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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

on the European health record exchange format (EEHRxF)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847¹, and in particular Article 15(1), first sentence and Article 15(2) thereof,

Whereas:

- (1) [General] Regulation (EU) 2025/327 aims to improve access to and control by natural persons over their personal electronic health data in the context of healthcare and to facilitate the exchange of such data. To this end, Article 15(1) of Regulation 2025/327 empowers the Commission to set up the European electronic health record exchange format (EEHRxF) for the exchange of the priority categories of personal electronic health data, as referred to in Article 14(1) of that Regulation.
- (2) [General] Commission Recommendation (EU) 2019/243 which established a framework for the development of the EEHRxF and expanded upon the eHealth Network guidelines on electronic exchange of electronic health data, serves as a reference for laying the foundations of the EEHRxF. The guidelines and the Recommendation provided a basis for further development of the EEHRxF through the Xt-EHR Joint Action funded under the EU4Health Programme and through the eHealth Network, comprising participants from EU Member States, Iceland and Norway.
- (3) [Article: Subject matter and scope] The EEHRxF is intended to facilitate the exchange of personal electronic health data as specified in Regulation (EU) 2025/327. This includes several use cases, namely the download of an electronic copy of personal electronic health data when exercising the right of access, the transmission of a downloaded electronic copy to healthcare providers, the transmission of personal electronic health data amongst healthcare providers in different Member States following a natural person's request when exercising the right to data portability, and the implementation of the harmonised interoperability software components of electronic health record systems.

- (4) [Article: Subject matter and scope] The EEHRxF defines a common baseline of semantic and technical capabilities, facilitating interoperability in the exchange of personal electronic health data for the EEHRxF use cases. The EEHRxF does not require any particular internal architecture or data storage model in EHR systems. It does not establish a minimum or maximum set of data that healthcare providers are required to register. In the course of registering treatment-related information into patients' electronic health records, healthcare providers may be subject to both national rules, and requirements stemming from the implementing act adopted under the empowerment of Article 13(4), first subparagraph, of Regulation (EU) 2025/327. Where such data are collected and recorded in an EHR system, they should be made available in the EEHRxF upon issuance or transmission, to the extent that the data collected correspond to the data elements and use cases defined in this Regulation.
- (5) [Article: Subject matter and scope] Member States' digital health infrastructures reflect their health system organisation, which may, inter alia, contain national and regional organisational, clinical and administrative requirements for the exchange of personal electronic health data that go beyond the EEHRxF use cases. Member States may develop national profiles of the EEHRxF tailored to their specific national or regional interoperability needs and the provision of healthcare services. Such national profiles may, for instance, provide for stricter cardinalities on data elements, introduce additional data elements necessary for national clinical workflows, support supplementary or alternative coding systems used in national healthcare provision, or add implementation constraints required for local administrative or operational purposes. The development of such national profiles should always be without prejudice and complement the EEHRxF, ensuring that the common baseline for the EEHRxF use cases defined in this Regulation is preserved across all Member States. Member States are encouraged to coordinate on the development of national profiles and to provide visibility of existing and planned national profiles to other Member States and the Commission.
- (6) [Article: Metadata specifications] To understand, correctly identify and use personal electronic health data, it is necessary to provide information describing that data in order to query and retrieve the data in the context of an electronic exchange. Such information, commonly referred to as metadata, does not form part of the clinical content itself, but provides essential context, such as how the data can be identified, organised or related to other information. The EEHRxF should therefore include common metadata specifications applicable to the exchange, search and retrieval of priority categories of personal electronic health data.
- (7) [Article: Technical interoperability and exchange] In order to enable the exchange of personal electronic health data in a consistent and interoperable manner, it is necessary to define technical specifications governing how such data are represented and exchanged. These technical interoperability and exchange specifications should therefore form part of the EEHRxF.
- (8) [Article: Technical interoperability and exchange] The EEHRxF should support the exchange of priority categories of personal electronic health data in both structured and unstructured form. Where the availability of structured data is limited, the possibility to exchange unstructured data, in the form of human-readable records such as text or PDF attachments, safeguards patient safety and ensures continuity of care. To further improve the usability of the exchanged health data, Member States ought to

progressively increase the share of structured data in health data exchanges. This may include, in particular, gradually increasing the use of structured data in national health data exchanges and working towards increased transmission of structured data through national contact points for digital health.

- (9) [Article: Technical interoperability and exchange] Considering the wide use of HL7 FHIR, DICOM and PDF in existing digital health infrastructures, these technical interoperability standards should be used in the EEHRxF for technical interoperability. Version R4 of HL7 FHIR should be used as part of technical interoperability and exchange specifications, considering its maturity. Where other versions of HL7 FHIR are used as part of national digital health infrastructures, Member States ought to be responsible for adopting necessary technical solutions that ensure compatibility with HL7 FHIR version R4 through appropriate mappings. Given the evolving nature of the HL7 FHIR standard, the version used as part of technical interoperability and exchange specifications may be subject to review in the updates of the EEHRxF to ensure that the EEHRxF remains aligned with technical developments and international standards.
- (10) [Article: Category-dependent specifications] The priority categories of personal electronic health data covered by the EEHRxF differ in their purpose of exchange, content and level of clinical detail. Category-dependent specifications should define, for each priority category of personal electronic health data, the required structural format and semantic representation, taking into account the specific characteristics of that category. Where appropriate, the category-dependent specifications should rely on common data groups or elements, whose meaning is defined in a uniform way in the EEHRxF.
- (11) [Article: Data groups] Some data groups are relevant to multiple priority categories of personal electronic health data. This includes shared clinical or administrative concepts, such as concepts relating to a natural person or a medicinal product. To avoid unnecessary duplication, inconsistencies in structure or meaning, and reduced interoperability, these data groups should be defined once and reused in category-dependent specifications where appropriate and maintained accordingly.
- (12) [Article: Coding systems and value sets] Semantic interoperability in the exchange of electronic health data requires the use of common coding systems and value sets. The EEHRxF defines, for each coded data field, the coding system or coding systems to be used, designating a preferred coding system where multiple options are defined. Where a Member State requires, for a specific data field, the use of a national or alternative international coding system to support the provision of healthcare services at national level, it should make available mapping rules to at least one of the coding systems defined in the EEHRxF for that data field. Member States should share information about such mapping rules with the Commission, to facilitate coordination at Union level when similar mapping rules are developed by multiple Member States. Following application of such mappings, both the original national coding and the result of the mapping should be provided as part of the coded element. Where mapping is not possible, the original national coding, together with its textual designation in English, should be provided. Where the EEHRxF explicitly provides for the use of national coding systems for specific data fields, the requirement to provide a mapping does not apply.

- (13) [Article: Coding systems and value sets] To define values to be used for a coded data field expressed in the EEHRxF, the EEHRxF may either directly provide a value set, reference a coding system from which the values should be drawn, or reference an existing value set defined as part of a standard. Regardless of the manner in which a value set is established, consistent governance at Union level is necessary to ensure its uniform application across Member States. Value sets not directly defined in the EEHRxF should, therefore, be approved by the EHDS Board. The EHDS Board should also be able to extend value sets defined in the EEHRxF in justified cases, for instance where clinical or scientific developments require the inclusion of additional values. The development and maintenance arrangements for such value sets should be aligned with the broader governance and maintenance plan for the EEHRxFF.
- (14) [Article: Governance] To assist the implementation of the EEHRxF, the Commission, together with the Member States and taking into account the input of relevant stakeholders, should develop the EEHRxF implementation guide on the basis of this Regulation. The EEHRxF implementation guide should be approved by the EHDS Board. The Commission should publish information on the approved implementation guide, including information on its versions and their applicability periods. That information should clearly indicate whether a particular requirement in the EEHRxF implementation guide is affected by any updates made in the latest version of the EEHRxF. To facilitate the systematic updating of the EEHRxF implementation guide, the Commission, together with the EHDS Board, should develop and publish an EEHRxF maintenance plan.
- (15) The European Data Protection Supervisor has been consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 and delivered an opinion on **XX XX 2026**.
- (16) This Implementing Regulation introduces binding requirements for cross-border digital public services within the meaning of Regulation (EU) 2024/903. Accordingly, an interoperability assessment has been carried out and the resulting report will be published on the Interoperable Europe Portal when the legal act is adopted.
- (17) The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 98(1) of Regulation (EU) 2025/327,

HAS ADOPTED THIS REGULATION:

Article 1
Subject matter and scope

- (1) This Regulation sets out the European electronic health record exchange format (EEHRxF) laying down technical specifications for the priority categories of personal electronic health data referred to in Article 14(1) of Regulation (EU) 2025/327.
- (2) The EEHRxF is intended to be used in the following use cases:
- (a) to download an electronic copy of personal electronic health data by natural persons pursuant to Article 3(2) of Regulation (EU) 2025/327;

- (b) to transmit a downloaded electronic copy of personal electronic health data to a healthcare provider of the natural person's choice pursuant to Article 7(4) of Regulation (EU) 2025/327;
- (c) to transmit personal electronic health data between healthcare providers pursuant to Article 7(2) of Regulation (EU) 2025/327;
- (d) to exchange personal electronic health data across borders through MyHealth@EU pursuant to Article 23(3) of Regulation (EU) 2025/327;
- (e) to implement the harmonised software components of EHR systems in accordance with common specifications referred to in Article 36 of Regulation (EU) 2025/327.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (a) 'structured content representation' means a method for machine-readable encoding of personal electronic health data that enables automatic identification of individual elements;
- (b) 'unstructured content representation' means a method for encoding personal electronic health data in a machine-readable transmission container, in the form of human-readable content, which does not enable automated identification of individual elements;
- (c) 'content transmission' means a technical method for electronic transmission of electronic health data between systems;
- (d) 'PDF' means the portable document format;
- (e) 'HL7 FHIR' means Fast Healthcare Interoperability Resources defined by Health Level Seven International;
- (f) 'DICOM' means the Digital Imaging and Communications in Medicine standard defined by the National Electrical Manufacturers Association;
- (g) 'REST API' means the application programming interface that adheres to the principles of representational state transfer (REST) in accordance with section "RESTful API" of HL7 FHIR;
- (h) 'element' means a defined unit that represents either a data field or a data group;
- (i) 'level' means the hierarchical level in the model on which each data element occurs;
- (j) 'data field' means an individual item of information that represents a single, specific piece of data;
- (k) 'data group' means a logical collection of related data fields that together represent a broader set of information;
- (l) 'data type' means a classification that determines how the content of a data field or data group is structured and expressed;
- (m) 'binding requirement' means a requirement that constrains the permitted values of a data element through the designation of a specific coding system or value set from which values of that element shall be drawn;

- (n) 'cardinality' means the minimum and maximum number of times that an element can occur in the containing data model or data element, it is expressed as:
 '0..1 (optional)' the data element is optional, it can be omitted entirely, but if present it can only appear once
 '1..1 (mandatory)' the data element is mandatory and must appear exactly once
 '0..*' (optional and repeatable)' the data element is optional but, if used, can be repeated multiple times
 '1..*' (mandatory and repeatable)' the data element is mandatory and must appear at least once, but can be repeated multiple times;
- (o) '[x]' means that the element can be represented by one of the alternative nested data elements that inherit the cardinality of the containing element;
- (p) 'coding system' means a set of codes used to represent values for a data field in a standardised and unambiguous way;
- (q) 'coded data field' means a data field whose value shall be drawn from a defined coding system or a value set;
- (r) 'logical information model' means a machine-readable structured representation of the data structures laid down in Annexes III to XI of this Regulation;
- (s) 'EEHRxF implementation guide' means machine-readable technical documentation, for the implementation of the EEHRxF and conformance testing of EHR systems that implement the EEHRxF;
- (t) 'national profile' means a specification adopted by a Member State that complements the EEHRxF for national interoperability needs and the provision of healthcare services within that Member State.

Article 3

Technical interoperability and exchange specifications

1. Where the EEHRxF is used for the exchange of personal electronic health data, this shall be performed by one or more of the following technical representations:

- (a) a representation consisting of a PDF attachment embedded in an HL7 FHIR resource, including the applicable metadata set;
- (b) a representation compliant with HL7 FHIR and consisting of a set of human-readable summaries organised per the relevant data groups and including the applicable metadata set;
- (c) a representation compliant with HL7 FHIR and consisting of structured data accompanied by human-readable summaries of the same data, organised per the relevant data groups and including the applicable metadata set;
- (d) for medical imaging studies and related manifests, a representation consisting of structured data using the DICOM standard.

2. The requirements laying down the technical interoperability and exchange specifications of the EEHRxF are set out in Annex I.

Article 4
Metadata specifications

The requirements laying down common specifications on metadata applicable to the exchange, search and retrieval of personal electronic health data are set out in Annex II.

Article 5
Category-dependent specifications

The specifications for each priority category of personal electronic health data as referred to in Article 14(1) of Regulation (EU) 2025/327, including the structural and semantic requirements, are set out in Annexes III to VIII.

Article 6
Coding systems and value sets

1. The coding systems to be used for each coded data field are set out in Annexes II to IX. Where the binding requirement designates a preferred coding system among multiple options, that coding system shall be used where technically feasible.
2. Where a Member State requires, for a coded data field, the use of a coding system that is not referred to in the binding requirements for that data field, it shall make available the mapping rules to at least one of the coding systems referred to in the binding requirements for that data field. Member States shall provide information on such mapping rules to the Commission.
3. Following the application of such mapping, both the original national coding and the result of the mapping shall be provided as part of the coded data field. Where mapping is not possible, the original national coding, together with its textual designation in English, shall be provided.
4. Where a value set from which values of a coded data field shall be drawn is not set out in this Regulation, the EHDS Board shall adopt the value set. The EHDS Board may, in justified cases, decide to extend a value set defined in the EEHRxF.
5. The Commission shall publish the value sets referred to in paragraph 4, and the mappings provided under paragraph 2, in a machine-readable format through a versioned terminology service. This requirement shall not apply to coded data fields that allow the use of national coding systems.

Article 7
Data groups

1. The requirements for data groups representing elements applicable to multiple priority categories of personal electronic health data pursuant to Article 14(1) of Regulation (EU) 2025/327 are set out in Annex IX.
2. Data groups may be exchanged both as part of documents or as individual resources, depending on the needs for a particular data exchange.

Article 8
Data types

The data types used in Annexes II to IX are set out in Annex X.

Article 9
Technical artefacts, governance and versioning of the EEHRxF

1. The Commission shall publish online the EEHRxF logical information models that represent the data structures set out in Annexes II to IX.
2. The Commission, in cooperation with the Member States and relevant stakeholders, shall develop the EEHRxF implementation guide on the basis of this Regulation, with the view of enabling the technical implementation of the EEHRxF. The EHDS Board, shall endorse the EEHRxF implementation guide that constitutes the normative implementation guide for the purposes of this Regulation. The Commission shall publish the EEHRxF implementation guide approved by the EHDS Board in machine-readable format.
3. The Commission shall make publicly available information on the versioning of the EEHRxF, including the applicable logical information models and the EEHRxF implementation guide, clearly distinguishing which requirements in the implementation guide are affected by updates to the new versions of the EEHRxF.
4. The Commission, together with the EHDS Board, shall develop and make publicly available an EEHRxF maintenance plan for the EEHRxF artefacts, covering at least:
 - (a) the process for changes to the EEHRxF implementation guide, including transition between its versions;
 - (b) the roles of the participants in that process, including standards development organisations and the Stakeholder Forum.

Article 10
Relation to national profiles

1. Member States may define national profiles of the EEHRxF, including for the purposes of operating national digital health infrastructures.
2. National profiles shall not remove or restrict the technical interoperability and exchange specifications, metadata, coding systems, data groups or data types required for the use cases referred to in Article 1(2).

Article 12
Entry into force and applicability

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
[\[...\]](#)

[Choose between the two options, depending on the person who signs.]

On behalf of the President

[...]

[Position]

Annex I

Technical interoperability and exchange specifications

Where references are made in the table to HL7 FHIR this shall mean version R4 of HL7 FHIR.
Where references are made in the table to PDF this shall mean version PDF/A-1a.

Priority data category	Unstructured content representation	Structured content representation	Content transmission
Patient summary	PDF or HL7 FHIR Narrative	HL7 FHIR	HL7 FHIR REST API
Electronic prescriptions	PDF or HL7 FHIR Narrative	HL7 FHIR	HL7 FHIR REST API
Electronic dispensations	PDF or HL7 FHIR Narrative	HL7 FHIR	HL7 FHIR REST API
Medical imaging studies and related imaging reports	Medical imaging studies: PDF Imaging reports: PDF or HL7 FHIR Narrative	Medical imaging studies manifest: HL7 FHIR and DICOM Medical imaging studies: DICOM Imaging reports: HL7 FHIR	Medical imaging studies manifest: HL7 FHIR REST API Medical imaging studies: DICOMWeb Imaging reports: HL7 FHIR REST API
Medical test results, including laboratory and other diagnostic results and related reports	PDF or HL7 FHIR Narrative	HL7 FHIR	HL7 FHIR REST API
Discharge reports	PDF or HL7 FHIR Narrative	HL7 FHIR	HL7 FHIR REST API

Annex II
Metadata applicable to all priority data categories

This Annex establishes the metadata applicable to the exchange, search and retrieval of personal electronic health data.

Table 1. EHDS – Document metadata.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	subject	Patient/subject information.	EHDSPatient	1..1	
	identifier	Unique identifier of the document.	Identifier	1..*	
	document Type	Type of document (e.g. 60591-5 Patient summary document).	CodeableConcept	1..1	LOINC
	document Title	Human readable document title that can be displayed in search results, etc. This can be documentType's display name, or it can be assembled from multiple elements. Examples: 'Laboratory Result Report', 'Patient Summary of Jane Green 10.12.2024'	string	1..1	
	period	Time of service that is being documented	Period	0..1	
	version	Version of the document.	string	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	author[x]	Information describing who authored the resource or document.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..*	
	attestation	Document attestation details.	Base	0..*	
+	attester[x]	Attester who validated the document.	EHDSHealthProfessional, EHDSDevice	1..1	
+	dateTime	Date and time of the approval of the document by the attester.	dateTime	1..1	
	legalAuthentication	Document legal authentication details. Legal authentication metadata is included only where required by applicable legal or organisational frameworks. Absence of legal authentication does not affect interoperability conformance under this profile.	Base	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	legalAuthenticator[X]	The person taking responsibility for the medical content of the document legalAuthenticator can be different from author and attester (e.g author=junior doctor, attester=senior physician, legalAuthenticator= attending physician).	EHDSHealthProfessional, EHDSOrganisation	1..1	
+	dateTime	Date and time when the document was authorised.	dateTime	1..1	
	eventCategory	Categorisation of the event covered by the document (e.g. laboratory study types, imaging study types including modality, etc.). Selection of such tags or labels depends on the use case and agreement between data sharing parties. This meta-data element serves primarily for searching and filtering purposes.	CodeableConcept	0..*	SNOMED GPS, LOINC, DICOM CID 33 Modality
	status	Status of the resource or document.		1..1	HL7 Composition Status
	language	Language in which the document or resource is written. Language is expressed by the IETF language tag.	CodeableConcept	1..1	BCP 47

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	lastUpdate	Date and time of the last system-level update to this document or resource (system update instant). This is technical metadata and does not represent a clinical event time.	dateTime	0..1	
	serviceSpecialty	Additional details about where the content was created (e.g. clinical specialty)	CodeableConcept	0..*	SNOMED GPS
	custodian	Organisation that is in charge of maintaining the document or resource.	EHDSEntity	0..1	

Annex III
Patient Summary

The model is a structured document designed to provide an overview of a patient's most important health information. The model aims to be compatible with the ISO International Patient Summary standard.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSPatientSummary	Patient summary model.	Derived from parent data type: EHDSDocument		
+	header	Patient summary header.	Base	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Unique identifier of the document.	Identifier	1..*	
++	author[x]	Author of the document.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..*	
++	date	Date of finalising/issuing the document.	dateTime	1..1	
++	status	Status of the document.	CodeableConcept	1..1	HL7 Composition Status
++	language	Language in which the document is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
++	documentType	Type of document (e.g. 60591-5 Patient summary document).	CodeableConcept	1..1	LOINC
++	documentTitle	Human readable document title that can be displayed in search results, etc. This can be documentType's display name, or it can contain further information. Example: 'Patient Summary of Jane Green 10.12.2024'.	string	1..1	
++	version	Version of the document.	string	1..1	
++	countryOfOrigin	Country of origin of the document.	CodeableConcept	0..1	ISO 3166-1 alpha-2

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	attestation	Document attestation details.	Base	0..*	
+++	attester[x]	Attester who validated the document.	EHDSHealthProfessional, EHDSDevice	1..1	
+++	dateTime	Date and time of the approval of the document by the attester.	dateTime	1..1	
++	legalAuthentication	Document legal authentication details.	Base	0..*	
+++	legalAuthenticator[x]	The person or organisation taking responsibility for the content of the document .	EHDSHealthProfessional, EHDSOrganisation	1..1	
+++	dateTime	Date and time when the document was authenticated.	dateTime	1..1	
++	eventCategory	Categorisation of the event covered by the document (e.g. in case of a partial patient summary related to a specific context). Selection of such tags or labels depends on the use case and agreement between data sharing parties. This meta-data element serves primarily for searching and filtering purposes.	CodeableConcept	0..*	SNOMED GPS (preferred), LOINC
++	serviceSpecialty	Additional details about where the content was created (e.g. clinical specialty).	CodeableConcept	0..*	SNOMED GPS

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	custodian	Organisation that is in charge of maintaining the document.	EHDSOrganisation	0..1	
+	presentedForm	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document.	EHDSAttachment	0..*	
+	alerts	Section: Alerts.	Base	0..1	
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
++	medicalAlert	Medical alerts.	EHDSAlert	0..*	
+	allergiesAndIntolerances	Section: Allergies and intolerances.	Base	1..1	
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
++	allergyIntolerance	Allergies and intolerances.	EHDSAllergyIntolerance	0..*	
++	emptyReason	Reason for absence of data. The field shall be present when no allergy or intolerance entries are present.	CodeableConcept	0..1	HL7 Data Absent Reason
+	problems	Section: Medical problems.	Base	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
++	emptyReason	Reason for absence of data. The field shall be present when no problem entries are present.	CodeableConcept	0..1	HL7 Data Absent Reason
++	currentProblem	Active health conditions affecting the health of the patient.	EHDSCondition	0..*	
++	pastProblem	Relevant past conditions the patient has suffered from that are no longer under currentProblem.	EHDSCondition	0..*	
+	medicationSummary	Section: Medication summary.	Base	1..1	
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
++	emptyReason	Reason for absence of data. The field shall be present when no medication entries are present.	CodeableConcept	0..1	HL7 Data Absent Reason
++	medicationUse	Use of medicinal product relevant for this patient summary. Typically, medicinal products whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not.	EHDSMedicationUse	0..*	
+	medicalDevicesAndImplants	Section: Medical devices and implants.	Base	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
++	emptyReason	Reason for absence of data. The field shall be present when no medical device or implant entries are present.	CodeableConcept	0..1	HL7 Data Absent Reason
++	deviceUse	Implanted and external medical devices and equipment.	EHDSDDeviceUse	0..*	
+	procedures	Section: Procedures.	Base	1..1	
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
++	emptyReason	Reason for absence of data. The field shall be present when no procedure entries are present.	CodeableConcept	0..1	HL7 Data Absent Reason
++	procedure	List of procedures.	EHDSPProcedure	0..*	
+	immunisations	Section: Immunisations,	Base	1..1	
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
++	emptyReason	Reason for absence of data. The field shall be present when no immunisation entries are present.	CodeableConcept	0..1	HL7 Data Absent Reason

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	immunisation	Immunisations.	EHDSImmunisation	0..*	
+	functionalStatus	Section: Functional status.	Base	0..1	
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
++	condition	Last assessment results recorded regarding conditions describing the patient's functional status or disability.	EHDSCondition	0..*	
++	assessment	Last assessment results regarding functional status.	EHDSObservation	0..*	
+	socialHistory	Section: Social history.	Base	0..1	
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
++	observation	Health related lifestyle factors or lifestyle observations and social determinants of health. Example: cigarette smoker, alcohol consumption.	EHDSObservation	0..*	
+	pregnancyHistory	Section: Pregnancy history.	Base	0..1	
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	currentPregnancyStatus	Current pregnancy status.	EHDSCurrentPregnancyStatus	0..1	
++	previousPregnancies	History of previous pregnancies.	EHDSPregnancyHistory	0..*	
+	travelHistory	Section: Travel history.	Base	0..1	
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
++	travelHistory	Travel history for one country	EHDSTravelHistory	0..*	
+	patientStory	Section: Patient story. A concise narrative from the patient's perspective about their present health state. This is a record of things that a person feels are important to communicate about their needs, strengths, values, concerns and preferences to others providing support and care.	Base	0..1	
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
+	advanceDirectives	Section: Advance Directives.	Base	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
++	advanceDirective	Provision for healthcare decisions if, in the future, a person is unable to make those decisions.	EHDSAAdvanceDirective	0..*	
+	observationResults	Section: Observation results.	Base	0..1	
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
++	result	Observation results pertaining to the patient's health condition.	EHDSObservation	0..*	
+	carePlan	Section: Care plans.	Base	0..1	
++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
++	carePlan	Describes the intention of how one or more practitioners intend to deliver care for the patient for a period of time, possibly limited to care for a specific condition or set of conditions.	EHDESCarePlan	0..*	

Annex IV
Electronic prescription

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSPrescription	Electronic prescription model.	Derived from parent data type: EHDSDataSet		
+	header	Prescription header.	Base	1..1	
++	subject	The person for whom a medicinal product is prescribed/ordered.	EHDSPatient	1..1	
++	identifier	Business identifier(s) for the prescription.	Identifier	1..*	
++	author	Author of the document.	EHDSHealthProfessional	1..*	
++	date	Time of issuing (signing) the prescription by prescriber.	dateTime	1..1	
++	status	Status of authorisation for dispensing the prescription items. For a multiple-item prescription, this conveys the aggregate status of the entire prescription. In case of a single-item prescription, prescriptionItem.status shall be the same as header.status.	CodeableConcept	1..1	HL7 Medication Request Status
++	language	Language in which the document is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	statusReason[x]	Reason for the current status of prescription, for example the reason why the prescription was cancelled or changed from a previous state.	CodeableConcept, string	0..1	Not defined
+	presentedForm	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document.	EHDSAttachment	0..*	
+	prescriptionItem	Prescription line for one medicinal product. In case multiple medicinal products are prescribed, all items need to be authored together.	Base	1..*	
++	identifier	Identifier for a single item on the prescription. This identifier may be linked to the prescription identifier. In case of a multiple-line prescription, this identifier can be constructed, for example, as the prescription identifier combined with the line number.	Identifier	1..*	
++	status	Status of a single item on prescription. In case of a single-item prescription, the status of the prescription has the same meaning as the status of the item.	CodeableConcept	1..1	HL7 Medication Request Status
++	statusReason[x]	Reason for the current status of prescription item, for example the reason why the prescription was cancelled or why the prescription was changed from previous.	CodeableConcept, string	0..1	Not defined

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	medication	Prescribed medicinal product.	EHDSMedication	1..1	
++	indication[x]	Reason for the prescription (typically diagnosis, or a procedure).	CodeableConcept, string	0..*	SNOMED GPS (preferred), ICD-10, Orphacode
++	intendedUseType	Intent of the prescription - prophylaxis, treatment, anaesthesia, etc.	CodeableConcept	0..1	SNOMED GPS
++	periodOfUse	Period over which the medicinal product is to be taken (in case of multiple dosage schemes, this shall be the overall period of all dosages).	Period	0..1	
++	quantityPrescribed	Overall quantity of prescribed medicinal product (e.g number of packages or number of tablets). In case of multiple items, this should indicate the overall quantity for the whole prescription. Where the total quantity cannot be determined unambiguously at issuance, the prescriber may express it on the basis of dosage instructions, validity period and number of repeats.	Quantity	1..1	UCUM for units of measurement, EDQM Standard Terms for units of presentation
++	dosageInstructions	Dosage and administration instructions.	EHDSDosage	0..1	
++	validityPeriod	The period over which the prescription is considered valid and dispensable. validityPeriod.start is, if missing, assumed to be the date of issuing the prescription.	Period	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	substitution	Whether and which type of substitution is allowed, as indicated by the prescriber, for this prescription. The legislation in the country of dispense applies for performing a substitution.	Base	0..1	
+++	allowed[x]	Whether and to what extent substitution is allowed.	boolean, CodeableConcept	0..1	HL7 Substance Admin Substitution
+++	reason[x]	Reason for the substitution requirement (e.g. Biological product, Patient allergic to an excipient in alternative products, etc).	CodeableConcept, string	0..1	SNOMED GPS
++	numberOfRepeats	Number of refills authorised - how many times the prescription item can be dispensed in addition to the original dispense. If the element is missing, no repeats are authorised.	integer	0..1	
++	minimumDispenseInterval	Minimum dispense interval. If a prescription allows for repeated dispensations, the interval between dispensations shall be stated here.	Quantity	0..1	
++	offLabel	Indicates that the medicinal product is knowingly prescribed for use for an age group, dosage, or route of administration not included in the authorised product information.	Base	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	isOffLabelUse	Indicates off-label use. Must be 'true' when reason is provided.	boolean	1..1	
+++	reason[x]	Reason or related clarification for off-label use.	CodeableConcept, string	0..1	Not defined
++	note	Additional information or comments, e.g. message to the dispenser.	string	0..1	

Annex V
Electronic dispensation

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSPatientDispense	Medication dispense model.	Derived from parent data type: EHDSPatientDispense		
+	header	Dispensation header.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the dispensation.	Identifier	1..*	
++	author[x]	Author of the document.	EHDSPatient, EHDSPatient, EHDSPatient,	1..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	date	Date and time of issuing the dispense record.	dateTime	1..1	
++	status	The status of the dispense, e.g. completed, declined, entered-in-error.	CodeableConcept	1..1	HL7 Medication Dispense Status Codes
++	language	Language in which the document is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	dispenseLocation	Location of dispense.	EHDSOrganisation	0..1	
+	receiver[x]	Identification of the person who received the dispensed medicinal products, especially when it was not the patient. When not present, it is assumed that the patient is the receiver.	EHDSPatient, EHDSHealthProfessional, EHDSRelatedPerson	0..1	
+	relatedRequest	Identifier of the prescription item the dispense is related to.	Identifier	1..*	
+	medication	Exact dispensed product. If multiple medicinal products are dispensed together, multiple dispense records should be created.	EHDSMedication	1..1	
+	dispensedQuantity	Number of dispensed packages if the package size is known, or number of smaller items/units, according to the medicinal product dispensed. A unit shall be provided.	Quantity	1..1	UCUM for units of measurement, EDQM Standard Terms for units of presentation

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	substitutionOccurred	Whether substitution was made by the dispenser. Definition of substitution is specific to the jurisdiction.	boolean	0..1	
+	dosageInstructions	Dosage and administration instructions for the dispensed medicinal product. These instructions may deviate from the instructions included in the prescription.	EHDSDosage	0..1	
+	note	Additional information or comments.	string	0..1	

Annex VI
Medical imaging studies and related imaging reports

Table 1. Imaging report.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSImagingReport	Imaging report model.	Derived from parent data type: EHDSDocument		
+	header	Document header.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	1..*	
++	author[x]	Author of the document.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..*	
++	date	Date and optionally time of authoring/issuing	dateTime	1..1	
++	status	Status of the document.	CodeableConcept	1..1	HL7 Imaging Study Status
++	language	Language in which the document is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
++	documentType	Type of document (e.g. 18748-4 Diagnostic imaging study).	CodeableConcept	1..1	LOINC
++	documentTitle	Human readable document title that can be displayed in search results, etc. This can be documentType's display name, or it can contain further information.	string	1..1	
++	period	Time of service (imaging study) that is being documented.	Period	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	version	Version of the document.	string	1..1	
++	attestation	Document attestation details.	Base	0..*	
+++	attester[x]	Attester who validated the document.	EHDSHealthProfessional, EHDSDevice	1..1	
+++	datetime	Date and time of the approval of the document by the attester	dateTime	1..1	
++	legalAuthentication	Document legal authentication details	Base	0..*	
+++	legalAuthenticator[x]	The person or organisation taking responsibility for the content of the document .	EHDSHealthProfessional, EHDSOrganisation	1..1	
+++	dateTime	Date and time when the document was authorised	dateTime	1..1	
++	eventCategory	Categorisation of the event covered by the document (e.g. imaging study types, body regions, modality, etc.). Selection of such tags or labels depends on the use case and agreement between data sharing parties. This meta-data element serves primarily for searching and filtering purposes.	CodeableConcept	0..*	DICOM CID 33 Modality (preferred), SNOMED GPS

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	serviceSpecialty	Additional details about where the content was created (e.g. clinical specialty)	CodeableConcept	0..*	SNOMED GPS
++	custodian	Organisation that is in charge of maintaining the document.	EHDSOrganisation	0..1	
++	countryOfOrigin	Country of origin of the document.	CodeableConcept	0..1	ISO 3166-1 alpha-2
++	accessionNumber	Accession number - an identifier, managed by the RIS at the local level, which usually uniquely identifies an imaging procedure request, and links it to imaging study and related imaging report.	Identifier	0..*	
++	intendedRecipient[x]	Intended recipient of the information, i.e. a person or organisation that should be notified or be aware of the content. This element is used to indicate explicit communication intent and does not represent routine storage or passive availability of information (e.g. in portals).	EHDSPatient, EHDSRelatedPerson, EHDSHealthProfessional, EHDSOrganisation	0..*	
+	presentedForm	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document.		0..*	
+	body	Imaging report structured body.	Base	0..1	
++	orderInformation	Order to which this imaging report is linked.	Base	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	orderId	Identifier of the imaging service order.	Identifier	1..*	
+++	orderDateAndTime	Date and time of the order placement.	dateTime	0..1	
+++	orderPlacer[x]	The person/organisation authorised to place the order.	EHDSHealthProfessional, EHDSOrganisation, EHDSPatient	0..1	
+++	orderReason[x]	An explanation or justification for why this service is being requested.	CodeableConcept, EHDSCondition, EHDSObservation, string	0..*	SNOMED GPS (preferred), ICD-10
+++	clinicalQuestion	Specification of clinical question (goal of the investigation) to be answered by the imaging investigation.	string	0..1	
++	supportingInformation	This information includes diagnosis, clinical findings and other observations. This includes observations explicitly requested by the producer (filler) to provide context or supporting information needed to complete the order. For example, reporting the metal implants present in patient's body.	Base	0..1	
+++	observation	Clinical findings and other observations (e.g., height and weight of the patient).	EHDSObservation	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	condition	Condition that may influence the service or result interpretation.	EHDSCondition	0..*	
+++	priorMedicationAdministration	Medication administered before ordering the service that may influence the service or result interpretation.	EHDSPriorMedicationUse	0..*	
+++	device	List of implants or devices that affect the course of the examination or its interpretation (e.g. metal implants).	EHDSDDeviceUse	0..*	
+++	pregnancyStatus	Pregnancy status when the imaging examination was performed, e.g., pregnant, not pregnant, unknown.	EHDSCurrentPregnancyStatus	0..1	
++	specimen	Specimen information.	EHDSSpecimen	0..*	
++	exposureInformation	Information on total exposure during the imaging investigation to ionising radiation.	Base	0..1	
+++	summary	Summary information about the exposure to ionised radiation.	string	0..1	
+++	structuredDose	Structured representation of the exposure.	Base	0..*	
++++	doseQuantity	Ionised radiation received during the imaging investigation.	Quantity	0..1	UCUM for units

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++++	doseModality	Imaging modality used during imaging investigation (DICOM CID029).	CodeableConcept	0..1	DICOM Modality
++++	bodySite	Body part investigated.	EHDSBodyStructure	0..1	
++++	numberOfSeries	Number of series in the study.	integer	0..1	
++	examinationReport	Examination report content.	Base	1..1	
+++	modality	Imaging modality used during imaging investigation (DICOM CID029).	CodeableConcept	1..*	DICOM Modality
+++	bodySite	Body part investigated.	EHDSBodyStructure	0..*	
+++	imagingProcedure	Imaging procedure performed during imaging study.	EHDSProcedure	0..*	
+++	medicationAdministration	Information about medications administered (contrast, sedation, stress agents, etc) to enable the imaging investigation or during it.	EHDSMedicationAdministration	0..*	
+++	adverseReaction	Adverse reaction manifested during imaging investigation.	EHDSAllergyIntolerance	0..*	
+++	results[x]	Imaging report result data.	EHDSObservation, string	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	conclusion	A concise and clinically contextualised summary including interpretation/impression of the diagnostic report.	Base	0..1	
++++	impression	Narrative description of the clinical conclusion (impression).	string	1..1	
++++	conditionOrFinding[x]	Condition or finding from imaging investigation.	EHDSCondition, EHDSObservation	0..*	
++	recommendation	Recommendation section for additional imaging investigations or other actions.	Base	0..1	
+++	description	Narrative description of the recommended activities including additional investigation, medication etc.	string	1..1	
+++	carePlan	A complex and structured information about recommended goals, activities and objectives in the form of one or more formal care plan to be implemented after this imaging investigation.	EHDSCarePlan	0..*	
++	comparisonStudy	Documentation (reference) of a prior Imaging Report to which the current images were compared.	EHDSImagingReport	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	dicomStudyMetadata	Metadata of the DICOM study. A study comprises a set of series, each of which includes a set of Service-Object Pair Instances (SOP Instances - images or other data) acquired or produced in a common context. A series is of only one modality (e.g. X-ray, CT, MR, ultrasound), but a study may have multiple series of different modalities.	EHDSImagingStudy	0..*	
+	attachments	Report attachments.	EHDSAttachment	0..*	

Table 2. Imaging study.

EHDSImagingStudy means the structured set of data elements for facilitating the exchange of imaging studies. Its goal is to enable the exchange of imaging studies regardless of whether the corresponding imaging report is available. It contains metadata that includes the endpoint where the imaging study is located. EHDSImagingStudy may be represented using DICOM KOS and/or HL7 FHIR, depending on the implementation guide.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSImagingStudy	Imaging study model.	Derived from parent data type: EHDSDataSet		
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within	Identifier	1..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		its system. Supporting disambiguation between different contexts (systems/countries).			
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..*	
++	date	Date and optionally time when the imaging study representation or manifest was authored or issued, distinct from the date and time when the imaging study started.	dateTime	1..1	
++	status	Status of the resource. Where the source representation does not provide a reliable lifecycle status, unknown may be used. Status available shall only be used where availability has been established.	CodeableConcept	1..1	HL7 Imaging Study Status
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	presentedForm	PDF version of the imaging study to be used where DICOM version is not available.		0..*	
+	modality	All of the distinct values for series' modalities.	CodeableConcept	0..*	DICOM CID 33 Modality
+	bodySite	All of the distinct values for series' examined	EHDSBodyStructure	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		body parts.			
+	encounter	Reference to the encounter with which this imaging study is associated.	EHDSEncounter	0..1	
+	started	Date and time the study started.	dateTime	0..1	
+	basedOn	Reference to the diagnostic request that resulted in this imaging study being performed.	EHDSServiceRequest	0..*	
+	numberOfSeries	Number of series in the study.	integer	0..1	
+	numberOfInstances	Number of service-object pair (SOP) instances in the study. This value given may be larger than the number of instance elements this resource contains due to resource availability, security, or other factors. This element should be present if any instance elements are present.	integer	0..1	
+	description	The imaging manager description of the study. Institution-generated description or classification of the study (component) performed.	string	0..1	
+	custodian	Organisation name, address, contact information.	EHDSOrganisation	0..1	
+	endpoint	Study endpoint describing the technical details	EHDSEndpoint	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		of a location that can be connected to for the delivery/retrieval of an imaging study. Sufficient information is required to ensure that a connection can be made securely, and appropriate data transmitted as defined by the endpoint owner. These may be locally hosted services, regional services, or national service.			
+	series	Series. Each study has one or more series of instances, but they may be absent when no series information needs to be conveyed.	Base	0..*	
++	seriesUid	DICOM Series Instance UID for the series.	Identifier	1..1	
++	number	Numeric identifier of this series.	integer	0..1	
++	seriesModality	Acquisition modality used for this series.	CodeableConcept	1..1	DICOM CID 29 Acquisition Modality
++	description	A short human readable summary of the series.	string	0..1	
++	numberOfInstances	Number of series related instances.	integer	0..1	
++	seriesEndpoint	Series endpoint describing the technical details of a location that can be connected to for the delivery/retrieval of an imaging study. Sufficient information is required to ensure that a connection can be made securely, and	EHDSEndpoint	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		appropriate data transmitted as defined by the endpoint owner. These may be locally hosted services, regional services, or national service.			
++	bodySite	Body part examined.	EHDSBodyStructure	0..1	
++	specimen	Specimen imaged.	EHDSSpecimen	0..*	
++	started	Date and time when the series started.	dateTime	0..1	
++	instanceInTheSeries	Instance that is part of the series.	Base	0..*	
+++	instanceTitle	Instance title that is the description of the instance.	string	0..1	
+++	instanceUid	DICOM SOP Instance UID.	Identifier	1..1	
+++	sopClass	SOP class - DICOM class type.	uri	1..1	
+++	instanceNumber	The number of this instance in the series.	integer	0..1	
+++	numberOfFrames	The number of frames in a multiframe instance.	integer	0..1	
+++	keyImage	List of key image flags with a reason why this image is selected as a key image, and reference to the Key Image Note that flags the image as significant.	Base	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++++	flag	Reason for flagging the image as significant.	CodeableConcept	1..1	DICOM PS3.6
++++	reason	Textual reason for flagging the image as significant.	string	0..1	

Annex VII
Medical test results, including laboratory and other diagnostic results and related reports

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSMedicalTestReport	Medical test result and report model.	Derived from parent data type: EHDSDocument		
+	header	Document header.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Unique identifier of the document.	Identifier	1..*	
++	author[x]	Author of the document.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..*	
++	date	Date and optionally time of authoring/issuing.	dateTime	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	status	Status of the document.	CodeableConcept	1..1	HL7 Composition Status
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
++	documentType	Type of document (e.g., 11502-2 'Laboratory report' or 18759-1 'Spirometry study').	CodeableConcept	1..1	LOINC
++	documentTitle	Human readable document title that can be displayed in search results, etc. This can be documentType's display name, or it can be assembled from multiple elements. Examples: Medical test report.	string	1..1	
++	period	Time of service that is being documented.	Period	0..1	
++	version	Version of the document.	string	1..1	
++	attestation	Document attestation details.	Base	0..*	
+++	attester[x]	Attester who validated the document.	EHDSHealthProfessional, EHDSDevice	1..1	
+++	dateTime	Date and time of the approval of the document by the attester.	dateTime	1..1	
++	legalAuthentication	Document legal authentication details.	Base	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	legalAuthenticator[x]	The person or organization taking responsibility for the content of the document.	EHDSHealthProfessional, EHDSOrganisation	1..1	
+++	dateTime	Date and time when the document was authorised.	dateTime	1..1	
++	eventCategory	Categorisation of the event covered by the document (e.g. medical study types etc.). Selection of such tags or labels depends on the use case and agreement between data sharing parties. This meta-data element serves primarily for searching and filtering purposes.	CodeableConcept	0..*	LOINC (preferred), SNOMED GPS
++	serviceSpecialty	Additional details about where the content was created (e.g. clinical specialty).	CodeableConcept	0..*	SNOMED GPS
++	custodian	Organisation that is in charge of maintaining the document.	EHDSOrganisation	0..1	
++	countryOfOrigin	Country of origin of the document.	CodeableConcept	0..1	ISO 3166-1 alpha-2
+	intendedRecipient[x]	Information recipient of the information, i.e. a person or organisation that should be notified or be aware of the content. This element is used to indicate explicit communication intent and does not represent routine storage or passive availability of information (e.g. in portals).	EHDSPatient, EHDSRelatedPerson, EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	presentedForm	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document.	EHDSAttachment	0..*	
+	body	Medical test result and report structured body.	Base	0..1	
++	orderInformation	Order information	Base	0..*	
+++	orderId	An identifier of the medical test order.	Identifier	1..*	
+++	orderDateAndTime	Date and time of the order placement.	dateTime	0..1	
+++	orderPlacer[x]	The person/organisation authorised to place the order.	EHDSHealthProfessional, EHDSOrganisation, EHDSPatient	0..1	
+++	orderReason[x]	An explanation or justification for why this service is being requested.	CodeableConcept, EHDSCondition, EHDSObservation, string	0..*	SNOMED GPS (preferred), ICD-10
+++	clinicalQuestion	Specification of clinical question (goal of the investigation) to be answered by the medical test.	string	0..1	
++	supportingInformation	Additional clinical information about the patient or specimen that may influence the services or their interpretations. This information includes diagnosis, clinical findings and other observations. In medical test ordering these are	Base	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		typically referred to as 'ask at order entry questions (AOEs).' This includes observations explicitly requested by the producer (filler) to provide context or supporting information needed to complete the order. For example, reporting the amount of inspired oxygen for blood gas measurements.			
+++	observation	Clinical findings and other observations.	EHDSObservation	0..*	
+++	condition	Condition that may influence the service or result interpretation.	EHDSCondition	0..*	
+++	medicationAdministration	Medication administered specifically in relation to this test.	EHDSMedicationAdministration	0..*	
+++	immunisation	Immunisation history that may influence the service or result interpretation.	EHDSImmunisation	0..*	
++	specimen	Specimen information.	EHDSSpecimen	0..*	
++	resultData	Medical test result data.	Base	1..1	
+++	comment	Narrative, potentially formatted, such as a textual interpretation or advice accompanying the result report.	Narrative	0..1	
+++	medicalTestResult[x]	Observation details.	EHDSObservation,	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
			EHDSLaboratoryObservation		
+	attachment	Report attachment.	EHDSAttachment	0..*	

Annex VIII
Discharge reports

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	DischargeReport	Discharge report model.	Derived from parent data type: EHDSDocument		
+	header	Discharge report Document header.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Unique identifier of the document.	Identifier	1..*	
++	author[x]	Author of the document.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..*	
++	date	Date of finalising/issuing the document.	dateTime	1..1	
++	status	Status of the document.	CodeableConcept	1..1	HL7 Composition Status

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	language	Language in which the document is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
++	documentType	Type of document e.g. 34105-7 Hospital discharge summary.	CodeableConcept	1..1	LOINC
++	documentTitle	Human readable document title that can be displayed in search results, etc. This can be documentType's display name or it can contain further information. Example: 'Hospital discharge report. Jane Green. 07.10.2025-10.10.2025').	string	1..1	
++	period	Time period of information covered in the document.	Period	0..1	
++	version	Version of the document.	string	1..1	
++	attestation	Document attestation details.	Base	0..*	
+++	attester[x]	Attester who validated the document.	EHDSHealthProfessional, EHDSDevice	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	dateTime	Date and time of the approval of the document by the attester.	dateTime	1..1	
++	legalAuthentication	Document legal authentication details.	Base	0..*	
+++	legalAuthenticator[x]	The person or organisation taking responsibility for the content of the document.	EHDSHealthProfessional, EHDSOrganisation	1..1	
+++	datetime	Date and time when the document was authenticated.	dateTime	1..1	
++	eventCategory	Categorisation of the event covered by the document (e.g. discharge type). Selection of such tags or labels depends on the use case and agreement between data sharing parties. This meta-data element serves primarily for searching and filtering purposes.	CodeableConcept	0..*	SNOMED GPS (preferred), LOINC
++	serviceSpecialty	Additional details about where the content was created (e.g. clinical specialty)	CodeableConcept	0..*	SNOMED GPS

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	custodian	Organisation that is in charge of maintaining the document.	EHDSOrganisation	0..1	
++	countryOfOrigin	Country of origin of the document.	CodeableConcept	0..1	ISO 3166-1 alpha-2
++	intendedRecipient[x]	Intended recipient of the information, i.e. a person or organisation that should be notified or be aware of the content. This element is used to indicate explicit communication intent and does not represent routine storage or passive availability of information (e.g. in portals).	EHDSRelatedPerson, EHDSHealthProfessional, EHDSOrganisation	0..*	
+	presentedForm	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document.	EHDSAttachment	0..*	
+	body	Discharge report structured body.	Base	0..1	
++	alerts	Section: Alerts.	Base	0..1	
+++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	medicalAlert	Medical alerts relevant in the context of the encounter.	EHDSAlert	0..*	
++	encounterInformation	Section: Encounter information.	Base	1..1	
+++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
+++	encounter	Encounter information.	EHDSEncounter	1..1	
+++	note	Free text notes by the health professional.	string	0..1	
++	admissionEvaluation	Section: Admission evaluation. Admission evaluation section should be reported only if it is relevant to ensure continuity of care.	Base	0..1	
+++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
+++	objectiveFindings	Objective findings, such as anthropometric measurements, vital signs, or objective anatomical findings of physical examination.	EHDSObservation	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	functionalStatus[x]	An individual's ability to perform normal daily activities required to meet basic needs, fulfil usual roles and maintain health and well-being.	EHDSCondition, EHDSObservation	0..*	
+++	note	Free text notes by the evaluation performer.	string	0..1	
++	patientHistory	Section: Patient health history (anamnesis) containing only information that is highly relevant for this specific episode of care. The model is designed with the expectation that patient summary is available.	Base	0..1	
+++	generatedNarrative	Narrative, potentially formatted, content of the whole section. In case the section includes structured information, it should also be included in generatedNarrative.	Narrative	0..1	
+++	pastProblems [x]	A list of conditions of a patient that the patient suffered in the past or still suffers. Unlike diagnostic summary, medical history is not only a list of problems, but could contain broader description of the condition and its progress, details about treatment including medication and patient response to treatment. Past problem section (unlike the same section of the patient summary) should include only conditions that are important for continuity of	EHDSCondition, EHDSObservation	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		care. This section, if provided, complements the diagnostic summary section of the discharge report.			
+++	devicesAndImplants	Devices and implants in patient anamnesis.	EHDSDeviceUse	0..*	
+++	procedures	Procedures in patient anamnesis.	EHDSProcedure	0..*	
+++	note	Free text notes by the health professional.	string	0..1	
++	courseOfEncounter	Section: Course of inpatient or outpatient encounter.	Base	1..1	
+++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	conditionSummary	Conditions that were treated or affected provisioning of care (diagnostics, therapy, nursing, monitoring) during the encounter. At least one attended condition should be marked. Other conditions are recorded only if they are important for continuity of care (after discharge).	EHDSCondition	1..*	
+++	procedures	Procedures performed during encounter which are significant for continuity of care, e.g. surgeries and other instrumental interventions (endoscopic, intravascular), chemotherapy, radiotherapy, purification methods (dialysis, hemoperfusion), circulation support methods (counterpulsation, etc.), administration of blood derivatives or others. Diagnostic procedures are typically captured as observation results and not repeated here.	EHDSProcedure	0..*	
+++	medicalDevicesAndImplants	Medical devices (including implants) whose use was started, stopped, or otherwise modified during the encounter.	EHDSDeviceUse	0..*	
+++	pharmacotherapy	Significant medication treatments during encounter.	EHDSMedicationUse	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	objectiveFindings	Objective findings, such as anthropometric measurements, vital signs, or objective anatomical findings of physical examination. The line between objective findings and test results is not clear and it is up to the implementers to decide how to logically display different measurements.	EHDSObservation	0..*	
+++	testResults[x]	Significant medical test results of functional, diagnostic (including laboratory), and imaging examinations performed during encounter.	EHDSObservation, EHDSLaboratoryObservation	0..*	
+++	note	Free text notes by the health professional.	string	0..1	
++	dischargeDetails	Section: Discharge details.	Base	0..1	
+++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
+++	objectiveFindings	Objective findings, such as anthropometric measurements, vital signs, or objective anatomical findings of physical examination.	EHDSObservation	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	functionalStatus[x]	An individual's ability to perform normal daily activities required to meet basic needs, fulfil usual roles and maintain health and well-being.	EHDSCondition, EHDSObservation	0..*	
+++	note	Free text notes by the health professional.	string	0..1	
++	medicationSummary	Summary information on the medication recommended for the period after discharge, indicating whether the medication is changed or newly started. Compared to previous practices, the overview is supplemented with medication that has been discontinued.	Base	0..1	
+++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	
+++	medicationUse	Details about medication and dosage.	EHDSMedicationUse	0..*	
+++	note	Free text notes by the health professional.	string	0..1	
++	carePlan	Section: Care plan and other recommendations after discharge.	Base	0..1	
+++	generatedNarrative	Narrative, potentially formatted, content of the whole section.	Narrative	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	structuredCarePlan	Structured care plan after discharge.	EHDSCarePlan	0..*	
+++	otherRecommendations	Other recommendations (advice) after discharge. E.g., recommendation to suggest hip replacement, reduce number of cigarettes, stop smoking, increase physical exercises, etc.	string	0..1	
+	attachment	Report attachment.	EHDSAttachment	0..*	

Annex IX
Common data groups

Table 1. EHDSAddress.

EHDSAddress means the structured set of data elements identifying a geographical or postal location.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSAddress	Address model.	Base		
+	use	Purpose of the address. If this attribute is not	CodeableConcept	0..1	HL7 Address Use

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		present, the address is assumed to be the default address useful for any purpose.			
+	type	Distinguishes between physical addresses (those that can be visited) and mailing addresses. Most addresses are both.	CodeableConcept	0..1	HL7 Address Type
+	text	Text representation of the address.	string	0..1	
+	street	Name of the street.	string	0..1	
+	houseNumber	House number.	string	0..1	
+	postBox	Post box.	string	0..1	
+	city	City.	string	0..1	
+	postalCode	Postal code.	string	0..1	
+	country	Country name and country code.	CodeableConcept	1..1	ISO 3166-1 alpha-2

Table 2. EHDSAdministeredDosage.

EHDSAdministeredDosage means the structured set of data elements describing a single instance of medication administration, including the dose given, the route and method of administration, and the time of administration.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
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Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSAdministeredDosage	Administered dosage model.	Derived from parent data type: EHDSDosage		
+	renderedDosageInstruction	Full dosage information as human-readable text covering all dosage steps. Generating the text follows local rules and should include all locally implemented dosage data even when such elements are not present in this model.	string	0..1	
+	dosageDetails	Details of single dosage scheme step.	Base	0..1	
++	note	Patient oriented instructions as free text for this dosage step.	string	0..1	
++	doseAndRate	Amount of medication administered per one dose (= one timing).	Base	0..*	
+++	dose[x]	Amount of medication per one dose (1 tablet, 2-3 tablets, 20ml).	Quantity, Range	0..1	UCUM (units of measurement), EDQM Standard Terms (units of presentation)
+++	rate[x]	Amount of medication per time period (e.g. 100mg per 1 hour). When rate is provided per 1 time unit, Quantity data type can be used with a suitable unit (e.g. mg/h, ug/min).	Quantity, Ratio	0..1	UCUM (units of measurement), EDQM Standard Terms (units of presentation)

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	bodySite	Body site of administration.	EHDSBodyStructure	0..1	
++	routeOfAdministration	Route of administration.	CodeableConcept	0..1	EDQM Standard Terms

Table 3. EHDSAdvanceDirective.

EHDSAdvanceDirective means a documented expression of a patient's wishes, preferences or instructions regarding their healthcare, including, but not limited to, decisions concerning life-sustaining treatment or arrangements to take effect after death.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSAdvanceDirective	Advance directive model.	Derived from parent data type: EHDSDataSet		
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	status	Status of the resource.	CodeableConcept	1..1	HL7 Consent State
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	category	Categories of directives, such as life support, resuscitation or organ donation.	CodeableConcept	0..*	SNOMED GPS
+	directiveType	The type of advance directive, indicating whether it applies before or after death.	CodeableConcept	0..1	SNOMED GPS
+	note	Textual description of the directive.	string	0..1	
+	attachment	Source document, such as a PDF, with the advance directive and the patient's signature.	EHDSAttachment	0..1	

Table 4. EHDSAAlert.

EHDSAAlert means a structured set of data elements describing a clinically relevant fact about a patient that requires attention during a healthcare encounter in order to ensure patient safety or prevent adverse outcomes, including, but not limited to, intolerances, rare diseases requiring special management, implanted devices, ongoing special treatments, transplanted organs, or participation in a clinical trial.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSAAlert	Alert model.	Derived from parent data type: EHDSDataSet		
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	
++	status	Current status of the alert.	CodeableConcept	1..1	HL7 Flag Status

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	code	A coded representation of the alert.	CodeableConcept	0..1	SNOMED GPS
+	description	Narrative representation of the alert.	Narrative	0..1	
+	priority	A code that identifies the priority of the alert.	CodeableConcept	0..1	HL7 Flag Priority Codes
+	period	Time period when alert is active. The period of time from the activation of the alert to inactivation of the alert. If the alert is active, the end of the period should be unspecified.	Period	0..1	
+	otherSupportingInformation	A reference to the resource the alert is about.	string	0..*	

Table 5. EHDSAlergyIntolerance.

EHDSAlergyIntolerance means a structured set of data elements describing a clinically identified predisposition of a patient to an adverse reaction upon exposure to a specific agent or allergen.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSAlergyIntolerance	Allergy intolerance model.	Derived from parent data type: EHDSDataSet		

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	
++	status	Current status of the allergy or intolerance, for example, whether it is active, inactive, or resolved..	CodeableConcept	1..1	HL7 AllergyIntolerance Clinical Status Codes
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	agentOrAllergen	Code that identifies the allergy or intolerance.	CodeableConcept	1..1	EMA SPOR SMS (preferred for medication), SNOMED GPS (for medication groupings), SNOMED GPS (preferred for other cases)

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	note	Free text notes by the health professional.	string	0..1	
+	criticality	Estimate of the potential clinical harm, or seriousness, of a reaction to an identified substance.	CodeableConcept	0..1	HL7 Allergy Intolerance Criticality
+	certainty	Assertion about the certainty associated with a propensity, or potential risk, of a reaction to the identified substance. Diagnostic and /or clinical evidence of condition.	CodeableConcept	0..1	HL7 Allergy Intolerance Verification Status Codes
+	onsetDate	When allergy or intolerance was identified.	dateTime	0..1	
+	endDate	Date of resolution of the allergy or intolerance (e.g. when the clinician deemed there is no longer any need to track the underlying condition).	dateTime	0..1	
+	reaction	Adverse reaction events linked to exposure to substance.	Base	0..*	
++	manifestation	Description of the clinical manifestation of the allergic reaction.	CodeableConcept	0..*	SNOMED GPS
++	severity	Severity of the clinical manifestation of the allergic reaction.	CodeableConcept	0..1	HL7 AllergyIntolerance Severity

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	onset	Date and time of the onset of the reaction.	dateTime	0..1	

Table 6. EHDSAAttachment.

EHDSAAttachment means a structured set of data elements describing additional content, in a format identifiable by a MIME type, including images, clinical reports, or other documents.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSAAttachment	Attachment model.	Base		
+	contentType	Mime type of the content, with charset etc.	CodeableConcept	0..1	BCP 13
+	language	Human language of the content.	CodeableConcept	0..1	BCP 47
+	data	The actual data of the attachment - a sequence of bytes, base64 encoded.	base64Binary	0..1	
+	url	A location where the data can be accessed.	uri	0..1	
+	size	The number of bytes of data that make up this attachment (before base64 encoding).	integer	0..1	
+	title	A label or set of text to display in place of the data.	string	0..1	

Table 7. EHDSBodyStructure.

EHDSBodyStructure means a structured set of data elements describing an anatomical structure of a patient.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSBodyStructure	Body structure model.	Base		
+	morphology	The kind of structure being represented by the body structure at BodyStructure.location. This can define both normal and abnormal morphologies.	CodeableConcept	0..1	SNOMED GPS
+	location	Body site.	CodeableConcept	0..1	SNOMED GPS
+	locationQualifier	Additional qualifier of the body structure (e.g. upper, lower, left side).	CodeableConcept	0..*	SNOMED GPS
+	laterality	Body structure laterality (e.g. left, right).	CodeableConcept	0..1	SNOMED GPS
+	description	Textual description of the body structure.	string	0..1	

Table 8. EHDSCarePlan.

EHDSCarePlan means a structured set of data elements describing the intended management of a patient's health conditions but excluding pharmacological treatment plans that are represented through medication model.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
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Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSCarePlan	Care plan model.	Derived from parent data type: EHDSDataSet		
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Identifier for the care plan.	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	
	status	Indicates whether the plan is currently being acted upon, represents future intentions, or is now a historical record.	CodeableConcept	1..1	HL7 Request Status
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	title	Human-friendly name for the care plan.	string	0..1	
+	description	A description of the scope and nature of the plan.	string	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	period	Indicates when the plan did (or is intended to) come into effect and end.	Period	0..1	
+	conditionAddressed[x]	Conditions/problems/concerns/diagnoses/etc whose management and/or mitigation are handled by this plan.	CodeableConcept, EHDSCondition	0..*	SNOMED GPS (preferred), ICD-10, Orphacode
+	activity[x]	The details of the proposed activity represented in a specific resource.	CodeableConcept, string	0..*	SNOMED GPS
+	goal[x]	Describes the intended objective of carrying out the care plan.	CodeableConcept, string	0..*	Not defined

Table 9. EHDSCondition.

EHDSCondition means a structured set of data elements describing a clinical condition, problem, or diagnosis.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSCondition	Condition model.	Derived from parent data type: EHDSDataSet		
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	
++	status	Status of the condition/problem, e.g. active, resolved, inactive, etc.	CodeableConcept	1..1	HL7 Condition Clinical Status Codes
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	code	Code identifying the condition, problem or diagnosis.	CodeableConcept	1..1	SNOMED GPS (preferred), ICD-10, ICD-O, Orphacode
+	onsetDate	Estimated or actual date the problem/condition began.	dateTime	0..1	
+	endDate	The date or estimated date that the condition resolved or went into remission.	dateTime	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	category	Category of the problem (e.g. POA - present on admission, HAC - hospital acquired condition, and other categorisations).	CodeableConcept	0..*	SNOMED GPS
+	resolutionCircumstances	Describes the reason for which the status of the problem changed from current to inactive (e.g. surgical procedure, medical treatment, etc.).	string	0..1	
+	severity	A subjective assessment of the severity of the condition.	CodeableConcept	0..1	SNOMED GPS
+	bodySite	The anatomical location including laterality where this condition manifests itself.	EHDSBodyStructure	0..*	
+	stage	Stage/grade usually assessed formally using a specific staging/grading system (e.g., TNM, ICD-O, BI-RADS etc). Multiple assessment systems could be used.	CodeableConcept	0..*	Not defined
+	diagnosisAssertionStatus	Assertion about the certainty associated with a diagnosis. Diagnostic and/or clinical evidence of condition.	CodeableConcept	0..1	HL7 Condition Verification Status
+	specialistContact	Health Professional who may be specifically related to the problem, as a preferred contact.	EHDSHealthProfessional	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	externalResource	External Resource which may be specifically related to the problem, for example a link to a guideline on a specific a rare disease problem.	uri	0..*	
+	note	Free text note by the health professional.	string	0..1	

Table 10. EHDSCurrentPregnancyStatus.

EHDSCurrentPregnancyStatus means a structured set of data elements describing a patient's pregnancy status at a given point in time.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSCurrentPregnancyStatus	Current pregnancy status model.	Derived from parent data type: EHDSDataSet		
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	
++	status	Status of the condition.	CodeableConcept	1..1	HL7 Observation Status
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	currentPregnancyStatus	Pregnancy status of the patient, e.g. pregnant, not pregnant, possible pregnancy.	CodeableConcept	1..1	SNOMED GPS
+	expectedDateOfDelivery	Date in which the woman is due to give birth. Year, day and month are required.	dateTime	0..1	
+	gestationalAge	Duration of the pregnancy (weeks and/or days) at the time of the observation.	Quantity	0..1	UCUM (units of measurement)
+	note	Free text notes by the health professional.	string	0..1	

Table 11. EHDSDataSet.

EHDSDataSet is a data group that is used as a template for deriving other data groups.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSDataSet	DataSet model.	Base		

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	
++	status	Status of the resource.	CodeableConcept	1..1	Defined in the individual data set
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47

Table 12. EHDSDevice.

EHDSDevice means a structured set of data elements describing a medical device or implant.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
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Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSDDevice	Device or implant model.	Base		
+	instanceIdentifier	Identifier of the device instance.	Identifier	0..*	
+	udiCarrier	Unique Device Identifier (UDI) value.	Identifier	0..*	
+	manufacturer	Name of device manufacturer. If the manufacturer code is included in an identifier, manufacturer must correspond to that code.	string	0..1	
+	manufactureDate	Date and optionally time when the device was manufactured.	dateTime	0..1	
+	expiryDate	The date and time beyond which this device is no longer valid or should not be used (if applicable).	dateTime	0..1	
+	lotNumber	Lot number of device. May be omitted if included in an identifier.	string	0..1	
+	serialNumber	Serial number assigned by the manufacturer. May be omitted if included in an identifier.	string	0..1	
+	name	The name and name type of the device.	Base	0..*	
++	value	The name of the device as known to e.g. the manufacturer and/or patient.	string	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	type	The type of name, e.g. UDI Label name, user friendly name.	CodeableConcept	1..1	HL7 Device name type
+	modelName	The manufacturer's model number for the device.	string	0..1	
+	version	The actual design of the device and/or software version running on the device.	string	0..*	
+	type	Device type.	CodeableConcept	0..*	SNOMED GPS (preferred), EMDN
+	note	Device note and/or comment.	string	0..1	

Table 13. EHDSDeviceUse.

EHDSDeviceUse means a structured set of data elements describing the use of a medical device.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSDeviceUse	Device use model.	Based on parent data group: EHDSDataSet		
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	
++	status	Current status of the device usage, e.g. active, completed, etc.	CodeableConcept	1..1	HL7 Device Use Statement Status
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	periodOfUse	The period of time during which the device was implanted in the patient or the external device was in use.	Period	0..1	
+	device[x]	The details of the device used.	CodeableConcept, EHDSDevice	1..1	SNOMED GPS (preferred), EMDN
+	bodySite	Anatomical location of the device. May include laterality.	EHDSBodyStructure	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	reason[x]	Reason or justification for the use of the device.	CodeableConcept, EHDSCondition, EHDSObservation, EHDSProcedure	0..*	SNOMED GPS (preferred), ICD-10, Orphacode
+	note	Free text notes by the health professional.	string	0..1	

Table 14. EHDSDocument.

EHDSDocument means a structured set of data elements common all health documents.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSDocument	Document model.	Derived from parent data type: EHDSDataSet		
+	header	Document header.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Unique identifier of the document.	Identifier	1..*	
++	author[x]	Author of the document.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	1..*	
++	date	Date of finalising/issuing the document.	dateTime	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	status	Status of the document.	CodeableConcept	1..1	HL7 Composition Status
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
++	documentType	Type of document (e.g. 60591-5 Patient summary document).	CodeableConcept	1..1	LOINC
++	documentTitle	Human readable document title that can be displayed in search results, etc. This can be documentType's display name, or it can be assembled from multiple elements. Examples: 'Laboratory Result Report', 'Patient Summary of Jane Green 10.12.2024'.	string	1..1	
++	period	Time of service that is being documented.	Period	0..1	
++	version	Version of the document.	string	1..1	
++	attestation	Document attestation details.	Base	0..*	
+++	attester[x]	Attester who validated the document.	EHDSHealthProfessional, EHDSDevice	1..1	
+++	datetime	Date and time of the approval of the document by the attester.	dateTime	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	legalAuthentication	Document legal authentication details.	Base	0..*	
+++	legalAuthenticator[x]	The person or organisation taking responsibility for the content of the document.	EHDSHealthProfessional, EHDSOrganisation	1..1	
+++	dateTime	Date and time when the document was authenticated.	dateTime	1..1	
++	eventCategory	Categorisation of the event covered by the document (e.g. laboratory study types, imaging study types including modality, etc.). Selection of such tags or labels depends on the use case and agreement between data sharing parties. This meta-data element serves primarily for searching and filtering purposes.	CodeableConcept	0..*	LOINC, SNOMED GPS, DICOM CID 33 Modality
++	serviceSpecialty	Additional details about where the content was created (e.g. clinical specialty).	CodeableConcept	0..*	SNOMED GPS
++	custodian	Organisation that is in charge of maintaining the document.	EHDSOrganisation	0..1	
++	countryOfOrigin	Country of origin of the document.	CodeableConcept	0..1	ISO 3166-1 alpha-2
+	presentedForm	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document.	EHDSAttachment	0..*	

Table 15. EHDSDosage.

EHDSDosage means a structured set of data elements describing the instructions for administering a medicinal product.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSDosage	Dosage model.	Base		
+	renderedDosageInstruction	Full dosage information as human-readable text covering all dosage steps. Generating the text follows local rules and should include all locally implemented dosage data even when such elements are not present in this model.	string	0..1	
+	dosageDetails	Details of single dosage scheme step.	Base	0..*	
++	sequence	Order of the dosage instruction, in case one treatment consists of several dosage steps. When two schemes share the same sequence number, they are meant to be running in parallel.	integer	0..1	
++	note	Patient oriented instructions as free text for this dosage step.	string	0..1	
++	doseAndRate	Amount of medicinal product administered per one dose (= one timing).	Base	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	dose[x]	Amount of medicinal product per one dose (1 tablet, 2-3 tablets, 20ml).	Quantity, Range	0..1	UCUM (units of measurement), EDQM Standard Terms (units of presentation)
+++	rate[x]	Amount of medicinal product per time period (e.g. 100mg per 1 hour). When rate is provided per 1 time unit, Quantity data type can be used with a suitable unit (e.g. mg/h, ug/min).	Quantity, Ratio	0..1	UCUM (units of measurement), EDQM Standard Terms (units of presentation)
++	repeat	Repetition of the administration.	Base	0..1	
+++	bounds[x]	Time bounds for the treatment (current dosage scheme), Quantity contains a number of time units (e.g. 10 days), Period contains start and end date (e.g. 05.08.2023 - 10.08.2023), Range .	Quantity, Period	0..1	
++++	duration	Duration of administration (e.g. '5 minutes', '1 hour').	Quantity	0..1	UCUM (units of measurement)
+++	frequency	Frequency of intake/administration.	Base	0..1	
++++	numberOfTimes	Number of times per period (e.g. '3 times').	integer	0..1	
++++	period	Duration to which the frequency applies (e.g. '... / 1 day').	Quantity	0..1	UCUM (units of measurement)

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	dayOfWeek	The day of the week of administration, e.g. Mon, Tue, etc.	CodeableConcept	0..*	HL7 Days Of Week
+++	timeOfDay	Exact time of day of administration (e.g. '10:00').	time	0..*	
+++	eventTime	Time period or event when the administration should happen ('before meal', 'immediately', 'morning').	CodeableConcept	0..*	HL7 Event Timing
++	asNeeded	Take as needed.	boolean	0..1	
++	bodySite	Body site of administration.	EHDStBodyStructure	0..1	
++	routeOfAdministration	Route of administration.	CodeableConcept	0..1	EDQM Standard Terms

Table 16. EHDSEncounter.

EHDSEncounter means a structured set of data elements describing a patient's interaction with a healthcare service, but excluding the tracking of broader episodes of care (e.g., a maternity episode from first antenatal visit through delivery and postnatal follow-up) extending beyond individual encounters.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSEncounter	Encounter model.	Derived from parent data type: EHDSDataSet		

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	
++	status	Status of the encounter (e.g. discharged, discontinued, completed).	CodeableConcept	1..1	HL7 Encounter Status
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	priority	Indicates the urgency of the encounter (e.g. urgent, routine).	CodeableConcept	0..1	HL7 Act Priority
+	class	Class of the encounter (inpatient, ambulatory, virtual).	CodeableConcept	1..1	HL7 Act Encounter Code
+	period	The actual start and end time of the encounter.	Period	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	serviceProvider	The organisation (facility) responsible for this encounter.	EHDSOrganisation	0..1	
+	referringProfessional	Referring healthcare professional.	EHDSHealthProfessional	0..1	
+	basedOn[x]	Reference to the request that initiated this encounter.	EHDSCarePlan, EHDSServiceRequest	0..*	
+	reason[x]	Reason for admission, e.g. problem, procedure or finding.	CodeableConcept EHDSCondition EHDSProcedure EHDSObservation string	0..*	SNOMED GPS (preferred), ICD-10, Orphacode
+	admission	Details about the admission to a healthcare service.	Base	0..1	
++	admitter	Admitting healthcare professional.	EHDSHealthProfessional	0..1	
++	admitSource	The type of admission indicating where the patient came in (e.g. born in hospital, from nursing home, physician referral, transferred from another hospital).	CodeableConcept	0..1	HL7 Admit Source
+	dischargeDiagnosis[x]	The diagnoses at the time of discharge.	CodeableConcept, EHDSCondition	0..*	SNOMED GPS (preferred), ICD-10, Orphacode

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	dischargeDestination	Location or organisation to which the patient is going after discharge.	Base	0..1	
++	type	Type of location (e.g. home, hospital, nursing home, etc.).	CodeableConcept	0..1	HL7 Discharge Disposition
++	location[x]	The location or organisation (including contact details).	EHDSOrganisation, string	0..1	
+	serviceLocation	List of locations where the patient was present during this encounter.	Base	0..*	
++	period	Time period during which the patient was present at the organisation.	Period	0..1	
++	organisation	Organisation or part of an organisation (e.g. department) where the patient was present during the encounter.	EHDSOrganisation	1..1	
+	subEncounter	Reference to encounters that are considered parts of this encounter.	EHDSEncounter	0..*	
+	note	Free text notes by the health professional	string	0..1	

Table 17. EHDSEndpoint.

EHDSEndpoint means a structured set of data elements describing the technical details of a connection point for electronic services.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSEndpoint	Endpoint model.	Base		
+	identifier	Identifier for the endpoint.	Identifier	1..*	
+	status	Status of the endpoint, e.g. active, limited.	CodeableConcept	1..1	HL7 Endpoint Status
+	connectionType	A coded value that represents the technical details of the usage of this endpoint, such as what WSDLs should be used in what way.	CodeableConcept	1..*	HL7 Endpoint Connection Type
+	name	A friendly name that this endpoint can be referred to with.	string	0..1	
+	managingOrganisation	The organisation that provides technical management services for this endpoint.	EHDSOrganisation	0..1	
+	payload	The set of payloads that are provided/available at this endpoint.	Base	0..*	
++	contentType	The mime type to send the payload in (e.g. application/fhir+xml, application/fhir+json).	CodeableConcept	0..*	BCP 13
++	profileCanonical	The technical profile that is expected at this endpoint. It describes the resources that are handled, or even simply which resource types.	uri	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	profileUri	The profile (as a URI) that is expected at this endpoint when not represented using a FHIR profile.	uri	0..*	
+	address	The URI that describes the actual end-point to connect to.	uri	1..1	
+	header	Additional headers / information to send as part of the notification. Usage depends on the channel type.	string	0..*	

Table 18. EHDSHealthProfessional.

EHDSHealthProfessional means a structured set of data elements describing a health professional.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSHealthProfessional	Health professional model.	Base		
+	identifier	An identifier of the health professional that is unique within a defined scope. Example: National health professional ID. Multiple identifiers could be provided.	Identifier	0..*	
+	name	Name of the health professional..	EHDSHumanName	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	address	Address of the health professional.	EHDSAddress	0..*	
+	telecom	Telecommunication contact information (address) associated with the health professional, such as phone number, email, or messaging service.	EHDSTelecom	0..*	
+	professionalRole	Professional role that the health professional is practicing at a given organisation.	Base	0..*	
++	role	Health professional role.	CodeableConcept	0..*	SNOMED GPS (preferred), ISCO-08
++	organisation	The organisation where this role is available.	EHDSOrganisation	0..1	
++	specialty	The specialty of the health professional they are practicing in the organisation.	CodeableConcept	0..*	SNOMED GPS

Table 19. EHDSHumanName.

EHDSHumanName means a structured set of data elements describing the name of a person.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSHumanName	Human name model.	Base		
+	use	The purpose of this name.	CodeableConcept	0..1	HL7 Name Use

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	text	The entire name as it should be displayed e.g. on an application UI.	string	0..1	
+	family	The family name/surname/last name.	string	0..*	
+	given	The given name/first name.	string	0..*	
+	prefix	Name part that appears at the start of the name. Prefixes shall appear in the correct order for presenting the name.	string	0..*	
+	suffix	Name part that appears at the end of the name. Suffixes shall appear in the correct order for presenting the name.	string	0..*	

Table 20. EHDSImmunisation.

EHDSImmunisation means a structured set of data elements describing the administration of a vaccine or immunoglobulin, but excluding natural immunity, immunisation outcomes, refusals, and administration planning.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSImmunisation	Immunisation model.	Derived from data type: EHDSDataSet		
+	header	Basic metadata for this information.	Base	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	
++	status	Status of the immunisation event, e.g., completed, not-done.	CodeableConcept	1..1	HL7 Immunization Status Codes
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	diseaseOrAgentTargeted	Disease or agent that the vaccination provides protection against.	CodeableConcept	0..*	SNOMED GPS (preferred), ICD-10
+	vaccine	Type of immunisation.	CodeableConcept	1..1	ATC, SNOMED GPS
+	administeredProduct	Administered medicinal product, including batch/lot details when necessary.	EHDSMedication	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	administrationTime	The date and optionally the exact time when the vaccination was administered.	dateTime	1..1	
+	administeringCentre	Administering centre or a health authority responsible for the vaccination event.	EHDSOrganisation	0..1	
+	administrator	Health professional responsible for administering the immunisation product.	EHDSHealthProfessional	0..1	
+	note	Free text notes by the health professional.	string	0..1	

Table 21. EHDSLaboratoryObservation.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSLaboratoryObservation	Model for observation performed by laboratory.	Derived from parent data type: EHDSObservation		
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	
++	status	Status of the resource.	CodeableConcept	1..1	HL7 Observation Status
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
++	directSubject[x]	The direct subject of the observation if different from the patient (subject of care), e.g. an implanted device, a location, or another person.	EHDSPatient, EHDSLocation, EHDSDevice, EHDSProcedure, string	0..1	
+	observationDate[x]	Clinically relevant time or time period for the observation.	dateTime, Period	1..1	
+	type	Observation type.	CodeableConcept	1..1	SNOMED GPS, LOINC, NPU
+	originalName	Original (conventional) name of the observation as used in the local laboratory or clinical system.	string	0..1	
+	method	Observation method (measurement principle) to	CodeableConcept	0..1	SNOMED GPS

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		obtain the result.			
+	specimen	Specimen used for this observation.	EHDSSpecimen	0..1	
+	order	Identifies order and order placer this observation belongs to.	EHDSServiceRequest	0..1	
+	performer[x]	Performer of the observation.	EHDSOrganisation, EHDSHealthProfessional, EHDSPatient, EHDSRelatedPerson	0..*	
+	bodySite	Anatomic location and laterality where the observation was performed.	EHDSBodyStructure	0..1	
+	result	Result of the observation including text, numeric, coded, and other types of results of the measurement and measurement uncertainty. Content of the observation result will vary according to the type of the observation.	Base	1..1	
++	value[x]	Observation result value according to the type of observation.	string, Quantity, Range, Ratio, CodeableConcept	0..1	UCUM for units, SNOMED GPS
++	uncertainty	Measurement uncertainty information about the observation result.	Base	0..1	
+++	value	The numerical value of the measurement	decimal	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		uncertainty.			
+++	type	Probability Distribution Type for uncertainty	CodeableConcept	0..1	HL7 Probability Distribution Type
++	dataAbsentReason	Provides a reason why the expected value in the element LaboratoryObservation.result.value[x] is missing.	CodeableConcept	0..1	HL7 Data Absent Reason
+	referenceRange	Reference range, multiple reference ranges of different types could be provided. Provides guide for interpretation of the result.	Base	0..*	
++	low	Low limit of the reference range.	Quantity	0..1	UCUM for units
++	high	High limit of the reference range.	Quantity	0..1	UCUM for units
++	normalValue	Normal value, if relevant for the reference range.	CodeableConcept	0..1	SNOMED GPS
++	type	Type of reference range.	CodeableConcept	0..1	HL7 Observation Reference Range Meaning Codes
++	appliesTo	Codes to indicate the target population this reference range applies to.	CodeableConcept	0..*	SNOMED GPS
++	age	Age range to which this reference range applies if applicable.	Range	0..1	UCUM for units

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	text	Text based reference range.	string	0..1	
+	interpretation	Result interpretation, e.g. in comparison with reference ranges.	CodeableConcept	0..*	SNOMED GPS
+	note	Free text notes by the health professional.	string	0..1	
+	component	Component in case the observation consists of multiple sub-observations (e.g. blood pressure).	Base	0..*	
++	type	Type of the component observation.	CodeableConcept	1..1	SNOMED GPS, LOINC, NPU
++	originalName	Original (user-friendly) name of the observation as used in the local laboratory or clinical system.	string	0..1	
++	result	Result of the observation including text, numeric, coded, and other types of results of the measurement and measurement uncertainty. Content of the observation result will vary according to the type of the observation.	Base	1..1	
+++	value[x]	Observation result value according to the type of observation.	string, Quantity, Range, Ratio, CodeableConcept	0..1	UCUM for units, SNOMED GPS
+++	uncertainty	Measurement uncertainty information about the	Base	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		observation result.			
++++	value	The numerical value of the measurement uncertainty.	decimal	1..1	
++++	type	Probability Distribution Type for uncertainty	CodeableConcept	0..1	HL7 Probability Distribution Type
+++	dataAbsentReason	Provides a reason why the expected value in the element component.result.value[x] is missing.	CodeableConcept	0..1	HL7 Data Absent Reason
++	referenceRange	Reference range, multiple reference ranges of different types could be provided. Provides guide for interpretation of the result.	Base	0..*	
+++	low	Low limit of the reference range.	Quantity	0..1	UCUM for units
+++	high	High limit of the reference range.	Quantity	0..1	UCUM for units
+++	normalValue	Normal value, if relevant for the reference range.	CodeableConcept	0..1	SNOMED GPS
+++	type	Type of reference range.	CodeableConcept	0..1	HL7 Observation Reference Range Meaning Codes
+++	appliesTo	Codes to indicate the target population this reference range applies to.	CodeableConcept	0..*	SNOMED GPS

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	age	Age range to which this reference range applies if applicable.	Range	0..1	UCUM for units
+++	text	Text based reference range.	string	0..1	
++	interpretation	Result interpretation, e.g. in comparison with reference ranges.	CodeableConcept	0..*	SNOMED GPS
+	derivedFrom[x]	Reference to the related resource from which the observation has been made. For example, a calculated anion gap or a fetal measurement based on an ultrasound image.	EHDSObservation, EHDSLaboratoryObservation, EHDSImagingStudy	0..*	
+	hasMember[x]	Member of the observation group that this observation forms (e.g. in case of a battery, a panel of tests, a set of vital sign measurements).	EHDSLaboratoryObservation, EHDSObservation	0..*	
+	triggeredBy[x]	References to the observation that triggered the performance of this observation.	EHDSLaboratoryObservation, EHDSObservation	0..*	
+	testKit	Laboratory test kit used during measurement.	EHDSDevice	0..1	
+	calibrator	Information about which end-user calibrator the laboratory used for the measurement to indicate the metrological traceability chain.	Identifier	0..1	
+	accreditationStatus	Accreditation status of the laboratory for the	boolean	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		observation.			
+	previousResults	Previous results of the same observation	EHDSLaboratoryObservation	0..*	
+	pointOfCareTest	Examination performed near or at the site of a patient.	boolean	0..1	

Table 22. EHDSLocation.

EHDSLocation means a structured set of data elements describing a place where health services are provided or resources and participants are accommodated.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSLocation	Location model.	Base		
+	identifier	Location identifier.	Identifier	0..*	
+	name	Human-readable name of the location. .	string	0..1	
+	description	Additional details about the location that could be displayed as further information to identify the location beyond its name.	string	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	address	Physical location address.	EHDSAddress	0..1	
+	managingOrganisation	The organisation responsible for the provisioning and upkeep of the location.	EHDSOrganisation	0..1	

Table 23. EHDSMedicationAdministration.

EHDSMedicationAdministration means a structured set of data elements describing a single instance of the administration of a medicinal product in the context of an imaging or laboratory procedure.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSMedicationAdministration	Medication administration model.	Derived from parent data type: EHDSDataSet		
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system.	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	date	Date and optionally time of authoring/issuing the resource.	dateTime	0..1	
++	status	Status of the resource.	CodeableConcept	1..1	HL7 Medication Administration Status Codes
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	medication	Administered medicinal product.	EHDSMedication	1..1	
+	occurrence[x]	Specific date/time or interval of time during which the administration took place (or did not take place).	dateTime, Period	1..1	
+	reason[x]	Condition or observation that supports why the medicinal product was administered.	CodeableConcept, EHDSCondition, EHDSObservation	0..*	SNOMED GPS (preferred), ICD-10, Orphacode
+	dosage	Details of how medicinal product was taken/administered.	EHDSAdministeredDosage	0..1	
+	note	Textual information about the administration.	string	0..1	

Table 24. EHDSMedication.

EHDSMedication means a structured set of data elements describing a medicinal product.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSMedication	Medication model.	Base		
+	identifyingCode	An identifier or a code for the product (virtual product, branded product, or package). If several identifiers are specified, they shall not have conflicting meanings or very different granularities. An identifier might not exist e.g. for substance-based prescriptions.	CodeableConcept	0..*	SNOMED GPS, EMA PMS ID or a national coding system
+	classification	Anatomical therapeutic chemical classification or another classification (e.g. narcotic/psychotropic; orphan drug).	CodeableConcept	0..*	WHO ATC, non-binding coding systems for other classifications
+	productName	Current trade name (authorised name) of the product. When medication is specified by a CodeableConcept, the name may be omitted when available as the display name of the concept.	string	0..1	
+	marketingAuthorisationHolder	Marketing authorisation holder of the medicinal product. Relevant for identifying the exact medicinal product. If the medicinal product does not have a marketing authorisation, the manufacturer information may be used.	Base	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	organisationName	Name of the organisation holding the authorisation for marketing/manufacturing.	string	0..1	
++	organisationIdentifier	Identifier of the organisation and/or its physical location.	Identifier	0..*	
+	doseForm	Dose form at the package level (e.g. authorised dose form), corresponding to IDMP Combined Pharmaceutical Dose Form (this includes terms from EDQM Combination Pack or Combined Dose Form lists). Dose form for a single package item is defined in item.doseForm.	CodeableConcept	0..1	EDQM Standard Terms
+	description	Textual description of the product, e.g. including package description.	string	0..1	
+	item	A medication item. For combination packs, this can be multiple manufactured items with each item having its own dose form and ingredients+strengths defined.	Base	0..*	
++	doseForm	Administrable or manufactured item dose form, depending on the type of medication definition. This should not include combined dose forms.	CodeableConcept	0..1	EDQM Standard Terms
++	ingredient	Ingredients.	Base	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	isActive	Marks whether the substance is considered an active substance. Excipients are typically not needed, and by default only active ingredients are expected.	boolean	0..1	
+++	substance	Substance.	CodeableConcept	1..1	EMA SPOR SMS
+++	strengthInfo	Amount of active substance per unit.	Base	0..1	
++++	strength[x]	Concentration or presentation strength, e.g '100 mg/1 ml' or '500 mg per 1 tablet'.	Ratio, string	1..1	UCUM for units of measure EDQM Standard Terms for units of presentation
++++	basisOfStrengthSubstance	Active substance that the strength refers to, especially when different from .item.strength.substance.	CodeableConcept	0..1	EMA SPOR SMS
++	unitOfPresentation	Unit of presentation for the medicinal product (tablet, vial, tube). Typically, the smallest countable object in the package.	CodeableConcept	0..1	EDQM Standard Terms for units of presentation
++	containedQuantity	Packaged item quantity per one item (3 ml / 1 vial)	Ratio	0..1	UCUM for units of measure EDQM Standard Terms for units of presentation

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	amount	Number of such items in this medicinal product (e.g. 5 vials in the package). The combined amount of all items will be considered to be the total package size.	Quantity	0..1	UCUM for units of measure EDQM Standard Terms for units of presentation
++	packageType	Type of package of the medicinal product item.	CodeableConcept	0..1	EDQM Standard Terms for packaging
+	device	Administration device included in the medicinal product. Devices that are not inside the package of medicinal product are excluded.	Base	0..*	
++	deviceQuantity	Number of devices.	integer	1..1	UCUM for units of measure
++	device	Device coded.	CodeableConcept	1..1	EDQM Standard Terms
+	characteristic	Additional features of the medicinal product (e.g. reimbursable, sugar-free, easy-open cap, score-lined). It is expected that implementers will define a value set supporting their use cases.	Base	0..*	
++	type	A code expressing the type of characteristic.	CodeableConcept	1..1	Not defined
++	value[x]	Description of the characteristic value.	boolean, CodeableConcept, string, Quantity, dateTime, integer, decimal, Ratio	0..1	UCUM for units of measure

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	batch	Batch information of a medicinal product. Typically recorded during dispense or administration, rarely known or relevant for a prescription/request.	Base	0..1	
++	lotNumber	Batch identifier of the medicinal product.	string	0..1	
++	expirationDate	Batch expiration date of the medicinal product.	dateTime	0..1	

Table 25. EHDSMedicationUse.

EHDSMedicationUse means a structured set of data elements describing a use of a single medicinal product as part of a medication summary.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSMedicationUse	Medication use model.	Derived from parent data type: EHDSDataSet		
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
			, EHDSOrganisation, EHDSDevice		
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	
++	status	Status of the medicinal product use statement, e.g. 'recorded'.	CodeableConcept	1..1	HL7 Medication Status Codes
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	medication	Describes the medicinal product.	EHDSMedication	1..1	
+	reason[x]	Reason for the use of the medicinal product (typically diagnosis, or a procedure).	CodeableConcept, string	0..*	SNOMED GPS (preferred), ICD-10, Orphacode
+	dosageInstructions	Details of how medicinal product is/was taken or should be taken.	EHDSDosage	1..1	
+	periodOfUse	Period when the patient took, is taking or is expected to take the medicinal product.	Period	0..1	
+	derivedFrom[x]	Prescriptions, dispenses or administrations that are the basis of this medicinal product use statement.	EHDSMedicationPrescription, EHDSMedication, EHDSMedicationAdministration	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	note	Additional information about the medicinal product use statement	string	0..1	

Table 26. EHDSObservation.

EHDSObservation means a structured set of data elements describing a clinical finding or measurement and its results. This includes simple observational findings (e.g., alcohol and tobacco use, blood pressure measurements) and complex medical test results (e.g., cardiopulmonary stress test, Holter monitor), supporting the grouping of related observations and the representation of multi-part results observed under shared or different conditions.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSObservation	Observation model.	Derived from parent data type: EHDSDataSet		
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	
++	status	Status of the resource.	CodeableConcept	1..1	HL7 Observation Status
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
++	directSubject[x]	The direct subject of the observation if different from the patient (subject of care), e.g. an observation of an implanted device. Additional types of subject may be allowed in implementations.	EHDSPatient, EHDSLocation, EHDSDevice, string	0..1	
+	observationDate[x]	Clinically relevant time or time period for the observation.	dateTime, Period	1..1	
+	type	Observation type that indicates what was observed.	CodeableConcept	1..1	SNOMED GPS, LOINC, NPU
+	originalName	Original (conventional) name of the observation as used in the local laboratory or clinical system.	string	0..1	
+	method	Observation method (measurement principle) to obtain the result.	CodeableConcept	0..1	SNOMED GPS

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	specimen	Specimen used for this observation.	EHDSSpecimen	0..1	
+	order	Identifies order and order placer this observation belongs to.	EHDSServiceRequest	0..1	
+	performer[x]	Performer of the observation.	EHDSOrganisation, EHDSHealthProfessional , EHDSPatient, EHDSRelatedPerson	0..*	
+	bodySite	Anatomic location and laterality where the observation was performed.	EHDSBodyStructure	0..1	
+	result	Result of the observation including text, numeric, coded, and other types of results of the measurement and measurement uncertainty. Content of the observation result will vary according to the type of the observation.	Base	1..1	
++	value[x]	Observation result value according to the type of observation.	string, Quantity, Range, Ratio, CodeableConcept	0..1	UCUM for units, SNOMED GPS
++	uncertainty	Measurement uncertainty information type and interval if needed about the observation result.	Base	0..1	
+++	value	The numerical value of the measurement uncertainty.	decimal	1..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	type	Probability Distribution Type for uncertainty		0..1	HL7 ProbabilityDistributionType
++	dataAbsentReason	Provides a reason why the expected value in the element Observation.result.value[x] is missing.	CodeableConcept	0..1	HL7 Data Absent Reason
+	referenceRange	Reference range, multiple reference ranges of different types could be provided. Provides guide for interpretation of the result.	Base	0..*	
++	low	Low limit of the reference range.	Quantity	0..1	UCUM for units
++	high	High limit of the reference range.	Quantity	0..1	UCUM for units
++	normalValue	Normal value, if relevant for the reference range.	CodeableConcept	0..1	SNOMED GPS
++	type	Type of reference range.	CodeableConcept	0..1	HL7 Observation Reference Range Meaning Codes
++	appliesTo	Codes to indicate the target population (e.g., in case of particular sex or race) this reference range applies to.	CodeableConcept	0..*	SNOMED GPS

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	age	Age range to which this reference range applies if applicable.	Range	0..1	UCUM for units
++	text	Text based reference range.	string	0..1	
+	interpretation	Result interpretation, e.g. in comparison with reference ranges.	CodeableConcept	0..*	SNOMED GPS
+	note	Free text notes by the health professional.	string	0..1	
+	component	Component in case the observation consists of multiple sub-observations (e.g. blood pressure).	Base	0..*	
++	type	Type of the component observation	CodeableConcept	1..1	SNOMED GPS, LOINC, NPU
++	originalName	Original (user-friendly) name of the observation as used in the local laboratory or clinical system.	string	0..1	
++	result	Result of the observation including text, numeric, coded, and other types of results of the measurement and measurement certainty. Content of the observation result will vary according to the type of the observation.	Base	1..1	
+++	value[x]	Observation result value according to the type	string, Quantity, Range,	0..1	UCUM for units, SNOMED

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		of observation.	Ratio, CodeableConcept		GPS
+++	uncertainty	Measurement uncertainty information type and interval if needed about the observation result.	Base	0..1	
++++	value	The numerical value of the measurement uncertainty.	decimal	1..1	
++++	type	Probability distribution type for uncertainty	CodeableConcept	0..1	HL7 ProbabilityDistributionType
+++	dataAbsentReason	Provides a reason why the expected value in the element component.result.value[x] is missing.	CodeableConcept	0..1	HL7 Data Absent Reason
++	referenceRange	Reference range, multiple reference ranges of different types could be provided. Provides guide for interpretation of the result.	Base	0..*	
+++	low	Low limit of the reference range.	Quantity	0..1	UCUM for units
+++	high	High limit of the reference range.	Quantity	0..1	UCUM for units
+++	normalValue	Normal value, if relevant for the reference range.	CodeableConcept	0..1	SNOMED GPS
+++	type	Type of reference range.	CodeableConcept	0..1	HL7 Observation Reference Range Meaning Codes

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+++	appliesTo	Codes to indicate the target population this reference range applies to.	CodeableConcept	0..*	SNOMED GPS
+++	age	Age range to which this reference range applies if applicable.	Range	0..1	UCUM for units
+++	text	Text based reference range.	string	0..1	
++	interpretation	Result interpretation, e.g. in comparison with reference ranges.	CodeableConcept	0..*	SNOMED GPS
+	derivedFrom[x]	Reference to the related resource from which the observation has been made. For example, a calculated anion gap or a fetal measurement based on an ultrasound image.	EHDSObservation EHDSLaboratoryObservation EHDSImagingStudy	0..*	
+	hasMember[x]	Member of the observation group that this observation forms (e.g. in case of a battery, a panel of tests, a set of vital sign measurements).	EHDSLaboratoryObservation, EHDSObservation	0..*	

Table 27. EHDSOrganisation.

EHDSOrganisation means a structured set of data elements describing an organisation.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSOrganisation	Organisation model.	Base		

+	identifier	Organisation identifier.	Identifier	0..*	
+	type	Kind of organisation.	CodeableConcept	0..*	HL7 Organisation Type
+	name	Organisation name.	string	0..1	
+	address	Mailing or office address.	EHDSAddress	0..*	
+	telecom	Telecommunication contact information (address) associated with the organisation, such as phone number, email, or messaging service.	EHDSTelecom	0..*	
+	partOf	The organisation of which this organisation forms a part.	EHDSOrganisation	0..1	

Table 28. EHDSPatient.

EHDSPatient means a structured set of data elements describing a subject of care.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSPatient	Patient model.	Base		
+	identifier	A stable identifier of the patient that is unique within a defined scope. In addition to the mandatory attributes listed below, other attributes compliant with the HL7	Identifier	1..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		FHIR Identifier structure may be included.			
++	type	Description of identifier.	CodeableConcept	1..1	HL7 Identifier Type, extended with the following: NI (national unique identifier) HI (health identifier) HIN (health insurance number) SS (social security identifier) REGPID (regional person identifier) REGION (region identifier)
++	value	The value that is unique.	string	1..1	
++	system	The namespace for the Identifier value.	uri	1..1	
+	name	Name associated with the patient.	EHDSHumanName	1..*	
+	dateOfBirth	Date of birth.	dateTime	0..1	
+	deceased[x]	Indicator stating whether the patient is	boolean, dateTime	0..1	

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Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		deceased or date and optionally time of death.			
+	administrativeGender	The gender that the patient is considered to have for administration and record keeping purposes.	CodeableConcept	1..1	HL7 Administrative Gender
+	genderIdentity	The gender identity as declared by the patient.	CodeableConcept	0..1	Not defined
+	sexForClinicalUse	A summary parameter that provides guidance on how a receiver should apply settings or reference ranges that are derived from observable information such as an organ inventory, recent hormone lab tests, genetic testing, menstrual status, obstetric history, etc.	CodeableConcept	0..1	HL7 Sex Parameter For Clinical Use
+	address	Address of the patient.	EHDSAddress	0..*	
+	telecom	Contact information.	EHDSTelecom	0..*	

Table 29. EHDS PregnancyHistory.

EHDSPregnancyHistory means a structured set of data elements describing a single past pregnancy.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSPregnancyHistory	Pregnancy history model.	Derived from parent data type: EHDSDataSet		

+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	
++	status	Status of this observation.	CodeableConcept	1..1	HL7 Observation Status
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	endDate	The end date of the pregnancy.	dateTime	0..1	
+	outcome	The outcome of the pregnancy.	CodeableConcept	0..1	SNOMED GPS
+	note	Free text notes by the health professional.	string	0..1	

Table 30. EHDSProcedure.

EHDSProcedure means a structured set of data elements describing a procedure performed on or for a patient, including surgical, therapeutic, and diagnostic procedures and specimen collection, but excluding procedures in the planning stage.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSProcedure	Procedure model.	Derived from parent data type: EHDSDataSet		
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional, EHDSOrganisation, EHDSDevice	0..*	
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	
++	status	Status of the procedure, e.g. completed, on hold, stopped.	CodeableConcept	1..1	HL7 Event Status
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	code	Concept code and display name identifying the	CodeableConcept	1..1	SNOMED GPS

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		type of procedure.			
+	procedureDate[x]	Date and time of the procedure or interval of its performance.	dateTime, Period	0..1	
+	performer	Actors who performed the procedure (only main responsible actors expected).	EHDSHealthProfessional	0..*	
+	bodySite	Target body site of the procedure.	EHDSBodyStructure	0..*	
+	reason[x]	The reason the procedure was performed. This may be a concept from a terminology or a reference to a specific instance that describes the reason.		0..*	
++	reasonCodeableConcept		CodeableConcept		SNOMED GPS (preferred), ICD-10, Orphacode
++	reasonEHDSCondition		EHDSCondition		
++	reasonEHDSObservation		EHDSObservation		
++	reasonEHDSProcedure		EHDSProcedure		
+	outcome	The immediate result of the procedure (e.g. successful, unsuccessful). This does not include assessment over a longer period of time.	CodeableConcept	0..1	SNOMED GPS

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	complication	Complication that occurred during the procedure, or in the immediate post-procedure period.	CodeableConcept	0..*	SNOMED GPS (preferred), ICD-10,
+	deviceUsed	Device used to perform the procedure.	EHDSDevice	0..*	
+	focalDevice	Device that is implanted, removed, or otherwise manipulated (calibration, battery replacement, fitting a prosthesis, attaching a wound-vac, etc.) as a focal portion of the Procedure.	EHDSDevice	0..*	
+	note	Free text notes by the health professional.	string	0..1	

Table 31. EHDSRelatedPerson.

EHDSRelatedPerson means a structured set of data elements describing a person related to the patient, such as a guardian, next of kin, or other related person.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSRelatedPerson	Related person model.	Base		
+	identifier	A stable identifier of the related person that is unique within a defined scope. In addition to the mandatory attributes listed below, other attributes compliant with the HL7	Identifier	0..*	

		FHIR Identifier structure may be included.			
++	type	Description of identifier.	CodeableConcept	1..1	HL7 Identifier Type, extended with the following: NI (national unique identifier) HI (health identifier) HIN (health insurance number) SS (social security identifier) REGPID (regional person identifier) REGION (region identifier)
++	value	The value that is unique.	string	1..1	
++	system	The namespace for the Identifier value.	uri	1..1	
+	name	Name associated with the person.	EHDSHumanName	1..*	
+	subject	The patient in relation to whom the related person is defined.	EHDSPatient	1..1	
+	relationship	Relationship between a patient and a contact person for that patient (e.g., relative, guardian	CodeableConcept	0..1	HL7 Patient Relationship Type

		or caring person).			
+	address	Address of the person.	EHDAddress	0..*	
+	telecom	Telecommunication contact information of the person.	EHDSTelecom	0..*	

Table 32. EHDSServiceRequest

EHDSServiceRequest means a structured set of data elements describing one or more requested services.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSServiceRequest	Service request model.	Derived from parent data type: EHDDataSet		
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDHealthProfessional, EHDSEorganisation, EHDSEDevice	0..*	
++	date	Date and optionally time of authoring/issuing.	dateTime	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	status	Status of the resource.	CodeableConcept	1..1	HL7 Request status
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	description	Textual description of the requested service	string	0..1	
+	code	A code and name that identifies a particular service (i.e., procedure, diagnostic investigation, or panel of investigations) that has been requested.	CodeableConcept	0..1	SNOMED GPS (preferred), LOINC, NPU
+	quantity	Number of requested services of the same type.	Quantity	0..1	UCUM
+	bodySite	Anatomic location and laterality where the procedure should be performed. This is the target site.	EHDSBodyStructure	0..*	
+	reason[x]	Reason why this service is being requested.	EHDSObservation, EHDSCondition, EHDSMedication, string	0..*	
+	priority	Indicates how quickly the request should be addressed with respect to other requests.	CodeableConcept	0..1	HL7 Request Priority
+	supportingInformation [x]	Health conditions relevant for the results	EHDSObservation, EHDSCondition,	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
		interpretation.	EHDSPcedure, EHDSMedicationAdmini stration		
+	specimen	Specimen to be used by the laboratory procedure.	EHDSSpecimen	0..*	
+	encounter	The encounter that provides additional information about the healthcare context in which this request is made.	EHDSEncounter	0..1	
+	occurrence[x]	Expected time of the service.	dateTime, Period	0..1	
+	patientInstructions	Patient or consumer-oriented instructions.	string	0..1	

Table 33. EHDSSpecimen.

EHDSSpecimen means a structured set of data elements describing a sample collected.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSSpecimen	Specimen model.	Base		
+	identifier	An identifier of the specimen which is unique within in a defined scope.	Identifier	1..*	
+	status	Availability of the specimen.	CodeableConcept	0..1	HL7 Specimen Status

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
+	type	The kind of material that forms the specimen.	CodeableConcept	0..1	SNOMED GPS
+	specimenSource[x]	The source where the specimen came from. This may be from a patient, from a location (e.g., the source of an environmental sample), or from a device.	EHDSPatient, EHDSLocation, EHDSDevice	0..1	
+	parentSpecimen	Specimen from which this specimen originated.	EHDSSpecimen	0..*	
+	request	Service request based on which the specimen was collected.	EHDSServiceRequest	0..*	
+	collection	Collection details.	Base	0..*	
++	performer[x]	Person or organisation who collected the specimen.	EHDSHealthProfessional, EHDSOrganisation, EHDSPatient, EHDSRelatedPerson	0..1	
++	collected[x]	The period or date and time of specimen collection.	Period, dateTime	1..1	
++	quantity	The quantity of specimen collected.	Quantity	0..1	
++	method	If relevant for the results, the method of obtaining the specimen.	CodeableConcept	0..1	SNOMED GPS
++	device	Device used to perform specimen collection.	EHDSDevice	0..1	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
++	bodySite	Anatomic location where the material is collected.	EHDSBodyStructure	0..1	
+	receivedDate	Date and time when specimen is received by the testing laboratory.	dateTime	0..1	
+	container	The container holding the specimen.	Base	0..*	
++	specimenQuantity	Quantity of specimen within container,	Quantity	0..1	
++	containerDevice	The device for the container holding the specimen.	EHDSDevice	1..1	
+	condition	State of the specimen. State of the specimen should be aligned with dataAbsentReason element of the Observation model.	CodeableConcept	0..*	HL7 Specimen Condition
+	note	Any details or issues about the specimen or during the specimen collection (for example: broken vial, sent with patient, frozen).	string	0..1	

Table 34. EHDSTelecom.

EHDSTelecom means a structured set of data elements describing a telecommunication contact point.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
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	EHDSTelecom	Telecom model.	Base		
+	use	Purpose of the contact point (e.g. home, work).	CodeableConcept	0..1	HL7 Contact point use
+	system	Type of communication form (e.g. phone, fax, email).	CodeableConcept	0..1	HL7 Contact point system
+	value	The actual contact point details (i.e. phone number or email address).	string	1..1	

Table 35. EHDSTravelHistory.

EHDSTravelHistory means a structured set of data elements describing a patient's past travel to a specific country.

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
	EHDSTravelHistory	Travel history model.	Derived from parent data type: EHDSDataSet		
+	header	Basic metadata for this information.	Base	1..1	
++	subject	Patient/subject information.	EHDSPatient	1..1	
++	identifier	Business identifier for the object, unique within its system. Supporting disambiguation between different contexts (systems/countries).	Identifier	0..*	
++	author[x]	Author of the resource.	EHDSHealthProfessional , EHDSOrganisation,	0..*	

Level	Element Name	Element Description	Data type	Cardinality	Binding requirements
			EHDSDevice		
++	date	Date and optionally time of authoring/issuing	dateTime	0..1	
++	status	Status of the resource or document	CodeableConcept	1..1	
++	language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
+	country	Country visited.	CodeableConcept	1..1	ISO 3166-1 alpha-2
+	period	The period during which the patient visited the country.	Period	0..1	

Annex X
Definition of data types

Data type name	Data type description
Base	A foundational data type that provides shared structure and characteristics for other data types. Carries no value itself.
base64Binary	A sequence of bytes encoded in base64 format.
boolean	A binary value, either true or false.

Data type name	Data type description
CodeableConcept	A coded data type used to designate data fields.
dateTime	A date, time, or partial date (e.g. YYYY, YYYY-MM, YYYY-MM-DD, or YYYY-MM-DDThh:mm:ss+zz:zz). When hours and minutes are included, a time zone offset is required.
decimal	A numerical value consisting of a whole and a fractional part. Precision is determined by the use case.
EHDS[Name of the data group]	A reference to the EHDS common data groups as defined in Annex X.
Identifier	A value that uniquely and unambiguously identifies an entity, coupled with its source system where applicable.
integer	A whole number, positive or negative, as determined by the use case.
integer	A signed 64-bit whole number ranging from -9,223,372,036,854,775,808 to +9,223,372,036,854,775,807. Used where very large counts or time values are required.
Period	A time interval defined by two dateTime values representing the start and end points. Precision is determined by the use case..
Quantity	A numerical value, integer or decimal, accompanied by a unit of measure, preferably expressed as a coded concept.
Range	An interval defined by a minimum and maximum Quantity (e.g. 2 mg – 4 mg).
Ratio	A relationship between two Quantity values expressed as a numerator and a denominator (e.g. 1 tablet per 4 hours).
string	A sequence of Unicode characters.
uri	A Uniform Resource Identifier (URI) reference.

Data type name	Data type description
Narrative	A human-readable XHTML summary of a resource, conveying its essential clinical and business information in a form safe to render independently of the resource's structured data. Its status indicates the relationship between the narrative content and the underlying encoded data.