

1 Preface

1.1 Aim of the specification

This document is one of several related specifications which aim to provide a common set of usage descriptions of international standards for packaging digital information for archiving purposes. These specifications are based on common, international standards for transmitting, describing and preserving digital data. They also utilise the Reference Model for an Open Archival Information System (OAIS), which has Information Packages as its foundation. Familiarity with the core functional entities of OAIS is a prerequisite for understanding the specifications.

The specifications are designed to help data creators, software developers, and digital archives to tackle the challenge of short-, medium- and long-term data management and reuse in a sustainable, authentic, cost-efficient, manageable and interoperable way. A visualisation of the current specification network can be seen here:

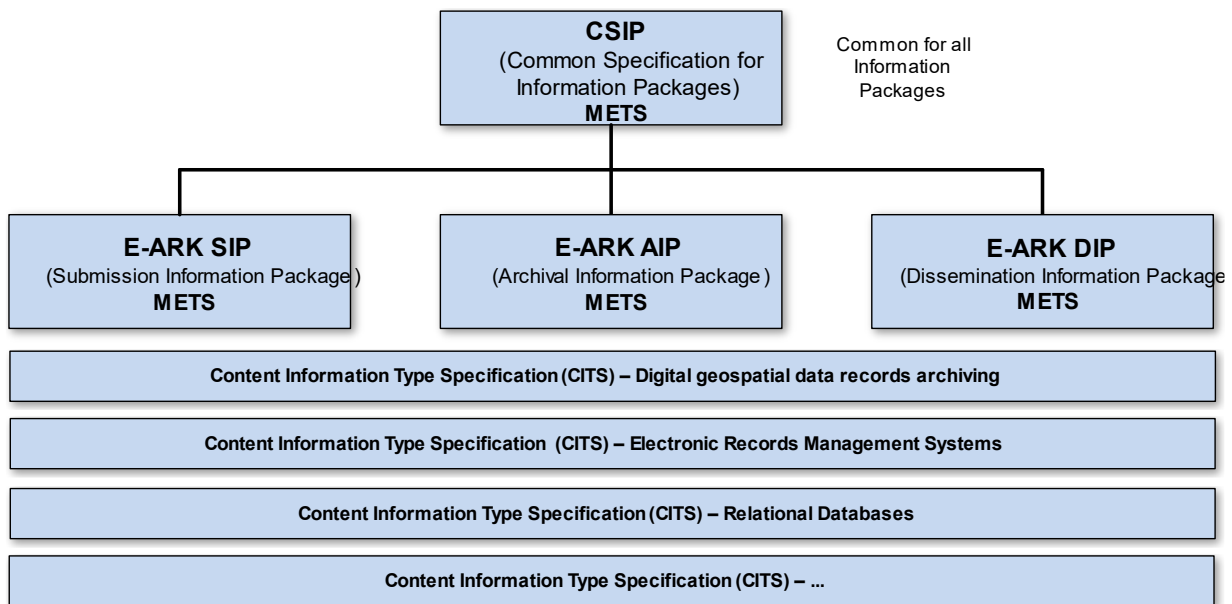


Figure 1: Diagram showing E-ARK specification dependency hierarchy. Note that the image only shows a selection of the published CITS and isn't an exhaustive list.

Specification	Aim and Goals
Common Specification for Information Packages	<p>This document introduces the concept of a Common Specification for Information Packages (CSIP). Its three main purposes are to:</p> <ul style="list-style-type: none"> • Establish a common understanding of the requirements, which need to be met in order to achieve interoperability of Information Packages. • Establish a common base for the development of more specific Information Package definitions and tools within the digital preservation community.

Specification	Aim and Goals
	<ul style="list-style-type: none"> Propose the details of an XML-based implementation of the requirements using, to the largest possible extent, standards which are widely used in international digital preservation. <p>Ultimately, the goal of the Common Specification is to reach a level of interoperability between all Information Packages so that tools implementing the Common Specification can be adopted by institutions without the need for further modifications or adaptations.</p>
E-ARK SIP	<p>The main aims of this specification are to:</p> <ul style="list-style-type: none"> Define a general structure for a Submission Information Package format suitable for a wide variety of archival scenarios, e.g. document and image collections, databases or geographical data. Enhance interoperability between Producers and Archives. Recommend best practices regarding metadata, content and structure of Submission Information Packages.
E-ARK AIP	<p>The main aims of this specification are to:</p> <ul style="list-style-type: none"> Define a generic structure of the AIP format suitable for a wide variety of data types, such as document and image collections, archival records, databases or geographical data. Recommend a set of metadata related to the structural and the preservation aspects of the AIP as implemented by the eArchiving Reference Implementation (eArkweb). Ensure the format is suitable to store large quantities of data.
E-ARK DIP	<p>The main aims of this specification are to:</p> <ul style="list-style-type: none"> Define a generic structure of the DIP format suitable for a wide variety of archival records, such as document and image collections, databases or geographical data. Recommend a set of metadata related to the structural and access aspects of the DIP.
Content Information Type Specifications	<p>The main aim and goal of a Content Information Type Specification is to:</p> <ul style="list-style-type: none"> Define, in technical terms, how data and metadata must be formatted and placed within a CSIP Information Package in order to achieve interoperability in exchanging specific Content Information. <p>The number of possible Content Information Type Specifications is unlimited. For a list of existing Content Information Type Specifications see the DILCIS Board webpage (DILCIS Board, http://dilcis.eu/).</p>

1.2 Organisational support

This specification is maintained by the Digital Information LifeCycle Interoperability Standards Board (DILCIS Board, <http://dilcis.eu/>). The role of the DILCIS Board is to enhance and maintain the draft specifications developed in the European Archival Records and Knowledge Preservation Project (E-ARK project, <http://eak-project.com/>), which concluded in January 2017. The Board consists of eight members, but no restriction is placed on the number of participants taking part in the work. All Board documents and specifications are stored in GitHub (<https://github.com/DILCISBoard/>), while published versions are made available on

the Board webpage. The DILCIS Board have been responsible for providing the core specifications to the Connecting Europe Facility eArchiving Building Block <https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/eArchiving/>.

1.3 Authors & Revision History

A full list of contributors to this specification, as well as the revision history, can be found in the Postface material..

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2 Context

2.1 Purpose

This guideline describes the eHealth2 Content Information Type Specification to stakeholders interested in keeping and preserving cancer registry exports. These can include, for example, cancer registries, international aggregators, research organisations, academia, and archives.

The eHealth2 specification describes which information, documents, and records have to be preserved to make the content of cancer registry exports available and reusable for the long term. It defines how a user of the specification can organise their data in a submission information package (package that enables maintenance of cancer registry export content), what kind of data should be included in the package (what are mandatory and optional elements).

The eHealth2 specification can also be used as a checklist or a protocol for the cancer registry to identify which information about the content of the export and executed procedures should be captured in the form of a document and included in the SIP.

2.2 Scope

In the eHealth2 specification, Cancer registry export is a data set and accompanying documentation exported from the cancer registry. Usually, it is prepared at the request of the external users, but it could be created for the needs of the Cancer Registry itself. Cancer Registry data can be exported from the primary environment (database) or its mirror (database snapshot). When the export procedures include any manipulation of the Cancer Registry data (e.g. change of structure, re-coding), use of the eHealth2 specification is relevant. When a Cancer Registry creates a snapshot of the database and does not manipulate data in any way, the use of the [SIARD specification](#) would be more appropriate.

This guideline will provide further information and insights into how to preserve exports from the cancer registry environment. This guideline will also give more information and insights into the information packages which are not covered in the [CSIP](#) and [E-ARK SIP](#).

Note

Be aware that to use the eHealth2 specification effectively, users should consult the “higher level” specifications ([CSIP](#) and [E-ARK SIP](#)). For a better overview, see chapter 1.1, The E-ARK specification dependency hierarchy.

2.3 Structure of the document

Section 3 will familiarise users with the cancer registries and the data they are gathering. It explains the concept of cancer registry data and its export in general and the digital preservation of the CR Data and its Export. It also describes the needs of different stakeholders and explains the standards in a cancer registry setting.

Section 4 explains where in the workflow of preparation of cancer registry exports, this specification can be used and what documentation should be preserved/prepared to be later used as a content of the SIP package.

Section 5 provides a rationale for each of the requirements found in the eHealth2 CITS. This provides a better basis for understanding the reasons behind the requirements. Each cause contains a requirement, description, rationale and an example from the actual cancer registry export.

Section 6 is a Glossary of less well-known terms used in the guidelines.

Section 7 provides a complete example of the information package specified in the eHealth2 CITS.

3 CR Exports – Introduction

The section will familiarise users of the specification with cancer registries and their activity. Users from the cancer registries, who are familiar with the role and activities of CRs, can find the specification terminology explained here.

3.1 Cancer Registry and cancer data

Population-based cancer registries worldwide systematically gather data on cancer patients' occurrence, characteristics, and outcomes in the underlying population. The primary purpose of cancer registries is to monitor the community's cancer burden for public health and clinical implications.

To achieve this, cancer registries gather (usually in databases) the following main categories of data and metadata related to cases of cancer diseases: patient, tumour case, incidence, the basis of diagnosis, topography, morphology, behaviour, grade, vital status of a patient and other data.

Population-based cancer registries collect additional statistical data about the population in a specified geographical area to estimate cancer burden.

3.2 Cancer Registry Export

A cancer registry export is a dataset containing at least one file with data from the cancer registry database (e.g. in CSV format) and other files that help contextualise and interpret data from the cancer registry database. These are usually text-based (agreements, code lists, reports, etc.) but can be in other formats (audio, interviews, images). The database export must consist of cancer case data, and possibly mortality, population data and life tables. The cancer case data is purely a health record, while the other three can provide context. Export content is influenced by the need of the entity (stakeholder) that requests the export.

3.3 Stakeholders and their needs

The eHealth2 specification identifies several types of stakeholders, grouped into three main categories: national and international aggregators, academia (researchers and scientific institutes) and cancer registries themselves (including the responsible archives).

The complexity of structure, the quantity of data and the retention period of the export depend on the user or the purpose of the export. For example, international or national aggregators will usually need more complex exports with potentially broader implications in health policies than an academic or local cancer registry research team.

If data is gathered by an international aggregator (e.g., ENCR-JRC, CONCORD), whose aim is to compare the cancer burden across several countries, a questionnaire, which provides data about the cancer registry and metadata on cancer registration process and tools, is an essential part of the data submission. On the other hand, individual researchers may have special requirements, and they apply for specific data directly from the cancer registries. Cancer registries share their data also with other national institutions (e.g. national health institute, statistical office, etc.). Such use is usually regulated by national legislation.

From the perspective of export data maintenance, all stakeholders can use the eHealth2 specification to specify the export requirements.

3.4 Use of standards

Part of cancer registry data is defined with international classifications and standards. Those classifications and standards exist in several versions, which can be used simultaneously.

Cancer registries code the data retrieved from different health data sources following international and internal guidelines, which are regularly updated. The use of specific classification (and updates) depends upon the cancer registry's decision, although international organisations (aggregators) promote the latest versions of the classifications.

It is common for different stakeholders to use different versions of classifications and/or standards. For example, ENCR-JRC and IACR and most other data calls, the submission in the ICD-O-3 coding system are required. At the same time, cancer registries can have some of their data coded in one of the ICD classifications.

When preparing the export calls for re-coding, the specification requires that re-coding should be somehow documented and the documentation included in the SIP, along with documentation that describes classifications and standards used in the exported data.

4 How to use the Specification (step by step)

Users of the eHealth2 specification can tailor the use of specification for their use case. Some will be able to use it at the beginning of the creating export (e. g. those requesting data from the cancer registry); alternatively, some will need it after the end of the export life cycle (long-term record keepers, archives). This chapter brings attention to the cancer registry export

preparation steps that produce the documentation that has to be included in the SIP. All descriptions in this section have a reference to requirements in section 5. We strongly recommend consulting the [CSIP](#) and [E-ARK SIP](#) before starting with SIP package preparation.

The SIP creation procedure can be executed by following these steps:

Step 1: The first step in archiving the export is gathering the content that we want to have in a SIP package. We export the data and documentation from the primary environment (database, file system) to the environment (usually the file system), where SIP will be created. The SIP creator software must have access to that environment.

Step 2: We create a folder and sub-folder structure as defined in chapter 6.1 of the eHealth2 specification, as shown in the Figure below. For a more detailed layout, you can download an empty SIP file from the specifications GitHub repository.

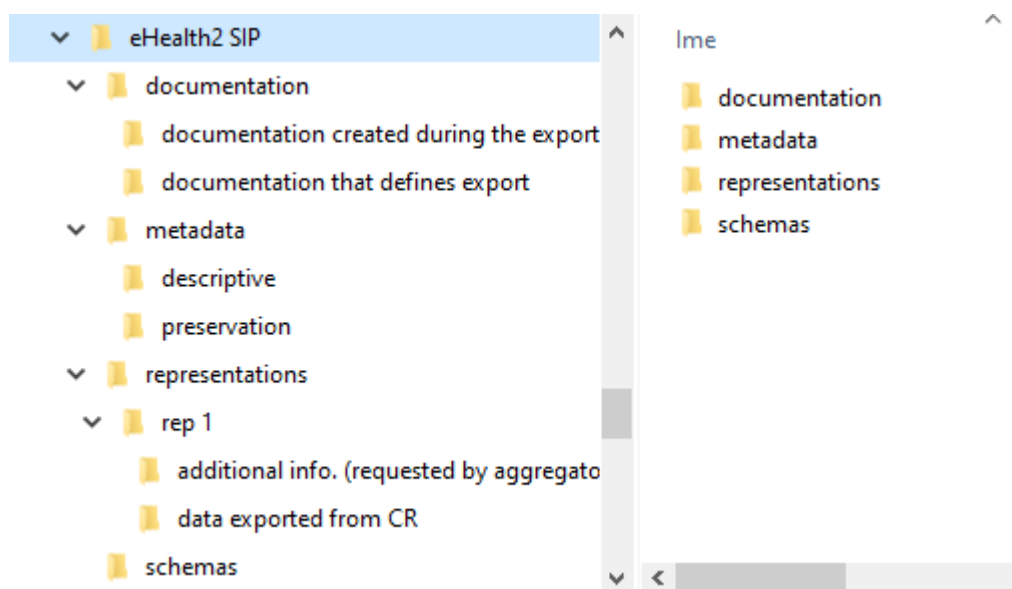


Figure 1: Folder structure of the eHealth2 SIP

Step 3: Every file put into the SIP package should be described (a list with what is in a particular file has to be made). By describing a file, we create the metadata set that helps us navigate the exports and better explain the package's content. We can describe files in a spreadsheet (e.g. Excel), XML file¹ or use software for SIP creation. An example is shown below.

¹ For creating xml file use the [EAD3 xml schema](#) or any other xml schema that is supported by software for SIP creation.

Table 1: Example of descriptive metadata set in the form of a spreadsheet

Title (<unittitle>)	Date (<unitdate>)	Scope and Content (<scopecontent>)	Conditions Governing Use (<userrestrict>)	Notes (<didnote>)
Data variable definitions	June 2015	Version 1.1 of the ENCR JRC 2015 Data Call Definitions of the variables	No restriction	/

We have identified a minimal set of five descriptive elements from the [EAD3](#) standard:

Title (<unittitle>): element that specifies a title for the described file.

Date (<unitdate>): element for indicating the date or dates the described files were created, maybe in the form of text or numbers, and may consist of a single date, a date range, or a combination of single dates and date ranges.

Scope and content (<scopecontent>): element that provides information about the nature of and activities reflected in the described file (what is in a file).

Condition governing use (<userrestrict>): element that can contain information about any limitations, regulations, or special procedures regarding the access and the use of the file.

Note (<didnote>): element that can express any kind of explanatory information.

Step 4: Once we prepare the structure, files and descriptive metadata set, we can package SIP with the software for SIP creation. The packaging procedure should follow the manual of the chosen software.

Note

Resubmission of the data, especially during data calls from aggregators, is not unusual and can happen even after a year or two. It is wise to wait with SIP preparation until certain that no new submissions of the export will be needed. We recommend preserving reports and documentation about communication between aggregator and cancer registry and include them in a SIP package. We recommend packaging only the last (complete) version of the

cancer registry data export. Delaying SIP packaging does not imply that most of the SIP preparing process (Steps 1–3) should not be executed beforehand.

Note

Since not all file formats are suitable for long-term preservation, files that will be included in the SIP should also follow the requirements of the keeper/archives about the file formats.

4.1 Data export definition documentation (Negotiation and Agreement/Data call)

When defining the content of a cancer registry export, different documentation can be produced. The type and quantity will depend on the kind of agreement between the cancer registry and the aggregator. For example, data calls of international aggregators will have different documentation than more minor requests from local research institutions or individual researchers. However, in this step, documentation that describes the content and the use of the cancer registry export is produced. Such documentation is essential for further use of the export and key for proper future interpretation of the export. Part of documentation that defines export is any amendments and/or clarifications of the content of the cancer registry export. This documentation should also be preserved. The same is true for requests from individual researchers. If there are several iterations of the user's request (for example, further clarifications), we keep the documentation representing the final and complete version of the export.

In some cases, users of the cancer registry data will change (clarify) their requests or add new demands several times during the creation of the export. It is important to identify all information that represents a user's requirements, take notes, and keep track of any documentation produced in the process (e.g., e-mails). We recommend using the eHealth2 specification as a checklist that can help identify the documents containing information that needs to be kept in the SIP. Ideally, the SIP package will include documentation representing the final set of requirements that defines the export.

If the stakeholder in the creation of the export is the archives (entity responsible for long-term preservation of data), it is strongly recommended that they are involved as early as possible: with clear instructions about what needs to be preserved.

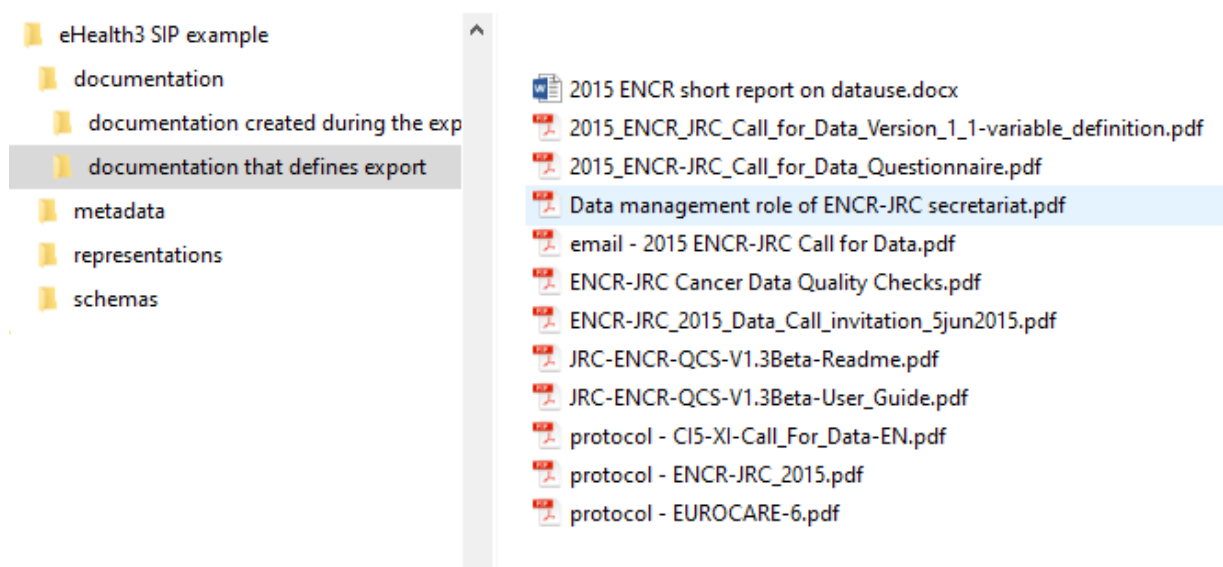


Figure 2: Example of documentation that defines export, based on the ENCR-JRC data call 2015

Note

Documentation that defines export is essential for correctly understanding the export and a mandatory part of the SIP package according to the eHealth2 specification.

4.2 Documentation about exporting data from CR

If the export needs to be kept long-term/indefinitely, we must ensure that its usability, integrity and authenticity are maintained. Documentation about exporting data from CR enables us to meet those requirements.

Especially with data calls from the international aggregator's cancer registry, data has to be restructured, selected or otherwise manipulated to conform with the aggregator's requirements. It is strongly recommended that those procedures are documented: if made with software, that documentation can be in the form of logs, reports, print-screens and, if made manually, in commented print-screens and/or reports. If the documentation that describes manipulation with cancer registry data, so it conforms to the aggregator's requirements, is available, it should be included in the SIP.

All documentation created during the process of exporting and explaining the methodology used for exporting can be included in this folder.

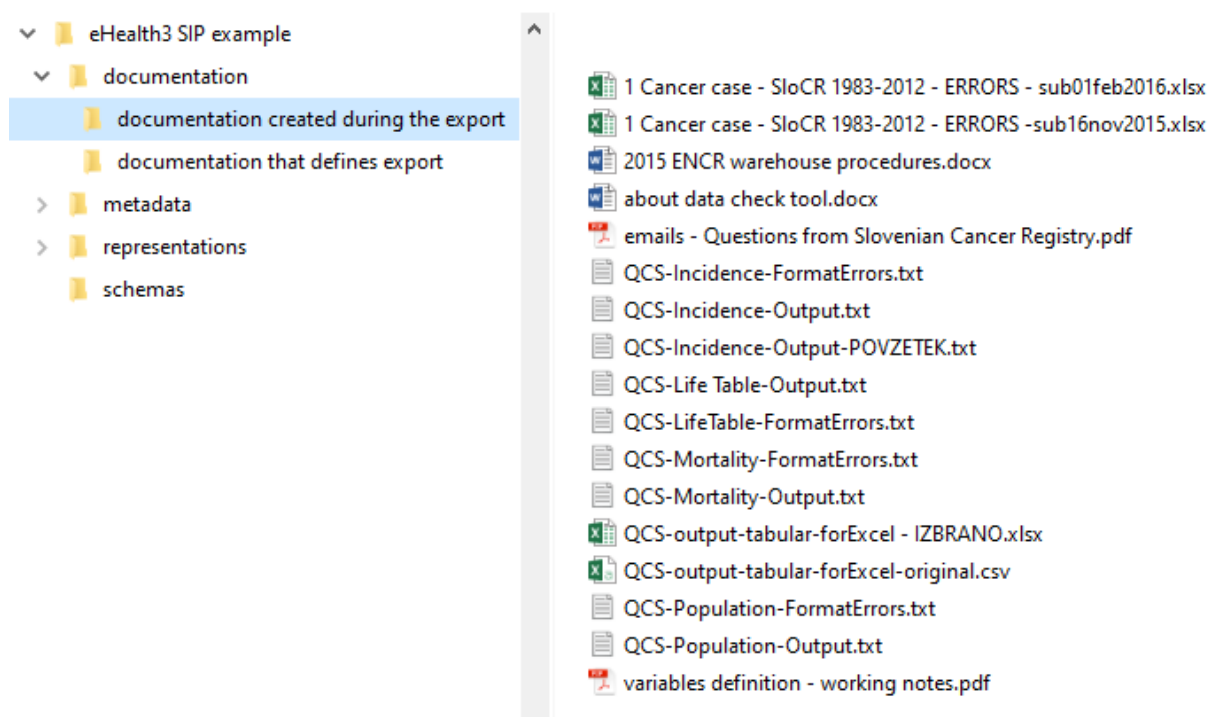


Figure 3: Example of documentation created during the export, based on the ENCR-JRC data call 2015

Note

Documentation in this folder is not mandatory according to specification but can be requested by the user of the export/institution that will maintain export long-term.

4.3 Data validation documentation

Validation ensures that an export meets the requirements specified by the export user. It can be performed manually, but software validation of the cancer registry export content is possible in some cases. Software is usually available when exports are created because of international data calls. Both the aggregator and cancer registry can perform it before or after submission of export. The validation result can be software-based reports or manual reports (commented print screens or written feedback from an aggregator).

Note

Including validation reports in the SIP is strongly recommended for the eHealth2 specification. It should be included in the documentation created during the export folder.

4.4 Export submission documentation

If available, documentation demonstrating the successful handover of the cancer registry (print screen of successful upload to the internet portal, e-mail, etc.) export should be included in the information package. Later, it can demonstrate the exported content,

adherence to what was agreed/required and possibly changed or added during the export preparation.

Note

Including export submission documentation in the SIP is strongly recommended for the eHealth2 specification. It should be included in the documentation created during the export folder.

4.5 Creating an Information Package

After submitting the cancer registry export, a SIP package can be created. Besides the documentation described in previous sections, the SIP package should have enough metadata describing IP content and assure the package's authenticity and completeness. Creating a specification compliant SIP is possible with for example the [software tools available within eArchiving Building Block](#).

Usually, SIP packaging tools automatically issue a printable report or similar documentation about packaging. This documentation should be kept according to the instructions of the responsible archive/keeping service.

4.6 Keeping and maintaining the Export IP

After ingestion in the preservation information system, the SIP package is transformed into the AIP package. Content of the AIP package must be regularly monitored to preserve the package's long term usability. Doing preservation actions (e.g., format migrations) ensures AIP's long-term usability. How frequent and what preservation actions have to be taken is decided according to the responsible archive/keeping service instructions.

5 Glossary

A glossary with terms mainly from the [OAIS](#) is described here to enhance understanding of the specifications and guideline.

Table 2: Glossary

Name	Description
Aggregator	Person or organisation that requires data from the cancer registry.
Archive	A state agency or organisational unit of the organisation responsible for the long-term preservation of data.
Cancer case data	In this specification, cancer case data is data gathered as a result of the cancer registry activity and prepared for the particular export.

Name	Description
Cancer registry (CR)	A population-based cancer registry that systematically receives and collects data about cancer patients and their incident tumours.
Cancer registry data	In the context of this specification, Cancer registry data is data that is created as a result of the cancer registry's activities.
Cancer registry export	In the context of this specification, Cancer registry export is a data set and accompanying documentation exported from the cancer registry based on an aggregator's specifications.
CONCORD Programme	CONCORD is the programme for worldwide surveillance of cancer survival trends, led by the London School of Hygiene and Tropical Medicine.
ENCR	European Network of Cancer Registries promotes collaboration between cancer registries, defines data collection standards, provides training for cancer registry personnel and regularly disseminates information on incidence and mortality from cancer in the European Union and Europe. Its secretariat is hosted at the European Commission's Joint Research Centre (JRC).
Export definitions	Documentation that defines the content and structure of the cancer registry export agreed between the cancer registry and the aggregator.
Exportation documentation	Documentation created during the export and the transfer to the aggregator.
Incidence data	The absolute number of all cancer cases who were newly diagnosed in a defined population in a given period, reported by gender and age at diagnosis.
JRC	The European Commission's Joint Research Centre.
Life table	A table that shows, for each age, gender, and year, the probability that a person of that age will die before their next birthday.
Mortality data	The absolute number of all persons who died because of a specific disease in a defined population in a given period, reported by gender, year and age at death.
Population data	Population data is provided from official censuses or other official sources. General population data is provided by sex, age and calendar year for the area covered by the cancer registry (i.e., the population the cancer cases come from).
TNM	The TNM Classification of Malignant Tumors is a globally recognised standard for classifying the size and the extent of the spread of cancer. TNM stands for tumour size (T), nodes involvement (N), and metastatic spread (M).

6 An example of the export using the CITS eHealth2 specification

The eHealth2 specification was tested in collaboration with the Slovenian Cancer Registry and the Slovenian National Archives. The SIP was built with data and documentation that was needed/created during ENCR-JRC 2015 data call. Data and documentation were described, classified in the folders and ready to be packed with the SIP packaging software. The descriptive metadata tables have been cropped for a better visual representation, so the dates and notes (also descriptive elements) are not visible.

The structure of the folders and descriptive metadata is shown below:

Data exported from a cancer registry

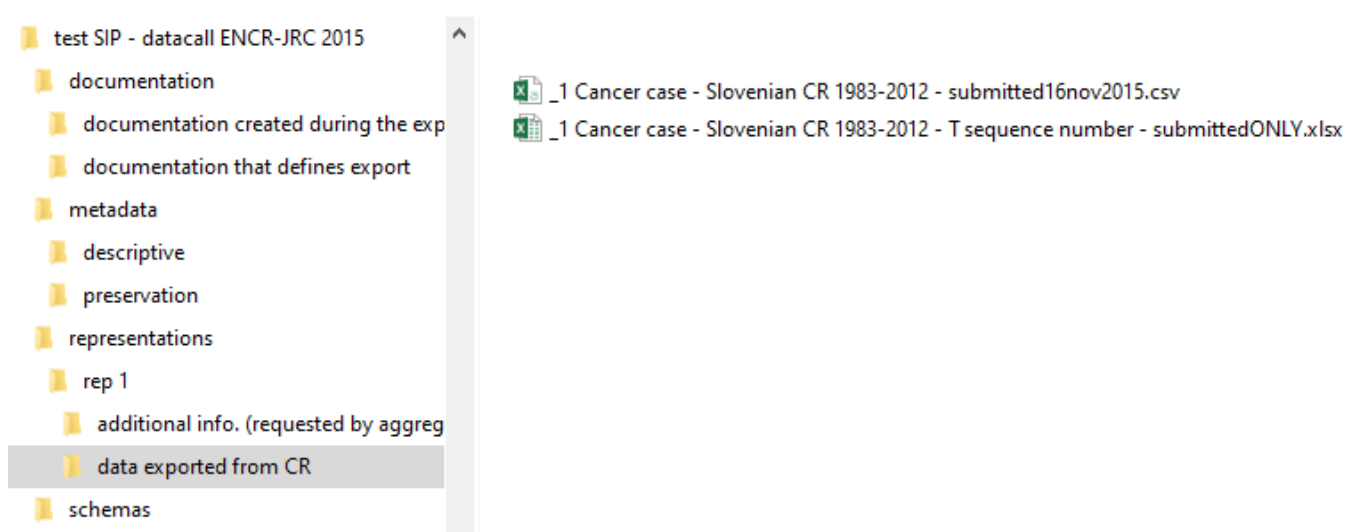


Figure 4: Example of data exported from a cancer registry folder, based on the ENCR-JRC data call 2015

Explanation of the files:

Table 3: Example of data exported from cancer registry descriptive metadata, based on the ENCR-JRC data call 2015

File	Description
_1 Cancer case - Slovenian CR 1983-2012 - submitted16nov2015.csv	Cancer case file for the 1983–2012 exported from SCR.
_1 Cancer case - Slovenian CR 1983-2012 - T sequence number - submittedONLYtoIICC.xlsx	Cancer case file for the years 1983–2012 exported from SCR. Additional information sent to the aggregator based on their inquiries.

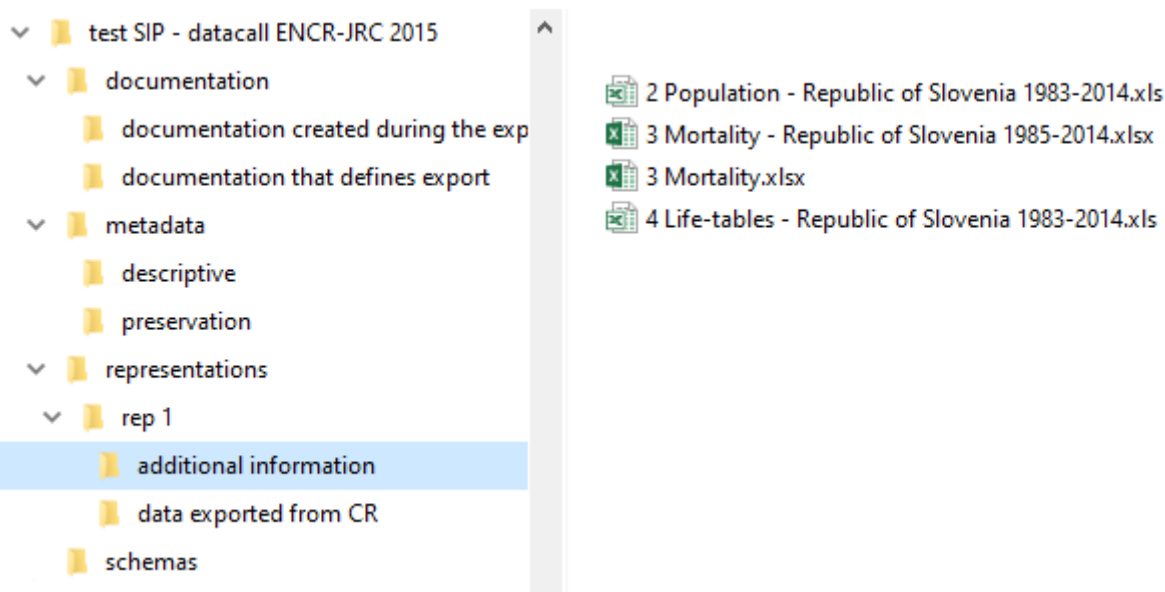
Additional information (requested by aggregator)

Figure 5: Example of additional information folder, based on the ENCR-JRC data call 2015

Explanation of the files:

Table 4: Example of additional information descriptive metadata, based on ENCR-JRC data call 2015

File	Description
2 Population - Republic of Slovenia 1983-2014.xls	Population file for the years 1983–2014 prepared by SCR, which was submitted to the aggregator.
3 Mortality - Republic of Slovenia 1985-2014.xlsx	Mortality file for the years 1983–2014 prepared by SCR, which was submitted to the aggregator.
4 Life-tables - Republic of Slovenia 1983-2014.xls	File with life tables for the years 1983–2014 prepared by SCR, which was submitted to the aggregator.
2015_ENCR-JRC_Call_for_Data_Questionnaire2-submitted-14jan2016.pdf	Completed Questionnaire

Documentation that defines export

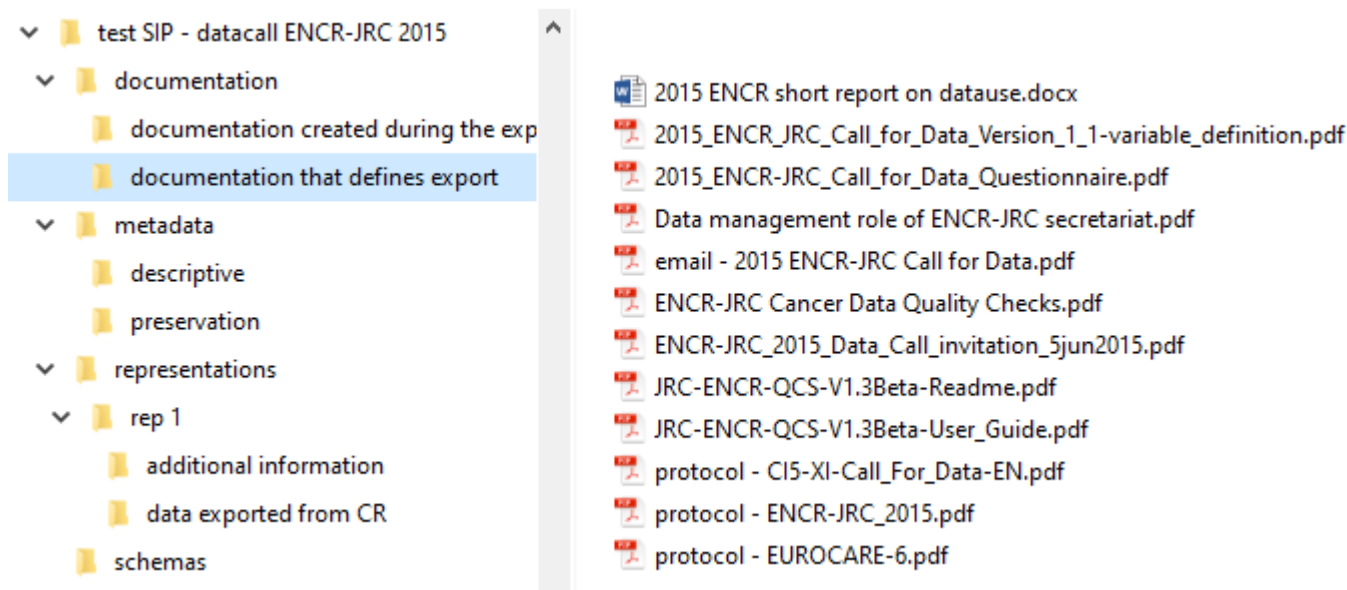


Figure 6: Example of the documentation that defines the export folder, based on the ENCR-JRC data call 2015

Explanation of the files:

Table 5: Example of documentation that defines export descriptive metadata, based on the ENCR-JRC data call 2015

File	Description
2015 ENCR short report on datause.docx	How many CRs submitted the data with a map.
2015_ENCR_JRC_Call_for_Data_Version_1_1-variable_definition.pdf	Call for data – variable definition.
2015_ENCR-JRC_Call_for_Data_Questionnaire.pdf	Call for data – questionnaire.
Data management role of ENCR-JRC secretariat.pdf	Call for data – describing legal framework (there is no need to sign an agreement).
e-mail - 2015 ENCR-JRC Call for Data.pdf	E-mail converted to PDF format. Information that calls for data is out.

File	Description
ENCR-JRC Cancer Data Quality Checks.pdf	Documentation of the ENCR/JRC data check programme V1.3Beta.
ENCR-JRC_2015_Data_Call_invitation_5jun2015.pdf	Call for data – invitation to the CR to participate.
JRC-ENCR-QCS-V1.3Beta-Readme.pdf	General information on data check tools.
JRC-ENCR-QCS-V1.3Beta-User_Guide.pdf	User guide for the ENCR/JRC data check programme V1.3Beta.
protocol - CI5-XI-Call_For_Data-EN.pdf	Call for data – protocol for CI5 XI data call where the same datasets will be used.
protocol - ENCR-JRC_2015.pdf	Call for data – protocol for ENCR-JRC data call where the same datasets will be used.
protocol - EUROCARE-6.pdf	Call for data – protocol for EUROCARE-6 data call where the same datasets will be used.

Documentation documentation created during the export

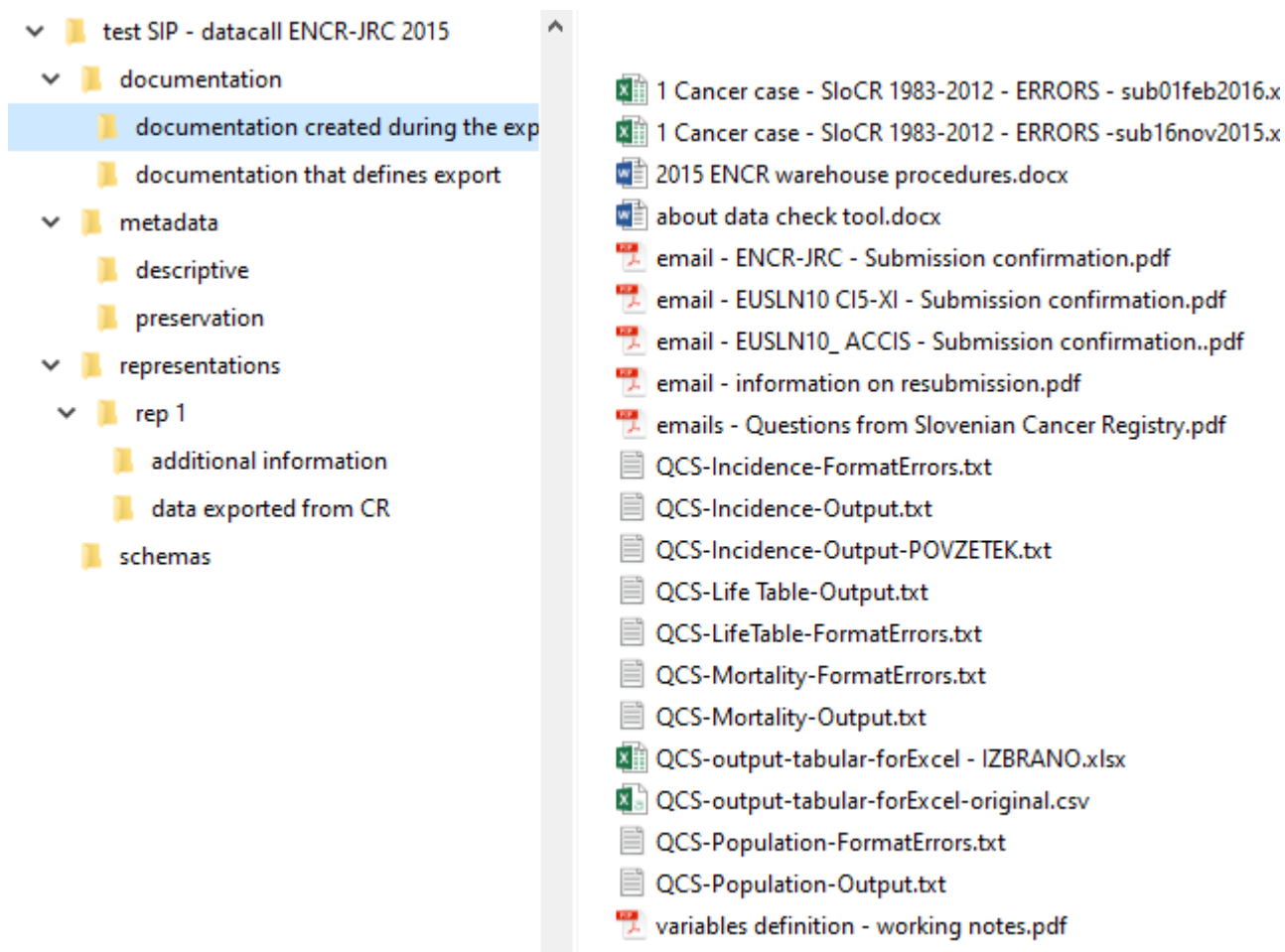


Figure 7: Example of the folder showing documentation created during the export, based on the ENCR-JRC data call 2015

Explanation of the files:

Table 6: Example of descriptive metadata documentation created during the export, based on the ENCR-JRC data call 2015

File	Description
1 Cancer case - SloCR 1983-2012 - ERRORS - sub1feb2016.xlsx	Datafile for communication with the aggregator on reported errors. Output from ENCR/JRC data check programme.

File	Description
1 Cancer case - SloCR 1983-2012 - ERRORS - sub16nov2015.xlsx	Datafile for communication with the aggregator on reported errors. Output from ENCR/JRC data check programme.
2015 ENCR warehouse procedures.docx	Procedures and codes implemented in SCR's warehouse. Created and documented by SCR's supervisor for datacall.
about data check tool.docx	Information on which data check tool was used.
e-mail - ENCR-JRC - Submission confirmation.pdf	E-mail converted to PDF format. Confirmation of data submission.
e-mail - EU SLN10_ ACCIS - Submission confirmation..pdf	E-mail converted to PDF format. Confirmation of data submission.
e-mail - EU SLN10 CI5-XI - Submission confirmation.pdf	E-mail converted to PDF format. Confirmation of data submission.
e-mail - information on resubmission.pdf	E-mail converted to PDF format. Communication with the aggregator that resubmission is needed.
mails - Questions from Slovenian Cancer Registry.pdf	E-mail converted to PDF format. Questions and other communications between SCR and aggregator.
QCS-Incidence-FormatErrors.txt	Output from ENCR/JRC data check programme.
QCS-Incidence-Output.txt	Output from ENCR/JRC data check programme.

File	Description
QCS-Incidence-Output-POVZETEK.txt	Output from ENCR/JRC data check programme.
QCS-Life Table-Output.txt	Output from ENCR/JRC data check programme.
QCS-LifeTable-FormatErrors.txt	Output from ENCR/JRC data check programme.
QCS-Mortality-FormatErrors.txt	Output from ENCR/JRC data check programme.
QCS-Mortality-Output.txt	Output from ENCR/JRC data check programme.
QCS-output-tabular-forExcel - IZBRANO.xlsx	Working file for resolving the errors and warnings produced by data check tool.
QCS-output-tabular-forExcel-original.csv	Output from ENCR/JRC data check programme.
QCS-Population-FormatErrors.txt	Output from ENCR/JRC data check programme.
QCS-Population-Output.txt	Output from ENCR/JRC data check programme.
variables definition - working notes.pdf	Scanned working paper pages with notes (by SCR's supervisor for datacall) on data preparation.

7 Postface

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Project co-funded by the European Commission Programme		within the ICT Policy Support
Dissemination Level		
P	Public	<input checked="" type="checkbox"/>
C	Confidential, only for members of the Consortium and the Commission Services	<input type="checkbox"/>

REVISION HISTORY AND STATEMENT OF ORIGINALITY

Submitted Revisions History

Revision No.	Date	Authors(s)	Organisation	Description
V 1.0	2021-04-30	eHealth2 team	Various	Draft for review
V1.0	2021-08-31	eHealth2 team	Various	Publication

Statement of originality:

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