



DATA MANAGEMENT PLAN

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 22NRM01

 Project short name
 TraMeXI

 Project full title
 Traceability in medical X-ray imaging dosimetry

 Data management plan
 1st ⋈ 2nd □ 3rd □

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Data Management Plan

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1 Data management plan

1.1 Data summary

1.1 Data summary			
Questions	Answers		
1 Will you re-use any existing	This project will re-use:		
data and what will you re-use	Internal data from the participants		
them for? State the reasons if	Publicly available data		
re-use of any existing data has			
been considered but discarded.	These data will be used for the following purpose:		
	Validation of the project's results		
	Calculation of conversion coefficients		
2 What types and formats of	The project will collect:		
data will the project generate or	Raw data in ASCII format		
re-use?	Graphics: jpg, bmp, png		
	Tables: xlsx, csv		
	Text: md, docx, pptx, pdf		
3 What is the purpose of the	Purpose of the data generation or re-use		
data generation or re-use and its	The data generated and re-used will be from measurements,		
relation to the objectives of the	simulations, calibrations, comparisons and validations. They will be used		
project?	in meeting the project's objectives and in conference and peer-reviewed		
	publications.		
	Data generated in relation to the objectives of the project		
	Data will be generated by the consortium in order to meet all five		
	objectives. Data from questionnaires, market surveys and scientific		
	literature will result from objectives 1 to 3, measurement and simulation		
	data from objectives 1 and 2 and comparison and validation data from		
	objectives 3 and 4. Data will be used to support end-user uptake		
	(objective 5).		
	Data re-used in relation to the objectives of the project		
	Data from questionnaires, market surveys and scientific literature as well		
	as measurement, simulation, calibration, comparison and validation		
	data will be re-used by the consortium so to meet objectives 1 and 4.		
4 What is the expected size of	The estimated overall size of the data/research outputs is expected to be		
the data that you intend to	in the range: between 200 GB to 1 TB.		
generate or re-use?			
5 What is the origin/provenance	Data generated in the project		
of the data, either generated or	The data generated will be from questionnaires, market surveys,		
re-used?	measurements, simulations, calibrations, comparisons and validations.		
	Re-used data		
	The existing data will originate from several sources, which will include:		
	participant's pre-existing data, data from the scientific literature, real-		
	world measurement data and data from simulation experiments.		
0.7			
6 To whom might your data be	The data might be useful to:		
useful ('data utility'), outside your	Stakeholders from industry, namely the manufacturers of dosimeters		
project?	and X-ray systems		
	Standardisation bodies: IEC, IAEA		
	NMIs/DIs performing type testing, verifications and/or calibrations of		
	dosimeters		
	Other scientists working in the field of X-ray imaging dosimetry		





1.2 Findable, Accessible, Interoperable and Re-usable (FAIR) Data

1.2.1 Making data findable, including provisions for metadata

Questions	Answers
7 Will data be identified by a	The project's deposited datasets and research outputs (protocols,
persistent identifier?	reports, software,) will be findable as each will be identifiable with
	preferably a DOI, or other persistent and unique identifier.
8 Will rich metadata be provided	The metadata created for all of the project's deposited datasets will be
to allow discovery? What	open under a Creative Commons Public Domain Dedication (CC 0) or
metadata will be created? What	equivalent (to the extend legitimate interests or constraints are
disciplinary or general standards	safeguarded), in line with the FAIR principles. The metadata will provide
will be followed? In case	information on the following: Description of the file (to help users
metadata standards do not exist in your discipline, please outline	understand what the file contains and how data need to be used); date of deposit; author(s); possible embargo; acknowledgement of the
what type of metadata will be	European Partnership on Metrology funding; grant project name,
created and how.	acronym and number; licensing terms; persistent identifiers for the
croated and new.	dataset, the authors involved in the action, and, if possible, for their
	organisations and the grant. Where applicable, the metadata will include
	persistent identifiers for related publications and other research outputs.
9 Will search keywords be	Yes, the following search keywords will be provided in the metadata to
provided in the metadata to	optimise the discovery and potential re-use of the deposited datasets:
optimise the possibility for	Traceability, calibration, radiology, standardization, Code of Practice,
discovery and then potential	semiconductor detectors, multimeter, radiation quality, X-ray imaging,
re-use?	dosimetry, ionizing radiation.
10 Will metadata be offered in	Yes, the data and associated metadata will be deposited in the trusted
such a way that it can be	open access repository Zenodo (https://zenodo.org) that complies with
harvested and indexed?	FAIR principles. Metadata of each record is indexed and searchable
	directly in Zenodo's search engine immediately after publishing. Metadata of each record is sent to DataCite servers during DOI
	registration and indexed there. Metadata for individual records as well
	as record collections are harvestable using the OAI-PMH protocol by the
	record identifier and the collection name.

1.2.2 Making data accessible

Questions	Answers
Repository:	
11 Will the data be deposited in a trusted repository?	The data and associated metadata, documentation and code will be deposited in the trusted open access repository Zenodo (https://zenodo.org)
12 Have you explored appropriate arrangements with the identified repository where your data will be deposited?	No. The data is expected to be uploaded via standard procedures, without any special arrangements.
13 Does the repository ensure that the data are assigned an identifier? Will the repository resolve the identifier to a digital object?	Yes, Zenodo will assign an identifier (DOI) to each of the project's deposited datasets. The repository will resolve the identifier to a digital object.
Data:	
14 Will all data be made openly available? If certain datasets cannot be shared (or need to be shared under restricted access conditions), explain why, clearly separating legal and contractual	All of the data that are needed to validate the results presented in scientific publications will be made openly available as the default unless there is a specific reason not to publish the data. Datasets which cannot be shared – voluntary restrictions





Questions	Answers
reasons from intentional restrictions. Note that in multi-beneficiary projects it is also possible for specific beneficiaries to keep their data closed if opening their data goes against their legitimate interests or other constraints as per the Grant Agreement.	Other data may be made available on a case-by-case basis if it is relevant for third parties. The following data will not be made publicly available: • Data obtained with the permission of third parties, when third parties have not agreed to make the data publicly available. • Data that discloses the identity of a manufacturer. • Data that compromises the protection of a participant(s) intellectual property. The level of data made available will also be considered, for example, pre-processed data will not be provided unless there is a clear reason for doing so. Datasets which cannot be shared - legal / contractual reasons
	All of the data from the project will be made available, with the exception of market or customer survey data, which are commercially sensitive and cannot be shared.
15 If an embargo is applied to give time to publish or seek protection of the intellectual property (e.g. patents), specify why and how long this will apply, bearing in mind that research data should be made available as soon as possible.	The data used in scientific publications, posters and oral presentations will be made available for re-use as soon as reasonably possible.
16 Will the data be accessible through a free and standardised	Yes, Zenodo provides well-described conditions for free and standardised access (see http://about.zenodo.org/policies/).
access protocol?	
17 If there are restrictions on use, how will access be provided to the data, both during and after the end of the project?	There are no restrictions on the use of the published data, but users will be required to acknowledge the project and the source of the data in any resulting publications, according to the CC-BY 4.0 license.
18 How will the identity of the person accessing the data be ascertained?	There is no need to ascertain the identity of persons accessing the data.
19 Is there a need for a data access committee (e.g. to evaluate/approve access requests to personal/sensitive data)?	This consortium will have a Data Access Committee. Their remit will be to select the data that will be openly accessible on a case-by-case basis. Ethical aspects and data security, including intellectual property requirements, will be considered as will access requests to personal/sensitive data. If necessary, some or all of a potential publication's data will be withheld. This will be decided in consultation with the relevant participant(s).
Metadata:	
20 Will metadata be made openly available and licensed under a public domain dedication CC0, as per the Grant Agreement? If not, please clarify why. Will metadata contain information to enable the user to access the data?	In Zenodo, metadata are licensed under CC0, except for email addresses. All metadata are exported via OAI-PMH and can be harvested.
21 How long will the data remain available and findable? Will metadata be guaranteed to	The data will remain available and findable for the lifetime of the Zenodo repository, which is expected to be a minimum of 20 years.





Questions	Answers
remain available after data are no longer available?	If data are withdrawn from Zenodo, the DOI and the URL of the original object are retained. In case of closure of the Zenodo repository, best efforts will be made by Zenodo to integrate all content into suitable alternative.
22 Will documentation or reference about any software be needed to access or read the data and will this be included? Will it be possible to include the relevant software (e.g. in open source code)?	The data are in a common format and can be read using widely available software (open source or commercial).

1.2.3 Making data interoperable			
Questions	Answers		
23 What data and metadata vocabularies, standards, formats or methodologies will you follow to make your data interoperable to allow data exchange and re-use within and across disciplines? Will you follow community-endorsed interoperability best practices? Which ones?	The datasets will use the trusted repository's basic metadata schema for administrative data, which is compliant with the recommended standards used by DataCite (https://search.datacite.org/) and OpenAIRE (https://www.basesearch.net/). For individual datasets, the following discipline-specific vocabularies, standards, formats, and methodologies will be used: 1. GUM (uncertainty procedure; subject-independent). 2. VIM (vocabulary; metrology). 3. ISO 17025 (QM procedure; calibration and testing). 4. IEC 61267 (definition of reference radiation qualities for calibrations; X-ray dosimetry) 5. ISO 4037(definition of X-ray radiation qualities for testing; X-ray dosimetry). 6. IEC 61674 (requirements for dosimeters; X-ray dosimetry) 7. IEC 61676 (requirements for dosimeters measuring tube voltage: X-ray dosimetry)		
24 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? Will you openly publish the generated ontologies or vocabularies to allow their re-use, refinement or extension?	No mappings will be necessary, as the datasets will be described using standard terminologies. Vec. the project's datasets that will be deposited in the chosen repository.		
25 Will your data include qualified references ¹ to other data (e.g. other data from your project, or datasets from previous research)?	Yes, the project's datasets that will be deposited in the chosen repository (Zenodo) will include qualified references to other datasets from the same project and from previous research.		

1.2.4 Increase data re-use

Questions					Answers
26	How	will	you pro	vide	A short README file will be provided together with the data, in order to
dod	umentat	ion	needed	to	enable data analysis and to facilitate data re-use.

1 A qualified reference is a cross-reference that explains its intent. For example, X is regulator of Y is a much more qualified reference than X is associated with Y, or X see also Y. The goal therefore is to create as many meaningful links as possible between (meta)data resources to enrich the $contextual\ knowledge\ about\ the\ data.\ (Source: \underline{https://www.qo-fair.org/fair-principles/i3-metadata-include-qualified-references-metadata/)$





Questions	Answers
validate data analysis and facilitate data re-use (e.g. readme files with information on methodology, codebooks, data cleaning, analyses, variable definitions, units of measurement, etc.)?	
27 Will your data be made freely available in the public domain to permit the widest re-use possible? Will your data be licensed using standard re-use licenses, in line with the obligations set out in the Grant Agreement?	The data will either be licensed under the latest available version of the Creative Commons Attribution International Public License (CC BY) or a license with equivalent rights as set out in the Grant Agreement. Users will be required to acknowledge the consortium and the source of the data in any resulting publications. Alternatively, the Creative Commons Public Domain Dedication License (CC 0) will be used.
28 Will the data produced in the project be useable by third parties, in particular after the end of the project?	Any data published in open-access journals will be usable by third parties after the datasets have been deposited in Zenodo. The data that do not relate to peer-reviewed publications will be made available for reuse on a case-by-case basis.
29 Will the provenance of the data be thoroughly documented using the appropriate standards?	Yes, the provenance and context of the data will be thoroughly documented to meet relevant standards using the Provenance and Context Content Standard (PCCS) Matrix. Data will be accompanied by information on how they were captured, processed, analysed, and validated. Other information that enables interpretation and use will also be provided.
30 Describe all relevant data quality assurance processes.	Data quality will be assured through several quality assurance procedures: Repeated and comparison measurements. Adherence to standards for data recording. Use of controlled vocabularies and standard terminology. Metrological characterisation of the measurement set-ups. Validation of the data collected. Provision of test results along with the data. Peer-review of publications based on the data.
31 Further to the FAIR principles, DMPs should also address research outputs other than data, and should carefully consider aspects related to the allocation of resources, data security and ethical aspects.	The estimated costs for making the (data and) other research outputs FAIR are 1,000 € (personnel costs) (see question 34). The costs for making other research outputs FAIR are included in the project's budget and will be claimed if compliant with the Grant Agreement's conditions. The consortium's Data Access Committee will also have overall responsibility for managing other research outputs (see question 36). Where feasible, long-term preservation will be ensured by depositing the other research outputs in repositories. The Data Access Committee will decide on a case-by-case basis on which other research outputs will be deposited and for how long.
	Security of other research outputs All participants are either accredited to, or work in compliance with, the ISO 17025 standard on the "General requirements for the competence of testing and calibration laboratories". The participants will store other research outputs on their organisations' networks, which are protected by firewall, backups etc. Other research outputs will also be stored in the project's SharePoint environment, with password-protected login. Deposition in public repositories will provide additional security as they have multiple replicas in a distributed file system which is backed up on





Questions	Answers
	a nightly basis. This project will not generate sensitive other research outputs. The other research outputs will be safely stored in open access repositories.
	Ethical aspects There are issues that could impact on the sharing of other research outputs. • Information relating to other research outputs acquired from third parties, e.g. manufacturers, will not be shared without their explicit consent. • Information relating to other research outputs collected by the consortium at commercial sites will not be shared without the site owner's explicit consent. The project will not share other research outputs with identifiable personal information. Sensitive information relating to the other research outputs will be collected, separated as soon as possible and kept secure. Please also see the information provided in section 1.3 below.

1.3 Other research outputs

1.3 Other research outputs			
Questions	Answers		
32 In addition to the management of data, beneficiaries should also consider and plan for the management of other research outputs that may be generated or re-used throughout their projects. Such outputs can be either digital (e.g. software, workflows, protocols, models, etc.) or physical (e.g. new materials, antibodies, reagents, samples, etc.).	The new calibration methods, and protocols and training materials produced by the project will be stored in a free repository (Zenodo).		
33 Beneficiaries should consider which of the questions pertaining to FAIR data above, can apply to the management of other research outputs, and should strive to provide sufficient detail on how their research outputs will be managed and shared, or made available for re-use, in line with the FAIR principles.	As far as possible, the FAIR data approaches specified in questions 7-30 above will be applied to the management of this project's other research outputs. This commitment will be met by placing the new calibration methods, protocols, and training materials in a repository in line with the requirements of the project's consortium agreement.		

1.4 Allocation of resources

1.4 Anocation of resources			
Questions	Answers		
34 What will the costs be for	The estimated costs for making the data and other research outputs		
making data or other research	Findable, Accessible, Interoperable and Re-usable (FAIR) are 1,000 €		
outputs FAIR in your project	(personnel costs). These costs have been kept to a minimum by using		
(e.g. direct and indirect costs	a free repository (Zenodo) and by making only relevant data and other		
related to storage, archiving,	outputs FAIR.		
re-use, security, etc.)?			





35 How will these be covered? Note that costs related to research data/output management are eligible as part of the European partnership on metrology grant (if compliant with the Grant Agreement conditions).	The costs for making the data FAIR are included in the project's budget and will be claimed if compliant with the Grant Agreement's conditions.
36 Who will be responsible for data management in your project?	The consortium's Data Access Committee will have overall responsibility for data management. The coordinator will lead this committee and will be responsible for coordinating updates to the data management plan. The committee will be responsible for organising data backup and storage, data archiving and for depositing the data within the repository.
37 How will long term preservation be ensured? Discuss the necessary resources to accomplish this	Long term preservation will be ensured by depositing the data within repository Zenodo. There are no costs associated with the long-term preservation of the data in this repository.
(costs and potential value, who decides and how, what data will be kept and for how long)?	The Data Access Committee (DAC) will decide on a case-by-case basis on what data will be kept and for how long.

1.5 Data security

Questions	Answers		
38 What provisions are or will be in place for data security (including data recovery as well as secure storage/archiving and transfer of sensitive data)?	All partners are either accredited to, or work in compliance with the ISO 17025 standard. The partners will store data on their organisations' networks, which are protected by firewall, backups etc. Data will also be stored in the project's SharePoint environment, with password-protected login.		
	Deposition in the Zenodo public repository will provide additional security as it has multiple replicas in a distributed file system which is backed up on a nightly basis.		
	Transfer of sensitive data		
	This project will not generate sensitive data.		
39 Will the data be safely stored	Yes, the data will be safely stored in the Zenodo open access repository.		
in trusted repositories for long			
term preservation and curation?	were designed according to the Open Archival Information Systems (OAIS) reference model. Zenodo is working towards ISO 16363 certification.		

1.6 Ethics

Questions	Answers
40 Are there, or could there be, any ethics or legal issues that can have an impact on data sharing? These can also be discussed in the context of the ethics review. If relevant, include references to ethics report(s) and the ethics section in the Annex 1.	 Issues that could impact data sharing: Data acquired from third parties, e.g., manufacturers will not be shared without their explicit consent; Data acquired together will collaborators will be subject to the Letter of Agreement signed between the consortium and the collaborator. The data from the market surveys will be made anonymous to comply with the General Data Protection Regulation (GDPR).
	Ethical issues that may emerge in the course of the project will be addressed in project meetings and reported in meeting reports.





Questions	Answers
41 Will informed consent for	Data acquired from third parties such as national and international
data sharing and long-term	organizations and QA provider will not be shared without their explicit
preservation be included in	consent. If any sensitive data are collected they will be separated as
questionnaires dealing with	soon as possible and kept secure.
personal data?	

1.7 Other issues

Questions	Answers	
42 Do you, or will you, make use of other national / funder / sectorial / departmental procedures for data	<i>''</i>	
management? If yes, which ones (please list and briefly describe them)?	- montational gardonnoo;	

2 Open science: research data management

Statement	Put an X in the box to confirm	Or, list any exceptions to this
All participants have adhered to the requirements of the project's GA and CA with respect to open science: research data management (GA Article 17 and its Annex 5) for this reporting period		