CITS eHealth1

Specification for the E-ARK Content Information Type
Specification for Patient Medical Records

DILCIS BOARD

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1 Preface

1.1 Aim of the specification

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

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

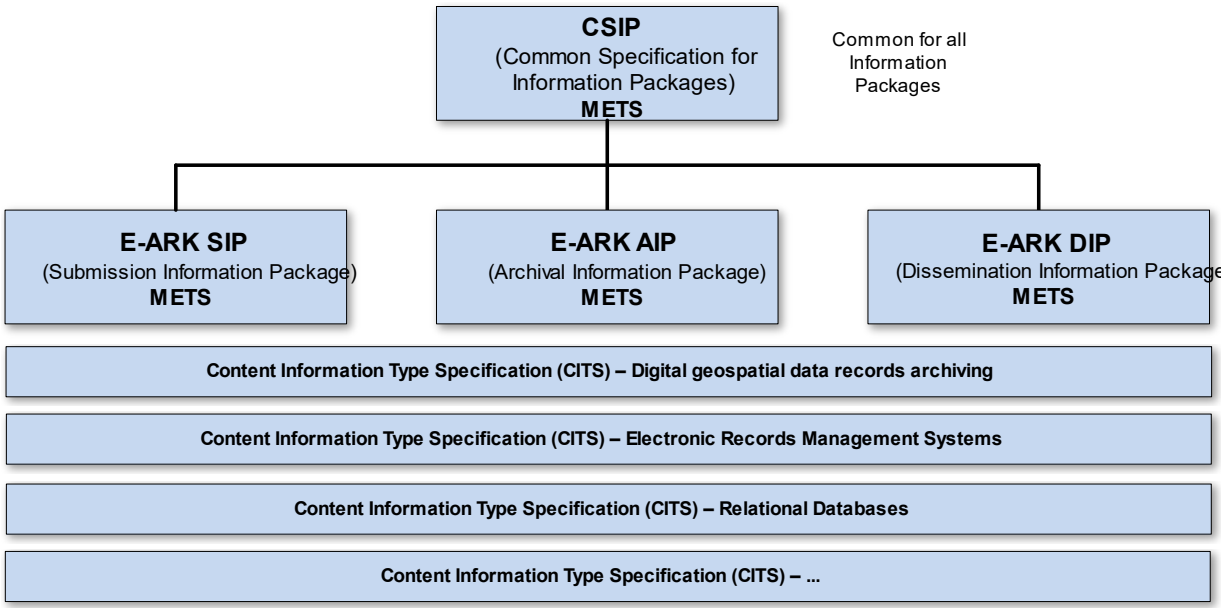

Figure I: Diagram showing E-ARK specification dependency hierarchy. Note that the image only shows a selection of the published CITS and isn't an exhaustive list.

Specification	Aim and Goals
Common Specification for Information Packages	This document introduces the concept of a Common Specification for Information Packages (CSIP). Its three main purposes are to: • Establish a common understanding of the requirements, which need to be met in order to achieve interoperability of Information Packages. • Establish a common base for the development of more specific Information Package definitions and tools within the digital preservation community. • 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	Aim and Goals
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, e.g. document and image collections, databases or geographical data. • Enhance interoperability between Producers and Archives. • Recommend best practices regarding metadata, content and structure of Submission Information Packages.
E-ARK AIP	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 geographical data. • Recommend a set of metadata related to the structural and the preservation aspects of the AIP as implemented by the eArchiving Reference Implementation (earkweb). • Ensure the format is suitable to store large quantities of data.
E-ARK DIP	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	The main aim and goal of a Content Information Type Specification is to: • 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. 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/).

1.2 Organisational support

This specification is maintained by the Digital Information LifeCycle Interoperability Standards Board (DILCIS Board, http://dilcis.eu/). The role of the DILCIS Board is to enhance and maintain the draft specifications developed in the European Archival Records and Knowledge Preservation Project (E-ARK project, http://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/.

1.3 Authors & Revision History

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

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2 Glossary

Table 1: Glossary

	Description
Archival Creator	Organisation unit or individual that creates records and/or manages records during their active 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).
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.
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.
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.
Healthcare Provider	An organisation providing primary or secondary healthcare. Can be general in scope or specialised, public or private.
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.
Patient Clinical Information	Structured patient clinical data related to Cases such as diagnoses, procedures, medication, allergies, etc.
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 Personal Information	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. Information will include but not be limited to name, patient ID(s), administrative gender, date of birth, date of death, address(es).
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.
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.
Submitting Organisation	Name of the organisation submitting the package to the archive.
Complete Patient Medical Record	The sum of the submissions of patient Records made for an individual.

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 METS profiles for the Root and Representation METS files.

3.2 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 deceased 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.
- Implementation of Electronic Health Record (EHR) systems is not widespread, and the creation of an eHealth archive that aggregates information from both EMR and EHR systems is considered to be a special case that 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 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. 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.

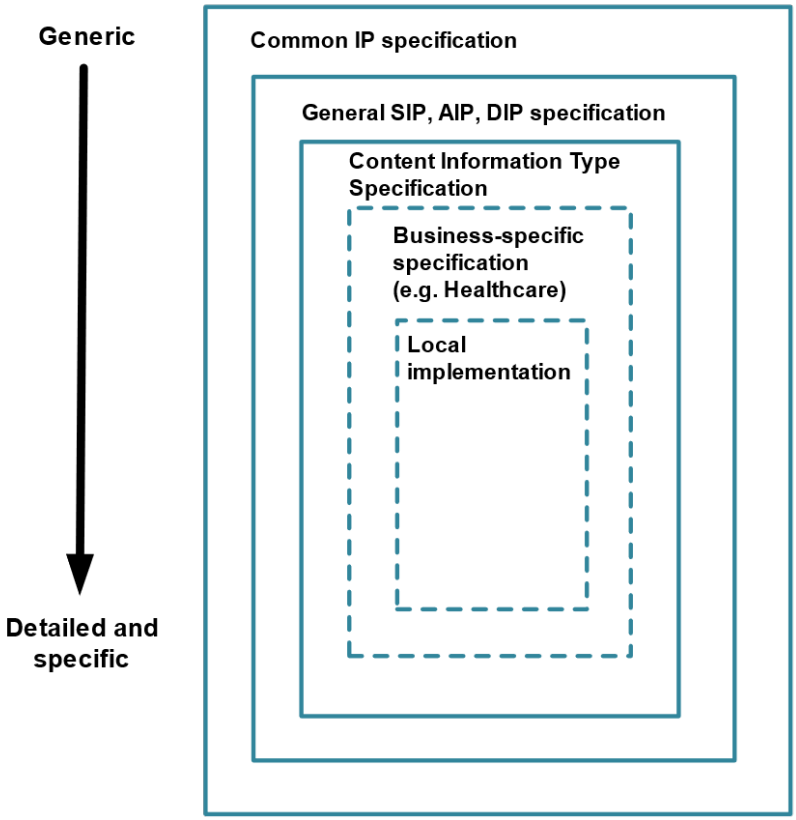

Figure 1: Data Model Structure

The eHealth1 specification omits all information that is specific to a 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 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 resource for patient personal information can be substituted for a local schema, but at minimum, there must be a metadata file with patient names and identifiers as specified in EHR12).

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."[1] 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 digital versions of 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 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 paper records.

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

[1] 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/

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."[2]

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[3] 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 sometimes 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 of 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 principle 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)[4] 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.

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

In order to achieve use case a, 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 b. 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

[2] https://www.healthcareusability.com/article/terminology-hit-emr-ehr

[3] HIMSS Analytics himssanalytics.org

[4] https://ehandbok.arkivverket.no/folder/92

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 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 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[5]

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.[6]

FHIR provides resources that can be used for the standardised description of Patient Personal Information and Patient Clinical Information, 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[7]

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:

- 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 Clinical Information. The use of international standards such as ICD within

[5] https://www.hl7.org/fhir/summary.html
[6] https://en.wikipedia.org/wiki/Fast_Healthcare_Interoperability_Resources
[7] https://www.who.int/classifications/icd/en/

supplied clinical metadata is encouraged but will be limited by their use within the source EMR or EHR system.

6.1.3 SNOMED[8]

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 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.[9]

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 Clinical Information. 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[10]

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 that 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 Information.

6.1.5 eHealth DSI (eHealth Digital Service Infrastructure)[11]

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 in this context, 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 Medical Record in its entirety.

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 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 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 (it is an aggregation of Patient Medical Records), and

[8] http://www.snomed.org

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

[10] https://www.dicomstandard.org/current/

[11] https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHealth+DSI+Operations+Home

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 (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 in this specification to be impractical.

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 can 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 (see 7.3.2 and EHR12). 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 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 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 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 specialised tools (such as ffprobe for video container formats).

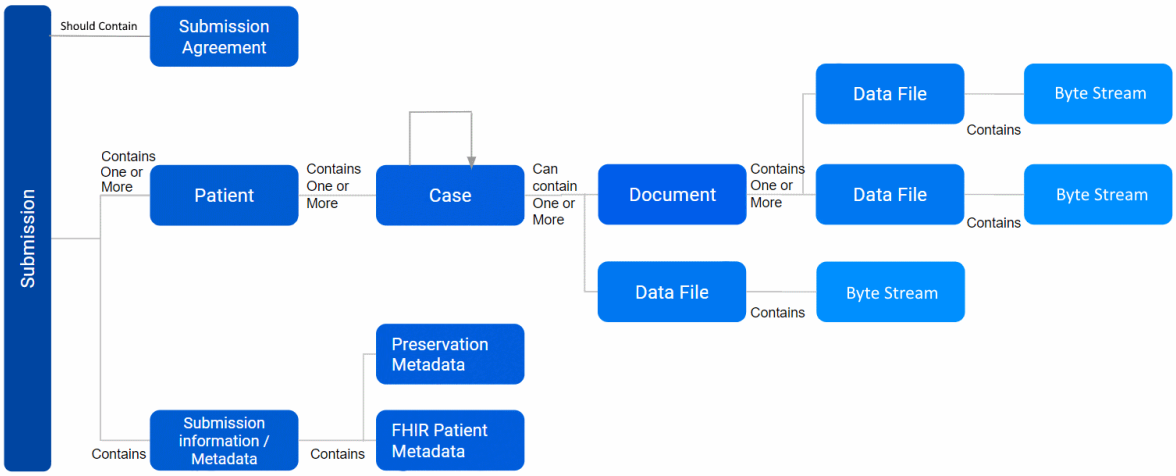

Figure 2: eHealth1 SIP Data Model

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 archived 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 4).

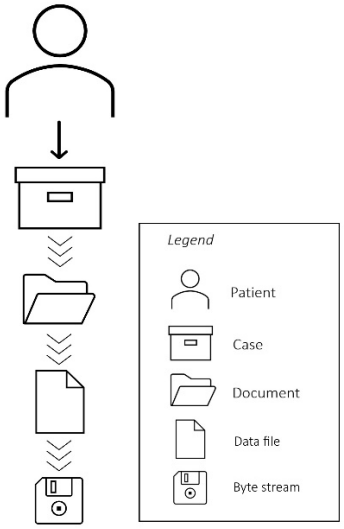

Figure 3: Archived Patient Medical Record as one file

6.3.2 Example 2: The archived 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 5).

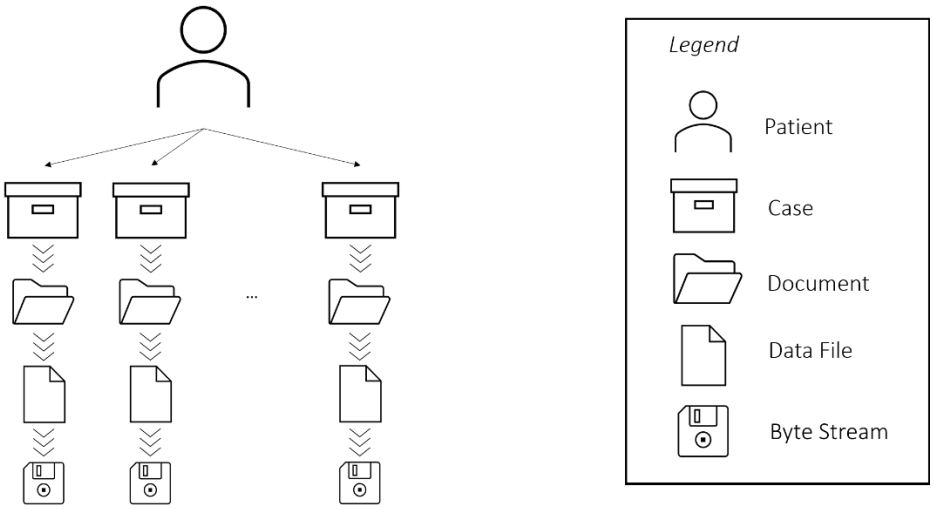

Figure 4 : Archived Patient Medical Record as a set of thematic files

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 6).

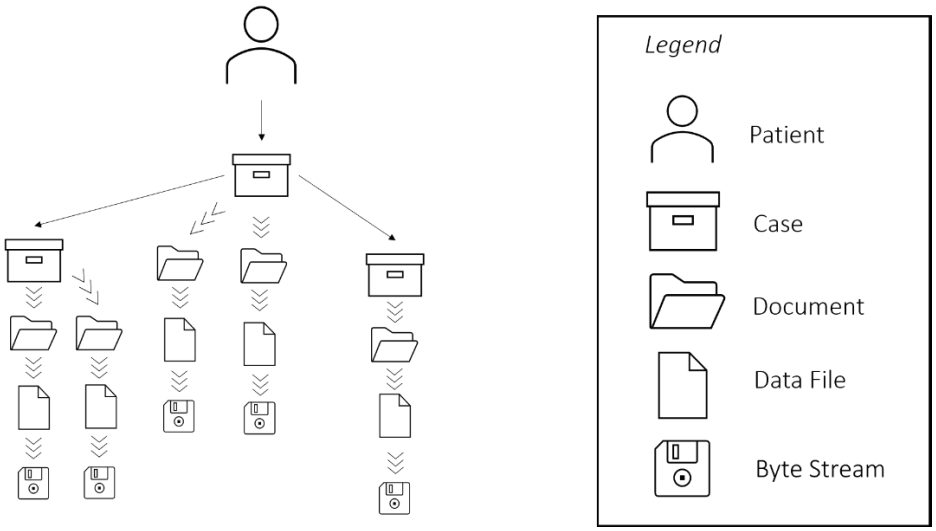

Figure 5: Archived Patient Medical Record as a set of Documents per Case or Sub-case

6.4 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.

6.5 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 the National Health Archive was for each AIP to consist of data from a single Patient and from a single Submitting Organisation (see 6.2).

Patient Medical Records are placed in multiple patient-related representations within the representations folder of the package. The ID of each representation should have a name that is unique within the package scope and relates to the patient's unique individual ID.

The Patient Medical Record representation should contain a METS file at its root (Representation METS). The folder structure for each should follow that defined by the CSIP and must have a 'data' folder. It is recommended but not mandated that within the 'data' folder that there are further folders that physically represent the Case, Sub-case, Document structure to aid human readability and navigation of the archive. If clinical descriptive metadata is to be supplied, the Patient Medical Record representation structure must include a folder '/metadata/descriptive', and any descriptive metadata files must be placed in this folder. Figure 7 shows an example of a folder structure for a representation where there are multiple patient submissions and clinical metadata included.

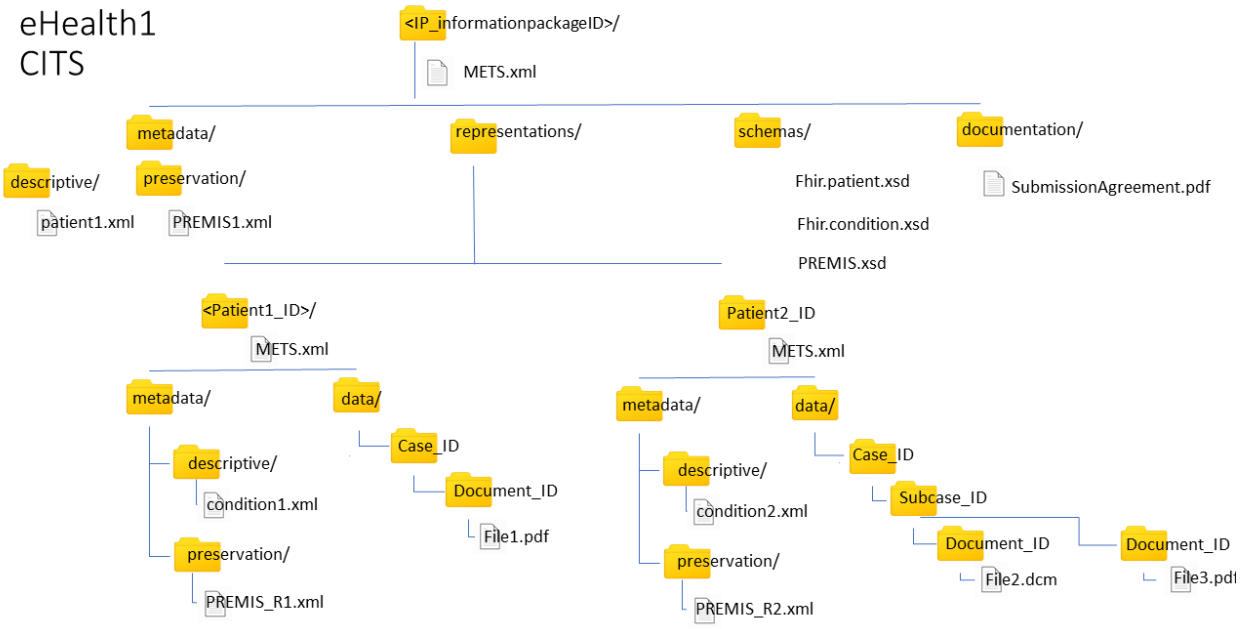

Figure 6: Example of Package Folder Structure with Multiple Patient Submissions and Case Structure

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 (Root 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 may contain information concerning either single or multiple patients. In the case of a multiple patient submission, there will be multiple Patient Record representations, each with its own Representation METS file.

7.2 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).

7.2.1 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 2: Root METS root element

ID	Name and location	Description and usage	Cardinality Level

EHR1 **Ref CSIP6**	METS profile mets/@PROFILE	The value is set to “https://citsehealth1.dilcis.eu/profile/E-ARK-eHealth1-ROOT.xml”	1..1 MUST
EHR2 **Ref CSIP2**	Content category mets/@TYPE	The `mets/@TYPE` attribute is set to the value “OTHER”	1..1 MUST
EHR3 **Ref CSIP 3**	Other content category mets/@csip:OTHERTYPE	The `mets/@csip:OTHERTYPE` attribute is set to the value “Patient Medical Records”	1..1 MUST
EHR4 **Ref CSIP 4**	Content information type specification mets/@csip:CONTENTINFORMATIONTYPE	The `mets/@csip:CONTENTINFORMATIONTYPE` attribute is set to the value " citesepj_v1_0" **See also:** Vocabulary Content information type specification	1..1 MUST

METS Example 1 : Root METS Element Example (element METS root)

```
<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=" citsehpj_v1_0 "
        PROFILE="https://citsehealth1.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>
```

7.2.2 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 3 : Root METS header section (element metsHdr)

ID	Name and location	Description and usage	Cardinality Level
EHR5 **Ref SIP5**	Submission Agreement metsHdr/altRecordID	There SHOULD be a reference to a Submission Agreement associated with the package as the SIP will contain personal data. @TYPE is used with the value "SUBMISSIONAGREEMENT". 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: http://www.loc.gov/standards/mets/profiles/00000041.xml A reference code for the Submission Agreement MAY be included with @TYPE used with the value "REFERENCECODE"	0..1 SHOULD
EHR6 **Ref SIP9**	Archival creator agent metsHdr/agent	A wrapper element that encapsulates the name of the organisation, the software and person that originally created the data being transferred. Please note that the creator organisation 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 **Ref SIP10**	Archival agent creator role metsHdr/agent/@ROLE	The role of the archival creator organisation is set to "CREATOR" Following the available vocabulary in METS.	1..1 MUST
EHR8 **Ref SIP11**	Archival agent creator type metsHdr/agent/@TYPE	The type of the archival creator agent is set to "ORGANIZATION".	1..1 MUST
EHR9 **Ref SIP12**	Archival agent creator name 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 **Ref SIP13**	Archival creator additional information 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

EHR11 **Ref SIP14**	Archival creator agent additional information metsHdr/agent/note/@csip:NOTETYPE	The archival creator agent note is typed with the value of "IDENTIFICATIONCODE"	1..1 MUST

METS Example 2 : Root METS Header with Submission Agreements (element METS Header)

```
<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="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="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>
```

7.2.3 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 4 : Root METS descriptive metadata section (element dmdSec)

ID	Name and location	Description and usage	Cardinality Level
EHR12 **Ref CSIP17**	Descriptive metadata dmdSec	There MUST be a reference to the Patient Personal Information held in the metadata/descriptive folder of the package. At minimum this file MUST contain patient names and unique identifiers and SHOULD contain personal and demographic information.	1..n MUST
EHR13 **Ref CSIP21**	Reference to the document with the descriptive metadata dmdSec/mdRef	There MUST be reference(s) to the descriptive metadata file(s) located in the "metadata" section of the IP. This is the path and filename of the descriptive metadata file, e.g "metadata/descriptive/fhirpatient.xml"	1..n MUST
EHR14 **Ref CSIP25**	Type of metadata dmdSec/mdref/@ MDTYPE	The value for the metadata type is set to "OTHER".	1..1 MUST
EHR15	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

METS Example 3 : Root METS Descriptive Metadata section with reference to HL7 FHIR Patient Personal Information (element dmdSec)

```
<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="fhirpatient"
        MIMETYPE="application/xml"
        SIZE="3733"
        CREATED="2018-04-24T14:11:29.309+01:00"
        CHECKSUM="66EEDDF0A22EF57078694B67CA45DF301034556D6CB493531356C4FFE92AB6B1"
        CHECKSUMTYPE="SHA-256" />
</mets:dmdSec>
```

7.2.4 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 representations should be held in the respective representation metadata folder, (see 7.2.4).

7.2.5 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, the use of the METS fileSec element at the package level becomes mandatory, such as to reference the mets files within each representation.

Table 5 : Root METS file metadata section (element fileSec)

ID	Name and Location	Description and Usage	Cardinality Level
EHR16 **Ref CSIP58**	File section fileSec	The transferred content is placed in representation folders and described by representation METS documents referenced from the Root METS file section. Only a single root file section <fileSec> element MUST be present.	1..1 MUST
EHR17 **Ref 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
EHR18 **Ref 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
EHR19 **Ref 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
EHR20 **Ref 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
EHR21 **Ref 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.	0..1 MAY

		For example, there are rights and/or digital provenance metadata that are general to the package.	
EHR22 **Ref CSIP62**	Content information type specification fileSec/fileGrp/@csip:CONTENTINFORMATIONTYPE	The value of the attribute `mets/fileSec/fileGrp/@csip:CONTENTINFORMATIONTYPE` is set to “citsehpj_v1_0 ”. **See also:** Vocabulary Content information type specification	1..1 MUST

METS Example 4 : Root METS File Section (element fileSec)

```
<mets:fileSec ID="filesec-example-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-patient1" USE="Representations"
csip:CONTENTINFORMATIONTYPE=" citsehpj_v1_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/patientrecord_123456//METS.xml"/>
```

```
            </mets:file>
        </mets:fileGrp>
<mets:fileGrp ID="filegrp-representation-patient2" USE="Representations" csip:CONTENTINFORMATIONTYPE="
citsehpj_v1_0 ">
            <mets:file ID="file-ptr-repmets2" 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/patientrecord_7891011/METS.xml"/>
            </mets:file>
        </mets:fileGrp>
<mets:fileGrp ID="filegrp-representation-patient3" USE="Representations" csip:CONTENTINFORMATIONTYPE="
citsehpj_v1_0 ">
            <mets:file ID="file-ptr-repmets3" 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/patientrecord__12131415/METS.xml"/>
            </mets:file>
        </mets:fileGrp>
    </mets:fileSec>
```

7.2.6 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 6 : Root METS structural map (element stuctMap)

ID	Name and location	Description and usage	Cardinality Level
EHR23 **Ref CSIP105**	Representation division structMap/div/div/div	There must be a discrete `div` element for each Patient Medical Record.	1..n MUST

METS Example 5: Root Structural Map

```
    <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-div1" LABEL="Representations/PatientRecord_123456">
              <mets:mptr LOCTYPE="URL" xlink:type="simple"
xlink:href="representations/patientrecord_123456/METS.xml" xlink:title="file-grp-rep-patient"/>
           </mets:div>
           <mets:div ID="struct-map-reps-sub-div2" LABEL="Representations/PatientRecord_7891011">
              <mets:mptr LOCTYPE="URL" xlink:type="simple"
xlink:href="representations/patientrecord_7891011/METS.xml" xlink:title="file-grp-rep-patient"/>
            </mets:div>
            <mets:div ID="struct-map-reps-sub-div3" LABEL="Representations/PatientRecord_12131415">
              <mets:mptr LOCTYPE="URL" xlink:type="simple"
xlink:href="representations/patientrecord_12131415/METS.xml" xlink:title="file-grp-rep-patient"/>
            </mets:div>
          </mets:div>
      </mets:structMap>
```

7.2.7 Root METS file example

Example 6 shows an example of a whole METS document describing a submission information package following CITS eHealth1.

METS Example 6 : Whole Root METS

```
<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=" citsehpj_v1_0"
        PROFILE="https://citsehealth1.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="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="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/patients.xml"
          xlink:type="simple"
          MDTYPE="OTHER"
          OTHERMDTYPE="fhirpatient"
          MIMETYPE="application/xml"
          SIZE="3733"
          CREATED="2018-04-24T14:11:29.309+01:00"
          CHECKSUM="66EEDDF0A22EF57078694B67CA45DF301034556D6CB493531356C4FFE92AB6B1"
          CHECKSUMTYPE="SHA-256" />
  </mets:dmdSec>
  <mets:fileSec ID="filesec-0ae05b23-44a0-44bf-afc1-6f4f8266c0e5">
        <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/patient.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-patient1” USE="Representations"
csip:CONTENTINFORMATIONTYPE=" citsehpj_v1_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/patientrecord__123456/METS.xml"/>
          </mets:file>
        </mets:fileGrp>
<mets:fileGrp ID="filegrp-representation-patient2" USE="Representations" csip:CONTENTINFORMATIONTYPE="
citsehpj_v1_0">
          <mets:file ID="file-ptr-repmets2" 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/patientrecord__7891011/METS.xml"/>
          </mets:file>
        </mets:fileGrp>
<mets:fileGrp ID="filegrp-representation-patient1" USE="Representations" csip:CONTENTINFORMATIONTYPE="
citsehpj_v1_0">
          <mets:file ID="file-ptr-repmets3" 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/patientrecord__12131415/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-div1" LABEL="Representations/PatientRecord_123456">
              <mets:mptr LOCTYPE="URL" xlink:type="simple"
xlink:href="representations/patientrecord_123456/METS.xml" xlink:title="file-grp-rep-patient"/>
            </mets:div>
            <mets:div ID="struct-map-reps-sub-div2" LABEL="Representations/PatientRecord_7891011">
              <mets:mptr LOCTYPE="URL" xlink:type="simple"
xlink:href="representations/patientrecord_7891011/METS.xml" xlink:title="file-grp-rep-patient"/>
            </mets:div>
            <mets:div ID="struct-map-reps-sub-div3" LABEL="Representations/PatientRecord_12131415">
              <mets:mptr LOCTYPE="URL" xlink:type="simple"
xlink:href="representations/patientrecord_12131415/METS.xml" xlink:title="file-grp-rep-patient"/>
            </mets:div>
          </mets:div>
        </mets:structMap>
      </mets:mets>
```

7.3 Representation METS

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

7.3.1 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 7 : Representation METS root element (element fileSec)

ID	Name and location	Description and usage	Cardinality Level
EH1 **Ref CSIP 1**	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 or Patient Medical Record folder, which MUST include the primary patient identifier).	1..1 MUST
EH2 **Ref SIP2**	METS profile mets/@PROFILE	The value is set to “https://citsehealth1.dilcis.eu/profile/E-ARK-eHealth1-REPRESENTATION.xml”	1..1 MUST
EH3 **Ref CSIP 2**	Content category mets/@TYPE	The `mets/@TYPE` attribute is set to the value “OTHER”	1..1 MUST

EH4 **Ref CSIP 3**	Other content category mets/@csip:OTHERTYPE	The `mets/@csip:OTHERTYPE` attribute is set to the value “Patient Medical Records”	1..1 MUST
EH5 **Ref CSIP 4**	Content information type specification mets/@csip:CONTENTINFORMATIONTYPE	The `mets/@csip:CONTENTINFORMATIONTYPE` attribute is set to the value "citsehpj_v1_0 "	1..1 MUST

METS Example 7 : Representation METS Root Element (element METS root)

```
<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_ID"
        TYPE="OTHER"
        csip:OTHERTYPE="Patient Medical Records"
        csip:CONTENTINFORMATIONTYPE=" citsehpj_v1_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>
```

7.3.2 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.

Note that the information contained in the Representation header element relate specifically to the Representation METS document.

7.3.3 Representation METS descriptive metadata section (element dmdSec)

The Representation 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) is encouraged. Where used, references to the specific schemas os resources should be given together with relevant version information.

Table 8 : Representation descriptive metadata section (element dmdSec)

ID	Name and location	Description and usage	Cardinality Level
EH6 **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
EH7 **Ref 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
EH8 **Ref CSIP19**	Descriptive metadata creation date dmdSec/@CREATED	Creation date of the descriptive metadata in this section.	1..1 MUST
EH9 **Ref CSIP20**	Status of the descriptive metadata dmdSec/@STATUS	Indicates the status of the descriptive metadata using a fixed vocabulary.	0..1 SHOULD
EH10 **Ref 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
EH11 **Ref 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

METS Example 8 : Representation METS Descriptive Metadata Section with reference to HL7 FHIR Patient Clinical Information (element dmdSec)

```
<mets:dmdSec ID="dmdSec-fhircondition-file" 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="fhircondition"
          MIMETYPE="application/xml"
          SIZE="758"
          CREATED="2018-04-24T14:37:49.609+01:00"
          CHECKSUM="31C54EC8D5632B262A62CC3D691A8A6A3DD647670865BE8596D2A7F62DBBC6AB"
          CHECKSUMTYPE="SHA-256"/>
    </mets:dmdSec>
<mets:dmdSec ID="dmdSec-fhirallergyintollerance-file" CREATED="2018-04-24T14:37:49.609+01:00"
STATUS="CURRENT">
        <mets:mdRef
          LOCTYPE="URL"
          xlink:type="simple"
          xlink:href="metadata/descriptive/allergyintollerance1.xml"
          MDTYPE="OTHER"
          OTHERMDTYPE="fhirallergyintollerance"
          MIMETYPE="application/xml"
          SIZE="234"
          CREATED="2018-04-24T14:21:36.302+01:00"
          CHECKSUM="B87FA9B95AFB0C0CECEAB79074B3F95098A5AB709B9603FE4A02B82E8BDDE744"
          CHECKSUMTYPE="SHA-256" />
</mets:dmdSec>
```

7.3.4 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.

7.3.5 Representation METS file section (element fileSec)

Table 9 : Representation METS file section (element fileSec)

ID	Name and Location	Description and Usage	Cardinality Level
EH13 **Ref CSIP58**	File section 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 **Ref CSIP114**	Representation (Patient Document) file groups fileSec/fileGrp	The representation (Patient Document) file groups contain the file elements that describe the Patient Documents. 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 element.	1..n MUST
EH15 **Ref CSIP64**	Description of the use of the representation (Patient Document) file group fileSec/fileGrp/@USE	The value in `mets/fileSec/fileGrp/@USE` is the name of the folder structure to the data, e.g "/data/Case_ID/Document_ID".	1..1 MUST
EH16 **Ref 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
EH17 **Ref CSIP62**	Content information type specification fileSec/fileGrp/@csip:CONTENTINFORMATIONTYPE	The value of the attribute CONTENTINFORMATIONTYPE` is set to “citsehpj_v1_0 ”	1..1 MUST

EH18 **Ref 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
EH20 **Ref CSIP66**	File fileSec/filegrp/file	The file group <fileGrp> contains the file elements which describe the digital objects.	1..1 MUST
EH21 **Ref 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	1..1 MAY
EH22	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
EH23	Component byte stream identifier fileSec/filgrp/file/stream/@ID	A unique xml:id for this object across the package.	1..1 MUST
EH24	Component byte stream mimetype fileSec/fileGrp/file/stream@MIMETYPE	The IANA mime type for the referenced byte stream.	1..1 MUST
EH25	Component byte 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
EH26	Component byte stream reference to 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

METS Example 9 : Representation METS File Section (element fileSec)

```
<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="D2DF16632617402BF279D61DBC9F73675E033ABA6B94A78D4B9607CE5CAAFA3E" CHECKSUMTYPE="SHA-
256">
              <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="documentation/file0.docxf"/>
           </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/file1.docx"/>
           </mets:file>
```

```
        </mets:fileGrp>
          <mets:fileGrp ID="filegrp-document1" USE="/data/case1/document1" csip:CONTENTINFORMATIONTYPE="
citsehpj_v1_0 ">
            <mets:file ID="file-ptr-representation-file1" MIMETYPE="PDF" SIZE="2314264" CREATED="2018-04-
24T14:37:49.617+01:00" CHECKSUM="9EC53E81CDEC19FA665BDDB30ECE11067EF536F3599C67713DCE0FF2FCD81CC7"
CHECKSUMTYPE="SHA-256" ADMID="digiprov-premis-file-2 digiprov-premis-file-1">
              <mets:FLocat LOCTYPE="URL" xlink:type="simple" xlink:href="/data/case1/document1/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/case1/document1/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/case1/document1/patientnotes2.pdf"/>
            </mets:file>
          </mets:fileGrp>
 </mets:fileSec>
```

METS Example 10 : Representation METS File Section with Component Byte Stream (element fileSec)

```
<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/file0.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/file1.docx"/>
          </mets:file>
        </mets:fileGrp>
          <mets:fileGrp ID="filegrp-document1" USE="/data/case1/document1"
csip:CONTENTINFORMATIONTYPE=" citsehpj_v1_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-premis-file-7 digiprov-premis-file-8">
              <mets:FLocat LOCTYPE="URL" xlink:type="simple"
xlink:href="/data/case1/document1/patientnotes0.pdf"/>
            </mets:file>
            <mets:file ID="file-ptr-document1-file1" 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/case1/document1/procedure.mp4"/>
                <mets:stream ID="file-ptr-document1-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>
```

7.3.6 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 10: Representation METS Structural Map (element structMap)

ID	Name and Location	Description and Usage	Cardinality Level
EH27 **Ref CSIP80**	Structural description of the representation	There MUST be one structural map following the requirements in the E-ARK SIP, and thus E-ARK CSIP present	1..1 MUST
EH28	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
EH29 **Ref CSIP81**	Type of structural description 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
EH30 **Ref CSIP82**	Name of the structural description structMap/@LABEL	The label attribute is set to value "eHealth1" from the vocabulary.	1..1 MUST

		See also: Structural map label	
EH31 **Ref CSIP83**	Structural description identifier structMap/@ID	An identifier for the structural description <structMap> used for referencing inside the package. It must be unique within the package.	1..1 MUST
EH32 **Ref CSIP84**	Main structural division structMap/div	The structural map comprises a single division.	1..1 MUST
EH33 **Ref CSIP85**	Main structural division identifier structMap/div/@ID	Mandatory, 'xml:id' identifier must be unique within the package.	1..1 MUST
EH34 **RefCSIP86**	Main structural division label structMap/div/@LABEL	The representation's top-level structural division 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
EH35 **Ref CSIP88**	Metadata division structMap/div/div	The metadata referenced in the representation metadata section is described in the structural map within one sub-division.	1..1 MUST
EH36 **Ref CSIP89**	Metadata division identifier structMap/div/div/@ID	Mandatory xml:id identifier must be unique within the package.	1..1 MUST
EH37 **Ref CSIP90**	Metadata division label structMap/div/div/@LABEL	The metadata division element's `@LABEL` attribute value must be "Metadata".	1..1 MUST
EH38 **Ref 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 <amdSec> identifiers are listed in a single `@ADMID` using spaces as delimiters.	0..1 SHOULD
EH39 **Ref 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
EH40 **Ref 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
EH41	Documentation division identifier	Mandatory, xml:id identifier must be unique within the package.	1..1 MUST

Ref CSIP94	structMap/div/div/@ID		
EH42 **Ref CSIP95**	Documentation division label structMap/div/div/@LABEL	The documentation division element in the package uses the value “Documentation” from the vocabulary as the value for the `@LABEL` attribute.	1..1 MUST
EH43 **Ref 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
EH44 **Ref CSIP116**	Documentation file group reference 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
EH45	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
EH46	Data division identifier structMap/div/div/@ID	Mandatory, xml:id identifier must be unique within the package.	1..1 MUST
EH47	Data division label structMap/div/div/@LABEL	The package’s data division element must have the `@LABEL` attribute value “DATA”, taken from the vocabulary.	1..1 MUST
EH48	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 representation must contain at least one Patient Case. A Case is represented within a second level sub-division.	1..n MUST
EH49	Patient Case division identifier structMap/div/div/div/@ID	Mandatory, xml:id identifier must be unique within the package.	1..1 MUST
EH50	Patient Case division label structMap/div/div/div/@LABEL	The Patient Case division `<div> element must have the `@LABEL` attribute value “CASE, taken from the vocabulary.	1..1 MUST
EH51	Patient 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
EH52	Patient Document division identifier	Mandatory, xml:id identifier must be unique within the package.	1..1 MUST

	structMap/div/div/div/div/@ID		
EH53	Patient 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
EH54	Data File division structMap/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
EH55	Data File division identifier structMap/div/div/div/div/div/@ID	Mandatory, xml:id identifier must be unique within the package.	1..1 MUST
EH56	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
EH57	Data File division file group reference structMap/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
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
EH59	Patient 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
EH60	Patient Sub-case division identifier StructMap/div/div/div/div/@ID	Mandatory, xml:id identifier must be unique within the package.	1..1 MUST
EH61	Patient Sub-case division label structMap/div/div/div/div/@LABEL	The Sub-case division elements must have the '@LABEL' attribute value "SUBCASE", taken from the vocabulary.	1..1 MUST
EH62	Patient 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

EH63	Patient Document division identifier structMap/div/div/div/div/div/@ID	Mandatory, xml:id identifier must be unique within the package.	1..1 MUST
EH64	Document division label StructMap/div/div/div/div/div/@LABEL	The Sub-case division element must have the @LABEL attribute value ”DOCUMENT”, taken from the vocabulary.	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 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.	
EH69	Data File division file group reference ID 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

METS Example 11 : Representation METS Structural Map Section with Case Structure (element structMap)

```
<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-fhircondition-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-document1-div" LABEL="DOCUMENT">
            <mets:div ID= "struct-map-case-1-document1-datafile0-div" LABEL="DATAFILE">
              <mets:fptr FILEID = "filegrp-document1">
              </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-subcase1-div" LABEL="SUBCASE">
```

```
                <mets:div ID="struct-map-case-2-subcase1-document2-div" LABEL="DOCUMENT">
                  <mets:div ID="struct-map-case-2-subcase1-document2-datafile1-div" LABEL="DATAFILE">
                    <mets:fptr FILEID = "filegrp-document2">
                    </mets:fptr>
                  </mets:div>
                </mets:div>
                </mets:div>
              </mets:div>
            </mets:div>
          </mets:div>
      </mets:structMap>
```

7.3.7 Representation METS file example

Example 12 shows an example of a whole representation METS document with Sub-case structure following CITS eHealth1.

METS Example 12 : Whole Representation METS

```
<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_ID"
        TYPE="OTHER"
        csip:OTHERTYPE="Patient Medical Records"
        csip:CONTENTINFORMATIONTYPE=" citsehpj_v1_0"
        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://earkcsip.dilcis.eu/schema/DILCISExtensionMETS.xsd
        https://DILCIS.eu/XML/METS/SIPExtensionMETS
        https://citsehealth1.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="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:metsHdr>
<mets:dmdSec ID="dmdSec-fhircondition-file" 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="fhircondition"
          MIMETYPE="application/xml"
          SIZE="758"
```

```
            CREATED="2018-04-24T14:37:49.609+01:00"
            CHECKSUM="31C54EC8D5632B262A62CC3D691A8A6A3DD647670865BE8596D2A7F62DBBC6AB"
            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.wordprocessingml.document" 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="documentation/file0.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/file1.docx"/>
            </mets:file>
        </mets:fileGrp>
            <mets:fileGrp ID="filegrp-document1" USE="/data/case1/document1"
csip:CONTENTINFORMATIONTYPE=" citsehpj_v1_0 ">
                <mets:file ID="file-ptr-representation-file1" MIMETYPE="PDF" SIZE="2314264" CREATED="2018-04-
24T14:37:49.617+01:00"
CHECKSUM="9EC53E81CDEC19FA665BDDB30ECE11067EF536F3599C67713DCE0FF2FCD81CC7"
CHECKSUMTYPE="SHA-256" ADMID="digiprov-premis-file-2 digiprov-premis-file-1">
                  <mets:FLocat LOCTYPE="URL" xlink:type="simple"
xlink:href="/data/case1/document1/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/case1/document1/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/case1/document1/patientnotes2.pdf"/>
                </mets:file>
            </mets:fileGrp>
 </mets:fileSec>
<mets:structMap ID="struct-map-example-1" 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-fhircondition-file"
ADMID="digiprov-premis-file-1 digiprov-premis-file-2 digiprov-premis-file-3 digiprov-premis-file-4"/>
            <mets:div ID="struct-map-doc-div" LABEL="Documentation">
                <mets:fptr FILEID="filegrp-documentation"/>
             </mets:div>
             <mets:div ID= "struct-map-data-div" LABEL= "DATA">
               <mets:div ID = "struct-map-case1-div" LABEL="CASE">
```

```
            <mets:div ID = "struct-map-case1-document1-div" LABEL="DOCUMENT">
              <mets:div ID= "struct-map-case1-document1-datafile0-div" LABEL="DATAFILE">
                <mets:fptr FILEID = "filegrp-document1">
                </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-subcase1-div" LABEL="SUBCASE">
              <mets:div ID="struct-map-case-2-subcase1-document2-div" LABEL="DOCUMENT">
                <mets:div ID="struct-map-case-2-subcase1-document2-datafile1-div" LABEL="DATAFILE">
                  <mets:fptr FILEID = "filegrp-document2">
                  </mets:fptr>
                </mets:div>
              </mets:div>
              </mets:div>
            </mets:div>
          </mets:div>
        </mets:div>
    </mets:structMap>
</mets:mets>
```

7.4 Use of Descriptive Metadata in eHealth1

7.4.1 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 (see EHR12).

7.4.2 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).[12] At a minimum this file MUST contain patient names and unique identifiers and SHOULD contain personal and demographic information, see requirement EHR12.

7.4.3 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 5.3. 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).[13] Clinical metadata should use recognised vocabularies and coding such as ICD and SNOMED.

[12] https://www.hl7.org/fhir/patient.html

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

Appendix 1 – Extended Vocabularies

Extending vocabularies used for stating the type od content and the different divisions present in the structural map.

Value	Description
Patient Medical Records	See 5.1, 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.
eHealth1	The specification for eHealth1 is used.
Case	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.
Sub-case	See 6.2; a Sub-case is a folder located in a Case folder within the representation and must contain at least one Document.
Document	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).
DataFile	See 6.2; 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.
Data	See 6.2, Data specifies that the section describes the data in the package/representation.

Appendix 2 - Postface

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P	**Public**	x
C	**Confidential, only for members of the Consortium and the Commission Services**	

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