



Patient Summaries content Interoperability Specification



Document Information		
Title:	Patient Summaries content Interoperability Specification	
Purpose:	The purpose of this document is to support several Core Interoperability Specifications and their associate use cases, in a specific area of interoperability and includes specific constraints for sharing clinical documents using the HL7 Clinical Document Architecture Release 2.0	
Owners:	HSE Enterprise Architecture and Department of Health	
Publication Date:	17 th December 2018	
Version:	1.1	
Target Audience:	All relevant stakeholders in the implementation of the Irish National Contact Point for eHealth Services.	
Review Date:	13 th May 2020	





EHEALTH DIGITAL SERVICES INFRASTRUCTURE OPEN NATIONAL CONTACT POINT IMPLEMENTATION AND TEST PLATFORM SERVICES

Patient Summaries content Interoperability Specification

Author Karima Bourquard

Contract Reference Test Harness Support Service – HSE9100-LOT-2

Date 17/12/y
Version 1.1
Status Final

Reference HSE9100-LOT2-IS-PATIENT_SUMMARY_CONTENT-1.1.docx

IHE-Europe – Bluepoint Building – 80, boulevard A. Ryers, 1030 Brussels Belgium



Document Lifecycle

Version	Date	Author	Update
0.1	27/07/2018	A-G BERGE	Creation of the template
0.2	14/08/2018	K. BOURQUARD	Creation of the content of the document
0.3	27/08/2018	A-G BERGE	Apply new template
0.4	24/09/2018	K. BOURQUARD	Update the document with HSE comments
0.5	8/10/2018	K. BOURQUARD	Update after the FTF meeting in Dublin (1-3 October 2018
1.0	17/12/2018	A-G BERGE	Clean up
1.1	05/02/2019	H. RAMANANTSALAMA	Correction after Eamon's review

Approval

Name	Responsibility	Signature
Eamon Coyne		

Distribution list

Name	Date	Contact	Purpose*
Eamon Coyne	27/07/2018	Eamon.Coyne@hse.ie	V
Caitriona Wray	27/07/2018	Caitriona_Wray@health.gov.ie	V
Peter Connolly	27/07/2018	PETER.CONNOLLY@hse.ie	V

^{*} A: for action / V: for Approval / C: for comments/ I: for information



Reference documents

This section gathers the documents which are referenced in this document. In the body of this document, any reference to an external document is formatted using [KEYWORD] from the first column.

Keyword	Name and reference	
[R1]	ePrescription and Patient Summary use cases analysis HSE9100-LOT-2-DELIVERABLE_1A	
[R2]	Design of general interoperability architecture to support use cases HSE9100-LOT-2-DELIVERABLE_1B	
[IS_GENE RAL_TER M]	General Terminology Interoperability Specification HSE9100-LOT-2-IS-TERMINOLOGY	
[R3]	eHDSI Patient Summary functional requirements v2.2.2 https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/Specifications? pr eview=/35210463/65979541/PS%20functional%20requirements v2.2.2.pdf	
[R4]	eHDSICDA templates https://art-decor.ehdsi.eu/art-decor/decor-templatesepsos-	
[R5]	Patient Identification Management Core Interoperability Specification HSE9100-LOT2-CORE_IS-PAT_ID_MGMT	
[R6]	eHDSI Patient Summary Section specifications https://art-decor.ehdsi.eu/art-decor/decor-templatesepsos- ?id=1.3.6.1.4.1.12559.11.10.1.3.1.1.3	
[R7]	eHDSI ePrescription functional requirements v2.2.3 https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/Specifications?pr eview=/35210463/65979542/eP%20functional%20requirements_v2.2.3.pdf	
[R9]	Irish ePrescription &eDispensation Content Interoperability Specification HSE9100-LOT2-IS-eP_eD_CONTENT	
[R10]	Health Level Seven (HL7) Clinical Document Architecture Release 2 (CDA R2) http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7	
[R11]	IHE IT Infrastructure Technical Framework Volume 3 (ITI TF-3) Integration Profiles,— Final Text — Cross-Enterprise Sharing of Scanned Documents (Section 5.2 XDS-SD)	
	https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol3.pdf	



Table of content

1	Do	cument Life Cycle Erreur!	Signet non défini.
2	Pre	eface	7
	2.1	Context	7
	2.2	Glossary	7
	2.3	Document purpose.	8
	2.4	How to read this document	8
	2.5	Document context	9
	2.6	Description	10
	2.7	Document convention	10
	2.7	.1 Requirements numbering conventions	10
	2.7	.2 Requirements language	11
	2.8	Methodology	11
	2.8	.1 Introduction of the use case driven approach	11
3	Use	e case overview	12
	3.1	Scope	12
	3.1	.1 Out of Scope	13
4	Co	nformance requirements	13
	4.1	CDA data type attributes and constraints	15
	4.1	.1 Date and time attributes and constraints	16
	4.1	.2 Names attributes and constraints	17
	4.1	.3 Identifier attributes and constraints	18
	4.1	.4 Address attributes and constraints	18
5	CD	A Header attributes and Constraints	19
6	Dis	scharge summaries	22
7	End	counter report	26
8	Sca	anned documents	29
	8.1 apply	[IPS-044] Constraints on CDA Header attributes described in the to all clinical scanned clinical documents.	
9	Apı	pendice	30



Figure 1: Patient Summary Core IS	10
Figure 2: PS Cross Border Exchange	13
Figure 3: Realm Code Example	15
Figure 4: Effective Time Example	17
Figure 5: Legal Name Example	18
Table 1: Time Components	16
Table 2: Names Attributes	17
Table 3: Address Attributes	19
Table 4: CDA Header Content	19
Table 5: Discharge Summary Content	22
Table 6: Encounter Report Content	27



1 Preface

Ireland as a European country is involved in the eHDSI (eHealth Digital Services Infrastructure) project led by the European Commission under the CEF (Connecting European Facilities) program and will participate to the deployment of the NCP (National Contact Point) in the wave 3 (2020). To prepare the deployment of the NCPeH (National Contact Point for eHealth) in Ireland, the HSE (Health Service Executive) procured in 2018 the support services that will facilitate the implementation of the NCPeH and its connection to central Irish services. The first step of the project was to define the needed use cases to support and to design the architecture for connecting the Irish NCPeH. Two reports were delivered during the period of February to July 2018. These tasks are followed by the design of the architecture within Ireland, the corresponding Interoperability Specifications, the testing strategy including test plans and the implementation of Gazelle test platform that includes test cases, test tools and test data.

1.1 Context

Directive 2011/24/EU provides rules for facilitating access to safe and high quality cross border healthcare and promotes cooperation on healthcare between member states. The aims of implementing the Irish NCPeH exchange of Patient Summaries and ePrescription are in line with the principles of cross-border care. The NCPeH and cross border exchange implementations are all key building blocks that will interact with the national data dictionary (single source of trust for clinical data definitions across the enterprise) and the Patient Summary and ePrescribing documents and associated metadata will be stored there as minimum data sets.

The main goals are to design the platform based on the needs that will be developed in the first steps of the project that includes

- Use Cases for ePrescription and Patient Summary;
- Corresponding Interoperability specifications and architecture orchestration;
- Validated version of IHE Gazelle. The test harness will provide to the authority the ability to test prospective vendors and products against the above interoperability specifications.

1.2 Glossary

IHE profile: provides a common language for purchasers and vendors to discuss the integration needs of healthcare sites and the integration capabilities of healthcare IT products. A Profile is a guideline for implementation of a specific process, by providing precise definitions of how standards can be implemented to meet specific clinical needs. [eHealth Interoperability Conformity Assessment Scheme for Europe (EURO-CAS)]

Patient Summary is an identifiable "dataset of essential and understandable health information" that is made available "at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in the unscheduled care" [PS/eP guidelines]

Interoperability use case: description of a specific use of HIT (Health Information



Technology) that includes depiction of both humans (business actors) and systems (technical actors), scope, workflows of tasks performed by healthcare professionals and associated data flows. Should be written in natural language. May include several scenarios. One or more use cases are derived from one business case [IHE taskforce]

Realisation scenario: description of human activities (business actors), systems (technical actors) roles (i.e., IHE actors) and transactions related to a set of technical use cases that support the interoperability infrastructure for use cases (implementable infrastructure). [IHE taskforce]

Interoperability Specification: description of the workflow, contents and terminology for the implementation of the exchange or share clinical documents and prescription using standards and IHE profiles in order to obtain interoperability when implemented by systems and solutions.

1.3 Document purpose

The purpose of this document is to support several Core Interoperability Specifications and their associate use cases, in a specific area of interoperability and includes specific constraints for sharing clinical documents using the HL7 Clinical Document Architecture Release 2.0 (CDA) standard [R10] as the basis of the specifications and the Patient Summary specifications of the eHDSI project.

This Supporting Interoperability Specification is applicable to existing and new information systems that will connect to exchange Health Information. In particular this Interoperability Specification applies to the deployment of the Patient Summary at the national level as the base for the "friendly" Patient Summary to be exchanged Cross Border for an Irish patient moving in Europe.

1.4 How to read this document

This document contains normative sections, as well as informative appendices for the reader convenience. The document is structured as follows:

This document contains seven sections, as well as informative appendices for your convenience. The document is structured as follows:

Section 1: Contains an introduction to the Interoperability Specification (IS). This section contains a summary of the IS purpose and scope, as well as other content to help orient the first time reader to the topic of the IS and how it relates to other specifications;

Section 2: Provides an overview of the use cases that were selected during the workshops held during the first period of the Irish project (Feb-July 2018);

Section 3: This section establishes the Content and Conformance Requirements for the Interoperability Specification;



Sections 4.: This section describes attributes and constraints on the header of the document based on HL7 CDA V2 standard used for the specifications of the clinical documents shared Cross border;

Sections 5, 6 and 7: provides additional constraints on the standard for clinical documents such as Discharge Summary and Encounter report that are shared within the Irish country;

Appendix A: Provides examples that conform to the requirements of this specification.

1.5 Document context

A (Core) Interoperability Specification (IS) is targeted to be the sole entry point for the technology developers, the compliance assessment testing and possibly certification, and the purchaser of IT systems in term of technical requirements that will ensure interoperability.

From this Interoperability Specification the following Interoperability Specifications is referenced:

☐ General Terminology Interoperability Specification [ITERM]

The above Interoperability Specifications include precise references to internationally adopted profiles and standards as well as Irish specific constraints.

Implementations are required to conform to the requirements within this Interoperability Specification; all referenced Interoperability Specifications, and the standards and profiles they specify.

This document is a Supporting Interoperability Specification that may be referenced by a number of Core Interoperability Specifications.

A Supporting Interoperability Specification (IS) may be referenced by multiple Core Interoperability Specifications and may also be referenced by other Supporting Interoperability Specifications.

Patient Summaries content Interoperability Specification

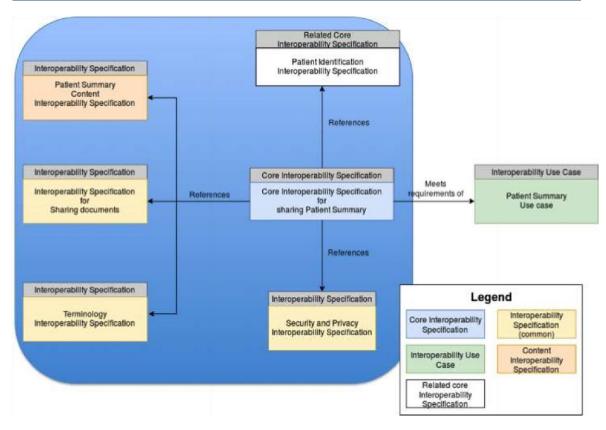


FIGURE 1: PATIENT SUMMARY CORE IS

FIGURE 1: PATIENT SUMMARY CORE IS

1.6 Description

This Supporting Interoperability Specification describes how elements for date, time, personal names, and common metadata about persons and organizations are to be provided in documents using the HL7 Clinical Document Architecture R2 (CDA) Standard for the Patient Summary content.

1.7 Document convention

1.7.1 Requirements numbering conventions

Interoperability Specifications contain numbered requirements that follow this format:

[ABCD-###] where ABCD is a three or four letter acronym unique to that Interoperability Specification for convenient purposes, and ### is the unique number for that requirement within the Interoperability Specification.

These numbered requirements are the elements of the Interoperability Specification that the system conforms to. In other words, in order to implement a system that fully supports the Use Case and Interoperability Specification, the system shall be able to demonstrate that it conforms to every numbered requirement for the system actors to which it is claiming conformance.



Please note that all numbered requirements are numbered uniquely, however numbered requirements are not always sequential.

1.7.2 Requirements language

Throughout this document the following conventions¹ are used to specify requirement levels:

- **SHALL:** the definition is an absolute requirement of the specification.
- SHALL NOT: the definition is an absolute prohibition of the specification.
- SHOULD: there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.
- SHOULD NOT: there may exist valid reasons in particular circumstances when the particular behaviour is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behaviour described with this label.
- MAY or OPTIONAL: means that an item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because the vendor feels that it enhances the product while another vendor may omit the same item.

1.8 Methodology

This Interoperability Specification has been developed with input from various Irish stakeholders collected during several months through workshops and teleconferences. Stakeholders included Clinicians from many different disciplines and Irish IT specialists.

The development of a Core Interoperability Specification relies on the high-level requirements set by the associated Use Case. These high-level requirements are not restated in this specification and readers may consider reviewing the related Use Case document.

1.8.1 Introduction of the use case driven approach

This methodology² has the objective to

- Define Use cases and their priorities to answer the eHealth strategy objectives of nation/region;
- From use cases to design the interoperability specifications and infrastructure based on IHE profiles;

¹ Definitions based upon IETF RFC 2119

² Bourquard, Karima and Berler, Alexander. Use case driven approach for a pragmatic implementation of interoperability in eHealth. IGI Global Journal



- To define the testing strategy and identify test plan and test methods (test cases, test tools and test data);
- To support Project teams to procure products or solutions for their eHealth Project

(Telemedicine, national/regional EHR, replacement of product in hospitals);

The methodology is based on experiences and good practices in other countries or regions.

It is further described in the report "ePrescription and Patient Summary use case analysis", HSE9100-LOT-2-1A and the report "Design of general interoperability architecture to support use cases", HSE9100-LOT-2-1B.

2 Use case overview

The use case is described in [R1]. During the workshops, two use cases were selected:

- Chest Pain on holiday in Latvia (Irish citizen);
- Chest pain of a female, 60 –sudden onset (Foreigners).

The first use case is extended by consensus to any European countries participating to the CEF program and for any type of diseases.

2.1 Scope

The scope of this document is the specification of the header, sections, entries and data types that appear within CDA documents exchanged Cross Border that need to be refined for "Discharge Summaries" and "Encounter documents" used in Irish care processes.

The following topics are in scope for this Interoperability Specification:

- Constraints on data types used within CDA documents;
- Constraints on the cardinality of common data elements appearing within CDA documents;
- Constraints on sections and entries which are used in one or more Interoperability Specifications and which are common in all cases.

As a reminder, the following schema describes what are the documents that are exchanged through the NCPeH:

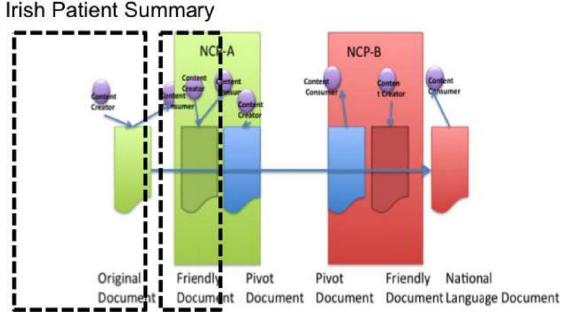


FIGURE 2: PS CROSS BORDER EXCHANGE

The Friendly Document is the Irish PS built and created by an actor called content creator after data aggregation from the discharge summaries and the encounters that are generated in the healthcare stakeholders (GP and hospitals) and indexed by the national registry of document (see [R2]).

The Friendly document is transformed and translated by the Irish NCPeH in order to obtain the PS Pivot Document before sending to the requested European country.

A PDF document representing the Patient Summary is also sent as it was created in Ireland (in native language).

Note that functional requirements of the Patient Summary are described in the [R3] and the PS template is now described in Art Décor [R4].

2.1.1 Out of Scope

The following is a list of content and specifications that are specifically out of scope for this Interoperability Specification:

None

3 Conformance requirements

This Section provides Irish constraints to be implemented for Patient Summary documents as defined in this Supporting Interoperability Specification.

The HL7 CDA standard has been identified as the standard for use in Cross Border exchanges. This interoperability specification establishes the conformance requirements



for documents using the HL7 Clinical Document Architecture R2 (CDA) standard documents such as Discharge summaries and encounter documents are created from HL7 messages that are exchanged in Ireland using the National Messaging Broker Healthlink or created by any other systems that feed the shared document repository.

[IPS-001] Requirements of the HL7 Clinical Document Architecture Release 2 (CDA R2) SHALL apply to clinical documents used for building the Friendly PS Document (aggregate PS).

Systems or the National Messaging Broker Healthlink SHOULD NOT claim conformance to this Interoperability Specification, but SHOULD claim conformance to the requirements defined in Core Interoperability Specifications that reference this document. However, this specification has been designed to provide a general set of constraints that apply to all CDA documents being exchanged via National Services.

Conformance to this specification is required of all Content Creator actors creating documents using the CDA standard. CDA documents created by systems conforming to this specification must assert conformance by including the appropriate identifier in a <realm Code> element inside the <Clinical Document> element. An example of this is shown in the figure below.



<ClinicalDocument> code='IE'> <realmCode ... </ClinicalDocument>

FIGURE 3: REALMCODE EXAMPLE

[IPS-002] The Clinical Document SHALL contain at least one [1..1] realm Code where @code='IE'

Content creator actors creating CDA documents must comply with this specification when creating data types, header elements, sections or entries. When creating a data element, header element, section or entry in a CDA Document for which this specification has requirements, those requirements shall be applied.

[IPS-003] The HL7 CDA R2 constraints for data types, CDA structures found in Section 3.1SHALL apply to all shared Clinical Documents registered in the shared document repository.

[IPS-004] A Content Creator Actor creating the HL7 CDA Release 2 document header for an Irish Clinical Document SHALL support the Irish CDA Header attributes and constraints (i.e., name format, date format, etc.) defined in the Section 4.

[IPS-005] A Content Creator creating the HL7 CDA Release 2 document body for an Irish eHealth Clinical Document SHALL support the additional attributes and constraints specific to the Clinical Document defined in Sections5, and Section 06.

3.1 CDA data type attributes and constraints

This section describes the attributes of various CDA data types that are constrained by this specification, and provides an explanation of these constraints. The main goal is to align this specification with the eHDSI Specification.

In some case, tables may be included in the description. The columns of the table are described below:

Attribute: This column provides a descriptive name for the attribute that will be used in any constraints following the table.

Attribute Definition: This column describes the purpose and definition of the attribute.

CDA Location: This column provides an XPath expression that is used to describe the location of the data element in the CDA document.



3.1.1 Date and time attributes and constraints

CDA uses the Time Stamp (TS) and Interval of Time (IVL_TS) data types to record dates and times. For all documents using the CDA standard, time stamps and time intervals SHALL be recorded using the Gregorian calendar. The dates and times value is implemented using the ISO 8601 standard which requires numbers without dashes (-) between date components, nor time separator character (T), nor colon (:) between time components. The syntax is CCYYMMDDhhmmss.SSS[+|-ZZzz] where:

TABLE 1: TIME COMPONENTS

SYMBOL	DESCRIPTION
CC	Is the century.
YY	Is the year.
MM	Is the month.
DD	Is the date.
hh	Is the hour.
Mm	Is the month.
SS	Is the seconds.
SSS	Is fractional seconds.
+ -	Is the direction of time offset from UTC.
ZZ	Is the offset from UTC in hours.
ZZ	Is the offset from UTC in minutes.

Dates and Date/Time stamps should be recorded in the greatest precision available.

A time stamp represents an activity occurring at a single point in time, such as the creation of a document, the date of a visit, the signing of a document, or the performance of an imaging study or laboratory test.

A time interval represents an activity that occurs over a period of time, usually days, such as a hospital stay or the time over which a diagnosis is active.

The list below provides the constraints for date and time values recorded in a CDA document.

[IPS-006] A Time Stamp Value, Start Date or End Date SHALL be precise to the day

[IPS-007] A Time Stamp Value, Start Date or End Date SHALL include a time zone if more precise to the day.



[IPS-008] A Time Stamp Value, Start Date or End Date SHOULD be precise to the second.

<effectiveTime value="20111113125600+0200"/>

FIGURE 4: EFFECTIVETIME EXAMPLE

3.1.2 Names attributes and constraints

Within a CDA document, names are captured in the <name> element, which allows for a number of components to be provided. It is common in many situations for a person to have one or more first names, middle names and last names. However, many information systems only support first, middle and last name. To support maximum interoperability, the rules regarding the structure of the names are given in $\Box R5 \Box$.

TABLE 2: NAMES ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION
@use	optional	@use
@nullFlavor	optional	@nullFlavor
Delimiter	Type code signifying the role of the part in the whole entity name	
Family Name	The family name.	./family
Given Name	The first given name.	./given[1]
Name Prefix	A prefix or honorific associated with the name (e.g., Dr.).	./prefix
Name Suffix	A suffix or degree associated with the name (e.g., Jr.).	./suffix
Valid Time		

[IPS-009] Person names SHALL NOT contain a name part qualified with 'LS' (Legal status for organizations).

[IPS-010] three name parts SHALL be present: Patient identifier, legal given name, legal family name.

[IPS-011] four names parts SHOULD be present: legal middle name, former names, nicknames, aliases.



<name use="L">
<family>0'Connon</family>
<given>Daisy</given>
</name>

FIGURE 5: LEGAL NAME EXAMPLE

3.1.3 Identifier attributes and constraints

3.1.3.1 Patient Identifiers

Patient Identifiers are nationally unique using IHI (Individual Health Identifier) service (see $\square 5$ } and provided by the IHI National Register.

[IPS-012] The Assigning Authority for the patient identifier SHALL be valued with " "1.2.372.980010.1.2".

[IPS-013] The Identifier SHALL be valued with the IHI National Register

3.1.3.2 Physician and Healthcare Professional Identifiers

Physicians and Healthcare Professional are identified uniquely in Ireland using the national assigned identifier. This identifier may be obtained using the services XXXX.

[IPS-014] The Assigning Authority for the healthcare professional identifier SHALL be valued with "1.2.372.980010.1.8".

3.1.3.3 Healthcare Organization Identifiers

Healthcare organizations are identified in Ireland using the assigned identifier (GS1). This identifier may be obtained from Health Link.

[IPS-015] The Assigning Authority for the Healthcare Organization identifier SHOULD be valued with "1.2.372.980010.1.6".

3.1.3.4 Document Identifiers

Document identifiers must be unique every time a new version of the document is published. Each system assigning clinical document identifiers must have a unique assigning authority, for example by the content creator.

[IPS-016] The Assigning Authority for a document identifier SHALL be the value assigned to the Content Creator actor that generated the document.

3.1.4 Address attributes and constraints

The physical postal address is represented as below:



TABLE 3: ADDRESS ATTRIBUTES

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION
Postal Address	Physical postal	addr
Street Address	The street address. Line 1.	./streetAddress
Address Other designation	May be repeated	./otherDesignationAddr ess
City	The city	./city
County	The county	./county
EIRcode	The postal code	./postalCode
Geographic Designation	The geographic designation	./geographic designation
Country	Country	./country

[IPS-017] The Postal Address SHALL have one or more [1..*] Street Address

[IPS-018] The Postal Address SHOULD at least contain Street address Line 1, City, EIRcode, Country

[IPS-019] The country code SHALL BE BASED on ISO 3166 Part 1 Country Codes

Note: the country code can be added in the right format for Irish citizens

4 CDA Header attributes and Constraints

This section describes the attributes found in the CDA Header that are constrained by this specification, and provides an explanation of these constraints. It is based both on the eHDSI and the Irish constraints.

These constraints shall apply to all healthcare documents based upon the HL7 CDA Release 2 standard, exchanged and stored in the national shared document repository.

TABLE 4: CDA HEADER CONTENT

ATTRIBUTE	ATTRIBUTE DEFINITION	CDA LOCATION
Clinical Document	Represents the Clinical Document.	/Clinical Document/
Document Identifier	Represents the unique instance identifier of a clinical document.	./id
Code	The code specifying the particular kind of document.	./code



Title	Represents the title of the document.	./title
Effective Time	Signifies the document creation date and time, when the document first came into being. Where the CDA document is a transform from an original document in some other format, this is the time the original document is created.	./effective Time
Confidentiality Code	Confidentiality is a required contextual component of CDA, where the value expressed in the header holds true for the entire document, unless overridden by a nested value.	./confidentiality Code
Patient Information	Contains information about the patient about whom this document is written.	./record Target
Author	Contains information about the authors who wrote this document.	./author
Custodian	Contains information about the organization who maintains this document.	./custodian
Legal Authenticator	Contains information about the person who signed this document and takes final responsibility for its content.	./legal Authenticator
Authenticator	Contains information about the person who reviewed this document but does not take final responsibility for its content.	./authenticator
Performers	Contains information about people performing the tasks associated with the document.	./documentationOf/se rviceEvent/performer
Previous Version	Identifies the previous document this document updates (if any).	/ClinicalDocument/ relatedDocument [@typeCode="RPLC"]/ parentDocument

Constraints are described below:

[IPS-020] The Clinical Document SHALL contain for each document instance exactly one [1..1] unique Document Identifier that SHALL NOT be null flavor.



[IPS-021] The Clinical Document SHALL contain exactly one [1..1] Code that SHALL NOT be null flavor. The Code is specialized by each specific type of document.

[IPS-022] The Clinical Document Code value SHALL use be included in the value set of

LOINC(2.16.840.1.113883.6.1)

[IPS-023] The Clinical Document SHOULD contain one title

[IPS-024] The Clinical Document SHALL contain exactly one [1..1] Effective Time that SHALL NOT be null flavour.

[IPS-025] The Clinical Document Confidentiality Code SHALL be set to values defined by eHDSI specification (HL7 Confidentiality Code, 2.16.840.1.113883.5.25)

[IPS-026] The Clinical Document SHALL contain exactly one [1..1] Legal Authenticator if the document is signed.

[IPS-027] The patient gender value SHALL be drawn from value set 2.16.840.1.113883.5.1 Administrative Gender (F, M, UN).

[IPS-028] The Patient date of birth SHALL be present

[IPS-029] The Patient Contact information telecom SHALL be present

Note: available in eReferral but not in other document.

[IPS-030] The Author Functional Code SHALL be drawn from value set 2.16.840.1.113883.1.11.10267ParticipationFunction

[IPS-031] The Author SHALL contain at least one [1..*] assigned Author that SHALL NOT be null flavour.

[IPS-032] The Author SHALL contain exactly one [1..1] Author Identifier per assigned Author

[IPS-033] The Author SHALL contain exactly one [1..1] Time and SHALL NOT be null flavour.

[IPS-034] The assigned Author SHOULD be assigned Person containing template <u>2.16.840.1.113883.10.12.152</u>CDA Person or assigned Authoring Device 2.16.840.1.113883.10.12.315CDA Device containing template.

Note: the system is the author for aggregating data. However author shall be identified for each specific section.

[IPS-035] The Custodian SHALL contain exactly one [1..1] Custodian Information that SHALL NOT be null flavour.



Note: the custodian is the organization producing the document (discharge summary or GP for encounter summary and eReferral

[IPS-036] The Previous Version SHALL contain exactly one [1..1] Document Identifier and SHALL NOT be null flavour.

5 Discharge summaries

This section describes the body of the clinical document related to the Irish Discharge Summaries and their specific constraints. The eHDSI Patient Summary will be built among other documents from those Discharge Summaries that are stored in the national clinical document shared repository.

For each, the eHDSI section identification is associated. Detailed information of the sections is available at [R6].

TABLE 5: DISCHARGE SUMMARY CONTENT

CONTENT MODULES (USE CASE CONCEPT)	CONTENT MODULES DEFINITION	CDA LOCATION
Medication Discharge Summary	The Discharge Medications contain the patient's current medications and pertinent medication history at the end of the hospital stay.	//section[templateId/@root= '1.3.6.1.4.1.12559.11.10.1.3.1.2.3]/
Allergies and Adverse Reactions Section (Allergies)	Allergies list describes any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives) used to assure the safety of healthcare delivery.	//section[templateId/@root= 1.3.6.1.4.1.19376.1.5.3.1.3.13
Immunizations Section (Immunizations)	The Immunization contains a list of the vaccinations administered to the patient during the encounter.	//section[templateId/@root= 1.3.6.1.4.1.19376.1.5.3.1.3.23



History of Past illness	The History of Present Illness describes the history related to the reason for the encounter. It contains the historical details leading up to and pertaining to the patient's current complaint or reason for seeking medical care.	//section[templateId/@root= 1.3.6.1.4.1.19376.1.5.3.1.3.8
List of Surgeries and Coded List of Surgeries Sections (History of Procedures)	The History of Procedures defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time of the encounter.	//section[templateId/@root 1.3.6.1.4.1.19376.1.5.3.1.3.12
Active Problems	Problems / diagnoses that fit under these conditions: conditions that may have a chronic or relapsing course (e.g. irritable bowel syndrome, otitis media), conditions for which the patient receives repeat medications (e.g. diabetes mellitus, hypertension) and conditions that are persistent and serious contraindications for classes of medication (e.g. dyspepsia, migraine and asthma)	//section[templateId/@root 1.3.6.1.4.1.19376.1.5.3.1.3.6
Medical Devices Coded Section (Devices)	Describes the patient's implanted and external medical devices and equipment that their health status depends on. Includes devices as cardiac pacemakers, implantable fibrillator, prosthesis, ferromagnetic bone implants, etc. that are important to be known by the Healthcare Professionals	//section[templateId/@root= 1.3.6.1.4.1.12559.11.10.1.3.1.2.4



Care Plan Section (Recommendation /Plan of Care)	The Plan of Care data elements define any pending orders, interventions, encounters, services. The Plan of Care may also include other information such as patient education, nutritional diet, follow-up orders, etc. CONTENT MODULES	//section[templateId/@root= 1.3.6.1.4.1.19376.1.5.3.1.1.9.50
MODULES	DEFINITION	ODA EGGATION
(USE CASE CONCEPT)		
Functional Status		//section[templateId/@root=
		1.3.6.1.4.1.19376.1.5.3.1.3.17
Social history	Health related "life-style factors" or "life style	//section[templateId/@root=
	observations"	1.3.6.1.4.1.19376.1.5.3.1.3.16.1
	Example: cigarette smoker, alcohol consumption	
Pregnancy Hstory	Date in which the woman	//section[templateId/@root=
	is due to give birth. Year, month day are required (e.g. 01/01/2014)	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4
•	The Vital Signs include a	//section[templateId/@root=
Sections (Vital Signs)	group of data elements containing relevant vital signs such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, pain assessment and pulse oximetry	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2
Coded Results Section	The results section shall contain the relevant diagnostic procedures the patient received in the past. It shall include entries for procedures and references to procedure reports when known as described in the	Coded Results Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.5



	Entry Content Modules. (Note 2)	
Discharge		//section[templateId/@root=
Diagnosis Section	information on the primary	TBC
(Discharge	reason for the encounter.	
Condition)		
Hospital	The Hospital Course	//section[templateId/@root=
Course Section	describes the sequence of events during the course	TBC
(Hospital Course)	of the hospital stay.	
Discharge	The Discharge Disposition	//section[templateId/@root=
Disposition Section	contains the place the patient is going or being	TBC
(Discharge Destination)	sent upon discharge from the hospital.	

[IPS-037] A Discharge Summary document SHALL contain exactly one [1..1] Medication discharge section.

[IPS-038] A Discharge Summary document SHALL contain exactly one [1..1] Allergies and Adverse Reactions Section.

[IPS-039] A Discharge Summary document SHALL contain exactly one [1..1] Coded list of surgeries section.

[IPS-040] A Discharge Summary document SHALL contain exactly one [1..1] Active problems section.



[IPS-041] A Discharge Summary document SHALL contain exactly one [1..1] Medical Devices coded section.

Examples from eHDSI Art Décor:

Coded list surgeries:

Patient had an operation on his urinary system in July 2018:

Patient had no procedures to be recorded:

Pregnancy Observation

6 Encounter report

Ireland has been exchanging clinical information recently with the Discharge Summaries and eReferral. After analysis of the existing workflow between hospitals and General Practitioner, the opportunity to create an encounter report was highlighted and can be performed at the same time as the eReferral, clinical information exchanged between the GP and hospital.

The following table provides an overview of the Encounter report. As for the Discharge Summary, it is based on the eHDSI specification of the Care Encounter report.



TABLE 6: ENCOUNTER REPORT CONTENT

CONTENT MODULES (USE CASI CONCEPT)	CONTENT MODULES DEFINITION	CDA LOCATION
Medication Summary	The Medications summary contain the patient's current medications and pertinent medication history at the end of the encounter	//section[templateId/@root= '1.3.6.1.4.1.12559.11.10.1.3.1.2.3]/

CONTENT MODULES (USE CASE CONCEPT)	CONTENT MODULES DEFINITION	CDA LOCATION
Allergies and Adverse Reactions Section (Allergies)	Allergies list describes any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives) used to assure the safety of healthcare delivery.	//section[templateId/@root= 1.3.6.1.4.1.19376.1.5.3.1.3.13
Immunizations Section (Immunizations)	The Immunization contains a list of the vaccinations administered to the patient during the encounter.	//section[templateId/@root= 1.3.6.1.4.1.19376.1.5.3.1.3.23
History of Past illness	The History of Present Illness describes the history related to the reason for the encounter. It contains the historical details leading up to and pertaining to the patient's current complaint or reason for seeking medical care.	//section[templateId/@root= 1.3.6.1.4.1.19376.1.5.3.1.3.8



List of Cursorias	The History of Dressedures	//o a ation [to man] a to [d/@ ro at
List of Surgeries and Coded List	The History of Procedures defines all interventional,	//section[templateId/@root
of Surgeries	surgical, diagnostic, or	1.3.6.1.4.1.19376.1.5.3.1.3.12
Sections	therapeutic procedures or	
(History of	treatments pertinent to the	
Procedures)	patient historically at the	
Frocedures)	time of the encounter.	
Active Problems	Problems / diagnoses that	//section[templateId/@root
7 OUVE 1 TODICITIS	fit under these conditions:	
	conditions that may have a	1.3.6.1.4.1.19376.1.5.3.1.3.6
	chronic or relapsing course	
	(e.g. irritable bowel	
	syndrome, otitis media),	
	conditions for which the	
	patient receives repeat	
	medications (e.g. diabetes	
	mellitus, hypertension) and	
	conditions that are	
	persistent and serious	
	contraindications for	
	classes of medication (e.g.	
	dyspepsia, migraine and	
	asthma)	
Medical Devices	Describes the patient's	//section[templateId/@root=
Coded Section	implanted and external	1.3.6.1.4.1.12559.11.10.1.3.1.2.4
(Devices)	medical devices and	
	equipment that their health	
	status depends on.	
	Includes devices as cardiac	
	pacemakers, implantable fibrillator, prosthesis,	
	ferromagnetic bone	
	implants, etc. that are	
	important to be known by	
	the Healthcare	
	Professionals	
Care Plan Section	The Plan of Care data	//section[templateId/@root=
	olomonte define any	
(Recommendation /Plan of Care)	pending orders,	
/i lail of Gale)	interventions, encounters,	1.3.6.1.4.1.19376.1.5.3.1.1.9.50
	services. The Plan of Care	
	may also include other	
	information such as patient	
	education, nutritional diet,	
	follow-up orders, etc.	
Social history		//section[templateId/@root=
	factors" or "life style	1.3.6.1.4.1.19376.1.5.3.1.3.16.1
	observations"	
	20	



itteroperability		
	Example: cigarette	
	smoker,	
	alcohol consumption	

CONTENT MODULES (USE CASE CONCEPT)	CONTENT MODULES DEFINITION	CDA LOCATION
Pregnancy Hstory	Date in which the woman is due to give birth. Year, month day are required (e.g. 01/01/2014)	//section[templateId/@root= 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4
Coded Vital Signs Sections (Vital Signs)	The Vital Signs include a group of data elements containing relevant vital signs such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, pain assessment and pulse oximetry	//section[templateId/@root= 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2
Coded Results Section	The results section shall contain the relevant diagnostic procedures the patient received in the past. It shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules. (Note 2)	Coded Results Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.5

[IPS-042] An Encounter Report document should contain the section described in the Table 6.

7 Scanned documents

The IHE profile is used for exchanging PDF embedded or plain text document. There are no additional constraints for the HL7 CDA header as already described in the present document.

[IPS-043] Constraints in the IHE IT Infrastructure (ITI) Volume 3 (ITI TF-3) Section 5.2 Scanned Document Content Profile XDS-SD [R11] using the PDF or plaintext Option SHALL apply to all clinical scanned clinical documents.



- 7.1 [IPS-044] Constraints on CDA Header attributes described in the section 4 SHALL apply to all clinical scanned clinical documents.
- 8 Appendice Example TBC