CITS eHealth1

E-ARK Content Information Type Specification for
Patient Medical Records

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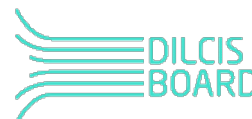
Executive Summary

The eHealth1 specification is built upon work done by the Directorate for Health in Norway on the establishment of a standard for electronically extracting health records from healthcare provider Electronic Medical Records (EMR) systems and their submission to a central health archive. The use cases envisaged for the central health archive are: a. to provide records to next of kin in compliance with open information regulation and b. to harvest the vast amount of historical healthcare-related data for medical research. The CITS takes input from the Norwegian specification on the structure of extractions from submitting systems and puts this into a framework that is compliant with the EARK common and package specifications. The eHealth1 specification also recommends the use of international domain standards for descriptive metadata. The specification is accompanied by two METS profiles for the Root and Representations within the packages.

Preface

I. 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:

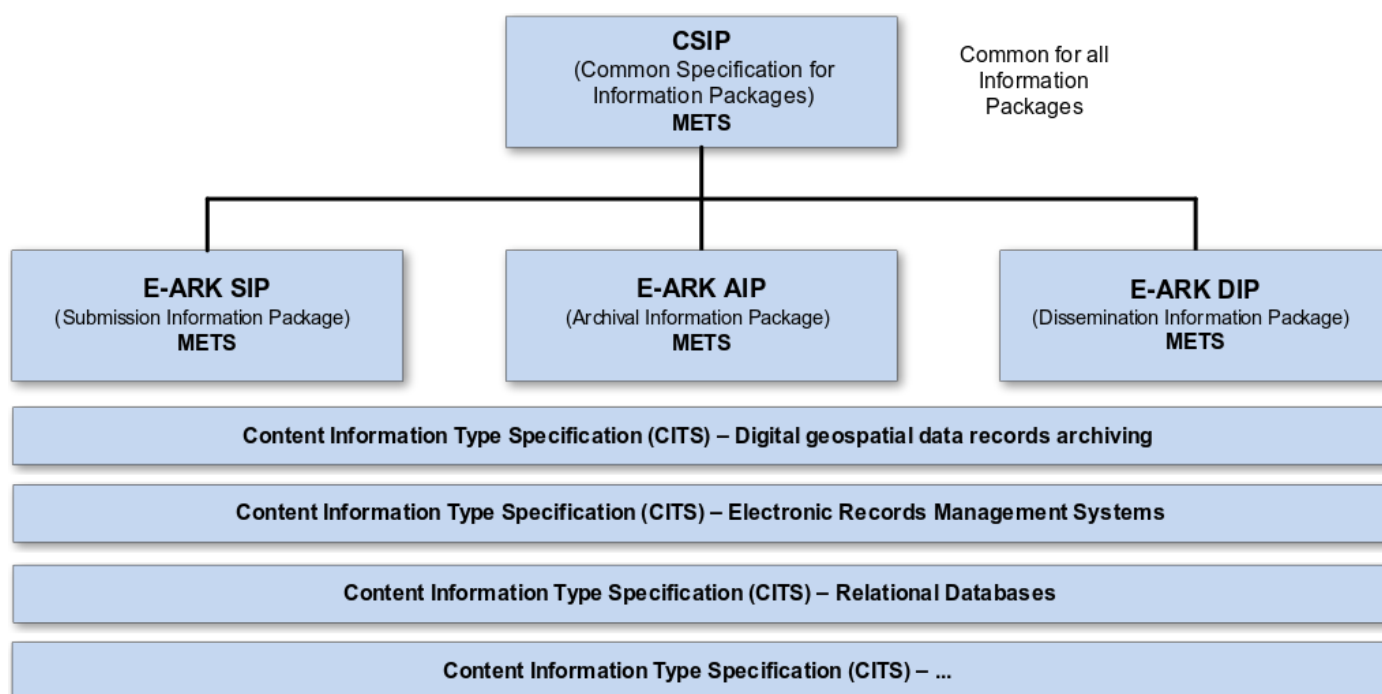**Figure 1:** Diagram showing E-ARK specification dependency hierarchy. Note that the image only shows a selection of the published CITS and isn't an exhaustive list.

Overview of the E-ARK Specifications

Common Specification for Information Packages (E-ARK CSIP)

This document introduces the concept of a Common Specification for Information Packages (CSIP). The main purposes of CSIP are to:

- Establish a common understanding of the requirements which need to be met 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.
- 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.

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.

Specification for Submission Information Packages (E-ARK SIP)

The main aims of this specification are to:

- Define a general structure for a Submission Information Package format suitable for a wide variety of archival scenarios, such as document and image collections, databases or geospatial data.
- Enhance interoperability between Producers and Archives.
- Recommend best practices regarding the structure, content and metadata of Submission Information Packages.

Specification for Archival Information Packages (E-ARK AIP)

The main aims of this specification are to:

- 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 geospatial 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.

Specification for Dissemination Information Packages (E-ARK DIP)

The main aims of this specification are to:

- 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 (E-ARK CITS)

The main aim of a Content Information Type Specification (CITS) is to:

- Define, in technical terms, how data and metadata must be formatted and placed within a CSIP Information Package to achieve interoperability in exchanging specific Content Information.

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/).

II. 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://eark-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/.

III. Authors & Revision History

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

Table of contents

1   Introduction

1.1   Purpose

The purpose of this document is to describe the Content Information Type Specification (CITS) for Patient Medical Records (eHealth1). This specification is supported by METS profiles for the Root and Representation METS files and an accompanying Guideline document.

1.2   Scope

This specification makes the following assumptions:

- A business case for the creation of an eHealth archive includes the incorporation of a backlog of physical and digital patient records.
- An eHealth archive concerns the Complete Patient Medical Records for patients within the jurisdiction. Note that the term "jurisdiction" does not imply that a Central Health Archive must be at a national or federal level. Many health administrations are organised at a state or region level, and the specification is equally valid for this scenario. Note also that there are significant potential benefits for the use of the standard for archiving of Patient Medical Records if complied with by all regional administrations within a federation. This can also apply to environments where there are private healthcare providers, and a Central Health Archive is being created by a controlling administration.
- The use cases considered by the specification for an eHealth archive are described in the accompanying Guideline.

There are two options for extracting patient records from an EMR or EHR system which can be dependent to a certain extent on the source system data structure:

1.2.1 Extracting data in a relational database structure

If the structure of the source EHR/EMR system is wholly a relational database, then the extraction of selected records can be made into a long-term database preservation format (SIARD) that preserves the properties of the database such that the data can be imported into a relational database management system (RDBMS) at the time of access. Access can happen through database queries or a search field.

Further information on the limitations of this approach, particularly for the use cases behind the eHealth1 CITS is given in the accompanying Guideline.

The SIARD specification, together with a Content Information Type Specification for SIARD, represents the SIP profile for the relational databases content type. More information can be found at https://dilcis.eu/content-types/siard.

Extractions can be made from such wholly relational database systems programmatically that create the aggregated structure required for eHealth1 and as seen in traditional EMR systems and physical Patient Record archives. For the use cases described in this Content Information Specification it is recommended that this approach is followed.

1.2.2 Extracting data and metadata as aggregations of patient medical records

Digitisation of physical Patient Medical Records or extraction of electronic records from more traditional EMR systems produces a case type structure of files and accompanying metadata as described in the Guideline. Being extracted in this manner makes them directly accessible for validation, data management, indexing and searching. The structured semantic metadata description is explicit rather than hidden inside an RDBMS. This methodology also supports the incremental extraction of records over time for submission to the Archive and in addition:

- Records from different sources can be merged (complete Patient Medical Records can be synthesised from multiple submissions)

- Search and access is possible across all records and sources
- Records can be managed individually and uniformly
- The original EMR/EHR system software does not need to be licensed or preserved

This specification considers this particular extraction method within the context of the use cases as described in the Guideline.

1.3 Layered Data Model

This section introduces the role of the CITS eHealth1 and its dependencies on the basic structures of the Information Package.

> This specification is created based on the requirements of the Common Specification for Information Packages (CSIP), the specification for Submission Information Packages (E-ARK SIP) and the specification for Archival Information Packages (E-ARK AIP). To fully understand its requirements, we highly recommend that users review the requirements and the terminology of the source documents, before using this specification.

The data model structure is based on a layered approach for information package definitions Figure 2. The Common Specification for Information Packages (CSIP) forms the outermost layer. The general SIP, AIP and DIP specifications add respectively, submission, archiving and dissemination information to the CSIP specification. The third layer of the model represents specific content information type specifications, such as this CITS eHealth1 specification. Additional layers for business-specific specifications and local variant implementations of any specification can be added to suit the needs of the organisation.
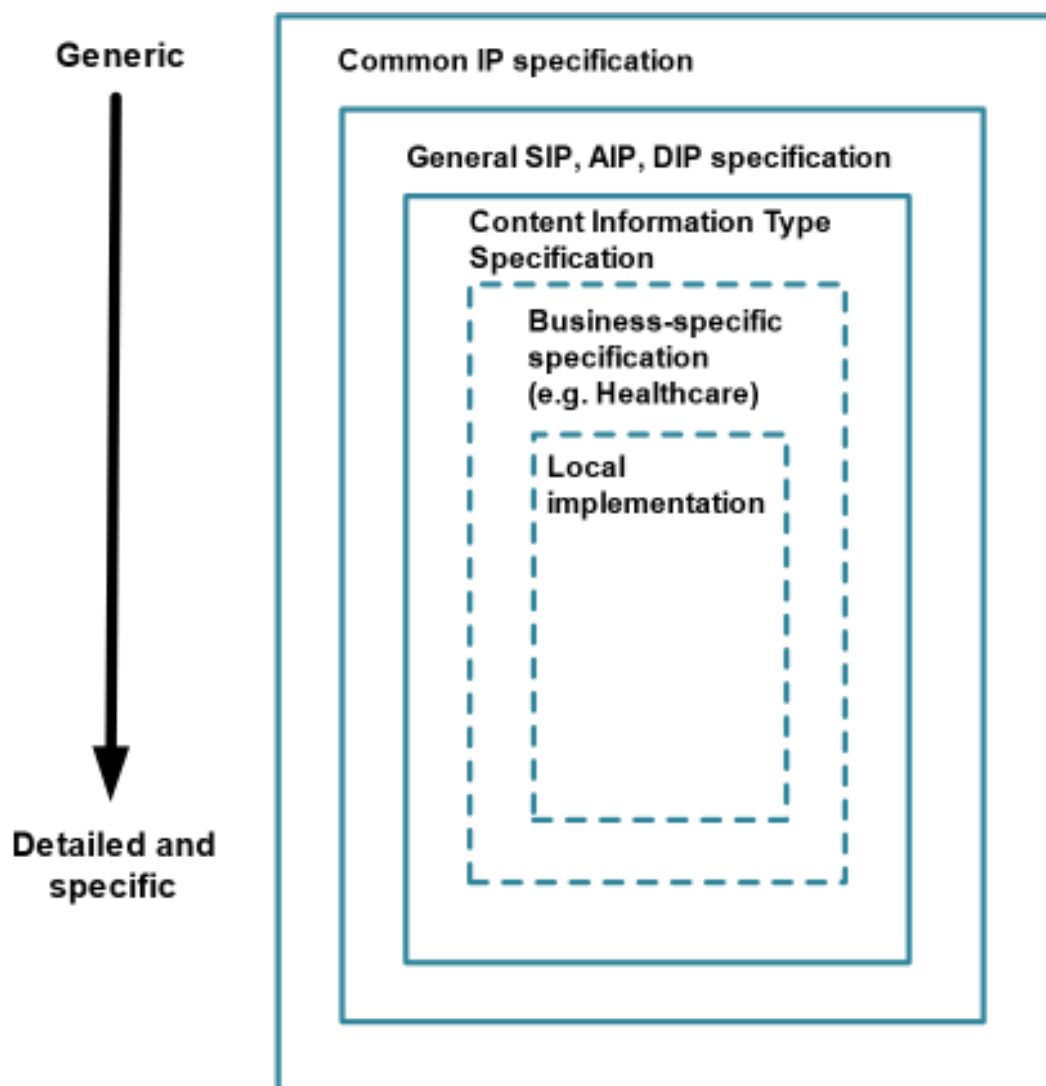
Figure 2: Data Model Structure

Every level in the data model structure inherits metadata entities and elements from the higher levels. In order to increase adoption, a flexible schema has been developed. This will allow for extension points where the schema in each layer can be extended to accommodate additional information on the next specific layer until, finally, the local implementation can add specific entities or metadata elements to satisfy specific local needs. Extension points can be implemented by:

Embedding foreign extension schemas (in the same way as supported by METS [http://www.loc.gov/standards/mets/] and PREMIS [http://www.loc.gov/standards/premis/]). These both support increasing the granularity of existing metadata elements by using more detailed data structures as well as adding new types of metadata.

Substituting metadata schemas for standards more appropriate for the local implementation.

The structure allows the addition of more detailed requirements for metadata entities, for example, by:

- Increasing the granularity of metadata elements by using more detailed data structures, or
- Adding local controlled vocabularies.
- For consistency, design principles are reused between layers as much as possible.

2 Specification

2.1 CITS eHealth1 Specification Requirements Structure

The Content Information Type Specification for Patient Medical Records (CITS eHealth1) aims to define the necessary elements required to preserve the accessibility and authenticity of Patient Medical Records over time and across changing technical environments. The specification elevates the level (and adjusts the cardinality) of some of the requirements set out in the Common Specification (CSIP) and package specifications (namely SIP) and adds new requirements for the package structure, descriptive metadata and accompanying METS files. The specification sets out general principles that underpin the specific requirements. Further context for the requirements and principles can be found in the accompanying Guideline to this document.

2.2 Principles

2.2.1 Principle 1– use of existing standards

Wherever possible the eHealth1 specification encourages the use of existing international specifications for patient administrative, clinical, diagnostics, medication information and vocabularies for diseases, conditions and treatments.

2.2.2 Principle 2 – the Complete Patient Medical Record and Patient centricity

CITS eHealth1 supports the creation of a centralised (national or regional) health archive of Complete Patient Medical Records, where the intention is to make data available to next of kin and should contain as much of the original data from source systems as possible. Data is organised to be patient centric and so access to a complete record from multiple submissions is possible.

2.2.3 Principle 3 – ability to create cohorts for research purposes

CITS eHealth1 supports the creation of a centralised (national or regional) health archive of Complete Patient Medical Records, where the intention is to make data available to researchers and should allow the creation of search databases and indexes based on key patient demographic and clinical data.

2.2.4   Principle 4 – support for born digital and digitised records

The specfaction allows for data submitted by producers (or generated at the archive) to be extractions from Electronic Record Management (EMR) or Electronic Health Record (EHR) systems or to be data generated through digitisation of physical records.

2.2.5   Principle 5 – bulk submission of Patient records from producers

Based on the principals above, the intellectual content of archival information packages (AIPs) in a health archive will most likely be limited to data about a single Patient. However, the specification recognises that submissions are likely to be made from healthcare providers on a batch basis on a regular schedule and the submission format should allow inclusion of multiple Patient records. Processes at the archive can then parse submission collections into individual patient SIPs and ingest into the archive such as to create individual patient AIPs.

2.3   Standards

Controlled vocabularies and coding provide a standardised way for the unambiguous recording of health data. Most EMR and all EHR systems will hold coded data concerning Patient Cases that can be extracted as metadata for the Patient Medical Record and will use international standard vocabularies such as ICD or SNOMED. Data can be recorded in standardised (such as ISO 13606 or FHIR) formats or to a local format which is specified by the health archive and referenced within a Submission Agreement. Background information on eHealth standards such as ISO 13606, FHIR, ICD and SNOMED is given in the Guideline.

2.4   Data Structure and Aggregations

2.4.1   Case Structure and Data Aggregation

The names of aggregation levels within an archive and represented within an archival package (IP) will depend on the agreements between data producers (Creators) and archives. EAD3 has defined a set of values (class, collection, file, fonds, item, otherlevel, recordgrp, series, subfonds, subgrp, subseries) for that purpose, and it allows other values to be used in addition if they are defined as "otherlevel". However, even though the aggregation levels in this context could be described in this way, the EAD template for archival description is considered unsuitable for describing the aggregations in a Patient Health Archive but may be used for general archival information Implementation.

A Central Patient Health Archive has a single purpose and may be instituted as a stand-alone entity or as a sub-entity within a larger institution (e.g. National Archive or Health Authority). The overall aggregation of a health archive is therefore implicit (it is an aggregation of Patient Medical Records), and further aggregation levels must be defined that suit the use cases for navigation within the archive and for the way in which the archive is populated.

Patient Medical Records will be submitted to a Central Health Archive either when a patient is known to have died or after a period of time when it is not feasible that a patient is still alive (determined through regulations). Depending

upon the availability of a National Death Register, the accessibility and responsiveness to such a register and the periodic batching of archival extracts at healthcare providers, it cannot be expected that individual patient submissions from multiple creators will be at all coordinated. Aggregation of a total patient record at the archive prior to submission into the preservation system is therefore deemed impractical in this specification.

The proposed data structure for the aggregations of the submissions of Patient Medical Records is as shown in the data model in Figure 3. As patient data is likely to be submitted in batches, each submission package will contain information from multiple Patients, and it is likely that these submissions will be split by the archive on receipt to create Patient-specific archival information packages (AIPs) in order to simplify the dissemination process. In this context, the submission package could be considered as a submission information collection (SIC) or collation of SIPs which is compiled to simplify extraction and transmission. However, for the purposes of this specification, the term SIP is used to mean both a submission package for a single Patient Record or a submission package containing multiple Patient Records.

The levels of the aggregation in an eHealth1 package are as follows:

- Patient: An individual who has received healthcare at any number of healthcare providers and who is described by Patient Personal Information Implementation. Each patient will be identified by means of a unique identifier (ID) which is provided from the source EMR system. This unique ID connects the Patient Personal Information and the Patient Medical Record in the information package.

- Case: A Patient Medical Record can be structured in various ways, which may be dictated by national standards, guidance or local practice. A Patient's Complete Medical Record will consist of multiple individual thematic Cases which may be concerned with particular medical conditions, periods or treatments. The proposed aggregation allows for flexibility in this grouping. These cases will be held in a healthcare provider's local archive and may contain a number of Sub-cases and/or Documents with associated Data Files.

- Sub-case: A Sub-case is an allowable type of component consisting of a set of Documents and Data Files that is nested below a Case. Sub-cases may originate in departments within a large hospital or may be related to a different diagnosis to other Sub-cases. A Sub-case may have common (to the Case) or specific metadata.

- Document: A Document is a component that may consist of multiple related Data Files with common metadata; for example, a document may be a PDF file together with associated attachments, or there may be a document and a separate signature sheet. A document can be considered to be an entity that is approved/signed as a whole.

- Data File: A Data file is a component that contains data and has an associated MIME file type. A Data File can be a single bit stream or can encapsulate bit streams and attributes according to a standard such as a DICOM or MP4, in which case it will have a recognised MIME file type. A Data File, which is a container for multiple byte streams and metadata, can be included in the package as a Data File or can be unpacked and included as separate Byte Streams and metadata in METS. It is expected that containers such as DICOM and MP4 files will be submitted unaltered in Submission Information Packages (SIPs) and that any decision to unpack them is part of a preservation plan at the archive.

- Byte Stream: A Byte Stream is a component that contains data, has an associated MIME file type and is encapsu-

lated in a container such as MP4, DICOM or Matroska. Each Byte Stream has its own associated metadata, such as technical metadata, but which is generally only accessible with specialised tools (such as ffprobe for video container formats).
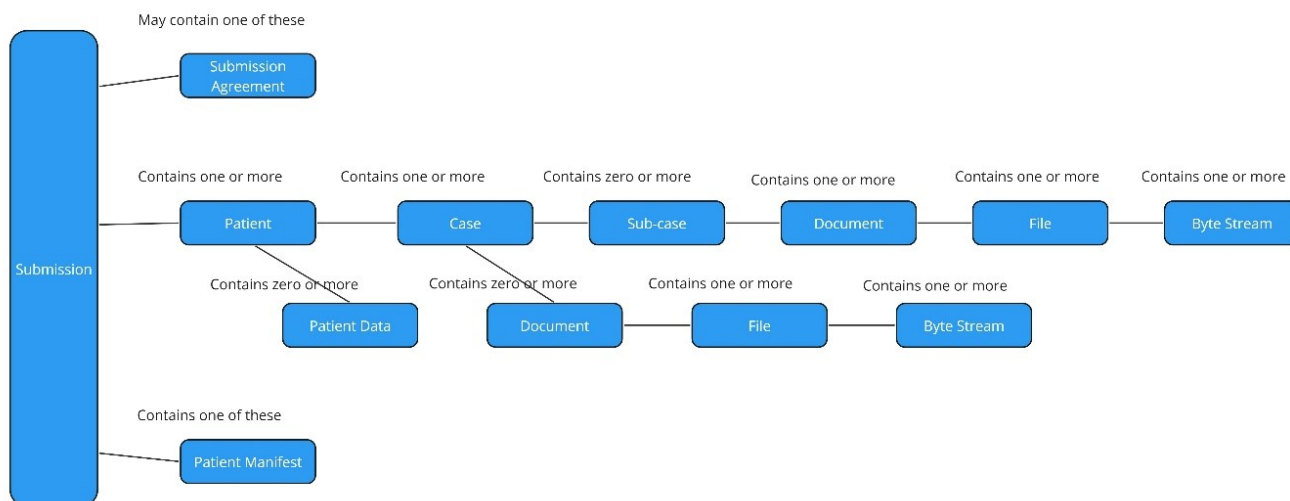
Figure 3: eHealth1 SIP Data Model

2.4.2 Using the eHealth1 specification together with the Common Specification for Information Packages (CSIP)

The eHealth1 specification conforms to and extends the Common Specification for Information Packages (CSIP) and the Specification for Submission Information Packages (E-ARK SIP). When extractions are made from EMR systems according to the structure described, they can be transmitted in a package following the principles described in the CSIP and IP specifications.

2.4.3 Placement of data in an eHealth1 Information Package

Patient data will most likely be submitted by hospitals or other healthcare providers in periodic batches, consisting of multiple patient records. The eHealth1 specification allows for the inclusion of multiple patients per package, and so these batches can be transmitted in a single submission. The number of patients included in each AIP is then a matter for local implementation, Section 6.1.

Patient Medical Records are placed in a single representation within the "representations" folder of the package. The representation should contain a METS file at its root (Representation METS), the folder structure of the representation should follow that defined by the CSIP and it must have a data folder. Within the data folder, there should be a folder for each Patient Record identified by a name that is unique within the package scope, follows the requirements of CSIP and contains to the Patient's unique individual ID.

It is recommended, but not mandated that within each Patient Record folder that there are further folders that physically represent a Case, Sub-case, Document structure to aid human readability and navigation of the archive. If Patient Administrative and Patient Clinical Information is to be supplied, then this should be included at the root of each Patient Record. Figure 4 shows an example of a folder structure for a package where there are multiple Patient submissions and Patient Clinical information is included.

The package should contain a patient administrative information or manifest file within the root metadata/descriptive folder that at minimum contains the names of the patients whose records are contained in the package and a reference to their Patient ID.
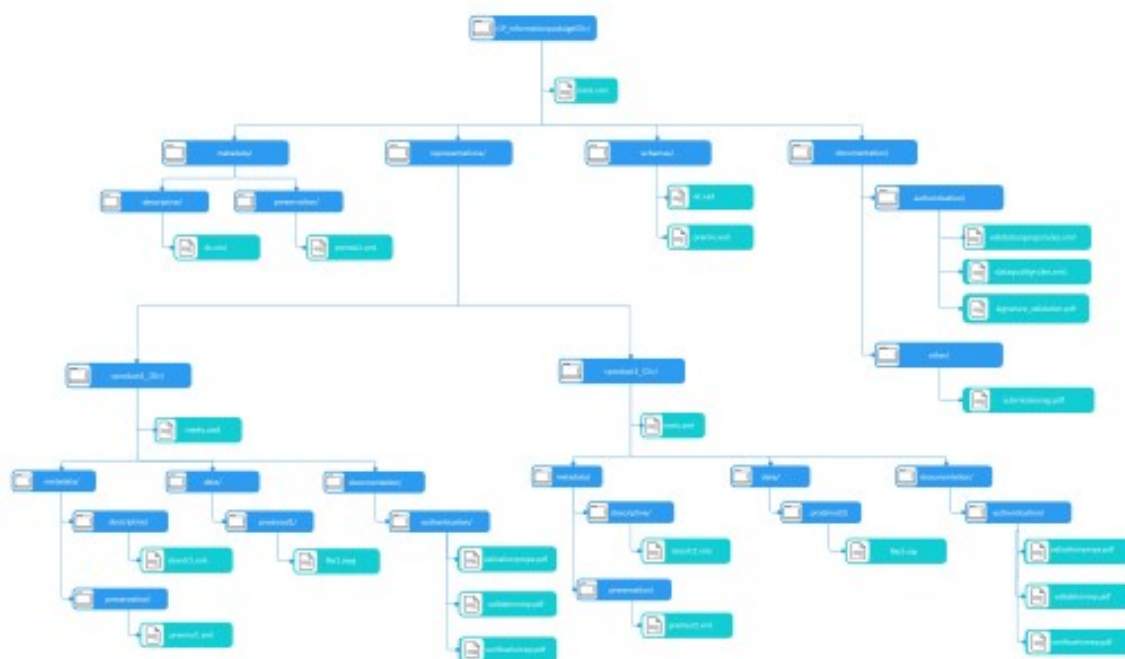
Figure 4: Example of Package Folder Structure and Multiple Patient Submissions and Case Structure

2.5 General Requirements

EHGR1 – submission packages MUST contain at least one representation containing data from one or more Patients.

EHGR2 – data from multiple Patients if present MUST be divided into separate Patient Record folders in the data folder of the representation.

EHGR3 – Patient data in a Patient Record SHOULD follow a logical structure such as that of the of the source system e.g a Case/Document/File or Case/Sub-case/Document/File , but may take account of local language and/or source system directory structures. If local terms are used, the addition of a revised vocabulary to the package for data structure terms is recommended, which should be placed in the schemas folder.

EHGR4 – each submission package SHOULD contain a submission agreement in the root /documentation folder.

EHGR5 – there MUST be a Patient manifest or Patient Administrative Information file located in the root /metadata/descriptive folder that at minimum contains a list of Patient names and unique identifiers. The Patient Administrative Information file MAY contain personal and demographic information such as to aid searches for next of kin and research cohorts.

EHGR6 – each Patient Record SHOULD contain Patient Administrative and Clinical Information file(s).

3 Implementation

3.1 Use of METS in eHealth1

CSIP specifies that METS files be located at the root of the package folder structure (Root METS) and optionally in each of the representations within its respective root folder (Representation METS).

3.1.1 Root METS File

The root METS file must adhere to the requirements of the CSIP and Information Package specifications. In addition, there are specific requirements for the eHealth1 CITS, and in some cases, the level of the CSIP or package requirements have been increased (but never decreased).

Root METS root element

The eHealth1 CITS specification does not change or extend any of the requirements for the Root METS root element. Information is given below regarding the specific content type attributes to be used in an eHealth1 CITS.

ID	Name, Location & Description	Card & Level
EHR1	**METS Profile**	**1..1**
	mets/@PROFILE	MUST
	The value is set to	
	"https://citsehealth1.dilcis.eu/profile/E-ARK-eHealth1-ROOT.xml".	
EHR2	**Content Category**	**1..1**
	mets/@TYPE	MUST
	The mets/@TYPE attribute is set to the value "OTHER".	
EHR3	**Other Content Category**	**1..1**
	mets[@TYPE='OTHER']/@csip:OTHERTYPE	MUST
	The mets/@csip:OTHERTYPE attribute is set to the value "Patient Medical Records".	
EHR4	**Content Information Type Specification**	**1..1**
	mets/@csip:CONTENTINFORMATIONTYPE	MUST

Example: METS example of root METS element for an IP following the CITS eHealth1

```
<mets:mets xmlns:mets="http://www.loc.gov/METS/" xmlns:csip="https://DILCIS.eu/XML/
   METS/CSIPExtensionMETS" xmlns:sip="https://DILCIS.eu/XML/METS/SIPExtensionMETS"
   xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:xlink="http://www.w3.
   org/1999/xlink" xsi:schemaLocation="http://www.loc.gov/METS/ http://www.loc.gov/
   standards/mets/mets.xsd          http://www.w3.org/1999/xlink http://www.loc.gov
   /standards/mets/xlink.xsd          https://DILCIS.eu/XML/METS/CSIPExtensionMETS
          https://earkcsip.dilcis.eu/schema/DILCISExtensionMETS.xsd
          https://DILCIS.eu/XML/METS/SIPExtensionMETS                 https://
   earksip.dilcis.eu/schema/DILCISExtensionSIPMETS.xsd" OBJID="ehealth1-root-mets-
   example" TYPE="OTHER" csip:OTHERTYPE="Patient Medical Records" csip:
   CONTENTINFORMATIONTYPE="citsehpj_v2_0" LABEL="Patient Medical Records from Skane
   University Hospital" PROFILE="https://citsehealth1.dilcis.eu/profile/E-ARK-eHealth1
   -ROOT.xml">
</mets:mets>
```

Root METS header element (element metsHdr)

The following describes the differences in the package metsHdr element between CSIP, IP and the eHealth 1 CITS

specification.

ID	Name, Location & Description	Card & Level
EHR5	**Submission agreement** mets/metsHdr/altRecordID[@TYPE='SUBMISSIONAGREEMENT'] There SHOULD be a reference to the Submission Agreement associated with the package as the SIP will contain personal data.@TYPE is used with the value "SUBMISSIONAGREEMENT". Example: http://submissionagreement.kb.se/dnr331-1144-2011/20120711/.Note: It is recommended to use a machine-readable format for a better description of a submission agreement.For example, the submission agreement developed by Docuteam GmbH http://www.loc.gov/standards/mets/profiles/00000041.xml	**0..1** SHOULD
EHR6	**Archival creator agent** mets/metsHdr/agent A wrapper element that encapsulates the name of the organisation, software and person that originally created the data being transferred. Please note that this might be different from the organisation which has been charged with preparing and sending the SIP to the archives.It MUST be easy to positively identify the creating organisation (healthcare provider) without which the data has no provenance.	**1..1** MUST
EHR7	**Archival creator agent role** mets/metsHdr/agent[@ROLE='CREATOR'] The role of the archvial creator organisation is set to the value "CREATOR".	**1..1** MUST
EHR8	**Archival creator agent type** mets/metsHdr/agent[@TYPE='ORGANIZATION'] The type of the archvial creator agent is set to the value "ORGANIZATION".	**1..1** MUST
EHR9	**Archival agent creator name** mets/metsHdr/agent/name The name of the organisation(s) that originally created the data being transferred MUST be given.Please note that this might be different from the organisation which has been charged with preparing and sending the SIP to the archives.	**1..n** MUST

ID	Name, Location & Description	Card & Level
EHR10	**Archival creator agent additional information**	**0..1**
	mets/metsHdr/agent/note	SHOULD
	The archival creator agent SHOULD have a note providing a unique identification code for the archival creator.As permitted by national identification systems for healthcare providers submitting Patient Medical Records, an identifier for the provider should be provided.	
EHR11	**Classification of the archival creator agent additional information**	**1..1**
	mets/metsHdr/agent/note/@csip:NOTETYPE	MUST
	The archival creator agent notetype has a value of "IDENTIFICATIONCODE".	

Example: METS example of root METS Header for an IP following CITS eHealth1

```
<mets:metsHdr CREATEDATE="2018-04-24T14:37:49.602+01:00" LASTMODDATE="2018-04-24T14
    :37:49.602+01:00" RECORDSTATUS="NEW" csip:OAISPACKAGETYPE="SIP">
  <mets:altRecordID TYPE="SUBMISSIONAGREEMENT">
    http://submissionagreement.kb.se/dnr331-1144-2011/20120711/
  </mets:altRecordID>
  <mets:altRecordID TYPE="PREVIOUSSUBMISSIONAGREEMENT">
    http://submissionagreement.kb.se/dnr330-1122-2009/20110613/
  </mets:altRecordID>
  <mets:altRecordID TYPE="REFERENCECODE">
    FM-12-2387/12726,2007-09-19
  </mets:altRecordID>
  <mets:altRecordID TYPE="PREVIOUSREFERENCECODE">
    SE/FM/123/123.1/123.13
  </mets:altRecordID>
  <mets:agent ROLE="CREATOR" TYPE="OTHER" OTHERTYPE="SOFTWARE">
    <mets:name>
      piql eHealth SIP Creator
    </mets:name>
    <mets:note csip:NOTETYPE="SOFTWARE VERSION">
      VERSION 1.1
    </mets:note>
  </mets:agent>
  <mets:agent ROLE="CREATOR" TYPE="ORGANIZATION">
    <mets:name>
      Skane University Hospital
```

```
    </mets:name>
    <mets:note csip:NOTETYPE="IDENTIFICATIONCODE">
      ID:89101112
    </mets:note>
  </mets:agent>
  <mets:agent ROLE="CREATOR" TYPE="INDIVIDUAL">
    <mets:name>
      Sven Svensson
    </mets:name>
    <mets:note>
      Phone: 08-123456, email: sven.svensson@mail.mail
    </mets:note>
  </mets:agent>
  <mets:agent ROLE="PRESERVATION" TYPE="ORGANIZATION">
    <mets:name>
      The Swedish Health Agency
    </mets:name>
    <mets:note csip:NOTETYPE="IDENTIFICATIONCODE">
      ID:1234567
    </mets:note>
  </mets:agent>
</mets:metsHdr>
```

Root METS descriptive metadata section (element dmdSec)

The CSIP and IP specifications do not make any assumptions regarding the use of specific descriptive metadata schemas. The structure of the eHealth1 CITS is built on the concept of being patient-centric, and so a standardised metadata schema is preferred for Patient Administrative Information. The use of schemas such as ISO 13606 or HL7 FHIR is suggested but is not mandatory as local regulations and standards may be used.

ID	Name, Location & Description	Card & Level
EHR12	**Descriptive metadata** `mets/dmdSec` There MUST be a reference to a metadata file held in the the metadata/descriptive folder of the package. At minimum this MUST be a Patient Manifest of Patient Names and unique personal identifiers. It CAN be a more detailed resource such as the FHIR Patient resource "FHIR.Patient".	**1..n** MUST

ID	Name, Location & Description	Card & Level
EHR13	**Reference to the document with the descriptive metadata** `mets/dmdSec/mdRef` There MUST be reference() to the descriptive metadata file(s) located in the "metadata" section of the IP.	**1..n** MUST
EHR14	**Type of metadata** `mets/dmdSec/mdRef[@MDTYPE='OTHER']` The value for the metadata type is set to "OTHER".	**1..1** MUST
EHR15	**Type of other metadata** `mets/dmdSec/mdRef[@MDTYPE='OTHER']/@OTHERMDTYPE` Specifies the type of metadata used for the Patient Manifest.For example the value will be "FHIR.Patient" if the FHIR Patient resource is used.	**1..1** SHOULD

Example: METS example of Root METS dmdSec following CITS eHealth1 with reference to HL7 FHIR Patient Administrative Information is used

```
<mets:dmdSec ID="dmd-ehealth-file" CREATED="2018-04-24T15:27:45.702+01:00" STATUS="
   CURRENT">
  <mets:mdRef LOCTYPE="URL" xlink:href="metadata/descriptive/patients.xml" xlink:type=
     "simple" MDTYPE="OTHER" OTHERMDTYPE="FHIR.Patient" MIMETYPE="application/xml"
     SIZE="643" CREATED="2018-04-24T14:11:29.309+01:00" CHECKSUM="66
     EEDDF0A22EF57078694B67CA45DF301034556D6CB493531356C4FFE92AB6B1" CHECKSUMTYPE="SHA
     -256">
  </mets:mdRef>
</mets:dmdSec>
```

Root METS administrative metadata section (element amdSec)

The eHealth1 CITS specification does not change or extend any of the requirements already defined by the CSIP or IP specifications' administrative metadata section. The eHealth1 root METS document amdSec element SHOULD comply with the amdSec requirements in the CSIP profile. Note that in eHealth1, it is required that any rights or digital provenance metadata that is general to the package should be held within the root metadata folder and that any rights or digital provenance metadata that is specific to the data held in the representations should be held in the respective representation metadata folder.

Root METS file section (element fileSec)

The CSIP does not make the use of the METS fileSec element mandatory, but it is strongly recommended. In the eHEALTH CITS, the use of the METS fileSec element at the package level becomes mandatory, such as to reference the mets files within each representation.

ID	Name, Location & Description	Card & Level
EHR16	**File section** `mets/fileSec` The transferred content is placed in a representation folder described with a representation METS document.Only a single file section (`<fileSec>`) element MUST be present.	1..1 MUST

EHR22	**Content Information Type Specification**
	`mets/fileSec/`
	`fileGrp[@csip:CONTENTINFORMATIONTYPE='citsehpj_v2_0']`
	The value of the attribute
	`mets/fileSec/fileGrp/@csip:CONTENTINFORMATIONTYPE` is set to "citsehpj_v2_0".
		1..1
		MUST

Example: METS example of Root METS fileSec following CITS eHealth1 with file information.

```xml
<mets:fileSec ID="file-sec-example">
  <mets:fileGrp ID="filegrp-documentation" USE="Documentation">
    <mets:file ID="file-submission-agreement" MIMETYPE="application/pdf" SIZE="
        43445212" CREATED="2012-08-15T12:08:15.432+01:00" CHECKSUM="160
        D71F56C2CE685CE7FBD679076FD76B3C67EE9AB5062F5EF5C99AE39C1F43B" CHECKSUMTYPE="
        SHA-256">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/
          subagreement.pdf">
      </mets:FLocat>
    </mets:file>
    <mets:file ID="file-ptr-documentation-file" MIMETYPE="application/vnd.
        openxmlformats-officedocument.wordprocessingml.document" SIZE="31462826"
        CREATED="2012-08-15T14:44:45.432+01:00" CHECKSUM="0
        FE9683451D0390BCDEF19CE10CFD287A2D944B6A33D246681FEF27F44FFAF1D" CHECKSUMTYPE="
        SHA-256">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/file2.
          docx">
      </mets:FLocat>
    </mets:file>
```

```
    </mets:fileGrp>
    <mets:fileGrp ID="filegrp-schemas" USE="Schemas">
      <mets:file ID="file-ptr-schema1" MIMETYPE="text/xsd" SIZE="123917" CREATED="
          2018-04-24T14:37:49.617+01:00" CHECKSUM="4073
          D09CA1BAE023D5A7E2010819BF0E8A8EB3C015444D0673733630DE08461C" CHECKSUMTYPE="SHA
          -256">
        <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="schemas/fhirpatient.
            xsd">
        </mets:FLocat>
      </mets:file>
      <mets:file MIMETYPE="application/xml" USE="Package METS" CHECKSUMTYPE="SHA-256"
          CREATED="2015-12-04T09:59:45" CHECKSUM="
          B565CA93CD86950503F233A7906E4DB709088BA42B9D109D4A8D6F183799603F" ID="file-ptr-
          schema2" SIZE="6814">
        <mets:FLocat xlink:href="schemas/METS.xsd" xlink:type="simple" LOCTYPE="URL">
        </mets:FLocat>
      </mets:file>
    </mets:fileGrp>
    <mets:fileGrp ID="filegrp-representation" USE="Representations" ADMD="digiProv-
        eHealth-file rights-eHealth-file" DMDID="dmd-eHealth-file" csip:
        CONTENTINFORMATIONTYPE="citsehpj_v2_0">
      <mets:file ID="file-ptr-repmets1" MIMETYPE="xml" SIZE="1338744" CREATED="
          2018-04-24T14:33:23.617+01:00" CHECKSUM="
          B1CF59678A21C2805370536AB1097735D7E9F3FDDDCAE3757426ED85F6350A48" CHECKSUMTYPE=
          "SHA-256">
        <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="representations/rep1/
            mets.xml">
        </mets:FLocat>
      </mets:file>
    </mets:fileGrp>
  </mets:fileSec>
```

Root METS structural map (element structMap)

The METS structural map element is the only mandatory element in the METS specification. It provides an overview of the components described in the METS document. It can also link the elements in the structure to associated content files and metadata. In the eHealth1 CITS, the package structMap describes the high-level structure of all the content in the package and links to at least one representation.

The representation METS file is referenced from the package METS.xml via the `<mptr>` element, and hence the requirements for the structMap element within the package METS.xml (CSIP requirements CSIP80 to CSIP118) are

unchanged. Because a representation is present, the need for a Content Division in the package METS.xml structMap is not required (CSIP101 to CSIP104 and CSIP109).

Implementers are welcome to define additional structural maps for their internal purposes by repeating the structMap element. The specific requirements for elements, sub-elements and attributes for eHealth1 CITS, which differ from the CSIP, are listed in the following table.

ID	Name, Location & Description	Card & Level
REF_CSIP	**Structural description of the package**	**N/A**
	N/A	MUST
	The eHealth1 root structMap element must comply with structMap requirements in the CSIP profile.	

3.1.2 Representation METS File

The representation METS files is used to describe the data structure as included in the data folder of the Representation Medical Record) via the structMap element and to reference any additional descriptive metadata.

Representation METS root element

Particular notice is drawn to the specific requirements for a representation METS root element as described in the CSIP specification.

ID	Name, Location & Description	Card & Level
EH1	**Representation Identifier**	**1..1**
	mets/@OBJID	MUST
	The mets/@OBJID attribute is mandatory, its value is a string identifier for the METS document. . For a representation level METS document, this value records the name of the representation (i.e. the name of the top-level representation folder. For example this could be: "Patient_Record_Submission".	
EH2	**METS Profile**	**1..1**
	mets/@PROFILE	MUST
	The value is set to "https://citsehealth1.dilcis.eu/profile/E-ARK-eHealth1-REPRESENTATION.xml".	

ID	Name, Location & Description	Card & Level
EH3	**Content Category**	**1..1**
	mets/@TYPE	MUST
	The mets/@TYPE attribute is set to the value "OTHER".	
EH4	**Other Content Category**	**1..1**
	mets[@TYPE='OTHER']/@csip:OTHERTYPE	MUST
	The mets/@csip:OTHERTYPE attribute is set to the value "Patient Medical Records".	
EH5	**Content Information Type Specification**	**1..1**
	mets/@csip:CONTENTINFORMATIONTYPE	MUST
	The mets/@csip:CONTENTINFORMATIONTYPE attribute is set to the value "citsehpj_v2_0".	

Example: METS example of representation METS root element for an IP following the CITS eHealth1

```
<mets:mets xmlns:mets="http://www.loc.gov/METS/" xmlns:csip="https://DILCIS.eu/XML/
    METS/CSIPExtensionMETS" xmlns:sip="https://DILCIS.eu/XML/METS/SIPExtensionMETS"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:xlink="http://www.w3.
    org/1999/xlink" OBJID="PatientRecord_Submission" TYPE="OTHER" csip:OTHERTYPE="
    Patient Medical Records" csip:CONTENTINFORMATIONTYPE="citsehpj_v2_0" PROFILE="https
    ://citsehealth1.dilcis.eu/profile/E-ARK-eHealth1-REPRESENTATION.xml" xsi:
    schemaLocation="http://www.loc.gov/METS/ http://www.loc.gov/standards/mets/mets.xsd
                http://www.w3.org/1999/xlink http://www.loc.gov/standards/mets/xlink.
    xsd          https://DILCIS.eu/XML/METS/CSIPExtensionMETS          https://
    earkcsip.dilcis.eu/schema/DILCISExtensionMETS.xsd          https://DILCIS.eu/
    XML/METS/SIPExtensionMETS          https://earksip.dilcis.eu/schema/
    DILCISExtensionSIPMETS.xsd">
</mets:mets>
```

Representation METS header element (element metsHdr)

There are no requirements for a specific header element in the representation METS. The eHealth1 representation metsHdr element should comply with the metsHdr requirements in the SIP profile. Note that the information contained in the representation header element relate specifically to the representation METS document.

Representation METS descriptive metadata section (element dmdSec)

The Representation may contain additional descriptive metadata within the metadata/descriptive folder as described in the CSIP. It is recommended however that Patient Clinical Information related to the Patient Cases that can contain clinical information (diagnoses, conditions, procedures, allergies, family history, care plans) such as can be found in ISO 13606 or the HL7 FHIR Clinical Module and that has been extracted from the source EMR system is included within each individual Patient Record in the repname/data folder, such as to simplify separation of Patient records into individual SIPs at the Archive. Use of metadata standards and codings (e.g. International Classification of Diseases ICD, https://www.who.int/classifications/icd/en/, Systematized Nomenclature of Medicine, SNOMED CT, <www.snomed.org>) is encouraged. Where used, references to the specific schemas os resources should be given together with relevant version information.

Representation METS administrative metadata section (element amdSec)

The administrative metadata section contains four sub-sections, each used to record different types of metadata for package content:

- technical metadata (element techMD) records technical metadata;
- rights metadata (element rightsMD) records intellectual property rights information;
- source metadata (element sourceMD) records descriptive, technical or rights metadata for an analogue source for a digital library object; and
- digital provenance metadata (element digiprovMD) records digital preservation information (e.g. audit information covering a digital library object's life-cycle).

The CSIP only describes the use of the elements digiprovMD and rightsMD within the administrative metadata section of the METS.

The CSIP (and METS) categorises preservation metadata as administrative metadata, specifically Digital Provenance metadata (following the available guidelines published by the PREMIS EC guidelines: http://www.loc.gov/standards/premis/guidelines2017-premismets.pdf). Hence all preservation metadata should be referenced from a digiprovMD element within the amdSec.

The METS amdSec element should include references to all relevant metadata located in the folder "repname/metadata/preservation". The package level METS.xml file should only reference package level preservation metadata. Representation level METS.xml files should only reference representation level preservation metadata.

In eHealth1, it is required that any rights or digital provenance metadata that is general to the package can be held within the root metadata folder and that any rights or digital provenance metadata that is specific to the data held in the representation should be held in the representation metadata folder.

The eHealth1 representation METS document amdSec element should comply with the requirements in the CSIP profile.

ID	Name, Location & Description	Card & Level
EH13	**File section** `mets/fileSec` The transferred content within the representation is referenced from the file section in different file group elements. Only a single file section (`<fileSec>`) element should be present.Representation of the Patient Case structural hierarchy is only possible if the file section (`<fileSec>`) is present in the representation.	**1..1** MUST
EH14	**Representations (Patient Document) file groups** `mets/fileSec/fileGrp` The representation (Patient Document) file groups contain the file elements that describe the Patient Documents, the Patient Administrative and the Patient Clinical Information.The hierarchical structure of the Patient Medical Records within the CITS eHealth1 requires that Documents groups of files that form a single intellectual entity) can be described through the structMap (`<div>`) element.	**1..n** MUST
EH15	**Description of the use of the representation (Patient Document) file group** `mets/fileSec/fileGrp/@USE` The value in the `mets`/`fileSec`/`fileGrp`/`@USE` is the name of the folder structure to the data, e.g "data/Patient_ID/Case_ID/Document_ID".	**1..1** MUST

EH17	**Content Information Type Specification**
	`mets/fileSec/fileGrp[@USE='Representations']/`
	`@csip:CONTENTINFORMATIONTYPE`
	The value of the attribute the `mets`/`fileSec`/`fileGrp`/`@csip`:`CONTENTINFORMATIONTYPE` is set to "citsehpj_v2_0".
		1..1
		MUST

EH22	**Component byte stream** `mets/fileSec/fileGrp/file/stream` A file may comprise one or more subsidiary byte streams (e.g. an MPEG4 file might contain separate audio and video streams, each of which is associated with technical metadata).The repeatable (`<stream>`) element provides a mechanism to record the existence of separate datastreams within a particular file and to associate (`<dmdSec>`) and (`<amdSec>`) with them.	**0..n** MAY
EH23	**Component byte stream identifier** `mets/fileSec/fileGrp/file/stream/@ID` A unique xml:id for this object across the package.	**1..1** MUST

ID	Name, Location & Description	Card & Level
EH24	**Component byte stream mimetype** `mets/fileSec/fileGrp/file/stream/@MIMETYPE` The IANA mime type for the referenced byte stream.	**1..1** MUST
EH25	**Component byte stream original identification** `mets/fileSec/fileGrp/file/stream/@OWNERID` If an identifier for the byte stream was supplied by the owner, it can be recorded in this attribute.	**0..1** MAY
EH26	**Component byte stream reference to administrative metadata** `mets/fileSec/fileGrp/file/stream/@ADMID` If administrative metadata has been provided for the byte stream this attribute refers to the streams's administrative metadata by ID.For the administrativ description of the byte stream the PREMIS standard is recommended.	**0..1** MAY

Example: METS example of representation fileSec for an IP following the CITS eHealth1

```xml
<mets:fileSec ID="file-sec-example">
  <mets:fileGrp ID="filegrp-documentation" USE="Documentation">
    <mets:file ID="file-ptr-documentation-file1" MIMETYPE="application/vnd.
      openxmlformats-officedocument.wordprocessing.document" SIZE="43445212" CREATED=
      "2012-08-15T12:08:15.432+01:00" CHECKSUM="160
      D71F56C2CE685CE7FBD679076FD76B3C67EE9AB5062F5EF5C99AE39C1F43B" CHECKSUMTYPE="
      SHA-256">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/File1.
        docx">
      </mets:FLocat>
    </mets:file>
    <mets:file ID="file-ptr-documentation-file2" MIMETYPE="application/vnd.
      openxmlformats-officedocument.wordprocessingml.document" SIZE="31462826"
      CREATED="2012-08-15T14:44:45.432+01:00" CHECKSUM="0
      FE9683451D0390BCDEF19CE10CFD287A2D944B6A33D246681FEF27F44FFAF1D" CHECKSUMTYPE="
      SHA-256">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/File2.
        docx">
      </mets:FLocat>
    </mets:file>
  </mets:fileGrp>
```

```xml
<mets:fileGrp ID="filegrp-schemas" USE="Schemas">
  <mets:file ID="file-ptr-schema1" MIMETYPE="text/xsd" SIZE="123917" CREATED="
      2018-04-24T14:37:49.617+01:00" CHECKSUM="4073
      D09CA1BAE023D5A7E2010819BF0E8A8EB3C015444D0673733630DE08461C" CHECKSUMTYPE="SHA
      -256">
    <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="schemas/fhirpatient.
        xsd">
    </mets:FLocat>
  </mets:file>
  <mets:file MIMETYPE="application/xml" USE="Package METS" CHECKSUMTYPE="SHA-256"
      CREATED="2015-12-04T09:59:45" CHECKSUM="
      B565CA93CD86950503F233A7906E4DB709088BA42B9D109D4A8D6F183799603F" ID="file-ptr-
      schema2" SIZE="6814">
    <mets:FLocat xlink:href="schemas/METS.xsd" xlink:type="simple" LOCTYPE="URL">
    </mets:FLocat>
  </mets:file>
</mets:fileGrp>
<mets:fileGrp ID="fileGrp-patient_12345-information" USE="data/patient_12345" ADMID=
    "digiProv-eHealth-file2 rights-eHealth-file2">
  <mets:file ID="file-ptr-patient-administrative-file1" MIMETYPE="application/xml"
      SIZE="2352367" CREATED="2012-08-15T12:08:15.432+01:00" CHECKSUM="
      D2DF16632617402BF279D61DBC9F73675E033ABA6B94A78D4B9607CE5CAAFA3E" CHECKSUMTYPE=
      "SHA-256">
    <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="data/patient_12345/
        patient_12345_admin.xml">
    </mets:FLocat>
  </mets:file>
  <mets:file ID="file-ptr-patient-patient-condition-file2" MIMETYPE="application/xml
      " SIZE="1344782" CREATED="2012-08-15T12:08:15.432+01:00" CHECKSUM="
      FD7EE6C02AC30570BA8C73E0E8CCDDA77C5428F3E6F6BEA7834F9B1AEB4D8F20" CHECKSUMTYPE=
      "SHA-256">
    <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="data/patient_12345/
        patient_12345_condition.xml">
    </mets:FLocat>
  </mets:file>
</mets:fileGrp>
<mets:fileGrp ID="filegrp-patient_12345_document1" USE="data/Patient_12345/case1/
    subcase1/document1/datafile1" ADMD="digiProv-eHealth-file2 rights-eHealth-file2"
    csip:CONTENTINFORMATIONTYPE="citsehpj_v2_0">
  <mets:file ID="file-ptr-document1-file0" MIMETYPE="PDF" SIZE="1337808" CREATED="
      2018-04-24T14:37:49.617+01:00" CHECKSUM="
      E5C853A25A1A86ADDBFA5F54FBF5F0F2D97E8F257E2DB7640CA85E462D38652A" CHECKSUMTYPE=
      "SHA-256" ADMID="digiprov-eHealth-file2 rights-eHealth-file2">
```

```
            <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="/data/patient_12345/
                case1/document1/patientnotes0.pdf">
            </mets:FLocat>
        </mets:file>
        <mets:file ID="file-ptr-document1-file1" MIMETYPE="application/mp4" SIZE="3189002"
             CREATED="2018-04-24T14:37:49.617+01:00" CHECKSUM="1
            A7FF5D05D4BEDBFD09447F633586646EF55F59480A1FF30B5D26D6866604F2F" CHECKSUMTYPE="
            SHA-256" ADMID="digiprov-eHealth-file2 rights-eHealth-file2">
            <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="/data/patient_12345/
                case1/document1/procedure.mp4">
            </mets:FLocat>
            <mets:stream ID="file-ptr-document1-file2-stream1" MIMETYPE="video/mp4" SIZE="
                4236737" CREATED="2018-04-24T14:37:49.617+01:00" CHECKSUM="3
                A4DF1ADB67D2E74F4A6A7E39A7714ED330F066144D0A8774DA83B1BB77FA9EB" CHECKSUMTYPE
                ="SHA-256" ADMID="digiprov-eHealth-file2 rights-eHealth-file2">
            </mets:stream>
            <mets:stream ID="file-ptr-document1-file2-stream2" MIMETYPE="audio/mp3" SIZE="
                1132354" CREATED="2018-04-24T14:37:49.617+01:00" CHECKSUM="7176
                A627870CFA3854468EC43C5A56F9BD8B30B50A983B8162BF56298A707667" CHECKSUMTYPE="
                SHA-256" ADMID="digiprov-eHealth-file2 rights-eHealth-file2">
            </mets:stream>
        </mets:file>
    </mets:fileGrp>
</mets:fileSec>
```

Representation METS structural map (structMap element)

The METS structural map element is the only mandatory element in the METS specification and is hence mandatory within the representation METS. The representation METS.xml is referenced from the package METS.xml via the `<mptr>` element, and hence the requirements for the structMap element within the package METS.xml (CSIP requirements CSIP80 to CSIP118) are unchanged. Because a representation is present, the need for a Content Division in the package METS.xml structMap is not required (CSIP101 to CSIP112 and CSIP 116, 118 and 119).

There MUST be one structural map present following the requirements of the CSIP.

ID	Name, Location & Description	Card & Level
EH28	**Structural description of the eHealth1 representation** `mets/structMap` Each representation METS file must include ONE structural map (`<structMap>`) element as exactly as described here.Institutions can add their own additional custom structural maps as separate `<structMap>` sections.	**1..n** MUST
EH30	**Structural description label** `mets/structMap[@LABEL='eHealth1']` The `mets`/`structMap`/`@LABEL` attribute value is set to "eHealth1" from the vocabulary.	**1..1** MUST
EH31	**Structural description identifier** `mets/structMap[@LABEL='eHealth1']/@ID` An `xml:id` identifier for the structural description (structMap) used for internal package references. It must be unique within the package.	**1..1** MUST
EH45	**Data division** `mets/structMap[@LABEL='eHealth1']/div/div/` Within eHealth1 all patient records must be held within a data folder within a minimum single representation and described in the structural map within a single sub-division. There are no files contained in the data division.	**1..1** MUST
EH46	**Data division identifier** `mets/structMap[@LABEL='eHealth1']/div/div/@ID` Mandatory, "xml:id" identifier must be unique within the package.	**1..1** MUST
EH47	**Data division label** `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']` The representations's data division `<div>` element must have the `@LABEL` attribute value "Data" taken from the vocabulary.	**1..1** MUST
EH70	**Patient Record division** `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/div` There must be a discrete "div" element for each patient record.	**1..1** MUST
EH71	**Patient record division label** `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/div[@LABEL='PATIENT RECORD']` The patient record division `<div>` element's `@LABEL` attribute value must be "Patient Record" as taken from the vocabulary.	**1..1** MUST

ID	Name, Location & Description	Card & Level

EH72	**Patient record division identifier**
	 `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	 `div/@ID`
	 Mandatory, "xml:id" must be unique wqithin the package.
		1..1
		 MUST

EH48	**Patient Case division**
	 `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	 `div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']`
	 Each Patient Case contains Documents that are related in some way (e.g. chronologically and/or share a particular set of diagnoses and/or treatments). A Patient Case is a folder located in the "data/patient_record" folder within the representation and may contain any number of Sub-cases and Documents. Every representation must contain at least one Patient Case. A Case is represented within a third level sub-division.
		1..n
		 MUST

EH50	**Patient case division label**
	 `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	 `div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']`
	 The package's patient case division `<div>` element must have the `@LABEL` attribute value "Case", taken from the vocabulary.
		1..1
		 MUST

EH51	**Patient Document division**
	 `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	 `div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	 `div[@LABEL='DOCUMENT']`
	 Each Patient Case MAY contain individual Data Files that are related logically and together form Documents (e.g. a book, video, image and annotation, document and audio notes).
		0..n
		 MAY

EH52	**Patient Document division identifier**
	 `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	 `div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	 `div[@LABEL='DOCUMENT']/@ID`
	 Mandatory, `xml:id` identifier must be unique within the package.
		1..1
		 MUST

ID	Name, Location & Description	Card & Level

EH53	**Patient Document division label**
	 `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	 `div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	 `div[@LABEL='DOCUMENT']`
	 The package's Patient Documentation division `<div>` element must have the `@LABEL` attribute value "Document", taken from the vocabulary.
		1..1
		 MUST

EH73	**Patient Document division file group reference**
	 `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	 `div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	 `div[@LABEL='DOCUMENT']/fptr`
	 All file groups containing content described in the package are referenced via the relevant file group identifiers. One file group reference per fptr-element.
		1..1
		 MUST

EH74	**Patient Document division file group reference ID**
	 `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	 `div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	 `div[@LABEL='DOCUMENT']/fptr/@FILEID`
	 The pointer to the identifier for the file group containing the data files.
		1..1
		 MUST

EH59	**Patient Subcase division**
	 `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	 `div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	 `div[@LABEL='SUBCASE']`
	 Each Patient Sub-case contains Documents that are related in some way (e.g. chronologically and/or share a particular set of diagnoses and/or treatments). A Patient Sub-case is a folder located in a Case folder within the representation and must contain at least one Document.
		1..n
		 MAY

EH60	**Patient Subcase division identifier**
	 `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	 `div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	 `div[@LABEL='SUBCASE']/@ID`
	 Mandatory, `xml:id` identifier must be unique within the package.
		1..1
		 MUST

ID	Name, Location & Description	Card & Level

EH61	**Patient Subcase division label**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='SUBCASE']`
	The package's patient sub-case division `<div>` element must have the `@LABEL` attribute value "Subcase", taken from the vocabulary.
		1..1
		MUST

EH62	**Patient Document division**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='SUBCASE']/div[@LABEL='DOCUMENT']`
	Each Patient sub-case can contain individual Data Files that are related logically and together form Documents (e.g. a book, video, image and annotation, document and audio notes).
		1..n
		MAY

EH63	**Patient Document division identifier**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='SUBCASE']/div[@LABEL='DOCUMENT']/@ID`
	Mandatory, `xml:id` identifier must be unique within the package.
		1..1
		MUST

EH64	**Patient Document division label**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='SUBCASE']/div[@LABEL='DOCUMENT']`
	The package's patient sub-case/documentation division `<div>` element must have the `@LABEL` attribute value "Document", taken from the vocabulary.
		1..1
		MUST

EH75	**Patient Document division file group reference**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='SUBCASE']/div[@LABEL='DOCUMENT']/fptr/@FILEID`
	The pointer to the identifier for the file group containing the data files.
		1..1
		MUST

EH76	**Patient Document division file group reference ID**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='DOCUMENT']/fptr/@FILEID`
	The pointer to the identifier for the file group containing the data files.
		1..1
		MUST

Example: METS example of the eHealth1 mandatory structural map present in the representation METS for eHealth1 with Case Structure

```
<mets:structMap ID="struct-map-example-representation" TYPE="PHYSICAL" LABEL="eHealth1
    ">
  <mets:div ID="struct-map-example-div" LABEL="eHealth1-repmets-example">
    <mets:div ID="struct-map-metadata-div" LABEL="Metadata" DMDID="dmd-ehealth-file2"
        ADMID="digiProv-eHealth-file2 rights-eHealth-file2">
    </mets:div>
    <mets:div ID="struct-map-doc-div" LABEL="Documentation">
      <mets:fptr FILEID="file-grp-documentation">
      </mets:fptr>
    </mets:div>
    <mets:div ID="struct-map-schema-div" LABEL="Schemas">
      <mets:fptr FILEID="file-grp-schema">
      </mets:fptr>
    </mets:div>
    <mets:div ID="struct-map-data-div" LABEL="Data">
      <mets:div ID="struct-map-patient_12345-record-div" LABEL="Patient Record">
        <mets:fptr FILEID="filegrp-patient_12345-information">
        </mets:fptr>
        <mets:div ID="struct-map-patient_12345-record-case-1" LABEL="Case">
          <mets:div ID="struct-map-patient_12345-record-case-1-subcase-1" LABEL="
              Subcase">
            <mets:fptr FILEID="filegrp-patient_12345-document1">
            </mets:fptr>
          </mets:div>
        </mets:div>
      </mets:div>
    </mets:div>
  </mets:div>
</mets:structMap>
```

3.2 Use of Descriptive Metadata in eHealth1

3.2.1 Archival Information

Medical Records or a mixed archive containing other types of records. In the case of a single subject archive the description of the archive is implicit and may be recorded outside of the archival packages themselves. In the case of a mixed archive it will be necessary to include archival description records in each archival package which should then

follow the requirements of the Common Specification for Archival Information and use a standardised schema such as EAD3 or Dublin Core.

3.2.2 Patient Identifiers

Patients must have a nationally unique identifier that is referenced within the source EMR system and can be referenced to a National Death Register, such as a Social Security or other unique individual identifier.

3.2.3 Patient Personal Information

Patient Personal Information should, wherever possible conform to an international or national standard for describing patient information within EMR of EHR systems (e.g. HL7 FHIR contains a well-specified resource for Patient Personal Information and provides schemas in a number of formats)[1]. At a minimum this file must contain patient names and unique identifiers and should contain personal and demographic information.

3.2.4 Patient Clinical Information

Structured Patient Clinical Information such as diagnoses, procedures, medication, allergies, etc., can add significant value to the Health Archive and, in particular, to the research use cases as described in 4.3. Clinical metadata associated with the Patient or Patient Cases can be added to the package or PatientRecord_ID/metadata/descriptive folders in the package. Clinical metadata should, wherever possible, conform to an international or national standard for describing patient clinical information with EMR and EHR systems (e.g. HL7 FHIR contains well-specified resources for clinical, diagnostic and medication data and provides schemas in a number of formats)[2]. Clinical metadata should use recognised vocabularies and coding such as ICD and SNOMED.

4 Deprecated Requirements in eHealth1

The work to improve this specification is ongoing. On occasion we retire a requirement, these are listed here for information. The majority of these deprecated requirements were duplicates of those in the CSIP and SIP specifications and have been removed for reasons of maintaining currency.

ID	Name, Location and Description	Cardinality & Level
EHR17Ref CSIP59	File section identifier, fileSec/@ID, An xml:id identifier for the file section used for internal package references. It must be unique within the package.	1..1, MUST

[1] https://www.hl7.org/fhir/patient.html
[2] https://www.hl7.org/fhir/clinicalsummary-module.html, https://www.hl7.org/fhir/diagnostics-module.html, https://www.hl7.org/fhir/medications-module.html

ID	Name, Location and Description	Cardinality & Level
EHR18Ref CSIP60	Documentation file group, fileSec/fileGrp/@USE, All documentation pertaining to the package should be referenced from one or more file groups with the "mets/fileSec/fileGrp/@USE" attribute value "Documentation". Note that any documentation pertaining to the transferred content is referenced within the representation METS files.	1..n, MUST
EHR19Ref CSIP113	Schema file group, fileSec/fileGrp/@USE, All XML schemas used in the information package MUST be referenced from one or more file group elements with "mets/fileSec/fileGrp/@USE" attribute value "Schemas". Schemas common to the transferred content should be held in the root schemas folder.	1..n, MUST
EHR20Ref CSIP114	Representations file group, fileSec/fileGrp/@USE, Pointers to each of the METS documents describing the representations MUST be present in file groups with the "mets/fileSec/fileGrp/ @USE" attribute "Representations".	1..n, MUST
EHR21Ref CSIP61	Reference to administrative metadata, fileSec/filegrp/@ADMID, If administrative metadata has been provided at file group "mets/fileSec/fileGrp/" level, this attribute refers to its administrative metadata section by ID. For example, there are rights and/or digital provenance metadata that are general to the package.	0..1, MAY
EHR23Ref CSIP105	Representation division, mets/structMap[@LABEL='CSIP']/div/div, There must be a discrete `<div>` element for each Patient Medical Record.	1..n, MUST
EH6Ref CSIP17	Descriptive metadata, dmdSec, Used to reference Patient Clinical Information held in the metadata/descriptive folder of the representation. There is one dmdSec present for each descriptive metadata file located in the "metadata/descriptive" section of the representation.	1..n, MUST
EH7Ref CSIP18	Descriptive metadata identifier, dmdSec/@ID, An xml:id identifier for the descriptive metadata section (`<dmdSec>`) used for internal package references. It must be unique within the package.	1..1, MUST

ID	Name, Location and Description	Cardinality & Level
EH8Ref CSIP21	Reference to the document with the descriptive metadata, mets/dmdSec/mdRef, There MUST be a reference to the descriptive metadata file located in the folder "metadata/descriptive" of the representation.	1..1, MUST
EH9Ref CSIP25	Type of metadata, mets/dmdSec/mdref/@MDTYPE, The value for the metadata type is set to "OTHER".	1..1, MUST
EH10Ref CSIP21	Reference to the document with the descriptive metadata, dmdSec/mdRef, There MUST be a reference to the descriptive metadata file located in the folder "metadata/descriptive" of the representation.	1..1, MUST
EH11Ref CSIP25	Type of metadata, dmdSec/mdref/@MDTYPE, The value for the metadata type is set to "OTHER".	1..1, MUST
EH12	Type of other metadata, dmdSec/mdref/@OTHERMDTYPE, Specifies the type of metadata used for Patient Clinical Information. For example, the value will be "fhircondition" if the FHIR Condition resource is used.	1..1, MUST
EH16Ref CSIP61	Reference to Patient Document administrative metadata, fileSec/filegrp/@ADMID, If administrative metadata has been provided at a filegroup level. For example there are rights and/or digital provenance metadata that is specific to the Patient Document, then this attribute refers to the `<amdSec>` of the representation METS.xml by ID.	1..1, MAY
EH18Ref CSIP65	Representation (Patient Document) file group identifier, fileSec/fileGrp/@ID, An xml:id identifier for the file group used for internal package references. It must be unique within the package.	1..1, MUST
EH20Ref CSIP66	File, fileSec/filegrp/file, The file group `<fileGrp>` contains the file elements which describe the digital objects.	1..1, MUST
EH21Ref CSIP75	File reference to Descriptive Metadata, fileSec/fileGrp/file/@DMDID, If descriptive metadata had been provided per file, this attribute refers to the file's descriptive metadata by ID.	0..1, MAY
EH27Ref CSIP80	Structural description of the representation, Each representation METS file must include ONE structural map `<structMap>` element exactly as described here. Institutions can add their own additional custom structural maps as separate `<structMap>` sections.	1..n, MUST

ID	Name, Location and Description	Cardinality & Level
EH29Ref CSIP81	Type of structural division, mets/structMap/@TYPE, The "mets/structMap/@TYPE" attribute MUST take the value of "PHYSICAL" from the vocabulary. An additional structural description @TYPE "Virtual" could be added to describe a virtual Case structure that has not been realised in physical folders. See also: Structural map typing.	1..1, MUST
EH32Ref CSIP84	Main structural division, structMap/div/@LABEL, The representation's top-level structural division `<div>` element's `@LABEL` attribute value must be identical to the representation (Patient Medical Record) identifier, i.e. the same value as the `mets`/`@OBJID` attribute.	1..1, MUST
EH33Ref CSIP85	Main structural division identifier, structMap/div/@ID, Mandatory, "xml:id" identifier must be unique within the package.	1..1, MUST
EH34Ref CSIP86	Main structural division label, structMap/div/@LABEL, The representation's top-level structural division `<div>` element's `@LABEL` attribute value must be identical to the representation (Patient Medical Record) identifier, i.e. the same value as the `mets`/`@OBJID` attribute.	1..1,MUST
EH35Ref CSIP88	Metadata division, structMap/div/div, The metadata referenced in the administrative and/or descriptive metadata section is described in the structural map with one sub division. When the transfer consists of only administrative and/or descriptive metadata this is the only sub division that occurs.	1..1, MUST
EH36Ref CSIP89	Metadata division identifier, structMap/div/div/@ID, Mandatory xml:id identifier must be unique within the package.	1..1, MUST
EH37Ref CSIP90	Metadata division label, structMap/div/div/@LABEL, The metadata division `<div>` element's `@LABEL` attribute value must be "Metadata".	1..1, MUST
EH38Ref CSIP91	Metadata division administrative metadata referencing, structMap/div/div/@ADMID, When there is administrative metadata, and the `<amdSec>` is present, all administrative metadata MUST be referenced via the administrative sections different identifiers. All of the identifiers are listed in a single `@ADMID` using spaces as delimiters.	0..1, SHOULD

ID	Name, Location and Description	Cardinality & Level
EH39Ref CSIP92	Metadata division descriptive metadata referencing, structMap/div/div/@DMDID, When there are descriptive metadata and one or more `<dmdSec>` is present, all descriptive metadata MUST be referenced via the descriptive section identifiers. Every `<dmdSec>` identifier is listed in a single `@DMDID` attribute using spaces as delimiters. Descriptive metadata in the representation will include clinical metadata as described in 7.3.3.	0..1, SHOULD
EH40Ref CSIP93	Documentation division, structmap/div/div/, The documentation referenced in the file section file groups is described in the structural map with one sub-division.	0..1, SHOULD
EH41Ref CSIP94	Documentation division identifier, structMap/div/div/@ID, Mandatory, xml:id identifier must be unique within the package.	1..1, MUST
EH42Ref CSIP95	Documentation division label, structMap/div/div/@LABEL. The documentation division `<div>` element in the package uses the value "Documentation" from the vocabulary as the value for the `@LABEL` attribute.	1..1, MUST
EH43Ref CSIP96	Documentation file referencing, structMap/div/div/@CONTENTID, All file groups containing documentation described in the package are referenced via the relevant file group identifiers. There MUST be one file group reference per `<fptr>` element.	1..1, MUST
EH44Ref CSIP116	Documentation file group pointer, structMap/div/div/fptr/@ID, A reference, by ID, to the "Documentation" file group. Related to the requirements which describe the "Documentation" file group in CSIP and the requirement which describes the file group identifier.	1..1, MUST
EH53	Data File division, mets/structMap[@LABEL='eHealth1']/div/div/div/div/div/, Data Files are components that contain data and have associated MIME file types. A Data File can be a single bit stream or can encapsulate bit streams and attributes according to a standard such as a DICOM or MP4.	1..n, MUST
EH54	Data File division identifier, mets/structMap[@LABEL='eHealth1']/div/div/div/div/div/@ID, Mandatory, xml:id identifier must be unique within the package.	1..1, MUST

ID	Name, Location and Description	Cardinality & Level
EH55	Data File division label, mets/structMap[@LABEL='eHealth1']/div/div/div/div/div/div/[@LABEL='D The Data File division `<div>` element must have the `@LABEL` attribute value "DATAFILE", taken from the vocabulary.	1..1, MUST
EH56	Data File division file group reference, mets/structMap[@LABEL='eHealth1']/div/div/div/div/div/div/fptr, All file groups containing content described in the package are referenced via the relevant file group identifiers. One file group reference per fptr-element.	1..1, MUST
EH57	Data File division file group reference ID. mets/structMap[@LABEL='eHealth1']/div/div/div/div/div/div/fptr/@FILEID The pointer to the identifier for the file group containing the data files.	1..1, MUST
EH58	Data File division file group reference ID,structMap/div/div/div/div/div/fptr/@FILEID, The pointer to the identifier for the file group containing the data files.	1..1, MUST
EH65	Data File division, structMap/div/div/div/div/div/div/, Data Files are components that contain data and have associated MIME file types. A Data File can be a single bit stream or can encapsulate bit streams and attributes according to a standard such as a DICOM or MP4.	1..n, MAY
EH66	Data File division identifier, structMap/div/div/div/div/div/div/@ID, Mandatory, xml:id identifier must be unique within the package.	1..1, MUST
EH67	Data File division label, StructMap/div/div/div/div/div/div/@LABEL, The Data File division `<div>` elements must have the @LABEL attribute value "DATAFILE", taken from the vocabulary.	1..1, MUST
EH68	Data File division file group reference, structMap/div/div/div/div/div/div/fptr/, All file groups containing content described in the package are referenced via the relevant file group identifiers—one file group reference per fptr-element.	1..1, MUST
EH69	Data File division file group reference ID, mets/structMap[@LABEL='eHealth1']/div/div/div/div/div/div/fptr/@FI The pointer to the identifier for the file group containing the data files.	1..1, MUST

5 Glossary

Term	Description
Archival Creator	Organisation unit or individual that creates records and/or manages records during their active use.
Archival Information Package (AIP)	An information package, consisting of the Content Information and the associated Preservation Description Information (PDI), which is preserved within an Open Archival Information System (OAIS).
Cardinality	The term describes the possible number of occurrences for elements in a set. The numbers have the following meanings:
	(1..1) – in each set, there is exactly 1 such element present
	(0..1) – the set can contain from 0 to 1 of such elements
	(1..n) – the set contains at least one element
	(0..n) – the set can contain up to n of such elements, but it is not mandatory
	(0..0) – the element is prohibited to use.
Case or Patient Case	Type of component consisting of a set of objects and/or sub-cases. This is represented in the specification as a directory that sits within the data directory of a representation (which in this case is a Patient's Medical Record). A Case is an aggregation of individual records related to one patient and which are related in a way that is defined by national standards, guidance or local practice. A Patient's Medical Record will consist of multiple individual thematic Cases which may be concerned with particular medical conditions, periods or treatments.
Central Health Archive	An organisation within a national or regional jurisdiction with a (usually legal) remit to create an archive of Patient Medical Records for people who have received primary or secondary healthcare in the jurisdiction. The Central Health Archive will be populated with Patient Medical Records from multiple healthcare providers in the jurisdiction, which will be drawn from Local Patient Health Archives (e.g. a hospital archive).

Term	Description
Component	In this standard: meaningful, logically delimited, and uniquely identifiable information that may be subject to treatment in manual and/or automated processes. This standard operates with four generic types of components: Case, Document, Data File and Byte Stream.
Complete Patient Medical Record	The sum of the submissions of patient Records made for an individual.
Content Data Object	The Data Object, that together with associated Representation Information comprises the Content Informartion (Source OAISA – ISO 14721:2012).
Content Information	A set of information that is the original target of preservation or includes part or all of that information. It is an Information Object composed of its Content Data Object and its Representation Information. (Source OAIS – ISO 14721:2012).
Data File	A component which contains data and has an associated MIME file type. A Data File can encapsulate multiple bit streams and metadata according to a standard such as a DICOM but must have a recognised MIME file type. A Data File may comprise one or more subsidiary Byte Streams; for example, an MP4 file might contain separate audio and video streams, each of which has its own associated metadata.
Death Register	National system which records deaths within the jurisdiction.
Dissemenation Information Package (DIP)	Information Package, derived from one or more AIPs and sent by Archives to the Consumer in response to a request to the OAIS.
Document	A single or group of related Data Files with common metadata. For example, a Document may consist of a PDF file together with associated attachments or a word file with a separate image signature sheet. A document can be considered to be an entity that is approved/signed as a whole by a practitioner.
General EMR System	Electronic Medical Record system intended for documentation of all forms of healthcare. Note: large scale healthcare providers may have a main general-purpose EMR system but can also have a number of distributed general-purpose EMR systems serving parts of the organisation that operate as separate sub-services.

Term	Description
Healthcare Provider	An organisation providing primary or secondary healthcare. Can be general in scope or specialised, public or private.
Information Package	A logical container composed of optional Content Information and optional associated Preservation Description Information used to delimit and identify the Content Information and Package Description information used to facilitate searches for the Content Information.
Internal Archival	Long Term Preservation guidelines.This type of guideline can have different names depending on the creator. Generally, archives specify technical guidelines and/or regulations for formats, specifying what they will accept and maintain for the long term/ Depending on the archive and available technical resources, the criteria for the selected formats can differ from archive to archive.
Level	The level of requirements of the element following RFC 2119 http://www.ietf.org/rfc/rfc2119.txt.
	MUST – this means that the definition is an absolute requirement
	SHOULD – this means that in particular circumstances, valid reasons may exist to ignore the requirement, but the full implications must be understood and carefully weighed before choosing a different course.
	MUST NOT – this means that the prohibition described in the requirement is an absolute prohibition of the use of the element.
	SHOULD NOT – this means that in particular circumstances, violating the prohibition described in the requirement is acceptable or even useful, but the full implications should be understood and the case carefully weighed before doing so. The requirement text should clarify such circumstances.
	MAY – means that a requirement is entirely optional.
Local Patient Health Archive	An archive of physical or electronic Patient Medical Records within a Healthcare Provider or group of Healthcare Providers. A Patient Medical Record will normally be expected to be transferred to an archive either when the patient is known to have died, or after a number of years have passed since its creation that exceeds normal life expectancy.

Term	Description
Open Archival Information System (OAIS)	An Archive consisting of an organisation, which may be part of a larger organisation, of people and systems, that has accepted the responsibility to preserve information and make it available for a Designated Community. It meets a set of responsibilities that allows an OAIS Archive to be distinguished from other uses of the term "Archive".
Patient	A person who has received medical treatment.
Patient Clinical Information	Structured patient clinical data related to Cases such as diagnoses, procedures, medication, allergies, etc. For example as can be described using ISO 13606 or HL7 FHIR.
Patient Manifest	Structured manifest containing at minimum the full names of the each Patient who has records in the package together with a unique ID (such as a social security or health number).
Patient Medical Record	Collection or compilation of recorded information about a patient in connection with healthcare. Note: a Patient Medical Record may contain information in digital form and/or information recorded on other types of media such as paper or film. For the purposes of this specification, Patient Medical Records are assumed to be digital where the content may be born digital and/or digitised from physical records.
Patient Medical Record Extraction	Extract from a Local Health Archive for the purposes of handing off to the Central Health Archive. All Patient Medical Record Extractions should be under a Submission Agreement.
Patient Administrative Information	Demographics and other administrative information about an individual receiving care or other health-related services. For example, as can be described using ISO 13606 or HL7 FHIR. Information will include but not be limited to name, patient ID(s), administrative gender, date of birth, date of death, address(es).
RDBMS	Relational Database Management System

Term	Description
Representation	A Representation within an Information Package contains archival data. If an Information Package contains the same data in two or more different formats (i.e. an original and a long term preservation format) or in different types of organisations (arrangements), the are placed within two or more separate Representations within the Representations folder of the Information Package of the Information Package.
Representation Information	The Representation Information must enable or allow the re-creation of the significant properties of the original data object.
Specialised EMR System	Electronic Medical Record system specially adapted for documentation of a type of specialised healthcare or integrated with a specialised device. Examples: food/maternity system, gastrosystem, laboratory system, etc.
Standardised Machine - readable Documentation	A standardised machine-readable document is a document whose content can be readily processed by computers and is based on a commonly accepted standard. Such documents are distinguished from machine-readable data by virtue of having sufficient structure to provide the necessary context to support the business processes for which they are created.
Sub-case	Type of component consisting of a set of thematically related Data Files which are also related to a Case. Sub-cases are represented in the specification as folders that sit within a Case.
Submission Agreement	The agreement reached between an archive and the submission producer that specifies a submission format (eHealth1 CITS), and any other arrangements needed, for the data submission session. Any special conditions on patient confidentiality could be specified in the submission agreement.
Submission Information Package (SIP)	An Information Package that is delivered by the Producer to the OAIS for use in the construction or update of one or more AIPs and/or the associated Descriptive Information.
Submitting Organisation	Name of the organisation submitting the package to the archive.

6 Appendices

6.1 Appendix A: CITS eHealth1 Information Package METS Examples

6.1.1 Example 1: Example of a whole representation METS document describing a submission information package representation following CITS eHealth1 (citsehpj_v2_0).

```xml
<mets:mets xmlns:mets="http://www.loc.gov/METS/" xmlns:csip="https://DILCIS.eu/XML/
   METS/CSIPExtensionMETS" xmlns:sip="https://DILCIS.eu/XML/METS/SIPExtensionMETS"
   xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:xlink="http://www.w3.
   org/1999/xlink" xsi:schemaLocation="http://www.loc.gov/METS/ http://www.loc.gov/
   standards/mets/mets.xsd          http://www.w3.org/1999/xlink http://www.loc.gov
   /standards/mets/xlink.xsd          https://DILCIS.eu/XML/METS/CSIPExtensionMETS
           https://earkcsip.dilcis.eu/schema/DILCISExtensionMETS.xsd
           https://DILCIS.eu/XML/METS/SIPExtensionMETS          https://
   earksip.dilcis.eu/schema/DILCISExtensionSIPMETS.xsd" OBJID="
   Patient_Records_Submission" TYPE="OTHER" csip:OTHERTYPE="Patient Medical Records"
   csip:CONTENTINFORMATIONTYPE="citsehpj_v2_0" PROFILE="https://citsehealth1.dilcis.eu
   /profile/E-ARK-eHealth1-REPRESENTATION.xml">
 <mets:metsHdr CREATEDATE="2018-04-24T14:37:49.602+01:00" LASTMODDATE="2018-04-24T14
    :37:49.602+01:00" RECORDSTATUS="NEW" csip:OAISPACKAGETYPE="SIP">
  <mets:altRecordID TYPE="SUBMISSIONAGREEMENT">
    http://submissionagreement.kb.se/dnr331-1144-2011/20120711/
  </mets:altRecordID>
  <mets:altRecordID TYPE="PREVIOUSSUBMISSIONAGREEMENT">
    http://submissionagreement.kb.se/dnr330-1122-2009/20110613/
  </mets:altRecordID>
  <mets:altRecordID TYPE="REFERENCECODE">
    FM-12-2387/12726,2007-09-19
  </mets:altRecordID>
  <mets:altRecordID TYPE="PREVIOUSREFERENCECODE">
    SE/FM/123/123.1/123.13
  </mets:altRecordID>
  <mets:agent ROLE="CREATOR" TYPE="OTHER" OTHERTYPE="SOFTWARE">
    <mets:name>
      piql eHealth SIP Creator
    </mets:name>
    <mets:note NOTETYPE="SOFTWARE VERSION">
      VERSION 1.1
    </mets:note>
  </mets:agent>
  <mets:agent ROLE="CREATOR" TYPE="ORGANIZATION">
    <mets:name>
```

```
      Skane University Hospital
    </mets:name>
    <mets:note csip:NOTETYPE="IDENTIFICATIONCODE">
      ID:89101112
    </mets:note>
  </mets:agent>
  <mets:agent ROLE="SUBMITTER" TYPE="INDIVIDUAL">
    <mets:name>
      Sven Svensson
    </mets:name>
    <mets:note csip:NOTETYPE="IDENTIFICATIONCODE">
      ID:4569865123
    </mets:note>
  </mets:agent>
  <mets:agent ROLE="CREATOR" TYPE="INDIVIDUAL">
    <mets:name>
      Sven Svensson
    </mets:name>
    <mets:note>
      Phone: 08-123456, Email: sven.svensson@mail.mail
    </mets:note>
  </mets:agent>
  <mets:agent ROLE="PRESERVATION" TYPE="ORGANIZATION">
    <mets:name>
      The Swedish Health Agency
    </mets:name>
    <mets:note csip:NOTETYPE="IDENTIFICATIONCODE">
      ID:1234567
    </mets:note>
  </mets:agent>
</mets:metsHdr>
<mets:amdSec>
  <mets:digiProvMD ID="digiProv-eHealth-file2" STATUS="CURRENT">
    <mets:mdRef LOCTYPE="URL" xlink:href="metadata/preservation/premis3.xml" xlink:
        type="simple" MDTYPE="PREMIS" MIMETYPE="application/xml" SIZE="984" CREATED="
        2018-04-24T14:11:29.309+01:00" CHECKSUM="66
        EEDDF0A22EF57078694B67CA45DF301034556D6CB493531356C4FFE92AB6B1" CHECKSUMTYPE=
        "SHA-256">
    </mets:mdRef>
  </mets:digiProvMD>
  <mets:rightsMD ID="rights-eHealth-file2" STATUS="CURRENT">
    <mets:mdRef LOCTYPE="URL" xlink:href="metadata/preservation/premis4.xml" xlink:
        type="simple" MDTYPE="PREMIS" MIMETYPE="application/xml" SIZE="563" CREATED="
```

```xml
                  2018-04-24T14:11:29.309+01:00" CHECKSUM="66
                  EEDDF0A22EF57078694B67CA45DF301034556D6CB493531356C4FFE92AB6B1" CHECKSUMTYPE=
                  "SHA-256">
            </mets:mdRef>
        </mets:rightsMD>
    </mets:amdSec>
    <mets:fileSec ID="filesec-docx-file-1">
        <mets:fileGrp ID="filegrp-documentation" USE="Documentation">
            <mets:file ID="file-ptr-documentation-file1" MIMETYPE="application/vnd.
                  openxmlformats-officedocument.wordprocessing.document" SIZE="43445212"
                  CREATED="2012-08-15T12:08:15.432+01:00" CHECKSUM="160
                  D71F56C2CE685CE7FBD679076FD76B3C67EE9AB5062F5EF5C99AE39C1F43B" CHECKSUMTYPE="
                  SHA-256">
                <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/File1
                    .docx">
                </mets:FLocat>
            </mets:file>
            <mets:file ID="file-ptr-documentation-file2" MIMETYPE="application/vnd.
                  openxmlformats-officedocument.wordprocessingml.document" SIZE="31462826"
                  CREATED="2012-08-15T14:44:45.432+01:00" CHECKSUM="0
                  FE9683451D0390BCDEF19CE10CFD287A2D944B6A33D246681FEF27F44FFAF1D" CHECKSUMTYPE
                  ="SHA-256">
                <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/File2
                    .docx">
                </mets:FLocat>
            </mets:file>
        </mets:fileGrp>
        <mets:fileGrp ID="filegrp-schemas" USE="Schemas">
            <mets:file ID="file-ptr-schema1" MIMETYPE="text/xsd" SIZE="123917" CREATED="
                  2018-04-24T14:37:49.617+01:00" CHECKSUM="4073
                  D09CA1BAE023D5A7E2010819BF0E8A8EB3C015444D0673733630DE08461C" CHECKSUMTYPE="
                  SHA-256">
                <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="schemas/fhirpatient
                    .xsd">
                </mets:FLocat>
            </mets:file>
            <mets:file MIMETYPE="application/xml" USE="Package METS" CHECKSUMTYPE="SHA-256"
                  CREATED="2015-12-04T09:59:45" CHECKSUM="
                  B565CA93CD86950503F233A7906E4DB709088BA42B9D109D4A8D6F183799603F" ID="file-
                  ptr-schema2" SIZE="6814">
                <mets:FLocat xlink:href="schemas/METS.xsd" xlink:type="simple" LOCTYPE="URL">
                </mets:FLocat>
            </mets:file>
```

```
  </mets:fileGrp>
  <mets:fileGrp ID="fileGrp-patient_12345-information" USE="data/patient_12345"
     ADMID="digiProv-eHealth-file2 rights-eHealth-file2">
    <mets:file ID="file-ptr-patient-administrative-file1" MIMETYPE="application/xml"
        SIZE="2352367" CREATED="2012-08-15T12:08:15.432+01:00" CHECKSUM="
        D2DF16632617402BF279D61DBC9F73675E033ABA6B94A78D4B9607CE5CAAFA3E"
        CHECKSUMTYPE="SHA-256">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="data/patient_12345/
          patient_12345_admin.xml">
      </mets:FLocat>
    </mets:file>
    <mets:file ID="file-ptr-patient-patient-condition-file2" MIMETYPE="application/
        xml" SIZE="1344782" CREATED="2012-08-15T12:08:15.432+01:00" CHECKSUM="
        FD7EE6C02AC30570BA8C73E0E8CCDDA77C5428F3E6F6BEA7834F9B1AEB4D8F20"
        CHECKSUMTYPE="SHA-256">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="data/patient_12345/
          patient_12345_condition.xml">
      </mets:FLocat>
    </mets:file>
  </mets:fileGrp>
  <mets:fileGrp ID="filegrp-patient_12345_document1" USE="data/Patient_12345/case1/
      subcase1/document1/datafile1" ADMD="digiProv-eHealth-file2 rights-eHealth-file2
      " csip:CONTENTINFORMATIONTYPE="citsehpj_v2_0">
    <mets:file ID="file-ptr-document1-file0" MIMETYPE="PDF" SIZE="1337808" CREATED="
        2018-04-24T14:37:49.617+01:00" CHECKSUM="
        E5C853A25A1A86ADDBFA5F54FBF5F0F2D97E8F257E2DB7640CA85E462D38652A"
        CHECKSUMTYPE="SHA-256" ADMID="digiprov-eHealth-file2 rights-eHealth-file2">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="/data/patient_12345
          /case1/document1/patientnotes0.pdf">
      </mets:FLocat>
    </mets:file>
    <mets:file ID="file-ptr-document1-file1" MIMETYPE="application/mp4" SIZE="
        3189002" CREATED="2018-04-24T14:37:49.617+01:00" CHECKSUM="1
        A7FF5D05D4BEDBFD09447F633586646EF55F59480A1FF30B5D26D6866604F2F" CHECKSUMTYPE
        ="SHA-256" ADMID="digiprov-eHealth-file2 rights-eHealth-file2">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="/data/patient_12345
          /case1/document1/procedure.mp4">
      </mets:FLocat>
      <mets:stream ID="file-ptr-document1-file2-stream1" MIMETYPE="video/mp4" SIZE="
          4236737" CREATED="2018-04-24T14:37:49.617+01:00" CHECKSUM="3
          A4DF1ADB67D2E74F4A6A7E39A7714ED330F066144D0A8774DA83B1BB77FA9EB"
          CHECKSUMTYPE="SHA-256" ADMID="digiprov-eHealth-file2 rights-eHealth-file2">
      </mets:stream>
```

```
          <mets:stream ID="file-ptr-document1-file2-stream2" MIMETYPE="audio/mp3" SIZE="
              1132354" CREATED="2018-04-24T14:37:49.617+01:00" CHECKSUM="7176
              A627870CFA3854468EC43C5A56F9BD8B30B50A983B8162BF56298A707667" CHECKSUMTYPE=
              "SHA-256" ADMID="digiprov-eHealth-file2 rights-eHealth-file2">
          </mets:stream>
        </mets:file>
      </mets:fileGrp>
    </mets:fileSec>
    <mets:structMap ID="struct-map-example-representation" TYPE="PHYSICAL" LABEL="
        eHealth1">
      <mets:div ID="struct-map-example-div" LABEL="eHealth1-repmets-example">
        <mets:div ID="struct-map-metadata-div" LABEL="Metadata" DMDID="dmd-ehealth-file2
            " ADMID="digiProv-eHealth-file2 rights-eHealth-file2">
        </mets:div>
        <mets:div ID="struct-map-doc-div" LABEL="Documentation">
          <mets:fptr FILEID="file-grp-documentation">
          </mets:fptr>
        </mets:div>
        <mets:div ID="struct-map-schema-div" LABEL="Schemas">
          <mets:fptr FILEID="file-grp-schema">
          </mets:fptr>
        </mets:div>
        <mets:div ID="struct-map-data-div" LABEL="Data">
          <mets:div ID="struct-map-patient_12345-record-div" LABEL="Patient Record">
            <mets:fptr FILEID="filegrp-patient_12345-information">
            </mets:fptr>
            <mets:div ID="struct-map-patient_12345-record-case-1" LABEL="Case">
              <mets:div ID="struct-map-patient_12345-record-case-1-subcase-1" LABEL="
                  Subcase">
                <mets:fptr FILEID="filegrp-patient_12345-document1">
                </mets:fptr>
              </mets:div>
            </mets:div>
          </mets:div>
        </mets:div>
      </mets:div>
    </mets:structMap>
  </mets:mets>
```

6.1.2 Example 2: Example of a whole METS document describing a submission information package following CITS eHealth1 (citsehpj_v2_0).

```xml
<mets:mets xmlns:mets="http://www.loc.gov/METS/" xmlns:csip="https://DILCIS.eu/XML/
    METS/CSIPExtensionMETS" xmlns:sip="https://DILCIS.eu/XML/METS/SIPExtensionMETS"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:xlink="http://www.w3.
    org/1999/xlink" xsi:schemaLocation="http://www.loc.gov/METS/ http://www.loc.gov/
    standards/mets/mets.xsd                 http://www.w3.org/1999/xlink http://www.loc.gov
    /standards/mets/xlink.xsd                 https://DILCIS.eu/XML/METS/CSIPExtensionMETS
             https://earkcsip.dilcis.eu/schema/DILCISExtensionMETS.xsd
             https://DILCIS.eu/XML/METS/SIPExtensionMETS                 https://
    earksip.dilcis.eu/schema/DILCISExtensionSIPMETS.xsd" OBJID="ehealth1-root-mets-
    example" TYPE="OTHER" csip:OTHERTYPE="Patient Medical Records" csip:
    CONTENTINFORMATIONTYPE="citsehpj_v2_0" LABEL="Patient Medical Records from Skane
    University Hospital" PROFILE="https://citsehealth1.dilcis.eu/profile/E-ARK-eHealth1
    -ROOT.xml">
  <mets:metsHdr CREATEDATE="2018-04-24T14:37:49.602+01:00" LASTMODDATE="2018-04-24T14
      :37:49.602+01:00" RECORDSTATUS="NEW" csip:OAISPACKAGETYPE="SIP">
   <mets:altRecordID TYPE="SUBMISSIONAGREEMENT">
     http://submissionagreement.kb.se/dnr331-1144-2011/20120711/
   </mets:altRecordID>
   <mets:altRecordID TYPE="PREVIOUSSUBMISSIONAGREEMENT">
     http://submissionagreement.kb.se/dnr330-1122-2009/20110613/
   </mets:altRecordID>
   <mets:altRecordID TYPE="REFERENCECODE">
     FM-12-2387/12726,2007-09-19
   </mets:altRecordID>
   <mets:altRecordID TYPE="PREVIOUSREFERENCECODE">
     SE/FM/123/123.1/123.13
   </mets:altRecordID>
   <mets:agent ROLE="CREATOR" TYPE="OTHER" OTHERTYPE="SOFTWARE">
     <mets:name>
       piql eHealth SIP Creator
     </mets:name>
     <mets:note csip:NOTETYPE="SOFTWARE VERSION">
       VERSION 1.1
     </mets:note>
   </mets:agent>
   <mets:agent ROLE="CREATOR" TYPE="ORGANIZATION">
     <mets:name>
       Skane University Hospital
     </mets:name>
     <mets:note csip:NOTETYPE="IDENTIFICATIONCODE">
       ID:89101112
     </mets:note>
```

```
      </mets:agent>
      <mets:agent ROLE="SUBMITTER" TYPE="INDIVIDUAL">
        <mets:name>
          Sven Svensson
        </mets:name>
        <mets:note csip:NOTETYPE="IDENTIFICATIONCODE">
          ID:4569865123
        </mets:note>
      </mets:agent>
      <mets:agent ROLE="CREATOR" TYPE="INDIVIDUAL">
        <mets:name>
          Sven Svensson
        </mets:name>
        <mets:note>
          Phone: 08-123456, Email: sven.svensson@mail.mail
        </mets:note>
      </mets:agent>
      <mets:agent ROLE="PRESERVATION" TYPE="ORGANIZATION">
        <mets:name>
          The Swedish Health Agency
        </mets:name>
        <mets:note csip:NOTETYPE="IDENTIFICATIONCODE">
          ID:1234567
        </mets:note>
      </mets:agent>
    </mets:metsHdr>
    <mets:dmdSec ID="dmd-ehealth-file" CREATED="2018-04-24T15:27:45.702+01:00" STATUS="
      CURRENT">
      <mets:mdRef LOCTYPE="URL" xlink:href="metadata/descriptive/patients.xml" xlink:
        type="simple" MDTYPE="OTHER" OTHERMDTYPE="FHIR.Patient" MIMETYPE="application/
        xml" SIZE="643" CREATED="2018-04-24T14:11:29.309+01:00" CHECKSUM="66
        EEDDF0A22EF57078694B67CA45DF301034556D6CB493531356C4FFE92AB6B1" CHECKSUMTYPE="
        SHA-256">
      </mets:mdRef>
    </mets:dmdSec>
    <mets:amdSec>
      <mets:digiProvMD ID="digiProv-eHealth-file" STATUS="CURRENT">
        <mets:mdRef LOCTYPE="URL" xlink:href="metadata/preservation/premis1.xml" xlink:
          type="simple" MDTYPE="PREMIS" MIMETYPE="application/xml" SIZE="984" CREATED="
          2018-04-24T14:11:29.309+01:00" CHECKSUM="66
          EEDDF0A22EF57078694B67CA45DF301034556D6CB493531356C4FFE92AB6B1" CHECKSUMTYPE=
          "SHA-256">
        </mets:mdRef>
```

```
      </mets:digiProvMD>
      <mets:rightsMD ID="rights-eHealth-file" STATUS="CURRENT">
        <mets:mdRef LOCTYPE="URL" xlink:href="metadata/preservation/premis2.xml" xlink:
            type="simple" MDTYPE="PREMIS" MIMETYPE="application/xml" SIZE="563" CREATED="
            2018-04-24T14:11:29.309+01:00" CHECKSUM="66
            EEDDF0A22EF57078694B67CA45DF301034556D6CB493531356C4FFE92AB6B1" CHECKSUMTYPE=
            "SHA-256">
        </mets:mdRef>
      </mets:rightsMD>
  </mets:amdSec>
  <mets:fileSec ID="filesec-docx-file-1">
    <mets:fileGrp ID="filegrp-documentation" USE="Documentation">
      <mets:file ID="file-ptr-documentation-file1" MIMETYPE="application/vnd.
          openxmlformats-officedocument.wordprocessing.document" SIZE="43445212"
          CREATED="2012-08-15T12:08:15.432+01:00" CHECKSUM="160
          D71F56C2CE685CE7FBD679076FD76B3C67EE9AB5062F5EF5C99AE39C1F43B" CHECKSUMTYPE="
          SHA-256">
        <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/File1
            .docx">
        </mets:FLocat>
      </mets:file>
      <mets:file ID="file-ptr-documentation-file2" MIMETYPE="application/vnd.
          openxmlformats-officedocument.wordprocessingml.document" SIZE="31462826"
          CREATED="2012-08-15T14:44:45.432+01:00" CHECKSUM="0
          FE9683451D0390BCDEF19CE10CFD287A2D944B6A33D246681FEF27F44FFAF1D" CHECKSUMTYPE
          ="SHA-256">
        <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/File2
            .docx">
        </mets:FLocat>
      </mets:file>
    </mets:fileGrp>
    <mets:fileGrp ID="filegrp-schemas" USE="Schemas">
      <mets:file ID="file-ptr-schema1" MIMETYPE="text/xsd" SIZE="123917" CREATED="
          2018-04-24T14:37:49.617+01:00" CHECKSUM="4073
          D09CA1BAE023D5A7E2010819BF0E8A8EB3C015444D0673733630DE08461C" CHECKSUMTYPE="
          SHA-256">
        <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="schemas/fhirpatient
            .xsd">
        </mets:FLocat>
      </mets:file>
      <mets:file MIMETYPE="application/xml" USE="Package METS" CHECKSUMTYPE="SHA-256"
          CREATED="2015-12-04T09:59:45" CHECKSUM="
          B565CA93CD86950503F233A7906E4DB709088BA42B9D109D4A8D6F183799603F" ID="file-
```

```xml
            ptr-schema2" SIZE="6814">
          <mets:FLocat xlink:href="schemas/METS.xsd" xlink:type="simple" LOCTYPE="URL">
          </mets:FLocat>
        </mets:file>
      </mets:fileGrp>
      <mets:fileGrp ID="filegrp-representation" USE="Representations" ADMD="digiProv-
          eHealth-file rights-eHealth-file" DMDID="dmd-eHealth-file" csip:
          CONTENTINFORMATIONTYPE="citsehpj_v2_0">
        <mets:file ID="file-ptr-repmets1" MIMETYPE="xml" SIZE="1338744" CREATED="
            2018-04-24T14:33:23.617+01:00" CHECKSUM="
            B1CF59678A21C2805370536AB1097735D7E9F3FDDDCAE3757426ED85F6350A48"
            CHECKSUMTYPE="SHA-256">
          <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="representations/
              rep1/mets.xml">
          </mets:FLocat>
        </mets:file>
      </mets:fileGrp>
    </mets:fileSec>
    <mets:structMap ID="struct-map-example-1" TYPE="PHYSICAL" LABEL="CSIP">
      <mets:div ID="struct-map-example-div" LABEL="struct-map-example">
        <mets:div ID="struct-map-metadata-div" LABEL="Metadata" DMDID="dmd-ehealth-file"
            ADMID="digiProv-eHealth-file rights-eHealth-file">
        </mets:div>
        <mets:div ID="struct-map-documentation-div" LABEL="Documentation">
          <mets:fptr FILEID="filegrp-documentation">
          </mets:fptr>
        </mets:div>
        <mets:div ID="struct-map-schema-div" LABEL="Schemas">
          <mets:fptr FILEID="filegrp-schemas">
          </mets:fptr>
        </mets:div>
        <mets:div ID="struct-map-reps-rep1" LABEL="representations/rep1/mets.xml">
          <mets:mptr LOCTYPE="URL" xlink:type="simple" xlink:href="representations/rep1/
              METS.xml" xlink:title="filegrp-representation">
          </mets:mptr>
        </mets:div>
      </mets:div>
    </mets:structMap>
  </mets:mets>
```

6.2 Appendix B: External Schema

6.2.1 E-ARK SIP METS Extension

Location: https://earksip.dilcis.eu/schema/DILCISExtensionSIPMETS.xsd

Context: XML-schema for the attributes added by SIP

Note: An extension schema with the added attributes for use in this profile. The schema is used with a namespace prefix of sip.

6.2.2 E-ARK CSIP METS Extension

Location: http://earkcsip.dilcis.eu/schema/DILCISExtensionMETS.xsd

Context: XML-schema for the attributes added by CSIP

Note: An extension schema with the added attributes for use in this profile. The schema is identified using the namespace prefix csip.

6.3 Appendix C: External Vocabularies

6.3.1 OAIS Package Type

Maintained By: DILCIS Board

Location: http://earksip.dilcis.eu/schema/CSIPVocabularyOAISPackageType.xml

Context: Used in `@csip:OAISPACKAGETYPE`

Note: Describes the type of the alternative record ID.

6.3.2 IANA media types

Maintained By: IANAs

Location: https://www.iana.org/assignments/media-types/media-types.xhtml

Context: Values for `@MIMETYPE`

Note: Valid values for the mime types of referenced files.

6.3.3 Content information type specification

Maintained By: DILCIS Board

Location: http://earkcsip.dilcis.eu/schema/CSIPVocabularyContentInformationType.xml

Context: Values for `@csip:CONTENTINFORMATIONTYPE`

Note: Lists the names of specific E-ARK content information type specifications supported or maintained in this METS profile.

6.3.4 File group names

Maintained By: DILCIS Board

Location: http://earkcsip.dilcis.eu/schema/CSIPVocabularyFileGrpAndStructMapDivisionLabel.xml

Context: Values for `fileGrp`/`@USE`

Note: Describes the uses of the file group <`fileGrp`> that are supported by the profile. Own names should be placed in an own extending vocabulary.

6.3.5 Structural map label

Maintained By: DILCIS Board

Location: http://earkcsip.dilcis.eu/schema/CSIPVocabularyStructMapLabel.xml

Context: Values for `structMap`/`@LABEL`

Note: Describes the label of the structural map that is supported by the profile. Own labels should be placed in an own extending vocabulary.

6.3.6 Structural map typing

Maintained By: DILCIS Board

Location: http://earkcsip.dilcis.eu/schema/CSIPVocabularyStructMapType.xml

Context: Values for `structMap`/`@TYPE`

Note: Describes the type of the structural map <`structMap`> that is supported by the profile. Own types should be placed in an own extending vocabulary.

6.3.7 Note type

Maintained By: DILCIS Board

Location: http://earkcsip.dilcis.eu/schema/CSIPVocabularyNoteType.xml

Context: Used in `@csip:NOTETYPE`

Note: Describes the type of a note for an agent.

6.3.8 Content Category

Maintained By: DILCIS Board

Location: http://earkcsip.dilcis.eu/schema/CSIPVocabularyContentCategory.xml

Context: Values for `mets`/`@type`

Note: Declares the categorical classification of package content.

6.3.9 Package Status

Maintained By: DILCIS Board

Location: http://earksip.dilcis.eu/schema/SIPVocabularyRecordStatus.xml

Context: Used in `@RECORDSTATUS`

Note: Describes the type of the alternative record ID.

6.3.10 Alternative record ID's

Maintained By: DILCIS Board

Location: http://earksip.dilcis.eu/schema/SIPVocabularyRecordIDType.xml

Context: Used in `altrecordID`/`@TYPE`

Note: Describes the type of the alternative record ID.

6.3.11 Structural map divisions labels in eHealth1

Maintained By: DILCIS Board

Location: https://citsehealth1.dilcis.eu/schema/VocabularyEHealth1.xml

Context: Predefined values for different eHealth1 classifications

Note: Describes the extra terms supported by this profile. Own names should be placed in an own extending vocabulary.

6.3.12 dmdSec status

Maintained By: DILCIS Board

Location: http://earkcsip.dilcis.eu/schema/CSIPVocabularyStatus.xml

Context: Values for `dmdSec`/`@STATUS`

Note: Describes the status of the descriptive metadata section (dmdSec) which is supported by the profile.

6.4 Appendix D: E-ARK CITS eHealth1 Metadata Requirements

6.4.1 E-ARK eHealth1 representation METS Profile 2.0.1 (citsehpj_v2_0) Requirements

ID	Name, Location & Description	Card & Level
EH1	**Representation Identifier** mets/@OBJID The mets/@OBJID attribute is mandatory, its value is a string identifier for the METS document. . For a representation level METS document, this value records the name of the representation (i.e. the name of the top-level representation folder. For example this could be: "Patient_Record_Submission".	**1..1** MUST
EH2	**METS Profile** mets/@PROFILE The value is set to "https://citsehealth1.dilcis.eu/profile/E-ARK-eHealth1-REPRESENTATION.xml".	**1..1** MUST
EH3	**Content Category** mets/@TYPE The mets/@TYPE attribute is set to the value "OTHER".	**1..1** MUST
EH4	**Other Content Category** mets[@TYPE='OTHER']/@csip:OTHERTYPE The mets/@csip:OTHERTYPE attribute is set to the value "Patient Medical Records".	**1..1** MUST
EH5	**Content Information Type Specification** mets/@csip:CONTENTINFORMATIONTYPE The mets/@csip:CONTENTINFORMATIONTYPE attribute is set to the value "citsehpj_v2_0".	**1..1** MUST
REF_SIP_1	**Package header** N/A The eHealth1 representation METS metsHdr element should comply with metsHdr requirements in the SIP profile.	**N/A** SHOULD
REF_CSIP_	**Descriptive metadata** N/A The SIP dmdSec element should comply with dmdSec requirements in the CSIP profile	**N/A** SHOULD

ID	Name, Location & Description	Card & Level
REF_CSIP_2	**Administrative metadata** N/A The eHealth1 representation METS document amdSec element should comply with amdSec requirements in the CSIP profile. In eHealth1 it is required that any rights or digital provenance metadata that is general to the package can be held within the root metadata folder and that any rights or digital provenance metadata that is specific to the data held in the representation should be held in the representation metadata folder.	**N/A** SHOULD
EH13	**File section** mets/fileSec The transferred content within the representation is referenced from the file section in different file group elements. Only a single file section (<fileSec>) element should be present.Representation of the Patient Case structural hierarchy is only possible if the file section (<fileSec>) is present in the representation.	**1..1** MUST
EH14	**Representations (Patient Document) file groups** mets/fileSec/fileGrp The representation (Patient Document) file groups contain the file elements that describe the Patient Documents, the Patient Administrative and the Patient Clinical Information.The hierarchical structure of the Patient Medical Records within the CITS eHealth1 requires that Documents groups of files that form a single intellectual entity) can be described through the structMap (<div>) element.	**1..n** MUST
EH15	**Description of the use of the representation (Patient Document) file group** mets/fileSec/fileGrp/@USE The value in the mets/fileSec/fileGrp/@USE is the name of the folder structure to the data, e.g "data/Patient_ID/Case_ID/Document_ID".	**1..1** MUST
EH17	**Content Information Type Specification** mets/fileSec/fileGrp[@USE='Representations']/ @csip:CONTENTINFORMATIONTYPE The value of the attribute the mets/fileSec/fileGrp/@csip:CONTENTINFORMATIONTYPE is set to "citsehpj_v2_0".	**1..1** MUST

ID	Name, Location & Description	Card & Level
EH22	**Component byte stream** `mets/fileSec/fileGrp/file/stream` A file may comprise one or more subsidiary byte streams (e.g. an MPEG4 file might contain separate audio and video streams, each of which is associated with technical metadata).The repeatable (`<stream>`) element provides a mechanism to record the existence of separate datastreams within a particular file and to associate (`<dmdSec>`) and (`<amdSec>`) with them.	**0..n** MAY
EH23	**Component byte stream identifier** `mets/fileSec/fileGrp/file/stream/@ID` A unique xml:id for this object across the package.	**1..1** MUST
EH24	**Component byte stream mimetype** `mets/fileSec/fileGrp/file/stream/@MIMETYPE` The IANA mime type for the referenced byte stream.	**1..1** MUST
EH25	**Component byte stream original identification** `mets/fileSec/fileGrp/file/stream/@OWNERID` If an identifier for the byte stream was supplied by the owner, it can be recorded in this attribute.	**0..1** MAY
EH26	**Component byte stream reference to administrative metadata** `mets/fileSec/fileGrp/file/stream/@ADMID` If administrative metadata has been provided for the byte stream this attribute refers to the streams's administrative metadata by ID.For the administrativ description of the byte stream the PREMIS standard is recommended.	**0..1** MAY
EH28	**Structural description of the eHealth1 representation** `mets/structMap` Each representation METS file must include ONE structural map (`<structMap>`) element as exactly as described here.Institutions can add their own additional custom structural maps as separate `<structMap>` sections.	**1..n** MUST
EH30	**Structural description label** `mets/structMap[@LABEL='eHealth1']` The `mets`/`structMap`/`@LABEL` attribute value is set to "eHealth1" from the vocabulary.	**1..1** MUST

ID	Name, Location & Description	Card & Level
EH31	**Structural description identifier** `mets/structMap[@LABEL='eHealth1']/@ID` An `xml:id` identifier for the structural description (structMap) used for internal package references. It must be unique within the package.	**1..1** MUST
EH45	**Data division** `mets/structMap[@LABEL='eHealth1']/div/div/` Within eHealth1 all patient records must be held within a data folder within a minimum single representation and described in the structural map within a single sub-division. There are no files contained in the data division.	**1..1** MUST
EH46	**Data division identifier** `mets/structMap[@LABEL='eHealth1']/div/div/@ID` Mandatory, "xml:id" identifier must be unique within the package.	**1..1** MUST
EH47	**Data division label** `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']` The representations's data division `<div>` element must have the `@LABEL` attribute value "Data" taken from the vocabulary.	**1..1** MUST
EH70	**Patient Record division** `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/div` There must be a discrete "div" element for each patient record.	**1..1** MUST
EH71	**Patient record division label** `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/div[@LABEL='PATIENT RECORD']` The patient record division `<div>` element's `@LABEL` attribute value must be "Patient Record" as taken from the vocabulary.	**1..1** MUST
EH72	**Patient record division identifier** `mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/div/@ID` Mandatory, "xml:id" must be unique wqithin the package.	**1..1** MUST

ID	Name, Location & Description	Card & Level

EH48	**Patient Case division**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']`
	Each Patient Case contains Documents that are related in some way (e.g. chronologically and/or share a particular set of diagnoses and/or treatments). A Patient Case is a folder located in the "data/patient_record" folder within the representation and may contain any number of Sub-cases and Documents. Every representation must contain at least one Patient Case. A Case is represented within a third level sub-division.
		1..n
		MUST

EH49	**Patient Case division identifier**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/@ID`
	Mandatory, `xml:id` identifier must be unique within the package.
		1..1
		MUST

EH50	**Patient case division label**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']`
	The package's patient case division `<div>` element must have the `@LABEL` attribute value "Case", taken from the vocabulary.
		1..1
		MUST

EH51	**Patient Document division**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='DOCUMENT']`
	Each Patient Case MAY contain individual Data Files that are related logically and together form Documents (e.g. a book, video, image and annotation, document and audio notes).
		0..n
		MAY

EH52	**Patient Document division identifier**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='DOCUMENT']/@ID`
	Mandatory, `xml:id` identifier must be unique within the package.
		1..1
		MUST

ID	Name, Location & Description	Card & Level

EH53	**Patient Document division label**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='DOCUMENT']`
	The package's Patient Documentation division `<div>` element must have the `@LABEL` attribute value "Document", taken from the vocabulary.
		1..1
		MUST

EH73	**Patient Document division file group reference**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='DOCUMENT']/fptr`
	All file groups containing content described in the package are referenced via the relevant file group identifiers. One file group reference per fptr-element.
		1..1
		MUST

EH74	**Patient Document division file group reference ID**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='DOCUMENT']/fptr/@FILEID`
	The pointer to the identifier for the file group containing the data files.
		1..1
		MUST

EH59	**Patient Subcase division**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='SUBCASE']`
	Each Patient Sub-case contains Documents that are related in some way (e.g. chronologically and/or share a particular set of diagnoses and/or treatments). A Patient Sub-case is a folder located in a Case folder within the representation and must contain at least one Document.
		1..n
		MAY

EH60	**Patient Subcase division identifier**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='SUBCASE']/@ID`
	Mandatory, `xml:id` identifier must be unique within the package.
		1..1
		MUST

ID	Name, Location & Description	Card & Level

EH61	**Patient Subcase division label**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='SUBCASE']`
	The package's patient sub-case division `<div>` element must have the `@LABEL` attribute value "Subcase", taken from the vocabulary.
		1..1
		MUST

EH62	**Patient Document division**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='SUBCASE']/div[@LABEL='DOCUMENT']`
	Each Patient sub-case can contain individual Data Files that are related logically and together form Documents (e.g. a book, video, image and annotation, document and audio notes).
		1..n
		MAY

EH63	**Patient Document division identifier**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='SUBCASE']/div[@LABEL='DOCUMENT']/@ID`
	Mandatory, `xml:id` identifier must be unique within the package.
		1..1
		MUST

EH64	**Patient Document division label**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='SUBCASE']/div[@LABEL='DOCUMENT']`
	The package's patient sub-case/documentation division `<div>` element must have the `@LABEL` attribute value "Document", taken from the vocabulary.
		1..1
		MUST

EH75	**Patient Document division file group reference**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='SUBCASE']/div[@LABEL='DOCUMENT']/fptr/@FILEID`
	The pointer to the identifier for the file group containing the data files.
		1..1
		MUST

EH76	**Patient Document division file group reference ID**
	`mets/structMap[@LABEL='eHealth1']/div/div/[@LABEL='DATA']/`
	`div[@LABEL='PATIENT RECORD']/div[@LABEL='CASE']/`
	`div[@LABEL='DOCUMENT']/fptr/@FILEID`
	The pointer to the identifier for the file group containing the data files.
		1..1
		MUST

ID	Name, Location & Description	Card & Level
REF_METS	**structLink** N/A Section not defined or used in CSIP, additional own uses may occur.Information regarding the structural links is found in the METS Primer	**N/A** MAY
REF_METS_2	**behaviorSec** N/A Section not defined or used in CSIP, additional own uses may occur.Information regarding the behavior section is found in the METS Primer	**N/A** MAY

6.4.2 E-ARK eHealth1 root METS Profile 2.0.1 (citsehpj_v2_0) Requirements

ID	Name, Location & Description	Card & Level
EHR1	**METS Profile** mets/@PROFILE The value is set to "https://citsehealth1.dilcis.eu/profile/E-ARK-eHealth1-ROOT.xml".	**1..1** MUST
EHR2	**Content Category** mets/@TYPE The mets/@TYPE attribute is set to the value "OTHER".	**1..1** MUST
EHR3	**Other Content Category** mets[@TYPE='OTHER']/@csip:OTHERTYPE The mets/@csip:OTHERTYPE attribute is set to the value "Patient Medical Records".	**1..1** MUST
EHR4	**Content Information Type Specification** mets/@csip:CONTENTINFORMATIONTYPE	**1..1** MUST

ID	Name, Location & Description	Card & Level
EHR5	**Submission agreement** mets/metsHdr/altRecordID[@TYPE='SUBMISSIONAGREEMENT'] There SHOULD be a reference to the Submission Agreement associated with the package as the SIP will contain personal data.@TYPE is used with the value "SUBMISSIONAGREEMENT". Example: http://submissionagreement.kb.se/dnr331-1144-2011/20120711/.Note: It is recommended to use a machine-readable format for a better description of a submission agreement.For example, the submission agreement developed by Docuteam GmbH http://www.loc.gov/standards/mets/profiles/00000041.xml	**0..1** SHOULD
EHR6	**Archival creator agent** mets/metsHdr/agent A wrapper element that encapsulates the name of the organisation, software and person that originally created the data being transferred. Please note that this might be different from the organisation which has been charged with preparing and sending the SIP to the archives.It MUST be easy to positively identify the creating organisation (healthcare provider) without which the data has no provenance.	**1..1** MUST
EHR7	**Archival creator agent role** mets/metsHdr/agent[@ROLE='CREATOR'] The role of the archvial creator organisation is set to the value "CREATOR".	**1..1** MUST
EHR8	**Archival creator agent type** mets/metsHdr/agent[@TYPE='ORGANIZATION'] The type of the archvial creator agent is set to the value "ORGANIZATION".	**1..1** MUST
EHR9	**Archival agent creator name** mets/metsHdr/agent/name The name of the organisation(s) that originally created the data being transferred MUST be given.Please note that this might be different from the organisation which has been charged with preparing and sending the SIP to the archives.	**1..n** MUST
EHR10	**Archival creator agent additional information** mets/metsHdr/agent/note The archival creator agent SHOULD have a note providing a unique identification code for the archival creator.As permitted by national identification systems for healthcare providers submitting Patient Medical Records, an identifier for the provider should be provided.	**0..1** SHOULD

ID	Name, Location & Description	Card & Level
EHR11	**Classification of the archival creator agent additional information** `mets/metsHdr/agent/note/@csip:NOTETYPE` The archival creator agent notetype has a value of "IDENTIFICATIONCODE".	**1..1** MUST
EHR12	**Descriptive metadata** `mets/dmdSec` There MUST be a reference to a metadata file held in the the metadata/descriptive folder of the package. At minimum this MUST be a Patient Manifest of Patient Names and unique personal identifiers. It CAN be a more detailed resource such as the FHIR Patient resource "FHIR.Patient".	**1..n** MUST
EHR13	**Reference to the document with the descriptive metadata** `mets/dmdSec/mdRef` There MUST be reference() to the descriptive metadata file(s) located in the "metadata" section of the IP.	**1..n** MUST
EHR14	**Type of metadata** `mets/dmdSec/mdRef[@MDTYPE='OTHER']` The value for the metadata type is set to "OTHER".	**1..1** MUST
EHR15	**Type of other metadata** `mets/dmdSec/mdRef[@MDTYPE='OTHER']/@OTHERMDTYPE` Specifies the type of metadata used for the Patient Manifest.For example the value will be "FHIR.Patient" if the FHIR Patient resource is used.	**1..1** SHOULD
REF_CSIP_1	**Administrative metadata** `N/A` The eHealth1 root METS document amdSec element SHOULD comply with amdSec requirements in the CSIP profile. In eHealth1 it is required that any rights or digital provenance metadata that is general to the package should be held within the root metadata folder and that any rights or digital provenance metadata that is specific to the data held in the representation should be held in the representation metadata folder.	**N/A** SHOULD
EHR16	**File section** `mets/fileSec` The transferred content is placed in a representation folder described with a representation METS document.Only a single file section (`<fileSec>`) element MUST be present.	**1..1** MUST

ID	Name, Location & Description	Card & Level

EHR22	**Content Information Type Specification**
	 `mets/fileSec/`
	 `fileGrp[@csip:CONTENTINFORMATIONTYPE='citsehpj_v2_0']`
	 The value of the attribute
	 `mets`/`fileSec`/`fileGrp`/`@csip`:`CONTENTINFORMATIONTYPE` is set to
	 "citsehpj_v2_0".
		1..1
		 MUST

REF_CSIP_	**Structural description of the package** `N/A` The eHealth1 root structMap element must comply with structMap requirements in the CSIP profile.	**N/A** MUST
REF_METS_	**structLink** `N/A` Section not defined or used in CSIP, additional own uses may occur.Information regarding the structural links is found in the METS Primer	**N/A** MAY
REF_METS	**behaviorSec** `N/A` Section not defined or used in CSIP, additional own uses may occur.Information regarding the behavior section is found in the METS Primer	**N/A** MAY

Postface

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II. Revision History

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Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

III. Contact & Feedback

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