility and motion accuracy; All associated raw data will be collected within a 3T MRI scanner (Magnetom Vida, Siemens Healthineers). Data will be directly retrieved from the MRI scanner and extracted from the MRI control computer in a physical format (CD-ROM). Acquired experimental MRI data will be converted into a digital format by copying the

data from the CD-ROM, sorting them into folders and saving them in dedicated local directories in a PC. Sorted digital raw data will be processed with the in-house control software to generate offline MR thermometry data, while raw data for MRI compatibility and motion accuracy will be analysed with a DICOM software (MicroDicom, MicroDicom Ltd.), with the generated numerical values recorded in Excel for further analysis.

***Objective 5*: Evaluation of the therapeutic system and protocol in a mouse model of GBM**

Associated WP: WP5

Data:

- Data from experiments in a GBM mouse model to assess the thermal capabilities of the developed system. Sonicated tumours will be surgically excised and sent for histopathological examination. H&E-stained histological slides will be scanned with a brightfield scanner (VENTANA DP200, Roche Diagnostics International AG, Rotkreuz, Switzerland) to examine the FUS-related therapeutic effects.

1.1.2) State the use of any existing data. If existing data will be used describe the source of that data and the relationship between the data that will be produced and the existing data that will be integrated into the project.

The control software to be developed over the course of this project will be based on a pre-existing software that was produced during a previous research grant focusing on the development of an MRI-guided focused ultrasound system for cancer in pets (SOUNDPET-INTEGRATED/0918/0008). The previous software provided essential functionalities for system control and MRI interfacing enabling treatment planning and tissue temperature monitoring during ablations.

During BRAINSONIC, substantial revisions and enhancements will be made to the software, aiming to streamline treatment planning while new features will also be added to enhance treatment monitoring capabilities (e.g., thermal dose and tissue necrosis mapping).

1.2) What data will be collected or produced.

1.2.1) Provide details on the kind, format, and volume of the expected key data outputs in the table below.

Table 1: Kind, format, and volume of key data to be generated during the BRAINSONIC project.

Subject	Type	Format	Software	Estimated number of files
CAD design of robotic system parts	CAD Model	.ipt	Inventor	50-100
CAD design of robotic system assembly	CAD Model	.iam	Inventor	1
Robotic system figures	Image	.tiff	Image viewer	10-20
Treatment planning/monitoring software documentation	Document	.docx	Microsoft Word	1
Thermocouple recordings	Tabular	.xls	Microsoft Excel	10-20
Photos of lesions on excised tissue	Image	.jpg	Image viewer	20-30
Digital MRI experimental data	Image	.dcm	DICOM viewer	20000-40000
Processed thermometry data (maps and temperature graphs)	Image	.png	Image viewer	14000-28000
Analysed MRI compatibility data	Tabular	.xls	Excel	1
Analysed MRI accuracy data	Tabular	.xls	Excel	1
Photos from experiments on mice	Image	.jpg	Image viewer	20-40
Digital histology slides from excised tissues	Image	.bif	PMA start	15-25
Analysed data on tumor size/progression	Tabular	.xls	Excel	1

1.2.2) Specify the storage location for data, considering the estimated storage requirements.

Data will be stored in local PC repositories and in the cloud drive service provided by Cyprus University of Technology (CUT), which is sufficient for storing all raw, processed, and analyzed digital data.

1.2.3) Justify the use of certain formats. Give preference to open and standard formats as they facilitate sharing and long-term re-use of data.

Data will be predominantly produced in non-proprietary formats to facilitate long-term accessibility and widespread usage by researchers and project partners in the future. In case data is generated in other specific formats, such as 3D CAD models, it will be produced with the associated software (Inventor, Autodesk) due to license availability by the partner organisation (CUT), as well as expertise of the staff involved in production of this dataset. Nevertheless, during archiving or publishing of these data, associated files will be converted to the equivalent preferred formats of the scientific journals to which the relevant manuscripts will be submitted to meet the requirements of FAIR principles.

2) Documentation, Metadata, and Data Quality

2.1) What metadata and documentation will accompany the data

2.1.1) Will the data produced and/or used in the project be discoverable with metadata, identifiable and locatable by means of a standard identification mechanism? If yes, indicate what metadata will be created.

Metadata will be generated to describe produced data providing a means of identifying and discovering data. Metadata standards will depend on the type of generated data and will be stored alongside produced data. For experimental results, Word documents will be produced to report methodologies and present analysed data. Raw data will always be referred to within these files with the date it is captured. Moreover, to enable reuse of the developed control/treatment planning software by researchers in the future, administrative metadata will be produced. Specifically, comments will be inserted within the code, and software installation and user guides will be produced as Word documents, elaborating on efficient future software use.

Furthermore, all scientific publications produced over the course of the project will be submitted to journals registered with a Digital Object Identifier (DOI) registration agency.

Consequently, manuscripts will be automatically assigned with a unique DOI upon publication, providing unique findability and citation of published research outcomes. Additionally, publications will be connected to specific search keywords that provide easy retrieval of the published manuscripts from databases such as PubMed and Google Scholar. Keywords will be selected from controlled vocabularies according to the manuscript content. Additionally, in publications, associated researchers will be linked to their persistent digital identifier (ORCiD ID), and the project will be acknowledged through its grant number and funding organisation, enabling easy web-based retrieval of related research.

The consortium will follow a self-archiving route to publication by depositing published articles to the dedicated institutional repository of CUT (Ktisis; https://ktisis.cut.ac.cy/) increasing data visibility. These datasets will be identifiable by the metadata standards described in Table 2.

Table 2: Metadata standards for manuscripts generated in the project and deposited in the Ktisis repository of CUT.

Metadata	**Description**
Title	Title of the published article.
Authors	Authors of the published article.
Major field of science	Major science field of published article (e.g. Engineering and Technology).
Field category	Field category of published article (e.g. Electronic Engineering).
Keywords	Search keywords.
Issue Date	Publication date in DD-Month-YYYY format.
Source	Original source of published article in the [submitted journal], [year], [volume] format.
Volume	Journal volume to which article was published.
Journal	Scientific journal to which article was published.
Abstract	Published abstract.
URI	Uniform Resource Identifier for article entry in Ktisis repository.
ISSN	International Standard Serial Number of the journal to which article was published.
DOI	Digital Object Identifier assigned by the journal to which article was published.
Rights	Publishing group that owns the journal to which article was published.

2.1.2) Indicate how data will be organised during the project mentioning naming conventions, version control and folder structures.

Research data will be stored in a consistent and well-ordered manner enabling easy location and re-use. Data will be stored in dedicated folders clearly named according to the intended objective of the project (i.e., robot, software, MRI experiments, laboratory experiments, etc.). Individual files within folders will be named according to the project name (i.e., BRAINSONIC) and associated content, while date stamps will also be included in the file name. For experimental reports, date stamps will correspond to the date experiments were executed, while for other files, date stamps will correspond to the date the document was last modified. Modifications of any file will be performed on a copy of the file, and upon completion the original, the unrevised file will be deleted. In the case of raw experimental data (i.e., MRI experiments), these will be sorted in sub-folders named according to the date experiments were executed. The date will be in the format YYYYMMDD to ensure proper chronological sorting of raw data. Regarding the developed software, the semantic versioning schema will be employed for file naming to distinguish between different versions of software release.

2.1.3) What documentation will be needed to enable re-use of data. Indicate how this information will be captured and where it will be recorded.

Data collected or generated over the course of the project during experimental procedures will be documented in detail in experimental reports. Reports will be produced as Word documents providing explicit information on followed methodologies and acquired results, enabling understanding and reproducibility of generated data. Reports will be generated based on the type of experiments conducted, using standard pre-set templates. Specifically, 3 different templates will be produced and used for reporting on experiments executed 1) in the laboratory setting, 2) within the MRI environment, and 3) on a GBM mouse model. These templates are correspondingly provided in Appendix 1, Appendix 2, and Appendix 3. In all templates, essential information relating to the objectives of the experiment, materials and equipment used for data collection and analytical information on the employed methodology will be provided, enabling future reproduction of data.

2.2) What data quality control measures will be used

Data collection will be performed according to best practices and standards set by the research community. Regular calibration of all instruments employed for experiments will be performed

ensuring the outmost performance of associated equipment. In the event of hardware or software issues, they will be promptly addressed, and experiments will be repeated if needed. Preliminary experiments will be performed to validate experimental methods and derive therapeutic protocols. For all experiments in the laboratory and MRI settings, multiple repeated measurements in identical samples will be acquired to validate results. The relevant WP leader will be responsible for ensuring the quality of collected data. Experimental results will always be reviewed by the scientific coordinator for any anomalies. Experiments on mice will always be performed under the supervision of the principal investigator, who will ensure that they are executed according to set guidelines.

3) Storage and Backup during the Research Process

3.1) How will data and metadata be stored and backed up during research

Describe where the data will be stored and backed up during research activities and how often backup will be performed

All research data will be separately stored in multiple locations to ensure data preservation. Raw and analysed data will be stored in local C: drive on laptops, external hard drives, as well as on the OneDrive file storage system offered by the IT services of the partner institution (CUT). This approach ensures secure long-term storage of data. Raw data will be individually stored at these 3 locations as soon as possible after collection. Data collected from the MRI scanner will be transferred from the CD-ROM to the workspace of researchers, sorted and immediately transferred to the external hard drive and OneDrive. Similarly, data collected with other instruments will again be transferred from their original external storage location (i.e., thermometer for thermocouple recordings, slide scanner for digital histology slides, cell phones for photos of experiments, etc.) to the laptops of researchers and then stored in the external hard drive and OneDrive. When raw data has been fully analyzed, the analyzed data along with any accompanying documentation will be saved in all 3 locations. Moreover, for any data generated in paper documents, photos of the documents will be taken and digitally stored.

3.2) How will data security and protection of sensitive data be ensured during the research

3.2.1) Explain how the data will be recovered in the event of an incident

All raw data and analysed data will always be stored in the OneDrive account of the scientific coordinator. As a result, backup versions of all data can be completely recovered and restored in the event of loss or damage.

3.2.2) Explain who will have access to the data during the research and how access to data will be controlled, especially in collaborative partnerships.

All researchers will have access to the majority of raw and analysed data according to the regulations set by the project and scientific coordinators. However, researchers will not have access to proprietary data underlying the patent application or other sensitive data. Such data will only be accessible by the coordinators. Email and WeTransfer (WeTransfer, Amsterdam, Netherlands) services will be used to quickly share data within the project team. Additionally, links to personal OneDrive accounts will be used to facilitate secure access to data for project researchers. Literature studies cited in publications produced during the project will be stored in a OneDrive folder, providing all project members with direct access to existing published work.

3.2.3) Specify measures that will be taken for protection of sensitive data.

As mentioned above, access to data will be strictly controlled by the coordinators, who will carefully monitor and document the access rights of each researcher to specific types of data. The scientific coordinator will exclusively access the data underlying the patent application. Furthermore, patent data will only be stored in local storage provided by CUT, thus securely protecting associated data from any unauthorised 3rd party access.

4) Legal and Ethical Requirements, Codes of Conduct

4.1) If personal data will be processed, indicate how compliance with legislation on personal data and on security will be ensured

No personal data will be processed in this project as experiments will be conducted solely on mice, and any photos taken during experiments (in the laboratory or MRI setting) will not include any persons, ensuring compliance with legislation on personal data and security.

4.2) How will other legal issues such as IP rights and ownership be managed

4.2.1) Explain who will be the owner of data and what access conditions will apply to data

The owner of data was defined in the consortium agreement signed between LINAC-PET SCAN OPCO LTD (LINAC) and CUT. Access to data will be managed by the data rightsholder according to the regulations stipulated in the grant agreement.

Generally, produced data will remain under the ownership of the rightsholder but will be freely usable and openly accessible between project stakeholders. Open science practices will be followed to promote transparency and achieve reproducibility of research outputs. Steps will be taken to provide green or gold open access to peer-reviewed scientific publications of the project. In case of green access publication, the consortium will adopt a self-archiving route to open access, submitting the published articles to the institutional repository of CUT. Raw data underlying publications will be accessible by 3rd parties upon request from the corresponding author (scientific coordinator). Access to personal, sensitive or IP protected data will be carefully restricted only to authorised personnel. Nevertheless, if such restrictions exist on underlying data requested to validate results in scientific publications, controlled access will be transiently granted to individuals with legitimate reasons and revoked when no longer required. Data that could potentially hinder the patent application process will not be included in any of the publications.

4.2.2) Indicate whether IP rights will be affected. If so, explain which and how these will be dealt with

No access to data pertaining to the patent application will be granted to 3rd parties. These data will be explicitly and exclusively controlled by the scientific coordinator according to the terms set out in the consortium agreement. Consequently, any IP rights resulting from the project will be protected from potential privacy or security risks.

4.2.3) Indicate whether there will be restrictions on the re-use of 3rd party data.

No 3rd party data will be re-used or repurposed, thus no such restrictions exist.

4.3) What ethical issues and codes of conduct will there be, and how will these be taken into account?

4.3.1) Indicate whether ethical issues will affect how data will be collected, stored, and shared.

Experiments on animals were approved by the relevant ethics committee (Veterinary Services of Cyprus, Ministry of Agriculture, Rural Development and Environment, Nicosia, Cyprus) prior to commencement of research. Accordingly, relevant data will be collected in approved environments according to the guidelines established in the granted ethics application. Collected data will be properly handled, shared, and published according to ethical guidelines. If relevant results are published, the ethics of publication will be considered by always referencing the number of the granted license.

4.3.2) Describe whether informed consent for data sharing and long-term preservation will be included in documents dealing with personal data.

Since *in-vivo* experiments will be conducted on mice and will not involve personal data, and no data from human subjects will be collected or processed as part of the project, informed consent for data sharing and long-term preservation is not applicable. All data collected from the experiments in mice, including images, raw data, and reports, will be stored for future submission to the Veterinary Services of Cyprus upon request.

5) Data Sharing, Interoperability, and Long-term Preservation

5.1) How, when, and where will data be shared? Are there possible restrictions to data sharing or embargo reasons?

5.1.1) Explain which data will be discoverable and shared (e.g., by deposit in a trustworthy data repository, indexed in a catalogue, use of a secure data service, direct handling of data requests, or use of another mechanism). Indicate whether data sharing will be postponed or restricted for legal, IP, contractual or voluntary reasons.

Peer-reviewed publications produced over the course of the project will be shared and made accessible to the public following the open-access policies set by Horizon Europe. Published work will include a detailed description of tools and methods necessary for replicating the presented results, in line with the "as open as possible, as closed as necessary" policy to protect personal, sensitive or IP related data. As such, in cases of data sensitivity, raw datasets underlying peer-reviewed publications will not be disclosed in open access research data repositories. Moreover, project deliverables containing processed data and output results will be openly accessible to the public following the declarations established in the grant agreement. However, this excludes deliverables related to the IPR management and Exploitation plan, as well as the development of the robotic system and accompanying software. Data relating to the design of the robotic system (figures, deliverables, publications) will not be made public to protect confidential information that could infringe on potentially granted patent rights.

5.1.2) Explain how data will be made accessible (e.g. by deposition in a repository)?

The consortium will follow open-science practices to make data accessible and promote transparency and reproducibility of research outcomes. Peer-reviewed publications not published with gold open access will be made publicly available by authors through the green open access route by self-archiving articles to the institutional repository of CUT. Additionally,

generated scientific publications will be announced on the social media platforms of the project (Facebook, LinkedIn). All data and associated metadata supporting reported findings will be deposited in suitable subject-specific repositories or cross-disciplinary generalist repositories (e.g., Zenodo), provided that specific legal or ethical constraints do not prohibit public sharing of a dataset. Links to the repository will be provided in the relevant publications to ensure easy access for interested parties.

Publicly available deliverables will be uploaded on the project website of the partner organisation (https://theralabcut.org). Non-public data such as datasets underlying peer-reviewed work, documentation reporting on experimental protocols and other sensitive or personal data will be deposited in an internal institutional data repository with restricted access option. For deposited data underlying published peer-reviewed works, a reference to the publication (DOI) will be indexed so that raw data can always be linked to published results.

5.1.3) Explain when data will be made available. Indicate the expected timely release.

Peer-reviewed scientific articles will become publicly available once accepted manuscripts are published online by the relevant journals. As such, availability of these data will be dependent on the duration of the peer-review process and the journal's speed of publication. Nevertheless, as soon as accepted manuscripts are available online, they will be deposited on the Ktisis repository (CUT) as well as announced on the project's social media platforms. Public deliverables will be uploaded on the project website upon project completion. Non-public research outcomes will be deposited on the institutional repository immediately after production. These data will not be made available in the foreseeable future. The design of the robotic system will become openly accessible by default once the patent is granted and IP rights are secured. Consequently, any associated data and publications can then be made public. A period of up to 5 years after the project ends will be allocated to allow researchers to protect their IP rights.

5.1.4) What methods or software tools will be needed to access and use data?

Generally, for open data, no specific software is required since data can be accessed online using common internet browsers. Peer-reviewed publications can be accessed through hypertext transfer protocols (HTTP), while public deliverables can be downloaded in computationally universal readable formats (.pdf).

Regarding all raw, processed, or analysed data deposited in the internal repository (not for general use), online access will depend on the type and format of the data. Deposited data

generated in common Microsoft formats (i.e., .docx, .xlsx, .jpg, etc.) will be viewable online. For all other kind of data, files will be downloadable from the repository, with the software required for offline viewing/editing depending on the file type. Generated 3D CAD models will only be able to be opened and edited with the Inventor software (Autodesk, USA). Raw MRI data will be operable with any DICOM viewer software, while digital histology slides will be viewable and interpretable with the open-source PMA start software (Pathomation, Antwerp, Belgium). However, if raw MRI data need to be processed to re-generate MR thermometry data, this will only be achievable with the control/treatment planning software.

5.1.5) Will documentation about the software be needed to access the data included?

For data that can be accessed with general or open-source software, no documentation will be needed. Accordingly, no documentation will be required for data that can be opened with commercial proprietary software (Inventor, Autodesk). However, documentation (installation and user guides) for the treatment planning/monitoring software developed during the project, which is necessary for regenerating MR thermometry data, should be included in the internal data repository along with the required executable files.

5.1.6) Describe the sustainability of software needed for accessing the data. Will it be possible to include the relevant software (e.g., in open-source code)?

Numerous open-source DICOM viewer software, needed to access raw MRI data, can be found online, so no such software needs to be included. The software required for accessing 3D CAD models (Inventor, Autodesk, USA) is license-based and cannot be provided to 3rd parties. In case Inventor (Autodesk) is not available for commercial use in the future, it is expected that CAD designs will remain accessible through a corresponding software from the same company (Autodesk). The PMA start software (Pathomation, Belgium) needed for viewing virtual histology slides is open-source, and thus the relevant link will be provided (https://free.pathomation.com).

As the host organisation intends to commercially exploit the robotic device as a complete system, the control software developed in the project framework will not be openly available to protect the data-driven business model of LINAC. The developed software will be an executable file that can run smoothly on new computers with a Windows operating system (Microsoft Corporation).

5.1.7) Indicate who will be able to use the data. If there are restrictions on use, how will access be provided?

All data and research outcomes that will not be openly available will only be accessible by authorised users. Restricted datasets will only be visible to the project and scientific coordinators and team researchers granted access by project leaders. Controlled access to raw data underlying peer-reviewed publications will be provided to external researchers after request to the scientific coordinator. Any requests will be evaluated on the basis of the reason for request and the purpose for which raw data will be used. If requests are authorised, transient access, for a period defined by the scientific coordinator, will be given to the requesting party following a formal data sharing agreement.

5.1.8) How will the identity of the person accessing the data be ascertained?

No access control is required for open data; however, data re-users are anticipated to abide with basic citation principles. For people requesting access to restricted data, appropriate measures will be taken to ascertain identities. For this purpose, the IT department of the partner organisation will be consulted.

5.2) How will data be preserved in long-term?

5.2.1) Indicate what data will be preserved and what data must be destroyed for contractual, legal or regulatory purposes.

All data, from raw to final, will be preserved after the end of the project, as no personal/sensitive data will be generated or collected through the project.

5.2.2) Give information on how long data will be retained.

Produced data will be retained for at least 10 years after the end of the project to enable re-usability.

5.2.3) Indicate where will data and associated metadata be deposited. If no established repository is proposed, demonstrate that the data can be curated effectively beyond the lifetime of the grant.

Data and associated documentation collected or produced by the project will be securely archived to internal data repositories of the partner organisation after the end of the project. All data will be accompanied by rich metadata to enable reproducibility.

Published peer-reviewed scientific papers will be indefinitely available and retrievable via their assigned DOI. The domain of the website of the partner organisation has been purchased

enabling long-term accessibility of the project's public deliverables. All data and associated metadata supporting the reported findings will be deposited in suitable subject-specific repositories (e.g., OpenfMRI) or cross-disciplinary generalist repositories (e.g., Zenodo, Dataverse, IEEE Dataport), provided that specific legal or ethical constraints do not prohibit public sharing. Links to the repository will be provided in the relevant publications to ensure easy access for interested parties.

5.2.4) Demonstrate that the repositories policies and procedures have been checked and appropriate arrangements have been made.

Regarding the Institutional repository, no special arrangements relating to the storage of data generated by the project need to be made, and no specific policies need to be followed.

We have ensured that the policies and procedures of generalist repositories, such as Zenodo, have been thoroughly reviewed and related guidelines will be followed to facilitate seamless deposition of non-sensitive project data.

5.3) How will data be interoperable?

5.3.1) Will the data produced in the project be interoperable, that is allowing data exchange and re-use between researchers, institutions, organisations, countries, etc. (i.e., adhering to standards for formats, as much as possible compliant with available (open) software applications, and in particular facilitating re-combinations with different datasets from different origins)?

The majority of data generated by the project will be fully interoperable facilitating data exchange and reuse. Open access data will be produced in standardised formats providing full unrestricted access. Analysed restricted access data will also conform to standard formats enabling data reuse between internal researchers. Raw restricted access data will be compliant with formats that can be read by numerous open-source software applications.

5.3.2) Describe the foreseeable research uses for the data.

Generated data will be particularly important to stakeholders and the broader scientific community. Peer-reviewed publications and deposited supplementing data and metadata will be useful to other researchers or experts in the field of focused ultrasound who wish to either replicate or validate results, or continue the research, further advancing the field. In this regard, publicly available project deliverables will serve as dissemination documents, raising awareness about the full range of project's activities to other research teams interested in this area, potentially encouraging their involvement. Raw and analysed restricted data may be

reused by the consortium partners or even stakeholders to establish the ground for future funded research grants. In addition to research purposes, some of the collected data will be particularly important to the host organisation, having an impact on the potential commercial exploitation of the technology and the securing of IP rights.

5.3.3) What data and metadata vocabularies, standards or methodologies will you follow to make your data interoperable?

Standard machine-readable file formats will be used to store datasets. Most numerical datasets will be stored in common .xlsx format, ensuring interoperability for sharing and re-use. Keywords acting as metadata to open peer-reviewed publications will be selected based on default vocabularies.

5.3.4) Are you going to use standard vocabularies for all data types present in your data set to allow inter-disciplinary interoperability?

Produced data will be described, to the extent possible, utilizing the most common definitions employed by the scientific community, enabling easy interdisciplinary use.

5.3.5) In case it is unavoidable that you use uncommon or generate project specific ontologies or vocabularies, will you provide mappings to more commonly used ontologies?

No project specific ontologies or vocabularies will be used, so mappings to common ontologies will not be provided.

6) Data Management, Responsibilities and Resources

6.1) Who (e.g., role, position, institution) will be responsible for data management?

6.1.1) Outline the roles and responsibilities for data management/stewardship activities (e.g., data capture, metadata production, data quality, storage and backup, data archiving, data sharing). Name responsible individuals where possible.

The project partners will collaboratively coordinate data management and assign specific activities and responsibilities to individuals as described in the following Table 3.

Table 3: List of individuals responsible for data management activities.

Data Management Activity	Person	Organisation
Data collection	Christakis Damianou (Scientific coordinator)	CUT
	Nikolas Evripidou (Researcher)	CUT
	Anastasia Antoniou (Researcher)	CUT
	Leonidas Georgiou (MRI technologist)	LINAC
Data quality	Christakis Damianou	CUT
	Yiannis Rousakis (Project Coordinator)	LINAC
	Cleanthis Ioannides (Radiology expert)	LINAC
Storage and/or backup	Christakis Damianou	CUT
	Nikolas Evripidou	CUT
	Yiannis Rousakis	LINAC
Data archiving	Christakis Damianou	CUT
	Nikolas Evripidou	CUT
	Leonidas Georgiou	LINAC
Data sharing	Christakis Damianou	CUT
	Yiannis Rousakis	LINAC

6.1.2) Indicate who will be responsible for implementing the data management plan, and for ensuring it is reviewed and if necessary revised.

The data management plan was prepared by the host (LINAC) and reviewed by the partner organisation (CUT). The coordinators will be responsible for implementing the data management plan effectively. The Data Management Plan will be updated throughout the first year of the project to incorporate any changes or updates to reported methodologies and expected data collection and generation. The developed plan will be submitted in month 12; however, any necessary updates (if applicable) will be made during the project and reported in the final report.

6.2) What resources (e.g., financial and time) will be dedicated to data management and ensuring that data will be FAIR?

6.2.1) Explain how the necessary resources (e.g., time) to prepare the data for sharing/preservation (data curation) will be costed in. Carefully consider and justify any resources needed to deliver the data. These may include storage costs, hardware, staff time, costs of preparing data for deposit, and repository charges.

Costs required for data collection, sharing and preservation and making data FAIR will be covered to a large extent by the project's budget. Therefore, no additional costs for data management are expected to emerge for this project.

Peer-reviewed scientific publications published as open access will be covered by available funds. Once these funds are exhausted, papers will be published following conventional publishing options (subscription-only) and will be made openly accessible by self-archiving in the Ktisis repository. This service is provided by CUT to research projects, with the costs (unknown amount) bared by the Library Services of CUT.

Costs for data storage in the institutional repository are also covered by CUT. Project deliverables will be shared to the public through the existing website of the partner organisation. In this sense, no costs will be associated with website development. Uploading deliverables to the website requires minimal time and personnel costs. If needed, costs associated with maintaining and updating the website after the end of the project will be covered by the scientific coordinator's research grant.

Data analysis, organisation and storage will be completed at the shortest possible timeframe after collection, thus actively reducing the costs needed for effective management of datasets. Researchers involved in data collection will spend approximately 20 % of their time on data management and curation according to FAIR principles to ensure findability and reusability.

6.2.2) Indicate whether additional resources will be needed to prepare data for deposit or to meet any charges from data repositories. If yes, explain how much is needed and how such costs will be covered.

No additional resources will be needed to prepare data for deposit or cover repository charges. Any necessary additional funds will be covered by the research grant of the scientific coordinator.

Appendix 1: Report template for laboratory experiments

CYPRUS UNIVERSITY OF TECHNOLOGY

DEPARTMENT OF ELECTRICAL ENGINEERING AND COMPUTER ENGINEERING AND INFORMATICS

TITLE OF EXPERIMENT

Date: Date on which experiments were executed.

Place: Place wherein experiments were performed.

Project: Project acronym and number.

Participants: Researchers performing experiments.

1. PURPOSE

Short description of the objectives of the executed experiment.

2. MATERIALS AND METHODS

- List of materials and equipment used for execution of the experiments.
- Details regarding the model and manufacturing company of instrumental equipment.
- Details relating to the nature and composition of sonicated target (e.g., phantom with 6% w/v agar).
- Photo of the experimental set-up.
- Description of the experimental procedure and followed methodology.

3. RESULTS

Analysed results in the form of figures, photos, and tables.

4. INTERPRETATION OF RESULTS/ CONCLUSIONS

Summary of acquired results and generated data, and discussion (where appropriate indicate the need for future experiments).

Appendix 2: Report template for MRI experiments

TITLE OF EXPERIMENT

Date: Date on which experiments were executed.

Place: Location at which experiments were performed.

Project: Project acronym and number.

Participants: Researchers performing experiments.

1. PURPOSE

Short description of the purpose and objectives of the performed MRI experiment.

2. MATERIALS AND METHODS

- List of materials used for execution of the experiments (e.g., sonication target; phantom or excised tissue).
- Details on equipment used, such as transducer, amplifier, MRI scanner, MR imaging coil, etc. (including model and manufacturing company where appropriate).
- Photo of the experimental setting.
- MR sequence parameters employed for imaging during the experiment in the form of a table:

Sequence name	**TR (ms)**	**TE (ms)**	**Flip Angle (^{o})**	**NEX**	**Transmit Coil Type**
Pixel Bandwidth (Hz/Pixel)	**FOV (mm^2)**	**Slice thickness (mm)**	**Matrix**	**ETL**	**Receive Coil Type**

3. RESULTS

- Results in the form of acquired MR images, processed figures, tables and photos. Describe results in the order with which sonications were executed.
- Short summary of executed sonications and relevant outcomes in the form of a table:

Sonication	**Imaging plane**	**Acoustic power (W)**	**Duration of sonication (s)**	**Delay (s)**	**Single/Grid sonication**	**ΔT (^{o}C)**
1	Coronal, Axial or Sagittal	Acoustic power in W	Sonication time	Time delay between sonications	Indicate single point or grid size	Peak temperature change achieved
….	….		….	….	….	

Appendix 3: Report template for mice experiments

Experiment X

Date: Date on which the experiment was executed.

Study ID: BRAINSONIC - X

Participants: Expert scientists involved in the experiment.

Species, **Weight (g)**: **Age (months)**:

Anaesthesia:

Tumour type: Glioblastoma

Size of tumour:

Procedure: e.g. 1) Anaesthesia, 2) FUS Treatment, 3) Surgical removal of tumour and biopsy.

FUS system, Transducer:

Amplifier:

Protocol: List of employed sonication parameters.

Biopsy procedure (if applicable): Tissue placed in formalin solution and sent for biopsy (H&E).

Analgesics: Type, amount, and frequency of administration of analgesics.

Euthanasia method: Indicate method used for euthanasia, e.g., cervical dislocation under general anaesthesia.

Experimental duration: Total duration of procedure.

Observation/Comments: Indicate any behavioural and physical observations.

Experiment photos: Photos taken during the experiments.

Histology exam outcomes (if applicable): Digital H&E-stained histological slides.

Conclusions: Short conclusion for the results of the histological examination or any other.