CEN/TC 251

Date: 2019-03

FprCEN/DTS 17288: 2019

Secretariat: NEN

Health informatics — The International Patient Summary: Guideline for European Implementation

ICS:

Contents

Page

European foreword 6

Introduction 7
The eHealth Network, the Cross border Directive, and the IPS Use Case 7
The relationship between the CEN IPS and other PS Initiatives 7

Figure 1 — CEN/TC 251's participative role in establishing the IPS Standards 8
The European Interoperability Framework 8

Figure 2 — An overview of the IPS Project 9

Table 1 — Description of the Clause mapping to ReEIF 9
Standardization initiatives relevant to the IPS 10

Figure 3 — Landscape affecting the IPS Guide for European Use 11

1 Scope 12

2 Normative references 12

3 Terms and definitions 12

4 Abbreviations 17

5 Conformance 18
5.1 The relationship between this Document and prEN 17269 18

6 The IPS Use Case, 4 Scenarios, and the Subject of Care 19
6.1 The IPS Use Case 19
6.2 IPS Scenario 1: Cross border, Unscheduled care 19
6.3 IPS Scenario 2: Cross border, Scheduled care 19
6.4 IPS Scenario 3: Local, Unscheduled care 19
6.5 IPS Scenario 4: Local, Scheduled care 19
6.6 The Subject of Care and Data, Chronic Health Conditions, and multiple versions of PS 20

7 Governance Consideration 20
7.1 Information Governance applicable to IPS 20

Figure 4 — Product and Process views of IPS and Stakeholder Responsibilities 21

Table 2 — Examples of stakeholder involvement in Information Governance 21
7.2 Information Governance (Product View) 22
7.3 Information Governance (Process View) 23
7.3.1 General 23
7.3.2 Request 24
7.3.3 Export 24
7.3.4 Import 24
7.3.5 Access 24
7.3.6 Use and Reuse 24

8 Data Protection, Privacy and Security Consideration 26
8.1 General 26
8.2 Data Protection Requirements and Principles 26

9 Legal and Regulatory Consideration 27
9.1 General 27
9.2 Regional and National Legislation 28
9.3 European Legislation 28
9.4 Examples of Directives and Regulation with respect to the IPS 28
10 Policy Consideration 28
10.1 General 28
10.2 Organisation Policy 29
10.3 European Policy 29
11 Care Process Consideration 29
12 Information Consideration 29
12.1 General 29
Figure 5 — The Information Consideration in the Interoperability Framework 30
12.2 Common Dataset 31
12.3 Value Sets 31
12.4 Information Models 32
12.4.1 General 32
12.4.2 EN ISO 13606 Archetypes 32
12.4.3 Detailed Clinical Models (DCM) 33
12.4.4 HL7 CDA Templates 34
12.4.5 HL7 FHIR Resources and FHIR Profiles 34
12.5 Terminology Requirements and Agreements 35
12.6 Terminologies and structures for Implementation Now and in the Future 35
13 Applications Consideration 36
13.1 General 36
Figure 6 — Two examples of IPS interchange (e.g. CDA, FHIR) 37
13.2 European eHealth Digital Service Infrastructure (eHDSI) 38
14 Infrastructure Consideration 38
15 Standards, Profiles and Evaluation 38
15.1 General 38
15.2 Standards/Profiles 38
15.2.1 Scope 38
15.2.2 Data patterns 39
Table 3 — Patterns from prEN 17269 realised in CDA IPS and in HL7 FHIR IPS 39
15.2.3 Elements mapping 40
Table 4 — HL7 CDA Standard realizes prEN 17269 40
Figure 7 — Examples of mappings between prEN 17269 dataset and the HL7 CDA IPS templates in ART DECOR® 41
Table 5 — IPS Document and required data mapped to HL7 Implementations 42
Table 6 — IPS Document Model Extensions 42
Table 7 — Remaining IPS Sections mapped to HL7 Implementations 43
Table 8 — IPS Patient Attributes mapped to HL7 Implementations 44
Table 9 — IPS Allergies and Intolerance mapped to HL7 Implementations 45
Table 10 — IPS Allergies and Intolerances Model Extensions 46

Table 11 — IPS Medication Summary mapped to HL7 Implementations 46
Table 12 — IPS Medication Summary Model Extensions 47
Table 13 — IPS Problems mapped to HL7 Implementations 48
Table 14 — IPS Problems Model Extensions 48
Table 15 — IPS Attribute Collection Cross border mapped to HL7 Implementations 49
Table 16 — IPS Patient's Address Book mapped to HL7 Implementations 49
Table 17 — IPS History of Procedures mapped to HL7 Implementations 50
Table 18 — IPS History of Procedures Model Extension 50
Table 19 — IPS Immunizations mapped to HL7 Implementations 51
Table 21 — IPS Medical Devices mapped to HL7 Implementations 52
Table 21 — IPS Medical Devices Model Extensions 52
Table 22 — IPS Results mapped to HL7 Implementations 52
Table 23 — IPS Results Model Extensions 53
Table 24 — IPS Advance Directives mapped to HL7 Implementations 54
Table 25 — IPS Functional Status mapped to HL7 Implementations 55
Table 26 — IPS History of Pregnancy mapped to HL7 Implementations 55
Table 27 — IPS History of Past Illness mapped to HL7 Implementations 56
Table 28 — IPS History of Past Illness Model Extensions 57
Table 29 — IPS Plan of Care mapped to HL7 Implementations 57
Table 30 — IPS Social History mapped to HL7 Implementations 58
Table 31 — IPS Provenance mapped to HL7 Implementations 58
Table 32 — IPS Provenance Model Extensions 59
15.3 Projects 59
15.3.1 General 59
15.3.2 eHDSI 59
15.3.3 Trillium II 60
15.4 Exchange Format Examples 60
15.4.1 IPS CDA example 60
15.4.2 IPS FHIR example 63
15.5 Testing 68
15.6 Deployment 69
15.7 Socio-technical Factors 70
15.8 Stakeholder evaluation 71
Annex A (Informative) The Refined eHealth European Interoperability Framework 73
Annex B (Informative) Detailed landscape for IPS 74
B.1 Overview 74
B.2 The eHealth Network 75
B.3 EC and European Projects concerning eHealth 75
B.4 The Health Informatics SDO's 75
B.5 European Policy 75

B.6 European Stakeholders 75
B.7 The IPS Standards for Europe 76
B.8 European Citizens 76
Bibliography 77

European foreword

This document (FprCEN/TS 17288:2019) has been prepared by Technical Committee CEN/TC 251 “Health Informatics”, the secretariat of which is held by NEN.

This document is proposed to be submitted for the CEN Formal Vote ballot.

Introduction

This document provides a European implementation guideline for the International Patient Summary (FprEN 17269). The target audience is primarily software developers, and project implementation teams, but policy makers and SDOs have a role in assuring that the guideline is relevant to IPS.

European policy, directives, organisational and professional culture, and a diverse market place require implementation guidance that is technically relevant and contextually sensitive. This document describes these implementation aspects from the European perspective. The different ways that the International Patient Summary (IPS) and its content are communicated are the subject of this document. This document will reference and credit initiatives, such as the eHealth Networks' patient summary dataset and the multiple European projects, that have contributed to the shared vision embodied in the joint CEN IPS and HL7 IPS Project.

The eHealth Network, the Cross border Directive, and the IPS Use Case

The requirements for the CEN IPS' deliverables come directly from the eHealth Network (eHN) and their support for the 'Specific Guidelines for Electronic Exchange of Health Data under the Cross border Directive 2011/24/EU'. "These guidelines, as adopted by the eHealth Network, are addressed to the Member States of the European Union and apply to the implementation of a patient dataset for cross border exchange." [1]

The objective of the EU policy is to support continuity and coordination of care for EU citizens across Member States (MS). In a cross border context, the eHN further asserts that "interoperability is essential to the provision of high-quality care. Member States shall therefore engage in taking appropriate measures to make their respective information systems interoperable, both technically and semantically, for this Use Case". [2]

The specific use case is more general, but the scenario from the eHN is to exchange a patient summary (PS) between countries, comprising an agreed minimal dataset, for unscheduled care. Member State needs, however, require the IPS to also be useful for localised use, and to support scheduled care too. The required, core data elements in the eHN guideline are the basis around which meaningful patient summary (PS) implementations can be built. These data, their descriptions and definitions, have been formalized and refined in prEN 17269 with the intention of making them usable, and reusable, for different communication purposes in the healthcare domain at a global level.

The relationship between the CEN IPS and other PS Initiatives

Patient Summaries are ubiquitous. The differences and diversity of existing implementations, however, make it currently difficult to safely communicate content. In what is an increasingly complex ecosystem there is a strong requirement to provide simple interoperable solutions for key applications. This has led to a drive to standardize patient summaries for widespread use. The EC chose to support this need for standardization by sponsoring a number of related projects, enabling international participation to consider how to deliver interoperability with respect to cross border exchange of the Patient Summary. The Health Informatics Committee of CEN (i.e., CEN/ TC 251) was commissioned to produce relevant IPS Standards based upon the eHN guideline. Figure 1 shows a map of key CEN IPS stakeholders.

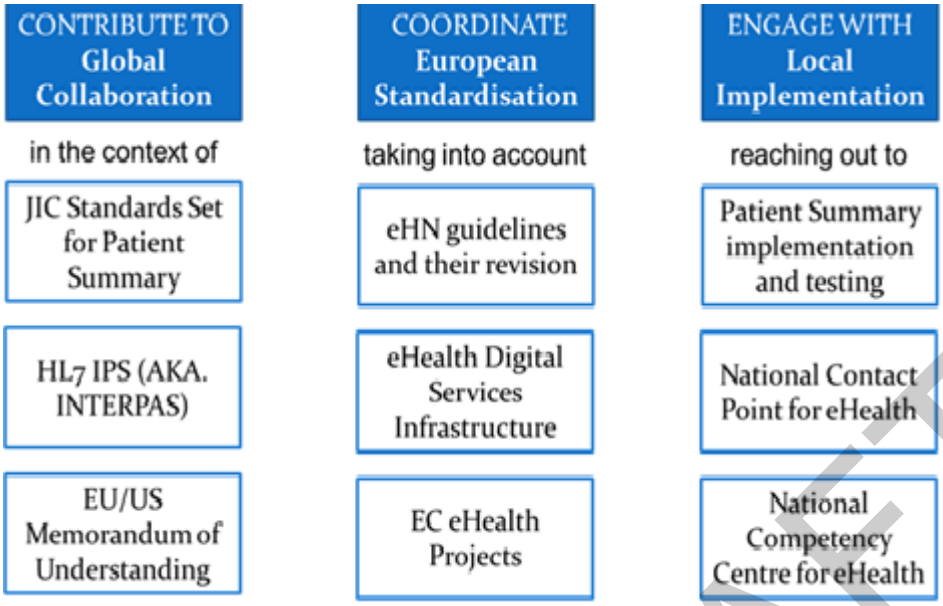


Figure 1 — CEN/TC 251's participative role in establishing the IPS Standards

The International Patient Summary Project is comprised of two concurrent standardization activities; one lead by CEN/TC 251 and the other by HL7 International. The standards developed by each of them are inter-related standard products, with informed coordination to realize coherent results.

The EC eHealth projects, aware of the EU/US MOU [3], have been supportive. The Trillium Bridge [4] and Trillium II [5] projects have taken as input the initial work from both CEN/TC 251 and HL7 IPS as the basis for its elaborations and analysis, thereby contributing to the new standardization approach, described by the eStandards [6] project, as "Co-creation, governance and alignment (CGA)". Concurrently, the eHDSI [7] under the CEF [8] project is realizing the cross border services for the Patient Summary based on the eHN PS guideline and using Patient Summary CDA specifications evolved from epSOS [9]. The lessons learnt by eHDSI (and its parent projects) have been taken into consideration for the development of the IPS Project. Figure 2 provides an illustration as to how the various products of these initiatives relate to each other.

The European Interoperability Framework

The Refined eHealth European Interoperability Framework (ReEIF) [10] is a "common refined framework for managing interoperability and standardisation challenges in the eHealth domain in Europe"; and it has been designed "for the communication and decision-making processes on projects and solutions for eHealth. ReEIF offers a framework of terms and methodologies for reaching a common language, a common starting point, for the analysis of problems and the description of eHealth solutions throughout Europe". To leverage that fact, ReEIF is used here to structure this document so as to provide relevant European guidance material for the International Patient Summary (IPS). The clause structure that maps to the Framework is presented in Table 1.

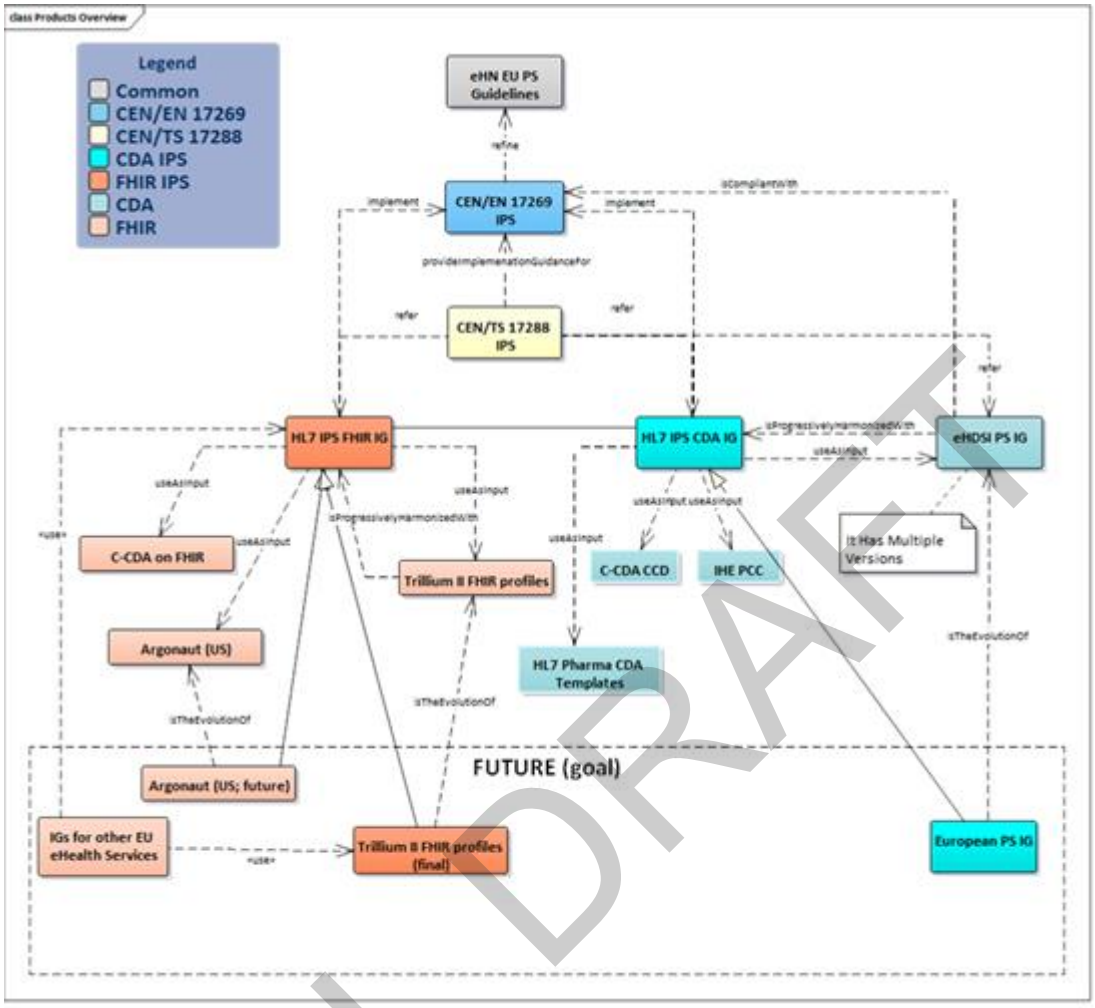


Figure 2 — An overview of the IPS Project

Table 1 — Description of the Clause mapping to ReEIF

Clause #	ReEIF's Consideration	Emphasis in this document
Clause 7	Governance	Information Governance
Clause 8	Security, Privacy and Confidentiality	Data Protection
Clause 9	Legal and Regulatory	Statutory requirements
Clause 10	Policy	European and organisational aspects
Clause 11	Care Process	Clinical Process and workflows
Clause 12	Information	The Datasets, models and terminologies
Clause 13	Applications	Standardized Interchange formats
Clause 14	Infrastructure	IT and protocols of exchange
Clause 15	Standards and Profiles, Certification	Examples, Conformance Testing, deployment, and Evaluation

The single topic 'Security, Privacy and Governance' in ReEIF has been managed here as two separate clauses to highlight their importance to the IPS; the original format of the ReEIF is illustrated in Annex A. Frameworks and models are simplifications of the world they attempt to represent. Consequently, interpretation plays a part in how the ReEIF categorises and differentiates between the different considerations. This document adapts the ReEIF to support this implementation guide.

The ReEIF provides a framework for the construction concepts, i.e., the identification and specifications concerning what is needed to deploy the solutions (here 'solution' is synonymous with the IPS). However, the operational aspects, including the project and deployment space, are not directly addressed by the ReEIF. This document considers these operational aspects in the latter part of Clause 15.

One example of ReEIF adoption and adaptation by Member States is given by Nictiz, the eHealth competency centre of the Netherlands. They make extensive use of the ReEIF in their national architectures (i.e., large, e.g. hospital network) and in local ones (i.e., small, e.g. GP office). The Centre deploys what are colloquially known as building blocks, positioned at the Information layer of ReEIF, as a means of controlling communication which is "achieved by making agreements about the semantics, the meaning of the data and data structures as well as establishing these agreements in the form of health and care information models." [11].

Standardization initiatives relevant to the IPS

From the European context there are a number of formal activities that are of interest to the Standards Development Organisations (SDOs), which are mutually beneficial and compatible. They are:

- The Informative Joint Initiative Council (JIC) Patient Summary Standards Set (PSSS)

  o This activity is not intended to create a new standard; it is essentially an informative activity and its value is to inform the stakeholders about existing or developing standards in the PS space. The PSSS has a wider scope, providing a catalogue. Both CEN and HL7 are members of JIC.

- The normative CEN IPS and HL7 IPS initiatives (known as the IPS Project) focus on delivering a single consistent IPS information standard, guideline and implementation guides.

  o The HL7 IPS project succeeds the earlier INTERPAS project, whereas the CEN IPS project was intended to support standardization in Europe by formalising the eHN Guideline through active participation in global SDO activities.

  o The IPS projects have been working together to produce a single compatible solution based on vision and agreements made at the Oslo workshop organised by Trillium Bridge back in 2016.

  o The IPS Project takes on board relevant detail from the JIC PSSS and will contribute to the PSSS content as their joint work proceeds to develop the formal standards required.

- The eHealth Digital Service Infrastructure (eHDSI) initiative for cross border health data exchange, which builds on the outputs of the epSOS pilot with a view of providing implementations for European Member States by 2019.

  o Whilst not strictly SDO related, it is a deployment activity, and considerable effort has been made by CEN and HL7, to harmonize their work to ensure European implementation is based upon a formal set of standards.

All these initiatives rely heavily on the eHN guideline for a PS dataset, version 2 of which was published in November 2016.

NOTE 1 The JIC PSSS differs from the other initiatives in that it introduces extra items reflecting homecare requirements but these are outside of the IPS Project's current scope.

These eHN guideline has supported the harmonization efforts made by CEN/TC 251 and HL7. Policy considerations, stakeholders' interests, and technical changes provide the context for this document as illustrated by a simplified overview given in Figure 3, with the lighter arrows representing the historic influences and the darker arrows indicating specific inputs.

NOTE 2 There have been a number of projects and consortia that have been funded by EC initiatives that have also contributed in direct and indirect ways to the IPS Standards. Details of these may be found in the Bibliography of this document.

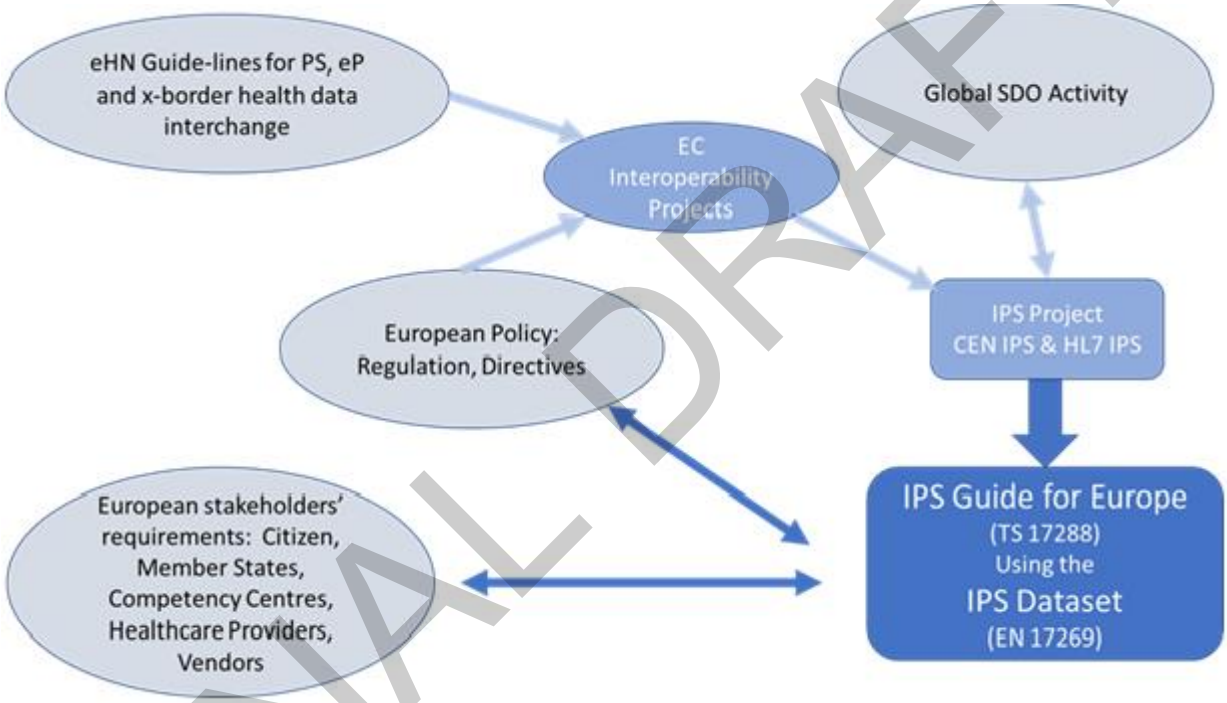


Figure 3 — Landscape affecting the IPS Guide for European Use

An amplified version of Figure 3, which explains the relationships between the CEN IPS and HL7 IPS deliverables and the context of the project work in more detail, is presented in Annex B (Informative).

1 Scope

This document is focussed on how the international patient summary (IPS) can be deployed within a European context. Specifically, this document provides guidance for the European implementation of prEN 17269.

The guideline is also intended to be usable for more localised deployment, benefitting Member States that want to use the IPS within their own borders and, as an additional benefit, its components may be reused to improve the interoperability of EHRs through common exchange formats.

This document addresses:

— Jurisdictional requirements, such as EU directives and regulations, relevant to the usability of the International Patient Summary.

— Governance, privacy and data protection, so as to support the safe, legitimate and sustainable use of patient summary data. Continuity of care and coordination of care are considered with respect to cross border scenarios of care.

— Conformance, providing examples of conformant, derived models from prEN 17269:2019 for both cross border and more localised use. Examples of transport formats for carrying patient summary data are given. Terminologies, deployment and migration guidance are also addressed.

Out of Scope:

This document will not recommend a particular delivery platform/service/template or terminology. The IPS is not a Personal Health Record (PHR), nor is it a comprehensive Electronic Health Record (EHR) both of which have different purposes.

2 Normative references

The following document is referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

prEN 17269:2018, *The International Patient Summary for unscheduled cross border care*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
condition independent IPS
set of data to help inform a person's treatment at the point of care, irrespective of the condition of the patient

[SOURCE: prEN 17269:2018]

3.2
continuity of care
efficient, effective, ethical care delivered through interaction, integration, co-ordination and sharing of information between different healthcare actors over time

[SOURCE: EN-ISO 13940:2016]

3.3

cross border

passing, occurring, or performed across a border between two countries

NOTE 1 to entry: This scenario emphasises the fact that countries will have different jurisdictions that might have legal, organisational and cultural implications for how personal data, and particularly health data are managed and shared.

NOTE 2 to entry: with respect to interoperability, cross border data interchange is the extreme case of the more general ones of organisational and professional boundaries found within a country's borders, and therefore the substantive part of the IPS standard is also applicable to national and local contexts.

3.4
extensible IPS Dataset
IPS content that can be extended for use in patient summary use case scenarios that complement the primary IPS Scenario

3.5
healthcare information request
request sent out by a healthcare actor to another healthcare actor for specific healthcare information needed for the provision of healthcare to a subject of care

[SOURCE: EN-ISO 13940:2016]

3.6
implementation independent IPS
IPS data model not bound to any implementation technology specification (e.g. XML, JSON) or implementable standard (e.g. HL7 FHIR; HL7 CDA) used to implement it.

NOTE 1 to entry: one or more implementation specific artifacts could be derived.

NOTE 2 to entry: it corresponds to the Conceptual and Logical Information Models, as defined by the HL7 SAIF Framework [18]; or to the Computational Independent and Platform Independent Models, as defined by the OMG Model-Driven Architecture approach [19].

3.7
IHE Profile
organization and leverage of the integration capabilities that can be achieved by coordinated implementation of communication standards, such as DICOM, HL7 W3C and security standards

Note 1 to entry: to entry: IHE Profiles provide precise definitions of how standards can be implemented to meet specific clinical needs.

3.8
HL7 FHIR (Resource) Profile
describes the general features that are supported by the system for each kind of FHIR resource. Typically, this is the superset of all the different use-cases implemented by the system. This is a resource-level perspective of a system's functionality.

3.9
IPS

Synonym: IPS Document

electronic patient summary for use at the point of care comprising, as a minimum, the required elements of the IPS Data Set.

NOTE 1 to entry: The Use Case is 'a patient summary for use at the point of care'; the following are IPS scenarios:

- 'Unscheduled, Cross Border care' is the initial IPS scenario 1;
- 'Scheduled, Cross Border care' is IPS Scenario 2;
- 'Unscheduled, Local care' is IPS Scenario 3;
- 'Scheduled, Local care' is IPS Scenario 4.

NOTE 2 to entry: National and local applications of IPS are served by this standard. The specific cross border scenario requires the Cross Border Data Block to be used, but this is not required for within border applications.

NOTE 3 to entry: IPS is applicable in any situation, irrespective of local/international and scheduled/unscheduled care situations.

NOTE 4 to entry: IPS Data Blocks may be readily used in other applications, but to be an IPS the application must have the same scope including the same purpose of summarising the patient's healthcare history for continuity of care.

NOTE 5 to entry: IPS is also used as shorthand to denote the activity of the two SDO initiatives focused on delivering the IPS, i.e. CEN IPS and HL7 IPS. The context in which the term is used determines the specific meaning, e.g. when it is associated with the SDO name it refers explicitly to the initiative rather than to the IPS content.

[SOURCE: prEN 17269: 2019]

3.10
IPS Consumer
healthcare provider or citizen who receives or accesses the IPS and manages its disposition

3.11
IPS Producer
healthcare provider, with possible patient as co-producer, who sources the IPS in response to an IPS request

3.12
IPS Request
healthcare information request where the requesting of the IPS can be made by any legitimate means of access

Note 1 to entry: There are many ways the IPS Request can be created and delivered; for example, it may be a message/document paradigm, or a legitimate query/view interaction, or a share between the healthcare provider and the patient or their proxy.

3.13
minimal IPS
IPS Dataset
core set of data items that all health care professionals can use

Note 1 to entry: The 'minimalist' concept reflects the ideas of 'summary' and the need to be concise at the point of care.

Note 2 to entry: It does not imply that all the items in the dataset will be used in every *patient summary*

3.14
non-exhaustive IPS
recognition that the ideal dataset **is not closed**, and is likely to be **extended**, not just in terms of requirement evolution, but also pragmatically in instances of use.

Note 1 to entry: However, such data is outside the scope of the IPS standards until revision.

3.15
open IPS Dataset
facilitation of extensions to allow for emerging solutions for unresolved issues or improvements

3.16
patient summary
health record extract comprising a standardized collection of clinical and contextual information (retrospective, concurrent, prospective) that provides a snapshot in time of a subject of care's health information and healthcare

Note 1 to entry: The eHN Guideline definition is: A Patient Summary is an identifiable "dataset of essential and understandable health information" that is made available "at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in the unscheduled care"; it can also be defined at a high level as: "the minimum set of information needed to assure health care coordination and the continuity of care". (eHN, article 2)

[SOURCE: ISO/TR 12773-1:2009]

3.17
personal information
PI
any data that describes some attribute of, or that is uniquely associated with, a natural person.

[SOURCE: OASIS PMRM TC, 2016]

3.18
personal identifiable information
PII
any (set of) data that can be used to uniquely identify a natural person

[SOURCE: OASIS PMRM TC, 2016]

3.19
specialty agnostic IPS
starter set of data to help inform a person's treatment at the point of care, irrespective of the specialist trying to manage the care

3.20
subject of care
healthcare actor with a person role; who seeks to receive, is receiving, or has received healthcare

[SOURCE: EN-ISO 13940:2016]

Note 1 to entry: The subject of care is also the subject of the communication.

Note 2 to entry: Synonyms: subject of healthcare, patient, client, service user.

3.21
terminology
collection of uniquely identifiable concepts with associated representations, designations, associations, and meanings.

[SOURCE: HL7 Common Terminology Services Service Functional Model Specification Release 2, May 2013]

Note 1 to entry: vocabulary, terminology and code system are used interchangeably. Examples of terminology are SNOMED CT, WHO ICD-10; LOINC and so on.

4 Abbreviations

For the purposes of this document, the following abbreviations apply:

CEF	Connecting Europe Facility
CEN	Comité Européen de Normalisation (European Committee for Standardization, a federation of 28 national standards bodies that are also ISO member bodies)
CEN IPS	CEN International Patient Summary; Partner in the IPS Project
CEN/ TC 251	CEN Technical Committee 251 (develops standards within health informatics)
EC	European Commission

eHAction	eHealth Action
eHDSI	eHealth Digital Service Infrastructure
eHN	eHealth Network
EHR	Electronic Health Record
EU	European Union
EU-MS MOU	EU-US Memorandum of Understanding
GDPR	General Data Protection Regulation
HL7	Health Level Seven
HL7 IPS	HL7 International Patient Summary; Partner in the IPS Project
IDMP	Identification of Medicinal Products; an ISO Standard
IHE	Integrating Healthcare Enterprise
IPS	International Patient Summary
ISO	International Organization for Standardization
JASeHN	Joint Action Supporting eHN
JIC	Joint Initiative Council
PS	Patient Summary
PSSS	Patient Summary Standards Set
ReEIF	Refined eHealth European Interoperability Framework
SPOR	Substance, product, organisation and referential

5 Conformance

The ReEIF has been used in this document to assist the reader in identifying requirements for the IPS implementation in Europe. The ReEIF is not a de jure standard but the framework is well known in Europe and its familiarity is intended to help. However, each layer may raise requirements for IPS implementations and these, in time will be subject to conformance. At present only a small set of examples is provided until a more comprehensive list is gleaned through experience of IPS implementations:

- IPS implementations within Europe shall conform to EU Directives and regulation. e.g. GDPR
- Cross Border application involving non-EU countries, should consider if there are legal differences when it comes to exchanging a person's healthcare information.
- Multiple, versions of an IPS might exist for the same subject of care. Implementations should minimise the risk of an IPS being used when the user is unaware of it containing incomplete or out of date information.

This technical specification does not recommend a particular delivery platform/service/template.

5.1 The relationship between this Document and prEN 17269

This document is a guideline for the IPS implementation within Europe. There is further discussion about conformance to the IPS implementation, with examples, in clause 15.1

6 The IPS Use Case, 4 Scenarios, and the Subject of Care

6.1 The IPS Use Case

The original use case topic was scoped to address a single, primary scenario, i.e., to exchange a Patient Summary cross border for unscheduled care of a visitor. This requirement has been the focus throughout the joint development of IPS. However, Member States' needs went beyond the original scope and it was agreed that other, secondary scenarios could be addressed at the same time providing this did not compromise the original requirement.

These new requirements were managed by retaining the focus on the given primary scenario and then relaxing the contextual constraints in a disciplined way. However, given that use case methodology is directed towards interactions between actors and systems rather than the precise specification of data elements, these changes do have greater significance for this document.

6.2 IPS Scenario 1: Cross border, Unscheduled care

The defining contexts and constraints for the IPS scenario are (1) cross border exchange and (2) unscheduled care. This is the primary scenario; the other scenarios broaden the focus of the IPS by relaxing these constraints.

6.3 IPS Scenario 2: Cross border, Scheduled care

The eHN guideline suggests that the standard might also accommodate planned or scheduled care, e.g. for rare diseases. This elective care scenario has a reduced likelihood that the health need of the person is urgent. Such care may mean more information can be made available, maybe even a full EHR rather than a summary. Scheduled care removes the urgency and, to some extent, removes the need to be concise. Different governance and data protection considerations may be affected. The information interoperability consideration is also affected by increasing the demand for additional terminology. However, The IPS will often not meet all the requirements for cross border scheduled care, but it may still be helpful by providing a consistent structure for a hand-over document or "executive summary" of the more complete records that are made available.

6.4 IPS Scenario 3: Local, Unscheduled care

It was readily appreciated that the majority of exchanges, and therefore the most clinical and economic value to be gained, were not cross border but were local. To accommodate this, the prEN 17269 data model had a separate IPS Section that could be used to manage the cross border data requirement. The cross border data element is defined as optional; it thereby permits local use of the remaining data without the associated overhead of considering data for crossing borders. From the implementation perspective, and therefore of direct relevance to this document, local use of the IPS means a simplified and reduced payload, yet one that enables national parties to leverage all the benefits of the standardised IPS. More significantly though, the use of IPS in the local context removes significant burden by simplifying interoperability considerations (i.e., governance, data protection, regulatory and legal, and policy considerations).

6.5 IPS Scenario 4: Local, Scheduled care

This is probably the most frequent use of patient summary data. IPS can serve as input to a hand-over document to inform a new clinician or be used in total as an aide memoir reminding the original author of their patient and associated health conditions; it is analogous to an 'executive summary' function prefixing a larger [clinical] record. In some implementations, it may take the form of a dashboard. This is also probably the scenario where the patient summary can take a myriad of non-standard forms,

following local custom, policy, and organisational culture. The IPS may be used as a framework for local scheduled care where there are not good reasons for maintaining another patient summary specification.

6.6 The Subject of Care and Data, Chronic Health Conditions, and multiple versions of PS

One misunderstanding to do with IPS, affecting all 4 scenarios, relates to the Subject of Care and their associated health conditions. It assumes that a chronic condition, or a reoccurring condition, invalidates the need for the IPS and argues that such conditions will always require additional data either about the condition or data specific to a particular specialty to be relevant. The need for more data, however, does not contradict the fact that a standard core dataset will still be of value, irrespective of the additional requirements arising from the uniqueness of every patient or of their conditions. IPS is a pragmatic start as additional data inevitably poses a challenge for all interchange and the more extensive the dataset the more difficult it will be to get agreement on what should be included or left out. These challenges affect all 4 scenarios. Consequently, the IPS has been designed to allow data to be added to complement the summary rather than stretch the summary to meet all requirements.

The IPS content has been designed to be condition-independent and specialty-independent as far as possible. It recognises that other data might be required to complement the core dataset and has provided a consistent, transparent way of extending the IPS. The given dataset is not intended to be exhaustive, rather it is meant to be a minimal dataset common to all scenarios. This feature even allows the IPS to contribute to Scenarios 3 and 4, by providing standardized data to be utilized as required. Extending the IPS in this way will widen the application area of interoperability.

For any person, there may be more than one of his/her summaries in existence (i.e., different versions). This case of multiple, possibly different versions is not explicitly dealt with by the above scenarios, which regards the current patient summary as the most relevant for treating the patient at the point of care. Implementations, however, should address how such situations are to be dealt with, to minimise the risk of an IPS being used when the user is unaware of it containing incomplete or out of date information

7 Governance Consideration

7.1 Information Governance applicable to IPS

Governance requirements permeate all the layers of the ReEIF and therefore apply to the IPS, which is one specific example of health data interchange. Information governance addresses both product and process perspectives as illustrated by Figure 4; the numbered arrows represent some examples of the associations between the interoperability consideration and the stakeholder' responsibilities. IPS Governance is evolving and these examples do not claim to be exhaustive. The examples are elaborated in Table 2 and explained further in the following sub-clauses.

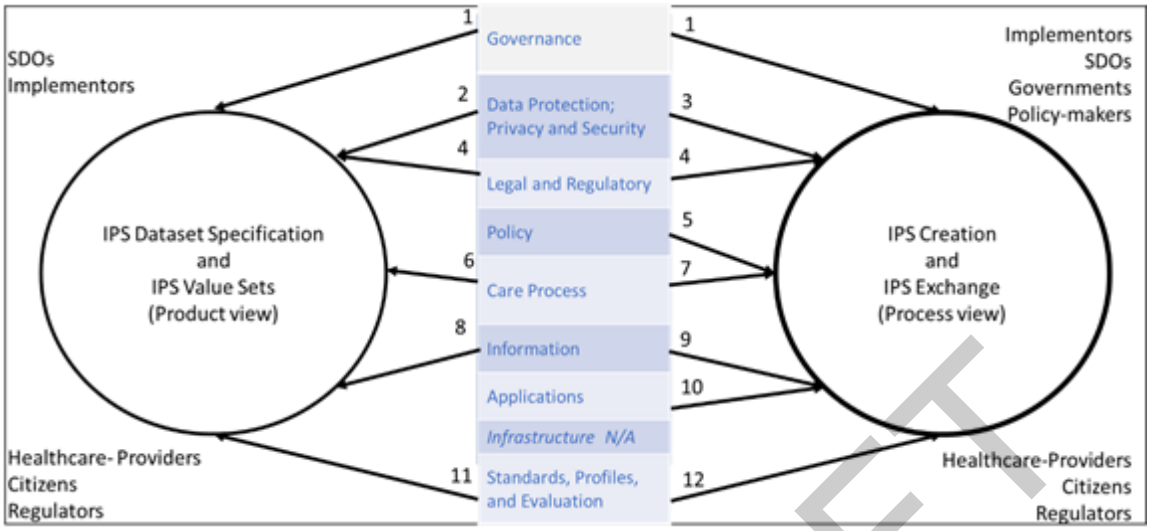


Figure 4 — Product and Process views of IPS and Stakeholder Responsibilities

Table 2 — Examples of stakeholder involvement in Information Governance

ReEIF	Arrow#	Stakeholders	Meaning
Governance	1	SDO	Design and Maintenance
Data Protection (DP) Privacy and security	2 3	SDO, Citizen Implementers, Healthcare providers	Provenance, fairness, transparency Assess risks, accountability, Data Protection by Design and by Default
Legal and Regulatory	4	Government, Regulators	Cross border health data, Data Protection, harmonisation and Enforcement
Policy	5	Policy makers	Selection, formalisation and sharing
Care Process	7 6	SDO, implementers Healthcare providers	Clinical and Citizen drivers; Trustworthy Use, validation
Information	8 9	SDO, implementers SDO, implementers	Models and terminologies Models and exchange formats
Applications	10	Implementers	Implementation considerations
Infrastructure N/A	-	-	-
Standards, Profiles, and Evaluation	11 12	SDO, Implementers Citizens, Healthcare providers	Feedback and sustainability Validation and Value

7.2 Information Governance (Product View)

The 'product view' of IPS considers the governance of the IPS dataset and the associated value sets as defined in prEN 17269. The 'product view' might also include educational and training artefacts required for communicating the value of the IPS. Change management is integral to providing sustainable governance that ensures the integrity and applicability as the product evolves. The website maintained by CEN/TC 251 introduces the IPS and its associated artefacts[1]

Information Governance is at the strategic level of the IPS life-cycle where the SDO's have a leading role in the design and then maintenance of the standard over time (see arrow #1 in Figure 4 and Table 2 respectively).

NOTE The lifecycle of the IPS in the eStandards project [6] is useful when considering the IPS Information Governance. The strategic levels of the life-cycle, relates to defining, standardising and evaluating the PS activities, which corresponds to the 'control' aspect of Information Governance, whereas the operational level, relates to various ways the PS is used, which corresponds to the 'use' aspect of Information Governance. In particular it addresses the management of the data, i.e., specification, creation, capture, formatting, maintenance and change requests to the existing IPS content and processes.

Other stakeholders (e.g. implementers, healthcare providers) provide the requirements, but the SDOs have the responsibility for designing (e.g. inclusion of provenance meta-data) and maintaining the data elements and ensuring the standard meets those requirements. The IPS standard is therefore the definitive one for the International Patient Summary content governance, and it is to be used to avoid diverging and conflicting implementations. The governance of prEN 17269 compliance will support efforts directed at achieving interoperability between healthcare systems.

One part of the design process (see arrow #2) from the product perspective is to factor in the needs for Data Protection for the individual citizen, specifically the subject of care. The healthcare mandate defines the rights and obligations of healthcare providers, for example, with regard to their involvement in healthcare processes performed for a specific subject of care. Consequently, the IPS standard needs data attributes defined to support provenance and means designed for representing and managing 'consent' for example need consideration.

Government and regulators are the principal stakeholders considering the legislation and regulations that surround the IPS product (see arrow #4). The governments produce policies for cross border exchange, and also for harmonising data protection rights across the Member States, that in turn become requirements of the IPS specification. The data for cross border exchanges are included in the IPS as a specific requirement of these stakeholders. An example of the Regulators impacting the IPS product by initiating changes to the IPS Medication Summary when IDMP is realised; in the European context, SPOR, is the present terminology.

The Care Process is essentially a formalisation of clinical and citizen driven requirements. It is the rationale for the existence of the IPS. The core dataset is a requirement for a minimum set of data to be provided at the point of care that is useful to any attending clinician who has to treat a new (i.e. unknown to that healthcare provider) subject of care. Although the Care Process is all about clinician and consumer requirement, it is the SDOs who are tasked with the IPS Product and have to manage the structures, value sets and terminologies of that product to enable the IPS to achieve interoperability and deliver meaningful, trustworthy, semantic clinical information at the point of care (see arrow #6).

The Information consideration is primarily the SDO stakeholder's responsibility (see Arrow #8). They create and control information models, their structures and components and the granularity of the data elements, and the bindings between the information models and terminologies. For example, they are responsible for the business rules of extending the IPS to include non-IPS data that is needed to provide relevant data for a specific condition. These rules are specified in prEN 17269. Furthermore, as things change and new requirements merge, they are responsible for finding ways to manage extensions in the

[1] Available at http://www.ehealth-standards.eu/en/projects/

derived models. For example, the model extensions in this document for specific interchange formats such as CDA or FHIR need to be considered as input to the revision of prEN17269.

The Standards, Profiles and Evaluation consideration, from a product' perspective, is relatively limited at this time. Sustainability (arrow #11) implies that there are effective ways of managing revisions based upon feedback from implementations. SDOs should not govern themselves but put in place effective ways that they obtain feedback to refine and improve their products.

At this time, the prEN 17269 content is relatively small as a dataset. Requests to change and systemic review after three to five years will not be too onerous. CEN is capable of maintaining this specification on those terms. Setting up third party maintenance bodies is also a possibility and experience can be obtained from how this has been done in regard to medical devices.

However, whereas CEN IPS has focused on trying to harmonise definitions from eHN, eHDSI, CEN/TC 251, and HL7, it could be argued that the IPS aspiration will only be satisfied by becoming truly global, and therefore it needs to go beyond these organisations. It is already part of the CEN and HL7 design principles to produce a global solution. Further steps will be to take forward this work into ISO and to involve WHO as well, thereby going beyond the original scope of the EU-US Memorandum of Understanding.

7.3 Information Governance (Process View)

7.3.1 General

The 'process view' of IPS is concerned with the dynamic nature of the IPS, i.e., how the IPS is used and controlled. It covers the operational levels of the IPS life-cycle from its creation to its consumption.

As with the 'product view', the 'process view' includes the design and maintenance aspects of the IPS illustrated by arrow #1. However, its focus is the exchange formats and the way they deliver the IPS. That having been said, the work of the SDOs is inclusive of both views and how they interact with each other.

Privacy by design and by default are matters which the SDOs have to address in much the same way as a vendor has to when producing a new software artefact (see arrow #3 in Figure 4 and Table 2 respectively). This is a work in progress but the citizen has to be assured that the IPS is a trustworthy exchange, otherwise it will not be supported.

NOTE The concept of 'Trustworthiness' is preferred as it permits mitigation in breach situations, whereas the term 'trusted' is absolute and binary, making it unrealistic (i.e., there will always be opportunities to improve) for digital health. [13]

With the GDPR legislation (see arrow #4), accountability has to be demonstrated leading to risk assessment, audit trails and the like. To what extent, these features affect the IPS Specification as opposed to the broader EHR system need to be considered by the SDOs and the implementers. IPS Scenario 1, i.e. cross border, unscheduled care, is a special case for the Member States of the EU, who are committed to an implementation and deployment project as part of the eHDSI. The eHDSI deployment activity rather has a governance scheme in place which determines whether one country can participate and safely transfer the required healthcare data.

Policy impacts the choice and use of the IPS (arrow #5). The required IPS Sections form a subset of the IPS Dataset. Policy shapes the organisational culture and hence determines which optional IPS Sections should be used. It formalises the agreements between the IPS Producers and IPS Consumers. For example, the IPS is concerned with 'Personal Information' and 'Personally Identifiable Information'. These matters directly engage data protection legislation and has implications for IPS interchange policies with respect to governance, privacy and security, within the legal and regulatory frameworks of a single jurisdiction and become more challenging still when cross border exchange is required across 2 or more jurisdictions with different policies.

The Care Process is the domain of the IPS Use (arrow #7). There follows a number of examples:

7.3.2 Request

The Healthcare Information Request is a concept in EN ISO 13940 but the workflow, and its content, are outside of the scope of the IPS Standards. Note that the 'request' can be served by different means, for example by sending a message or satisfying either 'push'/ 'pull' operations, or by a query by the IPS Consumer.

However, the content of the request action may well determine the relevance of the data provided. Given the IPS Scenario focuses upon urgent, unscheduled cross border care, the importance of relevance determines how concise, and optimal the response is for the attending clinician. IPS capabilities to express relevance are primitive, but the fact that the IPS Dataset represents the common core alleviates the difficulty by only providing what is considered to be the core PS content that is deemed relevant for any treatment.

7.3.3 Export

The IPS Producer determines what and how much can be exported, and this may be governed by organisational policy and/or professional norms; it may also be possible/required for the IPS Producer to take the Subject of Care's demands into consideration (e.g. not to export hidden data). This would be the case in a situation where the IPS is shared by the patient themselves. The data will be interpreted by others on receipt, so there is also a further requirement to ensure sufficient context is exchanged as part of the summary data. Content, context and relevance are challenging, particularly with respect to making the communication concise and optimal. These issues pose difficulties for achieving semantic interoperability. Whether the data is from a single system, from multiple sources, or from the patient themselves, the IPS Producer, probably regulated by an organisational policy, has control of what is shared in response to the healthcare information request and can stipulate who should access the IPS (subject to data control policies/regulation). Transaction details of the IPS must be kept for purposes of transparency.

7.3.4 Import

For applications that are not simply querying/viewing data, the first concern is to do with security against breaching the system at the point of care. Import of any communication from an external source requires screening by the requesting system. This will be the usual case; it requires checking to make it safe before use by the attending clinician.

The second concern is to how to manage the imported IPS, whether to integrate or keep separate, and how to treat the notion of updating a summary, an action that is deemed legitimate depending on the organisation's policy. Recipient Systems can import the structured data elements automatically into their own system. This relies on a mapping from the serialised form of the IPS Producer's domain model being mapped into structures in the recipient system. This should be simplified by the use of prEN 17269 which provides a mutually agreed-upon standard format.

7.3.5 Access

Legitimate access to the IPS by the IPS Consumer will depend upon the data protection policies, upholding security, confidentiality and privacy considerations of the subject of care. This will be addressed in more detail in clause 8 on data protection.

7.3.6 Use and Reuse

The use of the IPS information will, in part, be determined by the local context. Urgency of the treatment, professional norms, insight and trust in the IPS Producer all play a part. The languages of the patient and that of the attending clinician are also very important, as indeed are the interface terminologies used.

How some of these problems are managed will depend on the system's presentation and also on the type of implemented system. For example, a view rather than an exchange document may provide the means of focussing upon the relevant parts of the summary. It may be that instead of a single burst summary,

relevance may be tackled either by probabilities (e.g. using an intelligent system) or by the IPS Producer and IPS Consumer engaging in a dialogue rather than a single exchange where the attending clinician refines what they need from a summary as they carry out their assessment.

Reuse of any clinical data is potentially dangerous. Some data collected for a particular purpose are not suitable for use in another situation unless the context is completely explained. Systems are generally poor in capturing 'context', which in itself is a nebulous concept. Recorded data is open to multiple interpretations, both due to settings and to time. Organisational policy should control any reuse and make sure such use is transparent.

The Information consideration of ReEIF is key for the SDOs and implementers. This area involves the production of models, of various sorts and at different levels of granularity, required to support interoperability. The implementers use the standard and often have a requirement to improve it (see arrow #9). The implementers are at the business end and their use and deployment discovers new requirements or the need to redefine or correct the existing standards. As this area is very dynamic, it is often required to profile or extend the standard. The examples given in this document shows HL7 extensions to the various IPS Sections, which need to be accommodated. This is part of the feedback and maintenance needed by the SDOs (see arrow #11).

The final arrow #12 is concerned with the 'Standards, Profiling and Evaluation' consideration of ReEIF. As 'Standards and Profiles' have already featured in both governance views, this discussion will limit itself to considering 'Evaluation'. Governance is not evidence-based at this time. Control and Use of the IPS, however, will be determined in part by the evaluation of the IPS Product and the IPS Processes. Validation and assessment of its value will predominantly be by the IPS Consumers and this will come from its deployment and acceptance of whether or not it is fit for purpose.

8 Data Protection, Privacy and Security Consideration

8.1 General

Data protection is part of governance and is enshrined in European legislation (see Clause 9), which is intended to harmonise data protection regulation across the Member States. This clause considers how the regulation applies to the IPS.

8.2 Data Protection Requirements and Principles

Processing data of a natural person should respect the fundamental rights and freedoms in particular the right to the protection of personal data. Privacy policy is defined to protect personal data and personal identifiable data against any misuse of these data or breach of confidentiality. In the case of eHealth, the security mechanisms do not exclude access exceptions in the case of the safety of the natural person with traceability of the actions (for example, in the case of emergency when the patient is not able to give his/her consent).

The following should be taken into account for IPS implementation:

Data protection by design: appropriate organisational and technical measures that meet the principles of data protection by design and data protection by default. These measures minimize the processing of personal data. (e.g. pseudonymization or anonymization measures that improve security features).

Pseudonymization and/or anonymization measures are not that useful for the IPS use case given the purpose of the PS. However, if the IPS is integrated within a system or the stored IPS content is to be reused for another purpose (e.g. research) then such measures need to be considered.

Several organisational and technical mechanisms can be solicited to ensure the data protection of the IPS:

- Organisational mechanisms:
  - For each data element, define the security level and authorization profile to access to the data;
  - Identify user profiles
- Technical mechanisms:
  - Specify role-based access control security mechanism applied to the IPS (see ISO 22600-1: 2014[2] and ISO 22600-2:2014[3])
  - Limit the information to the strict minimal data set to ensure traceability in the log

Information and consent: the data subject is able to give his/her consent, freely, specifically and unambiguous indication according his/her wishes in the strict data processing needs. Upon request, Information can be provided to the data subject without delay.

Patient Consent is part of the Individual's right. Consent (and alternatively Dissent) is recorded in advance or at the point of care, if possible. The Patient consent is generally formalized as an electronic document. It might originate as a paper document, signed by the patient within a hospital for example, which is then scanned. For the IPS it may be a document included with, but not incorporated into the IPS in response to the healthcare information Request. It is generally recognised as being a separate form and not part of the IPS and therefore its definition and content is outside of the scope of this document.

The Patient's consent must be obtained before any access of personal data by authorized healthcare professionals who provide care to the patient.

[2] Health Informatics – Privilege management and access control – Part 1 : overview and policy management
[3] Health Informatics – Privilege management and access control – Part 2 : formal models

In the case of cross border exchange, the patient consent must be checked at the country or origin and the patient can at any time update his/her consent. In the country of treatment, the healthcare professional must verify that the consent is still active or must update it if the patient is willing to do so.

Accountability: the controller, i.e. the IPS Producer and the IPS Consumer, under European law should be able to demonstrate their compliance to the General Data Protection Regulation (GDPR); for example, they need to be able to demonstrate that the data subject provided his/her consent (traceability); Accountability implies that 'Provenance', specifically tracking of composition and access are potentially important for the IPS.

Minimisation: data that are processing are strictly those necessary and their storage is period limited. Minimisation for the IPS would seem to be a given, provided by the definition and meaning of a 'summary'. However, a summary demands sufficient 'context' to be included for it to be safely understood by the IPS Consumer, and that can be very broad, and it is difficult to constrain.

The particular interchange mechanism used (see Governance Clause) goes some way to ensure only relevant data is included. PrEN 17269 intentionally limits 'mandatory' designations, appreciating that the volume of the data could be quite considerable if all the IPS data elements were to be automatically included in the IPS interchange, which would violate the principle that data processing should be strictly limited to necessary data.

Portability: development of an interoperable format in order to meet the right to data portability of the data subject. "The data subject shall have the right to receive the personal data concerning him or her, which he or she has provided to a controller, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller without hindrance from the controller to which the personal data have been provided, where:

1. the processing is based on consent or on a contract and
2. the processing is carried out by automated means."

For healthcare, this means that persons must have access to medical data in a structured, machine-readable format. The IPS is a good example of such a format that can be delivered and processed by automated means.

NOTE Whilst GDPR is now law across European Member States, its flexibility and scope will likely create differences in how it is interpreted and applied. Furthermore, GDPR compliance is still a challenge, and is the subject of on-going research (see SHiELD [12]) on how to apply it to healthcare data interchange.

A CEN IPS workshop on GDPR and IPS was held in 2018; the report of the meeting can be found here [17]

9 Legal and Regulatory Consideration

9.1 General

National and local agreements interpret relevant legislation and regulations within a particular jurisdiction. At an international level, this layer is used to harmonise legislation and regulations across different countries. These local and international agreements are essentially the same as those made in de jure standardisation, except that standards are not automatically binding, unless legislation and/or regulation is put in place to empower them.

As the legislation and regulations are the same for all parties in a country, this layer is often left out for local, regional and national projects. However, the IPS is focussed on cross border transactions, for use beyond even the regional level, and therefore it is important that this layer is considered.

The IPS has the aspiration to be global (i.e., as in CEN and HL7's shared development principle). An implementation of IPS that is cross border operating under different jurisdictions will need to be aware of the applicable legal and regulatory policies, and the potential differences between the policies in place.

9.2 Regional and National Legislation

The United Nations have published a report in 2016 [13] that analyses the regulations on data protection and international data flows. Several regional initiatives on data protection are listed and among them:

- The European Union and the EU data protection directive (1995);
- The Asia economic cooperation (APEC) grouping 21 members' economies and has "1/ developed a set of common APEC Privacy principles, 2/ the development of a system for coordinating complaints that involve more than one APEC jurisdiction and 3/ the development of the cross border Privacy Rules system (BPRs)"
- The African Union that has adopted the African Union Convention on Cyber-security and Personal data Protection in June 2014. Other sub frameworks were also adopted in the east or west regions in Africa.

Other initiatives at the national level are also developed such as the USA with Health Insurance Portability and accountability (HIPAA) that was approved by the US congress in 1996, Australia (Privacy Act, 1988), Japan (act on Protection of personal information, 2003 and 2015).

9.3 European Legislation

The European General Data Protection Regulation (GDPR) EU 2016/679 [14] was adopted by the European Parliament in 2016 (it supersedes the 1995 directive mentioned in the UN report.) The GDPR provides principles and rules on "the protection of natural persons with regard to the processing of their personal data should, whatever their nationality or residence, respect their fundamental rights and freedoms, in particular their right to the protection of personal data".

European IPS implementations are subject to the GDPR but not all of it necessarily applies as GDPR's scope extends into sectors beyond healthcare. For example, in Europe, the EU charter of fundamental rights stipulates that EU citizens have the right to protection of their personal data, which would include financial data.

9.4 Examples of Directives and Regulation with respect to the IPS

The following are relevant:

- Specific Guidelines for Electronic Exchange of Health Data Under the Cross border Directive 2011/24/EU
- General Data Protection Regulation (GDPR) EU 2016/679
- Medical Devices: Medical Device Regulation (EU) 2017/745
- IDMP: Commission Implementing Regulation (EU) No 520/2012(articles 25 and 26)

10 Policy Consideration

10.1 General

Policies can inform legislation and regulation. The Policy Consideration for ReEIF relates to interoperability and can be seen in micro terms of the individual organisation, such as a healthcare provider, and in macro terms referring to those of a country or a group of countries. Policy, legislation and regulation may be formalized in software constructs and relevant ones may be part of the future IPS application.

10.2 Organisation Policy

Policies can take the form of agreements made at management level between cooperating organisations or for internal use between management and workforce. For interoperability this may generate educational and training artefacts related to using an IPS.

10.3 European Policy

An example of policy informing law and regulation in Europe is the policy relating to the 'Citizen or individual's rights' which has informed the GDPR.

11 Care Process Consideration

The ISO Standard, entitled 'Systems of Concepts for Continuity of Care', based its conceptual foundation for interoperability upon the 'clinical process'. The Care Process in ReEIF is a generalisation of that same idea and maintains the importance of that process to interoperable solutions.

Governance of these processes is the responsibility of the clinical professions. The Care Process layer of ReEIF is the rationale for the existence of the IPS as it is the business domain that provides the requirements for the standards. The IPS Use Case and the IPS Scenarios are all about the Care Process.

Within the scope of the IPS is the intent to support the coordination of healthcare and there is the fundamental, inherent process-aspect of improving the quality and efficiency of the delivered healthcare. Data is created and recorded throughout the care process and it is used and reused in the patient summaries for both coordination and continuity of care.

How the IPS is used and extended will depend on its fit with the purposes, requirements and workflows of the healthcare providers and clinical professions.

12 Information Consideration

12.1 General

The ReEIF considers this layer to be where the common dataset, value sets and terminologies are considered, in association with the care processes in the previous layer. Although ReEIF separates the Care Process and the Information considerations, it is recognised that Information and care are intertwined. The ISO standard 13940 'System of Concepts for Continuity of Care' (ContSys) provides conceptual support for interoperability and covers all the considerations thus far addressed up to and, to some extent, including the information consideration.

NOTE ISO 13940 does provide the concepts for information management, but to go beyond the conceptual world the need for datasets and information models provide the next steps on the road to interoperability.

ContSys considers concepts for Information Management but does not define any implementation detail. To build on these concepts, clinical reference information models can be created. This Information consideration in ReEIF is a busy, cluttered and complex space, but it is critical for the IPS and its interoperable use. Figure 5 gives the main topics to be addressed in this Clause.

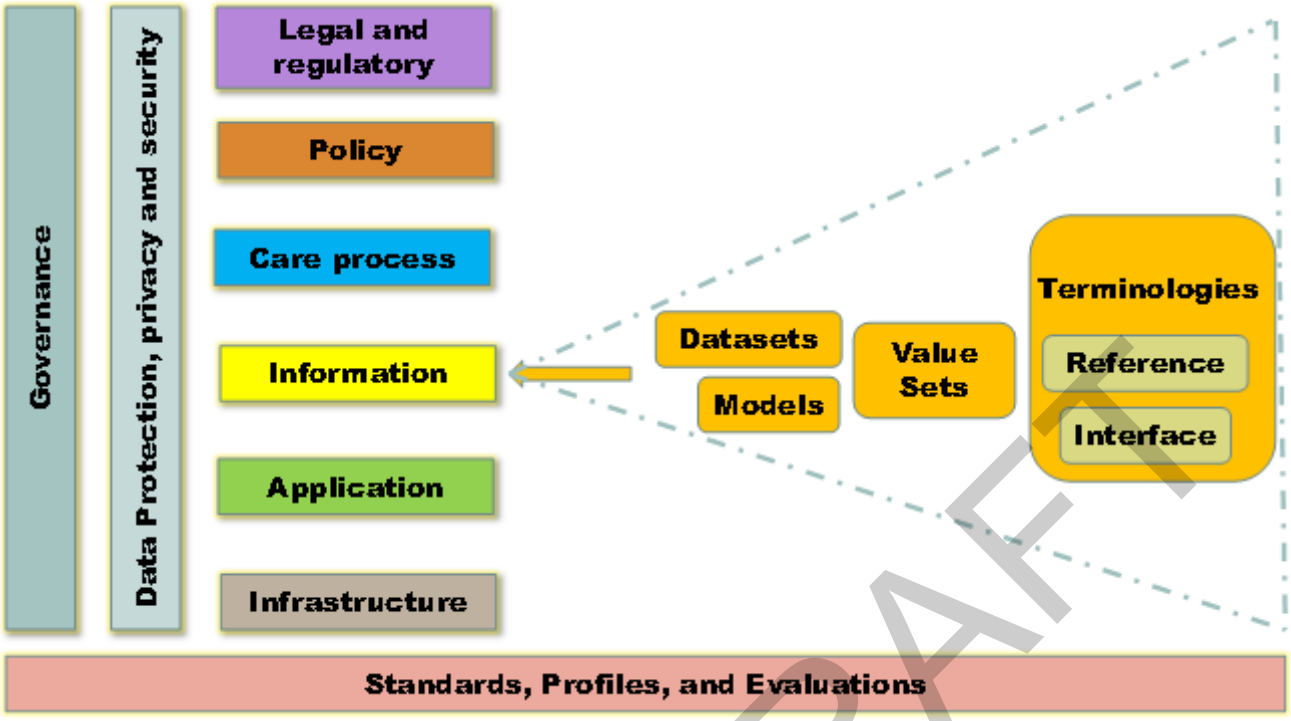


Figure 5 — The Information Consideration in the Interoperability Framework

The ReEIF is mainly designed for "communication and decision-making processes"; for that reason, it privileges clarity and simplicity to specificity. In that sense it does not pretend to be exhaustive. Not all the possible perspectives are highlighted, as for example, the fact that several abstraction levels (e.g. conceptual; logical and implementable models) can belong to the same layer. Moreover, readers should be conscious of the interdependencies among these layers and that real-world artefacts may belong to more than one of them. For example, an implemented service specification (Application), may require specific implemented information models (Information) that may restrict the dataset or the terminologies choices (Information).

Frameworks and models are simplifications of the world they attempt to represent.

ReEIF is one of the several existing interoperability frameworks. Each framework focuses on aspects that are relevant for specific purposes (e.g. communication; standard development) and potential readers (e.g. decision makers; interoperability architects). Other frameworks as the Service Aware Interoperability Framework developed by HL7 International; the National Interoperability Framework for E-Health by Nehta; that specified in the ONC roadmap; and others could be considered depending on the level of detail needed and the purpose of use.

Consequently, interpretation plays a part in how the ReEIF categorises and differentiates between the different considerations. The different layers are porous as a result. This document clarifies the distinctions for the purpose of this implementation guide. Figure 5 represents the 'Standards, Profiles and Evaluations' bar as a horizontal layer as the rationale for the IPS work is to produce these artefacts as deliverables, which take into consideration all the other aspects of the ReEIF. The standardization and evaluation part of this Consideration is at the strategic level of the IPS life-cycle and therefore is concerned with defining the IPS and ensuring it meets the requirements of its stake-holders.

12.2 Common Dataset

An IPS Dataset is defined for the purpose of identifying which data is to be transferred and to describe its structure and content (i.e. terms and value sets). For interchange to be possible it needs to set in place a set of mutual agreements between IPS Producers and IPS Consumers. This process is optimised if a standard from a consensus process is produced and leveraged for common use.

The IPS standard associated with this document describes and defines a minimal but non-exhaustive set of data elements that can be used for an International Patient Summary. Furthermore, prEN 17269 describes the IPS domain using a basic, generic document metaphor that is applicable to most, if not all, clinical documents. It is primarily meant for use within the setting of unplanned, cross border care and targets a given scenario of providing quality data at the point of care. The 17269-structure does not prohibit the standardized IPS Sections being used in different communication structures; its openness and extensibility facilitates a potential library of reusable clinical components.

The domain model and dataset from prEN 17269 can be harvested for use in different conditions, in different contexts and in different implementations. Whereas the core dataset described is an international one, its application may be subject to jurisdictional constraints and the actual use of that data may benefit from technical descriptions of how they can be used in different types of implementation.

12.3 Value Sets

prEN 17269 addresses value sets specifying a set of concept domains. In this sense, it provides a selective and minimal set of concepts that the value sets should include, intentionally not identifying the terminologies in which they will represented. In fact, Value Sets are too pervasive and closely tied to implementation considerations, which limit their use for implementation-independent description. Value sets define the possible choices of coded concepts for a data element. The concept domains often serve the function of a predicate to be tested.

An example of concept domain specified in prEN 17269 is in the Clinical Status of the condition in the *IPS **Section Allergies and Intolerances***, where prEN 17269 says that this data element should at least include the concepts:

— Active

— Inactive

— Resolved

In any clinical setting, implemented systems usually host many value sets. A value set ‘just’ specifies, a (value set definition) or enumerates a (value set expansion), a list of coded concepts. Possible associated terms, relationships and any other attribute or property associated to that concept belong to the code system (i.e. the Terminology (specifically ISO/HL7 27951:2009) not to the value set.

Often Value Sets are localised, making semantic interoperability between systems very difficult without extensive cross-mappings. Furthermore, these mappings are difficult to maintain in practice. The number of concepts chosen for value sets in the IPS have been minimized, to give examples that might be expressed in any terminology resource so as to avoid implementation dependence. prEN 17269 does not restrict the values that can actually be used in practice and is not intended to be an exhaustive set.

12.4 Information Models

12.4.1 General

Information models are widely used to express structure and process resulting in data interchange formats and behaviours. The definition and use of the IPS Sections or IPS Data Blocks in prEN 17269 are abstract examples, intended to be implementation-independent, and complementary to CDA Sections, which are more concrete representations of implementation. The IPS Sections identify data elements and interrelationships and use standardised data types to describe them in more detail. This type of modelling can be complex but it is relatively well understood compared with that which directly interfaces with terminologies.

There are multiple initiatives in approaches to formalise 'clinical content' relating it to Terminology; they have different purposes and are at different levels of abstraction. The ones included in this document have been selected as they are existing Standardization products from CEN, HL7 and ISO that are in use within Europe. The following subsections briefly describe these models that seek to manage the terminology considerations.

12.4.2 EN ISO 13606 Archetypes

The EN ISO 13606 (Electronic health record communication) five-part standard series specifies a means for communicating part or all of the electronic health record (EHR) of one or more identified subjects of care between EHR systems, or between EHR systems and a centralised EHR data repository. The forthcoming new version of the EN ISO 13606 standard, which has passed its ballot cycles and is now being processed for publication in 2018.

The approach adopted by the EN ISO 13606 standard series distinguishes:

- a Reference Model, defined in Part 1 of the series and used to represent the generic properties of health record information; and

- Archetypes (conforming to an Archetype Model, defined in Part 2 of the series), which are meta-data used to define patterns for the specific characteristics of the healthcare data that represents the requirements of each particular profession, specialty or service.

The Reference Model represents the global characteristics of health record components, how they are aggregated, and the context information required to meet ethical, legal and provenance requirements. This model defines the set of classes that form the generic building blocks of the EHR.

An Archetype is the formal definition of prescribed combinations of the building-block classes defined in the Reference Model for particular clinical domains or organisations. An archetype is a formal expression of a distinct, domain-level concept, expressed in the form of constraints on data whose instances conform to the reference model. For an EHR_EXTRACT, as defined in Part 1, an archetype instance specifies (and effectively constrains) a particular hierarchy of RECORD_COMPONENT sub-classes, defining or constraining their names and other relevant attribute values, optionality and multiplicity at any point in the hierarchy, the data types and value ranges that ELEMENT data values may take, and other constraints.

Archetype instances themselves conform to a formal model, known as an Archetype Model (which is a constraint model, also specified as an Open Data Processing Information Viewpoint Model). Although the Archetype Model is stable, individual archetype instances can be revised or succeeded by others as clinical practice evolves. Version control ensures that new revisions do not invalidate data created with previous revisions. The Archetype Model specified in this standard was originally developed by the openEHR Foundation[4].

[4] See www.openehr.org

The Archetype Model, when incorporated into editing tools that also recognise the Reference Model Part 1, enables the specification of clinical content models that automatically "plug in" to the EN ISO 13606 standard and enable semantically interoperable communications. Because the archetype approach is content agnostic, it is possible to define archetypes that represent any clinical data structure and associated term lists.

A set of archetypes was created, conforming to the previous published version of the EN ISO 13606 standard, to represent all of the clinical information components of the European epSOS project's Patient Summary. Since the new version of the EN ISO 13606 standard is now approved, it is planned to produce a new set of archetypes conforming to the standard, representing the clinical components of the EU patient summary guideline as defined in prEN 17269. An important aid to the consistent design of these archetypes will be the reference archetypes in Part 3 of 13606 (conforming to ISO 21090:2011 Harmonized data types for information interchange, and to EN ISO 13940:2016 'System of concepts to support continuity of care'). These reference archetypes specify archetype patterns for core aspects of demographics and continuity of clinical care, which will be specialised as needed to develop the EU Patient Summary Guideline set of archetypes.

12.4.3 Detailed Clinical Models (DCM)

12.4.3.1 General

Complimentary to the EN ISO13606 standard is the ISO 13972:2015 standard (Detailed clinical models, characteristics and processes). ISO/TS 13972 defines a DCM as "an information model designed to express one or more clinical concept(s) and their context in a standardized and reusable manner, specifying the requirements for clinical information as a discrete set of logical clinical data elements."

12.4.3.2 An Example of use: Healthcare Information Models (HCIM)

HCIM's are DCMs, but with a strong accent on the Information Model of a DCM. The HCIM focus strongly on the Information Model of a DCM, because that is the most important part in implementations. SNOMED CT is heavily used in HCIMs, both in elements in the Information Model and in the composition of value sets within the Information Model for those data elements that use the CE, CD, or CO datatype (ISO 21090). HCIM use UCUM to specify units for data elements that have PQ datatype (ISO 21090). They are included here for three reasons:

1) To show how a relatively abstract model can be made more concrete for a physical implementation;

2) Nictiz is a Competence Centre and is framing their use of the patient summary using combinations of HCIM and;

3) because the Netherlands deploy these in their use of the ReEIF and are actively advocating take up by other Member States. However, it should be stressed that this is one approach; other solutions maybe also possible.

Colloquially, Nictiz refers to HCIM's as standardised, building blocks for constructing healthcare documents and messages; in particular the PS is to be comprised of these building blocks. At the date of publishing, Belgium has been actively using the HCIMs for a couple of years; Sweden and Switzerland have shown interest in the Netherlands' work.

A HCIM is a model in the information layer, which

"defines the way in which (with regard to coding, unit of measurement, attributes etc.) a set of related data elements can be recorded in a system....

… For example: A care professional takes a blood-pressure reading and records this unambiguously in accordance with the method indicated in the HCIM (coding, unit of measurement, attributes etc.). This is then a piece of data or an observed fact. How this blood pressure should be interpreted in the context of

the treatment or the patient's health status is another question. In other words: the information the data provides depends on the context." [Architecture, Vol1, Feb 2017 Nictiz]

The HCIM developed are extensive, around a 100 are available, and are differentiated for Medical and Nursing applications. Those that originated from Medical use (as of February 2017) include:

Respiration : AlcoholUse : Alert : AllergyIntolerance : BarthelADLIndex : TreatmentDirective : Payer : BloodPressure : MaritalStatus : Contact : ContactPerson : DrugUse : FamilyHistory : FunctionalOrMentalStatus : GlasgowComaScale : HeartRate : LifeStance : BodyWeight : BodyHeight : BodyTemperature : MedicationUse : MedicationAdministration : MedicationDispense : MedicationPrescription : MedicalDevice : Nationality : O2Saturation : Education : Patient : PainScore : PulseRate : TobaccoUse : ConcernForTransfer : PlannedCareActivityForTransfer : LaboratoryTestResultForTransfer : TextResultForTransfer : ProcedureForTransfer : Vaccination : AdvanceDirective : LivingSituation : HealthcareProvider : HealthProfessional ...

12.4.4 HL7 CDA Templates

HL7 CDA is "a document markup standard that specifies the structure and semantics of 'clinical documents' for the purpose of exchange between healthcare providers and patients."[5] CDA is based on the HL7 V3 Reference Information Model and it is the most used world-wide standard for implementing the document-based interoperability paradigm. The CDA specification is designed to be used by constraining its richness and flexibility for each specific scope. The results of this process are the CDA templates. A template "represents a formal definition of a set of constraints on a model ... to specify a narrower and more focused scope"[6], this usually include also the value sets to be used. It may define the constraints applied to a specific kind of document (e.g. the International Patient Summary); to a section (e.g. the IPS Medication Summary); or to a specific statement or item (e.g. Medication Statement; Product information. CDA templates – above all section and entry level templates - are designed to be reused as a sort of library, as such, or specializing or adapting them. For example, a national CDA template for Patient Summary for unexpected care, is supposed to be a specialization of the CDA IPS template. The current HL7 CDA representation for the IPS has specified one document level template; nine header level templates; section templates for each included section, plus one for conveying translated narratives; about forties entry level templates to represent, e.g. problem concerns; product information; expected delivery dates and so on.

12.4.5 HL7 FHIR Resources and FHIR Profiles

HL7 FHIR is a "platform specification that defines a set of capabilities use across the healthcare process. … The basic building block in FHIR is a Resource. … FHIR resources aim to define the information contents and structure for the core information set that is shared by most implementations."[7]. Examples of existing resources are MedicationStatement; Concern, Patient, and so on[8]. As for the CDA, FHIR is designed to be adapted to particular use cases. This is done through profiles (e.g. implementation guides; conformance resources), profiles may constrain and/or extend the standard resources to fulfil that specific purpose. HL7 is specifying a FHIR based Implementation Guide for the IPS[9] to be used for IPS FHIR documents and, hopefully, as library of FHIR profiles. The expectation for local implementations of FHIR Patient Summary for unexpected care, is to profile the FHIR IPS Implementation Guide.

[5] HL7 Version 3 Clinical Document Architecture (CDA®)
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7.
[6] Templates Standard: Specification and Use of Reusable Information Constraint Templates, Release 1. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=377.
[7] HL7 FHIR® http://hl7.org/fhir/
[8] See http://hl7.org/fhir/resourcelist.html for a complete list of available resources
[9] See http://hl7.org/fhir/uv/ips/

12.5 Terminology Requirements and Agreements

There is no single terminology adopted for use across the whole field of healthcare. The IPS is a very small, constrained set of data elements from within that field, but even so different terminologies can be expected to be deployed in the different IPS Sections based upon local culture and legacy systems.

Agreements have to be made therefore on the following matters:

- The choice of terminology: Even with the minimal IPS dataset, there is the likelihood that more than one terminology standard will be used within one IPS Section and also for different IPS Sections and even more likely for the extended non-standard sections. The choice should reflect the current situation in the Health Care Systems involved and should be a "common denominator" for a best practice approach.

- Licensing activities and costs for different terminologies are in the scope of the Member States and this has implications for global adoption.

- Relatively new specialised structures, such as IDMP, and how they will be introduced. Note in Europe at this time SPOR provides the terminology.

- Governance and management mechanisms that have been put in place for the value sets definition and maintenance.

To help understand the position of SNOMED CT for the EU, a project called 'Assess CT' [15] was funded by the EC. The project highlighted also the different roles that terminologies could play, distinguishing between 'Reference' and 'User Interface' terminologies, both relevant to the IPS.

NOTE 1 Reference terminologies describe the meaning of terms of a domain, together with the properties of the objects that these terms denote. Representational units of reference terminologies are commonly called "concepts". SNOMED CT is an example of a Reference terminology.

NOTE 2 Following the notion of interface terminology by Rosenbloom ST et al. Interface terminologies: facilitating direct entry of clinical data into electronic health record systems. J Am Med Inform Assoc. 2006 May-Jun;13(3):277-88. Epub 2006 Feb 24. Due to the different facets of the term "interface" (user interfaces vs. machine interfaces) ASSESS CT has coined the term 'user interface terminology'

NOTE 3 User interface terminologies are collections of terms that are used in written and oral communication within a group of users, for example in a data entry form or in clinical documents. These are much closer to implementation."

12.6 Terminologies and structures for Implementation Now and in the Future

Europe, recognising that there will not be the adoption of a single clinical terminology across its Member States for some time has developed the Master ValueSet Catalogue (MVC) for its terminology services for eHealth. The MVC is a collection of Value Sets and it provides a common vocabulary to describe the clinical data [16]. MVC is used in the eHDSI deployment project for cross border patient summaries. The MVC is intended to be the central system to provide the value sets needed to transfer semantically structured information across Member States, translations and mappings. The terminologies used by IPS should be the common consensus and the common denominator used by the stakeholders and supply what is needed to provide the most meaningful and accurate information for the health care professionals.

A license agreement in which a relevant 'Free for Use' Set of SNOMED CT coded concepts will be used within the HL7 International Patient Summary (IPS) has been recently signed between HL7 Int. and SNOMED Int. Organizations, information systems, or mHealth apps creating or receiving an HL7 IPS may or may not have a SNOMED license. For organizations, regions or countries that have a SNOMED license, the SNOMED CT free set enables easier specification of the patient summary requirements and better

interoperability, while for those organizations, regions, or countries that do not have SNOMED licenses, the free set enables them to use the data for care and to store within their EHRs.

Within medicinal product regulation, the ISO standards that identify medicinal products (IDMP) will soon become the definitive set of standards for implementation of structures. This change will have implications for the IPS Section on Medications.

13 Applications Consideration

13.1 General

Functional specifications are laid down at the Information level. These form the basis for the technical specifications, which are described at the Application level.

At this level, agreements have to be made within both the IPS Producer and IPS Consumer regarding the integration of various applications between which information is exchanged.

Agreements on the technical exchange format of the information to be transferred determine how the information to be transferred is structured. Which data in a document or message is transferred depends on the context, which can determine the packaging format (application layer), while the content of the healthcare information building bricks remains the same in as far as that is possible (information layer). The representation chosen (e.g. CDA; FHIR; 13606; …) may affects the choices in the information layer because all of them rely on their own "reference" information models (the CDA model; the FHIR resources; and so on); they are not just a syntactical representation, like XML or a JSON representation. This explains why it is not always true that a logical model can be straightforwardly represented by a specific implementation.

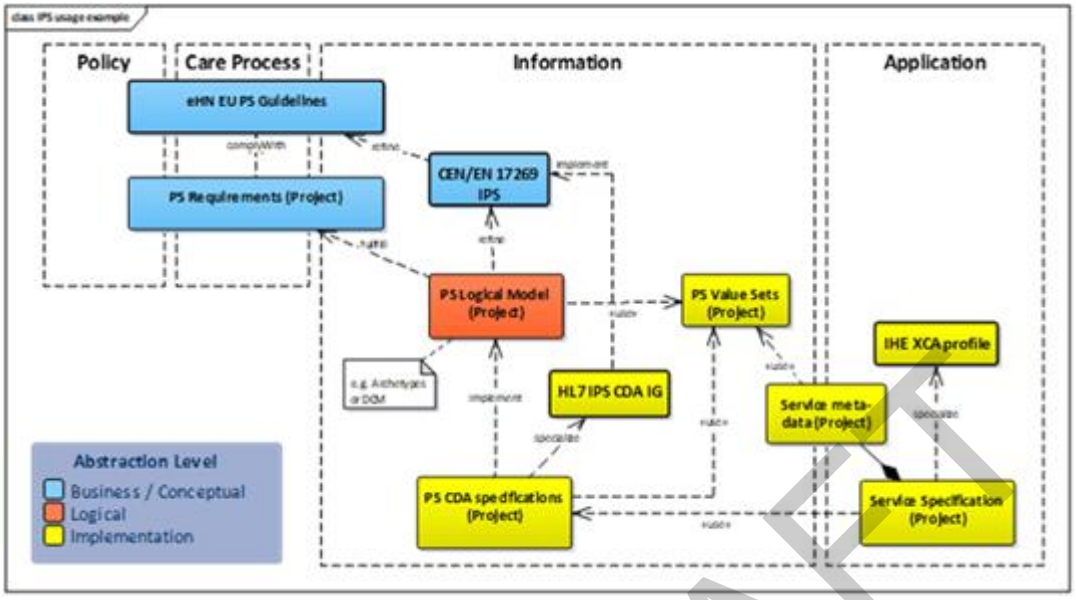
The application level includes the agreements made about the way import and export of [clinical] information is handled by the healthcare information systems. The technical specification of how information is transported is at this level (communication standards) … Another aspect in this layer is the integration and processing of exchanged information in user-friendly applications. As explained above, frameworks and models are simplifications of the world they attempt to represent. Consequently, interpretation plays a part in how the ReEIF categorizes but in the real-world artefacts may belong to more than one layer.

The following figures provides two possible examples of the process of model derivation, highlighting the different abstraction levels of the used artefacts; and the permeability among the different ReEIF layers.

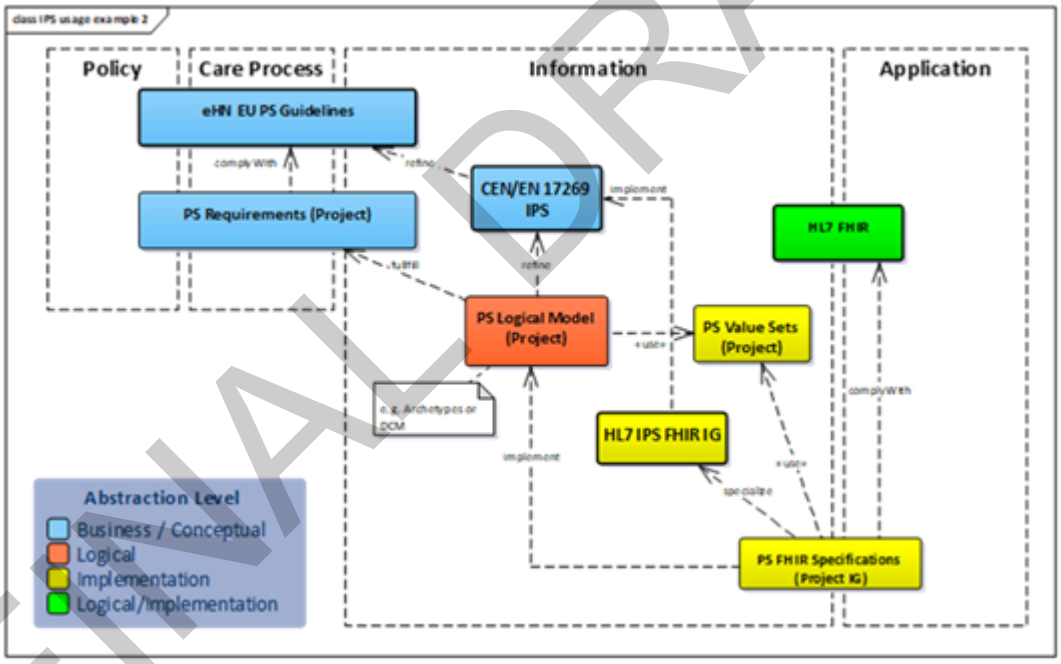
NOTE These are only two of the many possible examples; moreover, they do not pretend to show all the possible artifacts that may affect interoperability and all the existing relationships, for example the choice of the value set may depend on the standard used for the implementation.

As explained above the first picture shows the case of an IHE XCA based service that used HL7 CDAs for exchanging the Patient Summaries. In this scenario the eHN PS guideline is used as common reference, and additional requirements are then specified for the usage within a specific jurisdiction or for a specific deployment project.

All these requirements are then reflected into the model constraints specified by a Patient Summary logical model used in that context (it might be for example a DCM or an Archetype) that capture the eHN guideline information requirements through the prEN 17269 IPS dataset from which the model is derived from. The Patient Summary logical model is then realized by an implementable specification based on the HL7 CDA standard; specification that specializes the HL7 CDA IPS Implementation Guide. The service used in that context is then specified as specialization of the IHE XCA profile, referring to the PS CDA specification for the payload.



a)



b)

Figure 6 — Two examples of IPS interchange (e.g. CDA, FHIR)

The second picture shows the case of a FHIR REST based implementation. Preconditions and initial steps are identical to the first case, in this case the FHIR specification (e.g. a FHIR project specific Implementation guide) covers both the information and the application level; having the information component as implementation of the project specific Patient Summary logical model and as specialization of the HL7 IPS FHIR profiles.

13.2 European eHealth Digital Service Infrastructure (eHDSI)

eHDSI is the deployment and operational services for cross border exchanges of medical data under the Connecting Europe Facility (CEF). The goal is to deploy services for Patient Summary and ePrescription using the NCPeH (National Contact Point foe eHealth). An agreement was set up between national authorities or national organisations responsible for NCPeH on the criteria required for participating to the eHDSI. One of the requirements is to aim to be compliant with the Patient Summary guideline (directive 2011/24/EU), the starting point for prEN 17269.

The eHDSI developed specifications on use cases description and patient summary specifications. Each European country built their own Cross border infrastructure and test it within the eHDSI trust domain using the testing strategy which defines the different gates before a live operation.

14 Infrastructure Consideration

In the original ReEIF this consideration was termed 'IT Infrastructure'. This layer takes care of the infrastructure for the communication between systems in the different healthcare organisations but at a very generic level. At this level, agreements are laid down on the design of the infrastructures, databases, networks, exchange protocols, tokens and other technologies.

NOTE This clause has been included for completeness regarding the ReEIF description, but it is not in the scope of IPS and not in this document.

15 Standards, Profiles and Evaluation

15.1 General

This Clause describes, with some practical examples, how other standards may use the prEN 17269 IPS to specify technical specifications to achieve the technical and eventually the semantic interoperability for the IPS. For this scope all the current existing IPS-based standardization activities have been analysed:

- the HL7 CDA R2 International Patient Summary Implementation Guide standard [HL7 CDA IPS[10]]
- the HL7 FHIR International Patient Summary Implementation Guide standard [HL7 FHIR IPS[11]]

Other examples based on project specific activities are provided in the Projects clause 15.2.

In the following paragraphs it will be shown how the conditions specified by the Clause 5.2 of the EN 17269 are realized for the above-mentioned cases.

15.2 Standards/Profiles

15.2.1 Scope

This paragraph describes how the two existing IPS implementable standards, the HL7 CDA R2 and the HL7 FHIR International Patient Summary Implementation Guides, realizes the prEN 17269 IPS conformance rules.

The HL7 CDA IPS, the HL7 FHIR IPS and the prEN 17269 standards share the same scope.

Their relationships are explicitly stated in all of these standards.

[10] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=483
[11] http://hl7.org/fhir/uv/ips/index.html

15.2.2 Data patterns

The following table describes how the Patterns indicated in prEN 17269 are realized in the HL7 CDA IPS and in the HL7 FHIR IPS. In the first case the indicated data types refer to the HL7 V3 XML Implementation Technology Specification - Data Types Release 1.1; in the second case to the FHIR Data Types.

Table 3 — Patterns from prEN 17269 realised in CDA IPS and in HL7 FHIR IPS

prEN 17269	HL7 CDA IPS	HL7 FHIR IPS
Label Concept	Depends on the context, typically by a specific class (e.g. Participant, SubstanceAdministration)	Depends on the context, typically by a specific resource (e.g. Patient; MedicationStatement)
List	A list of entries is realized with a "to-many" cardinality (e.g. 0..*)	Even if FHIR specifies a List resource, a list of entries is realized with a "to-many" cardinality (e.g. 0..*)
Reference	Typically with a entryRelationship relation ship	Reference
Person Name	PN	HumanName
Coded Element	CD or CD derived data types	CodeableConcept or code
Date Time	TS	dateTime or Date
Identifier	II	Identifier
Address	AD	Address
Telecom	TEL	ContactPoint
Organization Name	ON	string
Text	ED (and its specializations) or ST	Narrative or string
Any	Depends on the context. It is formally mapped into the ANY data type but in the guide is typically constrained to a specific set of data types (e.g. PQ; CD).	Depends on the context. It is formally mapped into the Element data type but in the guide is typically constrained to a specific set of data types (e.g. Quantity; CodeableConcept).
Range	IVL_PQ	Range
Quantity	PQ	Quantity
Period	IVL_TS	Period
General Time Specification	Depends on the context. It is formally mapped into the GTS data type but in the guide is typically constrained to a specific set of time related data types.	Depends on the context.
Healthcare Provider	Depends on the context.	Depends on the context. Typically Practitioner; PractitionerRole or Organization resources

prEN 17269	HL7 CDA IPS	HL7 FHIR IPS
String	ST	String
Ratio	RTO	Ratio

15.2.3 Elements mapping

15.2.3.1 General

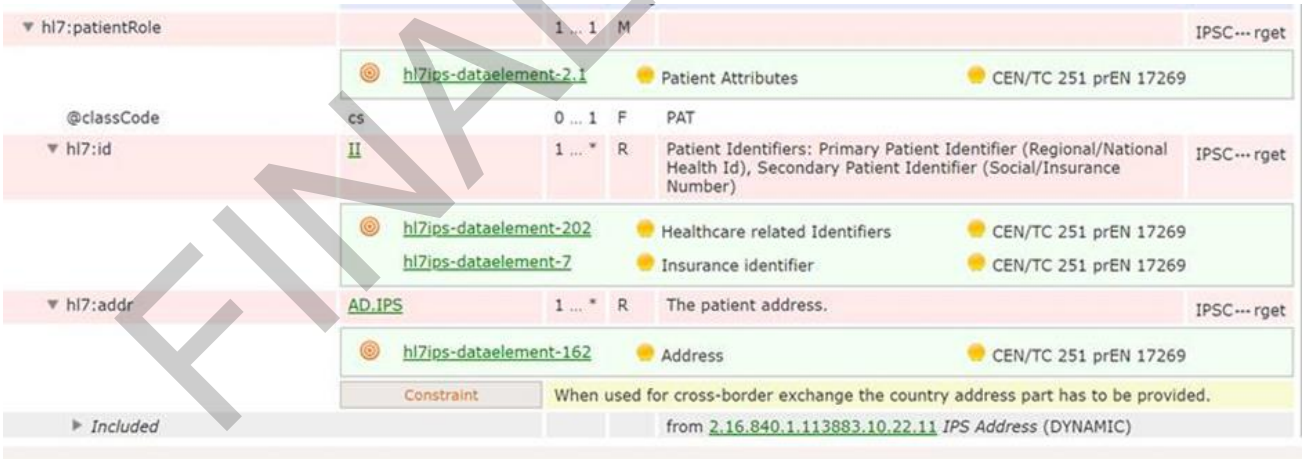
For each element specified in prEN 17269 a description of how the HL7 CDA IPS and the HL7 FHIR IPS realize that element is provided. That description includes the name of the root element or section, where applicable, and the cardinality in the correspondent representation (HL7 CDA or HL7 FHIR). The conformance strength (Mandatory, Optional, Conditional) is also provided for the HL7 CDA IPS and the mustSupport flag is indicated in the HL7 FHIR IPS, when is value is 'true'. Refer to the correspondent standards for the interpretation of these attributes[12].

The extensibility of the IPS model is realized in the HL7 CDA implementation specifying the IPS template as "open"; in the HL7 FHIR implementation, is supported by the FHIR extensibility mechanism and without constraining (e.g. flagging as not present) the elements that are not part of the prEN 17269 dataset. For more details on the profiling approach used to realize the prEN 17269 refer to the corresponding HL7 IPS implementation guides.

All the information and examples provided hereafter about the HL7 IPS reflect the current status of these standards. HL7 CDA and HL7 FHIR IPS implementation guides may be subject to changes in accordance with their maintenance process.

Updated forward and backward mappings between the prEN 17269 data set and the HL7 CDA IPS templates are available on-line in the ART DECOR® platform[13] . The HL7 CDA IPS standard makes in fact explicit how it realizes the prEN 17269 data set. An example is shown in Table 4[14].

Table 4 — HL7 CDA Standard realizes prEN 17269

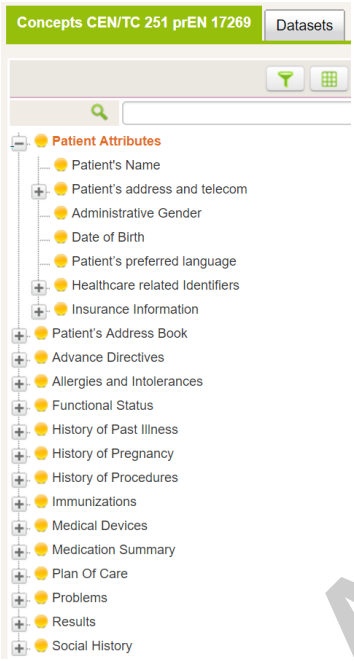


Hereafter, is an example of how the Patient Attributes are mapped into the HL7 CDA IPS.

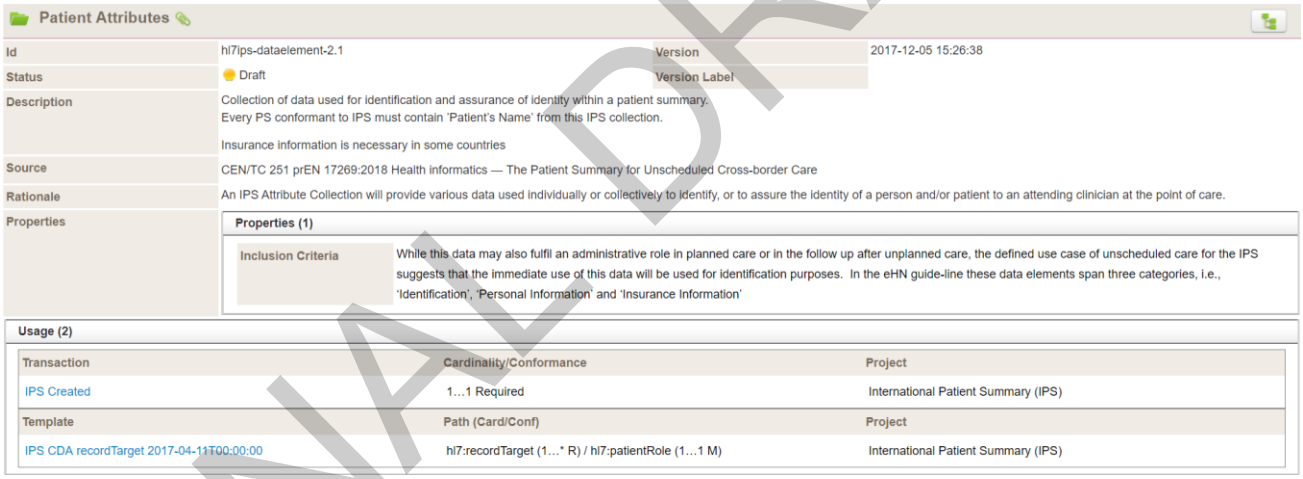
[12] The conformance strength for templates is described in "HL7 Templates Standard: Specification and Use of Reusable Information Constraint Templates, Release 1" (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=377); the mustSupport flag in http://hl7.org/fhir/conformance-rules.html#mustSupport

[13] http://art-decor.org/art-decor/decor-project--hl7ips-

[14] The examples shown can be accessed on-line from the following link https://art-decor.org/art-decor/decor-templates--hl7ips-?id=2.16.840.1.113883.10.22.2.1



a)



b)

Figure 7 — Examples of mappings between prEN 17269 dataset and the HL7 CDA IPS templates in ART DECOR®[15]

[15] The examples shown can be accessed on-line from the following link https://art-decor.org/art-decor/decor-datasets--hl7ips-?id=2.16.840.1.113883.3.1937.777.13.1.2.

15.2.3.2 Document, Sections and Attribute Collection

Table 5 — IPS Document and required data mapped to HL7 Implementations

prEN 17269			HL7 CDA IPS	HL7 FHIR IPS
IPS Document		M	ClinicalDocument {LOINC;'60591-5'}	Composition/Bundle {LOINC;'60591-5'}
	IPS Attribute Collection: Patient Attributes	M	see § 15.2.3.4 Patient Attributes for details	
	IPS Section: Allergies and Intolerances	M	IPS Allergies and Intolerances Section 1..1 R see § 15.2.3.5 Allergies and Intolerances for details	sectionAllergies (IPS Allergies and Intolerances Section) 1..1 see § 15.2.3.5 Allergies and Intolerances for details
	IPS Section: Medication Summary	M	IPS Medication Summary Section 1..1 R see § 15.2.3.6 Medication Summary for details	sectionMedications (IPS Medication Summary Section) 1..1 see § 15.2.3.6 Medication Summary for details
	IPS Section: Problems	M	IPS Problems Section 1..1 R see § 15.2.3.7 Problems for details	sectionProblems (IPS Problems Section) 1..1 see § 15.2.3.7 Problems for details
	IPS Attribute Collection: Provenance meta data Collection	M	See § 15.2.3.21 Provenance for details	
	IPS Attribute Collection: Cross border	C	See § 15.2.3.8 Cross- border for details	
	IPS Sections and IPS Attribute Collection, 'Patient's Address Book'	RK	See § 15.2.3.9 Patient's Address Book for details	
	IPS Sections that are optional	O	See § 15.2.3.3 IPS Not required sections for details	

15.2.3.2.1 Model extensions

Table 6 — IPS Document Model Extensions

	HL7 CDA IPS	HL7 FHIR IPS
IPS custodian	1..1 M	0..1 mustSupport
Translated section narrative	0..* O	Optionally part of the section narrative

15.2.3.3 IPS Not required sections

Table 7 — Remaining IPS Sections mapped to HL7 Implementations

prEN 17269			HL7 CDA IPS	HL7 FHIR IPS
	IPS Section: History of Procedures	RK	IPS History of Procedures Section 0..1 R	sectionProceduresHx (IPS History of Procedures Section) 0..1 mustSupport
	IPS Section: Immunizations	RK	IPS Immunizations Section 0..1 R	sectionImmunizations (IPS Immunizations Section = 0..1 mustSupport
	IPS Section: Medical Devices	RK	IPS Medical Devices Section 0..1 R	sectionMedicalDevices (IPS Medical Devices Section) 0..1 mustSupport
	IPS Section: Results	RK	IPS Results Section 0..1 R Note: only Diagnostic Results	sectionResults (IPS Results Section) 0..1 mustSupport Note: only Diagnostic Results sectionVitalSigns (IPS Vital Signs Section) 0..1
	IPS Section: Advance Directives	O	IPS Advance Directives Section 0..1 O	sectionAdvanceDirectives IPS Advance Directives Section 0..1
	IPS Section: Functional Status	O	IPS Functional Status Section 0..1 O	sectionFunctionalStatus (IPS Functional Status Section) 0..1
	IPS Section: History of Pregnancy	O	IPS History of Pregnancy Section 0..1 O	sectionPregnancyHx (IPS History of Pregnancy Section) 0..1
	IPS Section: History of Past Illness	O	IPS History of Past Illness Section 0..1 O	sectionPastIllnessHx (IPS History of Past Illness Section) 0..1

prEN 17269			HL7 CDA IPS	HL7 FHIR IPS
	IPS Section: Plan of Care	O	IPS Plan of Care Section 0..1 O	sectionPlanOfCare (IPS Plan of Care Section) 0..1
	IPS Section: Social History	O	IPS Social History Section 0..1 O	sectionSocialHistory (IPS Social History Section) 0..1

15.2.3.4 Patient Attributes

Table 8 — IPS Patient Attributes mapped to HL7 Implementations

prEN 17269			HL7 CDA IPS	HL7 FHIR IPS
IPS Attribute Collection Patient Attributes		M	PatientRole 1..1 M	Reference to the Patient Resource 1..1
	Patient's name	M	1..* M	0..* mustSupport
	Patient's address and telecom	RK		
	Address	C	1..* R	0..* mustSupport
	Telecoms	C	1..* R	0..* mustSupport
	Administrative gender	RK	1..1 R	1..1
	Date of Birth	R	1..1 R	1..1
	Patient's preferred language	O	0..*	0..*
	Healthcare related identifiers	RK		
	Patient identifier	RK	1..* R	0..* mustSupport
	Insurance information	O		
	Insurance identifier	RK	One of the possible patient identifiers	One of the possible patient identifiers

15.2.3.5 Allergies and Intolerances

Table 9 — IPS Allergies and Intolerance mapped to HL7 Implementations

prEN 17269		HL7 CDA IPS	HL7 FHIR IPS
IPS Section: ALLERGIES and INTOLERANCES	M	IPS Allergies and Intolerances Section 1..1 R	sectionAllergies (IPS Allergies and Intolerances Section) 1..1
Allergies/Intolerances content status	C	The known absence or the non-availability of information is explicitly coded in the allergy intolerance statement; in this case no other information is required by the model	
Allergies and Intolerances	C	At least one statement is present	
Allergy/Intolerance	M	1..* M	1..*
Allergy/Intolerance description	R	In the section text	In the section text
Clinical status	R	Status of the concern 1..1 R Clinical status of the observation0..1 R	1..1
Onset date	R	1..1 R	1..1
End date	C	0..1 C	0..1 mustSupport
Criticality	O	0..1 R	0..1 mustSupport
Certainty	O	0..1 R	0..1 mustSupport
Type of propensity	RK	1..1 M	0..1 mustSupport (the absence is interpreted as undetermined or unspecified allergy or intolerance)
Diagnosis	O	0..1	0..1
Reaction	RK	0..* R	0..* mustSupport
Manifestation of the reaction	RK	0..1 R	1..* mustSupport
Severity	RK	0..1 R	0..1 mustSupport
Agent	R	0..1 C	0..1 mustSupport
Agent code	R	1..1 R	1..1
Category	O	Not as distinct information; it might be covered using specialized concepts for the type of propensity (e.g. Drug Allergy)	0..*

15.2.3.5.1 Model extensions

Table 10 — IPS Allergies and Intolerances Model Extensions

	HL7 CDA IPS	HL7 FHIR IPS
Start date of the concern	1..1 R	Not explicitly specified
End date of the concern	0..1 C	Not explicitly specified
Start date of the Manifestation of the reaction	1..1 R	0..1
End date of the Manifestation of the reaction	0..1 C	Not explicitly specified

15.2.3.6 Medication Summary

Table 11 — IPS Medication Summary mapped to HL7 Implementations

prEN 17269		HL7 CDA IPS	HL7 FHIR IPS
IPS Section: MEDICATION SUMMARY	M	IPS Medication Summary Section 1..1 R	sectionMedications (IPS Medication Summary Section) 1..1
Medication summary content status	C	The known absence or the non-availability of information is explicitly coded in the Medication statement; in this case no other information is required by the model	
Medications	C	At least one statement is present	
Medication	M	1..* M (Medication Entry template)	1..* (MedicationStatement resource)
PS Section: MEDICATION SUMMARY **Medication**	M	1..* M (Medication Entry template)	1..* (MedicationStatement resource)
Reason	O	Not explicitly specified	0..*
Medicinal product	R	1..1 R ManufacturedProduct template	0..1 Medication resource required if there is content
Product code	O	0..1 R	0..* mustSupport
Product common name (and strength)	RK	0..1 R	0..1
Pharmaceutical dose form	R	0..1 R	0..* mustSupport
Brand name	O	0..1 R	0..1
Active ingredients	R		
Active ingredient	R	1..* R	0..* mustSupport

	Substance code	R	0..1 C (or the name or the code shall be provided)	0..* mustSupport (or the name or the code shall be provided)
	Strength	R	1..1 R	0..1 mustSupport
Administration Instruction		R		
	Instruction	O	Not explicitly specified	0..1
	Period of medication use	R	1..1 R	1..1
	Route of administration	O	0..1 R	0..* mustSupport
	Dose instruction	R	0..1 C required if there is content	0..* mustSupport
	No. of units per intake	R	1..1 R	0..1 mustSupport
	Frequency of intake	R	1..1 R	0..1 mustSupport

15.2.3.6.1 Model extensions

Table 12 — IPS Medication Summary Model Extensions

	HL7 CDA IPS	HL7 FHIR IPS
Status of the administration	1..1 M	1..1
Author of the assertion / Information source	0..*	Supported by the standard resource
Medicinal Product Identifier	0..1 R	0..1 mustSupport
Medicinal Product Name	0..1 R	0..1 mustSupport
Packaged Medicinal Product Identifier	0..1 R	0..1 mustSupport
Packaged Medicinal Product Name	0..1 R	0..1 mustSupport
Package structure (3 levels)	0..1	Not explicitly specified
WHO Anatomical Therapeutic Chemical (ATC) code	0..1 R	0..1 mustSupport
IDMP Pharmaceutical Product Identifier(s)	0..* R	0..1 mustSupport
IDMP Pharmaceutical Product name	0..* R	0..1 mustSupport
Rate quantity	0..1	Supported by the standard resource

15.2.3.7 Problems

Table 13 — IPS Problems mapped to HL7 Implementations

prEN 17269			HL7 CDA IPS	HL7 FHIR IPS
IPS Section: PROBLEMS		M	IPS Problems Section 1..1 R	sectionProblems (IPS Problems Section) 1..1
	Problem content status	C	The known absence or the non-availability of information is explicitly coded in the statement; in this case no other information is required by the model	
	Problems	C	At least one statement is present	
	Problem	M	1..* M (IPS Problem Concern Entry) Including, 1..* R (IPS Problem Entry)	1..* (Condition resource)
	Problem type	RK	1..1 R	0..1 mustSupport
	Problem description	R	Section text	Section and/or condition text
	Diagnosis	R	1..1 M	1..1
	Severity	RK	0..1 R	0..1 mustSupport
	Onset date	R	1..1 R	1..1
	Specialist contact	O	Not explicitly specified	Not explicitly specified

15.2.3.7.1 Model extensions

Table 14 — IPS Problems Model Extensions

	HL7 CDA IPS	HL7 FHIR IPS
Concern status	1..1 R	1..1
Observation start date	1..1 R	Supported by the standard resource
Observation end date	0..1 C	Supported by the standard resource
Abatement date	0..1 C Present because the same template is used for closed and open problems	0..1 0..1 because the same profile is used for closed and open problems
Clinical status	0..1 R	0..1 mustSupport
Verification status	0..1 R	0..1 mustSupport

15.2.3.8 Cross- border attribute Collection

Table 15 — IPS Attribute Collection Cross border mapped to HL7 Implementations

prEN 17269			HL7 CDA IPS	HL7 FHIR IPS
IPS Attribute Collection:: Cross Border		C		
	Country of affiliation	M	The Patient address is 1..* and the country is one of the conditional components of the address	The Patient address is 0..* mustSupport and the country is one of the mustSupport components of the address
	Country specific requirements	RK	It is a placeholder in prEN 17269; more specific instructions are needed to specify the mapping to the CDA model.	

15.2.3.9 Patient's Address Book

Table 16 — IPS Patient's Address Book mapped to HL7 Implementations

prEN 17269				HL7 CDA IPS	HL7 FHIR IPS
IPS Attribute Collection: Patient's Address Book			RK	0..* R (IPS Patient Contacts)	0..* mustSupport (Patient.contact) or 0..* (healthCareProviderParticipant)
	Preferred healthcare providers		RK	0..* R	0..*
		Healthcare provider (person)	C	0..1 C	0..1 (or practictionerRole or Organization or both)
		Name	R	1..* R	0..* mustSupport
		Telecoms	RK	1..* R	0..* mustSupport
		Healthcare provider (organisation)	C	0..1 C	0..1 (or practictionerRole or Organization or both)
		Organisation's name	R	1..* R	0..* mustSupport
		Telecoms	RK	1..* R	0..* mustSupport
	Other's address details		O	0..* R	0..* mustSupport
		Addressee	R	0..* R	0..* mustSupport
		Role	RK	0..1 R	0..* mustSupport
		Name	RK	1..* R	0..1 mustSupport
		Address	O	1..* R	0..* mustSupport
		Telecoms	RK	1..* R	0..* mustSupport

15.2.3.10 History of Procedures

Table 17 — IPS History of Procedures mapped to HL7 Implementations

prEN 17269			HL7 CDA IPS	HL7 FHIR IPS
IPS Section: HISTORY OF PROCEDURES		RK	IPS History of Procedures Section 0..1 R	sectionProceduresHx (IPS History of Procedures Section) 0..1 mustSupport
	Procedures content status	C	Explicit codes are used to express known absent or unknown situations. This code is provided in the main act/resource. In this case no other information is required by the model	
	Procedures	C	At least one statement is present	
	Procedure	R	1..* R	1..*
	Procedure code	R	1..1 R	1..1
	Procedure description	RK	Section text	Section and/or procedure text
	Body site	O	0..*	0..*
	Procedure date	R	1..1 R	1..1

15.2.3.10.1 Model extensions

Table 18 — IPS History of Procedures Model Extension

	HL7 CDA IPS	HL7 FHIR IPS
Procedure status	1..1 M	1..1
Target Site	0..*	0..1 mustSupport
Internal reference	0..*	Supported by the standard resource

15.2.3.11Immunizations

Table 19 — IPS Immunizations mapped to HL7 Implementations

prEN 17269		HL7 CDA IPS	HL7 FHIR IPS
IPS Section: IMMUNIZATIONS	RK	IPS Immunizations Section 0..1 R	sectionImmunizations (IPS Immunizations Section) 0..1 mustSupport
Immunizations content status	C	Explicit codes are used to express known absent or unknown situations. This code is provided in the main act/resource. In this case no other information is required by the model	
Immunizations	C	At least one statement is present	
Immunization	R	1..* R	1..*
Vaccine for type of disease	R	1..1 R	1...1
Target diseases	O		
Target disease	R	In this version supposed to be covered by the vaccine for type of disease.	0..*
Date of immunization	R	1..1 R	1..1
Product administered	O	Not explicitly specified	Not explicitly specified
Brand name	RK		
Product administration process	O	Not explicitly specified	
Performer	O		0..1 mustSupport
Route of administration	O		0..1

15.2.3.11.1 Model extensions

Table20 – IPS Immunizations Model Extensions

	HL7 CDA IPS	HL7 FHIR IPS
Entry author / Information source	0..* R	0..* mustSupport
Product Manufacturer	0..1 R	Supported by the standard resource
Lot number	0..1	x

	HL7 CDA IPS	HL7 FHIR IPS
Product code	0..*	0..* mustSupport
IDMP product identifiers	One of the possible product codes	0..* mustSupport

15.2.3.12 Medical Devices

Table 21 — IPS Medical Devices mapped to HL7 Implementations

prEN 17269				HL7 CDA IPS	HL7 FHIR IPS
IPS Section: MEDICAL DEVICES			RK	IPS Medical Devices Section 0..1 R	sectionMedicalDevices (IPS Medical Devices Section) 0..1 mustSupport
	Device content status		C	Explicit codes are used to express known absent or unknown situations. This code is provided in the main act/resource. In this case no other information is required by the model	
	Devices		C	At least one statement is present	
		Device	R	1..* R	1..*
		Device Type	R	1..1 R	1..1
		Device Identifier	RK	0..* R support to device serial numbers; UDI and other identifiers.	0..1 Serial Number 0..1 UDI
		Use start date	R	1..1 R	1..1
		Use end date	O	1..1 C	0..1

15.2.3.13 Model extensions

Table 21 — IPS Medical Devices Model Extensions

	HL7 CDA IPS	HL7 FHIR IPS
Device use status	No extensions	1..1
Body site		0..1 mustSupport

15.2.3.14 Results

Table 22 — IPS Results mapped to HL7 Implementations

prEN 17269		HL7 CDA IPS	HL7 FHIR IPS
IPS Section: RESULTS	RK	IPS Results Section 0..1 R Note: only Diagnostic Results	sectionResults (IPS Results Section) 0..1 mustSupport Note: only Diagnostic Results sectionVitalSigns (IPS Vital Signs Section) 0..1

prEN 17269			HL7 CDA IPS	HL7 FHIR IPS
Observation results		C	No entries if no diagnostic results are available or of interest.	No entries if no diagnostic results or vital signs observations are available or of interest.
	Observation result	R	1..* R	0..* mustSupport
			Four types of results are explicitly profiled: laboratory; imaging; pathology; generic (other) results	
	Date of observation	R	1..1 R	1..1 for Laboratory, Pathology and Vital Signs 0..1 mustSupport for all the others
	Observation type	R	1..1 M	1..1
	Result description	R	Section text	Section and/or observation text
	Value	C	1..1 R	0..1 Values are expected either in the parent or in the member observations or in both.
	Observation result	C	Observation results belonging to the same test procedure/panel can be grouped into the same organizer	Observation results belonging to the same test procedure/panel can be grouped into the same parent observation resource
	Performer	RK	Organizer 0..* R	0..1 mustSupport or 1..1 depending on the type of result
	Observer	RK	0..* R May be at the organizer or observation level	0..1 mustSupport or 1..1 depending on the type of result

15.2.3.14.1 Model extensions

Table 23 — IPS Results Model Extensions

	HL7 CDA IPS	HL7 FHIR IPS
Interpretation code	0..1 R (depends on the type of result)	Supported by the standard resource
Target Site	0..1	Not explicitly specified
Reference Range	0..* R	Supported by the standard resource
Result comment	0..*	Supported by the standard resource

	HL7 CDA IPS	HL7 FHIR IPS
Specimen Collection data	0..*	Supported by the standard resource

15.2.3.15Advance Directives

Table 24 — IPS Advance Directives mapped to HL7 Implementations

prEN 17269		HL7 CDA IPS	HL7 FHIR IPS
IPS Section: ADVANCE DIRECTIVES	O	IPS Advance Directives Section 0..1 O	sectionAdvanceDirectives IPS Advance Directives Section
		Only Narrative, structured entries not specified (but allowed)	
Advance directives	R		
Advance directive	R	As part of the section text	
Person authorising directive	RK	0..* R (as section author)	Not explicitly specified Reference to a generic Consent Resource
Name	RK	0..* R	
Telecoms	RK	0..* R	
Directive category	O	Not explicitly specified	Not explicitly specified Reference to a generic Consent Resource
Directive description	C	section text	section text
Reference to Legal Document	C	Not explicitly specified	Not explicitly specified Reference to a generic Consent Resource

15.2.3.16 Functional Status

Table 25 — IPS Functional Status mapped to HL7 Implementations

prEN 17269		HL7 CDA IPS	HL7 FHIR IPS
IPS Section: FUNCTIONAL STATUS	O	IPS Functional Status Section 0..1 O	sectionFunctionalStatus (IPS Functional Status Section) 0..1
		Only Narrative , structured entries not specified (but allowed)	
Disabilities	C		
Disability	R	As part of the section text	
Disability description	R	section text	section text
Disability code	O	Not explicitly specified	Not explicitly specified
Onset date	O		Reference to a generic Condition resource
Functional assessments	C		
Functional assessment description	O	As part of the section text	
Description	R	section text	section text
Date of assessment	RK	Not explicitly specified	Not explicitly specified Reference to a generic ClinicalImpression resource
Type	RK		
Result	C		
Functional Assessment	C		

15.2.3.17 History of Pregnancy

Table 26 — IPS History of Pregnancy mapped to HL7 Implementations

prEN 17269		HL7 CDA IPS	HL7 FHIR IPS
IPS Section: HISTORY OF PREGNANCY	O	IPS History of Pregnancy Section 0..1 O	sectionPregnancyHx (IPS History of Pregnancy Section) 0..1
Current pregnancy status	R	1..1 R	1..1
Pregnancy description	C	section text	section text
Pregnancy details	C	1..1 R	0..*
Date of observation	R	0..1 R	1..1
Pregnancy state	R	1..1 R	0..1 mustSupport
Expected delivery date	RK	0..1 R	0..1 mustSupport
Specialist contact	O	Not explicitly specified	Not explicitly specified

prEN 17269		HL7 CDA IPS	HL7 FHIR IPS
Previous history of Pregnancies	O	0..* R	0..*
Previous pregnancies status	C	Not explicitly specified	Not explicitly specified
Previous pregnancies description	C	section text	section text
Previous pregnancies	C	Not explicitly specified	Not explicitly specified
Previous pregnancy details	R		
Outcome date	RK		
Outcome	R		
Specialist contact	O		
Summary metric	C	0..* R	0..*

15.2.3.18 History of Past Illness

Table 27 — IPS History of Past Illness mapped to HL7 Implementations

prEN 17269		HL7 CDA IPS	HL7 FHIR IPS
IPS Section: HISTORY OF PAST ILLNESS	O	IPS History of Past Illness Section 0..1 O	sectionPastIllnessHx (IPS History of Past Illness Section) 0..1
Past health conditions and problems	R	If the section is present at least one entry shall be present. This may be used to document that no information, or not of interest, about past Illnesses are available.	If the section is present at least one entry shall be present. .
Health condition / Problem	R	1..* R (IPS Problem Concern Entry) Including, 1..* R (IPS Problem Entry)	1..* (Condition resource)
Problem Type	RK	1..1 R	0..1 mustSupport
Description	R	Section text	Section and/or condition text
Diagnosis	R	1..1 M	1..1
Severity	O	0..1 R	0..* mustSupport
Onset date	R	1..1 R	1..1
Resolution	O	Not explicitly specified	Not explicitly specified

prEN 17269			HL7 CDA IPS	HL7 FHIR IPS
	Date resolved	R	0..1 C	0..1 The same profile is used for open and closed problems, the cardinality is 0..1 to serve both; but it is expected to be valued when used for closed problems
	Specialist contact	O	Not explicitly specified	

15.2.3.18.1 Model extensions

Table 28 — IPS History of Past Illness Model Extensions

	HL7 CDA IPS	HL7 FHIR IPS
Concern status	1..1 R	1..1
Observation start date	1..1 R	Supported by the standard resource
Observation end date	0..1 C	Supported by the standard resource
Abatement date	0..1 C Conditional because the same template is used for closed and open problems	0..1 0..1 because the same profile is used for closed and open problems
Clinical status	0..1 R	0..1 mustSupport
Verification status	0..1 R	0..1 mustSupport

15.2.3.19Plan of Care

Table 29 — IPS Plan of Care mapped to HL7 Implementations

prEN 17269		HL7 CDA IPS	HL7 FHIR IPS
IPS Section: PLAN OF CARE	O	IPS Plan of Care Section 0..1 O	sectionPlanOfCare (IPS Plan of Care Section) 0..1
Plans	R	If the section is present textual information about the plan(s) is required	If the section is present textual information about the plan(s) is required
Plan	R		
Plan type	O	Not explicitly specified	Not explicitly specified
Plan date	RK		

prEN 17269			HL7 CDA IPS	HL7 FHIR IPS
Plan description		C	section text	section text
Recommendations (Core Care Plan)		C	Not explicitly specified	Not explicitly specified
	Recommendation	R		
	Recommendation for treatment	R	Not explicitly specified	Not explicitly specified
	Given recommendation date	RK		
	Applicable date	RK		
Extensive Plan		C	Not explicitly specified	Not explicitly specified

15.2.3.20Social History

Table 30 — IPS Social History mapped to HL7 Implementations

prEN 17269			HL7 CDA IPS	HL7 FHIR IPS
IPS Section: SOCIAL HISTORY		O	IPS Social History Section 0..1 O	sectionSocialHistory (IPS Social History Section) 0..1
			Structured entries defined only for tobacco and alcohol use	
Life style factors		R	Required as narrative; optional as structured entry	
	Life style factor	R	Required as narrative; optional as structured entry	
	Life style factor description	R	section text	section text
	Life style factor details	O	1..1 R when structured entry	0..* mustSupport when structured entry
	Reference date range	RK	1..1 R when structured entry	0..1 mustSupport when structured entry

15.2.3.21Provenance

Table 31 — IPS Provenance mapped to HL7 Implementations

prEN 17269		HL7 CDA IPS	HL7 FHIR IPS
Asserter (source of information)	RK	0..* at the section level Not specified but possible at the entry level	At the resource level depending on the resource
Date of IPS Document creation	M	1..1 M	1..1
Language of document	O	1..1 M	0..1
Date of last update of IPS content	R	1..1 R (as end date of the service event)	0..1 mustSupport (as end date of the service event)

prEN 17269		HL7 CDA IPS	HL7 FHIR IPS
Generation of IPS content	R		
Nature of the IPS	R	Derived from authors and authenticators information	May be derived from authors and authenticators information and / or from standard Provenance resources
Healthcare providers	R		
Authoring healthcare provider	R	1...* M	1..*
Legitimacy	RK		
Legal authenticator	RK	0..1 R	0..* mustSupport

15.2.3.21.1 Model extensions

Table 32 — IPS Provenance Model Extensions

	HL7 CDA IPS	HL7 FHIR IPS
IPS author	1..* M	1..*
IPS Autenticator	0..* O	0..* mustSupport
Section author	0..* O	Not explicitly specified
Section informant	0..* O	Not explicitly specified

15.3 Projects

15.3.1 General

Research and deployment projects specifications could also claim compliance with the prEN 17269 IPS dataset if they fulfil prEN 17269 IPS conformance rules. For exemplification purposes two cases are summarized hereafter: the eHDSI specification[16], profiling the HL7 CDA R2 standard and based on the epSOS Patient Summary specification; and the European project Trillium II using the HL7 FHIR standard.

15.3.2 eHDSI

The scope of the eHDSI Patient Summary (eHDSI PS) is based on the European Guideline for the Patient Summary; it therefore coincides with that of the prEN 17269 IPS.

Technically the eHDSI templates are open, even if the eHDSI PS is conceptually closed, that is no additional information respect to that specified are expected to be provided.

The eHDSi data patterns are the same specified in the column “HL7 CDA IPS” in section 15.2.2 “Data patterns”.

eHDSI has extended the number of required sections adding to the three required by prEN 17269 IPS the History of Procedure (surgical procedures in the last six months); the Immunizations and the Medical Devices sections.

The result section is in the case of eHDSI truly optional and limited to the Blood Group information.

[16] See https://art-decor.ehdsi.eu/art-decor/decor-project--epsos-

All the optional IPS sections, with the exception of the Advance Directive, have been included in the eHDSI PS.

Some improvements in the realization of the prEN 17269 “content status” mechanism for known absent or non-available information, in term of harmonization of and extension of the cases covered.

15.3.3 Trillium II

The scope of Trillium II is to evaluate how the IPS could be extended to additional use cases, in this context it extends the original scope of the IPS beyond the (cross border) unscheduled care case. It aims also to investigate the possible usage of the IPS components, as a library of reusable fragments, beyond the document interoperability paradigm and for building a cross border encounter report.

The Trillium II data patterns are the same specified in the column “HL7 FHIR IPS” in section 15.2.2 “Data patterns”.

Trillium II has adopted the same sections structure and cardinality in the prEN 17269 IPS. Based on the feedbacks collected during its assessments with stakeholder, it has specified and it is evaluating some additional non-IPS section as the encounters history; the family history; the risks section.

The Trillium II profiles have been used as input for the specification of the HL7 FHIR IPS Guide, and it is envisioned that the final Trillium II specifications will be defined as extensions of the HL7 IPS profiles.

Generally speaking the Trillium II profiles specifies additional information not currently part of the HL7 IPS profile as external references to reports or evidences; details about vaccinations; and so on.

15.4 Exchange Format Examples

15.4.1 IPS CDA example

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:pharm="urn:hl7-org:pharm" xmlns="urn:hl7-org:v3" >
 <realmCode code="EU"/>
 <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
 <templateId root="2.16.840.1.113883.10.22.1.1"/>
 <id root="2.16.840.1.113883.19.999.1" extension="175bd032-8b00-4728-b2dc-
748bb1501aed"/>
 <code code="60591-5" codeSystem="2.16.840.1.113883.6.1" displayName="Patient
Summary"/>
 <title>Minimal Patient Summary Example</title>
 <effectiveTime value="201805150214+0100"/>
 <confidentialityCode code="N" displayName="normal"
codeSystem="2.16.840.1.113883.5.25"/>
 <languageCode code="en-GB"/>
 <setId root="2.16.840.1.113883.19.999.1" extension="3f69e0a5-2177-4540-baab-
7a5d0877428f"/>
 <versionNumber value="2"/>
 <recordTarget typeCode="RCT" contextControlCode="OP">
 <patientRole classCode="PAT">
 <id root="2.16.840.1.113883.19.999.2" extension="pat_id_example"/>
 <addr>
 <streetAddressLine>Some Street, 1</streetAddressLine>
 <city>SomeCity</city><country>SomeCountryCode</country>
 </addr>
 <telecom use="HP" value="tel:+31788700800"/>
 <patient>
 <name> <given>PatNameExample</given> <family>PatSurnameExample</family></name>
 <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1"
displayName="Female"/>
 <birthTime value="19500115"/>
 </patient>
```

```
 </patientRole>
 </recordTarget>
 <author>
 <time value="20170720214300+0100"/>
 <assignedAuthor>
 <id extension="129854633" root="2.16.528.1.1007.3.1"
assigningAuthorityName="CIBG"/>
 <code code="2211" codeSystem="2.16.840.1.113883.2.9.6.2.7"
displayName="Generalist medical practitioners" codeSystemName="ISCO"><translation
code="01.015" codeSystem="2.16.840.1.113883.2.4.15.111" displayName="Huisarts"
codeSystemName="RoleCodeNL"/> </code>
 <addr use="WP"> <!— OMISSIS --> </addr><telecom use="WP" value="tel:+31-51-
34343434"/>
 <assignedPerson><name><given>Beetje</given>
<family>Hulp</family></name></assignedPerson>
 </assignedAuthor>
 </author>
 <custodian typeCode="CST">
 <assignedCustodian classCode="ASSIGNED">
 <representedCustodianOrganization classCode="ORG" determinerCode="INSTANCE">
 <id root="2.16.528.1.1007.3.3" extension="564738757"/>
 <name>The best custodian ever</name>
 <telecom use="WP" value="tel:+31-51-34343400"/><addr use="WP"> <!— OMISSIS --
></addr>
 </representedCustodianOrganization>
 </assignedCustodian>
 </custodian>
 <documentationOf typeCode="DOC">
 <serviceEvent classCode="PCPR" moodCode="EVN"><effectiveTime><low
nullFlavor="UNK"/> <high
value="20170720214300+0100"/></effectiveTime></serviceEvent>
 </documentationOf>
 <component>
 <structuredBody classCode="DOCBODY">
 <component>
 <section classCode="DOCSECT">
 <templateId root="2.16.840.1.113883.10.22.3.3"/>
 <id root="1.2.3.999" extension="759d86e8-026e-4f6a-952a-5e28a8d3a554"/>
 <code code="11450-4" codeSystem="2.16.840.1.113883.6.1" displayName="Problem
list"/>
 <title>Active Problems</title>
 <text> <content ID="prob-1">Hot flushes</content></text>
 <entry typeCode="COMP" contextConductionInd="true">
 <act classCode="ACT" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.22.4.7"/>
 <id root="1.2.3.999" extension="c87bf51c-e53c-4bfe-b8b7-aa62bdd93002"/>
 <code code="CONC" codeSystem="2.16.840.1.113883.5.6"/>
 <statusCode code="active"/>
 <effectiveTime> <low value="201610"/> </effectiveTime>
 <entryRelationship typeCode="SUBJ" inversionInd="false">
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.22.4.8"/>
 <id root="1.2.3.999" extension="7b63382d-5f10-4c8c-a94c-65b99579b601"/>
 <code code="75326-9" codeSystem="2.16.840.1.113883.6.1" displayName="Problem"/>
 <statusCode code="completed"/>
 <effectiveTime> <low value="201610"/> </effectiveTime>
 <value xsi:type="CD" code="198436008" displayName="Menopausal flushing
(finding)" codeSystem="2.16.840.1.113883.6.96"><translation code="N95.1"
codeSystem="2.16.840.1.113883.6.3" displayName="Menopausal and female climacteric
states"/></value>
```

```
 </observation>
 </entryRelationship>
 </act>
 </entry>
 </section>
 </component>
 <component>
 <section classCode="DOCSECT">
 <templateId root="2.16.840.1.113883.10.22.3.1"/>
 <id root="1.2.3.999" extension="11ef34d3-0077-4a15-84cc-19adb11ba2f1"/>
 <code code="10160-0" codeSystem="2.16.840.1.113883.6.1" displayName="Medication
use"/>
 <title>Medication</title>
 <text> <table> <thead><tr><th>Medication</th><th>Strength</th><th>Form</th>
<th>Dosage</th><th>Comment</th></tr></thead> <tbody> <tr ID="med-1">
<td>Anastrozole</td><td>1 mg</td> <td>tablet</td><td>once daily</td><td>treatment
for breast cancer</td> </tr> </tbody> </table> </text>
 <entry typeCode="COMP" contextConductionInd="true">
 <substanceAdministration classCode="SBADM" moodCode="EVN">
 <!-- IPS Medication Statement -->
 <templateId root="2.16.840.1.113883.10.22.4.4"/>
 <id root="1.2.3.999" extension="b75f92cb-61d4-469a-9387-df5ef70d25f0"/>
 <code code="DRUG" displayName="Drug therapy"
codeSystem="2.16.840.1.113883.5.4"/>
 <text> <reference value="#med-1"/></text>
 <statusCode code="completed"/>
 <effectiveTime xsi:type="IVL_TS"><low value="201503"/></effectiveTime>
 <routeCode code="20053000" codeSystem="0.4.0.127.0.16.1.1.2.1" displayName="Oral
use" codeSystemName="EDQM"/>
 <consumable typeCode="CSM">
 <manufacturedProduct classCode="MANU">
 <templateId root="2.16.840.1.113883.10.22.4.2"/>
 <manufacturedMaterial classCode="MMAT" determinerCode="KIND">
 <templateId root="2.16.840.1.113883.10.22.4.3"/>
 <code code="108774000" codeSystem="2.16.840.1.113883.6.96"
displayName="Anastrozole (product)"><translation code="99872"
codeSystem="2.16.840.1.113883.2.4.4.1" displayName="ANASTROZOL 1MG TABLET"
codeSystemName="GPK"/> </code>
 <pharm:formCode code="10219000" codeSystem="0.4.0.127.0.16.1.1.2.1"
displayName="Tablet"/>
 <pharm:ingredient classCode="ACTI" determinerCode="KIND">
 <pharm:quantity> <pharm:numerator value="1" unit="mg"/> <pharm:denominator
value="1" unit="{tablet}"/> </pharm:quantity>
 <pharm:ingredientSubstance><pharm:code code="386910003"
codeSystem="2.16.840.1.113883.6.96" displayName="Anastrozole (substance)"/>
</pharm:ingredientSubstance>
 </pharm:ingredient>
 </manufacturedMaterial>
 </manufacturedProduct>
 </consumable>
 <entryRelationship typeCode="COMP">
 <sequenceNumber value="1"/>
 <substanceAdministration classCode="SBADM" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.22.4.33"/>
 <statusCode code="completed"/>
 <effectiveTime xsi:type="PIVL_TS" institutionSpecified="true"><period value="1"
unit="d"/> </effectiveTime>
 <doseQuantity><low value="1" unit="{tablet}"/></doseQuantity>
 <consumable><manufacturedProduct> <manufacturedMaterial nullFlavor="NA"/>
</manufacturedProduct></consumable>
```

```
 </substanceAdministration>
 </entryRelationship>
 </substanceAdministration>
 </entry>
 </section>
 </component>
 <component>
 <section classCode="DOCSECT">
 <templateId root="2.16.840.1.113883.10.22.3.2"/>
 <id root="1.2.3.999" extension="d3760a22-fd4f-400c-b35c-5f6301cb3bd9"/>
 <code code="48765-2" codeSystem="2.16.840.1.113883.6.1" displayName="Allergies
&amp;or adverse reactions"/>
 <title>Allergies and Intolerances</title>
 <text><content ID="ai1">Penicillin, high criticality, active</content></text>
 <entry typeCode="COMP" contextConductionInd="true">
 <act classCode="ACT" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.22.4.5"/>
 <id root="1.2.3.999" extension="3a462598-009c-484a-965c-d6b24a821424"/>
 <code code="CONC" codeSystem="2.16.840.1.113883.5.6"/>
 <statusCode code="active"/>
 <effectiveTime><low value="2010"/></effectiveTime>
 <entryRelationship typeCode="SUBJ" inversionInd="false">
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.22.4.1"/>
 <id root="1.2.3.999" extension="6273319e-b6f4-46f4-a4f1-72f3a8db673a"/>
 <code code="allergy" displayName="Allergy"
codeSystem="2.16.840.1.113883.4.642.1.122"/>
 <text><reference value="#ai1"/></text>
 <statusCode code="completed"/>
 <effectiveTime><low value="2010"/></effectiveTime>
 <participant typeCode="CSM"> <participantRole classCode="MANU"> <playingEntity
classCode="MMAT"> <code code="373270004" codeSystem="2.16.840.1.113883.6.96"
displayName="Penicillin"/> </playingEntity> </participantRole> </participant>
 </observation>
 </entryRelationship>
 </act>
 </entry>
 </section>
 </component>
 </structuredBody>
 </component>
</ClinicalDocument>
```

15.4.2 IPS FHIR example

This is an example of HL7 FHIR IPS. The most updated sample(s) of HL7 FHIR IPS can be found in https://build.fhir.org/ig/HL7/fhir-ips/examples.html.

```
<Bundle xmlns="http://hl7.org/fhir" xmlns:xhtml="http://www.w3.org/1999/xhtml"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
 <id value="IPS-examples-Bundle-01"/> <language value="en-GB"/>
 <identifier><system value="urn:oid:2.16.724.4.8.10.200.10"/><value
value="175bd032-8b00-4728-b2dc-748bb1501aed"/></identifier>
 <type value="document"/>
 <entry><fullUrl value="http://hapi.fhir.org/baseR4/Composition/IPS-examples-
Composition-01"/>
   <resource>
    <Composition> <id value="IPS-examples-Composition-01"/>
```

```
      <meta> <profile
value="http://hl7.org/fhir/uv/ips/StructureDefinition/Composition-uv-ips"/> </meta>
      <identifier><system value="urn:oid:2.16.724.4.8.10.200.10"/><value
value="3f69e0a5-2177-4540-baab-7a5d0877428f"/></identifier>
      <status value="final"/>
      <type> <coding><system value="http://loinc.org"/> <code value="60591-
5"/><display value="Patient summary Document"/></coding> </type>
      <subject><reference value="Patient/IPS-examples-Patient-01"/></subject>
      <date value="2017-07-20T14:30:00+01:00"/>
      <author><reference value="Practitioner/IPS-examples-Practitioner-
01"/></author>
      <title value="Patient Summary as of July 20, 2017 14:30"/>
      <confidentiality value="N"/>
      <attester><mode value="legal"/><time value="2017-07-20T14:30:00+01:00"/>
<party> <reference value="Practitioner/IPS-examples-Practitioner-01"/> </party>
</attester>
      <custodian> <reference value="Organization/IPS-examples-Organization-
01"/></custodian>
      <event> <code> <coding> <system
value="http://terminology.hl7.org/CodeSystem/v3-ActClass"/> <code value="PCPR"/>
</coding> </code>
       <period><end value="2017-07-20T14:30:00+01:00"/>    </period>
      </event>
      <section>
       <title value="Active Problems"/> <code><coding><system
value="http://loinc.org"/>    <code value="11450-4"/><display value="Problem list
Reported"/></coding></code>
       <text><status value="generated"/><xhtml:div>Hot flushes</xhtml:div></text>
       <entry> <reference value="Condition/IPS-examples-Condition-01"/> </entry>
      </section>
      <section>
       <title value="Medication"/> <code>  <coding> <system
value="http://loinc.org"/> <code value="10160-0"/> <display value="History of
Medication use Narrative"/> </coding> </code>
       <text>
        <status value="generated"/>
        <xhtml:div>
          <xhtml:table><xhtml:thead><xhtml:tr> <xhtml:th>Medication</xhtml:th>
<xhtml:th>Strength</xhtml:th> <xhtml:th>Form</xhtml:th>
<xhtml:th>Dosage</xhtml:th> <xhtml:th>Comment</xhtml:th> </xhtml:tr>
</xhtml:thead>
           <xhtml:tbody>
            <xhtml:tr><xhtml:td>Anastrozole</xhtml:td><xhtml:td>1
mg</xhtml:td><xhtml:td>tablet</xhtml:td><xhtml:td>once
daily</xhtml:td><xhtml:td>treatment for breast cancer</xhtml:td></xhtml:tr>
           </xhtml:tbody>
          </xhtml:table>
        </xhtml:div>
       </text>
       <entry><reference value="MedicationStatement/IPS-examples-
MedicationStatement-01"/></entry>
      </section>
      <section>
       <title value="Allergies and Intolerances"/> <code> <coding> <system
value="http://loinc.org"/> <code value="48765-2"/> <display value="Allergies and
adverse reactions Document"/> </coding> </code>
       <text><status value="generated"/><xhtml:div>Allergy to penicillin, high
criticality, active</xhtml:div></text>
       <entry><reference value="AllergyIntolerance/IPS-examples-
AllergyIntolerance-01"/></entry>
```

```
      </section>
    </Composition>
  </resource>
 </entry>
 <entry><fullUrl value="http://hapi.fhir.org/baseR4/Patient/IPS-examples-Patient-
01"/><resource>
    <Patient> <id value="IPS-examples-Patient-01"/>
      <meta> <profile
value="http://hl7.org/fhir/uv/ips/StructureDefinition/Patient-uv-ips"/> </meta>
      <identifier> <system value="urn:oid:2.16.840.1.113883.2.4.6.3"/> <value
value="574687583"/> </identifier>
      <active value="true"/>
      <name> <family value="DeLarosa"/> <given value="Martha"/></name>
      <telecom> <system value="phone"/> <value value="+31788700800"/> <use
value="home"/> </telecom>
      <gender value="female"/>
      <birthDate value="1972-05-01"/>
      <address>
       <line value="Laan Van Europa 1600"/> <city value="Dordrecht"/> <postalCode
value="3317 DB"/> <country value="Netherlands"/>
      </address>
      <contact>
       <relationship> <coding> <system
value="http://terminology.hl7.org/CodeSystem/v3-RoleCode"/><code value="MTH"/>
</coding> </relationship>
       <name> <family value="Mum"/> <given value="Martha"/> </name>
       <telecom> <system value="phone"/> <value value="+33-555-20036"/> <use
value="home"/> </telecom>
       <address>
        <line value="Promenade des Anglais 111"/> <city value="Lyon"/>
<postalCode value="69001"/> <country value="France"/>
       </address>
      </contact>
    </Patient>
  </resource>
 </entry>
  <entry> <fullUrl value="http://hapi.fhir.org/baseR4/Practitioner/IPS-examples-
Practitioner-01"/>
  <resource>
   <Practitioner>
     <id value="IPS-examples-Practitioner-01"/>
     <identifier> <system value="urn:oid:2.16.528.1.1007.3.1"/> <value
value="129854633"/> <assigner> <display value="CIBG"/> </assigner> </identifier>
     <active value="true"/>
     <name> <family value="van Hulp"/> <given value="Beetje"/> </name>
     <qualification> <code> <coding> <system
value="urn:oid:2.16.840.1.113883.2.9.6.2.7"/> <code value="2211"/> <display
value="Generalist medical practitioners"/> </coding>
        <coding> <system value="urn:oid:2.16.840.1.113883.2.4.15.111"/> <code
value="01.015"/> <display value="Huisarts"/> </coding> </code>
     </qualification>
   </Practitioner>
  </resource>
 </entry>
  <entry>
  <fullUrl value="http://hapi.fhir.org/baseR4/Organization/IPS-examples-
Organization-01"/>
  <resource>
   <Organization>
     <id value="IPS-examples-Organization-01"/>
```

```
      <identifier> <system value="urn:oid:2.16.528.1.1007.3.3"/> <value
value="564738757"/> </identifier>
      <active value="true"/>
      <name value="Anorg Aniza Tion BV / The best custodian ever"/>
      <telecom> <system value="phone"/> <value value="+31-51-34343400"/> <use
value="work"/> </telecom>
      <address> <use value="work"/> <line value="Houttuinen 27"/> <city
value="Dordrecht"/> <postalCode value="3311 CE"/> <country value="Netherlands"/>
</address>
    </Organization>
  </resource>
 </entry>
  <entry>
  <fullUrl value="http://hapi.fhir.org/baseR4/Condition/IPS-examples-Condition-
01"/>
  <resource>
   <Condition><id value="IPS-examples-Condition-01"/>
      <meta> <profile
value="http://hl7.org/fhir/uv/ips/StructureDefinition/Condition-uv-ips"/> </meta>
      <identifier> <system value="urn:oid:1.2.3.999"/> <value value="c87bf51c-
e53c-4bfe-b8b7-aa62bdd93002"/> </identifier>
      <clinicalStatus> <coding> <system
value="http://terminology.hl7.org/CodeSystem/condition-clinical"/> <code
value="active"/> </coding>
      </clinicalStatus>
      <verificationStatus> <coding> <system
value="http://terminology.hl7.org/CodeSystem/condition-ver-status"/> <code
value="confirmed"/> </coding> </verificationStatus>
      <category> <coding> <system value="http://loinc.org"/> <code value="75326-
9"/> <display value="Problem"/> </coding> </category>
      <severity> <coding> <system value="http://loinc.org"/> <code value="LA6751-
7"/> <display value="Moderate"/> </coding> </severity>
      <code> <coding> <extension
url="http://hl7.org/fhir/StructureDefinition/translation"> <extension url="lang">
<valueCode value="nl-NL"/> </extension> <extension url="content"> <valueString
value="opvliegers"/> </extension> </extension> <system
value="http://snomed.info/sct"/> <code value="198436008"/> <display
value="Menopausal flushing (finding)"/> </coding> <coding> <system
value="http://hl7.org/fhir/sid/icd-10"/> <code value="N95.1"/> <display
value="Menopausal and female climacteric states"/> </coding> </code>
      <subject><reference value="Patient/IPS-examples-Patient-01"/></subject>
      <onsetDateTime value="2015"/>
      <recordedDate value="2016-10"/>
    </Condition>
  </resource>
 </entry>
 <!--e6-->
 <entry><fullUrl value="http://hapi.fhir.org/baseR4/MedicationStatement/IPS-
examples-MedicationStatement-01"/>
  <resource>
   <MedicationStatement> <id value="IPS-examples-MedicationStatement-01"/>
      <meta> <profile
value="http://hl7.org/fhir/uv/ips/StructureDefinition/MedicationStatement-uv-
ips"/> </meta>
      <identifier> <system value="urn:oid:1.2.3.999"/> <value value="b75f92cb-
61d4-469a-9387-df5ef70d25f0"/> </identifier>
      <status value="active"/>
      <medicationReference> <reference value="Medication/IPS-examples-Medication-
01"/> </medicationReference>
      <subject> </<reference value="Patient/IPS-examples-Patient-01"/>
```

```
      </subject>
      <effectivePeriod>
       <start value="2015-03"/>
      </effectivePeriod>
      <dosage>
       <timing>
        <repeat>
          <count value="1"/>
          <periodUnit value="d"/>
        </repeat>
       </timing>
       <route>
         <coding> <system value="http://hl7.org/fhir/uv/ips/CodeSystem/edqm-uv-
ips"/> <code value="20053000"/> <display value="Oral use"/> </coding>
       </route>
       <doseAndRate>
        <type>
          <coding>
           <system value="http://terminology.hl7.org/CodeSystem/dose-rate-
type"/>
           <code value="ordered"/>
           <display value="Ordered"/>
          </coding>
        </type>
        <doseQuantity>
          <value value="1"/>
          <unit value="tablet"/>
          <system value="http://unitsofmeasure.org"/> <code value="1"/>
        </doseQuantity>
       </doseAndRate>
      </dosage>
    </MedicationStatement>
  </resource>
 </entry>
<!--e8-->
<entry>
  <fullUrl value="http://hapi.fhir.org/baseR4/Medication/IPS-examples-
Medication-01"/>
  <resource>
   <Medication>
     <id value="IPS-examples-Medication-01"/>
     <meta>
      <profile value="http://hl7.org/fhir/uv/ips/StructureDefinition/Medication-
uv-ips"/>
     </meta>
     <code> <coding> <system value="http://snomed.info/sct"/> <code
value="108774000"/> <display value="Anastrozole (product)"/> </coding> <coding>
<system value="urn:oid:2.16.840.1.113883.2.4.4.1"/> <code value="99872"/>
<display value="ANASTROZOL 1MG TABLET"/> </coding> <coding> <system
value="urn:oid:2.16.840.1.113883.2.4.4.7"/> <code value="2076667"/> <display
value="ANASTROZOL CF TABLET FILMOMHULD 1MG"/> </coding>
     </code>
   </Medication>
  </resource>
 </entry>
<entry>
  <fullUrl value="http://hapi.fhir.org/baseR4/AllergyIntolerance/IPS-examples-
AllergyIntolerance-01"/>
  <resource>
   <AllergyIntolerance>
```

```
      <id value="IPS-examples-AllergyIntolerance-01"/>
      <meta>
       <profile
value="http://hl7.org/fhir/uv/ips/StructureDefinition/AllergyIntolerance-uv-
ips"/>
      </meta>
      <identifier> <system value="urn:oid:1.2.3.999"/> <value value="3a462598-
009c-484a-965c-d6b24a821424"/> </identifier>
      <clinicalStatus> <coding> <system
value="http://terminology.hl7.org/CodeSystem/allergyintolerance-clinical"/> <code
value="active"/> </coding>
      </clinicalStatus>
      <verificationStatus> <coding> <system
value="http://terminology.hl7.org/CodeSystem/allergyintolerance-verification"/>
<code value="confirmed"/> </coding>
      </verificationStatus>
      <type value="allergy"/>
      <category value="medication"/>
      <criticality value="high"/>
      <code> <coding> <system value="http://snomed.info/sct"/> <code
value="373270004"/> <display value="Penicillin -class of antibiotic-
(substance)"/> </coding>
      </code>
      <patient> </<reference value="Patient/IPS-examples-Patient-01"/> </patient>
      <onsetDateTime value="2010"/>
    </AllergyIntolerance>
  </resource>
 </entry>
</Bundle>
```

15.5 Testing

Evaluation of the quality of the Patient Summary that will be exchanged or shared between providers and consumers is a critical key for the adoption and the use of the Patient Summary. A test Framework was developed in eHDSI project to minimize risks and errors when the patient summaries are exchanged.

The assessment is based on:

- The design that includes the test strategy, the test plan and the acceptance criteria (for example the level of coverage of the patient summaries items, the number of alerts etc.
- The execution that includes the test specifications (test cases and test scripts), the relevant test tools and the test report.

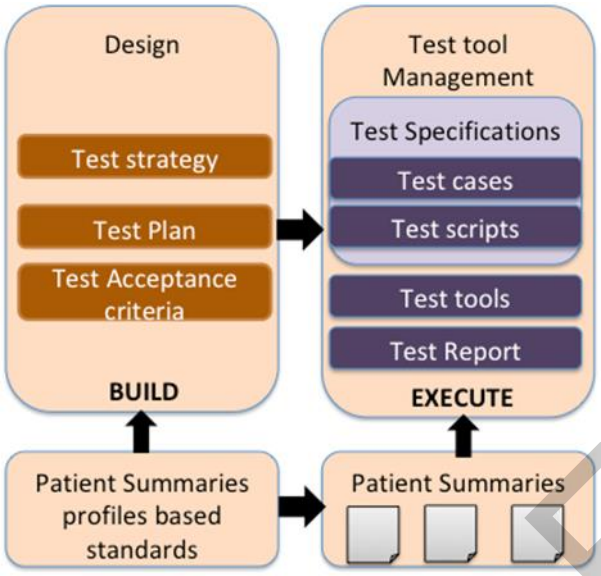


Figure 8 — Test Framework

The test strategy will describe processes needed for testing the patient summaries within a project according the profiles specifications i.e. the specifications that are implemented based on the standards such as HL7 CDA, FHIR etc. Note that these profiles are compliant with EN 17269 on IPS and this document. The test strategy includes the pre-production testing (testing with test data in a testing environment) and the production testing (testing with test data in real environment to complete the tests in pre-production).

A test management tool such as Gazelle management tool, a GITB compliant testbed, is useful to register, store and to archive all the test logs and test reports.

The test tools are tools that will analyse the patient summaries documents submitted for testing the rules and requirements described in the profiles i.e., implementation guides. Different types of testing are available today using:

- Schematron: rules-based language for xml files (assertions)
- Model based validation where the tool is based on the standard data model and support the implementation guide or profiles as an extension.
- Test data generator that provides patient summaries document for testing.

Generally, the test tools (such as Gazelle Object checker) are coupled with the design workbench (such as Art Decor® and test management tool such as Gazelle test management tool.

The EU project EURO-CAS (Conformity Assessment Scheme) defines the CASforEU CATP (Conformity Assessment Test Plan). The interest for a vendor having a product assessed for CASforEU IPS is the recognition of the product compliance in any European country.

15.6 Deployment

The IPS as a simple object is part of the more complex infrastructure that should be defined. A project which uses IPS should also deliver specific support and activities for IPS for the success of the deployment and among them:

- Change management that includes communication, education and training

- Testing (pre-production and production)
- Migration
- Maintenance activities

These all can be seen as implementations of information governance (see Clause 7) and play their part in making the IPS sustainable.

How the IPS is deployed is critical to its successful take up and acceptance by citizens (e.g. as custodians of the IPS), by healthcare providers (e.g. as those responsible for continuity and coordination of care), and by vendors (e.g. as those who have to implement the IPS). The healthcare providers should be aware of the importance of ensuring how the IPS information they are responsible for is communicated so the right information permits better care for the patient. The healthcare providers must be carefully trained with regard to the care processes that they are involved in.

Migration is usually associated with the system level, perhaps moving from a legacy to a new version, or from one vendor's offering to another's. The IPS is an extract from an EHR and a snapshot in time and therefore 'migration' considerations are constrained to the interfaces and services between IPS and the wider infrastructure that may be affected. Maintenance will deal with any changes caused by a change in IPS design, i.e., its content and rules, which need to be managed.

15.7 Socio-technical Factors

The IPS is essentially a very simple technology when considered in isolation. Its complexity, however, stems from the fact that it has to be considered in a holistic way, situated and embedded within a web of relationships that make it extremely complicated to realise. Interoperability is a behaviour but also a goal that has to be evaluated in different contexts and must offer incentives to the many stakeholders who often have quite different objectives.

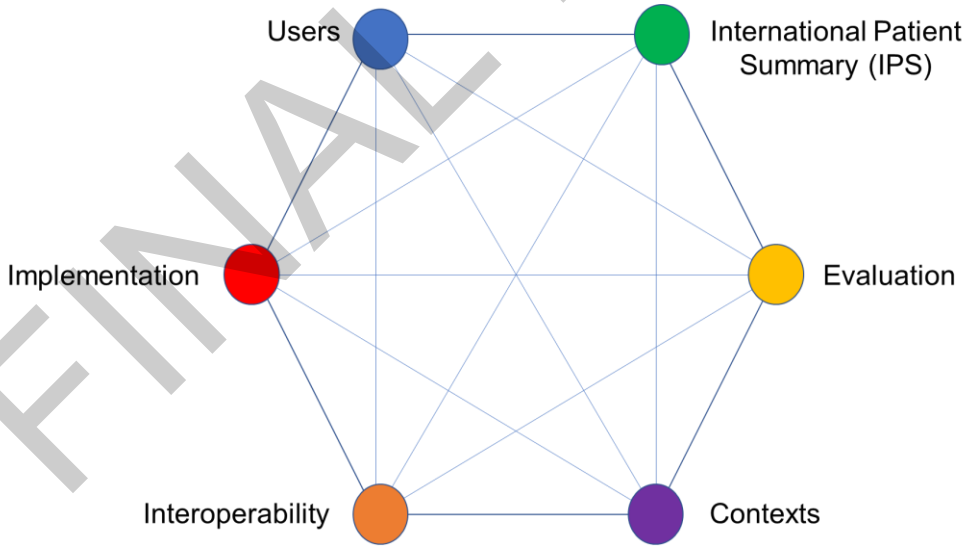


Figure 9 — Relationships between the IPS and its Socio-Technical Environment

In this perspective, illustrated by Figure 9, the term 'user' is broadly defined to include all key stakeholders but chief among them is the Subject of Care, also the data subject.

The IPS contains personal identifiable data, which may be held and transported by the patient in one style of implementation, expected to work in different settings (e.g. national and cross border), taking context

into consideration (e.g. languages, norms), and thereby influencing a better outcome from the unscheduled, cross border healthcare event.

NOTE The GDPR entitles the subject to have access to their records, which assumes a level of literacy and, perhaps, technical competence

As with the variety of users, there are various implementations of the IPS from different vendors. Interoperability in part will be determined by local and global contexts, and aspirations, based upon standards, policies, legislation and regulation. Testing (see 15.5) of conformance plus the different technology assessment schemes (not within scope of this document) may all be part of any evaluation of the outputs. Deployment (see 15.6) is a measure of acceptance of IPS implementation.

Workforce (e.g. Healthcare providers) skills and competences are described in the ReEIF and recognise that interoperability is not simply confined to the technical concerns. The IPS, how it and its extensions are used, will impact and change current systems, behaviours, and training. Change management is necessary and educational and training artefacts need to be considered.

15.8 Stakeholder evaluation

Standards have conformance statements that can be tested. Many of these tests are at the use case level and test the specification in terms of technical output (see 15.5 and the eHDSI Test framework). This is necessary and an important step in verifying the quality of the products based upon the standard. This may later lead to certification schemes being deployed, but note, these are not considered here in this document.

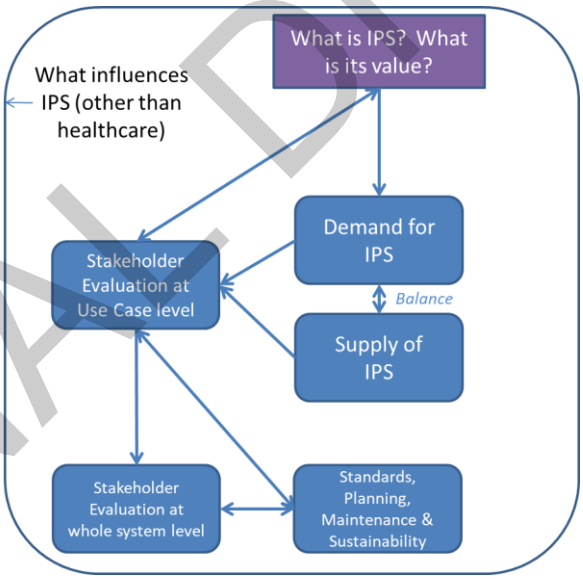


Figure 10 — Stakeholder Value and Sustainability of the IPS

The value of the IPS depends on the feedback of these tests and this assessment will impact the demand and supply of IPS, which also help to define and refine the nature of the IPS. The outputs are also feedback for the SDOs who maintain the specification with updates by systematic review after a maximum period of 5 years, which can be brought forward). Other influences external to the healthcare domain may also affect the IPS.

Stakeholder evaluation at the use case level is necessary. However, it is not sufficient to determine the value of IPS (see Figure 10 which shows two types of evaluation being deployed). Even if the tests are extended to incorporate validation by healthcare providers, more will be needed to convince and compel adoption of the IPS. IPS has to be evaluated at the holistic system level for full validation to be possible,

for outcome (not just output) metrics to be assessed and for sustainability to be effective. This will require a longer-term approach to the evaluation, and a sophisticated form of evaluation to be put in place. The dynamic ecosystem will make this a challenge, but the focus of the IPS use case and its scenarios will support such evaluation.

Consider the nature of the IPS. The IPS provides a library of core data elements considered to be specialty-agnostic, condition-independent as well as implementation-independent. Consequently, IPS will be a product embedded in many different types of healthcare artefacts from different implementation solutions and with the different IPS data elements contributing to the relevant information available at the point of care (within countries and across borders). It follows, that any holistic evaluation must take this macro-perspective into consideration. Furthermore, the feedback of the results to the SDOs to complement the use case evaluation will be critical to enhance sustainability, and to improve continuity and coordination of care with respect to its original goals.

Annex A
(Informative)

The Refined eHealth European Interoperability Framework

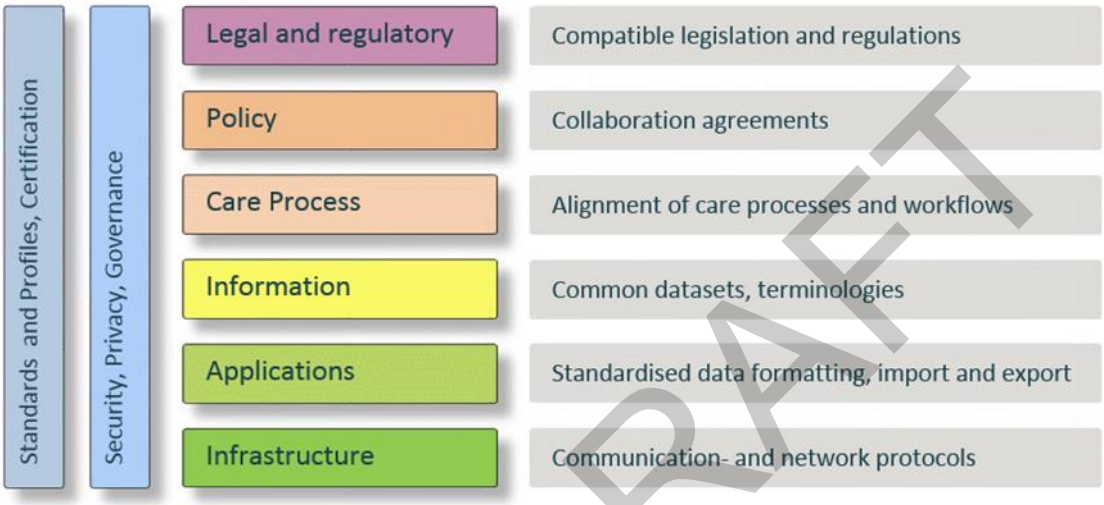


Figure A.1 — ReEIF illustrated and six considerations, shown as annotated layers

In terms of ReEIF, the EN 17269 is primarily concerned with the Care Process consideration (i.e., restricted to request and answer of the PS information request), Information consideration (i.e., common datasets) and Application consideration (i.e., data formatting, to support import and export of the IPS).

Although EN 17269 addressed value sets, it did not address the full complexity of 'terminologies', which, in as far as they are pervasive, are closely tied to implementation considerations. In so far as prEN 17269 uses business rules it addresses conformance and profiling.

This document offers guidance on how to use EN 17269 in the European realm, and consequently it focuses on those parts of the framework that are more context-sensitive when it comes to implementing the IPS. Governance, Data Protection (encompassing privacy and security), Legal and regulatory considerations and EU policy are all part of the specific jurisdiction detail. Whereas every effort has been taken to ensure that the IPS Standard is international in scope and use, profiling and assessment are also addressed here as part of the jurisdiction context.

Annex B
(Informative)

Detailed landscape for IPS

B.1 Overview

Figure B.1 provides a simplified overview of the main considerations that have been taken into account during the development of the IPS Standards. These include:

1. the eHealth Network, with its important contribution of a guideline for interchanging health data cross borders,
2. the EC promotes European Projects exploring eHealth interoperability
3. the Health Informatics SDO's, with their focus on formalising agreements and facilitating the use of standards,
4. European Policy, and their specific commitment to mobility of their citizens across member states
5. the requirements of the European stakeholders.
6. The formal consensus process surrounding the IPS standards (i.e., the EN and the TS)

The Mind map in Figure B.1 expands these 6 considerations (above) providing some more detail about the relationships.

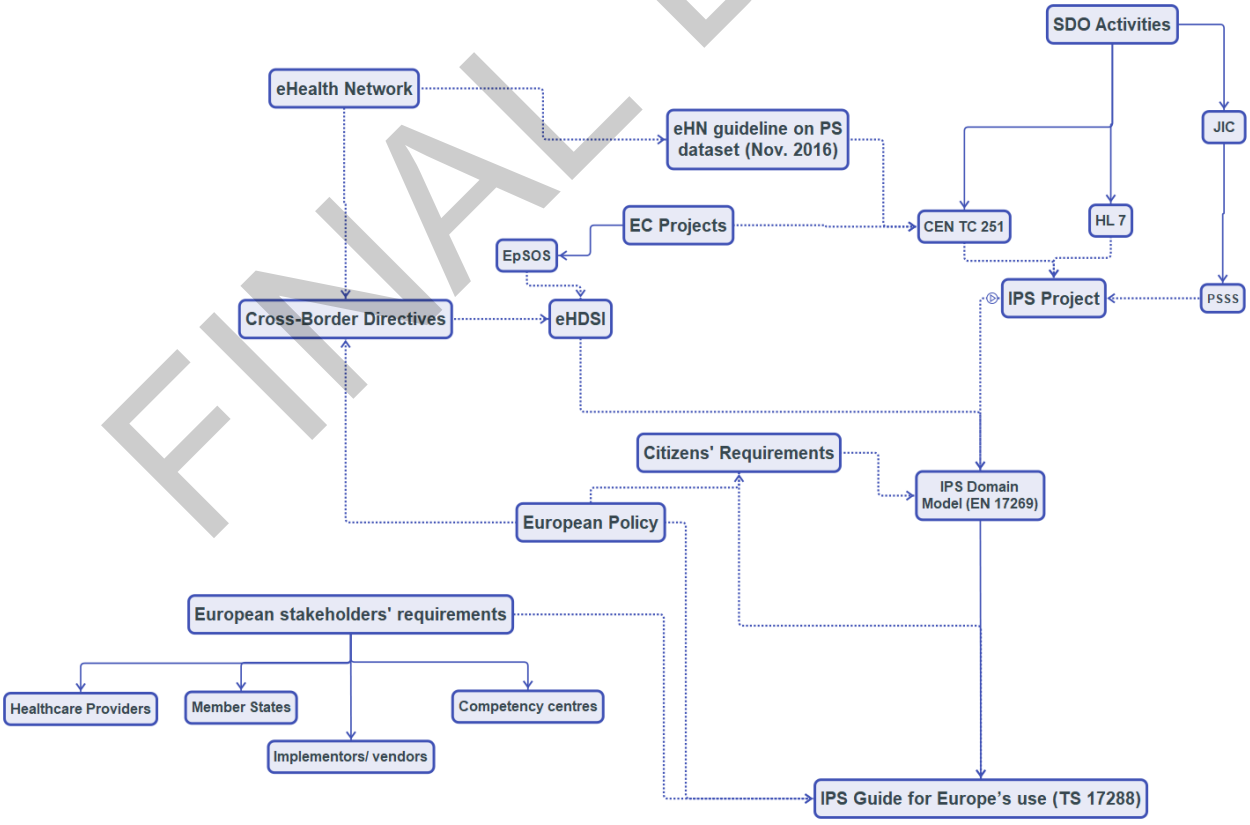


Figure B.1 — IPS Landscape in more detail

B.2 The eHealth Network

The eHealth Network (eHN) comprises representatives from the European member states, including governments and competency centres responsible for eHealth in their own nations. The EU has no mandate or direct control over the health systems of its Member States. It does however provide an opportunity to consider cross border implications. It has provided important guidance (November 2016), generically on cross border exchange of health data, and more specifically for electronic prescribing and for Patient Summaries. It also has considerable influence on the establishment of EC projects and involvement with the same, particularly with respect to governance and policy.

B.3 EC and European Projects concerning eHealth

There have been many projects over the years, but the one that might be considered to be a would-be blueprint for cross border exchange of health data across borders was the epSOS pilot project (2011) that involved 27 Member States. This pilot project has spawned the eHDSI activity which is directly concerned with implementing the PS across borders, to be complete by 2019. It uses the eHN guideline and cross border considerations.

Concurrently another EC project, stimulated by the eHN became CEN IPS; an approach to CEN/TC 251 to formalise the eHN guideline, such that they would become suitable for international deployment and regulation.

B.4 The Health Informatics SDO's

CEN/TC 251 and HL7 were the founding members of the International Standardisation Organisation involvement in Health Informatics (ISO/TC 215 in 1998). There is now a Joint Initiative Council (JIC) that comprises 8 SDO's including the 3 founding members.

HL7 had started a PS initiative in 2013 (INTERPAS) but it stalled and briefly seemed to restart in 2015. The CEN IPS project had a particular remit to engage and participate in the HL7 work. In part, another EC project, Trillium Bridge, was instrumental in bringing the CEN IPS and the now renamed HL7 IPS together and a common declaration of vision for the IPS was agreed.

The interest in PS standardisation had been noted by JIC, and they set out to provide an informative only guide to the PS landscape; its purpose was to help stakeholders understand the scope and nature of existing standards. JIC is not a standards-making body, and the output of the JIC standards Set was not a normative output. It also, helpfully used the eHN guideline and INTERPAS as its core dataset, and the intent was synergistic in that it would inform (by means of the Patient Summary Standards Set (PSSS)) and this would inform the IPS project (i.e., CEN IPS and HL7 IPS) and would be informed by the resulting standards as the guidance evolved.

B.5 European Policy

One of the principles underpinning European Union policies relates to the free movement of its citizens throughout its member states. This freedom relates to the workforce so the well-being of its citizens and the expectation of quality care, wherever within the EU, means that the exchange of citizen information to support them when they need it is important. It follows that digital and healthcare infrastructure supports initiatives such as IPS and such initiatives include citizen-centric policies such as GDPR to provide confidence and to safeguard its peoples.

B.6 European Stakeholders

Member States and Competency Centres are represented in the eHN and their focus is upon cross border and infrastructure projects. To some extent the national requirements of each Member State are also

served through such engagement, and government agencies may be able to regulate use of particular standards in procurement and require conformance. For the IPS to be of value to the national and local settings (where the majority of the traffic occurs and most benefit accrues), the domain model, dataset and exchange formats must also serve the healthcare providers and their clinical staff. As any change in something as fundamental as a PS will have implications for workflow, training, and capabilities, all of which can test capacity and resources. The vendors and implementers must also see value in the introduction of the proposed standards in this area if they are to adopt and conform to the IPS Standards.

B.7 The IPS Standards for Europe

New standards can be a disruptive influence and may impose significant costs and burden upon the stakeholders. Part of the design and definition was to maximise benefit by making the core dataset (EN 17269) an implementation-independent standard which can be leveraged for local and, eventually global use - and also for subsequent reuse.

This standard (prCEN/TS 17288) shows how different implementation architectures, in use throughout Europe, can use the prEN 17269-standard to exchange a meaningful PS in the European landscape, minimising wholescale disruption by providing an evolution path to interoperable solutions.

B.8 European Citizens

As noted the European eHealth ecosystem with its policies and stakeholders, highlights the citizen and resources are directed towards supporting their healthcare. The more detailed landscape shown in Figure B.1 consequently separates out the citizen (i.e., the potential patient) from the other stakeholders (subsumed in Figure 2), recognizing that this stakeholder should be privileged., as being the ultimate beneficiary.

The Mind map shows direct links from with both standards; the17269 standard describes a citizen's personal data and their specific health data, whereas 17288 provides the information governance and data protection mechanisms that are essential for safe and secure interchange.

Bibliography

[1] Joint support Action for the eHealth Network, Patient Summary for Unscheduled Care, version 2, 2016

[2] The European Commission in its Communication on the digital transformation of health and care. Digital Assembly, Sofia, 2018

[3] EU/US MOU
http://ec.europa.eu/information_society/newsroom/image/document/2016-30/eu_us_roadmap_annex_16675.pdf
(Visited January 2019)

[4] Trillium Bridge. http://www.hl7.it/trillium/index_file/Page338.htm
(Visited January 2019)

[5] Trillium II. https://trillium2.eu/deliverables/
(Visited January 2019)

[6] eStandards, http://www.estandards-project.eu/index.cfm/deliverables/
(Visited January 2019)

[7] eHDSI,
https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Reference+Documents
(Visited January 2019)

[8] CEF https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Mission
(Visited January 2019)

[9] epSoS
https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Reference+Documents
Note - epSOS: the epSOS.eu site is no longer active; most relevant deliverables are included in the above eHDSI reference document page.

[10] ReEIF http://ec.europa.eu/health/ehealth/docs/ev_20151123_co03_en.pdf
(Visited January 2019)

[11] HCIM Architecture Document, UK, Final, 2017 https://www.nictiz.nl/wp-content/uploads/2018/03/HCIM_Architecture_Document_UK_v1.0.pdf
(Visited January 2019)

[12] SHiELD. https://project-shield.eu
(Visited January 2019)

[13] Data protection regulations and international data flows : implications for trade and development – UN 2016 : http://unctad.org/en/PublicationsLibrary/dtlstict2016d1_en.pdf
(Visited January 2019)

[14] GDPR: http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32016R0679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

[15] ASSESS CT http://www.assess-ct.eu
(Visited January 2019)

[16] MVC https://ec.europa.eu/cefdigital/wiki/display/CEFDSIS/eHealth+Terminology+Services
(Visited January 2019)

[17] Kay S et al. CEN TC 251 Workshop on GDPR and IPS. http://www.ehealth-standards.eu/en/documents/
(Visited January 2019)

[18] HL7 Service-Aware Interoperability Framework: Canonical Definition Specification, Release 2.

[19] OMG MDA, https://www.omg.org/mda/specs.htm
(Visited January 2019)