

## Specification for the E-ARK Content Information Type Specification for eHealth1 (CITS eHealth1)

**A proper front page will be created for the publication occurring after implementation of review comments.**

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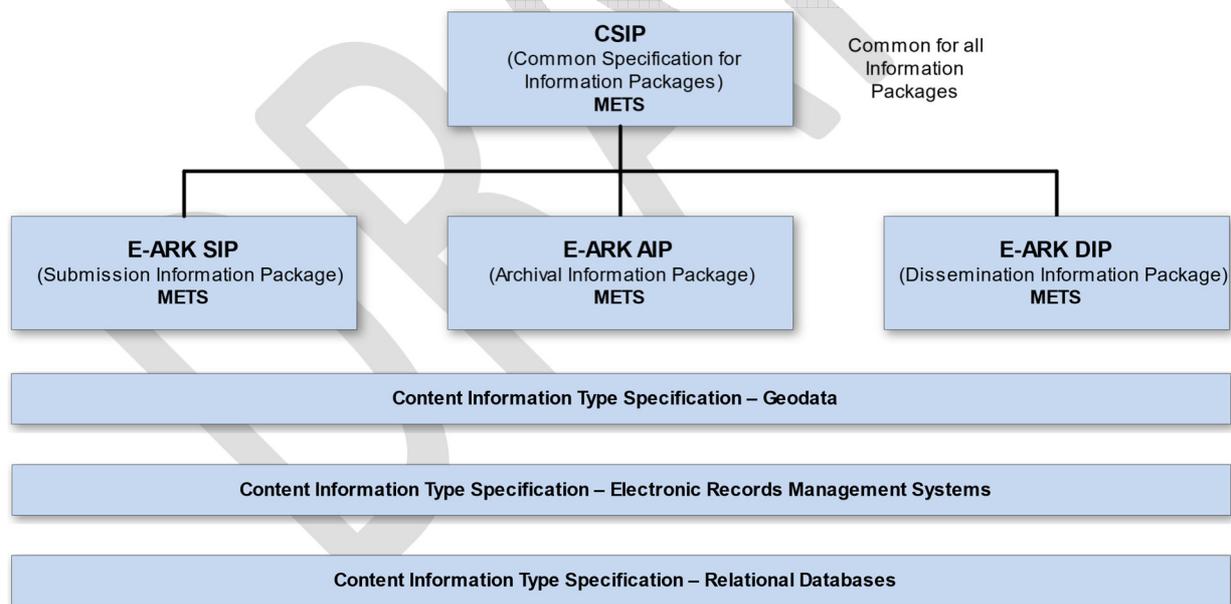
# 1 Preface

**The correct preface will be inserted for the publication occurring after implementation of review comments.**

## 1.1 Aim of the specification

This E-ARK specification is part of a family of specifications that provide a common set of requirements for packaging digital information. These specifications are based on common, international standards for transmitting, describing and preserving digital data. They have been produced to help data creators, software developers and digital archives tackle the challenge of short-, medium- and long-term data management and reuse in a sustainable, authentic, cost-efficient, manageable and interoperable way.

The foundation for these specifications is the Reference Model for an Open Archival Information System (OAIS) which has Information Packages at its core. Familiarity with the core functional entities of OAIS is a prerequisite for understanding the specifications. A visualisation of the current specification network can be seen here:



The E-ARK specification dependency hierarchy

Specification	Aim and Goals
<b>Common Specification for Information Packages</b>	This document introduces the concept of a Common Specification for Information Packages (CSIP). Its three main purposes are to: <ul style="list-style-type: none"> <li>Establish a common understanding of the requirements which need to be met in order to achieve interoperability of Information Packages.</li> </ul>

	<ul style="list-style-type: none"> <li>• Establish a common base for the development of more specific Information Package definitions and tools within the digital preservation community.</li> <li>• 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.</li> </ul> <p>Ultimately the goal of the Common Specification is to reach a level of interoperability between all Information Packages so that tools implementing the Common Specification can be adopted by institutions without the need for further modifications or adaptations.</p>
<b>E-ARK SIP</b>	<p>The main aims of this specification are to:</p> <ul style="list-style-type: none"> <li>• Define a general structure for a Submission Information Package format suitable for a wide variety of archival scenarios (e.g. document and image collections, databases or geographical data).</li> <li>• Enhance interoperability between Producers and Archives.</li> <li>• Recommend best practices regarding metadata, content and structure of Submission Information Packages.</li> </ul>
<b>E-ARK AIP</b>	<p>The main aims of this specification are to:</p> <ul style="list-style-type: none"> <li>• Define a generic structure of the AIP format suitable for a wide variety of data types, such as document and image collections, archival records, databases or geographical data.</li> <li>• Recommend a set of metadata related to the structural and the preservation aspects of the AIP as implemented by the reference implementation eArchiving ToolBox (formerly E-ARKweb).</li> <li>• Ensure the format is suitable to store large quantities of data.</li> </ul>
<b>E-ARK DIP</b>	<p>The main aims of this specification are to:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Recommend a set of metadata related to the structural and access aspects of the DIP.</li> </ul>
<b>Content Information Type Specifications</b>	<p>The main aim and goal of a Content Information Type Specification is to:</p> <ul style="list-style-type: none"> <li>• Define, in technical terms, how data and metadata must be formatted and placed within a CSIP Information Package in order to achieve interoperability in exchanging specific Content Information.</li> </ul> <p>The number of possible Content Information Type Specifications is unlimited.</p>

## 1.2 Organisational support

This specification is maintained by the Digital Information LifeCycle Interoperability Standards Board (DILCIS Board). The DILCIS Board (<http://dilcis.eu/>) was created to enhance and maintain the draft specifications developed in the European Archival Records and Knowledge Preservation Project (E-ARK project) which concluded in January 2017 (<http://E-ARK-project.com/>). The Board consists of eight members, but there is no restriction on the number of participants 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. Since 2018 the DILCIS Board has been responsible for the core specifications in the Connecting Europe Facility eArchiving Building Block (<https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/eArchiving>).

### 1.3 Authors

A full list of contributors to this specification, as well as the revision history can be found in Appendix 1.

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## 2 Glossary

	Description
<b>Archival Creator</b>	Organisation unit or individual that creates records and/or manages records during their active use.
<b>Case or Patient Case</b>	<p>Type of component consisting of a set of objects and/or sub-cases. This is represented in the specification as a directory which sits within the data directory of a representation.</p> <p>A Case is an aggregation of individual patient records 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.</p>
<b>Central Patient Health Archive</b>	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).
<b>Component</b>	<p>In this standard: meaningful, logically delimited and uniquely identifiable information that may be subject to treatment in manual and/or automated processes.</p> <p>This standard operates with four generic types of components: Case, Document, Data File and Byte Stream.</p>
<b>Data File</b>	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.
<b>Death Register</b>	National system which records deaths within the jurisdiction.
<b>Document</b>	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 which is approved/signed as a whole by a practitioner.

<b>General EMR System</b>	<p>Electronic Medical Record system intended for documentation of all forms of healthcare.</p> <p>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.</p>
<b>Healthcare Provider</b>	<p>An organisation providing primary or secondary healthcare. Can be general in scope or specialised, public or private.</p>
<b>Local Patient Health Archive</b>	<p>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.</p>
<b>Patient Administrative Information</b>	<p>Structured Personal data related to the patient for whom the Patient Medical Record is compiled. Information will include but not be limited to name, patient ID(s), administrative gender, date of birth, date of death, address(es)</p>
<b>Patient Clinical Information</b>	<p>Structured patient clinical data related to Cases such as diagnoses, procedures, medication, allergies, etc.</p>
<b>Patient Medical Record</b>	<p>Collection or compilation of recorded information about a patient in connection with healthcare.</p> <p>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.</p>
<b>Patient Medical Record Extraction</b>	<p>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.</p>
<b>Patient Personal Information</b>	<p>Demographics and other administrative information about an individual receiving care or other health-related services. For example, as can be described using the resource FHIR.Patient.</p>
<b>Specialised EMR System</b>	<p>Electronic Medical Record system specially adapted for documentation of a type of specialised healthcare or integrated with a specialised device.</p> <p>Examples: food/maternity system, Gastro system, laboratory system, etc.</p>
<b>Sub-case</b>	<p>Type of component consisting of a set of thematically related Data Files which are also related to a Case. Sub-</p>

	cases are represented in the specification as folders that sit within a Case.
<b>Submitting Organisation</b>	Name of the organisation submitting the package to the archive.

## 3 Introduction

### 3.1 Purpose

The purpose of this document is to describe the E-ARK Content Information Type Specification (CITS) for eHealth1. This specification is supported by an XML-schema and a Schematron document which includes rules that the XML-schema cannot validate.

### 3.2 Scope

This specification makes the following assumptions:

- A 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 medical records for deceased patients within the jurisdiction (the complete Patient Medical Record).
- Implementation of Electronic Health Record (EHR) systems is not widespread, and creation of an eHealth archive which aggregates information from both EMR and EHR systems is considered to be a special case which can be considered within future iterations of this specification (see section 5).
- The use cases for an eHealth archive are described in section 5.3.

## 4 Layered Data Model

This section introduces the structure of the data model, which is based on a layered approach for information package definitions (Figure 1). 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. These two layers are not part of this document. The third layer of the model represents specific content information type specifications, such as this eHealth1 specification. Additional layers for business-specific specifications and local variant implementations of any specification can be added.

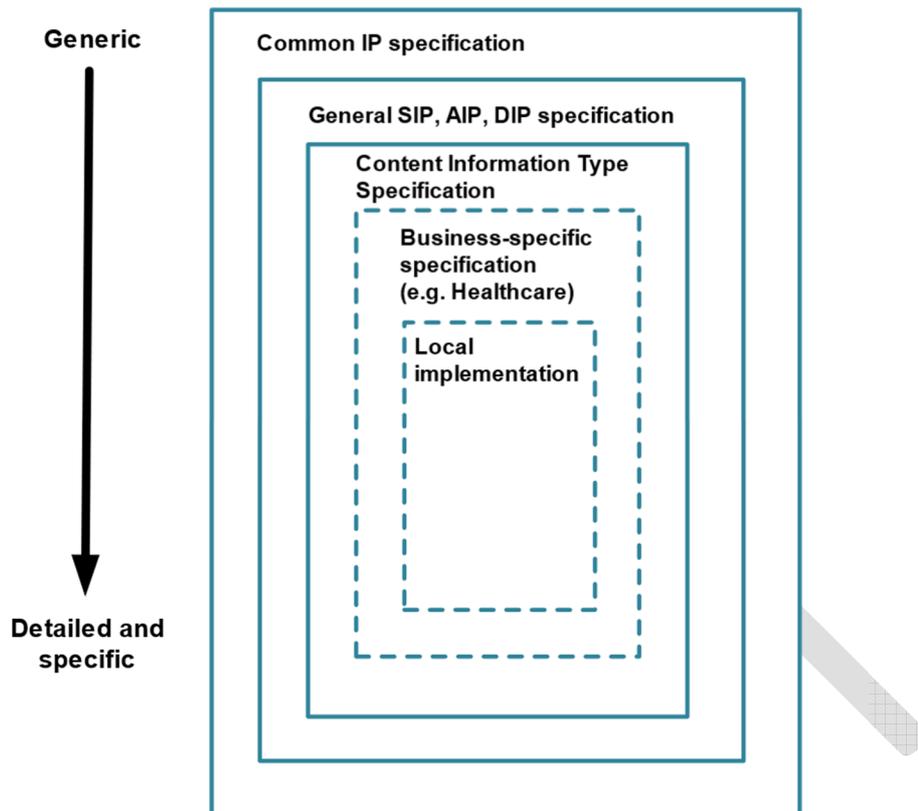


Figure 1: Data Model Structure

The eHealth1 specification omits all information that is specific to jurisdiction (such as individual or patient identifiers). The specification is tied to a specific content type (healthcare) but does not rely on the extraction of data from EMR systems in ways that would rely on an underlying specification for the content information type (e.g. ERMS or RDMS). The eHealth1 specification is a combination of Content Information Type and Business-specific specifications but does not restrict local implementation. This need is addressed by providing extension mechanisms in the eHealth1 specification so that local (e.g. national) extensions to accommodate local requirements can be added by users.

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 very 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 support both 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 (e.g. the use of the HL7 FHIR schema for patient personal information can be substituted for a local schema).

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.

## 5 Elements of an eHealth Archive

### 5.1 Physical and Electronic Patient Records

A Patient Medical Record can be defined as: “a collection or compilation of recorded information about a patient in connection with healthcare, the patient record is the principal repository for information concerning a patient’s health care.”<sup>1</sup> Prior to the widespread implementation of Electronic Medical Record (EMR) systems, the recording of patient health records was paper and film-based (plus additional materials which could be images, video, audio).

Electronic Medical Records (EMRs) are a digital version of the paper or film records. A healthcare provider may have a single EMR system for all of its patient records or for larger organisations there can be fragmentation because of specialisation or organisational sub-division and a patient’s total medical record at that organisation may be constituted from many subsidiary systems. A considerable volume of these patient records exists at healthcare providers and within centralised organisations because of legal remits to store the records for extended periods.

A complete Patient Medical Record may contain information that is sourced from several different organisations systems (e.g. different hospitals, specialist healthcare providers, primary healthcare providers) and viewed from an archive academic perspective, the information in each of these organisations constitutes an archive (or several archives). In creating a Central Health Archive, it is necessary for a healthcare provider to make separate extractions from each system for the patients to be included in a delivery and to aggregate them before submission to the central archive.

The creation of a Central Health Archive can encompass the digitisation and preservation of physical records as well as the collection and preservation of electronic records from EMR systems. In general, as a patient’s aggregated medical record is not complete until there are no new additions to it (i.e. when the individual has died), then a health archive will consist only of records for patients who are known or who are believed to be deceased).

### 5.2 Electronic Medical Record and Health Record Systems

The terms “electronic medical record” and “electronic health record” (or “EMR” and “EHR”) can be used interchangeably. However, the difference between the two terms is quite significant and particularly so in the context of archiving standards.

EMR is the older term, and early EMRs were ‘medical’ in nature, they were for use by clinicians mostly for diagnosis and treatment. Because of a lack of available standards when EMR systems were first developed, the information in EMRs does not travel easily out of a healthcare provider. In fact, the

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<sup>1</sup> Institute of Medicine (US) Committee on Improving the Patient Record; Dick RS, Steen EB, Detmer DE, editors. The Computer-Based Patient Record: Revised Edition: An Essential Technology for Health Care. Washington (DC): National Academies Press (US); 1997. 1, Introduction. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK233055/>

patient's record might have to be printed out and delivered by mail to specialists or other members of the care team. In that regard, EMRs are not much better than a paper record.

Electronic health records (EHRs) focus on the total health of the patient—going beyond standard clinical data collected in the provider's office and inclusive of a broader view on a patient's care. EHRs are designed to reach out beyond the health organisation that originally collects and compiles the information. They are built to share information with other health care providers, such as laboratories and specialists, so they contain information from all the clinicians involved in the patient's care. The National Alliance for Health Information Technology stated that EHR data “can be created, managed, and consulted by authorised clinicians and staff across more than one healthcare organisation.”<sup>2</sup>

The information moves with the patient—to the specialist, the hospital, the nursing home, or even across a region or country. In comparing the differences between record types, HIMSS<sup>3</sup> Analytics stated that “the EHR represents the ability to easily share medical information among stakeholders and to have a patient's information follow him or her through the various modalities of care engaged by that individual.” EHRs are designed to be accessed by all people involved in the patient's care—including the patients themselves. Indeed, that is an explicit expectation in the Stage 1 definition of “meaningful use” of EHRs.

The benefits of EHR systems to patient care mean that the trajectory for healthcare worldwide is towards national EHR systems. The complexity and lack of standards in existing systems mean that realisation is difficult and expensive. Adoption is hence not yet widespread. Implementations of EHR systems can also rely on summary patient data gathered by means of standardised clinical documents (such as HL7 CDAs). This means that extractions from EHR systems can only yield patient summary data and not the complete patient medical record.

The development of standards and technology that make EHR systems possible (such as the encoding of key clinical data, medical data interoperability standards such ICD, DICOM, SNOMED and HL7 FHIR) makes the future scope a national health archive a different proposition; systems will exist containing a patient's total health history, richly encoded and ideally suited to analytical techniques for ‘big data’. Systems in principal will be able to grow over time containing records from both live and dead patients.

### 5.3 Use Cases for a Central Health Archive

According to the health archive regulation, the mission of the Norwegian National Health Archive (NHA)<sup>4</sup> is to:

- a) receive and preserve patient archives from public and private hospitals, and
- b) to disseminate health information for researchers and the patients next of kin in compliance with regulations and confidentiality acts.

There is no limit to the age of the records to be presented to the NHA from hospitals and so consist of physical and electronic patient records.

The Norwegian regulation envisions two possible use cases for the archive when built, which are:

- a) To provide records to next of kin in compliance with open information regulation.

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<sup>2</sup> <https://www.healthcareusability.com/article/terminology-hit-emr-ehr>

<sup>3</sup> HIMSS Analytics [himssanalytics.org](http://himssanalytics.org)

<sup>4</sup> <https://ehandbok.arkivverket.no/folder/92>

- b) To harvest the vast amount of historical healthcare-related data within the archive for medical research.

In order to achieve use case 1, it is necessary to ensure that the specification allows for access to all of the records pertaining to a single patient, regardless of the submitting institution.

Use case 2 requires that the specification allows for ingestion of digitised records and the ingestion of extracts from EMR systems for all deceased patients and that sufficient metadata is provided to enable searches across the archive to create cohorts to support medical research. Metadata regarding patient personal information and patient clinical information may be encoded in EMR systems or may have to be entered at a digitisation stage. The scope of the metadata to be included in the archive is therefore very much a determination for the local and national organisations based on the existing records, resources available, standards, etc.

## 6 Metadata and Mapping

### 6.1 eHealth standards and use in the eHealth1 specification

Controlled vocabularies and coding provide a standardised way for 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 an international standard such as ICD or SNOMED. Data can be recorded in a number of standardised (such as HL7 FHIR) formats or to a local format which is specified by the Health Archive and referenced within a submission agreement.

#### 6.1.1 HL7 FHIR<sup>5</sup>

Fast Healthcare Interoperability Resources (FHIR, pronounced “fire”) is a standard describing data formats and elements (known as ‘resources’) and an application programming interface (API) for exchanging electronic health records (EHR). The standard was created by the Health Level Seven International (HL7) healthcare standards organisation.

Its goals are to facilitate interoperation between legacy health care systems, to make it easy to provide health care information to health care providers and individuals on a wide variety of devices from computers to tablets to mobile phones and to allow third-party application developers to provide medical applications which can be easily integrated into existing systems.<sup>6</sup>

FHIR provides resources that can be used for the standardised description of Patient Personal data and Patient Clinical metadata which reference controlled vocabulary and coding standards such as ICD and SNOMED. The use of FHIR is suggested within eHealth1, but local standards for encoding metadata are allowable if specified elsewhere and referenced within a submission agreement.

#### 6.1.2 ICD<sup>7</sup>

The International Classification of Diseases is the foundation for the identification of health trends and statistics globally, and the international standard for reporting diseases and health conditions. It is the diagnostic classification standard for all clinical and research purposes. ICD defines the universe of diseases, disorders, injuries and other related health conditions, listed in a comprehensive, hierarchical fashion that allows for:

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<sup>5</sup> <https://www.hl7.org/fhir/summary.html>

<sup>6</sup> [https://en.wikipedia.org/wiki/Fast\\_Healthcare\\_Interoperability\\_Resources](https://en.wikipedia.org/wiki/Fast_Healthcare_Interoperability_Resources)

<sup>7</sup> <https://www.who.int/classifications/icd/en/>

- easy storage, retrieval and analysis of health information for evidence-based decision-making;
- sharing and comparing health information between hospitals, regions, settings and countries; and
- data comparisons in the same location across different time periods.

ICD is mapped from other standards such as HL7 FHIR and will be part of the process used by many institutions to record patient medical data. The use of international standards such as ICD within supplied clinical metadata is encouraged but will be limited by their use within the source EMR or EHR system.

### 6.1.3 SNOMED<sup>8</sup>

SNOMED CT or SNOMED Clinical Terms is a systematically organised computer processable collection of medical terms providing codes, terms, synonyms and definitions used in clinical documentation and reporting. SNOMED CT is considered to be the most comprehensive, multilingual clinical healthcare terminology in the world. The primary purpose of SNOMED CT is to encode the meanings that are used in health information and to support the effective clinical recording of data to improve patient care. SNOMED CT provides the general core terminology for electronic health records.<sup>9</sup>

SNOMED CT is mapped from other standards such as HL7 FHIR and will be part of the process used by many institutions to record patient medical data. The use of international standards such as SNOMED CT within supplied clinical metadata is encouraged but will be limited by their use within the source EMR or EHR system.

### 6.1.4 DICOM<sup>10</sup>

Digital Imaging and Communications in Medicine (DICOM) is the standard for the communication and management of medical imaging information and related data.

A DICOM file is a file which encapsulates attributes and bit streams (image, video, etc.) and has embedded patient personal information and IDs. DICOM files have a recognised MIME file type. Extraction of DICOM files from specialised EMR systems for inclusion in Patient Medical Records should present no problem, but it should be ensured that patient IDs in DICOM files match those in archival package Patient Personal data.

### 6.1.5 eHealth DSI (eHealth Digital Service Infrastructure)<sup>11</sup>

The eHealth Digital Service Infrastructure (eHDSI or eHealth DSI) is the initial deployment and operation of services for cross-border health data exchange under the Connecting Europe Facility (CEF). It defines a document framework or Clinical Document Architecture (CDA) for sharing medical data across borders (Patient Summary). As E-ARK eHealth1 considers the totality of a Patient Medical Record, the eHDSI is too limited in scope to be useful. eHDSI aims to specify an interchangeable derivation and extract of a Patient Medical Record, whereas the E-ARK eHealth1 CITs aims to preserve the patient record in its entirety.

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<sup>8</sup> <http://www.snomed.org>

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[https://en.wikipedia.org/wiki/SNOMED\\_CT#:~:text=SNOMED%20CT%20or%20SNOMED%20Clinical,in%20clinical%20documentation%20and%20reporting.](https://en.wikipedia.org/wiki/SNOMED_CT#:~:text=SNOMED%20CT%20or%20SNOMED%20Clinical,in%20clinical%20documentation%20and%20reporting.)

<sup>10</sup> <https://www.dicomstandard.org/current/>

<sup>11</sup> <https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHealth+DSI+Operations+Home>

## 6.2 Data Aggregations in eHealth1

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 as well 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 broadly unsuitable for a Central Patient Health Archive.

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, 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 data will most likely be submitted by hospitals or other healthcare providers in periodic batches, consisting of multiple patient records. 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. 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 co-ordinated. Aggregation of a total patient record at the archive prior to submission into the preservation system is therefore deemed impractical.

As the archive is intended as a Patient Medical Record archive, the structure proposed for the aggregations of the records is as shown in the data model in Figure 2. The levels of the aggregation are as follows:

### *Patient*

An individual who has received healthcare at any number of healthcare providers who is described by Patient Administrative Information (see 7.3.2).

### *Case*

A Patient Medical Record can be structured in various ways which may be dictated by national standards or guidance or local practice. A Patient's total 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 one 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 which 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 which 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 which is approved/signed as a whole.

### Data File

A Data file is a component which 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 which contains data, has an associated MIME file type and is encapsulated 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 tools (such as ffprobe for video container formats).

## 6.3 Examples of Different Patient Record Submissions

With the flexibility of the structure of the eHealth1 archival package and the differences that are likely to be found in making Patient Medical Record extractions from disparate EMR systems, there can be expected to be different cases for the extraction of records.

### 6.3.1 Example 1: The entire archive Patient Medical Record as one file (document)

In this example, the extraction of a Patient's Medical Record consists of one unstructured file in, for example, PDF format, which contains a complete extract from an EMR system. In such a case, an Archived Patient Medical Record will consist of one Case containing one Document and one Data File (see Figure 2).

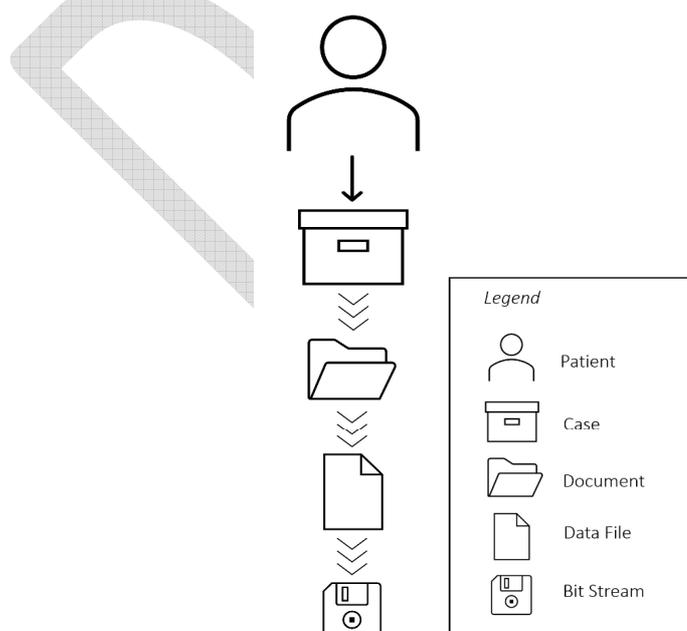


Figure 2: Archived Patient Medical Record as One File

### 6.3.2 Example 2: The archive Patient Medical Record as a set of thematic files (documents)

In this example, extraction of the Patient’s Medical Record consists of a set of unstructured files, typically PDF documents where each file includes all of the information within a subject/theme that reflects the organisation of information in the current system. In this example, an Archived Patient Medical Record would consist of a number of Cases, each containing one Document, each containing one Data File (see Figure 3).

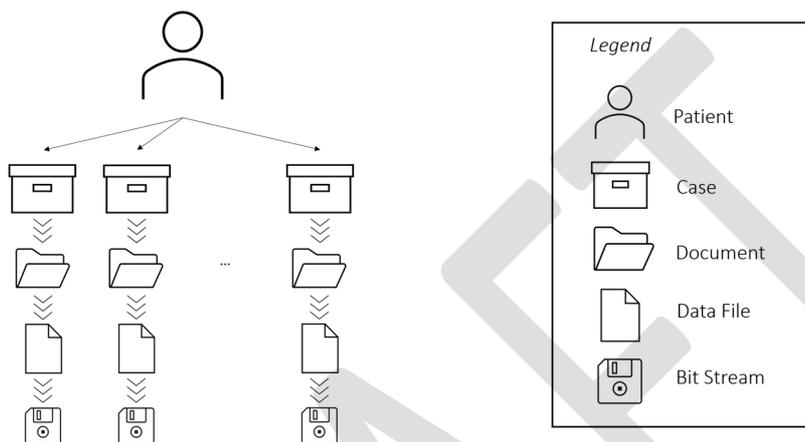


Figure 3: Archived Patient Medical Record as a Set of Thematic Files

### 6.3.3 Example 3: The archived Patient Medical Record as a set of Documents per Case

In this example, extraction of the Patient’s Medical Record consists of a set of unstructured files which can be documents, images, videos, DICOM files, etc., and where each Data File may be related to other Data Files within a Document which can be related to each other within a Case or a Sub-case (see Figure 4).

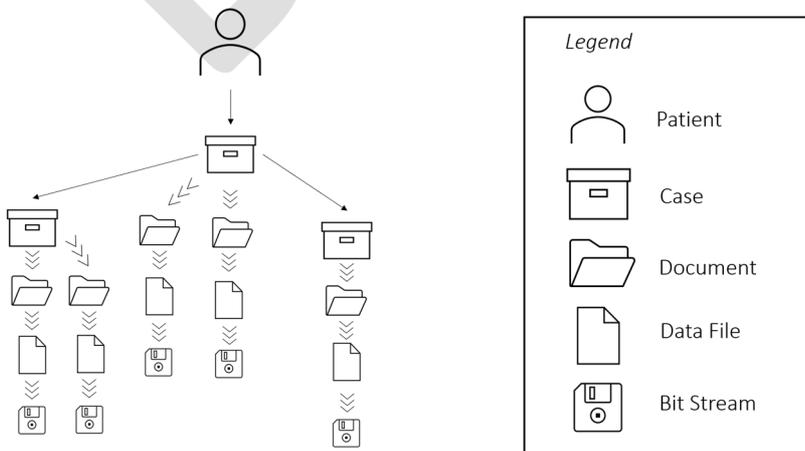


Figure 4: Archived Patient Medical Record as a Set of Documents per Case or Sub-case

## 6.4 Model picture

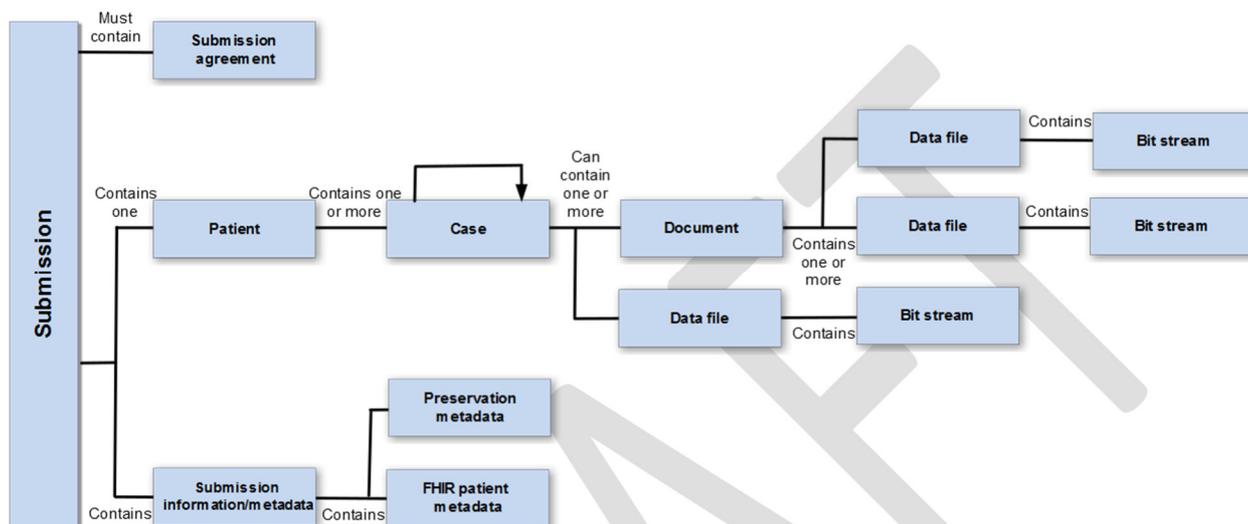


Figure 5: Example of model

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

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

## 6.6 Placement of data in an eHealth1 Information Package

As described in 6.2, Patient data as submitted by hospitals or healthcare providers are likely to be periodically extracted from source systems and sent in batches. 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 then included in each AIP is then a matter for local implementation, although the decision in Norway at NHA was for each AIP to consist of data from a single Patient and from a single Submitting Organisation.

The Patient Medical Record is placed in a single representation within the representations folder of the package. The ID of the representation should follow instructions for naming of representation folders in CSIPTR10 to have a string name that is unique within the package scope.

The representation should contain a METS file at its root (Representation METS). The folder structure should follow that defined by the CSIP and must have a 'data' folder. If clinical descriptive metadata is to

be supplied, the representation structure must include a folder ‘/metadata/descriptive’ and any descriptive metadata files must be placed in this folder. Figure 6 shows an example of a folder structure for a representation where there is clinical metadata included.

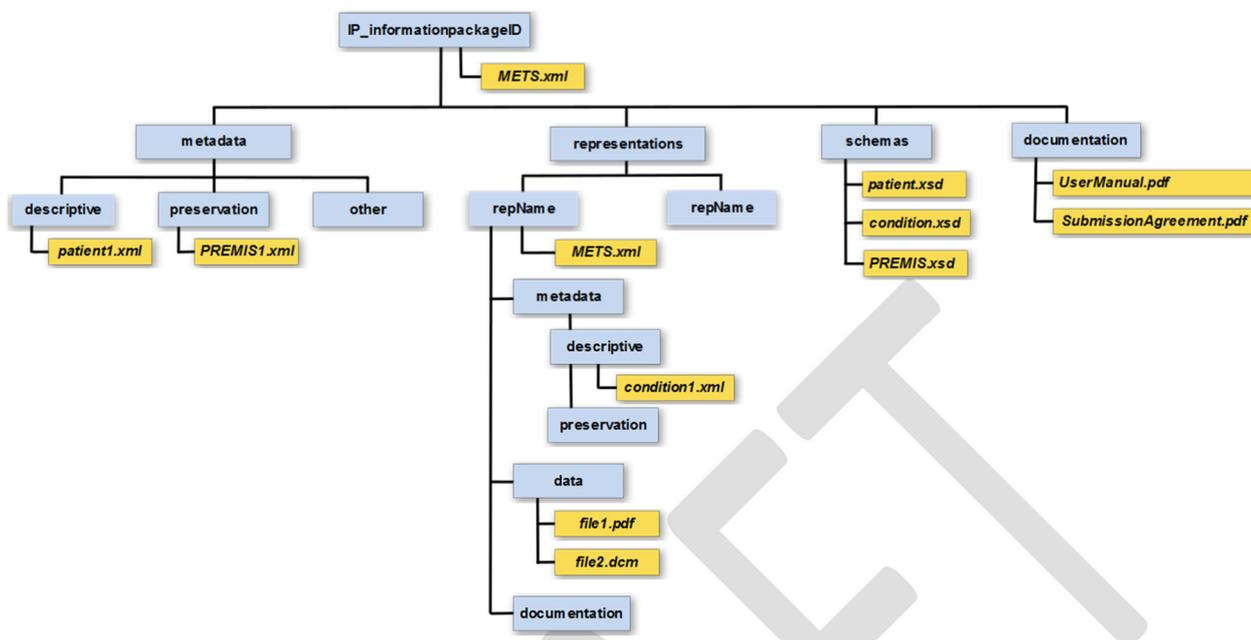


Figure 6: Example of Package Folder Structure with Representation

## 7 METS

### 7.1 Use of METS in eHealth1

The CSIP specifies that METS files be located at the root of the package folder structure (Package METS) and optionally in each of the representations within its respective root folder (Representation METS). As has been described previously, the eHealth1 CITS defines a package that has been submitted by a single institution and will contain information concerning either single or multiple patients. Allowance is also given for multiple representations with each package, to anticipate the situation where the processing of SIPs at the Central Patient Archive produces derivatives through format migration of patient data that should be contained in a separate representation to the originals within the AIP.

#### 7.1 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.

Table 1: Root METS root element

ID	Name and location	Description and usage	Cardinality Level
<b>EHR1</b> <b>Ref CSIP6</b>	METS profile mets/@PROFILE	The value is set to "https://earkehealth1.dilcis.eu/profile/E-ARK-eHealth1-ROOT.xml"	1..1 MUST
<b>EHR2</b> <b>Ref CSIP2</b>	Content category mets/@TYPE	The `mets/@TYPE` attribute is set to the value "OTHER"	1..1 MUST
<b>EHR3</b> <b>Ref CSIP 3</b>	Other content category mets/@csip:OTHERTYPE	The `mets/@csip:OTHERTYPE` attribute is set to the value "Patient Medical Records"	1..1 MUST
<b>EHR4</b> <b>Ref CSIP 4</b>	Content information type specification mets/@csip:CONTENTINFORMATIONTYPE	The `mets/@csip:CONTENTINFORMATIONTYPE` attribute is set to the value "eHealth1"	1..1 MUST

Example 1: Root METS element example.

```
<mets:mets
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns:mets="http://www.loc.gov/METS/"
  xmlns:xlink="http://www.w3.org/1999/xlink"
  xmlns:csip="https://DILCIS.eu/XML/METS/CSIPExtensionMETS"
  xmlns:sip="https://DILCIS.eu/XML/METS/SIPExtensionMETS"
  OBJID= "ehealth1-root-mets-example"
  TYPE= "OTHER"
  csip:OTHERTYPE="Patient Medical Records"
  csip:CONTENTINFORMATIONTYPE="eHealth1"
  PROFILE="https://earkehealth1.dilcis.eu/profile/E-ARK-eHealth1-ROOT.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>
```

### 7.1.2 Root METS header element (element metsHdr)

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

Table 2: Root METS header section

ID	Name and location	Description and usage	Cardinality Level
<b>EHR5</b> <b>Ref SIP5</b>	Submission agreement  mets/Hdr/altRecordID	There <b>MUST</b> 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: RA 13-2011/5329; 2012-04-12 For example, the submission agreement developed by Docuteam GmbH at: <a href="http://www.loc.gov/standards/mets/profiles/00000041.xml">http://www.loc.gov/standards/mets/profiles/00000041.xml</a>  Note: A machine-readable format is recommended for a better description of a submission agreement. For example, the submission agreement developed by Docuteam GmbH at: <a href="http://www.loc.gov/standards/mets/profiles/00000041.xml">http://www.loc.gov/standards/mets/profiles/00000041.xml</a>	1..1  MUST
<b>EHR6</b> <b>Ref SIP9</b>	Archival creator agent  metsHdr/agent	A wrapper element that enables to encode the name of the organisation or 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 <b>MUST</b> be easy to positively identify the creating organisation (healthcare provider) without which the data has no provenance.	1..1  MUST
<b>EHR7</b> <b>Ref SIP11</b>	Archival agent creator type  metsHdr/agent/@TYPE	The type of the archival creator agent is set to "ORGANISATION".	1..1  MUST
<b>EHR8</b> <b>Ref SIP12</b>	Archival agent creator name  metsHdr/agent/name	The name of the organisation(s) that originally created the data being transferred <b>MUST</b> 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
<b>EHR9</b> <b>Ref SIP13</b>	Archival creator additional information  metsHdr/agent/note	The archival creator agent has 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
<b>EHR10</b> <b>Ref SIP14</b>	Archival creator agent additional information  metsHrd/agent/note/@csip:NOTE TYPE	The archival creator agent note is typed with the value of "IDENTIFICATIONCODE"	1..1  MUST

## Example 2: Root METS header with submission agreements

```

<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: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="OTHER" TYPE="INDIVIDUAL" OTHERROLE="SUBMITTER">
    <mets:name>Sven Svensson</mets:name>
    <mets:note>Phone: 08-123456, Email: sven.svensson@mail.mail</mets:note>
  </mets:agent>
  <mets:agent ROLE="ARCHIVIST" TYPE="ORGANIZATION">
    <mets:name>The Swedish health agency</mets:name>
    <mets:note csip:NOTETYPE="IDENTIFICATIONCODE">ID:1234567</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:altRecordID TYPE="SUBMISSIONAGREEMENT">http://submissionagreement.kb.se/dnr331-1144-
2011/20120711/</mets:altRecordID>
  <mets:altRecordID TYPE="PREVIOUSSUBMISSIONAGREEMENT">FM 12-2387/12726, 2007-09-19</mets:altRecordID>
  <mets:altRecordID TYPE="REFERENCECODE">SE/RA/123456/24/P</mets:altRecordID>
  <mets:altRecordID TYPE="PREVIOUSREFERENCECODE">SE/FM/123/123.1/123.1.3</mets:altRecordID>
</mets:metsHdr>

```

### 7.1.3 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 the HL7 FHIR schema for a Patient Resource (<https://www.hl7.org/fhir/patient.html>) is suggested but is not mandatory as local regulations and standards may be used.

Table 3: Root METS descriptive metadata section

ID	Name and location	Description and usage	Cardinality Level
<b>EHR11</b> <b>Ref CSIP17</b>	Descriptive metadata dmdSec	There MUST be reference(s) to the Patient Administrative Information held in the metadata/descriptive folder of the package.	1..n MUST
<b>EHR12</b>	Reference to the document with the	There MUST be reference(s) to the descriptive metadata file(s) located in the "metadata" section of the IP.	1..n

<b>Ref CSIP21</b>	descriptive metadata  dmdSec/mdRef		MUST
<b>EHR13</b>	Type of metadata	The value for the metadata type is set to "OTHER".	1..1
<b>Ref CSIP25</b>	dmdSec/mdref/@MDTYPE		MUST
<b>EHR14</b>	Type of other metadata  dmdSec/mdref/@OTHERMDTYPE	Specifies the type of metadata used for Patient Personal Information.  For example, the value will be "FHIR.Patient" if the FHIR Patient resource is used.	1..1  SHOULD

Example 3: Root METS dmdSec with reference to HL7 FHIR Patient Administrative Information

```
<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/patient1.xml"
    xlink:type="simple"
    MDTYPE="OTHER"
    OTHERMDTYPE="FHIR.Patient"
    MIMETYPE="application/xml"
    SIZE="643"
    CREATED="2018-04-24T14:11:29.309+01:00"
    CHECKSUM="66EEDDF0A22EF57078694B67CA45DF301034556D6CB493531356C4FFE92AB6B1"
    CHECKSUMTYPE="SHA-256" />
</mets:dmdSec>
```

#### 7.1.4 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 representation should be held in the representation metadata folder. Administrative metadata which is specific to the content of the representation(s) is held at the representation level (see 7.2.4).

#### 7.1.5 Root METS file metadata 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 use of the METS fileSec element at the package level becomes mandatory in order to reference the files held within the representation.

Table 4: Root METS file metadata section

ID	Name and Location	Description and Usage	Cardinality Level
<b>EHR15</b> <b>Ref CSIP58</b>	File section 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
<b>EHR16</b> <b>Ref CSIP59</b>	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
<b>EHR17</b> <b>Ref CSIP60</b>	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.	1..n MUST
<b>EHR18</b> <b>Ref CSIP113</b>	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".	1..n MUST
<b>EHR19</b> <b>Ref CSIP114</b>	Representations file group fileSec/fileGrp/@USE	A pointer to the METS document describing the representation(s) or a pointer to the content being transferred MUST be present in one or more file groups with the 'mets/fileSec/fileGrp/@USE' attribute "Representations".	1..n MUST
<b>EHR20</b> <b>Ref CSIP61</b>	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
<b>EHR21</b>	Reference to descriptive metadata group fileSec/fileGrp/@USE	All Patient Personal Information included in the information package MUST be referenced from a file group element with 'mets/fileSec/fileGrp/@USE' attribute "Patient Personal Information"	0..n MUST
<b>EHR22</b> <b>Ref CSIP62</b>	Content information type specification fileSec/fileGrp/@csip:CONTENTINFORMATIONTYPE	The value of the attribute 'mets/fileSec/fileGrp/@csip:CONTENTINFORMATIONTYPE' is set to "OTHER".	1..1 MUST
<b>EHR23</b> <b>Ref CSIP63</b>	Other content information type specification	The value of the attribute 'mets/fileSec/fileGrp/@csip:OTHERCONTENTINFORMATIONTYPE' is set to "eHealth1"	1..1 MUST

```
fileSec/fileGrp/@csip:OTHERCONTENT
INFORMATIONTYPE
```

#### Example 4: Root METS file metadata section

```
<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="160D71F56C2CE685CE7FBD679076FD76B3C67EE9AB5062F5EF5C99AE39C1F43B" CHECKSUMTYPE="SHA-256">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/File1.docx"/>
    </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="0FE9683451D0390BCDEF19CE10CFD287A2D944B6A33D246681FEF27F44FFAF1D" CHECKSUMTYPE="SHA-256">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/File2.docx"/>
    </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="4073D09CA1BAE023D5A7E2010819BF0E8A8EB3C015444D0673733630DE08461C" CHECKSUMTYPE="SHA-256">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="schemas/fhirpatient.xsd"/>
    </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:file>
  </mets:fileGrp>
  <mets:fileGrp ID="filegrp-representation" USE="Representations/submission/data" csip:CONTENTINFORMATIONTYPE="eHealth1">
    <mets:file ID="file-ptr-representation-mets" 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/submission/METS.xml"/>
    </mets:file>
  </mets:fileGrp>
</mets:fileSec>
```

### 7.1.5 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. To allow for the inclusion of multiple Patient Medical Records in each package, the eHealth1 specification requires that each Patient Medical Record has a discrete div element.

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.

Table 5: Root METS structural map

ID	Name and location	Description and usage	Cardinality Level
<b>EHR24</b>	Representation division	There must be a discrete `div` element for each Patient Medical Record.	1..n
<b>Ref CSIP105</b>	structMap/div/div		MUST

### 7.1.6 Root METS file example

Example 5 shows an example of a whole METS document describing a submission information package following CITS eHealth1.

Example 5: Whole root METS example

```
<mets:mets
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns:mets="http://www.loc.gov/METS/"
  xmlns:xlink="http://www.w3.org/1999/xlink"
  xmlns:csip="https://DILCIS.eu/XML/METS/CSIPExtensionMETS"
  xmlns:sip="https://DILCIS.eu/XML/METS/SIPExtensionMETS"
  OBJID= "ehealth1-root-mets-example"
  TYPE= "OTHER"
  csip:OTHERTYPE="Patient Medical Records"
  csip:CONTENTINFORMATIONTYPE="eHealth1"
  PROFILE="https://earkehealth1.dilcis.eu/profile/E-ARK-eHealth1-ROOT.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: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: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="OTHER" TYPE="INDIVIDUAL" OTHERROLE="SUBMITTER">
    <mets:name>Sven Svensson</mets:name>
    <mets:note>Phone: 08-123456, Email: sven.svensson@mail.mail</mets:note>
  </mets:agent>
  <mets:agent ROLE="ARCHIVIST" TYPE="ORGANIZATION">
    <mets:name>The Swedish health agency</mets:name>
    <mets:note csip:NOTETYPE="IDENTIFICATIONCODE">ID:1234567</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:altRecordID TYPE="SUBMISSIONAGREEMENT">http://submissionagreement.kb.se/dnr331-1144-
2011/20120711/</mets:altRecordID>
  <mets:altRecordID TYPE="PREVIOUSSUBMISSIONAGREEMENT">FM 12-2387/12726, 2007-09-
19</mets:altRecordID>
  <mets:altRecordID TYPE="REFERENCECODE">SE/RA/123456/24/P</mets:altRecordID>
  <mets:altRecordID TYPE="PREVIOUSREFERENCECODE">SE/FM/123/123.1/123.1.3</mets:altRecordID>
</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/patient1.xml"
    xlink:type="simple"
    MDTYPE="OTHER"
    OTHERMDTYPE="FHIR.Patient"
    MIMETYPE="application/xml"
    SIZE="643"
    CREATED="2018-04-24T14:11:29.309+01:00"
    CHECKSUM="66EEDDF0A22EF57078694B67CA45DF301034556D6CB493531356C4FFE92AB6B1"
    CHECKSUMTYPE="SHA-256" />
</mets:dmdSec>
<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="160D71F56C2CE685CE7FBD679076FD76B3C67EE9AB5062F5EF5C99AE39C1F43B" CHECKSUMTYPE="SHA-256">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/File1.docx"/>
    </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="0FE9683451D0390BCDEF19CE10CFD287A2D944B6A33D246681FEF27F44FFAF1D" CHECKSUMTYPE="SHA-256">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/File2.docx"/>
    </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="4073D09CA1BAE023D5A7E2010819BF0E8A8EB3C015444D0673733630DE08461C"
CHECKSUMTYPE="SHA-256">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="schemas/fhirpatient.xsd"/>
    </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:file>
  </mets:fileGrp>
  <mets:fileGrp ID="filegrp-representation" USE="Representations/submission/"
csip:CONTENTINFORMATIONTYPE="eHealth1">
    <mets:file ID="file-ptr-representation-mets" 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/submission/METS.xml"/>
    </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="csip-mets-example">
    <mets:div ID="struct-map-metadata-div" LABEL="Metadata" DMDID="dmd-ehealth-file"/>
    <mets:div
      ID="struct-map-documentation-div" LABEL="Documentation">
      <mets:fptr FILEID="filegrp-documentation"/>
    </mets:div>
    <mets:div ID="struct-map-schema-div" LABEL="Schemas">
      <mets:fptr FILEID="filegrp-schemas"/>
    </mets:div>
    <mets:div ID="struct-map-reps-sub-div" LABEL="Representations/submission">
      <mets:mptr LOCTYPE="URL" xlink:type="simple" xlink:href="representations/submission/METS.xml"
xlink:title="file-grp-rep-sub"/>
    </mets:div>
  </mets:div>
</mets:structMap>
</mets:mets>

```

## 7.2 Representation METS

The representation METS file is used to describe the data structure as included in the data folder via the structMap element and to reference any additional descriptive metadata

### 7.2.1 Representation METS root element

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

Table 6: Representation METS root element

ID	Name and location	Description and usage	Cardinality Level
<b>EH1</b> <b>Ref SIP 1</b>	Package 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 rename/ID of the representation (i.e. the name of the top-level representation folder).	1..1 MUST
<b>EH2</b> <b>Ref SIP2</b>	METS profile mets/@PROFILE	The value is set to "https://earkehealth1.dilcis.eu/profile/E-ARK-eHealth1-REPRESENTATION.xml"	1..1 MUST
<b>EH3</b> <b>Ref CSIP 2</b>	Content category mets/@TYPE	The `mets/@TYPE` attribute is set to the value "OTHER"	1..1 MUST
<b>EH4</b> <b>Ref CSIP 3</b>	Other content category mets/@csip:OTHERTYPE	The `mets/@csip:OTHERTYPE` attribute is set to the value "Patient Medical Records"	1..1 MUST

<b>EH5</b>	Content information type specification	The `mets/@csip:CONTENTINFORMATIONTYPE` attribute is set to the value "eHealth1"	1..1
<b>Ref CSIP 4</b>			<b>MUST</b>
	mets/@csip:CONTENTINFORMATIONTYPE		

Example 6: Representation METS root element example.

```
<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="ehealth1-root-mets-example-submission"
  TYPE="OTHER"
  csip:OTHERTYPE="Patient Medical Records"
  csip:CONTENTINFORMATIONTYPE="eHealth1"
  PROFILE="https://earksip.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://earksip.dilcis.eu/schema/DILCISExtensionMETS.xsd
  https://dilcis.eu/XML/METS/SIPExtensionMETS
  https://earksip.dilcis.eu/schema/DILCISExtensionSIPMETS.xsd">
</mets:mets>
```

### 7.2.2 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.

### 7.2.3 Representation METS descriptive metadata section (element dmdSec)

The Representation METS may contain additional descriptive metadata within the metadata/descriptive folder. This descriptive metadata will be related to the patient Cases and can contain clinical information (diagnoses, conditions, procedures, allergies, family history, care plans) such as can be found in the HL7 FHIR Clinical Module (<https://www.hl7.org/fhir/clinicalsummary-module.html>), that have been extracted from the source EMR system. 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](http://www.snomed.org)) is encouraged. Where used, references to the specific codings should be given together with relevant version information.

Table 7: Representation descriptive metadata section (element dmdSec)

ID	Name and location	Description and usage	Cardinality Level
----	-------------------	-----------------------	-------------------

<b>EH6</b> <b>CSIP17</b>	Descriptive metadata  dmdSec	Used to reference Case 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 “rename/metadata” section of the representation.	1..n  MUST
<b>EH7</b> <b>Ref CSIP18</b>	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
<b>EH8</b> <b>Ref CSIP19</b>	Descriptive metadata creation date  dmdSec/@CREATED	Creation date of the descriptive metadata in this section.	1..1  MUST
<b>EH9</b> <b>Ref CSIP20</b>	Status of the descriptive metadata  dmdSec/@STATUS	Indicates the status of the package using a fixed vocabulary.	0..1  SHOULD
<b>EH10</b> <b>Ref CSIP21</b>	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” section of the representation.	1..1  MUST
<b>EH11</b> <b>Ref CSIP25</b>	Type of metadata dmdSec/mdref/@MDTYPE	The value for the metadata type is set to “OTHER”.	1..1  MUST
<b>EH12</b>	Type of other metadata dmdSec/mdref/@eHealth1:OTHERMDTYPE	Specifies the type of metadata used for Case clinical information.  For example, the value will be “FHIR.Condition” if the FHIR Condition resource is used	1..1  MUST

Example 7: Representation METS dmdSec with reference to HL7 FHIR case clinical data

```
<mets:dmdSec ID="dmd1-ehealth" CREATED="2018-04-24T15:27:45.702+01:00" STATUS="CURRENT">
  <mets:mdRef
    LOCTYPE="URL"
    xlink:type="simple"
```

```

xlink:href="metadata/descriptive/condition1.xml"
MDTYPE="OTHER"
OTHERMDTYPE="FHIR.condition"
MIMETYPE="application/xml"
SIZE="758"
CREATED="2018-04-24T14:37:49.609+01:00"
CHECKSUM="31C54EC8D5632B262A62CC3D691A8A6A3DD647670865BE8596D2A7F62DBBC6AB"
CHECKSUMTYPE="SHA-256"/>
</mets:dmdSec>

```

#### 7.2.4 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 "repID/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.

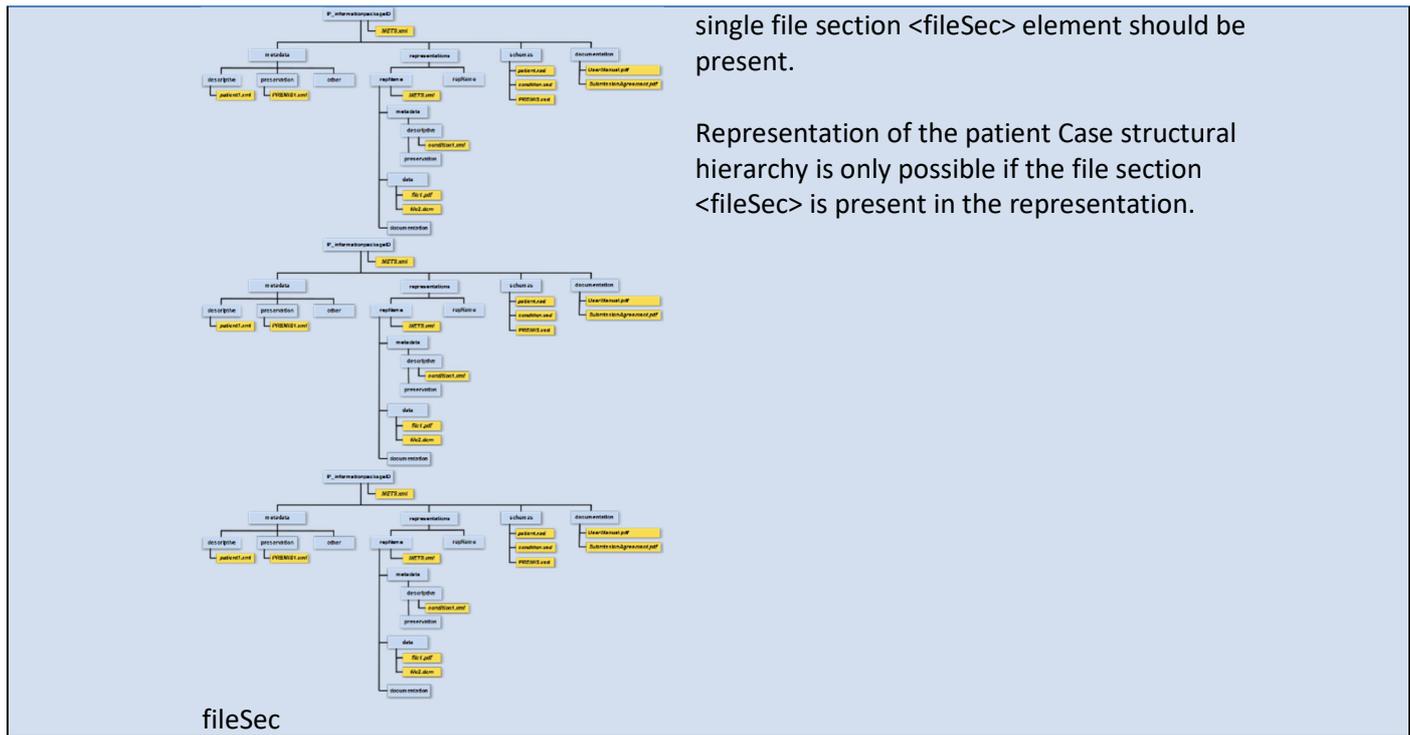
In eHealth1 it is required that any rights or digital provenance metadata that is general to the package can be held within the root metadata folder and that any rights or digital provenance metadata that is specific to the data held in the representation should be held in the representation metadata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

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

#### 7.2.5 Representation METS file section (element fileSec)

Table 8: Representation METS file section (element fileSec)

ID	Name and Location	Description and Usage	Cardinality Level
<b>EH13</b>	File section	The transferred content within the representation is referenced from the file	1..1 MUST
<b>Ref CSIP58</b>		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.

fileSec

<p><b>EH14</b> <b>Ref CSIP114</b></p>	<p>Representation file groups fileSec/fileGrp</p>	<p>The representation file groups contain the file elements that describe the Case digital objects.</p>	
		<p>The file group contains the file elements which describe the digital objects. The hierarchical structure of the Patient Medical Records within the CITS eHealth1 requires that digital objects (groups of files that form a single intellectual entity) can be described through the structMap element.</p>	
<p><b>EH15</b> <b>Ref CSIP61</b></p>	<p>Reference to representation administrative metadata fileSec/filegrp/@ADMID</p>	<p>If administrative metadata has been provided at a representation level (i.e. there is rights and/or digital provenance metadata that is specific to the patient data) then this attribute refers to the &lt;admSec&gt; of the representation METS.xml by ID.</p>	<p>1..1 MAY</p>
<p><b>EH16</b></p>	<p>Reference to descriptive metadata</p>	<p>All Patient Personal Clinical Information included in the representation MUST be referenced from a file group element with 'mets/fileSec/fileGrp/@USE' attribute "Patient Clinical Information"</p> <p>For example, as can be described using the resource FHIR.Condition.</p>	
<p><b>EH17</b> <b>Ref CSIP62</b></p>	<p>Content information type specification fileSec/fileGrp/@csip:CONTENTINFORMATIONTYPE</p>	<p>The value of the attribute 'CONTENTINFORMATIONTYPE` is set to "OTHER"</p>	<p>1..1 MUST</p>

<b>EH18</b> <b>Ref CSIP63</b>	Other content information type specification  fileSec/fileGrp/@csip:OTHERCONTENTINFORMATIONTYPE	The value of the attribute OTHERCONTENTINFORMATIONTYPE` is set to "eHealth1"	1..1 MUST
<b>EH19</b> <b>Ref CSIP64</b>	Description of the use of the representation file group  fileSec/fileGrp/@USE	The value in `mets/fileSec/fileGrp/@USE` is the name of the folder structure to the data, e.g "Representations/submission/data".	1..1 MUST
<b>EH20</b> <b>Ref CSIP65</b>	Representation 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
<b>EH21</b> <b>Ref CSIP66</b>	File  fileSec/filegrp/file	The file group <fileGrp> contains the file elements which describe the digital objects.	1..1 MUST
<b>EH22</b>	Component byte stream  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
<b>EH23</b>	Component byte stream identifier  fileSec/filegrp/file/stream@ID	A unique xml:id for this object across the package.	1..1 MUST
<b>EH24</b>	Stream mimetype  fileSec/fileGrp/file/stream@MIMETYPE	The IANA mime type for the referenced byte stream.	1..1 MUST
<b>EH25</b>	Stream original identification  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
<b>EH26</b>	Stream reference to the administrative metadata  fileSec/fileGrp/file/stream/@ADMID	If administrative metadata has been provided for the byte stream, this attribute can reference it by means of an ID.	0..1 MAY
<b>EH27</b>	Stream reference to descriptive metadata  fileSec/fileGrp/file/stream/@DMDID	If descriptive metadata has been provided for the byte stream, this attribute can reference it by means of an ID.	0..1 MAY

Example 9: METS example of the representation METS file section without a component byte stream.

```
<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.wordprocessingml.document" SIZE="2352367" CREATED="2012-08-15T12:08:15.432+01:00" CHECKSUM="D2DF16632617402BF279D61DBC9F73675E033ABA6B94A78D4B9607CE5CAAF3E" CHECKSUMTYPE="SHA-256">
  <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/File.docx"/>
</mets:file>
<mets:file ID="file-ptr-documentation-file2" MIMETYPE="application/vnd.openxmlformats-officedocument.wordprocessingml.document" 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="documentation/File2.docx"/>
</mets:file>
</mets:fileGrp>
<mets:fileGrp ID="filegrp-representation" USE="/data/" csip:CONTENTINFORMATIONTYPE="eHealth1">
  <mets:file ID="file-ptr-representation-file1" MIMETYPE="PDF" SIZE="2314264" CREATED="2018-04-24T14:37:49.617+01:00" CHECKSUM="9EC53E81CDEC19FA665BDDDB30ECE11067EF536F3599C67713DCE0FF2FCD81CC7" CHECKSUMTYPE="SHA-256" ADMID="digiprov-premis-file-2 digiprov-premis-file-1">
    <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="/data/patientnotes0.pdf"/>
  </mets:file>
  <mets:file ID="file-ptr-representation-file2" MIMETYPE="PDF" SIZE="1385742" CREATED="2018-04-24T15:27:39.617+01:00" CHECKSUM="0EA28B91A3B36D1D90E598301E6F1556B073BAE7DA9C2F242D93D2091D10D426" CHECKSUMTYPE="SHA-256" ADMID="digiprov-premis-file-4 digiprov-premis-file-3">
    <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="/data/patientnotes1.pdf"/>
  </mets:file>
  <mets:file ID="file-ptr-representation-file3" MIMETYPE="PDF" SIZE="1341744" CREATED="2018-04-24T14:37:49.617+01:00" CHECKSUM="8FE5B1B292B0CD7741C2CD33221AAA80B6B4EB576D129A2CB5C16D7101CB1C1C" CHECKSUMTYPE="SHA-256" ADMID="digiprov-premis-file-6 digiprov-premis-file-5">
    <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="/data/patientnotes2.pdf"/>
  </mets:file>
</mets:fileGrp>
</mets:fileSec>

```

Example 10: METS example of the representation METS file section with a component Byte Stream

```

<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.wordprocessingml.document" SIZE="153246" CREATED="2012-08-15T12:08:15.432+01:00" CHECKSUM="1E07128C776A1228EC192CA41CC75A763479246F096F68D4EB058ACE5C94D428" CHECKSUMTYPE="SHA-256">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/File.docx"/>
    </mets:file>
    <mets:file ID="file-ptr-documentation-file2" MIMETYPE="application/vnd.openxmlformats-officedocument.wordprocessingml.document" SIZE="5214532" CREATED="2012-08-15T12:08:15.432+01:00" CHECKSUM="46E46C9CC1A9F07FAA42BFA1853C1466B235AD58DD0D827C9D06C1910A1B9366" CHECKSUMTYPE="SHA-256">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/File2.docx"/>
    </mets:file>
  </mets:fileGrp>
  <mets:fileGrp ID="filegrp-representation" USE="/data/" csip:CONTENTINFORMATIONTYPE="eHealth1">
    <mets:file ID="file-ptr-representation-file1" MIMETYPE="PDF" SIZE="1337808" CREATED="2018-04-24T14:37:49.617+01:00" CHECKSUM="E5C853A25A1A86ADDBFA5F54FBF5F0F2D97E8F257E2DB7640CA85E462D38652A" CHECKSUMTYPE="SHA-256" ADMID="digiprov-premis-file-7 digiprov-premis-file-8">
      <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="/data/patientnotes0.pdf"/>
    </mets:file>
  </mets:fileGrp>
</mets:fileSec>

```

```

</mets:file>
<mets:file ID="file-ptr-representation-file2" MIMETYPE="application/mp4" SIZE="3189002" CREATED="2018-04-
24T14:37:49.617+01:00" CHECKSUM="1A7FF5D05D4BEDBFD09447F633586646EF55F59480A1FF30B5D26D6866604F2F"
CHECKSUMTYPE="SHA-256" ADMID="digiprov-premis-file-2 digiprov-premis-file-1">
  <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="/data/procedure.mp4"/>
  <mets:stream ID="file-ptr-representation-file2-stream1" MIMETYPE="video/mp4" SIZE="4236737"
  CREATED="2018-04-24T14:37:49.617+01:00"
  CHECKSUM="3A4DF1ADB67D2E74F4A6A7E39A7714ED330F066144D0A8774DA83B1BB77FA9EB" CHECKSUMTYPE="SHA-
  256" ADMID="digiprov-premis-file-4 digiprov-premis-file-3"/>
  <mets:stream ID="file-ptr-representation-file2-stream2" MIMETYPE="audio/mp3" SIZE="1132354"
  CREATED="2018-04-24T14:37:49.617+01:00"
  CHECKSUM="7176A627870CFA3854468EC43C5A56F9BD8B30B50A983B8162BF56298A707667" CHECKSUMTYPE="SHA-256"
  ADMID="digiprov-premis-file-6 digiprov-premis-file-5"/>
</mets:file>
</mets:fileGrp>
</mets:fileSec>

```

### 7.2.6 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 CSIP105).

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

Table 9: Representation METS structural map

ID	Name and Location	Description and Usage	Cardinality Level
<b>EH28</b>	Structural description of the package	There MUST be one structural map following the requirements in the E-ARK SIP and thus E-ARK CSIP present	1..1 MUST
<b>EH29</b>	Structural description of the eHealth1 representation  structMap	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
<b>EH30</b> <b>Ref CSIP81</b>	Type of structural description structMap/@TYPE	The 'mets/structMap/@TYPE' attribute MUST take the value of "PHYSICAL" from the vocabulary.	1..1 MUST
<b>EH31</b> <b>Ref CSIP82</b>	Name of the structural description structMap/@LABEL	The label attribute is set to value "eHealth1" from the vocabulary.	1..1 MUST

<b>EH32</b>	Structural description identifier	An identifier for the structural description <structMap> used for referencing inside the package. It must be unique within the package.	1..1 MUST
<b>Ref CSIP83</b>	structMap/@ID		
<b>EH33</b>	Main structural division	The structural map comprises a single division.	1..1 MUST
<b>Ref CSIP84</b>	structMap/div		
<b>EH34</b>	Main structural division identifier	Mandatory, 'xml:id' identifier must be unique within the package.	1..1 MUST
<b>Ref CSIP85</b>	structMap/div/@ID		
<b>EH35</b>	Main structural division label	The package's top-level structural division <div> element's '@LABEL' attribute value must be identical to the package identifier, i.e. the same value as the 'mets/@OBJID' attribute.	1..1 MUST
<b>RefCSIP86</b>	structMap/div/@LABEL		
<b>EH36</b>	Metadata division	The metadata referenced in the representation metadata section is described in the structural map within one sub-division.	1..1 MUST
<b>Ref CSIP88</b>	structMap/div/div		
<b>EH37</b>	Metadata division identifier	Mandatory xml:id identifier must be unique within the package.	1..1 MUST
<b>Ref CSIP89</b>	structMap/div/div/@ID		
<b>EH38</b>	Metadata division label	The metadata division <div> element's '@LABEL' attribute value must be "Metadata".	1..1 MUST
<b>Ref CSIP90</b>	structMap/div/div/@LABEL		
<b>EH39</b>	Metadata division administrative metadata referencing	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 <amdSec> identifiers are listed in a single '@ADMID' using spaces as delimiters.	0..1 SHOULD
<b>Ref CSIP91</b>	structMap/div/div/@ADMID		
<b>EH40</b>	Metadata division descriptive metadata referencing	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 5.2.2.3	0..1 SHOULD
<b>Ref CSIP92</b>	structMap/div/div/@DMDID		
<b>EH41</b>	Documentation division	The documentation referenced in the file section file groups is described in the structural map with one sub-division.	0..1 SHOULD
<b>Ref CSIP93</b>	structmap/div/div/		
<b>EH42</b>	Documentation division identifier	Mandatory, xml:id identifier must be unique within the package.	1..1 MUST

<b>Ref CSIP94</b>	structMap/div/div/@ID		
<b>EH43</b>	Documentation division 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
<b>Ref CSIP95</b>	structMap/div/div/@LABEL		
<b>EH44</b>	Documentation file referencing	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
<b>Ref CSIP96</b>	structMap/div/div/@CONTENTID		
<b>EH45</b>	Documentation file group reference pointer	A reference, by ID, to the “Documentation” file group.	
<b>Ref CSIP116</b>	structMap/div/div/fptr/@ID	Related to the requirements which describe the “Documentation” file group in CSIP and the requirement which describes the file group identifier.	
<b>EH46</b>	Data division structMap/div/div/	Within eHealth1 Patient Cases 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 within the data division.	1..1 MUST
<b>EH47</b>	Data division identifier structMap/div/div/@ID	Mandatory, xml:id identifier must be unique within the package.	1..1 MUST
<b>EH48</b>	Data division label structMap/div/div/@LABEL	The package’s data division <div> element must have the `@LABEL` attribute value “DATA”, taken from the vocabulary.	1..1 MUST
<b>EH49</b>	Patient Case division structMap/div/div/div	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” folder within the representation and may contain any number of Sub-cases and Documents. Every package must contain at least one Patient Case. A Case is represented within a second level sub-division.	1..n MUST
<b>EH50</b>	Patient Case division identifier structMap/div/div/div/@ID	Mandatory, xml:id identifier must be unique within the package.	1..1 MUST
<b>EH51</b>	Patient Case division label structMap/div/div/div/@LABEL	The Patient Case division `<div>` element must have the `@LABEL` attribute value “DOCUMENT”, taken from the vocabulary.	1..1 MUST
<b>EH52</b>	Document division structMap/div/div/div/div	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

<b>EH53</b>	Document division identifier  structMap/div/div/div/div/@ID	Mandatory, xml:id identifier must be unique within the package.	1..1 MUST
<b>EH54</b>	Document division label  structMap/div/div/div/div/@LABEL	The Document division <div> element must have the '@LABEL' attribute value "DOCUMENT", taken from the vocabulary.	1..1 MUST
<b>EH55</b>	Data File division  structMap/div/div/div/div/div	Data Files are components which 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
<b>EH56</b>	Data File division identifier  structMap/div/div/div/div/div/@ID	Mandatory, xml:id identifier must be unique within the package.	1..1 MUST
<b>EH57</b>	Data File division label  structMap/div/div/div/div/div/@LABEL	The Data File division <div> element must have the '@LABEL' attribute value "DATAFILE", taken from the vocabulary.	1..1 MUST
<b>EH58</b>	Data File division file group references  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
<b>EH59</b>	Data File division file group references  structMap/div/div/div/div/div/div/fptr/@FILEID	The pointer to the identifier for the file group containing the data files.	1..1 MUST
<b>EH60</b>	Sub-case division  StructMap/div/div/div/div	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
<b>EH61</b>	Sub-case division identifier  StructMap/div/div/div/div/@ID	Mandatory, xml:id identifier must be unique within the package.	1..1 MUST
<b>EH62</b>	Sub-case division label  structMap/div/div/div/div/@LABEL	The Sub-case division <div> elements must have the '@LABEL' attribute value "SUBCASE", taken from the vocabulary.	1..1 MUST

<b>EH63</b>	Document division structMap/div/div/div/div/div	Each Patient Case or 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
<b>EH64</b>	Document division identifier structMap/div/div/div/div/div/@ID	Mandatory, xml:id identifier must be unique within the package.	1..1 MUST
<b>EH65</b>	Document division label StructMap/div/div/div/div/div/@LABEL	The Sub-case division <div> element must have the @LABEL attribute value "DOCUMENT", taken from the vocabulary.	1..1 MUST
<b>EH66</b>	Data File division structMap/div/div/div/div/div/div/	Data Files are components which 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
<b>EH67</b>	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
<b>EH68</b>	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
<b>EH69</b>	Data File division file group references structMap/div/div/div/div/div/div/fptr/@FILEID	The pointer to the identifier for the file group containing the data files	1..1 MUST

Example 11: METS example of the representation METS structMap section with Case, Sub-case, Documents and Data Files

```
<mets:structMap ID="struct-map-example-2" TYPE="PHYSICAL" LABEL="eHealth1" >
  <mets:div ID="struct-map-example-div" LABEL="struct-map-example-div">
    <mets:div ID="struct-map-metadata-div" LABEL="Metadata" DMDID="dmd-ead-file" ADMID="digiprov-premis-file-1 digiprov-premis-file-2 digiprov-premis-file-3 digiprov-premis-file-4"/>
    <mets:div ID="struct-map-data-div" LABEL="DATA">
      <mets:div ID="struct-map-case-1-div" LABEL="CASE">
        <mets:div ID="struct-map-case-1-document-div" LABEL="DOCUMENT">
          <mets:div ID="struct-map-case-1-document-datafile-div" LABEL="DATAFILE">
            <mets:fptr FILEID="filegrp-representation">
          </mets:fptr>
        </mets:div>
      </mets:div>
    </mets:div>
    <mets:div ID="struct-map-case-2-div" LABEL="CASE">
      <mets:div ID="struct-map-case-2-subcase-div" LABEL="SUBCASE">
        <mets:div ID="struct-map-case-2-subcase-document-div" LABEL="DOCUMENT">
```



<b>Patient Personal Information</b>	Demographics and other administrative information about an individual receiving care or other health-related service. For example, as can be described using the resource FHIR.Patient.
<b>eHealth1</b>	The specification for eHealth1 is used.
<b>FHIR</b>	The specification for Fast Healthcare Interoperability Resources- FHIR.
<b>FHIR.Patient</b>	The FHIR resource for Patient Personal Information. <a href="https://www.hl7.org/fhir/patient.html">https://www.hl7.org/fhir/patient.html</a>
<b>Patient Clinical Information</b>	Clinical information about a specific patient
<b>FHIR.condition</b>	Possible resource example for Patient Clinical Information using the FHIR resource 'Condition'.
<b>FHIR.allergyintolerance</b>	Possible resource example for Patient Clinical Information using the FHIR resource 'Allergyintolerance'.
<b>Case</b>	See 6.2, a Case is a folder located in the "Data" folder within the representation and may contain any number of Sub-cases and Documents.
<b>Sub-case</b>	See 6.2, a Sub-case is a folder located in a Case folder within the representation and must contain at least one Document.
<b>Document</b>	See 6.2, each Case or 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).
<b>Data File</b>	See 6.2, Data Files are components which 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.

## 9 Postface

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<b>Dissemination Level</b>		
<b>P</b>	<b>Public</b>	<b>X</b>
<b>C</b>	<b>Confidential, only for members of the Consortium and the Commission Services</b>	

## REVISION HISTORY AND STATEMENT OF ORIGINALITY

### Submitted Revisions History

Revision No.	Date	Authors(s)	Organisation	Description
0.1.0	30th September 2020	Stephen Mackey	piql AS	Draft for review

**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.

DRAFT