

SECURE

Project Number 101061230




DELIVERABLE D6.2

DATA MANAGEMENT PLAN

Lead Beneficiary: EVALION

Due date: 31/03/2023

Released on: 09/06/2024

Authors:	Jakub Heller, Michaela Velčková, Ronald Schram, Marco Capogni, Renata Milolajczak, Dimitris Visvikis		
Version:	1.1		
For the Lead Beneficiary	Reviewed by Work package Leader	Approved by Coordinator	
Jakub Heller	Renata Mikołajczak	Renata Mikołajczak	
			

Dissemination Level		
PU	Public	X
RE	Restricted to a group specified by the Beneficiaries of the SECURE	
SEN	Sensitive, only for Beneficiaries of the SECURE project	

Version control table

Version number	Date of issue	Author(s)	Brief description of changes made
0.1	31/03/2023	Jakub Heller	1 st draft
0.2	28/04/2023	Jakub Heller	Reviewed by WP leaders, dataset descriptions amended
1.0	12/05/2023	Jakub Heller	Final version for submission
1.1	07/06/2023	Jakub Heller	Request for revision by PO Updated

Project information

Project number:	101061230
Project full title:	Strengthening the European Chain of sUPply for next generation medical RadionuclidEs
Acronym:	SECURE
Call and topic:	HORIZON-EURATOM-2021-NRT-01-10
Type of action:	EURATOM-RIA
Project Coordinator Organization:	NCBJ
Coordinator:	Renata Mikołajczak
EC Project Officer:	Renata Bachorczyk-Nagy
Start date – End date:	01/10/22 – 30/09/25 (36 months)
Coordinator contact:	Renata.Mikolajczak@polatom.pl
Administrative contact:	+420 245 008 599, jakub.heller@evalion.cz
Online contacts (website):	https://enen.eu/index.php/portfolio/secure-project/

Disclaimer

The text, figures and tables in this report can be reused under a provision of the Creative Commons Attribution 4.0 International License. Logos and other trademarks are not covered by this license.

The content of the publication herein is the sole responsibility of the publishers and it does not necessarily represent the views expressed by the European Commission or its services.

While the information contained in the documents is believed to be accurate, the authors(s) or any other participant in the SECURE consortium make no warranty of any kind with regard to this material including, but not limited to the implied warranties of merchantability and fitness for a particular purpose.

Neither the SECURE Consortium nor any of its members, their officers, employees or agents shall be responsible or liable in negligence or otherwise howsoever in respect of any inaccuracy or omission herein.

Without derogating from the generality of the foregoing neither the SECUR Consortium nor any of its members, their officers, employees or agents shall be liable for any direct or indirect or consequential loss or damage caused by or arising from any information advice or inaccuracy or omission herein.

EXECUTIVE SUMMARY

This report is the first deliverable of Task 6.3 “Data Management” and describes the initial Data Management Plan (DMP) for the SECURE project, funded by the EU’s Horizon 2020 Programme under Grant Agreement number 101061230. The purpose of the DMP is to provide an overview of all datasets collected and generated by the project and to define the SECURE consortium’s data management policy that is used with regard to these datasets.

The SECURE DMP reflects the status of the data that is collected, processed or generated and following what methodology and standards, whether and how this data will be shared and/or made open, and how it will be curated and preserved.

This initial version of the DMP defines the general policy and approach to data management in SECURE that handles data management related issues on the administrative and technical level. This includes for example topics like data and meta-data collection, publication and deposition of open data and the data repository infrastructure.

CONTENT

1.	BACKGROUND OF THE DATA MANAGEMENT PLAN AND DEFINITIONS	5
1.1.	BACKGROUND	5
1.2.	DEFINITIONS.....	5
1.3.	VERSIONS OF THE DATA MANAGEMENT PLAN.....	6
2.	SECURE DATA.....	7
2.1.	OPEN SCIENCE.....	7
2.2.	DATA SUMMARY.....	8
3.	FAIR DATA MANAGEMENT IN SECURE.....	10
3.1.	MAKING DATA FINDABLE, INCLUDING PROVISIONS FOR METADATA	11
3.1.1	<i>Are the data produced and/or used in the project discoverable with metadata, identifiable and locatable by means of a standard identification mechanism (e.g. persistent and unique identifiers such as Digital Object Identifiers)?.....</i>	11
3.1.2	<i>What naming conventions do you follow?.....</i>	11
3.1.3	<i>Will search keywords be provided that optimize possibilities for re-use?.....</i>	11
3.1.4	<i>Do you provide clear version numbers?.....</i>	12
3.1.5	<i>What metadata will be created? In case metadata standards do not exist in your discipline, please outline what type of metadata will be created and how.</i>	12
3.2.	MAKING DATA OPENLY ACCESSIBLE	12
3.2.1.	<i>Which data produced and/or used in the project will be made openly available as the default? If certain datasets cannot be shared (or need to be shared under restrictions), explain why, clearly separating legal and contractual reasons from voluntary restrictions.....</i>	12
3.2.2.	<i>How will the data be made accessible (e.g. by deposition in a repository)?.....</i>	13
3.2.3.	<i>What methods or software tools are needed to access the data?.....</i>	14
3.2.4.	<i>Is documentation about the software needed to access the data included?.....</i>	14
3.2.5.	<i>Where will the data and associated metadata, documentation and code be deposited? Preference should be given to certified repositories which support open access where possible.....</i>	14
3.2.6.	<i>Have you explored appropriate arrangements with the identified repository?.....</i>	15
3.2.7.	<i>If there are restrictions on use, how will access be provided?.....</i>	15
3.2.8.	<i>Is there a need for a data access committee?.....</i>	15
3.3.	MAKING DATA INTEROPERABLE	15
3.3.1.	<i>Are the data produced in the project 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)? 15</i>	15
3.3.2.	<i>What data and metadata vocabularies, standards or methodologies will you follow to make your data interoperable?.....</i>	15
3.3.3.	<i>Will you be using standard vocabularies for all data types present in your data set, to allow interdisciplinary interoperability?.....</i>	15
3.3.4.	<i>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?.....</i>	15
3.4.	INCREASE DATA RE-USE.....	16
3.4.1.	<i>How will the data be licensed to permit the widest re-use possible?.....</i>	16
3.4.2.	<i>When will the data be made available for re-use? If an embargo is sought to give time to publish or seek patents, specify why and how long this will apply, bearing in mind that research data should be made available as soon as possible. 16</i>	16
3.4.3.	<i>Are the data produced and/or used in the project usable by third parties, in particular after the end of the project? If the re-use of some data is restricted, explain why.</i>	16
3.4.4.	<i>How long is it intended that the data remains re-usable?.....</i>	16
3.4.5.	<i>Are data quality assurance processes described?.....</i>	16
3.5.	ALLOCATION OF RESOURCES.....	17
3.5.1.	<i>What are the costs of making data FAIR in your project?.....</i>	17
3.5.2.	<i>How will these be covered? Note that costs related to open access to research data are eligible (if compliant with the Grant Agreement conditions).....</i>	17
3.6.	WHO WILL BE RESPONSIBLE FOR DATA MANAGEMENT IN YOUR PROJECT?.....	17
3.7.	DATA SECURITY	17
3.7.1.	<i>What provisions are in place for data security (including data recovery as well as secure storage and transfer of sensitive data)?.....</i>	17
3.7.2.	<i>Is the data safely stored in certified repositories for long-term preservation and curation?.....</i>	18
3.8.	ETHICAL ASPECTS.....	18
4.	CONCLUSION.....	19
5.	BIBLIOGRAPHY	19
	ANNEX 1 – INITIAL DATA SURVEY	20

1. BACKGROUND OF THE DATA MANAGEMENT PLAN AND DEFINITIONS

1.1. Background

This document presents the SECURE Data Management Plan (DMP).

According to the EC, Open access (OA) refers to the practice of providing online access to scientific information that is free of charge to the end-user and reusable. 'Scientific' refers to all academic disciplines. In the context of research and innovation, 'scientific information' can mean:

- peer-reviewed scientific research articles (published in scholarly journals);
- research data (data underlying publications, curated data and/or raw data).

The rationale is that data management is not a goal itself, but a way that leads to knowledge discovery and innovation, and to subsequent data and knowledge integration and reuse. Therefore, projects must aim at improving and maximising access to and reuse of research data generated, while balancing openness and protection of scientific information, commercialisation and Intellectual Property Rights, privacy concerns, etc.

DMPs are a key element of good data management. As part of making research data findable, accessible, interoperable, and reusable (FAIR), a DMP should include information on the data life cycle:

- the handling of research data during and after the project,
- what data will be collected, processed or generated,
- what methodology and standards will be applied,
- whether data will be shared/made open and how,
- how data will be curated and preserved.

While open access to research data has become applicable by default in Horizon Europe, the Commission acknowledges that there could be good reasons to keep the research data confidential.

1.2. Definitions

Before explaining the consortium strategy in terms of Data Management, several terms must be defined:

- **Data:** Data refers to unstructured facts and figures, which are not organised in any way and which provide no further information regarding patterns, context, etc. For instance, data on production, demand, results from technical tests and so on, is unstructured data.
- **Information:** For data to become information, it must be contextualized, categorized, calculated and condensed. Information thus paints a bigger picture; it is data with relevance and purpose. It may convey a trend in the environment, or perhaps indicate a pattern of sales for a given period of time.
- **Knowledge:** Knowledge is closely linked to doing and implies know-how and understanding. The knowledge possessed by every individual is a product of his/her experience and encompasses the norms by which he/she evaluates new inputs from his/her surroundings. For instance, knowledge is related to the know-how acquired in R&D projects, commercial activities or the expertise that is inherent to each partner.
- **Dataset:** a dataset is a collection of data. Most commonly a data set corresponds to the contents of a single database table, or a single statistical data matrix, where every column of the table represents a particular variable. The data set lists values for each of the variables, such as height and weight of an object, for each member of the dataset. The data set may comprise data for one or more members, corresponding to the number of rows.
- **Data codebook:** A codebook is an essential document that informs the data user about the study, data file(s), variables, categories, etc., that make up a complete dataset. The codebook may include a dataset's record layout, list of variable names and labels, concepts, categories, cases, missing value codes, frequency counts, notes, universal statements, and so on.

1.3. Versions of the Data Management Plan

According to the EU's guidelines regarding the DMP (European Commission, 2022), the document may be updated, if necessary, during the project lifetime. The minimum requirement is that the DMP is updated at least for each periodic evaluation of the project.

The DMP is intended to be a living document in which information can be made available on a finer level of granularity through updates as the implementation of the project progresses. The DMP should, therefore, have a clear version number and include a timetable for updates.

2. SECURE DATA

2.1. Open Science

Open access to scientific publications

The beneficiaries must ensure open access to peer-reviewed scientific publications relating to their results. In particular, they must ensure that:

- at the latest at the time of publication, a machine-readable electronic copy of the published version or the final peer-reviewed manuscript accepted for publication, is deposited in a trusted repository for scientific publications
- immediate open access is provided to the deposited publication via the repository, under the latest available version of the Creative Commons Attribution International Public Licence (CC BY) or a licence with equivalent rights; for monographs and other long-text formats, the licence may exclude commercial uses and derivative works (e.g. CC BY-NC, CC BY-ND) and
- information is given via the repository about any research output or any other tools and instruments needed to validate the conclusions of the scientific publication.

Beneficiaries (or authors) must retain sufficient intellectual property rights to comply with the open access requirements. Metadata of deposited publications must be open under a Creative Commons Public Domain Dedication (CC 0) or equivalent, in line with the FAIR principles (in particular machine-actionable) and provide information at least about the following: publication (author(s), title, date of publication, publication venue); Horizon Europe or Euratom funding; grant project name, acronym and number; licensing terms; persistent identifiers for the publication, the authors involved in the action and, if possible, for their organisations and the grant. Where applicable, the metadata must include persistent identifiers for any research output or any other tools and instruments needed to validate the conclusions of the publication.

Only publication fees in full open access venues for peer-reviewed scientific publications are eligible for reimbursement.

Research data management

The beneficiaries must manage the digital research data generated in the action ('data') responsibly, in line with the FAIR principles and by taking all of the following actions:

- establish a data management plan ('DMP') (and regularly update it) Associated with document Ref. Ares(2022)4053005 - 31/05/2022 12
- as soon as possible and within the deadlines set out in the DMP, deposit the data in a trusted repository; if required in the call conditions, this repository must be federated in the EOSC in compliance with EOSC requirements
- as soon as possible and within the deadlines set out in the DMP, ensure open access — via the repository — to the deposited data, under the latest available version of the Creative Commons Attribution International Public License (CC BY) or Creative Commons Public Domain Dedication (CC 0) or a licence with equivalent rights, following the principle 'as open as possible as closed as necessary', unless providing open access would in particular:
 - be against the beneficiary's legitimate interests, including regarding commercial exploitation, or

- be contrary to any other constraints, in particular the EU competitive interests or the beneficiary's obligations under this Agreement; if open access is not provided (to some or all data), this must be justified in the DMP
- provide information via the repository about any research output or any other tools and instruments needed to re-use or validate the data.

Metadata of deposited data must be open under a Creative Common Public Domain Dedication (CC 0) or equivalent (to the extent legitimate interests or constraints are safeguarded), in line with the FAIR principles (in particular machine-actionable) and provide information at least about the following: datasets (description, date of deposit, author(s), venue and embargo); Horizon Europe or Euratom funding; grant project name, acronym and number; licensing terms; persistent identifiers for the dataset, the authors involved in the action, and, if possible, for their organisations and the grant. Where applicable, the metadata must include persistent identifiers for related publications and other research outputs.

Additional practices

Where the call conditions impose additional obligations regarding open science practices, the beneficiaries must also comply with those. Where the call conditions impose additional obligations regarding the validation of scientific publications, the beneficiaries must provide (digital or physical) access to data or other results needed for validation of the conclusions of scientific publications, to the extent that their legitimate interests or constraints are safeguarded (and unless they already provided the (open) access at publication). Where the call conditions impose additional open science obligations in case of a public emergency, the beneficiaries must (if requested by the granting authority) immediately deposit any research output in a repository and provide open access to it under a CC BY licence, a Public Domain Dedication (CC 0) or equivalent. As an exception, if the access would be against the beneficiaries' legitimate interests, the beneficiaries must grant nonexclusive licenses — under fair and reasonable conditions — to legal entities that need the research output to address the public emergency and commit to rapidly and broadly exploit the resulting products and services at fair and reasonable conditions. This provision applies up to four years after the end of the action (see Data Sheet, Point 1)

2.2. Data Summary

The project implementation will require the collection, processing and storage of a large variety of data sets related to whole value chain of production of medical radioisotopes.

As the data identification and collection activities are still ongoing, the initial DMP can currently only provide an incomplete picture of the datasets that will be used and/or produced. Nevertheless, the current data summary provides already a good overview of the different types of datasets that are expected to be generated and the way these datasets will be treated in line with the FAIR data management principles.

The initial data survey was carried out during the first six months of project implementation and the results are briefly summarized below while the detailed overview is provided in Annex 1.

WP1: Target Development

The WP will focus on exchange of experience and information on alpha-emitting target materials, including experimental effort to support handling, processing, purification and target manufacturing (particularly for Ra-226). It will also aim to optimize the target composition and determine production yields for selected beta-emitters.

The workpackage will re-use some data already available, which relates mostly to definition of requirements and collection of the previous experience.

The newly generated data will mostly come from the planned experimental work related to Ra-226 target manufacturing and recycling for reactor applications, alpha emitter encapsulation, Target development and yield determination of selected beta-emitters and target development and yield determination of the production via 14 MeV fusion sources.

WP2: Production routes

The second WP will provide solutions for production methods of therapeutic and diagnostic radionuclides. It will focus on reactor-based production methods for α -emitters and β -emitters, Experimental methods of accelerator-driven of Cu-64 production and alternative ways of Pb-212 generation.

Significant amount of experimental data will be generated in frame of WP2 – this will include for example (but not only) the data related to Monte Carlo simulation with thermal neutron spectrum, data from test irradiation in Maria research reactor to assess the Ac-225 production yield, test irradiations of enriched Pd-110 samples (Ag-111 yield), Gd-160 samples (Tb-161 yield), Pt-198 samples (Au-199 yield), test target irradiations in 14 MeV facility (for Cu-64 production) or data related to testing of alternative Pb-212 generator.

WP3: W-188/Re-188 isotope generator

This WP aims to develop optimized W-186 irradiation targets, optimized dissolution technologies and finally to make available W-188/Re-188 generators.

The data expected to be created relates to planned experimental activities for example neutron diffraction data from measurements of WxReyOsz-oxide samples, outcomes of calculations related to analysis of different tungsten targets and subsequent experiments with dissolution of tungsten target materials.

WP4: Recommendations for clinical trials and radiation protection

The works in WP4 include development of recommendations for clinical applications of alpha emitter-based therapies, benchmark analysis for RP measures in relation to radionuclide therapy and elaboration of recommendations to ensure the safety of new treatment options based on alpha particle emitters.

The main datasets serving as a baseline for elaboration of the recommendations will be related to Radiological Life Cycle assessment for different alpha emitter therapy scenarios and simulations for alpha emitter therapy activity distributions.

WP5 and WP6 (Communication and dissemination / Project management)

Data collected and produced in WP6 and WP7 relates mainly to the user account and profile information that is needed for project internal administrative purposes as well as external dissemination, community building and exploitation activities. This encompasses both personal data of SECURE partner personnel for operating the project's mailing lists, and document repository.

The datasets comprise information like name, organization, email address, role, etc. that is for the most part collected from the respective users through direct input when registering at the respective websites and confirmed with double-opt-in.

The datasets are stored in an internal restricted repository under the regime of data protection and privacy and will not be made openly available.

3. FAIR DATA MANAGEMENT IN SECURE

In compliance with applicable rules, every Horizon Europe project is required to draft a DMP in order to make the data Findable (1), Accessible (2), Interoperable (3) and available for Re-use (4) (FAIR principles).

In 2016, the 'FAIR Guiding Principles for scientific data management and stewardship were published in Scientific Data <https://www.nature.com/articles/sdata201618>. The authors intended to provide guidelines to improve the Findability, Accessibility, Interoperability, and Reusability of digital assets. The principles emphasise machine- actionability (i.e., the capacity of computational systems to find, access, interoperate, and reuse data with none or minimal human intervention) because humans increasingly rely on computational support to deal with data as a result of the increase in volume, complexity, and creation speed of data.

Findable

The first step in (re)using data is to find them. Metadata and data should be easy to find for both humans and computers. Machine-readable metadata are essential for automatic discovery of datasets and services, so this is an essential component of the FAIRification process.

- F1. (Meta)data are assigned a globally unique and persistent identifier.
- F2. Data are described with rich metadata (defined by R1 below).
- F3. Metadata clearly and explicitly include the identifier of the data they describe.
- F4. (Meta)data are registered or indexed in a searchable resource.

Accessible

Once the user finds the required data, she/he/they need to know how they can be accessed, possibly including authentication and authorisation.

- A1. (Meta)data are retrievable by their identifier using a standardised communications protocol.
 - A1.1 The protocol is open, free, and universally implementable.
 - A1.2 The protocol allows for an authentication and authorisation procedure, where necessary.
- A2. Metadata are accessible, even when the data are no longer available.

Interoperable

The data usually need to be integrated with other data. In addition, the data need to interoperate with applications or workflows for analysis, storage, and processing.

- I1. (Meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation.
- I2. (Meta)data use vocabularies that follow FAIR principles.
- I3. (Meta)data include qualified references to other (meta)data.

Reusable

The ultimate goal of FAIR is to optimise the reuse of data. To achieve this, metadata and data should be well-described so that they can be replicated and/or combined in different settings.

R1. (Meta)data are richly described with a plurality of accurate and relevant attributes.

R1.1. (Meta)data are released with a clear and accessible data usage license.

R1.2. (Meta)data are associated with detailed provenance.

R1.3. (Meta)data meet domain-relevant community standards.

The principles refer to three types of entities: data (or any digital object), metadata (information about that digital object), and infrastructure. For instance, principle F4 defines that both metadata and data are registered or indexed in a searchable resource (the infrastructure component).

3.1. Making data findable, including provisions for metadata

3.1.1 Are the data produced and/or used in the project discoverable with metadata, identifiable and locatable by means of a standard identification mechanism (e.g. persistent and unique identifiers such as Digital Object Identifiers)?

All open data produced in SECURE will be identifiable and locatable by means of a persistent Uniform Resource Locator (URI). If possible, open SECURE results will be assigned a Digital Object Identifier (DOI) in order to make content easily and uniquely citable. Thereby, SECURE relies on external services, since DOIs can only be assigned by DOI registrants through a DOI registration agency (see https://www.doi.org/doi_handbook/8_Registration_Agencies.html).

Open SECURE results that are deposited in the SECURE default Open Access repository (Zenodo) will be assigned a DOI automatically and will benefit also from Zenodo's DOI versioning support.

Open SECURE results that are deposited in institutional repositories, repositories of scientific publishers or other data and research repositories will be at least identifiable by a persistent URI. If the institution is a DOI registrant that has an agreement with a DOI registration agency, a DOI will be assigned, too.

Whether scientific publications will be assigned a unique identifier like DOI, Publisher Item Identifier (PII), International Standard Serial Number (ISSN), etc. depends on the open access strategy (green or gold) chosen by the editors and thus also on the respective scientific publisher and the chosen research repository. Zenodo (<http://help.zenodo.org/features/>) is for example, one of the open data repository repositories that can generate DOIs for research results.

3.1.2 What naming conventions do you follow?

The naming conventions are defined in the D6.1 (Project Handbook). The file name should be constituted as follows:

YYMMDD_Secure_Document_Author_NN.xxx, where

“Document” shall clearly identify the type of the document and its content

“YYMMDD” stands for date of the last change

“NN” is identification of the document version coherent with the information given inside the document, e.g. “v1.0”

“xxx” is the file extension.

3.1.3 Will search keywords be provided that optimize possibilities for re-use?

All open SECURE results deposited in a repository will provide search keywords together with their metadata. Keywords for open data will be selected from controlled vocabularies that are suitable for the specific type of the data.

3.1.4 Do you provide clear version numbers?

For publications, versioning is in general not necessary. All open data, publications and open source software deposited in the Zenodo repository will use DOI versioning. DOI versioning allows for updating a dataset after it has been published.

3.1.5 What metadata will be created? In case metadata standards do not exist in your discipline, please outline what type of metadata will be created and how.

Metadata for describing the data that is collected and generated by the SECURE project is needed for facilitating open access to the data. There are many different meta-data standards for many different types of data and it may not be possible to find one that fits all purposes. Therefore, a pragmatic and feasible approach is to agree on a common and minimal catalogue metadata schema for those datasets that are published in public catalogues and data repositories and to use data-type specific schema extensions, if necessary.

Default Catalogue Metadata schema for open data generated by the project

In general, the Zenodo deposition metadata domain model which is based on DataCite's metadata schema (<https://schema.datacite.org/>) minimum and recommended terms will be used for open data generated by the project and deposited in an appropriate.

This minimal metadata schema can be extended by arbitrary subjects from a taxonomy or controlled vocabulary as described in the Zenodo API documentation. It is compatible with the Dublin Core metadata standard (<http://dublincore.org/>) and thus can be interpreted by OAI-PMH (<https://www.openarchives.org/pmh/>) catalogue harvesters like those used by CKAN (<https://ckan.org/portfolio/federate/>) and OpenAIRE (http://api.OpenAIRE.eu/#cha_oai_pmh). Metadata is stored internally in JSON-format according to a defined JSON schema (<https://zenodo.org/schemas/records/record-v1.0.0.json>) and can be exported in several standard formats such as MARCXML, Dublin Core, and DataCite Metadata Schema.

Default Catalogue Metadata schema for open data collected by the project

The CKAN domain model (<http://docs.ckan.org/en/ckan-1.7.4/domain-model.html>) is used for metadata of data collected by the project if this data is also stored in a dedicated public CKAN catalogue. This domain model can be extended by arbitrary metadata fields as described in the CKAN extension guide (<http://docs.ckan.org/en/latest/extensions/adding-custom-fields.html>) and is therefore compatible with Zenodo's deposition metadata domain model.

Additionally, separate metadata files that follow a different standard than the default catalogue metadata schema can be published together with the original dataset in the respective catalogue or repository.

3.2. Making data openly accessible

Open accessibility of the data is the second key aspect for making data FAIR. This section will describe the type of data to be made available, its location and the procedure to obtain it. Several degrees of accessibility are identified, including both open access and restricted access.

3.2.1. Which data produced and/or used in the project will be made openly available as the default? If certain datasets cannot be shared (or need to be shared under restrictions), explain why, clearly separating legal and contractual reasons from voluntary restrictions

The different types of data that are generated during the project are **open by default** with the following general exceptions:

- **Copyright and permissions for reusing third-party data sets.** Processing and combining input data from many different sources may lead to **unclear IPR situations** regarding the

generated output data, therefore such repurposed data (e.g. model output data) can only be made open if any of the underlying data (e.g. model input data) is open, too.

- **Personal data treatment and confidentiality issues.** Datasets referring to the quality and quantity of certain elements at risk, such as people and critical infrastructures, are not open by default as their publication may pose **privacy, ethical or security risks**.
- **Data-driven business model.** Data that is **exploited commercially** through the MyClimateService.eu marketplace will not be made open.
- **User-generated content** can only be made open with **explicit permission** from the end user.

If there are restrictions on data needed to validate the results presented in scientific publications, access to individuals with legitimate interest will be granted on request. For more information on data generated and collected by the project and specific exceptions from open access, please refer to the datasets listed in Annex 1.

3.2.2. How will the data be made accessible (e.g. by deposition in a repository)?

SECURE project open results will be made accessible according to the Rules on Open Access to Scientific Publications and Open Access to Research Data in Horizon 2020.

Open Data

All open results (data, scientific publications) of the project will be openly accessible at an appropriate Open Access repository as soon as possible. Specifically, research data needed to validate the results in the scientific publications will be deposited in a data repository at the same time as a publication unless the data relates to sensitive deliverable. Non-public research data will be archived at the repository using a restricted access option.

Scientific Publications

Providing open access to peer-reviewed scientific publications can be ensured either by publishing in green or gold open access journals with or without author processing fees. Any scientific publications from SECURE and the related bibliographic metadata must be made available as open access and announced on the project website, as well as in the OpenAIRE portal (<https://www.OpenAIRE.eu/>). To automate the process of reporting scientific publications and related research data in OpenAIRE, the publication should be deposited in an OpenAIRE-compliant repository, either by the authors of the publication (green open access) or by a scientific publisher (gold open access). While additional forms of disseminating open access papers, including academic social network sites such as ResearchGate (<https://www.researchgate.net/>) are possible, an electronic copy of the publication has to be deposited in suitable open access repository in the first place. According to the European Research Council's Guidelines on Open Access, "Venues such as Research Gate or Academia.edu that require users to register in order to access content do not count as repositories. The posting of publications on a personal, institutional or project specific webpage or the deposit in a publicly accessible Dropbox account is not sufficient to satisfy the requirements either."

If the chosen repository is not fully OpenAIRE compliant, the publications or data must be linked at <https://www.openaire.eu/participate/claim> with the respective funding agency (European Commission). Green open access journals or gold open access journals without author processing fees should be preferred for disseminating SECURE scientific publications. Nevertheless, the journal's visibility and prestige (translated in the Impact Factor) of the journal, together with the speed of publication, should be considered when choosing a journal for publication of a manuscript.

Green open access (self-archiving)

Green open access or self-archiving means that the published article or the final peer-reviewed manuscript is archived by the researcher itself in an online repository, in most cases after its publication in the journal. The journal must grant the researcher the permission to self-archive the final peer-reviewed article, at the latest, 12 months after publication.

Gold open access (open access publishing)

Gold open access means that the publication is available by the scientific publisher as open access. Some journals require an author-processing fee for publishing open access. Author-publishing fees for gold

open access journals can be reimbursed within the project period and budget. Some publishers allow the researcher to deposit a copy of the article in a repository, sometimes with an embargo period (see 2.4.2).

3.2.3. What methods or software tools are needed to access the data?

Regarding the mere access to open data deposited as data files in a data repository, there are no special methods or software tools needed. The files can be downloaded from the data repository via HTTP protocol using a standard web browser. This implies, however, that open data that is originally stored in a database or another type of data store, has to be exported (“dumped”) to a file before it can be deposited in a repository. Repository APIs, DOI versioning) and the respective database tools can help to automate this export tasks. Regarding software and tools for offline viewing, interpreting, processing and editing of data files downloaded from the data repository, it heavily depends on the type and format of the data. At the moment it is expected that the data generated by SECURE project should be readable by standard and commonly used software tools (MS Office formats, PDF etc.).

3.2.4. Is documentation about the software needed to access the data included?

As stated above, no need for the documentation about the software needed to access the data is anticipated.

3.2.5. Where will the data and associated metadata, documentation and code be deposited? Preference should be given to certified repositories which support open access where possible.

Open Data

To ensure that data management procedures are unified across the project, a common default Open Access repository for open data and open source software generated within the project has been chosen. In the end, it is up to the owner of the data or software to decide whether he wants to use an institutional repository or the SECURE default repository. However, repositories other than the default one should be OpenAIRE-compliant and issue a DOI. The default repository of the SECURE project for depositing open data is Zenodo (<http://www.zenodo.org>). Zenodo is an EC-co-funded, multidisciplinary repository, for publications and data. A DOI is automatically assigned to all Zenodo files, which can be uploaded in any file format. Zenodo allows researchers to deposit both publications and research data, while providing means to link them. Data is stored in the CERN cloud infrastructure. Zenodo is compliant with the open data requirements of Horizon Europe.

Sensitive and confidential data with limited access will be stored at the SECURE project restricted repository operated by NCBJ.

Scientific Publications

There are two possibilities for a researcher: publishing in green or in gold open access journals. In case of green open access, Zenodo can be chosen by the researcher as a primary repository for self-archiving. This leaves still the possibility for the additional dissemination of the published publication also at academic social network sites like ResearchGate that do not count as suitable open access repository. In case of gold open access, the scientific publisher’s modalities for open access (e.g. embargo periods) must allow the researcher to fulfil the EC’s open access obligations. Furthermore, the repository used by the scientific publisher should be OpenAIRE-compliant and issue a DOI if the researcher is not allowed to allow to deposit a copy of the publication in a repository of his choice. For finding suitable gold open access publishers, researchers are encouraged to consult the Directory of Open Access Journals (<https://doaj.org/>), a service that indexes high quality, peer-reviewed open access academic journals that use an appropriate quality control system.

3.2.6. Have you explored appropriate arrangements with the identified repository?

Currently, there is no need for such an arrangement. Zenodo is OpenAIRE's recommended "catch-all" repository for projects like SECURE without ready access to an organized data centre.

3.2.7. If there are restrictions on use, how will access be provided?

Where a restriction on open access to research data is necessary, attempts will be made to make data available under controlled conditions to other individual researchers. In the case where restricted or embargoed data is stored in the Zenodo repository, information about the restricted data will be published in the repository, and details of when the data will become available will be included in the metadata. Data files and data sets for restricted access records are only visible to their owners and to those the owner grants access. Restricted access allows a researcher to upload a dataset and provide the conditions under which he/she grants access to the data. Researchers wishing to request access must provide a justification for how they fulfil these conditions. The owner of the dataset gets notified for each new request and can decide to either accept or reject the request. If the request is accepted, the requester receives a secret link which usually expires within 1-12 months.

3.2.8. Is there a need for a data access committee?

In case there are any issues regarding the restricted access to research results, SECURE's Governing Board can act as data access committee and seek clarification.

3.3. Making data interoperable**3.3.1. Are the data produced in the project 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)?**

This can only be partially answered, as the data collection is still in progress. However, most datasets will be produced in very common SW tools and thus easily interoperable.

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

See 3.1.5.

3.3.3. Will you be using standard vocabularies for all data types present in your data set, to allow interdisciplinary interoperability?

Yes, see 3.1.5.

3.3.4. 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?

Currently, SECURE does not intend to introduce new project specific ontologies or vocabularies

3.4. Increase data re-use

3.4.1. How will the data be licensed to permit the widest re-use possible?

Open Data and Open Source Software

According to article 26 of the Grant Agreement, data and software are owned by the beneficiary that generates them. Notwithstanding the above owners of open results arising from the SECURE project are encouraged to release their work under a Creative Commons license, preferably Creative Commons Attribution 4.0 (CC-BY-4.0).

Scientific Publications

Authors of scientific publications arising from the SECURE project are encouraged to seek an agreement with the scientific publisher of the publication that allows the authors to

- retain the ownership of the copyright for their work and to
- deposit the publication in an Open Access repository.

3.4.2. When will the data be made available for re-use? If an embargo is sought to give time to publish or seek patents, specify why and how long this will apply, bearing in mind that research data should be made available as soon as possible.

Research data needed to validate the results of the scientific publications will be made available as open access at the same time as the publication. If an embargo period is imposed by the publisher, the publication and the related data are not made openly accessible until the embargo period has expired. In Horizon 2020, the embargo period must be shorter than 6 months. Information (metadata) about the publication and the related data will be made available at the same time as the publication, regardless of whether an embargo period has been imposed. Details of when the publication and the data will become available will be included in the metadata.

3.4.3. Are the data produced and/or used in the project usable by third parties, in particular after the end of the project? If the re-use of some data is restricted, explain why.

Open results produced by the project and deposited in a respective repository are usable by third parties after the end of the project. If confidentiality, security, personal data protection obligations or IPR issues related to specific research data that is needed to validate a scientific publication forbid open access, the data may be deposited in a restricted repository and access may be granted upon request and under the conditions of a restricted license.

3.4.4. How long is it intended that the data remains re-usable?

The open results that are deposited in the Zenodo repository will be available at least 5 years after the conclusion of the project. According to Zenodo's general policies (<http://about.zenodo.org/policies/>), "items will be retained for the lifetime of the repository. This is currently the lifetime of the host laboratory CERN, which currently has an experimental programme defined for the next 20 years at least."

3.4.5. Are data quality assurance processes described?

Quality assurance concerning accuracy and completeness of is the sole responsibility of the beneficiary creating them. The data will be verified by the corresponding WP leader before making them openly accessible.

3.5. Allocation of resources

3.5.1. What are the costs of making data FAIR in your project?

There are no immediate costs anticipated to make the open results generated in SECURITY FAIR. Especially no costs are foreseen for storing open results in the project's default repository (Zenodo). Additional details will be reported, as needed, in future versions of the DMP.

3.5.2. How will these be covered? Note that costs related to open access to research data are eligible (if compliant with the Grant Agreement conditions).

As indicated above, no additional costs related to making data FAIR have been identified.

3.6. Who will be responsible for data management in your project?

Data management activities concern the whole project and needs to be coordinated and monitored both at project and work package level. Data management is also linked to publication of project results and thus dissemination activities. Therefore, the following roles and responsibilities can be identified:

Project Data Manager (Task 6.3. Leader – Evalion) is responsible for:

- developing the Data Management Plan (D6.2) in cooperation with the coordinator and the technical partners
- monitoring data management activities (both collection and publication) and deadlines and sending reminders to WP data managers
- monitoring that open results are deposited in the default repository or a complementary OpenAIRE-compliant repository and sending reminders to partners
- providing support to WP data managers
- providing solutions for specific issues in accordance with project management

The Workpackage Data Managers are responsible for

- the implementation of the data management policy in their respective WPs
- asking partners for missing information or clarifications
- providing input to the data management plan by analysing and summarising the WP-specific data surveys

The Data Provider / Scientist is responsible for

- informing the data & dissemination managers when new open data / papers ready for publication are available
- describing the data (by means of appropriate metadata) or scientific publication in accordance to the SECURE data management policy (e.g. according to the chosen metadata standard) and with help of the tools (e.g. template, web form, ...) provided by the project
- depositing (publishing into a repository) the data or scientific publication in accordance with the SECURE data management policy.

3.7. Data security

3.7.1. What provisions are in place for data security (including data recovery as well as secure storage and transfer of sensitive data)?

Open results deposited in the Zenodo repository are stored in CERN's disk cluster.. The servers are managed according to the CERN Security Baseline for Servers. For more information see <http://about.zenodo.org/infrastructure/>.

3.7.2. Is the data safely stored in certified repositories for long-term preservation and curation?

Open results deposited in the Zenodo repository are safely stored for long time preservation.

3.8. Ethical aspects

This DMP was drafted and updated taking into account the GDPR for the collection, storage and re- use of the data, in line with the following general principles.

Personal data shall be:

1. processed lawfully, fairly and in a transparent manner in relation to the data subject ('lawfulness, fairness and transparency');
2. collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall not be considered to be incompatible with the initial purposes ('purpose limitation');
3. adequate, relevant and limited to what is necessary for relation to the purposes for which they are processed ('data minimisation');
4. accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay ('accuracy');
5. kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject ('storage limitation');
6. processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures ('integrity and confidentiality').

4. CONCLUSION

This report collects information about the Data Management Plan to be implemented within the SECURE project. It provides information on the data that will be generated and collected in the different work packages, as well on the underlying principles that will be used for the generation, collection, storage, dissemination, and curation of the SECURE data.

5. BIBLIOGRAPHY

European Commission. Directorate-General for Research & Innovation (August 2022). HORIZON EUROPE Data Management Plan – General Definition. Retrieved from: https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/data-management_en.htm

European Commission. Directorate-General for Research & Innovation (August 2022). HORIZON EUROPE Programme Guidelines to the Rules on Open Access to Scientific Publications and Open Access to Research Data in Horizon 2020. Retrieved from: https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/open-access_en.htm

ANNEX 1 – INITIAL DATA SURVEY

WP1									
Dataset title	Dataset description	Format	Origin of data	Expected size	Open Access	Data identification	Metadata	Data Archiving and Open Access	Expected date of availability
Ra-226 target manufacturing and recycling Data Set	Experimental data on Ra-226 target preparation and characterization	xlsx, pdf	Generated	< 1GB	No	Data related to sensitive D1.3 (internal, no DOI)	Metadata to be included in the deliverable	SECURE repository	M36
Encapsulation Data Set	Experimental data on capsule welding parameters	xlsx, doc, pdf	Generated	< 1GB	No	Data related to sensitive D1.5 (internal, no DOI)	Metadata to be included in the deliverable	SECURE repository	M36
Target development and yield determination beta-emitters Data Set	Data on target development and yield determination for selected beta emitters	xlsx, doc, pdf	Generated	< 1GB	No	Data related to sensitive D1.6 (internal, no DOI)	Metadata to be included in the deliverable	SECURE repository	M36
Target development and yield determination fusion Data Set	Data on target development and yield determination for Cu-64 by 14 MeV neutrons	xlsx, pdf	Generated	< 1GB	No	Data related to sensitive D1.8 (internal, no DOI)	Metadata to be included in the deliverable	SECURE repository	M36
WP Data manager	Ronald Schram (NRG)								

WP2									
Dataset title	Dataset description	Format	Origin of data	Expected size	Open Access	Data identification	Metadata	Data Archiving	Expected date of availability
Ac-225 irradiation yield by thermal neutrons	Data set from tests irradiation in research reactors to assess the Ac-225 production yield completed by Monte Carlo simulations taking into account the input provided from WP1 on Ra-226 target	xlsx + docx files	generated	<1 GB	No. Use of SECURE repository	Data related to sensitive D2.1 (internal, no DOI)	Metadata to be included in the deliverable	SECURE repository	30.09.2024
Au-199, Ag-111 and Tb-161 production yield by thermal neutrons	Data sets from test irradiations in research reactors to assess the Au-199, Ag-111 and Tb-161 production yield completed by Monte Carlo simulation taking into account input from WP1 on related target	xlsx + docx files	generated	<1 GB	No. Use of SECURE repository	Data related to sensitive D2.2 (internal, no DOI)	Metadata to be included in the deliverable	SECURE repository	31.12.2024
Cu-64 production yield by 14 MeV fusion neutrons	Data sets from test irradiations in research FNG facility to assess Cu-64 production yield completed by Monte Carlo simulation to upscale the results till neutron emission rate of 10^{14} n/s	xlsx + docx files	generated	<1 GB	No. Use of SECURE repository	Data related to sensitive D2.3 (internal, no DOI)	Metadata to be included in the deliverable	SECURE repository	31.03.2025
Proof of utility of alternative Pb-212 generator	Data from analysis of new Pb-212 generator for assessment of its suitability for radiolabelling of different peptides in nuclear medicine	xlsx + docx files	generated	<1 GB	No. Use of SECURE repository	Data related to sensitive D2.4 (internal, no DOI)	Metadata to be included in the deliverable	SECURE repository	31.03.2025

Comparative analysis and perspectives for supply chain robustness and security	Report on alpha, beta (+/-) emitters produced by thermal and 14 MeV neutrons, and also on Pb-212 generator for clinic use.	xlsx + docx files	generated	<1 GB	No. Use of SECURE repository	Data related to sensitive D2.5 (internal, no DOI)	Metadata to be included in the deliverable	SECURE repository	30.09.2025
WP Data manager	Marco Capogni								
WP3									
Dataset title	Dataset description	Format	Origin of data	Expected size	Open Access	Data identification	Metadata	Data Archiving and Open Access	Expected date of availability
Neutron diffraction data	Data from measurements of WxReyOsz-oxide samples	.xml (metadate), nxs (neutron scattering standard) and .pdf	Generated	< 1 GB	Initially not. Will become Open Access after publication and latest 5 years after experiment.	Dedicated DOI will be generated after the experiment.	Metadata saved together with neutron scattering data.	Report of analysed data in SECURE repository and after publication in ZENODO . Raw data and preprocessed data will be managed according to ILL's data management policy (https://www.ill.eu/users/user-guide/after-your-experiment/data-management) and be accessible under data.ill.fr latest 5 years after the experiment.	Raw data 31.10.2023, analysed data later

Report and prototypes of low density or hollow tungsten metal targets (ILL)	Calculations and analysis of different tungsten targets	.pdf	Generated	<1 GB	No. Use of SECURE repository	Internal sensitive data, no DOI.	Metadata to be included in the deliverable	SECURE repository	Tbd (probably rather 2024)
Report on dissolution of non-irradiated low density or hollow tungsten metal targets from ILL	Results of experiments with dissolution of tungsten target materials	pdf	Generated	<1 GB	No. Use of SECURE repository	Internal sensitive data, no DOI.	Zenodo deposition metadata domain model. Experimental data and photos will be included in report.	SECURE repository	30.09.2024
Report on metal targets and associated dissolution strategy	Results of experiments on fabrication and analysis of metal targets and associated dissolution strategies	pdf	Generated	<1 GB	Initially not. Will become Open Access after publication and latest 5 years after experiment	Internal sensitive data, no DOI.	Metadata to be included in the deliverable	Raw data and pre-processed data will be managed according to SCK CEN data management policy	30.09.2023
Supply of W-188 solutions or Re-188 product for non-profit R&D purposes	Summary containing data from productions of low activity R&D 188W/188Re generators	pdf	Generated	<1 GB	No. Use of SECURE repository	Internal sensitive data. DOI may be generated by Zenodo after publication.	Metadata to be included in the deliverable	Raw data and pre-processed data will be managed according to SCK CEN data management policy	31.10.2023
Report on advanced oxide targets and associated dissolution strategy	Results of experiments on advanced oxide targets and associated dissolution of tungsten target materials	pdf	Generated	<1 GB	Initially not. Will become Open Access after publication and latest 5 years after experiment	Internal sensitive data. DOI may be generated by Zenodo after publication.	Metadata to be included in the deliverable	Raw data and pre-processed data will be managed according to SCK CEN data management policy	30.09.2024

Prototype and report on process to set up a device ("R&D generator") for small-scale harvesting of Re-188 from a W-188 solution	Report containing description of process for manufacturing 188W/188Re generators	pdf	Generated	<1 GB	Initially not. Will become Open Access after publication and latest 5 years after experiment			Report in SECURE repository	30.09.2024
WP Data manager	Renata Mikolajczak (NCBJ)								
WP4									
Dataset title	Dataset description	Format	Origin of data	Expected size	Open Access	Data identification	Metadata	Data Archiving and Open Access	Expected date of availability
Bibliography review on available a-particle therapies and associated clinical trails, projects reports already available publicly, review articles	Published papers and reviews	pdf	re-used	< 1 GB	No, use of SECURE, repository. Internal report.	These are already published works that can be downloaded from authorised access of different publisher sites	No specific metadata	SECURE storage for the purpose of the project reporting	01.01.2023
Report on future potential clinical trials using alpha particle therapies	Report	pdf	Generated	<1 GB	Yes.	DOI will be generated by Zenodo	Zenodo deposition metadata domain model. Search keywords will be included.	Zenodo (open access)	March 2024
Radiological Life Cycle assessment for different a-therapy scenarios	Report	pdf	Generated	<1 GB	Yes	DOI will be generated by Zenodo	Zenodo deposition metadata domain model. Search keywords will be included.	Zenodo (open access)	March 2024
Simulated datasets for a-particle therapy activity distributions	Simulated	raw data file format	Generated	Few GBs	Initially not since these simulated datasets will serve in the development of	DOI will be generated by Zenodo	Zenodo deposition metadata domain model.	UBO LaTIM storage system Zenodo after publication	End 2024

					optimised dosimetry protocols within the consortium. Following publication of the results these datasets can become publicly available.				
Treatment planning and dosimetry recommendations	Report	pdf	Generated	<1 GB	Yes.	DOI will be generated by Zenodo.	Search keywords will be included.	Zenodo (open access)	November 2025
WP Data manager	Dimitris VISVIKIS (EFOMP)								