CEN/TC 251
Health informatics

Email of secretary: shirin.golyardi@nen.nl
Secretariat: NEN (Netherlands)

FprCEN/TS 17288 Health informatics - The International Patient Summary: Guidance for European Implementation Technical Specification

Document type: FV ballot

Date of document: 2018-09-28

Expected action: VOTE

Action due date: 2018-12-20

Background: Please vote, using the balloting portal on CEN livelink. Deadline for voting: 2018-12-20

Committee URL: https://cen.iso.org/livelink/livelink/open/centc251
### Dispatch Notice

<table>
<thead>
<tr>
<th>Reference</th>
<th>FprCEN/TS 17288</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work item</td>
<td>00251338</td>
</tr>
<tr>
<td>Procedure</td>
<td>Vote on TS</td>
</tr>
<tr>
<td>Submission date</td>
<td>2018-09-27</td>
</tr>
<tr>
<td>Deadline</td>
<td>2018-12-20</td>
</tr>
<tr>
<td>Title</td>
<td>'Health Informatics - The International Patient Summary: Guidance for European Implementation Technical Specification'</td>
</tr>
<tr>
<td>Titre</td>
<td>Informatique de santé - Résumé international de dossier patient : Recommandations relatives aux spécifications techniques de mise en œuvre européenne</td>
</tr>
<tr>
<td>Titel</td>
<td>Medizinische Informatik - Die internationale Patienten-Kurzakte: Leitfaden für die europäische Technische Spezifikation (TS) zur Umsetzung</td>
</tr>
<tr>
<td>ICS Classification</td>
<td></td>
</tr>
<tr>
<td>Supersedes</td>
<td></td>
</tr>
<tr>
<td>Mandate</td>
<td></td>
</tr>
<tr>
<td>Directive(s)</td>
<td></td>
</tr>
<tr>
<td>Date of Announcement (DOA)</td>
<td>DAV+3 Months</td>
</tr>
<tr>
<td>Date of Publication (DOP)</td>
<td>-</td>
</tr>
<tr>
<td>Date of Withdrawal (DOW)</td>
<td>-</td>
</tr>
</tbody>
</table>

Balloting takes place on the eBalloting portal on Livelink, in accordance with BT decision CA 4/1996.

Balloters are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.
This draft Technical Specification is submitted to CEN members for Vote. It has been drawn up by the Technical Committee CEN/TC 251.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning: This document is not a Technical Specification. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a Technical Specification.
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>European foreword</td>
<td>5</td>
</tr>
<tr>
<td>Introduction</td>
<td>6</td>
</tr>
<tr>
<td>The eHealth Network, the Cross-Border Directive and the IPS Use Case</td>
<td>6</td>
</tr>
<tr>
<td>The relationship between the CEN IPS and other PS Initiatives</td>
<td>6</td>
</tr>
<tr>
<td>Figure 1 — CEN/TC 251’s participative role in establishing the IPS Standards</td>
<td>7</td>
</tr>
<tr>
<td>The European Interoperability Framework</td>
<td>7</td>
</tr>
<tr>
<td>Table 1 — Description of the Clause mapping to ReEIF</td>
<td>8</td>
</tr>
<tr>
<td>Standardization initiatives relevant to the IPS</td>
<td>9</td>
</tr>
<tr>
<td>1 Scope</td>
<td>11</td>
</tr>
<tr>
<td>2 Normative references</td>
<td>11</td>
</tr>
<tr>
<td>3 Terms and definitions</td>
<td>11</td>
</tr>
<tr>
<td>4 Abbreviations</td>
<td>14</td>
</tr>
<tr>
<td>5 Conformance: The relationship between prEN 17269 and this Document</td>
<td>15</td>
</tr>
<tr>
<td>6 The IPS Use Case, 4 Scenarios, and the Subject of Care</td>
<td>15</td>
</tr>
<tr>
<td>6.1 The IPS Use Case</td>
<td>15</td>
</tr>
<tr>
<td>6.2 IPS Scenario 1: Cross-Border, Unscheduled care</td>
<td>15</td>
</tr>
<tr>
<td>6.3 IPS Scenario 2: Local, Unscheduled care</td>
<td>16</td>
</tr>
<tr>
<td>6.4 IPS Scenario 3: Cross-border, Scheduled care</td>
<td>16</td>
</tr>
<tr>
<td>6.5 IPS Scenario 4: Local, Scheduled care</td>
<td>16</td>
</tr>
<tr>
<td>6.6 The Subject of Care</td>
<td>16</td>
</tr>
<tr>
<td>7 Governance Consideration</td>
<td>17</td>
</tr>
<tr>
<td>7.1 Information Governance applicable to IPS</td>
<td>17</td>
</tr>
<tr>
<td>Figure 4 — Product and Process views of IPS and Stakeholder Responsibilities</td>
<td>17</td>
</tr>
<tr>
<td>Table 2 — Examples of stakeholder involvement in Information Governance</td>
<td>17</td>
</tr>
<tr>
<td>7.2 Information Governance (Product View)</td>
<td>18</td>
</tr>
<tr>
<td>7.3 Information Governance (Process View)</td>
<td>19</td>
</tr>
<tr>
<td>7.3.1 General</td>
<td>19</td>
</tr>
<tr>
<td>7.3.2 Request</td>
<td>20</td>
</tr>
<tr>
<td>7.3.3 Export</td>
<td>20</td>
</tr>
<tr>
<td>7.3.4 Import</td>
<td>20</td>
</tr>
<tr>
<td>7.3.5 Access</td>
<td>21</td>
</tr>
<tr>
<td>7.3.6 Use and Reuse</td>
<td>21</td>
</tr>
<tr>
<td>8 Data Protection, Privacy and Security Consideration</td>
<td>22</td>
</tr>
<tr>
<td>8.1 General</td>
<td>22</td>
</tr>
<tr>
<td>8.2 Data Protection Requirements and principles</td>
<td>22</td>
</tr>
<tr>
<td>9 Legal and Regulatory Consideration</td>
<td>23</td>
</tr>
<tr>
<td>9.1 General</td>
<td>23</td>
</tr>
<tr>
<td>9.2 Regional and National Legislation</td>
<td>24</td>
</tr>
<tr>
<td>9.3 European Legislation</td>
<td>24</td>
</tr>
<tr>
<td>9.4 Examples of Directives and Regulation with respect to the IPS</td>
<td>24</td>
</tr>
</tbody>
</table>
10 Policy Consideration .................................................................................................................. 25
10.1 General .................................................................................................................................. 25
10.2 Organisation Policy .................................................................................................................. 25
10.3 European Policy ...................................................................................................................... 25
11 Care Process Consideration ...................................................................................................... 25
12 Information Consideration ......................................................................................................... 25
12.1 General .................................................................................................................................. 25

Figure 5 — The Information Consideration in the Interoperability Framework ...................... 26
12.2 Common Dataset ..................................................................................................................... 27
12.3 Value Sets ............................................................................................................................... 27
12.4 Information Models .................................................................................................................. 28
12.4.1 General ............................................................................................................................... 28
12.4.2 I3606 Archetypes .................................................................................................................. 28
12.4.3 Detailed Clinical Models (DCM) ........................................................................................ 29
12.4.4 HL7 CDA Templates ............................................................................................................ 30
12.4.5 HL7 FHIR Resources and FHIR Profiles ............................................................................ 30
12.5 Terminology Requirements and Agreements .......................................................................... 30
12.6 Terminologies for Implementation Now and in the Future ...................................................... 31

13 Applications Consideration ....................................................................................................... 31
13.1 General .................................................................................................................................. 31

Figure 6 — Two examples of IPS interchange (e.g. CDA, FHIR) .................................................... 33
13.2 European eHealth Digital Service Infrastructure (eHDSI) ..................................................... 33

14 Infrastructure Consideration ...................................................................................................... 34
15 Standards, Profiles and Evaluation ............................................................................................. 34
15.1 General .................................................................................................................................. 34
15.2 Standards/Profiles .................................................................................................................. 35
15.2.1 Scope ................................................................................................................................. 35
15.2.2 Data patterns ..................................................................................................................... 35

Table 3 — Patterns from prEN 17269 realised in CDA IPS and in HL7 FHIR IPS .................. 35
15.2.3 Elements mapping ............................................................................................................. 36

Table 4 — HL7 CDA Standard realizes prEN 17269 ...................................................................... 37

Table 5 — IPS Document and required data mapped to HL7 Implementations .......................... 39
Table 6 — IPS Document Model Extensions .................................................................................. 39
Table 7 — Remaining IPS Sections mapped to HL7 Implementations ....................................... 40

Table 8 — IPS Patient Attributes mapped to HL7 Implementations ............................................... 41
Table 9 — IPS Allergies and Intolerance mapped to HL7 Implementations .................................. 42
Table 10 — IPS Allergies and Intolerances Model Extensions ...................................................... 43
Table 11 — IPS Medication Summary mapped to HL7 Implementations ..................................... 43
Table 12 — IPS Medication Summary Model Extensions ............................................................. 44
Table 13 — IPS Problems mapped to HL7 Implementations .......................................................... 45
Table 14 — IPS Problems Model Extensions ................................................................................ 45
Table 15 — IPS Cross-border Metadata mapped to HL7 Implementations .................................. 46
Table 16 — IPS Patient’s Address Book mapped to HL7 Implementations ................................. 46
Table 17 — IPS History of Procedures mapped to HL7 Implementations ........................................ 47
Table 18 — IPS History of Procedures Model Extension .............................................................. 47
Table 19 — IPS Immunizations mapped to HL7 Implementations ................................................ 48
Table 21 — IPS Medical Devices mapped to HL7 Implementations ............................................. 49
Table 21 — IPS Medical Devices Model Extensions ....................................................................... 49
Table 22 — IPS Results mapped to HL7 Implementations ............................................................. 50
Table 23 — IPS Results Model Extensions ..................................................................................... 51
Table 24 — IPS Advanced Directives mapped to HL7 Implementations ...................................... 51
Table 25 — IPS Functional Status mapped to HL7 Implementations ........................................... 52
Table 26 — IPS History of Pregnancy mapped to HL7 Implementations ...................................... 52
Table 27 — IPS History of Past Illness mapped to HL7 Implementations ...................................... 53
Table 28 — IPS History of Past Illness Model Extensions ............................................................ 54
Table 29 — IPS Plan of Care mapped to HL7 Implementations ..................................................... 54
Table 30 — IPS Social History mapped to HL7 Implementations .................................................. 55
Table 31 — IPS Provenance mapped to HL7 Implementations ...................................................... 55
Table 32 — IPS Provenance Model Extensions ............................................................................. 56

15.3 Projects ........................................................................................................................................ 56
15.3.1 General .................................................................................................................................... 56
15.3.2 eHDSI ..................................................................................................................................... 56
15.3.3 Trillium II .............................................................................................................................. 57
15.4 Exchange Format Examples ..................................................................................................... 57
15.4.1 IPS CDA example .................................................................................................................. 57
15.4.2 IPS FHIR example ................................................................................................................ 62
15.5 Testing ....................................................................................................................................... 68
15.6 Deployment ............................................................................................................................... 69
15.7 Socio-technical Factors ............................................................................................................ 70
15.8 Stakeholder evaluation .............................................................................................................. 70

Annex A (Informative) The Refined eHealth European Interoperability Framework ....................... 72
Annex B (Informative) Detailed landscape for IPS ............................................................................ 73

B.1 Overview .................................................................................................................................... 73
B.2 The eHealth Network ................................................................................................................ 74
B.3 EC and European Projects concerning eHealth ....................................................................... 74
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 ................................................................................................. 75
B.8 European Citizens .................................................................................................................... 76
Bibliography ....................................................................................................................................... 77
European foreword

This document (FprCEN/TS 17288:2018) has been prepared by Technical Committee CEN/TC 251 "Health Informatics", the secretariat of which is held by NEN.

This document is currently submitted to the CEN Enquiry.
Introduction

This document provides European implementation guidance for the International Patient Summary (prEN 17269).

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 subjects 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.”

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”. [1]

The specific use case 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 guidelines 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.

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 guidelines. Figure 1 shows a map of key CEN IPS stakeholders.
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 independent standard products, with informed coordination to realize coherent results.

The EC eHealth projects, aware of the EU/US MOU, have been supportive. The Trillium I and II projects have taken as input the initial work from both CEN/TC 251 and HL7 IPS as basis for its elaborations and analysis, thereby contributing to the new standardization approach, described by the eStandards project, as “Co-creation, governance and alignment (CGA)”. Concurrently, the eHDSI under the CEF project is realizing the cross-border services for the Patient Summary based on the eHN PS guidelines and using Patient Summary CDA specifications evolved from epSOS. The lessons learnt by eHDSI (and its parent projects) have been taken in 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 Framework1 (ReEIF) 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.

---

1 Available at [http://ec.europa.eu/health/ehealth/docs/ev_20151123_co03_en.pdf](http://ec.europa.eu/health/ehealth/docs/ev_20151123_co03_en.pdf)
**Figure 2 — An overview of the IPS Project**

**Table 1 — Description of the Clause mapping to ReEIF**

<table>
<thead>
<tr>
<th>Clause #</th>
<th>ReEIF’s Consideration</th>
<th>Emphasis in prTS 17288</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clause 7</td>
<td>Governance</td>
<td>Information Governance</td>
</tr>
<tr>
<td>Clause 8</td>
<td>Security, Privacy and Confidentiality</td>
<td>Data Protection</td>
</tr>
<tr>
<td>Clause 9</td>
<td>Legal and Regulatory</td>
<td>Statutory requirements</td>
</tr>
<tr>
<td>Clause 10</td>
<td>Policy</td>
<td>European and organisational aspects</td>
</tr>
<tr>
<td>Clause 11</td>
<td>Care Process</td>
<td>Clinical Process and workflows</td>
</tr>
<tr>
<td>Clause 12</td>
<td>Information</td>
<td>The Datasets, models and terminologies</td>
</tr>
<tr>
<td>Clause 13</td>
<td>Applications</td>
<td>Standardized Interchange formats</td>
</tr>
<tr>
<td>Clause 14</td>
<td>Infrastructure</td>
<td>IT and protocols of exchange</td>
</tr>
<tr>
<td>Clause 15</td>
<td>Standards and Profiles, Certification</td>
<td>Examples, Conformance Testing, deployment and Evaluation</td>
</tr>
</tbody>
</table>
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.” [HCIM Architecture Document, UK, Final, 2017]

Standardization initiatives relevant to the IPS

From the European context there are four formal activities that engage the Standards Development Organisations (SDOs), which are mutually beneficial and compatible. They are:

- The 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 output and its value is to inform the stakeholders about existing or developing standards in the PS space. The PSSS has a wider scope. Both CEN and HL7 are members of JIC.

- In contrast to the JIC PSSS, HL7’s IPS and CEN’s IPS (the IPS Project) are normative and focus on delivering a consistent IPS information standard.
  
  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 Guidelines 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 1 back in 2016.

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

- The fourth project is 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, HL7, and eHDSI to harmonize their work to ensure European implementation is based upon a formal set of standards.
All these initiatives rely heavily on the eHN guidelines for a PS dataset, version 2 of which was published in November 2016 [1].

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 guidelines have 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 2, 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 [3-13] 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.
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 implementation of prEN 17269: 2018 'The patient summary for unscheduled cross-border care', within Europe.

The guidance in this document is also intended to be usable for more localised deployment, benefitting Member States that want to use the IPS within their own borders [1] and, as an additional benefit, its components may be reused to improve the interoperability of EHRs through common exchange formats [2].

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 17269:2018 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. The IPS is not a Personal Health Record (PHR), nor is it a comprehensive Electronic Health Record (EHR).

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 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:

- 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 **Extensible IPS Dataset**
IPS content that can be extended for use in patient summary use case scenarios that complement the primary IPS Scenario

3.4 **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]

3.5 **implementation-independent IPS**
IPS Dataset and IPS Document specified by prEN 17269:2018

3.6 **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: IHE Profiles provide precise definitions of how standards can be implemented to meet specific clinical needs.

3.7 **HL7 FHIR (Resource) Profile**
describe 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

3.8 **IPS**
electronic patient summary comprising, as a minimum, the required elements of the IPS Dataset

Note 1 to entry: The specific use case for the cross-border scenario does not restrict the IPS value to national or local applications

Note 2 to entry: access to the summary is not restricted to a particular situation

Note 3 to entry: The IPS is a “focused” Patient Summary that has the following properties:

- a minimal and non-exhaustive Patient Summary, which is
- specialty-agnostic, and
- condition-independent,
- but still clinically relevant
3.9 **IPS Consumer**
healthcare provider or citizen who receives or accesses the IPS and manages its disposition

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

3.11 **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.

3.12 **Minimal IPS**
**IPS Dataset**
core set of data items that all healthcare 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

3.13 **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.

3.14 **Open IPS Dataset**
facilitation of extensions to allow for emerging solutions for unresolved issues or improvements

3.15 **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]
3.16 personal information
PI
any data that describes some attribute of, or that is uniquely associated with, a natural person.

[SOURCE: OASIS PMRM TC, 2016]

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

[SOURCE: OASIS PMRM TC, 2016]

3.18 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

3.19 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.

3.20 healthcare mandate
mandate (commission) based on a commitment and either an informed consent or an authorization by law, defining the rights and obligations of one healthcare actor with regard to his involvement in healthcare processes performed for a specific subject of care

[SOURCE: EN-ISO 13940:2016]

4 Abbreviations

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

- **CEN** Comité Européen de Normalisation (European Committee for Standardization, a federation of 28 national standards bodies that are also ISO member bodies)
- **CEN/ TC 251** CEN Technical Committee 251 (develops standards within health informatics)
- **EC** European Commission
- **eHN** eHealth Network
- **EHR** Electronic Health Record
- **EU** European Union
- **HL7** Health Level Seven
- **IPS** International Patient Summary
5 Conformance: The relationship between prEN 17269 and this Document

prEN 17269 specifies “the core dataset for a patient summary document that supports continuity of care for a person and coordination of healthcare.” and the conformance rules that have to be applied to a derived model in order to comply with this standard.

NOTE “that the compliance with this standard doesn’t imply automatic technical interoperability; this result (i.e., technical interoperability), enabled by this document, can be reached with the conformity to standards indicated in the associated technical specifications.”

A prEN 17269 IPS compliant model, including a conformant implementation, shall:

1. Share the same scope of the IPS. The scope of the derived models could be however wider.
2. Declare, if not self-evident, how the data patterns defined in section 6.2 of prEN 17269 are realized.
3. Fulfil the conformance rules for the IPS data components and elements.

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

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 prEN 17269 and this document. 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.

NOTE The adoption of generally recognized, high level use cases, such as have been described in the Antelope and eStandards projects [see https://usecase-repository.ihe-europe.net/], (see the Patient Summary use case in the use case repository – no 4).

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: 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).

6.4 IPS Scenario 3: Cross-border, Scheduled care

The eHN guidelines suggested 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 is not intended to be the perfect solution for cross-border scheduled care, but it can, if necessary be used in absence of more specific solutions and offers support to more generic EHR exchange.

6.5 IPS Scenario 4: Local, Scheduled care

This is probably the most frequent use of a patient summary. It can serve as a hand-over document to inform a new clinician or 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 takes a myriad of non-standard forms, following local custom, policy, and organisational culture.

6.6 The Subject of Care

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 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 the cross-border care, however, there is another consideration related to the subject of care and the country of their treatment if it is not the same as their country of origin or affiliation. If the person is a visitor, and this is the first demand for contact, then that is deemed to be the norm for scenario 1, i.e.,
there is a single request and a single IPS from the country of affiliation; this is consistent with the eHN guideline. If, however, that person has already received treatment in that country then there may be more than one of his/her summaries in existence (i.e., different versions), which is a situation not specified within the eHN guideline; this case of multiple versions is not explicitly dealt with by this document, which regards the current patient summary as the most relevant for treating the patient at the point of care.

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](image)

Table 2 — Examples of stakeholder involvement in Information Governance

<table>
<thead>
<tr>
<th>ReEIF</th>
<th>Arrow#</th>
<th>Stakeholders</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Governance</td>
<td>1</td>
<td>SDO</td>
<td>Design and Maintenance</td>
</tr>
<tr>
<td>Data Protection (DP)</td>
<td>2</td>
<td>SDO, Citizen Implementers, Healthcare providers</td>
<td>Provenance, fairness, transparency Assess risks, accountability, Data Protection by Design and by Default</td>
</tr>
<tr>
<td>Privacy and security</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Legal and Regulatory</td>
<td>4</td>
<td>Government, Regulators</td>
<td>Cross-border health data, Data Protection, harmonisation and Enforcement</td>
</tr>
</tbody>
</table>
7.2 Information Governance (Product View)

The ‘product view’ of IPS considers the governance of the IPS dataset and the associated value sets as formally 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.

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 [8] 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. It also elaborates the business rules for using non-IPS Sections and attributes.

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. prEN 17269 is therefore the definitive standard 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.

---

2 Available at https://standards.cen.eu/dyn/www/f?p=204:7:0:::FSP_ORG_ID:6232&cs=18CA078392807EDD402B798AAEF1644E1
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 meta-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.

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 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 3-5 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 defined 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\(^3\) and ISO 22600-2: 2014\(^4\))
  - 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.

---

3 Health Informatics – Privilege management and access control – Part 1 : overview and policy management
4 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 [13]) on how to apply it to healthcare data interchange.

### 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 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 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 (prEN 17269) 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 prEN17269 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) 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 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 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 Foundation⁶.

⁶See 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 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 Guidelines set of archetypes.

12.4.3 Detailed Clinical Models (DCM)

12.4.3.1 General

Complimentary to the 13606 standard is the ISO 13972:2015 standard (Detailed clinical models, characteristics and processes). Both are 'models of use' rather than meaning. 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 Healthcare Information Models (HCIM)

HCIM's are DCMs, but with a strong accent on the Information Model of a DCM. 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. 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.

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:


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.”7 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”8, 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.”9. Examples of existing resources are MedicationStatement; Concern, Patient, and so on10. 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 IPS11 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.

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.

---

7 HL7 Version 3 Clinical Document Architecture (CDA®)
9 HL7 FHIR http://hl7.org/fhir/
10 See http://hl7.org/fhir/resourcelist.html for a complete list of available resources
11 See http://hl7.org/fhir/uv/ips/
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 for different IPS Sections and even more likely for the extended non-standard sections.
- Licensing costs for different terminologies and the implications for global adoption.
- Relatively new specialised terminologies, such as IDMP, and how they will be introduced.
- 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’ 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 for Implementation Now and in the Future

Europe, recognising that there will not be 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. MVC is used in the eHDSI deployment project for cross-border patient summaries.

Within pharmaceutical regulation, the ISO standards that identify medicinal products (IDMP) will soon become the definitive set of standards for implementations. 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...

---

13 See [https://ec.europa.eu/cefdigital/wiki/display/CEFDSIS/eHealth+Terminology+Services](https://ec.europa.eu/cefdigital/wiki/display/CEFDSIS/eHealth+Terminology+Services)
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. In fact, all of them rely on their own “reference” information models (the CDA model; the FHIR resources; and so on. 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 guidelines are 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 guidelines 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.
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.

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; ...) affects the information layer because all of them rely on their own “reference” information models (the CDA model; the FHIR resources; and so on). So, they are not just 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.

13.2 European eHealth Digital Service Infrastructure (eHDSI)

eHDSI is the deployment and operational services\textsuperscript{14} 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 NCP (National Contact Point). An agreement was set up between national authorities or national organisations responsible for NCP on the criteria required for participating to the eHDSI. One of the requirements is to be compliant with the Patient Summary guideline\textsuperscript{15} (directive 2011/24/EU), the starting point for prEN 17269.

\textsuperscript{14} https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Mission
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 (see section 14).

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 dataset 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\textsuperscript{16}]
- the HL7 FHIR International Patient Summary Implementation Guide standard [HL7 FHIR IPS\textsuperscript{17}]

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

\textsuperscript{16} At this time, the successfully balloted HL7 CDA R2 International Patient Summary Implementation Guide is still under publication. When this process will be completed this standard will be available at the HL7 web site \url{www.hl7.org}.

\textsuperscript{17} At this time, the HL7 FHIR International Patient Summary Implementation Guide is still under ballot the latest available version is published at \url{http://hl7.org/fhir/uv/ips/index.html}. 
A prEN 17269 IPS compliant model, including a conformant implementation, shall:

1. Share the same scope of the IPS. The scope of the derived models could be however wider.

2. Declare, if not self-evident, how the data patterns defined in section 6.2 of the prEN 17269 are realized.

3. Fulfil the conformance rules for the IPS data components and elements.

In the following paragraphs it will be shown how these conditions 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.

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

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label Concept</td>
<td>Depends on the context, typically by a specific class (e.g. Participant, SubstanceAdministration)</td>
<td>Depends on the context, typically by a specific resource (e.g. Patient; MedicationStatement)</td>
</tr>
<tr>
<td>List</td>
<td>A list of entries is realized with a &quot;to-many&quot; cardinality (e.g. 0..*)</td>
<td>Even if FHIR specifies a List resource, a list of entries is realized with a &quot;to-many&quot; cardinality (e.g. 0..*)</td>
</tr>
<tr>
<td>Reference</td>
<td>Typically with an entryRelationship relationship</td>
<td>Reference</td>
</tr>
<tr>
<td>Person Name</td>
<td>PN</td>
<td>HumanName</td>
</tr>
<tr>
<td>Coded Element</td>
<td>CD or CD derived data types</td>
<td>CodeableConcept or code</td>
</tr>
<tr>
<td>Date Time</td>
<td>TS</td>
<td>date</td>
</tr>
<tr>
<td>Identifier</td>
<td>II</td>
<td>Identifier</td>
</tr>
<tr>
<td>Address</td>
<td>AD</td>
<td>Address</td>
</tr>
<tr>
<td>Telecom</td>
<td>TEL</td>
<td>ContactPoint</td>
</tr>
<tr>
<td>Organization Name</td>
<td>ON</td>
<td>string</td>
</tr>
<tr>
<td>Text</td>
<td>ED (and its specializations) or ST</td>
<td>Narrative or string</td>
</tr>
<tr>
<td>prEN 17269</td>
<td>HL7 CDA IPS</td>
<td>HL7 FHIR IPS</td>
</tr>
<tr>
<td>------------</td>
<td>-------------</td>
<td>--------------</td>
</tr>
<tr>
<td><strong>Any</strong></td>
<td>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).</td>
<td>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).</td>
</tr>
<tr>
<td><strong>Range</strong></td>
<td>IVL_PQ</td>
<td>Range</td>
</tr>
<tr>
<td><strong>Quantity</strong></td>
<td>PQ</td>
<td>Quantity</td>
</tr>
<tr>
<td><strong>Period</strong></td>
<td>IVL_TS</td>
<td>Period</td>
</tr>
<tr>
<td><strong>General Time Specification</strong></td>
<td>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.</td>
<td>Depends on the context.</td>
</tr>
<tr>
<td><strong>Healthcare Provider</strong></td>
<td>Depends on the context. Typically Practitioner; PractitionerRole or Organization resources</td>
<td>Depends on the context.</td>
</tr>
<tr>
<td><strong>String</strong></td>
<td>ST</td>
<td>String</td>
</tr>
<tr>
<td><strong>Ratio</strong></td>
<td>RTO</td>
<td>Ratio</td>
</tr>
</tbody>
</table>

### 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 attributes18.

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.

The following tables reflect the current status, future improvements and changes are possible based on the comments collected during the balloting and the Standard for Trail Use (STU) phases. Updated forward and backward mappings between the prEN 17269 data set and the HL7 CDA IPS templates are

---

18 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
available on-line in the ART DECOR® platform. The HL7 CDA IPS standard will make explicit in its published standard how this document realizes prEN 17269 data set. An example is shown in Table 4.

Table 4 — HL7 CDA Standard realizes prEN 17269

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>hl7:patientRole</td>
<td>1..1 M</td>
</tr>
<tr>
<td>@classCode</td>
<td>cs</td>
</tr>
<tr>
<td>hl7:id</td>
<td>II</td>
</tr>
<tr>
<td>hl7:ids</td>
<td>1..* R</td>
</tr>
<tr>
<td>hl7:ids</td>
<td>1..* R</td>
</tr>
<tr>
<td>hl7:ids</td>
<td>1..* R</td>
</tr>
</tbody>
</table>

Hereafter, is an example of how the Patient Attributes are mapped into the HL7 CDA IPS.
Figure 7 — Examples of mappings between prEN 17269 dataset and the HL7 CDA IPS templates in ART DECOR®
### 15.2.3.2 Document, Sections and Attribute Collection

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

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
</table>
| IPS Document | M | ClinicalDocument
{LOINC;'60591-5'} | Composition/Bundle
{LOINC;'60591-5'} |
| IPS Attribute Collection: Patient Attributes | M | see § 15.2.3.3 Patient Attributes for details |
| IPS Section: Allergies and Intolerances | M | IPS Allergies and Intolerances Section
1..1 R
see § 15.2.3.4 Allergies and Intolerances for details | sectionAllergies
(IPS Allergies and Intolerances Section) 1..1
see § 15.2.3.4 Allergies and Intolerances for details |
| IPS Section: Medication Summary | M | IPS Medication Summary Section
1..1 R
see § Medication Summary 15.2.3.5 for details | sectionMedications
(IPS Medication Summary Section) 1..1
see § Medication Summary 15.2.3.5 for details |
| IPS Section: Problems | M | IPS Problems Section
1..1 R
see § 15.2.3.6 Problems for details | sectionProblems
(IPS Problems Section) 1..1
see § 15.2.3.6 Problems for details |
| IPS Attribute Collection: Provenance metadata Collection | M | See § 15.2.3.19 Provenance for details |
| IPS Section: Cross border metadata | C | See § 15.2.3.7 Cross- border metadata for details |
| IPS Sections and IPS Attribute Collection, ‘Patient’s Address Book’ | RK | See § 15.2.3.8 Patient’s Address Book for details |
| IPS Sections that are optional | O | See § 15.2.3.2 IPS Not required sections for details |

#### 15.2.3.3 Model extensions

#### Table 6 — IPS Document Model Extensions

<table>
<thead>
<tr>
<th></th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS custodian</td>
<td>1..1 M</td>
<td>0..1 mustSupport</td>
</tr>
<tr>
<td>Translated section narrative</td>
<td>0..* O</td>
<td>0..*</td>
</tr>
</tbody>
</table>
### 15.2.3.4 IPS Not required sections

Table 7 — Remaining IPS Sections mapped to HL7 Implementations

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Section: History of Procedures</td>
<td>IPS History of Procedures Section 0..1 R</td>
<td>sectionProceduresHx (IPS History of Procedures Section) 0..1 mustSupport</td>
</tr>
<tr>
<td>IPS Section: Immunizations</td>
<td>IPS Immunizations Section 0..1 R</td>
<td>sectionImmunizations (IPS Immunizations Section) 0..1 mustSupport</td>
</tr>
<tr>
<td>IPS Section: Medical Devices</td>
<td>IPS Medical Devices Section 0..1 R</td>
<td>sectionMedicalDevices (IPS Medical Devices Section) 0..1 mustSupport</td>
</tr>
<tr>
<td>IPS Section: Results</td>
<td>IPS Results Section 0..1 R Note: only Diagnostic Results</td>
<td>sectionResults (IPS Results Section) 0..1 mustSupport Note: only Diagnostic Results</td>
</tr>
<tr>
<td>IPS Section: Advanced Directives</td>
<td>IPS Advance Directives Section 0..1 O</td>
<td>sectionAdvanceDirectives IPS Advance Directives Section 0..1</td>
</tr>
<tr>
<td>IPS Section: Functional Status</td>
<td>IPS Functional Status Section 0..1 O</td>
<td>sectionFunctionalStatus (IPS Functional Status Section) 0..1</td>
</tr>
<tr>
<td>IPS Section: History of Pregnancy</td>
<td>IPS History of Pregnancy Section 0..1 O</td>
<td>sectionPregnancyHx (IPS History of Pregnancy Section) 0..1</td>
</tr>
<tr>
<td>IPS Section: History of Past Illness</td>
<td>IPS History of Past Illness Section 0..1 O</td>
<td>sectionPastIllnessHx (IPS History of Past Illness Section) 0..1</td>
</tr>
<tr>
<td>IPS Section: Plan of Care</td>
<td>IPS Plan of Care Section 0..1 O</td>
<td>sectionPlanOfCare (IPS Plan of Care Section) 0..1</td>
</tr>
</tbody>
</table>
### 15.2.3.5 Patient Attributes

<table>
<thead>
<tr>
<th>IPS Attribute Collection Patient Attributes</th>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Section: Social History</td>
<td>O</td>
<td>IPS Social History Section 0..1 O</td>
<td>sectionSocialHistory (IPS Social History Section) 0..1</td>
</tr>
</tbody>
</table>

#### Table 8 — IPS Patient Attributes mapped to HL7 Implementations

<table>
<thead>
<tr>
<th>IPS Attribute Collection Patient Attributes</th>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Attribute Collection Patient Attributes</td>
<td>prEN 17269</td>
<td>HL7 CDA IPS</td>
<td>HL7 FHIR IPS</td>
</tr>
<tr>
<td>Patient's Name</td>
<td>M</td>
<td>1..*M</td>
<td>0..* mustSupport</td>
</tr>
<tr>
<td>Patient's address and telecom</td>
<td>RK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td>C</td>
<td>1..* R</td>
<td>0..* mustSupport</td>
</tr>
<tr>
<td>Telecoms</td>
<td>C</td>
<td>1..* R</td>
<td>0..* mustSupport</td>
</tr>
<tr>
<td>Administrative Gender</td>
<td>RK</td>
<td>1..1 R</td>
<td>1..1</td>
</tr>
<tr>
<td>Date of Birth</td>
<td>R</td>
<td>1..1 R</td>
<td>1..1</td>
</tr>
<tr>
<td>Patient's preferred language</td>
<td>O</td>
<td>0..*</td>
<td>0..*</td>
</tr>
<tr>
<td>Healthcare related identifiers</td>
<td>RK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Identifier</td>
<td>RK</td>
<td>1..* R</td>
<td>0..* mustSupport</td>
</tr>
<tr>
<td>Insurance Information</td>
<td>O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insurance Identifier</td>
<td>RK</td>
<td>One of the possible patient identifiers</td>
<td>One of the possible patient identifiers</td>
</tr>
</tbody>
</table>
### 15.2.3.6 Allergies and Intolerances

**Table 9 — IPS Allergies and Intolerance mapped to HL7 Implementations**

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Section: ALLERGIES and INTOLERANCES</td>
<td>IPS Allergies and Intolerances Section 1..1 R</td>
<td>sectionAllergies IPS Allergies and Intolerances Section 1..1</td>
</tr>
<tr>
<td>Allergies/Intolerances Content Status</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>Allergies and Intolerances list</td>
<td>At least one statement is present</td>
<td></td>
</tr>
<tr>
<td>Allergy/Intolerance</td>
<td>M</td>
<td>1..* M</td>
</tr>
<tr>
<td>Description</td>
<td>R</td>
<td>In the section text</td>
</tr>
<tr>
<td>Clinical Status</td>
<td>R</td>
<td>Status of the concern 1..1 R</td>
</tr>
<tr>
<td>Onset date</td>
<td>R</td>
<td>1..1 R</td>
</tr>
<tr>
<td>End Date</td>
<td>C</td>
<td>0..1 C</td>
</tr>
<tr>
<td>Criticality</td>
<td>O</td>
<td>0..1 R</td>
</tr>
<tr>
<td>Certainty</td>
<td>O</td>
<td>0..1 R</td>
</tr>
<tr>
<td>Type of propensity</td>
<td>RK</td>
<td>1..1 M</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>O</td>
<td>0..1</td>
</tr>
<tr>
<td>Reaction</td>
<td>RK</td>
<td>0..* R</td>
</tr>
<tr>
<td>Manifestation of the reaction</td>
<td>RK</td>
<td>0..1 R</td>
</tr>
<tr>
<td>Severity</td>
<td>RK</td>
<td>0..1 R</td>
</tr>
<tr>
<td>Agent</td>
<td>R</td>
<td>0..1 C</td>
</tr>
<tr>
<td>Agent code</td>
<td>R</td>
<td>1..1 R</td>
</tr>
<tr>
<td>Category</td>
<td>O</td>
<td>Not as distinct information; it might be covered using specialized concepts for the type of propensity (e.g. Drug Allergy)</td>
</tr>
</tbody>
</table>
### 15.2.3.7 Model extensions

#### Table 10 — IPS Allergies and Intolerances Model Extensions

<table>
<thead>
<tr>
<th></th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start date of the concern</td>
<td>1..1 R</td>
<td>Not explicitly specified</td>
</tr>
<tr>
<td>End date of the concern</td>
<td>0..1 C</td>
<td>Not explicitly specified</td>
</tr>
<tr>
<td>Start date of the Manifestation of the reaction</td>
<td>1..1 R</td>
<td>0..1</td>
</tr>
<tr>
<td>End date of the Manifestation of the reaction</td>
<td>0..1 C</td>
<td>Not explicitly specified</td>
</tr>
</tbody>
</table>

### 15.2.3.8 Medication Summary

#### Table 11 — IPS Medication Summary mapped to HL7 Implementations

<table>
<thead>
<tr>
<th></th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Section: MEDICATION SUMMARY</td>
<td>IPS Medication Summary Section 1..1 R</td>
<td>sectionMedications (IPS Medication Summary Section) 1.1</td>
</tr>
<tr>
<td>Medication Summary content status</td>
<td>C</td>
<td>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</td>
</tr>
<tr>
<td>List of medication</td>
<td>C</td>
<td>At least one statement is present</td>
</tr>
<tr>
<td>Medication</td>
<td>M</td>
<td>1..* M (Medication Entry template) 1..* (MedicationStatement resource)</td>
</tr>
<tr>
<td>Reason</td>
<td>O</td>
<td>Not explicitly specified 0..*</td>
</tr>
<tr>
<td>Medicinal Product</td>
<td>R</td>
<td>1..1 R ManufacturedProduct template 0..1 Medication resource required if there is content</td>
</tr>
<tr>
<td>Product Code</td>
<td>O</td>
<td>0..1 R 0..* mustSupport</td>
</tr>
<tr>
<td>Product Common Name (and Strength)</td>
<td>RK</td>
<td>0..1 R 0..1</td>
</tr>
<tr>
<td>Pharmaceutical dose form</td>
<td>R</td>
<td>0..1 R 0..* mustSupport</td>
</tr>
<tr>
<td>Brand name</td>
<td>O</td>
<td>0..1 R 0..1</td>
</tr>
<tr>
<td>Active ingredient List</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Active Ingredient</td>
<td>R</td>
<td>1..* R</td>
</tr>
<tr>
<td>-------------------</td>
<td>---</td>
<td>--------</td>
</tr>
<tr>
<td>Substance code</td>
<td>R</td>
<td>0..1 C (or the name or the code shall be provided)</td>
</tr>
<tr>
<td>Strength</td>
<td>R</td>
<td>1..1 R</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Administration Instruction</th>
<th>R</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Instruction</td>
<td>O</td>
<td>Not explicitly specified</td>
</tr>
<tr>
<td>Period of Medication Use</td>
<td>R</td>
<td>1..1 R</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>O</td>
<td>0..1 R</td>
</tr>
<tr>
<td>Dose Instruction</td>
<td>R</td>
<td>0..1 C required if there is content</td>
</tr>
<tr>
<td>No. of units per intake</td>
<td>R</td>
<td>1..1 R</td>
</tr>
<tr>
<td>Frequency of intake</td>
<td>R</td>
<td>1..1 R</td>
</tr>
</tbody>
</table>

15.2.3.9 Model extensions

Table 12 — IPS Medication Summary Model Extensions

<table>
<thead>
<tr>
<th>Status of the administration</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author of the assertion / Information source</td>
<td>0..*</td>
<td>Supported by the standard resource</td>
</tr>
<tr>
<td>Medicinal Product Identifier</td>
<td>0..11 R</td>
<td>0..1 mustSupport</td>
</tr>
<tr>
<td>Medicinal Product Name</td>
<td>0..11 R</td>
<td>0..1 mustSupport</td>
</tr>
<tr>
<td>Packaged Medicinal Product Identifier</td>
<td>0..11 R</td>
<td>0..1 mustSupport</td>
</tr>
<tr>
<td>Packaged Medicinal Product Name</td>
<td>0..11 R</td>
<td>0..1 mustSupport</td>
</tr>
<tr>
<td>Package structure (3 levels)</td>
<td>0..1</td>
<td>Not explicitly specified</td>
</tr>
<tr>
<td>WHO Anatomical Therapeutic Chemical (ATC) code</td>
<td>0..11 R</td>
<td>0..1 mustSupport</td>
</tr>
<tr>
<td>IDMP Pharmaceutical Product Identifier(s)</td>
<td>0..** R</td>
<td>0..1 mustSupport</td>
</tr>
<tr>
<td>IDMP Pharmaceutical Product name</td>
<td>0..** R</td>
<td>0..1 mustSupport</td>
</tr>
<tr>
<td>Rate quantity</td>
<td>0..1</td>
<td>Supported by the standard resource</td>
</tr>
</tbody>
</table>
### 15.2.3.10 Problems

#### Table 13 — IPS Problems mapped to HL7 Implementations

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Section: PROBLEMS</td>
<td>M</td>
<td>IPS Problems Section 1..1 R</td>
</tr>
<tr>
<td>Problem content status</td>
<td>C</td>
<td>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</td>
</tr>
<tr>
<td>Problem list</td>
<td>C</td>
<td>At least one statement is present</td>
</tr>
<tr>
<td>Problem</td>
<td>M</td>
<td>1..* M (IPS Problem Concern Entry) Including, 1..* R (IPS Problem Entry)</td>
</tr>
<tr>
<td>Problem type</td>
<td>RK</td>
<td>1..1 R</td>
</tr>
<tr>
<td>Description</td>
<td>R</td>
<td>Section text</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>R</td>
<td>1..1 M</td>
</tr>
<tr>
<td>Severity</td>
<td>RK</td>
<td>0..1 R</td>
</tr>
<tr>
<td>Onset date</td>
<td>R</td>
<td>1..1</td>
</tr>
<tr>
<td>Specialist Contact</td>
<td>O</td>
<td>Not explicitly specified</td>
</tr>
</tbody>
</table>

#### 15.2.3.11 Model extensions

#### Table 14 — IPS Problems Model Extensions

<table>
<thead>
<tr>
<th>Concern status</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation start date</td>
<td>1..1 R</td>
<td>Supported by the standard resource</td>
</tr>
<tr>
<td>Observation end date</td>
<td>0..1 C</td>
<td>Supported by the standard resource</td>
</tr>
<tr>
<td>Abatement date</td>
<td>0..1 C</td>
<td>0..1 because the same profile is used for closed and open problems</td>
</tr>
<tr>
<td>Clinical status</td>
<td>0..1 R</td>
<td>0..1 mustSupport</td>
</tr>
<tr>
<td>Verification status</td>
<td>0..1 R</td>
<td>0..1 mustSupport</td>
</tr>
</tbody>
</table>
### 15.2.3.12 Cross-border metadata

#### Table 15 — IPS Cross-border Metadata mapped to HL7 Implementations

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Metadata: Cross Border</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>Country of Affiliation</td>
<td>M</td>
<td>The Patient address is 1..* and the country is one of the conditional components of the address</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The Patient address is 0..* mustSupport and the country is one of the mustSupport components of the address</td>
</tr>
<tr>
<td>Country specific requirements</td>
<td>RK</td>
<td>It is a placeholder in prEN 17269; more specific instructions are needed to specify the mapping to the CDA model</td>
</tr>
</tbody>
</table>

### 15.2.3.13 Patient's Address Book

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

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Attribute Collection: Patient's Address Book</td>
<td>RK</td>
<td></td>
</tr>
<tr>
<td>Preferred Healthcare providers</td>
<td>RK</td>
<td>0..* R (IPS Patient Contacts)</td>
</tr>
<tr>
<td>Healthcare Provider (person)</td>
<td>C</td>
<td>0..1 C</td>
</tr>
<tr>
<td>Name</td>
<td>R</td>
<td>1..* R</td>
</tr>
<tr>
<td>Telecoms</td>
<td>RK</td>
<td>1..* R</td>
</tr>
<tr>
<td>Healthcare Provider (organisation)</td>
<td>C</td>
<td>0..1 C</td>
</tr>
<tr>
<td>Organisation's Name</td>
<td>R</td>
<td>1..* R</td>
</tr>
<tr>
<td>Telecoms</td>
<td>RK</td>
<td>1..* R</td>
</tr>
<tr>
<td>Other's Contacts’ Details</td>
<td>O</td>
<td>0..* R</td>
</tr>
<tr>
<td>Contact</td>
<td>R</td>
<td>0..* R</td>
</tr>
<tr>
<td>Role</td>
<td>RK</td>
<td>0..1 R</td>
</tr>
<tr>
<td>Name</td>
<td>RK</td>
<td>1..* R</td>
</tr>
<tr>
<td>Address</td>
<td>O</td>
<td>1..* R</td>
</tr>
<tr>
<td>Telecoms</td>
<td>RK</td>
<td>1..* R</td>
</tr>
</tbody>
</table>
### 15.2.3.14 History of Procedures

#### Table 17 — IPS History of Procedures mapped to HL7 Implementations

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Section: HISTORY OF PROCEDURES</td>
<td>IPS History of Procedures Section 0..1 R</td>
<td>mustSupport</td>
</tr>
<tr>
<td>Procedures Content Status</td>
<td>C</td>
<td>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</td>
</tr>
<tr>
<td>Procedure list</td>
<td>C</td>
<td>At least one statement is present</td>
</tr>
<tr>
<td>Procedure</td>
<td>R</td>
<td>1..* R</td>
</tr>
<tr>
<td>Procedure code</td>
<td>R</td>
<td>1..1 R</td>
</tr>
<tr>
<td>Procedure description</td>
<td>RK</td>
<td>Section text</td>
</tr>
<tr>
<td>Body site</td>
<td>O</td>
<td>0..*</td>
</tr>
<tr>
<td>Procedure date</td>
<td>R</td>
<td>1..1 R</td>
</tr>
</tbody>
</table>

### 15.2.3.15 Model extensions

#### Table 18 — IPS History of Procedures Model Extension

<table>
<thead>
<tr>
<th></th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure status</td>
<td>1..1 M</td>
<td>1..1</td>
</tr>
<tr>
<td>Target Site</td>
<td>0..*</td>
<td>0..1 mustSupport</td>
</tr>
<tr>
<td>Internal reference</td>
<td>0..*</td>
<td>Supported by the standard resource</td>
</tr>
</tbody>
</table>
### 15.2.3.16 Immunizations

**Table 19 — IPS Immunizations mapped to HL7 Implementations**

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Section: IMMUNIZATIONS</td>
<td>IPS Immunizations sectionImmunizations (IPS Immunizations Section = 0..1 mustSupport)</td>
<td></td>
</tr>
<tr>
<td>Immunizations Content Status</td>
<td>C</td>
<td>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</td>
</tr>
<tr>
<td>Immunizations list</td>
<td>C</td>
<td>At least one statement is present</td>
</tr>
<tr>
<td>Immunization</td>
<td>R</td>
<td>1..* R</td>
</tr>
<tr>
<td>Vaccine for type of disease</td>
<td>R</td>
<td>1..1 R</td>
</tr>
<tr>
<td>Target disease list</td>
<td>O</td>
<td>0..*</td>
</tr>
<tr>
<td>In this version supposed to be covered by the vaccine for type of disease.</td>
<td>1..1</td>
<td>1..1</td>
</tr>
<tr>
<td>Date of immunization</td>
<td>R</td>
<td>1..1</td>
</tr>
<tr>
<td>Product administered</td>
<td>O</td>
<td>Not explicitly specified</td>
</tr>
<tr>
<td>Not explicitly specified</td>
<td>Not explicitly specified</td>
<td></td>
</tr>
<tr>
<td>Brand name</td>
<td>RK</td>
<td></td>
</tr>
<tr>
<td>Product Administration Process</td>
<td>O</td>
<td>0..1 mustSupport</td>
</tr>
<tr>
<td>Performer</td>
<td>O</td>
<td>0..1</td>
</tr>
<tr>
<td>Route of administration</td>
<td>O</td>
<td></td>
</tr>
</tbody>
</table>
15.2.3.17 Model extensions

Table 20 — IPS Immunizations Model Extensions

<table>
<thead>
<tr>
<th>Entry author / Information source</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>0..* R</td>
<td>0..* mustSupport</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Manufacturer</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>0..* R</td>
<td>Supported by the standard resource</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lot number</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>0..1</td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product code</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>0..* mustSupport</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IDMP product identifiers</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>One of the possible product codes</td>
<td></td>
<td>0..* mustSupport</td>
</tr>
</tbody>
</table>

15.2.3.18 Medical Devices

Table 21 — IPS Medical Devices mapped to HL7 Implementations

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Section: MEDICAL DEVICES</td>
<td>RK</td>
<td>sectionMedicalDevices</td>
</tr>
<tr>
<td>0..1 mustSupport</td>
<td></td>
<td>(IPS Medical Devices Section)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device content Status</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device List</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least one statement is present</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device</th>
<th>R</th>
<th>1..* R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td></td>
<td>1..1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Identifier</th>
<th>RK</th>
</tr>
</thead>
<tbody>
<tr>
<td>0..* R support to device serial numbers; UDI and other identifiers.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Use start date</th>
<th>R</th>
<th>1..1 R</th>
</tr>
</thead>
<tbody>
<tr>
<td>0..1 Serial Number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use end date</td>
<td>O</td>
<td>1..1 C</td>
</tr>
<tr>
<td>0..1 mustSupport</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

15.2.3.19 Model extensions

Table 21 — IPS Medical Devices Model Extensions

<table>
<thead>
<tr>
<th>Device use status</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>No extensions</td>
<td></td>
<td>1..1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Body site</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>0..1 mustSupport</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 15.2.3.20 Results

#### Table 22 — IPS Results mapped to HL7 Implementations

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Section: RESULTS</td>
<td>RK: IPS Results Section</td>
<td>sectionResults</td>
</tr>
<tr>
<td></td>
<td>0..1 R</td>
<td>(IPS Results Section)</td>
</tr>
<tr>
<td></td>
<td>Note: only Diagnostic Results</td>
<td>0..1 mustSupport</td>
</tr>
<tr>
<td></td>
<td>Note: only Diagnostic Results</td>
<td>Note: only Diagnostic Results</td>
</tr>
<tr>
<td>Observation Results Content Status</td>
<td>C</td>
<td>No explicit codes have been defined in this case. The section is omitted if no diagnostic results are available or of interest.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Explicit codes are used to express known absent or unknown situations. In this case no other information is required by the model</td>
</tr>
<tr>
<td>Observation results list</td>
<td>C</td>
<td>No entries if no diagnostic results are available or of interest.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No entries if no diagnostic results are available or of interest.</td>
</tr>
<tr>
<td>Observation Result</td>
<td>R</td>
<td>1..* R</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Four types of results are explicitly profiled: laboratory; imaging; pathology; generic (other) results</td>
</tr>
<tr>
<td>Date of observation</td>
<td>R</td>
<td>1..1 R</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0..1 mustSupport for all the others</td>
</tr>
<tr>
<td>Observation Type</td>
<td>R</td>
<td>1..1 M</td>
</tr>
<tr>
<td>Result Description</td>
<td>R</td>
<td>Section text</td>
</tr>
<tr>
<td>Value</td>
<td>C</td>
<td>1..1 R</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Values are expected either in the parent or in the member observations or in both.</td>
</tr>
<tr>
<td>Observation Result</td>
<td>C</td>
<td>Observation results belonging to the same test procedure/panel can be grouped into the same organizer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Observation results belonging to the same test procedure/panel can be grouped into the same parent observation resource</td>
</tr>
<tr>
<td>Performer</td>
<td>RK</td>
<td>Organizer 0..* R</td>
</tr>
<tr>
<td>Observer</td>
<td>RK</td>
<td>0..* R</td>
</tr>
</tbody>
</table>

---

20 It is expected that the behaviour will be harmonized with the other recommended sections as part of the STU comment phase.
### 15.2.3.21 Model extensions

#### Table 23 — IPS Results Model Extensions

<table>
<thead>
<tr>
<th>Interpretation code</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>0..1 R</strong></td>
<td><strong>0..1 R</strong></td>
<td><strong>Supported by the standard resource</strong></td>
</tr>
<tr>
<td>(depends on the type of result)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Site</td>
<td><strong>0..1</strong></td>
<td><strong>Not explicitly specified</strong></td>
</tr>
<tr>
<td>Reference Range</td>
<td><em><em>0..</em> R</em>*</td>
<td><strong>Supported by the standard resource</strong></td>
</tr>
<tr>
<td>Result comment</td>
<td><strong>0..</strong>*</td>
<td><strong>Supported by the standard resource</strong></td>
</tr>
<tr>
<td>Specimen Collection data</td>
<td><strong>0..</strong>*</td>
<td><strong>Supported by the standard resource</strong></td>
</tr>
</tbody>
</table>

### 15.2.3.22 Advanced Directives

#### Table 24 — IPS Advanced Directives mapped to HL7 Implementations

<table>
<thead>
<tr>
<th>prEN 17269 IPS Section: ADVANCE DIRECTIVES</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Advance Directives Section</td>
<td><strong>0..1 O</strong></td>
<td>sectionAdvanceDirectives</td>
</tr>
<tr>
<td>Only Narrative, structured entries not specified (but allowed)</td>
<td></td>
<td>IPS Advance Directives Section</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Advance Directives</th>
<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advance Directive</td>
<td>R</td>
</tr>
<tr>
<td>As part of the section text</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Person authorising Directive</th>
<th>RK</th>
<th>0..* R (as section author)</th>
<th>Not explicitly specified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>RK</td>
<td>0..* R</td>
<td></td>
</tr>
<tr>
<td>Telecoms</td>
<td>RK</td>
<td>0..* R</td>
<td></td>
</tr>
<tr>
<td>Directive category</td>
<td>O</td>
<td>Not explicitly specified</td>
<td>Not explicitly specified</td>
</tr>
<tr>
<td>Description</td>
<td>C</td>
<td>section text</td>
<td>section text</td>
</tr>
<tr>
<td>Reference to Legal Document</td>
<td>C</td>
<td>Not explicitly specified</td>
<td>Not explicitly specified</td>
</tr>
</tbody>
</table>
## 15.2.3.23 Functional Status

**Table 25 — IPS Functional Status mapped to HL7 Implementations**

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Section: FUNCTIONAL STATUS</td>
<td>O</td>
<td>IPS Functional Status Section 0..1 O</td>
</tr>
<tr>
<td><strong>Disabilities List</strong></td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>Disability</td>
<td>R</td>
<td>As part of the section text</td>
</tr>
<tr>
<td>Description</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Disability Code</td>
<td>O</td>
<td>Not explicitly specified</td>
</tr>
<tr>
<td>Onset date</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td><strong>Functional Assessments List</strong></td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>Functional Assessment</td>
<td>O</td>
<td>As part of the section text</td>
</tr>
<tr>
<td>Description</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Date of assessment</td>
<td>RK</td>
<td>Not explicitly specified</td>
</tr>
<tr>
<td>Type</td>
<td>RK</td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>Functional Assessment</td>
<td>C</td>
<td></td>
</tr>
</tbody>
</table>

## 15.2.3.24 History of Pregnancy

**Table 26 — IPS History of Pregnancy mapped to HL7 Implementations**

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Section: HISTORY OF PREGNANCY</td>
<td>O</td>
<td>IPS History of Pregnancy Section 0..1 O</td>
</tr>
<tr>
<td><strong>Status of Pregnancy</strong></td>
<td>R</td>
<td>1..1 R</td>
</tr>
<tr>
<td>Pregnancy Description</td>
<td>C</td>
<td>section text</td>
</tr>
<tr>
<td>Structured Description</td>
<td>C</td>
<td>1..1 R</td>
</tr>
<tr>
<td>Date of Observation</td>
<td>R</td>
<td>0..1 R</td>
</tr>
<tr>
<td>Pregnancy State</td>
<td>R</td>
<td>1..1 R</td>
</tr>
<tr>
<td>Expected delivery date</td>
<td>C</td>
<td>0..1 R</td>
</tr>
<tr>
<td><strong>Specialist Contact</strong></td>
<td>O</td>
<td>Not explicitly specified</td>
</tr>
<tr>
<td><strong>Previous pregnancies</strong></td>
<td>O</td>
<td>0..* R</td>
</tr>
</tbody>
</table>
### 15.2.3.25 History of Past Illness

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Section: HISTORY OF PAST ILLNESS</td>
<td>sectionPastIllnessHx (IPS History of Past Illness Section) 0..1</td>
<td>sectionPastIllnessHx (IPS History of Past Illness Section) 0..1</td>
</tr>
<tr>
<td>Past illness content status</td>
<td>The section is usually omitted if no information are available or of interest.</td>
<td>The section is usually omitted if no information are available or of interest.</td>
</tr>
<tr>
<td></td>
<td>The known absence or the non-availability of information may be however explicitly coded in the statement; in this case no other information is required by the model.</td>
<td>The known absence or the non-availability of information may be however explicitly coded; in this case no other information is required by the model.</td>
</tr>
<tr>
<td>Past health conditions and problems list</td>
<td>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.</td>
<td>If the section is present the entry could be omitted and / or the emptyReason element valued.</td>
</tr>
<tr>
<td>Health condition / Problem</td>
<td>1..* R (IPS Problem Concern Entry) Including, 1..* R (IPS Problem Entry)</td>
<td>1..* (Condition resource)</td>
</tr>
<tr>
<td>Problem Type</td>
<td>1..1 R</td>
<td>0..1 mustSupport</td>
</tr>
<tr>
<td>Description</td>
<td>Section text</td>
<td>Section and/or condition text</td>
</tr>
</tbody>
</table>
### 15.2.3.26 Model extensions

**Table 28 — IPS History of Past Illness Model Extensions**

<table>
<thead>
<tr>
<th></th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concern status</td>
<td>1..1 R</td>
<td>1..1</td>
</tr>
<tr>
<td>Observation start date</td>
<td>1..1 R</td>
<td>Supported by the standard resource</td>
</tr>
<tr>
<td>Observation end date</td>
<td>0..1 C</td>
<td>Supported by the standard resource</td>
</tr>
<tr>
<td>Abatement date</td>
<td>0..1 C</td>
<td>0..1 because the same profile is used for closed and open problems</td>
</tr>
<tr>
<td>Clinical status</td>
<td>0..1 R</td>
<td>0..1 mustSupport</td>
</tr>
<tr>
<td>Verification status</td>
<td>0..1 R</td>
<td>0..1 mustSupport</td>
</tr>
</tbody>
</table>

### 15.2.3.27 Plan of Care

**Table 29 — IPS Plan of Care mapped to HL7 Implementations**

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Section: PLAN OF CARE</td>
<td>IPS Plan of Care Section 0..1 O</td>
<td>sectionPlanOfCare (IPS Plan of Care Section) 0..1</td>
</tr>
<tr>
<td></td>
<td>Only Narrative, structured entries not specified (but allowed)</td>
<td></td>
</tr>
<tr>
<td>Plan Description</td>
<td>C</td>
<td>section text</td>
</tr>
<tr>
<td>Plan Description list</td>
<td>C</td>
<td>section text</td>
</tr>
<tr>
<td>Plan</td>
<td>R</td>
<td>Not explicitly specified</td>
</tr>
</tbody>
</table>
### 15.2.3.28 Social History

**Table 30 — IPS Social History mapped to HL7 Implementations**

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS Section: SOCIAL HISTORY</td>
<td>IPS Social History Section 0..1 O</td>
<td>sectionSocialHistory (IPS Social History Section) 0..1</td>
</tr>
<tr>
<td>Life Style Factor list</td>
<td></td>
<td>Structured entries defined only for tobacco and alcohol use</td>
</tr>
<tr>
<td>Life Style Factor</td>
<td>Required as narrative; optional as structured entry</td>
<td>Required as narrative; optional as structured entry</td>
</tr>
<tr>
<td>Description</td>
<td>section text</td>
<td>section text</td>
</tr>
<tr>
<td>Life Style Factor</td>
<td>1..1 R when structured entry</td>
<td>0..* mustSupport when structured entry</td>
</tr>
<tr>
<td>Reference date range</td>
<td>1..1 R when structured entry</td>
<td>0..1 mustSupport when structured entry</td>
</tr>
</tbody>
</table>

### 15.2.3.29 Provenance

**Table 31 — IPS Provenance mapped to HL7 Implementations**

<table>
<thead>
<tr>
<th>prEN 17269</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asserter (Source of Information)</td>
<td>0..* at the section level Not specified but possible at the entry level</td>
<td>At the resource level depending on the resource</td>
</tr>
<tr>
<td>Date of IPS Document Creation</td>
<td>1..1 M</td>
<td>1..1</td>
</tr>
<tr>
<td>Language of document</td>
<td>1..1 M</td>
<td>0..1</td>
</tr>
<tr>
<td>Date of Last Update of IPS content</td>
<td>1..1 R (as end date of the service event)</td>
<td>0..1 mustSupport (as end date of the service event)</td>
</tr>
</tbody>
</table>
15.2.3.30 Model extensions

Table 32 — IPS Provenance Model Extensions

<table>
<thead>
<tr>
<th>IPS author</th>
<th>HL7 CDA IPS</th>
<th>HL7 FHIR IPS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1..* M</td>
<td>1..*</td>
</tr>
<tr>
<td>IPS Authenticator</td>
<td>0..* O</td>
<td>0..* mustSupport</td>
</tr>
<tr>
<td>Section author</td>
<td>0..* O</td>
<td>Not explicitly specified</td>
</tr>
<tr>
<td>Section informant</td>
<td>0..* O</td>
<td>Not explicitly specified</td>
</tr>
</tbody>
</table>

15.3 Projects

15.3.1 General

Research and deployment projects specifications could also claim compliance with the prEN 17269 IPS dataset if they fulfill prEN 17269 IPS conformance rules. For exemplification purposes two cases are summarized hereafter: the eHDSI specification, 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 Guidelines 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.

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

---

21 See https://art-decor.ehdsi.eu/art-decor/decor-project--epsos-
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

```xml
<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>
    </patientRole>
  </recordTarget>
</ClinicalDocument>
```
<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"/></translation></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>
  </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">
  </structuredBody>
</component>
<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>
<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>
</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">

</tbody></table>
</text>
</component>
Anastrozole 1 mg tablet once daily for breast cancer.

Anastrozole 1 mg tablet, treatment for breast cancer.

<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"/></translation>
        </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 codeSystem="2.16.840.1.113883.6.96" displayName="Anastrozole (substance)"/>
        </pharm:ingredientSubstance>
      </pharm:ingredient>
      </manufacturedMaterial>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
<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 &and; 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>

<observationRelationship typeCode="SUBJ" inversionInd="false">

<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>
15.4.2 IPS FHIR example

```xml
<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://fhirtest.uhn.ca/baseDstu3/Composition/IPS-examples-Composition-01"/>
    <resource>
  </subject>
  <date value="2017-07-20T14:30:00+01:00"/>
  <author> <reference value="http://fhirtest.uhn.ca/baseDstu3/Practitioner/IPS-examples-Practitioner-01"/>
    <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="http://fhirtest.uhn.ca/baseDstu3/Practitioner/IPS-examples-Practitioner-01"/>
        </party>
      </attester>
      <attester> <mode value="legal"/> <time value="2017-07-20T14:30:00+01:00"/>
          </party>
        </attester>
      </author>
    </Composition>
  </entry>
</Bundle>
```
<event>
<code><coding><system value="http://hl7.org/fhir/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"/></coding></code>
<text><status value="generated"/> <xhtml:div>Hot flushes</xhtml:div></text>
<entry><reference value="http://fhirtest.uhn.ca/baseDstu3/Condition/IPS-examples-Condition-01"/></entry></section>

<section><title value="Medication"/>
<code><coding><system value="http://loinc.org"/> <code value="10160-0"/><display value="Medication use"/></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>

<section><title value="Allergies and Intolerances"/>
<code><coding><system value="http://loinc.org"/> <code value="48765-2"/><display value="Allergies and/or adverse reactions"/></coding></code>
<text></text></section>
<text><status value="generated"/></text><xhtml:div>Allergy to penicillin, high criticality, active</xhtml:div></text>

<entry>
<reference value="http://fhirtest.uhn.ca/baseDstu3/AllergyIntolerance/IPS-examples-AllergyIntolerance-01"/></entry>

</section>
</Composition>
</resource>
</entry>
<entry>
<fullUrl value="http://fhirtest.uhn.ca/baseDstu3/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="PatSurnameExample"/><given value="PatNameExample"/></name>
<telecom>
<system value="phone"/><value value="+31788700800"/><use value="home"/>
</telecom>
<gender value="female"/>
<birthDate value="1950-01-15"/>
<address>
<line value="Some Street, 1"/><city value="SomeCity"/><country value="SomeCountryCode"/>
</address>
<contact>
<relationship>
<coding>
<system value="http://hl7.org/fhir/v3/RoleCode"/>
<code value="MTH"/></coding>
</relationship>
<name>
<family value="PatSurnameExample"/><given value="Mum"/>
</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="FR"/></address>
</contact>
</Patient>
</resource>
</entry>
<entry>
<fullUrl value="http://fhirtest.uhn.ca/baseDstu3/Practitioner/IPS-examples-Practitioner-01"/>

<resource>
<Practitioner>
<id value="IPS-examples-Practitioner-01"/>
</Practitioner>
</resource>
</entry>
<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>


<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="NL"/></address>
</Organization>
</resource>
</entry>

<entry> <fullUrl value="http://fhirtest.uhn.ca/baseDstu3/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-aa62bd93002"/></identifier>
<clinicalStatus value="active"/><verificationStatus value="confirmed"/>

</Condition>
</resource>
</entry>
<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></code>
<subject> <reference value="http://fhirtest.uhn.ca/baseDstu3/Patient/IPS-examples-Patient-01"/>
<onsetDateTime value="2015"/>
<assertedDate value="2016-10"/>
</Condition>
</resource>
</entry>
<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>
<effectivePeriod><start value="2015-03"></effectivePeriod>
<subject> <reference value="http://fhirtest.uhn.ca/baseDstu3/Patient/IPS-examples-Patient-01"/>
<taken value="y"/>
<dosage>
<timing><repeat><count value="1"/><periodUnit value="d"></repeat></timing>
<route><coding><system value="urn:oid:0.4.0.127.0.16.1.1.2.1"/> <code value="20053000"/> <display value="Oral use"/></coding></route>
<doseQuantity><value value="1"/> <unit value="tablet"/> <system value="http://unitsofmeasure.org"/> <code value="1"/></doseQuantity>
</dose>
</MedicationStatement>
</resource>
</entry>
<entry> <fullUrl value="http://fhirtest.uhn.ca/baseDstu3/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://fhirtest.uhn.ca/baseDstu3/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 value="active"/> <verificationStatus value="confirmed"/>
<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>
<onsetDateTime value="2010"/>
</AllergyIntolerance>
</resource>
</entry>
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.
The test strategy will describe processes needed for testing the patient summaries within a project according to 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 [13]. 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 Environment](image)

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](image)

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.
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 guidelines 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 guidelines 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 guidelines, 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 guidelines 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 wholesale 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; the 17269 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


[3] D1.1 Refinement of Antilope Use Cases (v1.2),

[4] D2.1 Extension of the eEIF: five new Use Cases,
http://www.estandards-project.eu/estandards/assets/File/deliverables/estandards%20D2_1%20Extension%20of%20the%20eEIF%20Five%20new%20Use%20Cases%20V1_3.pdf


[9] eHDSI,
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] SEMANTIC HEALTH NET. www.semantichealthnet.eu/

