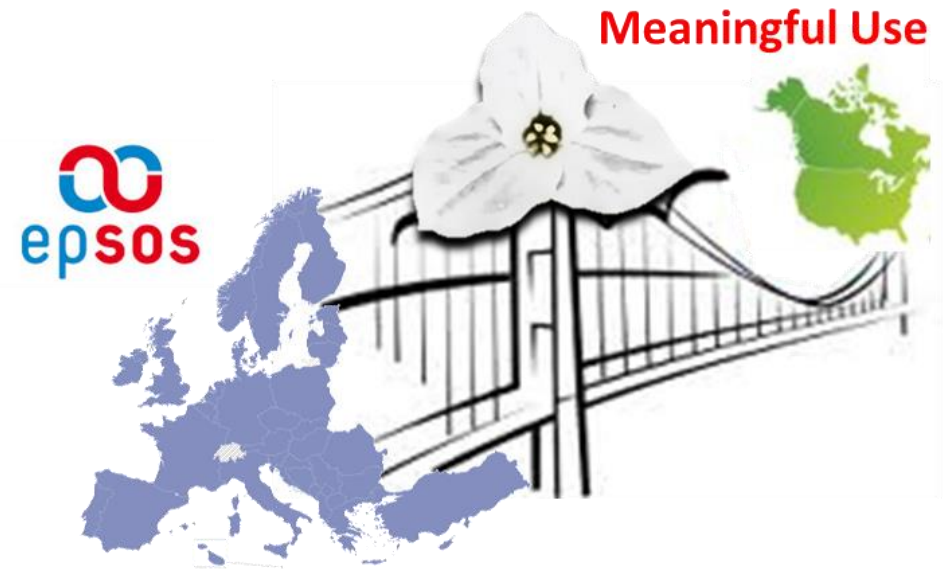
Trillium Bridge

Bridging Patient Summaries across the Atlantic



WP 2 – Comparing Patient Summaries

Deliverable 2.2

Comparing Patient Summaries in the EU and US: Gap Analysis and Pilot Use Case Definition

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1 Executive Summary

The Trillium Bridge project supports the Transatlantic eHealth/health IT Cooperation Memorandum of Understanding (EC-HHS MoU)[1] and Roadmap[2] and the Digital Agenda for Europe[5] (DAE) in achieving a win for eHealth (health IT) by establishing the foundations of an interoperability bridge for **the meaningful exchange of patient summaries and electronic health records between the EU and US.**

Framing the system of transatlantic exchange of EHRs as a bridge, Trillium Bridge Work Package 2 (WP2) "Comparing Patient Summaries" is the first step in making concrete the structures needed for EU-US EHR interoperability.

The expected outcomes of the Trillium Bridge project are:

(a) Improved international interoperability of eHealth Systems in the US and in Europe

(b) Accelerated establishment of interoperability standards in eHealth and of secure, seamless communication of health related data

The Trillium Bridge project focuses on the epSOS Patient Summary and the HL7 C-CDA Continuity of Care Document (CCD). The epSOS project (www.epSOS.eu) designed, built, and evaluated a service infrastructure for cross-border interoperability between electronic health record systems in Europe and created the Patient Summary specifications on which the European Guideline for Patient Summaries is based. HL7 C-CDA/CCD is referenced in the US Meaningful Use Stage II program that cites certification criteria for EHR technology and provides incentives for its use.

This document, Deliverable D2.2 ("Comparing Patient Summaries in the EU and the US: Gap Analysis and Pilot Use Case Definition") consolidates the work of WP2, reporting on the following tasks:

- Create an inventory of resources including standards, profiles, tools, methodologies, etc. (§3)
- Develop user stories extending the epSOS use case and Meaningful Use-Transitions of Care in the transatlantic context to cover patient and provider mediated exchange of patient summaries (§4)
- Compare patient summary documents and clinical domains and perform a gap analysis (§5, §6, §7)
- Develop a business architecture to support pilot use cases addressing legal and regulatory issues (§8)

Readers will have the opportunity to understand the way HL7 CDA is used to express patient summaries in the EU (EU PS Guideline/epSOS) and in the US (MU2/ Transitions of Care/Bluebutton), and the possibility of extending existing infrastructures (epSOS and the health information exchanges in the US) to meet each other. They will also gain a sense of the prospects, as we move forward towards consolidation in global standards for patient summaries.

User stories were provided by Elaine Blenchman of SmartPHR, Larry Garber of Atrius Health, Iciar Abad of the Spanish Ministry of Health, and Dipak Kalra of EuroRec. Overall, there was great interaction and exchange of ideas with the ONC S&I Framework EHR Interoperability Workstream and several user stories that emerged from the relevant calls are referenced here.

[1] Memorandum of Understanding between the United States Department of Health and Human Services and the European Commission on Cooperation surrounding health related information and communication technologies (ICT): http://ec.europa.eu/information_society/activities/health/docs/policy/eu-usa-mou-ehealth-signed2010.pdf

[2] Transatlantic eHealth/health IT Cooperation MoU Roadmap: http://ec.europa.eu/information_society/newsroom/cf/dae/itemdetail.cfm?item_id=9389.

The EU Trillium Bridge partners, Spanish Ministry of Health, Portuguese Ministry of Health and Lispa for the Lombardy Region, expressed selected user stories based on their epSOS implementation. The US Trillium Bridge partners, Lantana, Atrius Health, and Kaiser Permanente, expressed patient summaries associated with user stories in HL7 CCDA/CCD. The HL7 Foundation reviewed this information and developed the "gold standard" epSOS patient summary for two user stories: Martha, an American woman, cancer survivor, who has an accident in a visit to Italy, and Paolo a retired businessman from Europe that loses his new hypertension medicine while visiting Boston and experiences side-effects. Lantana provided the "gold standard" for the HL7 CCDA/CCD expression of user stories. The patient summary samples in the EU and US version of CCD are available in http://www.trilliumbridge.eu/repository. For more information please review section 4 (From User Stories to Use Cases).

Starting from a set of user stories and the Patient Access (PAC) and Health Care Encounter Report (HCER) services developed in epSOS, use cases of transatlantic patient summary exchange were elaborated.

The use cases developed in Trillium Bridge use technology to target a clear need: when a patient needs unplanned care overseas, an EHR summary fit for the purpose of safe and efficient health care is available. After the health care encounter, the patient receives an encounter report in a format and language that can be understood back home. The use cases are presented and analyzed in section 5 (Use Case Analysis) where issues of security and privacy are also addressed with contributions by the Trillium Bridge Legal Team.

Considering the emerging health information technology infrastructure in the EU and the US, the recognized need of EU/US EHR exchange maps into two use cases: (a) Provider mediated (provider initiated, citizen controlled), and (b) Patient mediated (citizen initiated, citizen controlled).

In the eHealth Forum 2014, May 12-14, in Athens Greece, in collaboration with the OpenNCP community and Gnomon Informatics, parts of the logical architecture presented in section 8 (Architectural Design) were demonstrated. Engaging the OpenNCP community of practice is critical aspect of advancing interoperability.

Gap analysis proceeded in three parallel streams: (a) participating the activities of the ONC S&I EHR Interoperability WG, (b) carrying out an independent analysis of the EU PS Guideline Specification, the epSOS specification, and HL7 C-CCDA CCD, (c) analyzing the patient summaries of Paolo and Martha to gain insights on how the relevant specifications are implemented, and whether a common vocabulary and syntax transformation were possible. Ana Esterlich (PHAST), Harold Solbrig (Mayo), Zabrina Gonzaga, Russ Ham, and Sarah Gaunt (Lantana), Giorgio Cangioli (HL7), Dipak Kalra (EuroRec), and Marcelo Melgara (Lispa) contributed directly or indirectly to this effort. Notable among findings are the following:

(1) The need for education in use or constraining of standards: differences in the use of the CCDA/CCD templates to convey clinical information were noted in Europe and the US. Perhaps endorsement, wide adoption, and use of automated tools can alleviate some of these discrepancies.
(2) The need to address structure and value sets together: mapping value sets and quality assuring those mapping is very difficult. Minimal confirmed, validated, and authorized value sets can help in the transition phase.
(3) The need to weigh differences in culture, policy or purpose: the emphasis in the US clinical summary is on continuity of care, while the EU PS Guideline is predominately a snapshot to be used in unplanned care. We decided to deliver on the baseline interoperability assets, so that other initiatives can follow through.
(4) Engaging a community of practice such as the OpenNCP community is a critical aspect of advancing interoperability in a sustainable and incremental way.

Further information is provided in section 6 (Comparison) and 7 (Challenges of Mapping). This work will continue in WP3 (Interoperability Assets).

Having established the patient summary baseline in the work presented here, Trillium Bridge will proceed to identify and deliver interoperability assets in WP3 (led by Ana Estelrich of Phast and Harold Solbrig of Mayo) to be validated in WP4 (led by Karima Bourquard IHE Europe).

2 Introduction

Trillium Bridge is a collaborative project to establish the foundations of an interoperability bridge between European Patient Summaries and United States (US) Meaningful Use Stage 2 Transitions of Care documents so that patient health data can follow patients when they travel between the US and European Union (EU) countries.

Trillium Bridge addresses Objective ICT-2013.5.1 e4: "Interoperability of patient summary between EU and US". The aim of proposals submitted under FP7 ICT Call 10, page 57, is *"To compare specifications of EU and US patient summaries with the aim of developing and testing common and consistent specifications and systems allowing the interoperability of electronic health records across the Atlantic."*

The exchange of patient summaries between the EU and US will serve as a case study for exploring possible extensions of the eHealth Action Plan 2012-2020[3], which will foster EU-US collaboration on topics of common interest in the area of health-related ICT. Trillium Bridge's game-changing approach employs **patient-** and **provider-mediated** user scenarios to address all aspects of interoperability (**clinical, technical, semantic, organizational, and legal**) as detailed in the eHealth Action plan 2012-2020 and the ISA eHealth Interoperability Framework report[4]. The project will create a community of knowledge, identify knowledge gaps and mobilize resources to help bridge those gaps, and assemble interoperability assets. These results will foster synergies and collaborations that will catalyze common understanding and will drive wide adoption of common **global eHealth standards** and specifications. The linkages created by Trillium Bridge will ensure sustainable healthcare systems and delivery of high quality care, unlocking the market potential for innovative solutions.

This deliverable, D2.2 completes the work of WP2, presenting comparison and gap analysis of patient summary specifications as used in the US under MU-II and Europe under EU PS Guideline and epSOS, then in the context of a logical business architecture presents the selected use cases as derived from user stories.

2.1 Background

The Trillium Bridge Work Package 2 (WP2) compares selected patient summary specifications from the EU and US and to conduct a gap analysis. WP2 has four parts with the following objectives:

- [O.WP2.1] Develop user stories by extending the European Patients - Smart Open Services (epSOS) use case and Meaningful Use/Transitions of Care in the transatlantic context to cover patient and provider mediated exchange of patient summaries
- [O.WP2.2] Create an inventory of resources including standards, profiles, tools, methodologies, etc.
- [O.WP2.3] Develop a business architecture to support the pilot use cases addressing legal and regulatory issues
- [O.WP2.4] Compare patient summary documents and clinical domains and perform a gap analysis

[3] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: eHealth Action Plan 2012-2020: Innovative Healthcare for the 21's century http://ec.europa.eu/information_society/newsroom/cf//document.cfm?doc_id=1252

[4] ISA eHealth Interoperability Framework program and recent workshop report: http://ec.europa.eu/isa/documents/isa_action2-12.pdf http://ec.europa.eu/isa/actions/documents/isa_2.12_ehealth1_workprogramme.pdf; Presentation and report from the Nov 7, eHealth EIF workshop organised on 8/11 in Brussels; final project report is about to be released.

2.2 Scope and Objectives of This Analysis

This document, D2.2, is the public deliverable based on the initial analysis in Internal Deliverable 2.1 (D2.1), restricted to program participants, which identified interoperability resources and developed the outline of user stories for use case selection upon which the Trillium Bridge will be built. D2.1 also outlined elements of possible business architecture and presented a collection of relevant patient summary data sets currently used on the two sides of the Atlantic. This analysis continues that initial work, taking into account the wider context of activities related to the EU-US Memorandum of Understanding (MoU) on eHealth/Health IT cooperation and the activities performed in conjunction with the Standards and Interoperability (S&I) Framework WG on EHR interoperability.

Exchange of health data in the EU is guided by the recently adopted European Guideline on a minimum data set for Patient Summaries, defined by epSOS and adopted by eHealth Governance Initiative and eHealth Network.[5] Health data exchange in the US is guided by the Meaningful Use C-CDA/CCD specification. In the analysis described in this document, epSOS and C-CDA/CCD are applied to a set of proposed use cases that illustrate EU citizens visiting the US and vice versa. In addition, the use cases illustrate both patient mediated and provider mediated document exchange.

Deliverable D2.2 addresses three tasks:

(1) The use cases from D2.1 are extended by comparing patient summary documents and clinical domains.
(2) A gap analysis of these use cases identifies a small number of constrained use cases that will guide alignment in WP3 and testing and validation in WP4.
(3) An analysis of how each use case can be architected details the interoperability resources and interactions that need be considered to implement the Trillium Bridge.

The analysis details how clinical concepts are rendered in the EU Member State Patient Summaries, transformed to epSOS CDA, and are made available to US health professionals. The analysis then details how C-CDA CCDs of the same patients are rendered into epSOS CDA format.

A high-level comparison of the underlying clinical document specifications is compared, section by section, from a clinical and terminology viewpoint. The goal is to establish whether there is equivalence between the document templates and the associated value sets. This analysis is a clinical support to WP3, the detailed comparison between EU and US data sets and value sets.

The business architecture includes all aspects of interoperability: who, what, where, when, and how. Particular attention is given to the elements addressing Identification (e.g. electronic identification), security, and privacy. On these topics, the analysis crosses over to WP5: “Aligning Policy, Standardization and Future Sustainability” and deliverable D5.1 (draft strategy briefs in areas relevant to the adoption and sustainability of the Trillium Bridge summary focusing on security and trust). The analysis addresses questions of document creation and storage; identification of patients, health professionals, and healthcare facilities; attesting to the authenticity of content; and how security and privacy issues are addressed. Legal and organizational interoperability aspects of the document exchange processes will be addressed as part of WP5. These issues are briefly addressed here in the form of assumptions, preconditions, and post conditions associated to the presented use cases.

The business architecture analysis examines high-level specifications of components and processes, as input to WP4 for the implementation of the first proof of concept and the consolidated demonstrators.

[5] See 3.1.2 for details on eHealth Governance Initiative (eHGI) and eHealth Network (eHN).

2.3 Methodological Approach

The D.2.2 activities were organized to minimize the impact of working over nine time zones (from Central Europe to US Pacific time), concentrating EU-US call conferences in limited time slots, complementing them with exchange of written material and Continental sub-calls. Input has also been provided through fruitful discussion in the US Office of the National Coordinator Standards and Interoperability (ONC S&I) EHR Interoperability work stream weekly calls.

2.3.1 Use Case Analysis

The initial identification of the user stories and of use cases was performed before the Trillium Bridge kick-off meeting in September 2013 so that the meeting could focus on the analysis and the initial selection of the use cases.

The preparation of the D.2.1 internal document allowed project participants to better understand contents and constraints of Meaningful Use and epSOS, and to draw on relevant initiatives such as the S&I Framework, EU-US Memorandum of Understanding, EU eHealth Network (EC DG Sanco), eHealth Governance Initiative (EC DG-Connect/EC DG Sanco). Chapter 3, International Background, in this document provides both a political/strategic view on these initiatives and a first look at the clinical interoperability assets provided by epSOS and Meaningful Use.

After the scoping, collecting and analyzing phase of user stories and use cases, the describing and selecting phase graded the narratives according to criteria of:

- Relevance, as identified by the key EU / US experts
- Clinical matching between the selected documents and the associated organizational processes
- Technical feasibility in the Trillium Bridge time frame

The final step of the analysis in this document was transferring identified issues to WP5 "*Aligning Policy, Standardization and Future Sustainability*", for a thorough gap analysis and proposing further actions to fill the legal, clinical, organizational and technical gaps. For further details about the methodology applied for the user stories and use cases please refer to the methodology section of the chapter: From User Stories to Use Cases.

2.3.2 Gap Analysis

The gap analysis performed in WP2 examines document structures and the clinical purpose of the sections and data elements. It represents a macro level assessment in preparation for a detailed, micro level analysis that will be performed by WP3.

In particular, WP2 checks the contents, the list of the sections, and the data elements. This high level analysis is shared with ONC S&I work group dealing with the EU-US interoperability topics from the US side, with the goal of reciprocal support and quality assessment.

Gap analysis is also provided on the way in which jointly agreed standardized patient summaries for the citizens of the user's stories, are implemented in the US services and in the EU Countries. These gaps represent a significant evaluation of the distance between the goal of document exchange and the reality given the current healthcare service practices.

2.4 High Level Architecture

The basic clinical document exchanged in the EU is the Patient Summary, defined in epSOS over HL7 CDA and adopted through eHealth Network under Article 14, EU Guideline for Patient Summary.

On the US side, the basic exchange document is the Continuity of Care Document (CCD), based on HL7 C-CDA, specified by Meaningful Use. [6] CDA defines the structure and semantics of clinical document using XML to define the structure of the document and controlled terminologies to unambiguously represent clinical concepts being conveyed. There are two main parts to a CDA document, the CDA *Header*, and the CDA *Body*. The CDA Header contains information about the document and defines the context for the information conveyed in the body of the document. Information in the CDA Header includes but is not limited to:

- Participants such as the patient, physician, and author
- The type of document, the encounter or event
- The location of the encounter or event, the document recipient's location
- The date the document was created, the date of the encounter or event

The CDA Body contains clinical information about the patient represented by the Header. The content of the Body is structured using XML and separated into document *Sections* such as Chief Complaint, Medications, Allergies, etc. Each Section is required to contain human readable narrative text. Optionally, a section can also include coded *Entries*. CDA Entries are combined with and compliment the Structured Body in a CDA document. The narrative text is used for human readability while Entries are used for computational interoperability. Entries allow terminologies such as SNOMED CT, LOINC or RxNorm to encode the narrative text for use by systems for automated organization, parsing, reporting or other secondary uses of information like research.

At a functional level, a document generated in Europe must be translated and mapped to a European Patient Summary in epSOS format and then be transformed for transmission to the US.

The following picture gives a high level view of the process of "Provider Mediated Interoperability" initiated in the European Union (EU). Providers in the EU prepare the document for transformation and transmission.

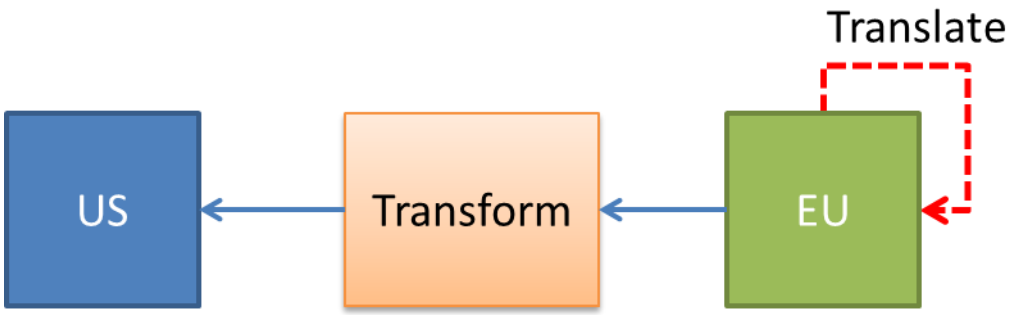

Figure 1 - Provider Mediated Interoperability when Information is Directed from the EU to the US

On the other side, a US patient summary document must be transformed into an epSOS patient summary document and translated for the health professional into his own language.

[6] HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1 - US Realm: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258

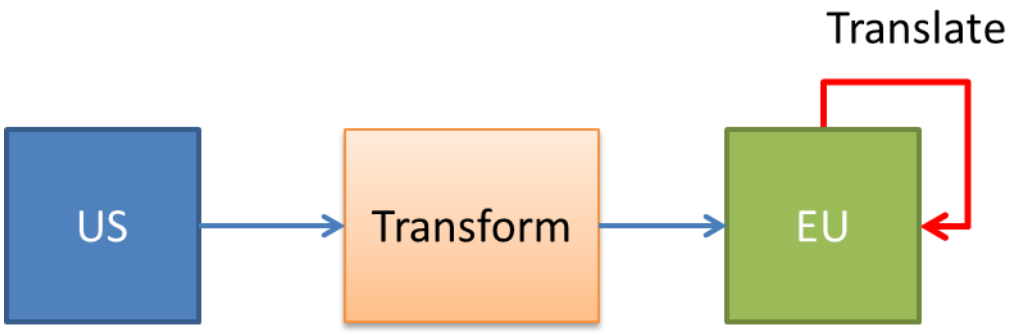

Figure 2 - Provider Mediated Interoperability Initiated in the US

In the case of the "User Mediated Interoperability", one of the transmission paths is performed or initiated by a citizen. Transmission can be performed directly by her, or through a media service provider, but always under the citizen's control.

The first picture displays the case of a document generated in US "ready for use" in the EU.

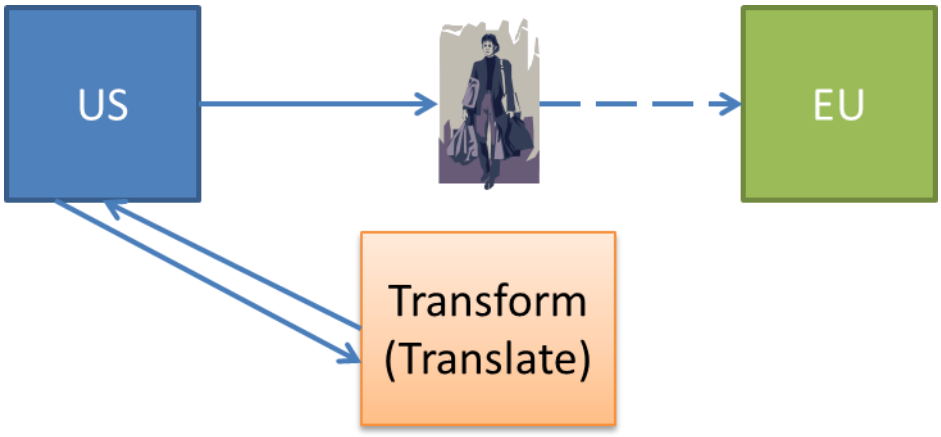

Figure 3 – Patient (User) Mediated Interoperability: Patient Summary Document Generated in the US for Use in the EU

The following picture illustrates the case in which the document is treated (transformed and translated) by the receiver.

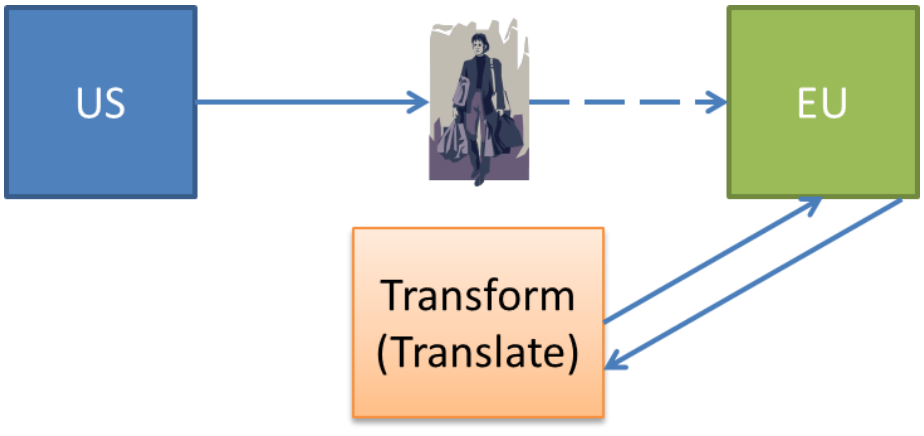

Figure 4 – Patient (User) Mediated Interoperability: Patient Summary Document Generated in the US and Transformed in the EU

The Trillium Bridge user stories and use cases have been developed from these four simplified examples. The Trillium Bridge Architecture is described in detail in Chapter 8, Architectural Design.

3 International Background

3.1 EU / US Memorandum of Understanding (MoU)

Trillium Bridge supports the objectives of the Memorandum of Understanding (EC-HHS MoU) and Roadmap for EU/US cooperation on health related information and communication technologies signed between the European Commission (Vice President N Kroes) and the United States Department of Health and Human Services (Secretary K. Sibelius)[7,8]:

- *"…cooperation on topics directly pertaining to the use and advancement of eHealth/health IT, in pursuit of improved health and health care delivery as well as economic growth and innovation…"*
- *"…the development of internationally recognized and utilized interoperability standards and interoperability implementation specifications for electronic health record systems that meet high standards for security and privacy protection..."*

The vision of the MoU Roadmap is:

> *"…to support an innovative collaborative community of public and private-sector entities including suppliers of eHealth solutions working together for the shared objective of developing, deploying and using eHealth science and technology to empower individuals, support care, improve clinical outcomes, enhance patient safety and improve the health of the populations..."*.

This vision is furthered by the consortium and wider community of Trillium Bridge, which includes policy makers, government officials, industry representatives, provides, standardization experts, and academicians. The Trillium Bridge community shares best practices and collaborates on eHealth innovations, starting with the exchange of patient summaries. This collaboration leads to shared understanding that can produce globally adopted standards and specifications in healthcare IT. The table below summarizes the alignment of the EC-HHS Roadmap objectives with the activities of WP2 and WP3.

Roadmap Objectives	Trillium Bridge WP	Trillium Bridge Deliverable/ Milestone
Create initial set of use cases, based on community and stakeholder input	WP2	D2.2: Comparing Patient Summaries in the EU and US: Gap analysis and Pilot Use Case definition
Compare existing US and EU vocabularies, terminologies and clinical models to identify areas of overlap and commonality	WP2/WP3	D2.1: Inventory of Patient Summaries in the EU & US: Use Cases, Projects, Specs, Terminologies, Privacy & Security. D3.1 Clinical Model and Terminology Mappings: Methodological Approach and User Guidance
Identify available resources and opportunities for aligning them (technology and standards to support ongoing collaboration with vocabularies, modeling, and interoperability)	WP2/WP3	D2.1: Inventory of Patient Summaries in the EU & US: Use Cases, Projects, Specs, Terminologies, Privacy & Security D3.1 Clinical Model and Terminology mappings: Methodological Approach and User Guidance
Agree on specifications, standards and architecture for the pilot	WP2/WP3	D2.2 Comparing Patient Summaries in the EU and US: Gap Analysis and Pilot Use Case Definition

[7] Memorandum of Understanding between the United States Department of Health and Human Services and the European Commission on Cooperation surrounding health related information and communication technologies (ICT): http://ec.europa.eu/information_society/activities/health/docs/policy/eu-usa-mou-ehealth-signed2010.pdf

[8] Transatlantic eHealth/health IT Cooperation MoU Roadmap: http://ec.europa.eu/information_society/newsroom/cf/dae/itemdetail.cfm?item_id=9389.

Roadmap Objectives	Trillium Bridge WP	Trillium Bridge Deliverable/ Milestone
Compare the data/document structures used in the US and EU by comparing the consolidated CDA (C-CDA) and the exchange standards used in epSOS	WP2/WP3	D2.2: Comparing Patient Summaries in the EU and US: Gap Analysis and Pilot Use Case definition D3.1 Clinical Model and Terminology mappings: Methodological Approach and User Guidance
Compare existing US and EU legal, policy and organizational frameworks regarding eIdentification of patients and healthcare providers, data privacy, security and exchange to identify potential barriers to piloting	WP2/WP5	D2.2: Comparing Patient Summaries in the EU and US: Gap Analysis and Pilot Use Case definition D5.1 Draft Strategy Briefs in Areas Relevant to the Adoption and Sustainability of the Trillium Bridge Summary Focusing on Security and Trust D5.2 Final Versions of Strategy Briefs, as Outputs from Multi-Stakeholder Workshops Held in Collaboration with Other Initiatives: Feasibility Analysis for EU/US Patient Summary Exchange
Define framework requirements for semantic infrastructure and services	WP2/WP5	D2.1: Inventory of Patient Summaries in the EU & US: Use Cases, Projects, Specs, Terminologies, Privacy & Security D5.1 Draft Strategy Briefs in Areas Relevant to the Adoption and Sustainability of the Trillium Bridge Summary Focusing on Security and Trust

Table 1 - EC-HHS Roadmap and Trillium Bridge Activities

Through its members, Trillium Bridge is engaged in leading initiatives in the EU and the US. In the context of the Transatlantic Exchange of Patient Summaries, key linkages are the S&I Framework (EHR Interoperability Work Group) and the Guideline for European Patient Summaries. The Guideline is based on epSOS, developed by the eHealth Governance Initiative, and approved in November 2013 by the eHealth Network established under Article 14 of the Directive 2011/24/EU of the Parliament and Council (eHN) on the application of patients' rights in cross-border healthcare.[9] Each of these initiatives is briefly outlined below in relation to use cases and specifications relevant to the transatlantic exchange of patient summaries.

3.1.1 Standards & Interoperability (S&I) Framework EHR Interoperability Work Group

The ONC S&I Framework is a method of organizing collaborative projects related to standards and interoperability. The S&I Framework is sponsored by the United States Office of the National Coordinator (ONC) for Health IT of the Department of Health and Human Services (HHS). Through the use of the project wiki[10] and regular weekly conference calls, the project coordinators have guided a group of international collaborators from industry, government, and academia to develop user stories and use cases for testable pilot projects.

Several user stories have been proposed and discussed in this group. These include: moving from country to country (immunization record), broken eyeglasses, planned care, emergency care (heart attack/admission emergency), someone acting on behalf of another (medical emergency while a group of students is traveling), lost prescription/refill (e.g., blood pressure medication), and general practitioner/ambulatory admission for a pre-existing condition out of control (e.g., diabetes).

Starting from these user stories, the group is developing a limited number of use cases that will be analyzed for actors involved, pre-conditioned and post-conditions, data types, etc. Selected use cases are being reviewed and their feasibility assessed before the attempting a pilot project. Establishing assumptions and

[9] EC Directive on the application of patients' rights in cross-border healthcare (2011/24/EU) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF

[10] Standards and Interoperability Framework – EHR Interoperability Workstream: http://wiki.siframework.org/EU-US+eHealth+Cooperation+Initiative

testing these use cases to show successful exchange of health information will reveal gaps and limitations, articulating areas for further engagement and improvement.

One barrier that has already been recognized is the need for shared vocabularies, including governance and maintenance mechanisms, for the transatlantic exchange of patient summaries. Trillium Bridge addresses this topic in the context of selected use cases by comparing the epSOS value sets with those of the National Library of Medicine (referenced by MU2) as part of WP2 and WP3. Governance will be addressed as part the feasibility analysis in WP5. Additional barriers to security and privacy are recognized. In epSOS, security and privacy are addressed by the Framework Agreement for National Contact Points.[11] In the US Nationwide Health Information Network (NHIN), Health Information Exchanges co-sign a trust agreement, i.e., Data Use and Reciprocal Support Agreement (DURSA)[12]. DURSA provides the legal framework governing participation in the NHIN by requiring participants to abide by a common set of terms and conditions.

Trillium Bridge follows the S&I Framework and plans to share the project progress and key deliverables, which are focused on epSOS and MU2 Transitions of Care.

3.1.2 eHealth Governance Initiative (eHGI) - Guideline European Patient Summaries

The objective of the eHealth Governance Initiative (eHGI) is to actively contribute to shaping the eHealth political agenda at the EU level, with a specific focus on interoperability. In particular, eHGI supports three priorities of the eHealth Network[13]:

(1) Submitted draft conclusions on eID EU Governance for eHealth Services to the eHealth Network
(2) Commissioned analysis of the domain of Semantic and Technical Interoperability including development of recommendations for a minimum data set to be used in the cross-border exchange of patient summaries[14] and ePrescriptions
(3) Facilitated dialog dealing with the health data element for replacement of the earlier Directive on Data Protection with a regulation

The 3rd meeting of the eHN in May 2013 recognized the importance of adopting the basic and extended Patient Summary (PS) data sets from epSOS and requested that the eHealth Governance Initiative create guideline on patient summary data that can be exchanged electronically across borders. The Guideline on Patient Summaries is seen as a living document that will be enhanced over time.

The primary focus of the Guideline is to support the objective of continuity of care and patient safety across borders, as stated in article 14, paragraph 2 of the Directive on patients' rights in cross-border healthcare.[15] The Guideline focuses on **emergency** or **unplanned care in a cross-border context** (section 2.3 provides illustrative use cases). The secondary focus of the Guideline is **for reference use at a national level**. More advanced and elaborate patient summaries exist in some Member States (MSs), but the eHealth Network agreed that the Guideline could serve as a common baseline of Patient Summaries at national level.

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[11] Framework Agreement on National Contact Points in the context of the epSOS Project http://www.epsos.eu/fileadmin/content/pdf/Framework_Agreement_on_National_Contact_Points_V2.pdf

[12] Data Use an Reciprocal Support Agreement http://www.nationalehealth.org/dursa#sthash.HUJz6ea4.dpuf

[13] Priority areas for the eHealth Network: http://www.ehgi.eu/Pages/default.aspx?articleID=20

[14] Guideline on Patient Summary minimum/non exhaustive dataset for electronic exchange under the cross-border directive 2011/24/EU

[15] EC Directive on the application of patients' rights in cross-border healthcare (2011/24/EU) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF

Member States refer to the Guideline to understand what data are to be included in the PS and to assess the implications of adopting such a PS in practice, especially in terms of organizational, technical, and semantic requirements. The goal of eHN is for Member States to commit to implement the data set in their national systems.

Annex B and C of the Guideline list terminologies and standards that are relevant to the implementation of Patient Summaries. For cross-border exchange, the document structure should be conformant to the epSOS Patient Summary Specification, which is based on HL7 Clinical Document Architecture (CDA) Version 2 and the IHE Patient Care Coordination Technical Framework (IHE PCD TF). The exchange should be conformant to the epSOS Common Components Specifications using IHE profiles XCPD, XCA, XDR and optionally XCF.

3.1.3 Relations among the EU and US Initiatives

The EU/US MoU refers to activities planned and performed in eHN and eHGI (in the EU) and in the S&I Framework (in the US). On both sides of the Atlantic, technical inputs and practical actions are performed by co-operative projects such as epSOS, Trillium Bridge, and EXPAND (starting in 2014).

All these initiatives are aligning their activities towards strengthening synergies much as possible.

3.2 European Patient Smart Open Services (epSOS)

epSOS is a large-scale pilot co-funded by the European Commission (EC) for 66 months (1st July 2008 – 30 June 2014) with 36,5M€ under the EC CIP/PSP Program with 47 Beneficiaries from 22 EU member countries and 3 non-EU members. National ministries of health, competence centers, an industry consortium, and the Project Management Team design, build, and evaluate a service infrastructure that demonstrates cross-border interoperability between electronic health record systems in Europe. The epSOS services are:

(1) Cross-border use of electronic prescriptions
(2) Patient Summary (PS) access to important medical data for patient treatment and other PS-based services
(3) Return of Healthcare Encounter Report (HCER) to the country of affiliation
(4) Medication related overview (including allergies) for pharmacists
(5) Patient access to individual data

Availability of epSOS services is updated with indication of the points of care.[16]

Trillium Bridge will work with the epSOS patient summary specifications in the context of two scenarios: (a) integration of Patient Summary Services (providing the PS from the country of affiliation and receiving the Healthcare Encounter Reports generated in the country of care), and (b) patient access to individual data. User stories in a transatlantic setting associated with these use cases were developed under Lispa, the architecture lead in epSOS, with participation of the Ministry of Health in Spain and Portugal. These participants are committed to providing validation sites for the Trillium Bridge and running their National Contact Points infrastructure.

The epSOS interoperability assets (semantic resources) are evaluated leveraging the transcoding and translation already performed and extending those to the Meaningful Use Stage 2 (MU-2) value set. A CTS2 based approach will facilitate the efforts. License and quality assurance aspects will be addressed in common with IHTSDO, under the “public good” principle. Relations with the standards development organizations (SDOs) will be assessed for legal/business constraints. Synergy and direct cooperation with epSOS partners is at the core of the work performed in WP2 (Use Case and Gap Analysis), WP3 (Assembling Interoperability

[16] http://www.epsos.eu/point-of-care-database/poc-database.html

Assets), WP4 (Testing and Validation), and WP5 (Policy Alignment, Standardization, and Future Sustainability).

For the purposes of this project, it is important to make the distinction between **Country A** (the patient country of affiliation, where his or her documents are created/stored) and **Country B** (the country of treatment where the patient receives unplanned care). The primary purpose of the electronic Patient Summary in the epSOS Large Scale Project is to provide the Health Care Professional (HCP) with a data set of key health information at the point of care for delivery of safe patient care during both unscheduled and planned care. The PS is not the entire medical record but the essential patient information needed so that assistance can be provided.[17]

An epSOS[18] Patient Summary document is delivered via the National Contact Point (NCP) of the country of origin (Country A) to the healthcare professional (HCP) in the country of treatment (Country B).

The general model of communication between NCPs is manifested by a mutual cycle of trust, which assumes a minimal set of centralized services. The following figure summarizes the typical sequences of interactions that may occur between the epSOS NCPs.

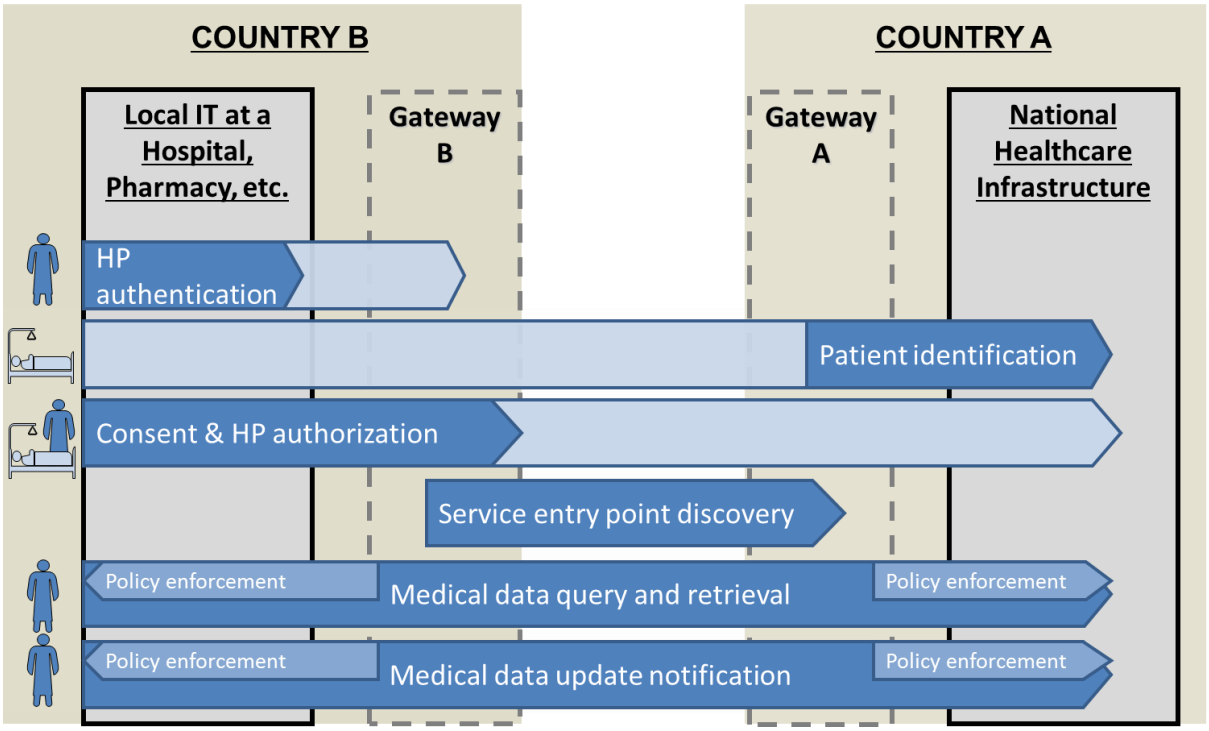


Figure 5 - Overview of epSOS Interactions

When a patient summary is transmitted from Country A (origin) to Country B (treatment), the patient summary is transformed so that it is fit for use. The original (authorized) patient summary accompanies the transformed version, which is in the HL7 CDA R2 standard.

[17] Final definition of functional service requirements - Patient Summary, D 3.2.2, version 0.6 29/10/2012

[18] Smart Open Services for European Patients: Open eHealth initiative for a European large scale pilot of Patient Summary and Electronic Prescription, WorkPackage 3.9 – Appendix B1: epSOS Semantic Implementation Guidelines (D3.9.1) http://www.epsos.eu/uploads/tx_epsosfileshare/D3.9.1_Appendix_B1_Implementation_01.pdf page 188 forward.

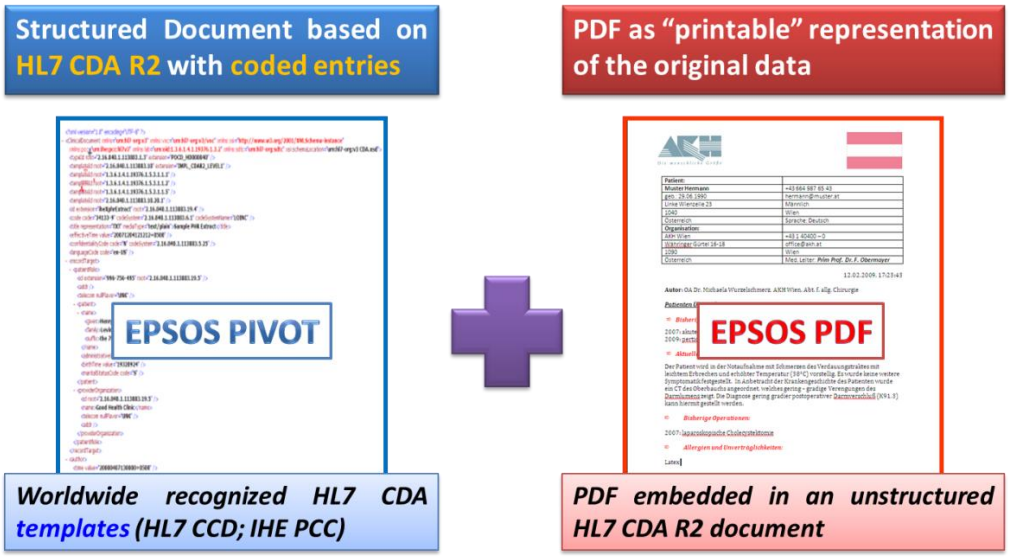


Figure 6 - Transformed Patient Summaries in epSOS Accompanied by the Original Summary in pdf

The epSOS patient summary or pivot document is expressed in the HL7 CDA R2 standard and may include several sections like: Medication Summary, Allergies and Other Adverse Reactions, Immunizations, History of Past Illness, Coded List of Surgeries, Active Problems, Coded Medical Devices, Procedures and Interventions, Health Maintenance Care Plan, Functional Status, Coded Social History, Pregnancy History, Coded Vital Signs, Coded Results.

Data optionality in the epSOS project is defined for Basic, Mandatory, and Extended data sets.

Basic data set is the set of essential health information that is required from a clinical point of view to be sent to deliver safe patient care. The fields included in the basic data set (also known as **Minimum data set**) are allowed to have null flavors. The Figure below shows the Minimum data set:

Information/data set	Contains
Patient Identifcation	Unique Identifier for the patient in the country of affiliation
Patient Personal information	FullName, Date of Birth and Gender
Contact Information	Name of the Preferred HCP/Legal organization to contact
Allergies and intolerances	Theagent and the type of clinical manifestation of the allergy reaction.
List of Current Problems/Diagnosis	Problems/diagnosis that fit under these conditions: conditions that may have a chronic or relapsing course (eg: exacerbations of asthma, irritable bowel syndrome), conditions for which the patient receives repeat medications (eg: diabetes mellitus, hypertension) and conditions that are persistent and serious contraindications for classes of medication (eg: dyspepsia, migraine and asthma)
Major Surgical Procedures in the past 6 months	Procedure description and date
Medication Summary	Current Medications
Country	Name of country of affiliation of the patient (CountryA)
Date Created	Data on which PS was generated
Date of Last Update	Data on which PS was updated (data of last version)
Author/Nature of the patient summary	To highlight if the data is collected manually by an HCP or is collected automatically form different sources (eg: hospital doctor repository, GPs…etc) through predetermine clinical rules
Author Organization	At least an author organization (HCPO) shall be listed. In case there is not HCPO identified at least a HCP shall be listed

Figure 7 - epSOS Minimum Data set for a Patient Summary

Mandatory data set is a subgroup of the Basic data set not allowed to have a null flavor.

Extended data set is defined as the desirable health information to be exchanged between the epSOS participants. The extended data set is optional, meaning a country can chose to send it if desired. The extended data set is also known as the Maximum data set: the maximum of information the system can translate. Any data set not included in the basic and extended data set is not treated and should be discarded to avoid clinical risks to the patient.

The member states have agreed upon the content of the Minimum and the Maximum data set, which are part of the Guideline for the European Patient Summaries, taking into consideration the clinical relevance and the availability of possibly coded information in the Countries. Availability is a dynamic concept: extensions are expected mainly for the section in which the number of concept is currently very limited, like "Physical findings" (only blood pressure) and "Diagnostic tests" (only blood group).

3.2.1 Identifying Semantic Resources and Services in epSOS

The epSOS semantic resource most commonly used is the Patient Summary. There are other semantic resources in epSOS and the definitions of all epSOS semantic resources are listed here. The resources were elaborated and designed based on the specifications of all the member states involved in the project.

3.2.1.1 Patient Summary (PS)

The epSOS Patient Summary is a "reduced set of patient's data which would provide a health professional with essential information needed primarily in case of unexpected or unscheduled care (emergency, accident...), but also in case of planned care (citizen movement, cross-organizational care path..)"[19]. Note that the main purpose of the Patient Summary is for unscheduled patient care. The Patient Summary contains the patients' general information, the medical summary, and the medication summary, but does not include a detailed medical history, details of clinical conditions, or the full set of the prescriptions and medicines dispensed. (Detailed and complete data are usually contained in the Electronic Health Record). The data elements present in a Patient Summary are listed in Appendix D.

The following services are extension of the basic PS service.

3.2.1.1.1 Patient Access Service (PAC)

The epSOS PAC allows a citizen to request, print, and in some cases download his Patient Summary in a language different from the one in which it was generated (Country A language).

The purpose of this service is to increase the understandability of a PS by foreign caregivers and to provide the citizen with an electronic document for use abroad.

The Patient Access Service is fundamental to allow any patient mediated use case.

3.2.1.1.2 Health Care Encounter Report (HCER)

The HCER service is designed to offer a health professional in the country where patient is visiting or working (Country B) the flexibility to record a wide range of medical information, enough to cover the most basic healthcare encounters. The Health Care Encounter Report service supports the patient summary extension use case and the ePrescription use case. Based on the use cases, Trillium Bridge will look only at the HCER service to generate information to be returned to the Country of Origin for patient empowerment.

[19]Final definition of functional service requirements - Patient Summary, D 3.2.2, version 0.6 29/10/2012, page 13.

3.2.1.1.3 Medication Related Overview (MRO)

The MRO is a document requested by the Health Professional in Country B for informational purposes only. The MRO supports all possible information that might be needed in the process of prescribing, dispensing, or administering medication to the patient in a foreign country.

The goal of the MRO is to provide a pharmacist, who is not allowed to access the PS, the needed information to avoid risks while dispensing.

The absolute minimum set of medical information in the MRO consists of the PS Medication Summary. Other useful information for the medication process, such as allergies and intolerances, are in the extended data set of the MRO. The Trillium project will not address the MRO.

3.2.1.2 ePrescription Service

The **ePrescription Service**, namely ePrescribing and eDispensing can be described as follows[20]:

- **ePrescribing** is prescribing of medicines in software by a health care Professional legally authorized to do so, for dispensing once it has been electronically transmitted, at the pharmacy.
- **eDispensing** is the act of electronically retrieving a prescription and giving out the medicine to the patient as indicated in the corresponding ePrescription. Once the medicine is dispensed, the dispenser shall report via software the information about the dispensed medication.

The information in the Medication Summary found within the Patient Summary is a subset of the content of ePrescription and eDispensation. The Medication Summary in fact, neither contains the dispensed medicine information, nor is supposed to be used for dispensing. The Medication Summary information is updated with the completion of the treatment.

The ePrescribing and eDispensing services are not relevant in the context of the Trillium Bridge project.

3.3 Meaningful Use 2 / Transition of Care

3.3.1 Overview of Meaningful Use

The US Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) provides the US Department of Health and Human Services (HHS) with the authority to establish programs to improve health care quality, safety, and efficiency through the promotion of health information technology, including electronic health records and private and secure electronic health information exchange. Under HITECH, eligible health care professionals and hospitals can qualify for government incentive payments when they adopt “certified EHR technology” and use it to achieve specified objectives.

Certified EHR technology is defined by the ONC through a series of “Meaningful Use” regulations. Stage 1 of Meaningful Use (MU1) established criteria for standardized data capture and data sharing. Stage 2 of Meaningful Use (MU2) extends the criteria for certified EHR technology by raising the bar on required interoperability standards, including standards designed to support transitions of care and clinical quality reporting. In 2016, Stage 3 of Meaningful Use (MU3) will build upon MU2, tying the ability to measure care with interventions that improve clinical outcomes.

MU2 cites a number of CDA-based standards (see table below). Trillium Bridge will focus on the Consolidated CDA (C-CDA) standard.

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

[20] D3.1.2 Final definition of functional service requirements – ePrescription, version 1.2, 26/03/2010, page 10

170.205(a)(3)	**Consolidated CDA (C-CDA)**: Standardized representation of the Consult Note, Diagnostic Imaging Report, Discharge Summary, History and Physical, Operative Note, Procedure Note, Progress Note, and Continuity of Care Document (CCD).
170.205(h)	**CDA Guide for Quality Reporting Document Architecture, Category I (QRDA-I)**: Standardized representation of quality data for an individual patient. Data in a QRDA-I report can be consumed by a calculation engine to determine if the patient met the numerator or denominator criteria for a given quality measure.
170.205(i)	**CDA Guide for Reporting to Central Cancer Registries**: Standardized cancer registry reporting format.
170.205(k)	**CDA Guide for Quality Reporting Document Architecture, Category III (QRDA-III)**: Standardized representation of aggregate quality data (e.g., number of patients meeting the numerator criteria for a given quality measure).

Table 2 - CDA Content Exchange Standards Under Meaningful Use Stage 2

3.3.2 Use of Consolidated CDA in MU2

MU2 requires a certified EHR to use C-CDA for care coordination and patient engagement scenarios. Criteria required of a certified EHR include:

- § 170.314(b) Care Coordination
  - (1) **Transitions of care – receive, display, and incorporate transition of care/referral summaries**: Addresses human readability aspects of C-CDA, and the requirement to incorporate medications, problems, and allergies
  - (2) **Transitions of care – create and transmit transition of care/referral summaries**: Addresses the ability to create C-CDAs
  - (3) **Clinical information reconciliation**: Addresses the ability to reconcile medications, problems, and allergies from imported C-CDAs against objects in the EHR
  - (4) **Data portability**: Addresses the ability to create C-CDAs
- § 170.314(e) Patient Engagement
  - (1) **View, download, and transmit to 3rd party**: Addresses the patient's ability to download C-CDA
  - (2) **Ambulatory setting only – clinical summary**: Addresses the ability to create C-CDAs

Thus, when, say, a patient transitions their care from one provider to another, the sending provider must be capable of creating a C-CDA, and the accepting provider must be capable of receiving the C-CDA, and incorporating it into their system.

3.3.3 Overview of Consolidated CDA

C-CDA is a standardized representation of the Consult Note, Diagnostic Imaging Report, Discharge Summary, History and Physical, Operative Note, Procedure Note, Progress Note, and Continuity of Care Document (CCD). A brief definition for each document is extracted from HL7 CCDA publication as to identify the most likely candidate to be used in the exchange between the two sides based on the use cases

A **Consultation Note** is generated as a result of a physician or non-physician practitioner's (NPP) request for an opinion or advice from another physician or NPP. Consultations must involve face-to-face time with the patient or fall under recommendations for telemedicine visits. A Consultation Note must be provided to the referring physician or NPP and must include the reason for the referral, history of present illness, physical examination, and decision-making component (Assessment and Plan). As this is a report of an encounter with a specialist, it is not within the scope of Trillium.

A Diagnostic Imaging Report (DIR) is a document that contains a consulting specialist's interpretation of image data. It conveys the interpretation to the referring (ordering) physician and becomes part of the patient's medical record. It is for use in Radiology, Endoscopy, Cardiology, and other imaging specialties. This is not within the scope of Trillium.

The **Discharge Summary** is a document that is a synopsis of a patient's admission to a hospital; it provides pertinent information for the continuation of care following discharge. The Joint Commission requires the following information to be included in the Discharge Summary:

- The reason for hospitalization
- The procedures performed
- The care, treatment, and services provided
- The patient's condition and disposition at discharge
- Information provided to the patient and family
- Provisions for follow-up care

The scope of this document is not in line with that of the European Patient Summary.

A **History and Physical (H&P) Note** is a medical report that documents the current and past conditions of the patient. It contains essential information that helps determine an individual's health status.

The first portion of the report is a current collection of organized information unique to an individual, typically supplied by the patient or their caregiver, about the current medical problem or the reason for the patient encounter. This information is followed by a description of any past or ongoing medical issues, including current medications and allergies. Information is also obtained about the patient's lifestyle, habits, and diseases among family members.

The next portion of the report contains information obtained by physically examining the patient and gathering diagnostic information in the form of laboratory tests, imaging, or other diagnostic procedures.

The report ends with the clinician's assessment of the patient's situation and the intended plan to address those issues.

A History and Physical Examination is required upon hospital admission as well as before operative procedures. An initial evaluation in an ambulatory setting is often documented in the form of an H&P Note.

This is too specific for the scope of this project.

The **Operative Note is** created immediately following a surgical procedure and records the pre- and post-surgical diagnosis, pertinent events of the procedure, as well as the condition of the patient following the procedure. The report should be sufficiently detailed to support the diagnoses, justify the treatment, document the course of the procedure, and provide continuity of care.

Procedure Note is a broad term that encompasses many specific types of non-operative procedures including interventional cardiology, interventional radiology, gastrointestinal endoscopy, osteopathic manipulation, and many other specialty fields. Procedure Notes are documents that are differentiated from Operative Notes in that the procedures documented do not involve incision or excision as the primary act. The Procedure Note is created immediately following a non-operative procedure and records the indications for the procedure and, when applicable, post-procedure diagnosis, pertinent events of the procedure, and the patient's tolerance of the procedure. The document should be sufficiently detailed to justify the procedure, describe the course of the procedure, and provide continuity of care.

A **Progress Note** documents a patient's clinical status during a hospitalization or outpatient visit; thus, it is associated with an encounter.

Taber's[21] medical dictionary defines a Progress Note as "An ongoing record of a patient's illness and treatment. Physicians, nurses, consultants, and therapists record their notes concerning the progress or lack of progress made by the patient between the time of the previous note and the most recent note."

Mosby's[22] medical dictionary defines a Progress Note as "Notes made by a nurse, physician, social worker, physical therapist, and other health care professionals that describe the patient's condition and the treatment given or planned." A Progress Note is not a re-evaluation note.

Unstructured Document: It is interesting here to mention the unstructured document which is used when the patient record is captured in an unstructured format that is encapsulated within an image file or as unstructured text in an electronic file such as a word processing or Portable Document Format (PDF) document. Since the original document can be transformed into a pdf in order to keep the document's original form, this kind of CDA can be used for sharing the "original" summaries.

Continuity of Care Document (CCD)/HITSP C32 is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care. The primary use case for the CCD is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient[23].

3.4 epSOS Patient Summary (PS) and MU Continuity of Care Document (CCD)

The panoply of documents from both sides of the Atlantic is considerable; however upon careful inspection one can see that each document serves a particular clinical purpose. The two documents with a similar clinical purpose are epSOS Patient Summary and MU2 CCD.

The epSOS Patient Summary is a "reduced set of patient's data which would provide a health professional with essential information needed in case of unexpected or unscheduled care (emergency, accident) and, partially, in case of planned care (citizen movement, cross-organizational care path)".

CCD is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care. The primary use case for the CCD is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient.

Chapter 6 "Comparison Between epSOS Patient Summary (PS) and Consolidated CDA (C-CDA)" will compare the data sets representing the "essential information" in the epSOS summary with the "most relevant administrative, demographic, and clinical information" adopted in the United States.

[21] Taber's Cyclopedic Medical Dictionary, 21st Edition, F.A. Davis Company. http://www.tabers.com

[22] Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier.

[23] HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1

(US Realm), Draft Standard for Trial Use, July 2012

4 From User Stories to Use Cases

The initial identification of user stories and use cases started at the Trillium Bridge kick off meeting on 20-21 September 2013, and thereafter continued as we tried to identify the value proposition for the various stakeholders. Starting with the easy wins building upon epSOS and Meaningful Use 2/Transitions of Care, the next steps should ensure sustainability of the results and continuing effective collaboration.

Already in Deliverable D2.1, in a preliminary analysis, user stories were correlated to the use cases reporting on the level of complexity they entailed. In this document, we will go a bit further and look at the user stories from two lenses: (a) the lens of the validation partners in Europe i.e. Spain, Italy, and Portugal and the US i.e. Kaiser Permanente, Atrius Health, SmartPHR and (b) the lens of patient summary content considering three formats: epSOS pivot document, epSOS friendly document in local Language, and C-CDA/CCD as produced by the systems of the US providers.

A third viewpoint is contributed by the Architectural Design and Business architecture (Chapter 8), which is also focusing on technical implementation aspects.

All the user stories share the same underlying components:

- citizen that has access to their patient summary fit for the purpose of using abroad
- patient summary is shared in an unplanned contact with the overseas health system
- Informed health care is provided and patient receives updated patient summary or encounter report for informed health care in home health system.

In the use case analysis, the underlying questions are the same: what makes the patient summary fit for purpose abroad? What are the policy considerations for the stakeholders? What are the strengths, weaknesses, opportunities and threads?

The next subsections will provide more details in the methodological approach, present the consolidated uses cases, analyze user stories under their lens, and consolidate the insights provided in a detailed use case analysis on the next section.

4.1 Methodological Approach

The methodology followed in collecting the User Stories puts particular emphasis on balancing input from the US and the EU. Initial input is limited to consortium partners and the ONC S&I Framework EHR interoperability work stream. At a later stage input from EU Member states that have provided a letter of interest will be included.

Participating experts and the Standards Advisory Forum provided additional input during the kick off meeting at MIT, Cambridge US on Sep 21-22, 2013. In principle, no limitations were in place while collecting Users Stories, to facilitate brainstorming and allow the as wide as possible range of stories. However, while all submitted user stories are relevant for our feasibility analysis, only some of the User Stories are in scope for the EU Patient Summary Guideline and thus eligible for validation in Trillium Bridge. This section focuses on just two stories that provide the basis for the use cases and adequate ground for debate and discussions on future directions. The full range of user stories is included in Appendix A.

The use cases are framed by the user stories, but are limited by the epSOS infrastructure, documents and tools as well as the policy decisions of the EU Patient Summary Guideline.[24]

[24] Guidelines on minimum/nonexhaustive patient summary dataset for electronic exchange in accordance with the cross-border directive 2011/24/EU. Guidelines on minimum/nonexhaustive patient summary dataset for electronic exchange in accordance with the cross-border directive 2011/24/EU

The users stories presented may be realized adopting different approaches for the exchange of Patient Summaries and could be setup in different EU member states and possibly with different US health systems in mind. They could also be realized through a patient mediated or facilitated approach where the patient plays an active role, that of the mediator in the information exchange, or through a provider mediated approach where the patient still has control as reflected in his/her providing consent (opt in/out). These are all elements considered in the use case analysis.

This section describes – in term of use cases - the set of EU/US patient summary exchange approaches that have been identified by the Work Package 2 group with the support of stakeholders and domain experts[25].

The use case-based description has been chosen – in agreement with a layered approach separating conceptual, logical and implementation levels - for facilitating the identification of potential political, organizational, legal, technical and semantic interoperability issues associated to those use cases by domain experts. All that was finalized before facing the technical/implementation aspects that will be considered by the following phases.

The use cases here reported are the result of a longer process during which several use cases – describing different possible perspectives - have been proposed, analyzed and processed (reorganized, collapsed, discarded) within the team.

Therefore, although several perspectives could have been applied to classify those use cases: e.g., based on the means of transport (paper, removable media, network), the responsible for the exchange, the content transported, how of the exchanged summary is consumed (view with standard or Trillium specialized display services, inclusion of exchanged information in the PHR or in the EHR); it has been agreed to collect the use case based on the following aspects:

(1) How the patient summary content is presented in the EU/US?
   a. as epSOS pivot document
   b. as epSOS friendly document in participating EU Member states
   c. as C-CDA/CCD in participating US health care providers

(2) Who is the responsible for (and triggers) the patient summary exchange?
   a. Patient Mediated exchange: patient has access and control of the patient summary
   b. Provider Mediated exchange: providers asks home country/health system for patient summary

(3) How the patient summary content is produced?
   a. epSOS Patient Access Service in the EU country of origin case
   b. Blue Button in the US country of origin case
   c. Home health system in the EU/US country of origin case

(4) How the initial patient summary content is used?
   a. visualized by the receiving provider using accompanying or own style sheet
   b. incorporated (imported) in a Personal Health Record (PHR)
   c. incorporated (imported) in an Electronic Health record (EHR)
   d. maintained separately in a special section of the providers Electronic Health Record

(5) When the syntactical transformation, from and to epSOS-CDA and C-CDA, and/or the translation of the Patient Summary performed?
   a. prepared in advance upon request the patient (in the country of origin)

[25] A face to face meeting in Boston and several Conference calls have been organized for involving both US and EU domain and standard experts with the cooperation of the WP 5.

b. when the care is provided (ad hoc and as needed)
c. by the patient using an accredited service (e.g., epSOS)

The limited resources available in Trillium Bridge caused several of these important choices to be out of scope for validation. For instance, incorporation of the patient summary content in a target PHR/EHR was discussed during the kickoff meeting for prioritizing and was considered out of scope for Trillium Bridge.

The focus of the current use case analysis section is on (1) through (4) above focusing mainly on content and policy aspects. The business architecture section (to follow) will further elaborate on the architectural and business architecture aspects (5 above).

Seven use cases were recorded in the kick off meeting and further analyzed in Deliverable D2.1. The User Stories were collected and the use cases were inserted into a correlation matrix, to facilitate analysis by experts and decision makers. For the sake of completion, the relevant content is now presented in the Appendix B. As part of this work, the use cases were consolidated into the two main ones based on #2 and #4 incorporating elements of the use cases that were not selected. These are the use cases that will be analyzed in detail for each of the user stories partly or fully in scope:

(1) **Patient mediated**: patient accesses patient summary in a format fit for use in another country; presents it to health professional in the context of unplanned care; after care patient receives updated care summary, encounter report, or discharge note. Alternatively, patient requests that patient summary is send to the provider by his/her home health system (a.k.a. patient facilitated)
(2) **Provider mediated**: provider requests with the patient`s consent, their patient summary from country or health system or origin; care is provided; after care patient receives updated care summary, encounter report, or discharge note.

Note that the epSOS HCER has been considered as the means to provide a report following care. Unfortunately, none of the epSOS participating nations has decided to pilot this service. Thus, in both the patient and provided mediated scenario, the discharge note, or encounter report, is still not confirmed for the validation, but is included to facilitate gap analysis and future directions. Collaboration with the OpenNCP team will help evaluation this functionality and make it available for MS not part of epSOS.

4.1.1 Use Case Analysis Template

The description of use cases has been performed following the Use Case Framework for Concurrent Use proposed by CEN TC 251, which is also used as basis for describing use cases in other European Projects (e.g., Antilope). Through this template it was possible to collect, beside the general use case information (name, identifier, description, actors….), also the results of a first analysis expressed in term of Strength, Weakness, Opportunity and Threat associated to each use case.

This template will be gradually adopted, leaving to following project steps the responsibility to adequately complete the provisioning of the expected information at a sufficient level of detail. In that sense the cooperation with WP 5, and the collection of their inputs, is considered a fundamental step for completing this task.

Reference #	Description
Use case name	Use case name is used together with the Stakeholder Story section.
Stakeholder story	A requirement formulated as 2 to 4 sentences in everyday or business language
Starting event	A trigger that starts the use case, which can be external, internal or temporal.
Actor and Users	The actor that initiates this use case and all users who participate in this use case
Goal	A goal briefly describes what the initiating actor intends to achieve
Stakeholders	A list of those who are affected by the outcome (good or bad) of the use case
Primary Scenario	Typical and expected sequence of events
Strength	Internal: Preconditions & Constraints that support
Weakness	Internal Preconditions & Constraints that oppose

Reference #	Description
Opportunity	External : Beneficial Outcomes to safety, security and improvements
Threat	External Adverse Risk factors for safety, security and improvements
Extras (optional)	Additional Information that is felt to be relevant, but not found elsewhere in the template; this material might make the use case description more complete and/or more formal

4.2 Outline of Consolidated Use Cases

4.2.1 UC I - Visualization of Patient Summary, Patient Mediated

Reference #	Description
Use case name	***Visualization of Patient Summary, Patient Mediated***
Stakeholder story (framework)	Patients have access to their patient summary in format that is fit for use in the context of unplanned care in EU member states and the US.
Primary Scenario (citizen of *EU Member State*)	- ***Precondition****:* EU citizen has a patient summary available and accessible in their national patient portal that can be rendered as EU patient summary (a.k.a. epSOS pivot document). - ***Prior to unplanned care event*****:** EU Citizen accesses patient portal and receives copy of his/her Patient Summary fit for the purpose of use in an unplanned care setting in the US. o ***Outcome***: Original & Transformed patient summary documents (epSOS Pivot Document, epSOS friendly Patient Summary, C-CDA/CCD document) are maintained by the patient in a personal device or online Personal Health Record - ***Unplanned Care Setting***: Patient presents translated Patient Summary to health professional (e.g., the foreign physician) using his/her personal device. o ***Outcome****:* The receiver is able to read and understand key elements of the patient summary - ***Following provision of care*****:** Patient receives encounter report from US physician (C-CDA/CCD format). [*Enhancement*] Using online service, patient is able to transform encounter report to epSOS patient summary format. o ***Outcome***: Original & Transformed patient encounter report (epSOS Pivot Document, epSOS friendly Patient Summary, C-CDA/CCD) are maintained by the patient in a personal device or online Personal Health Record
Alternative Scenario (citizen of *EU Member State*)	- ***Unplanned Care Setting:*** Patient is able to access patient portal and display own patient summary for foreign provider in a format/language that can be understood. - ***Following provision of care in the US*****:** Patient receives encounter report from foreign physician (C-CDA/CCD format). [*Enhancement*] Using online service, patient is able to transform encounter report to epSOS Patient Summary.
Alternative Scenario (citizen of *EU Member State*)	- ***Unplanned Care Setting:*** Patient grants the provider access to their online patient summary. Provider updates patient summary in accordance to the provided care. - ***Following provision of care in the US*****:** Patient receives updated patient summary from foreign physician (C-CDA/CCD format). [*Enhancement*] Using online service, patient is able to transform encounter report to epSOS Patient Summary format..

Reference #	Description
Primary Scenario (US citizen)	- ***Precondition***: US Citizen through Blue Button plus or his/her health provider has access to his patient summary in C-CDA/CCD in a personal device or Personal health record. - ***Prior to unplanned care event*****:** US Citizen uses online service to transform his/her clinical patient summary into the epSOS Patient Summary Format and its transcoding into the language(s) of the EU Member State he/she travels to. o ***Outcome***: Original & Transformed EU patient summary documents (epSOS Pivot Document, epSOS friendly Patient Summary, C-CDA/CCD document) are maintained by the patient in a personal device or online Personal Health Record - ***Unplanned Care Setting*****:** Patient presents translated Patient Summary to health professional (e.g., the foreign physician) using his/her personal device. o ***Outcome****:* The EU physician is able to read and understand key elements of the clinical patient summary of US origin. - ***Following provision of care*****:** Patient receives encounter report from EU physician (epSOS pivot document). [*Enhancement*] Using online service, patient is able to transform encounter report into C-CDA/CCD. o ***Outcome***: Original & Transformed patient encounter report (epSOS Pivot Document, C-CDA/CCD) are maintained by the patient in a personal device or online Personal Health Record

4.2.2 UC II- Patient Summary Visualization on Provider's Device, Provider Mediated

Reference #	Description
Use case name	***Patient Summary visualization using provider's device, Provider Mediated***
Stakeholder story	While providing unplanned care, the healthcare professional accesses the Patient Summary, with patient consent, via own EHR-S and visualizes the translated document
Primary Scenario	- The patient is receiving unplanned care abroad. - The foreign healthcare professional, after having identified the patient, requests - using own EHR-S - to the patient's Country of Affiliation the Patient Summary of that patient. - A secure connection is established. - The remote country verifies if is entitled to fulfill such a request (correct patient identification, consent provided as applicable). - The patient summary is retrieved and returned to the foreign healthcare professional in a format "suitable" for the receiver visualization, translated in the receiver language. - The foreign healthcare professional visualizes the Patient Summary using own EHR-S.
Alternative Scenario	- The patient is receiving unplanned care abroad. - The foreign healthcare professional, after having identified the patient, requests - using own EHR-S - to the patient's Country of Affiliation a Patient Summary of that patient. - A secure connection is established. - The remote country verifies if is entitled to fulfill such a request (correct patient identification, consent provided when applicable). - If it is, the summary is retrieved and returned to the foreign healthcare professional in a "source" format (epSOS Pivot is sent to US; C-CDA/CCD in sent to EU) in English. - The foreign healthcare professional visualizes the Patient Summary using own EHR-S. Before being visualized the document is processed (transformed, translated) as needed by the supporting mediating infrastructure of the Trillium Gateway.

4.3 From User Stories to Patient Summaries

4.3.1 Martha's Story: a Cancer-survivor Traveling Corporate Executive (*provided by Elaine Blechman, Prosocial, US*)

4.3.1.1 Stakeholder Story

Martha Smith, a 45-year old US corporate executive and breast cancer survivor travels frequently on business between the US and EU countries. She carries a clinical summary including a plan of care on her mobile phone and on paper just in case she needs to seek medical care regarding recurring symptoms.

Demographics: Age 45 years, Gender female

Problems: Breast cancer Stage II with no evidence of recurrence following treatment; hot flashes

Medications: Anastrozole 1 mg. once daily; Black Cohosh Extract herbal supplement;

Allergies: Penicillin

Plan of Care: Continue hormone medication with Anastrozole for total of 5 years; monitor for potential breast cancer recurrence.

4.3.1.2 Starting Event

During a visit in Italy, Martha walks up a hill and experiences shortness of breath, faints, and wakes up a few minutes later after hitting her head on a stone step.

4.3.1.3 Actor and Users

- Martha
- Passerby
- Admitting physician

4.3.1.4 Goal

Martha, a cancer survivor wishes to receive unplanned care safely while traveling, offering the admitting physicians her patient summary in a format and language that can be clearly understood.

4.3.1.5 Stakeholders

- Martha
- Passerby
- Local Hospital
- Admitting Physician
- Cardiologist
- Oncologist

4.3.1.6 Primary Scenario – Patient Mediated

During a visit in Italy, while walking up a hillside, Martha experiences shortness of breath, faints, and wakes up a few minutes later after hitting her head on a stone step. A passerby helps her get to the emergency department of a local hospital.

During registration and admission, Martha presents the admitting physician a translated paper copy of her clinical summary in Italian. She also shows, on her mobile phone, in her PHR, the original and the Italian (if needed) translation of her clinical summary. At the hospital, Martha is evaluated by an oncologist and a cardiologist.

During discharge from the Italian hospital, Martha downloads an updated clinical summary including information from the oncologist and cardiologist, translated from Italian to her PHR, via EPSOS transform on her mobile phone.

The following figure summarizes how the patient mediated use case applies to the Martha and Paolo scenarios.

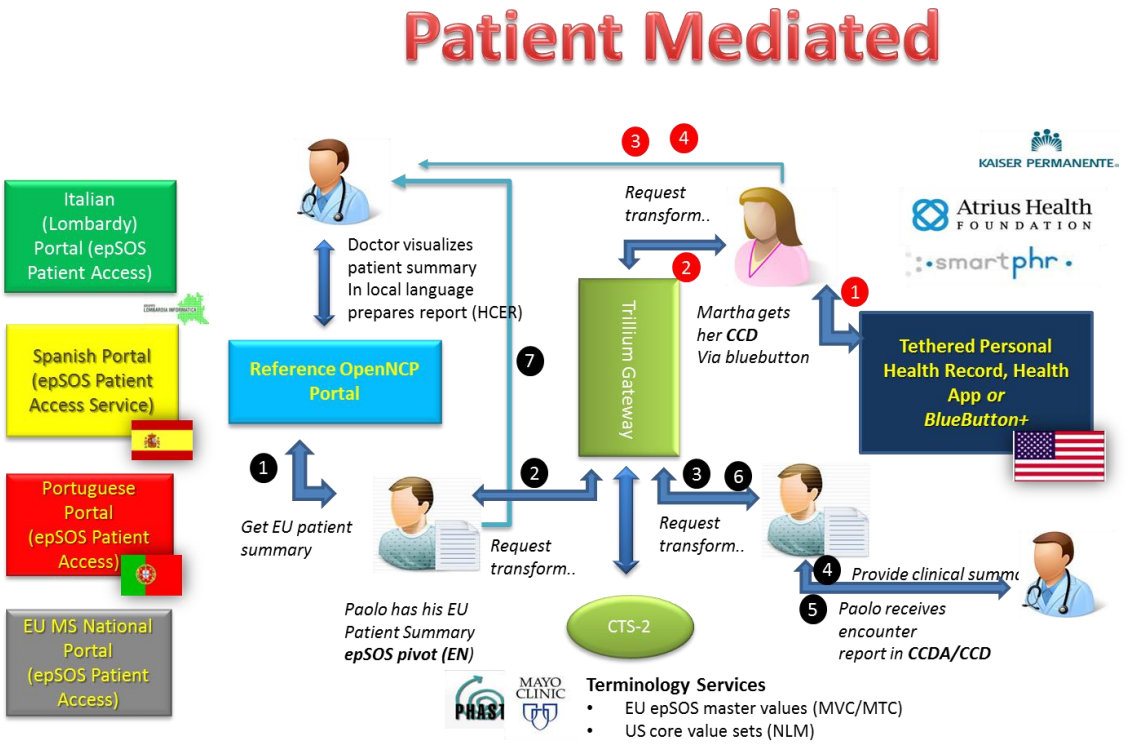


Figure 8 – The Patient Mediated use case for Martha and Paolo

4.3.1.7 Alternative Scenario – Provider Mediated

During a visit in Italy, while walking up a hillside, Martha experiences shortness of breath, faints, and wakes up a few minutes later after hitting her head on a stone step. A passerby helps her get to the emergency department of a local hospital.

During registration and admission, the admitting nurse asks Martha if she has a patient summary. Martha mentions that she is with Atrius Health, which is part of Trillium. The admitting physician, accesses epSOS and requests Martha's patient summary after she provides her consent. Through the Trillium Gateway, the patient summary is retrieved and translated into Italian. Then, after she provides her consent to the medical team in charge of her care, it is presented to the physician on his computer, who shares the patient summary with the Cardiologist and Oncologist who evaluate Martha.

During discharge from the hospital, Martha is presented with an updated clinical summary including information from the oncologist and cardiologist, translated from Italian to her PHR, via EPSOS transform on her mobile phone.

4.3.1.8 The Martha's Patient Summary as CCDA/CCD

Developing the patient summaries for the CCD was straight forward in terms of representing the patient demographic and clinical information contained in the user stories. Data elements from the user stories were easily mapped to elements in the CCD Header and Body. Coded values required for CDA Entries were obtained from SNOMED CT and RxNorm to code problems and medications to be included in the CCD. A

sample mapping spreadsheet is included for Martha in Appendix C, which details the data elements from the user story and where in the CCD they were mapped.

The largest challenge encountered in developing the patient summary for the CCD was identifying and generating values for information that was missing from the user story that is required for a complete a valid CCD. This missing information has more to do with the user stories not being specific enough in describing the use case as opposed to the CDA being too specific or granular, and was in line with the types of information that a patient would not typically know or would easily forget. Examples of information required for a valid CCD that was missing from the user story included elements such as the following:

- When representing allergy information the CCD Allergy Intolerance Observation template requires than an effective time be present to represent when the allergy was first identified, and when it ended (if applicable).
- When representing medications the CCD Medication Activity requires start and stop dates (if applicable) to identify when a medication was started when it ended stopped.
- CCD requires a custodian to be included who is responsible for managing the CCD. This was assumed to be Atrius Health, who the GP of the patient represents.
- CCD requires several ID values that needed to be created to create a valid CCD. Many of these IDs would be generated by the CCD system, and would not necessarily be included in a user story

These missing data elements, while not explicitly in the user story would be included in a typical CCD document generated within the US healthcare domain.

Health Summary

Patient	Martha XXXXX		
Date of birth	June 7, 1968	**Sex**	Female
Contact info	Primary Home: 1357 Amber Drive Beaverton, OR 97867, US Tel: (555)555-5555	**Patient IDs**	998991 2.16.840.1.113883.19.5.99999.2 111-00-2330 2.16.840.1.113883.4.1
Document Id	TT988 - 2.16.840.1.113883.19.5.99999.1		
Document Created:	September 15, 2013, 00:00 -0400		
Care provision	Check-up from September 8, 2013, 10:15 to September 8, 2013, 10:45		
Performer (primary care provider)	Person Dr. Henry Oncologist PseudoMD-1 - 2.16.840.1.113883.4.6	Organization Atrius Health 2.16.840.1.113883.19.5.9999.1393	
Author	Henry Oncologist		
Contact info	1002 Healthcare Drive Portland, OR 99123, US Tel: 555-555-1002		
Legal authenticator	Henry Oncologist signed at February 27, 2013, 13:00:00 +0500		
Contact info	1002 Healthcare Drive Portland, OR 99123, US Tel: 555-555-1002		
Document maintained by	Atrius Health		
Contact info	Work Place: 1002 Healthcare Drive Portland, OR 99123, US Tel: 555-555-1002		

Table of Contents

- Allergies, Adverse Reactions, Alerts
- Medications
- Problems
- Results
- Plan of Care

Allergies, Adverse Reactions, Alerts

Type	Substance	Overall Severity	Reaction	Reaction Severity	Status
Drug allergy	ALLERGENIC EXTRACT, PENICILLIN	Moderate to Severe	Nausea	Moderate to Severe	Active

Medications

Medication	Directions	Start Date	Status
Anastrozole	1 mg once daily	20130103	Active

Problems

1. Breast Cancer Stage II Status: Resolved
2. Hot Flashes Status: Active

Results

No information

Plan of Care

Planned Activity	Planned Start Date	Planned End Date
Medication: Anastrozole	20130103	20180102
Monitor for potential breast cancer recurrence	20130103	

Figure 9 – The Martha's C-CDA CCD

The CDA sample based on this scenario is available from the Project Repository (http://www.trilliumbridge.eu/repository) [RTD_CCD_Martha.xml]

4.3.1.9 Alternative Flows: What if Martha was European?

If Martha were European, in theory she would have had an epSOS Patient Summary.

The following picture provides a view on the “best” European PS that in theory could be generated.

In reality, every European Country participating in epSOS has adopted the National Patient Summary and transformed to make it compliant with the epSOS document specifications to exchange it with other countries.

The epSOS specifications, evolved in the European Guidelines on Patient Summary, leave flexibility on optional section and even in the mandatory sections.

As an example, “Allergies” is a mandatory section, however, if an EU Country has not adopted any coding system, but uses free text to describe the allergy, this information cannot be transferred as coded information, hence it cannot be translated.

Another objective cause of difference is the fact not all the Countries adopted the same code system to express clinical concept. A typical example is the Illness and disorder sections where ICD10 should be used, but several Countries adopt ICD 9. Even WHO does not provide an official mapping between ICD9 and ICD10, hence it happens several ICD9 codes cannot be univocally mapped into an ICD10 code.

This condition will tend to improve, because EU Countries are in the process of adopting EU Guidelines in a more and more strict way, converging to the use of the proposed code systems. The biggest step is the decision of using SNOMED-CT, having that a significant economical, clinical and organizational impact. However this process is strictly related with the National policies and strategies: it might require several months before reaching a stable situation.

In the following sections we provide some example, closer to the current reality, in which we make the hypothesis Martha was Italian or Portuguese or Spanish. The example in this section is built applying the best case it is possible to obtain from the epSOS Pivot document.

The following sections provide the same document generated according to Lombardy, Portugal and Spanish implementation.

Patient	MARTHA TRILLIUM		
Date of birth	April 1, 1969	Sex	Female
Contact info	60 TRIQ IS-SALLUR GHAXAQ, LU	Patient IDs	998991 2.16.840.1.113883.19.5.99999.2
Document Id	TB1 2.16.840.1.113883.19.5.99999.1		
Document Created:	June 19, 2013		
Author	TRILLIUM DOCTOR, Ministry for Health, Trillium Bridge		
Contact info	15, Merchants Street Valletta, MT Tel: +3912325455335		
Personal relationship	PCPTRILLIUM DOCTOR		
Contact info	15, Merchants Street Valletta, MT Tel: +3912325455335		
Legal authenticator	TRILLIUM DOCTOR of Ministry for Health, Trillium Bridge signed at June 26, 2013		
Contact info	15, Merchants Street Valletta, MT Tel: +3912325455335		
Document maintained by	Ministry for Health, Trillium Bridge		
Contact info	15, Merchants Street Trillium, MT Tel: +35625455335		

Allergies, adverse reactions, alerts

Type	Substance		Reaction	Allergy Onset Date
Allergy to Drugs	J01C	Pennicillin	Anaphylaxis	2009

Problem list

- Breast cancer Stage II with no evidence of recurrence following treatment
- Hot flashes

Problem		Onset Date
C50	Malignant neoplasm of breast	February 2012

Medication Summary

- Anastrozole 1 mg. once daily
- Black Cohosh Extract herbal supplement

Substance		Strenght	Frequency of intakes	Number of units per intake	Date of onset of treatment	Date of end of treatment	Dose Form
L02BG03	Anastrozole	1 mg	once a day	1 tablet	2014/05/20	2019/05/20	film-coated tablet
	Black Cohosh Extract	40 mg	twice a day	1 capsule	2014/05/20	2015/05/20	capsule

History of medical device use

No Devices Used

History of Procedures

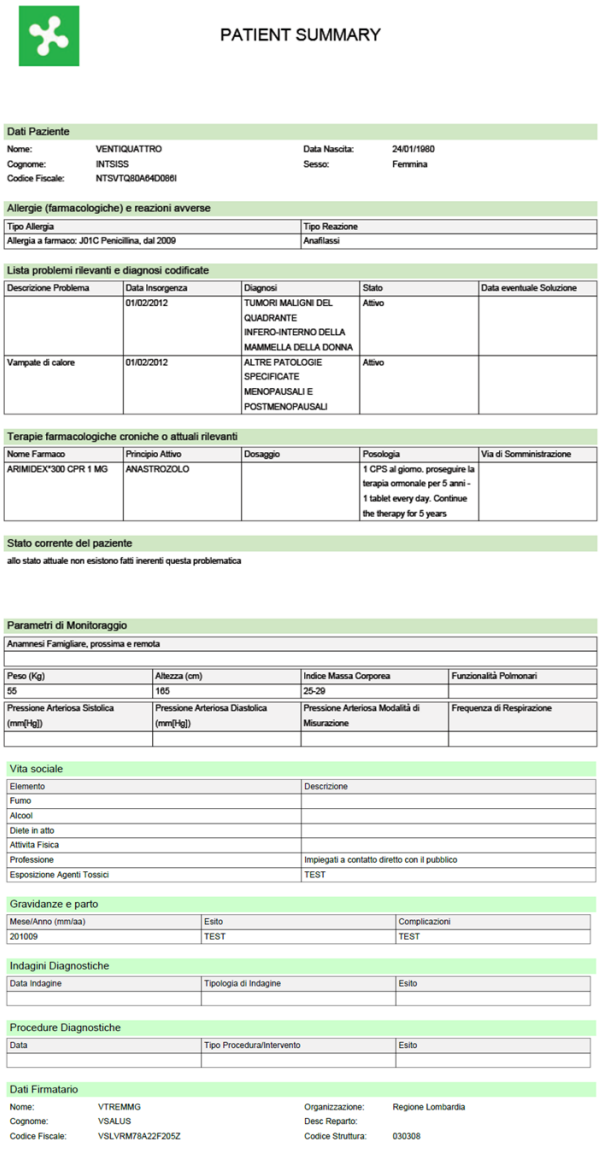
No Surgical Procedures

Health Maintenance Care Plan

- Continue hormone medication with Anastrozole for total of 5 years
- monitor for potential breast cancer recurrence

4.3.1.9.1 Alternative Flows: What if Martha was Italian?

If Marta was Italian (Lombardy region) and she had an epSOS patient summary she will be able to access that document that will contain her most relevant information as represented by the figures below : the printable representation of the Lombardy's Patient Summary reflecting the Martha's case, and the associated epSOS Patient Summary (in Italian).



PATIENT SUMMARY

Dati Paziente

Nome:	VENTIQUATTRO	Data Nascita:	24/01/1980
Cognome:	INTSISS	Sesso:	Femmina
Codice Fiscale:	NTSVTQ80A64D086I		

Allergie (farmacologiche) e reazioni avverse

Tipo Allergia	Tipo Reazione
Allergia a farmaco: J01C Penicillina, dal 2009	Anafilassi

Lista problemi rilevanti e diagnosi codificate

Descrizione Problema	Data Insorgenza	Diagnosi	Stato	Data eventuale Soluzione
	01/02/2012	TUMORI MALIGNI DEL QUADRANTE INFERO-INTERNO DELLA MAMMELLA DELLA DONNA	Attivo	
Vampate di calore	01/02/2012	ALTRE PATOLOGIE SPECIFICATE MENOPAUSALI E POSTMENOPAUSALI	Attivo	

Terapie farmacologiche croniche o attuali rilevanti

Nome Farmaco	Principio Attivo	Dosaggio	Posologia	Via di Somministrazione
ARIMIDEX*300 CPR 1 MG	ANASTROZOLO		1 CPS al giorno. proseguire la terapia ormonale per 5 anni - 1 tablet every day. Continue the therapy for 5 years	

Stato corrente del paziente

allo stato attuale non esistono fatti inerenti questa problematica

Parametri di Monitoraggio

Anamnesi Famigliare, prossima e remota			
Peso (Kg)	**Altezza (cm)**	**Indice Massa Corporea**	**Funzionalità Polmonari**
55	165	25-29	
Pressione Arteriosa Sistolica (mm[Hg])	**Pressione Arteriosa Diastolica (mm[Hg])**	**Pressione Arteriosa Modalità di Misurazione**	**Frequenza di Respirazione**

Vita sociale

Elemento	Descrizione
Fumo	
Alcool	
Diete in atto	
Attività Fisica	
Professione	Impiegati a contatto diretto con il pubblico
Esposizione Agenti Tossici	TEST

Gravidanze e parto

Mese/Anno (mm/aa)	Esito	Complicazioni
201009	TEST	TEST

Indagini Diagnostiche

Data Indagine	Tipologia di Indagine	Esito

Procedure Diagnostiche

Data	Tipo Procedura/Intervento	Esito

Dati Firmatario

Nome:	VTREMMG	Organizzazione:	Regione Lombardia
Cognome:	VSALUS	Desc Reparto:	
Codice Fiscale:	VSLVRM78A22F205Z	Codice Struttura:	030308

All the main information identified in the stakeholder story have been represented in the Lombardy Patient Summary, even not all of them as structured and coded data and so not processible for the translation.

Neither the Lombardy PS nor the epSOS PS allows recording coded information about herbal treatments (Black Cohosh Extract). In this case, the textual descriptions were not included because this treatment has not being considered relevant for the scope of the Patient Summary. (Note; in Italy the PS is a report produced by the GP including only relevant information for unscheduled / emergency encounters)

It is not foreseen the usage of qualifiers for providing coded information about the stage of the Brest Cancer, so this problem is recorded as (ICD9-CM) "Malignant neoplasm of lower-inner quadrant of female breast" in the Lombardy PS and remapped into the ICD10 concept of "Malignant neoplasm of breast" . Even if specificity of the information exchanged is different, this doesn't affect the current overall scope of the EU Patient Summary, the high level concept that this woman suffered for oncological problems at breast is anyhow provided. Shortages in the representation of allergies as structured and coded data is moreover experienced, even if foreign HPs can understand that there is a risk with allergies, and can figure out the kind of problem getting the Italian words ("Pennicellina", "Anafilassi"). Medications treatment plan are included in the posology fields as text, there is not a Plan of Care section collecting all of them. The Lombardy PS includes additional information about the Social History, Pregnancies and diagnostic procedures that are not included in the epSOS PS (since that info is not in the epSOS data set)

Different capabilities on capturing data for the Patient Summary can experienced in other Italian Regions, (Veneto, Emilia, Tuscany,..), but since they are not piloting with epSOS, the analysis of those experiences is out of scope for this document.

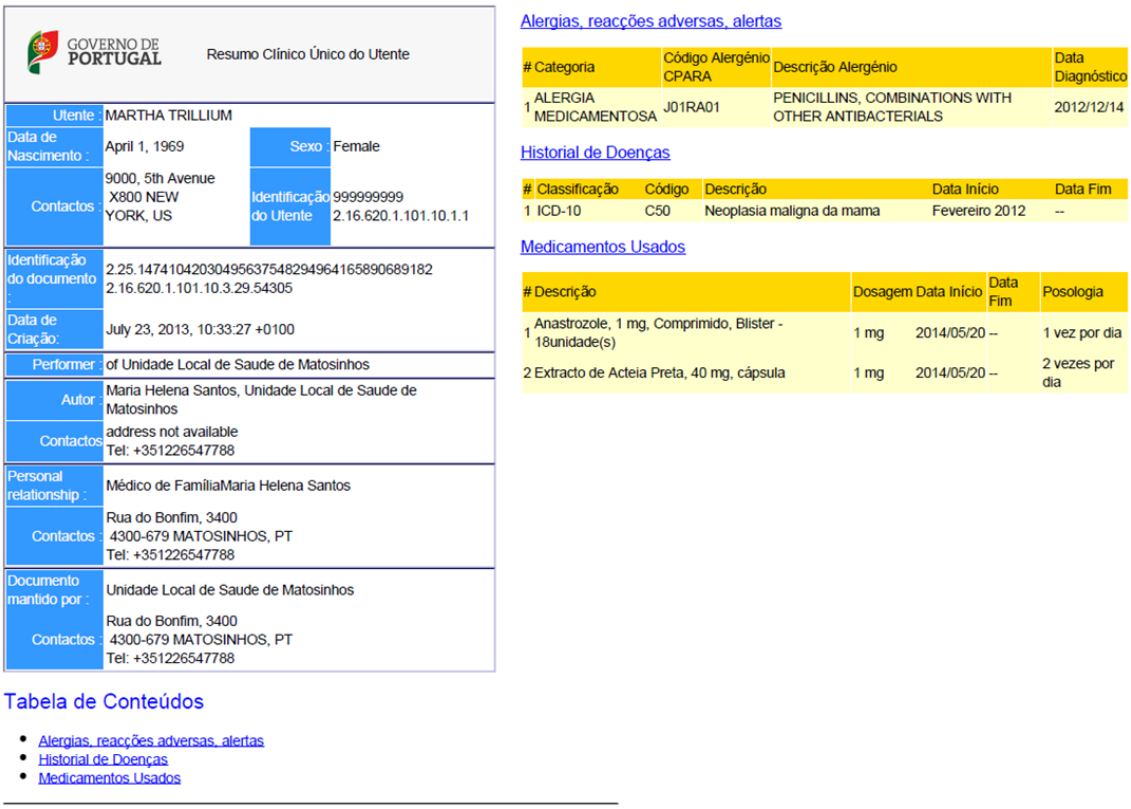
4.3.1.9.2 Alternative Flows: What if Martha was Portuguese?

If Marta was Portuguese and she had an epSOS patient summary she would be able to access a document that would contain the most relevant information but it won't include the whole oncologist care plan (as it is not part of an epSOS patient summary, nor described in the EU PS Guidelines).

In Portugal, the Patient Summary is kept as a summary that contains information relevant for ANY health professional that has to attend the patient and can be consulted easily and fast.

Nowadays Marta will be able to consult her own patient summary, and print it. She only needs to access the Internet and use her citizen card to be authenticated at the Portuguese Patient Portal. (Note: the translation service through epSOS is not implemented on the Patient Portal but we intend to implement PAC Service to provide a translated PS.)

The figure below shows the printable representation of a Portuguese (and epSOS) Patient Summary reflecting the Martha's case.



GOVERNO DE PORTUGAL — Resumo Clínico Único do Utente

Utente :	MARTHA TRILLIUM		
Data de Nascimento :	April 1, 1969	Sexo :	Female
Contactos :	9000, 5th Avenue X800 NEW YORK, US	Identificação do Utente	999999999 2.16.620.1.101.10.1.1
Identificação do documento :	2.25.147410420304956375482949641658906891822.16.620.1.101.10.3.29.54305		
Data de Criação:	July 23, 2013, 10:33:27 +0100		
Performer :	of Unidade Local de Saude de Matosinhos		
Autor :	Maria Helena Santos, Unidade Local de Saude de Matosinhos		
Contactos :	address not available Tel: +351226547788		
Personal relationship :	Médico de FamíliaMaria Helena Santos		
Contactos :	Rua do Bonfim, 3400 4300-679 MATOSINHOS, PT Tel: +351226547788		
Documento mantido por :	Unidade Local de Saude de Matosinhos		
Contactos :	Rua do Bonfim, 3400 4300-679 MATOSINHOS, PT Tel: +351226547788		

Tabela de Conteúdos

- Alergias, reacções adversas, alertas
- Historial de Doenças
- Medicamentos Usados

Alergias, reacções adversas, alertas

#	Categoria	Código Alergénio CPARA	Descrição Alergénio	Data Diagnóstico
1	ALERGIA MEDICAMENTOSA	J01RA01	PENICILLINS, COMBINATIONS WITH OTHER ANTIBACTERIALS	2012/12/14

Historial de Doenças

#	Classificação	Código	Descrição	Data Início	Data Fim
1	ICD-10	C50	Neoplasia maligna da mama	Fevereiro 2012	--

Medicamentos Usados

#	Descrição	Dosagem	Data Início	Data Fim	Posologia
1	Anastrozole, 1 mg, Comprimido, Blister - 18unidade(s)	1 mg	2014/05/20	--	1 vez por dia
2	Extracto de Acteia Preta, 40 mg, cápsula	1 mg	2014/05/20	--	2 vezes por dia

Similar considerations, like those made for the Lombardy PS, can be applied to the Portuguese PS, in term of capability of capturing some kind of information, like the cancer stage, or herbal treatments (Black Cohosh Extract) (being out of scope of epSOS), or collecting coded and structured data for some kind of data like medical devices and vaccinations. Thanks to the new ePrescription Portugal is instead capable of providing structured and coded element about medications, excluding posology; as it happens for example for the allergies information. The Portuguese PS specifications are aligned with the epSOS format.

Portugal uses a local code system (as CPARA) that can be mapped into SNOMED CT. The country has recently started the process of SNOMED CT adoption. Illnesses, currently coded in ICD9-CM, may in the future be coded using ICD-10.

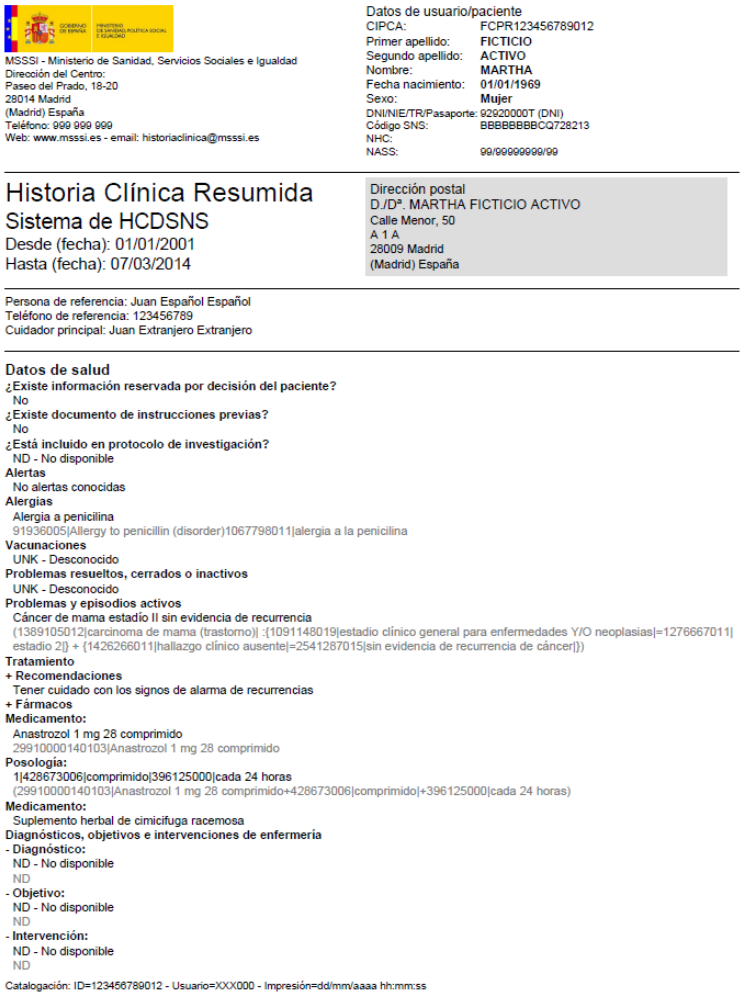
4.3.1.9.3 Alternative Flows: What if Martha was Spanish?

If Marta was Spanish and she had an epSOS patient summary she will be able to access that document that will contain the most relevant information but it won't include the whole oncologist care plan (as it is not part of an epSOS patient summary or describe in the EU Guidelines). In Spain, the Patient Summary is collected on the fly as a summary that contains information relevant for any health professional that attends the patient. More detailed or useful information preferably should be exchanged in other ways or documents so the patient summary keeps its main purpose. Nowadays Marta will be able to consult her own patient summary, print it or store it, and do it through an Internet access but using an advanced signature to be authenticated. The translation service through epSOS is not implemented but is foreseen as a positive and possible option in the future. If Marta will use that translation/transcoding system some information will be

lost for the semantic constraints that still exist so the recommendation still will be to carry both patient summaries, original and translated.

Also Martha will be able to hide the Patient Summary in case that she does not want other professionals to be able to look at it. Any information contained at the national electronic health system can be hidden by the patient.

Hereafter how the Martha's Spanish Patient Summary would look like (note: the codification used is shown in grey in the example for clarification even if normally it won't be shown.)



MSSSI - Ministerio de Sanidad, Servicios Sociales e Igualdad
Dirección del Centro:
Paseo del Prado, 18-20
28014 Madrid
(Madrid) España
Teléfono: 999 999 999
Web: www.msssi.es - email: historiaclinica@msssi.es

Datos de usuario/paciente
CIPCA: FCPR123456789012
Primer apellido: FICTICIO
Segundo apellido: ACTIVO
Nombre: MARTHA
Fecha nacimiento: 01/01/1969
Sexo: Mujer
DNI/NIE/TR/Pasaporte: 92920000T (DNI)
Código SNS: BBBBBBBBCQ728213
NHC:
NASS: 99/99999999/99

Historia Clínica Resumida
Sistema de HCDSNS
Desde (fecha): 01/01/2001
Hasta (fecha): 07/03/2014

Dirección postal
D./Dª. MARTHA FICTICIO ACTIVO
Calle Menor, 50
A 1 A
28009 Madrid
(Madrid) España

Persona de referencia: Juan Español Español
Teléfono de referencia: 123456789
Cuidador principal: Juan Extranjero Extranjero

Datos de salud
¿Existe información reservada por decisión del paciente?
No
¿Existe documento de instrucciones previas?
No
¿Está incluido en protocolo de investigación?
ND - No disponible
Alertas
No alertas conocidas
Alergias
Alergia a penicilina
91936005|Allergy to penicillin (disorder)1067798011|alergia a la penicilina
Vacunaciones
UNK - Desconocido
Problemas resueltos, cerrados o inactivos
UNK - Desconocido
Problemas y episodios activos
Cáncer de mama estadio II sin evidencia de recurrencia
(1389105012|carcinoma de mama (trastorno)| :{1091148019|estadio clínico general para enfermedades Y/O neoplasias|=1276667011| estadio 2|} + {1426266011|hallazgo clínico ausente|=2541287015|sin evidencia de recurrencia de cáncer|})
Tratamiento
+ Recomendaciones
Tener cuidado con los signos de alarma de recurrencias
+ Fármacos
Medicamento:
Anastrozol 1 mg 28 comprimido
2991000014010 3|Anastrozol 1 mg 28 comprimido
Posología:
1|428673006|comprimido|396125000|cada 24 horas
(2991000014010 3|Anastrozol 1 mg 28 comprimido+428673006|comprimido|+396125000|cada 24 horas)
Medicamento:
Suplemento herbal de cimicifuga racemosa
Diagnósticos, objetivos e intervenciones de enfermería
- Diagnóstico:
ND - No disponible
ND
- Objetivo:
ND - No disponible
ND
- Intervención:
ND - No disponible
ND

Catalogación: ID=123456789012 - Usuario=XXX000 - Impresión=dd/mm/aaaa hh:mm:ss

Even if in the Spanish sample uses SNOMED CT post coordinates for expressing the "Breast cancer Stage II with no evidence of recurrence following treatment;" this "richness" cannot be brought into the epSOS Pivot so similar considerations, like those made for the Lombardy PS, can be applied here for problem and herbal treatments (being out of scope of epSOS).

To be moreover able to better analyzed the impact of the regional based organization on the actual capability of each region to provide coded and structured information as expected by the epSOS specifications, and the mapping of the used code systems with the epSOS value sets (e.g., all the PS sample exchanged so far in epSOS uses the ICD9-CM code system for coding illnesses).

4.3.2 Paolo's Story: a Retired Businessman with Hypertension (Real World User Story provided by Dipak Kalra, EuroRec, EU)

4.3.2.1 Stakeholder Story

Paolo Cerruti is a 67-year-old retired businessman, who normally lives in the outskirts Bergamo, near Lake Como, in Lombardy. He is generally healthy, but has long-standing hypertension.

Demographics: Age 67 years, Gender Male
Problems: Active: Hypertension; Resolved: Migraine headaches and Fractured neck of (left) femur.
Medications: Metoprolol 100mg. once daily;
Allergies: Erythromycin, Allergic rash
Vaccination: Pneumococcal pneumonia
Surgical Procedures prior to the past six months: Appendectomy

4.3.2.2 Starting Event

His back and medication is lost.

4.3.2.3 Actor and Users

Paolo Cerruti a 67-year-old retired businessman.

4.3.2.4 Goal

Share with attending physician details of his medication to identify possible adverse drug reaction events.

4.3.2.5 Stakeholders

- Patient: Paolo
- Italian GP
- GP in Atrius Health

4.3.2.6 Primary Scenario – Provider Mediated

Paolo Cerruti is a 67-year-old retired businessman, who normally lives in the outskirts Bergamo, near Lake Como, in Lombardy. He is generally healthy, but has long-standing hypertension. His regular physician changed his medication two weeks ago because of poor blood pressure control on his previous medication. He is on holiday going through New England, US, travelling on his own to enjoy the autumn foliage, and is presently in Boston, MA. He is nearing the end of his holiday, and will be returning to Italy in three days' time. Two days ago his day bag was stolen in a market square. The bag included his hypertension medication, and he has not been able to take his tablets for two days.

This morning he has woken up feeling dizzy and has blurred vision. The hotel is able to put him in urgent contact with a local general practitioner (GP). Having assessed him, the GP noted a raised blood pressure, but is uncertain about whether to attribute these symptoms to the raised blood pressure or a side effect of the new medication. Feeling otherwise healthy, Paolo had not thought to request a handwritten or printed medical summary from his Italian GP, but upon Paolo's providing consent confirmation his online epSOS Patient Summary for emergency access can be retrieved in the US. Now, the GP in Boston needs to know the medication, and the past few blood pressure readings to determine how exceptional the present reading is and manage Paolo appropriately.

Immediate access to the Trillium Bridge summary would be the perfect answer.

The GP is with Atrius Health, a New England health system, part of the Trillium Bridge network. This means that the particular health system has signed mutual data-sharing agreements with other members of the network, including the Lombardy region where Paolo lives. Patient demographic and provider directory services are accessible through search functions, and are maintained by each participating member. The GP is able to enter demographic information about Paolo into a patient search facility, which relays his request to the Italian National Contact Point. Once the patient match is confirmed, Paolo is able to confirm and consent.

The GP requests the up-to-date patient summary from Lombardy. The credentials of the US GP are registered within the audit log at the Italian National Contact Point, which also timestamps the request of the summary. The summary document is relayed between the Italian Contact Point and the US. In the process, most of the clinical terminology and medication codes are translated into those recognized by the US health record system. An audit log within the health record system also records the receipt of that summary. The GP find that the blood pressure he has recorded on Paolo is only a little higher than his recent readings, but notes that visual disturbances are a recognized side effect of this medication. No specific treatment is indicated, and Paolo is reassured that side effects will gradually subside, and his GP can prescribe a suitable antihypertensive medication upon his return to Lake Como.

4.3.2.7 Alternative Scenario – Patient Mediated

Paolo can access his patient summary online through the epSOS portal. After downloading his patient summary in the C-CDA/CCD format using an online service if the epSOS portal does not provide this service.

4.3.2.8 The Paolo's Patient Summary as epSOS PS

The general considerations made for the Martha's case (see section 4.3.1.8) can be substantially repeated also for the Paolo's scenario. In this case however the clinical content of the Paolo's Summary has been defined basing on the epSOS Patient Summary data set, so that the implementation of the clinical content into the Patient Summary have been almost straight forward.

The following pictures show to the epSOS pivot Patient Summary generated according to the described clinical case.

Patient Summary

Creation Date : 1/05/2014		Last Update : 1/05/2014	
Patient			
Prefix	**Family Name**	**Given Name**	
	CERRUTI	PAOLO	
Patient IDs	CRRPLA47H13A794V		
Gender	Male	**Date of Birth**	13/06/1947

See details

Allergies, adverse reactions, alerts

Show Original

Tipo Allergia	Tipo di Reazione
Allergia a farmaco: Eritromicina (ATC: D10AF02), dal 1995	Eruzione allergica

Reaction Type	Clinical Manifestation	Agent	Onset Date
Drug allergy	Atopic dermatitis and related conditions	erythromycin (D10AF02)	/01/1995

Problem list

Show Original

Descrizione del Problema	Data Insorgenza	Diagnosi	
	2008	I10	Ipertensione Essenziale Non Specificata

Active Problem	Onset Date
Essential (primary) hypertension(I10)	/01/2008

History of medication use

Show Original

Nome Farmaco	Principio Attivo		Dosaggio	Posologia	Via di Somministrazione	Data inizio terapia	Data fine terapia	Note
METOPROLOLO SAN*30 CPR 100MG	C07AB02	Metoprolol	100 mg	1compressa die, prima di colazione		01-06-2014		Terapia Continuativa

Active Ingredient	Strength	Dose Form	Units per intake	Frequency of Intakes	Route of Administration	Onset Date	End Date
metoprolol (C07AB02)	100 mg per unit	Tablet	1 unit(s)	before breakfast		1/06/2014	Positive infinity

History of medical device use

Show Original

- Nessun dispositivo medico in uso

Not applicable

History of Procedures

Show Original

Data	Tipo di Procedura
1963	Appendicectomia

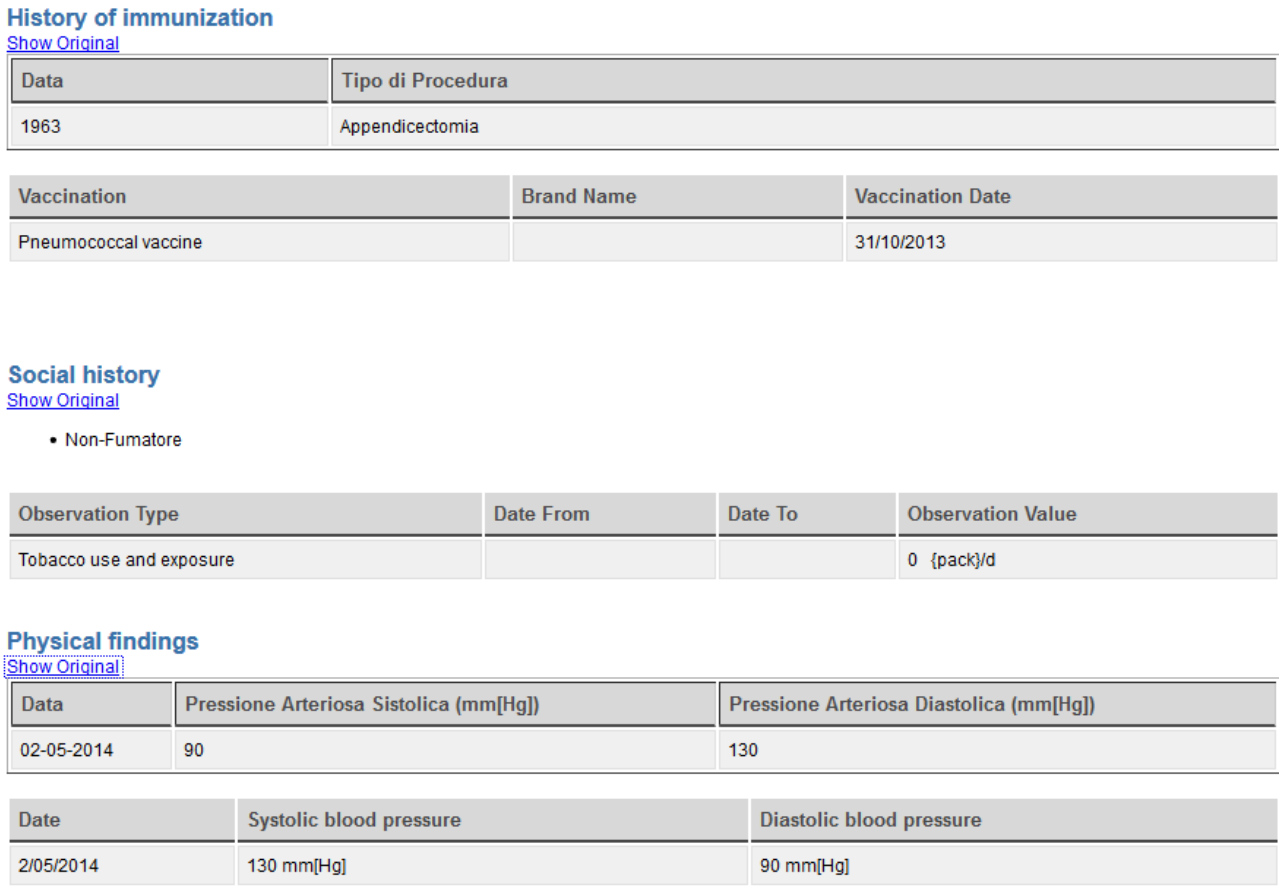
Procedure	Procedure Date
Excision of appendix	//1963

History of past illness

Show Original

- Il paziente non riferisce episodi recenti di emicrania
- Frattura del collo del femore sinistro

Closed/Inactive Problem	Onset Date	End Date
Migraine	/01/1982	/01/1998
Fracture of femur	12/12/2007	Unknown



History of immunization

Show Original

Data	Tipo di Procedura
1963	Appendicectomia

Vaccination	Brand Name	Vaccination Date
Pneumococcal vaccine		31/10/2013

Social history

Show Original

- Non-Fumatore

Observation Type	Date From	Date To	Observation Value
Tobacco use and exposure			0 {pack}/d

Physical findings

Show Original

Data	Pressione Arteriosa Sistolica (mm[Hg])	Pressione Arteriosa Diastolica (mm[Hg])
02-05-2014	90	130

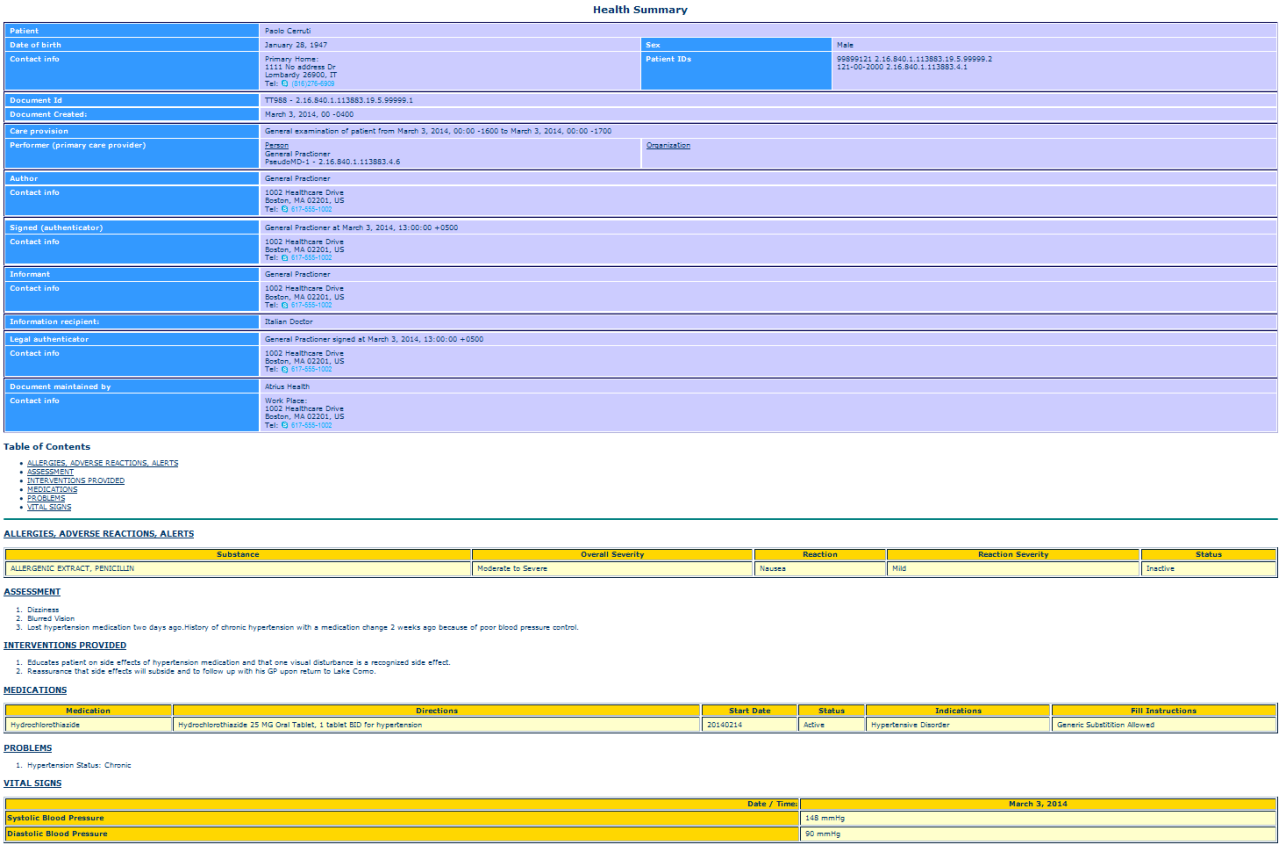
Date	Systolic blood pressure	Diastolic blood pressure
2/05/2014	130 mm[Hg]	90 mm[Hg]

Figure 10 – The Paolo's epSOS Patient Summary

The CDA sample based on this scenario is available from the Project Repository (http://www.trilliumbridge.eu/repository) [RTD_CCD_Martha.xml]

4.3.2.9 *Alternative Flows: What if Paolo was US Citizen?*

If Paolo was a US Citizen his summary would be recorded into a C-CDA CCD, therefore different constrains will be applied to the Paolo's demographic information contained in the CDA header as well as information pertaining to the document's Author, Steward, and Paolo's healthcare provider. The way also the clinical information would be recorded in the body and the vocabulary used will often differ, as described in section 6 and in more detail in WP3. The following figure provides a snapshot of the Paolo's CCD in case he was an US citizen.



Health Summary

Patient	Paolo Cerruti		
Date of birth	January 28, 1947	**Sex**	Male
Contact info	Primary Home: 1111 No address Dr Lombardy 26900, IT Tel: (010)274-4909	**Patient IDs**	99999121 2.16.840.1.113883.19.5.99999.2 121-00-2000 2.16.840.1.113883.4.1
Document Id	TT988 - 2.16.840.1.113883.19.5.99999.1		
Document Created:	March 3, 2014, 00 -0400		
Care provision	General examination of patient from March 3, 2014, 00:00 -1600 to March 3, 2014, 00:00 -1700		
Performer (primary care provider)	Person General Practioner PseudoMD-1 - 2.16.840.1.113883.4.6	Organization	
Author	General Practioner		
Contact info	1002 Healthcare Drive Boston, MA 02201, US Tel: 617-555-1002		
Signed (authenticator)	General Practioner at March 3, 2014, 13:00:00 +0500		
Contact info	1002 Healthcare Drive Boston, MA 02201, US Tel: 617-555-1002		
Informant	General Practioner		
Contact info	1002 Healthcare Drive Boston, MA 02201, US Tel: 617-555-1002		
Information recipient:	Italian Doctor		
Legal authenticator	General Practioner signed at March 3, 2014, 13:00:00 +0500		
Contact info	1002 Healthcare Drive Boston, MA 02201, US Tel: 617-555-1002		
Document maintained by	Altius Health		
Contact info	Work Place: 1002 Healthcare Drive Boston, MA 02201, US Tel: 617-555-1002		

Table of Contents

- ALLERGIES, ADVERSE REACTIONS, ALERTS
- ASSESSMENT
- INTERVENTIONS PROVIDED
- MEDICATIONS
- PROBLEMS
- VITAL SIGNS

ALLERGIES, ADVERSE REACTIONS, ALERTS

Substance	Overall Severity	Reaction	Reaction Severity	Status
ALLERGENIC EXTRACT, PENICILLIN	Moderate to Severe	Nausea	Mild	Inactive

ASSESSMENT

1. Dizziness
2. Blurred Vision
3. Lost hypertension medication two days ago.History of chronic hypertension with a medication change 2 weeks ago because of poor blood pressure control.

INTERVENTIONS PROVIDED

1. Educates patient on side effects of hypertension medication and that one visual disturbance is a recognized side effect.
2. Reassurance that side effects will subside and to follow up with his GP upon return to Lake Como.

MEDICATIONS

Medication	Directions	Start Date	Status	Indications	Fill Instructions
Hydrochlorothiazide	Hydrochlorothiazide 25 MG Oral Tablet, 1 tablet BID for hypertension	20140214	Active	Hypertensive Disorder	Generic Substitition Allowed

PROBLEMS

1. Hypertension Status: Chronic

VITAL SIGNS

Date / Time:	March 3, 2014
Systolic Blood Pressure	148 mmHg
Diastolic Blood Pressure	90 mmHg

Figure 11 – The Paolo's C-CDA CCD

5 Use Case Analysis

In this section we analyze in detail the consolidated use cases UC-I and UC-II focusing on policy issues with particular emphasis on security and privacy.

5.1 UC#I – Visualization of Patient Summary, Patient Mediated

Reference #	Description
Use case name	*Visualization of Patient Summary, Patient Mediated*
Stakeholder story	The patient obtains access to the Patient Summary, gets a copy of it in a format suitable for being used abroad. The Healthcare Professional visualize this translated document on own or on receiver's device. This use case may include the exchange of a translated printable copy. After the unplanned care event, the patient receives an encounter report.
Starting event	The patient plans to leave his/her country.
Actor and Users	The patient initiates this use case, other involved actors are the foreign Health Care Professionals involved in the provision of care. Possible involved actors could be the customs and border protection officers
Goal	Provide the care provider with understandable health information (health conditions, treatments, alerts, etc.) in order to obtain a better treatment quality and improve patient safety. Facilitate the customs and border control processes while traveling with medicinal products.
Stakeholders	Health care providers, EHR vendors, Patient Advocacy Groups
Primary Scenario	- Before leaving the country, the patient gets a translated copy of his/her Patient Summary. - The document is carried by the patient. - When abroad, the patient accesses the translated Patient Summary and shows it to the receiver (e.g. the foreign physician) using his/her device. - The receiver reads the summary - After the care event, the patient receives an encounter report.
Strength	a) No special requirements (display, translation services, etc.) for receivers. b) No consent management required (implicit) c) No cross-borders patient identification required d) No syntactical transformations from and to epSOS-CDA and C-CDA required e) EU countries piloting epSOS Patient Access Service.
Weakness (Assumptions)	a) The translated document has to be prepared by the patient before leaving the country of affiliation. b) A service allowing the patient to access his/her Patient Summary needs to be available c) The patient has to have a patient summary d) A service allowing the patient to obtain a translated/transformed representation of his/her Patient Summary needs to be provided e) When not within the case of exchange of printable representation, the Patient device shall be enabled to display correctly the translated Patient Summary. f) Authenticity of the information
Opportunity	a) Even when limited in scope or not fully translated, the healthcare professional may access patient clinical information otherwise not accessible b) This scenario can be extended to more complex use cases (e.g. data incorporation) and used for the time being for understanding common gaps and traps.

Reference #	Description
Threat	(3) Low quality of data may impact on translation capabilities: in fact only coded information included in the epSOS PS data set can be translated in English and used for creating the text to be printed. Information encoded or not mapped into the epSOS MVC are shown in the original language.
Alternative Scenario #1: translation of	- When abroad, the patient accesses his/her Patient Summary and gets a translated copy of it. - The patient shows the translated Patient Summary to the receiver (e.g. the foreign physician) using his/her device. - The receiver reads the summary This can be considered an enhancement of the primary scenario, since is reasonable to imagine that if the patient is able to access and obtain a translated copy of the PS from abroad, the same would apply when at home.
Strength	- Strengths of Primary Scenario
Weakness (Assumption)	Weaknesses of Primary Scenario, excepting (a) and (b), plus: -Services allowing the patient to access his/her Patient Summary from abroad needs to be available (PAC)
Opportunity	- Opportunities of Primary Scenario
Threat	Threats of Primary Scenario plus: - Secure access to the country of Affiliation Infrastructure to obtain the Patient Summary and to access translation/transformation services.
Alternative Scenario #2: patient summary using provider device	- Before leaving the country, the patient gets a translated copy of his/her Patient Summary. - The document is maintained by the patient. - When abroad, the patient provides the receiver (e.g. the foreign physician) with the translated Patient Summary. - The receiver reads the summary using his/her device - After the care scenario the patient receives a care summary (encounter) report.
Strength	Strengths of Primary Scenario excepting (a) and (d), plus: If the receiver device is the epSOS display, the patient is not required to translate the document in advance.
Weakness (Assumptions)	Weaknesses of Primary Scenario excepting (e), plus: a) The Provider's device shall be enabled to display correctly the translated Patient Summary.
Opportunity	Opportunities of Primary Scenario
Threat	Threats of Primary Scenario, plus: a) Receiver policies that may prevent the loading of external file from the patient's media
Alternative Scenario #3: patient summary using provider device	- When abroad, the patient accesses his/her Patient Summary and gets a translated copy of it. - The document is maintained by the patient. - When abroad, the patient provides the receiver (e.g. the foreign physician) with the translated Patient Summary. - The receiver reads the summary using his/her device - After the care scenario the patient receives a care summary report.
Strength	Strengths of Alternative Scenario 1, plus: If the receiver device is the epSOS display, the patient is not required to translate the document in advance.

Reference #	Description
Weakness (Assumptions)	Weaknesses of Alternative Scenario 1, plus: The Provider's device shall be enabled to display correctly the translated Patient Summary.
Opportunity	Opportunities of Alternative Scenario 1
Threat	Threats of Alternative Scenario 1 plus: a) Receiver policies that may prevent the loading of external file from the patient's media
Extras (optional)	Keywords: - Patient mediated - Optional PDF Comments: Transformation from/to C-CDA CCD and epSOS Pivot: - Realized by a Trillium Transformation Service (4) The document is generated in the target language and saved into a media - EU: this is may be done using the epSOS Display and the epSOS PAC service, that can transform the original friendly A epSOS into an epSOS pivot PS (English) and then save it on a media as CDA Level 3 and PDF. The "save as" function is an enhancement of OpenNCP software that is going to be developed for supporting the patient mediated scenario The document is selected and displayed : - If the display used is the epSOS display, a load function is required for this component. The "load & display" function is an enhancement of the OpenNCP software that is going to be developed for supporting the patient mediated scenario. The adoption of the IHE XDM profile is suggested for the realization of the patient mediated scenario. All those options could be considered : - the translated PS display (for example a style sheet) is on the device - The style sheet is provided with the CDA - the device visualizes the content through an external display service (e.g. web portal) As it happened in epSOS the "standard" CDA stylesheet (that show the texts of sections) is not sufficient for supporting this scenario. It is suggested that : - also a printable representation of the original summary will be provided. The display will show both the translated content (based on the coded concepts) and the CDA narrative text (i.e. section texts)

5.2 UC#II- Patient Summary visualization using provider's device, Provider Mediated

Reference #	Description
Use case name	*Patient Summary visualization using provider's device, Provider Mediated*
Stakeholder story	While providing unplanned care, the healthcare professional accesses the Patient Summary via own EHR-S and visualizes the translated document

Reference #	Description
Starting event	The patient is subject of an unplanned care episode.
Actor and Users	The foreign Health Care Professional initiates this use case, other involved actors: Patient.
Goal	Access to foreign patient health information (health conditions, treatments, alerts, etc.) – and understand it - in order to provide a better treatment to the patient and improve his/her safety.
Stakeholders	See Actors
Primary Scenario	- The patient is receiving unplanned care abroad. - The foreign healthcare professional, after having identified the patient, requests - using own EHR-S - to the patient's Country of Affiliation a Patient Summary of that patient. - The remote country verifies if is entitled to fulfill such a request (correct patient identification, consent provided when applicable, etc.). - If it is, the summary is retrieved and returned to the foreign healthcare professional in a format “suitable” for the receiver visualization, translated in the receiver language. - The foreign healthcare professional visualizes the Patient Summary using own EHR-S.
Strength	Reflect the actual way of working of the Health Professionals It is the natural extension into the Trans-Atlantic context of the epSOS services surrounding the Patient Summary Kaiser Permanente a validating partner of Trillium Bridge, is ready to commit to its validation
Weakness	Consent management required Cross-borders patient identification required Availability of a Patient Summary transformation service able to produce a document in a format consumable by the receiver. Capability of the provider’s EHR-S to access external services to retrieve Patient Summaries. Capability of the provider’s EHR-S to display the translated Patient Summary
Opportunity	Re-usage of the open source software components developed within the epSOS project Even when limited in scope or not fully translated, the healthcare professional may access patient clinical information otherwise not accessible This scenario can be extended to more complex provider mediated use cases (e.g. incorporation of clinical data into the EHR) and used for understanding common gaps and traps.

Reference #	Description
Threat	Mutual trust agreements need to be accomplished. It implies: - mutual Patient identification processes - mutually recognized consent management policies - mutually recognized provider authentication and authorization policies (including roles) The will of provider's organizations to modify their EHR-S for supporting the visualization of translated (localized) Patient Summaries. (Mitigating action: adoption of internationally standardized templates for Patient Summaries) Low quality of data may impact on translation capabilities: in fact only coded information included in the epSOS PS data set can be translated in English and used for creating the text to be printed. Information uncoded or not mapped into the epSOS MVC are shown in the original language.
Alternative Scenario	- The patient is receiving unplanned care abroad. - The foreign healthcare professional, after having identified the patient, requests - using own EHR-S - to the patient's Country of Affiliation a Patient Summary of that patient. - The remote country verifies if is entitled to fulfill such a request (correct patient identification, consent provided when applicable, etc.). - If it is, the summary is retrieved and returned to the foreign healthcare professional in a "source" format (epSOS Pivot is sent to US; C-CDA ToC in sent to EU) in English. - The foreign healthcare professional visualizes the Patient Summary using own EHR-S. Before being visualized the document is processed (transformed, translate) as needed by the EHR-S.
Strength	- Reflect the actual way of working of the Health Professionals
Weakness	- Consent management required - Cross-borders patient identification required - Availability of a Patient Summary translation / transformation service – accessible by the EHR-S - able to produce a document in a format consumable by the EHR-S. - Capability of the provider's EHR-S to access external services to retrieve Patient Summaries. - Capability of the provider's EHR-S to display the translated Patient Summary
Opportunity	- Re-usage of the open source software components developed within the epSOS project - Even when limited in scope or not fully translated, the healthcare professional may access patient clinical information otherwise not accessible - This scenario can be extended to more complex provider mediated use cases (e.g. incorporation of clinical data into the EHR) and used for understanding common gaps and traps.

Reference #	Description

Threat	- Mutual trust agreements need to be accomplished. It implies:
	  - mutual Patient identification processes
	  - mutually recognized consent management policies
	  - mutually recognized provider authentication and authorization policies (including roles)
	- The will of provider's organizations to modify their EHR-S for supporting the visualization of translated (localized) Patient Summaries. (Mitigating action: adoption of internationally standardized templates for Patient Summaries)
	- Low quality of data may impact on translation capabilities: in fact only coded information included in the epSOS PS data set can be translated in English and used for creating the text to be printed. Information encoded or not mapped into the epSOS MVC are shown in the original language.

Extras (optional)	Keywords: - Provided mediated - Optional PDF

Alternative Scenario: (beyond Trillium Bridge)	**1. The patient is receiving care abroad.** **2. The foreign healthcare professional made available to the patient a Patient Summary of that patient.** **3. The patient uses transformation/translation service before integrating the content of the obtained document (or part of it) within his/her own PHR.**

5.3 Policy Background

Trillium Bridge aims at delivering a pragmatic feasibility study on the exchange of Patient Summaries across the Atlantic. This is to be achieved through comparing, analyzing, and mapping patient summaries starting with Meaningful Use 2 C-CDA/CCD and EU patient summaries (epSOS).

This legal analysis is part of the feasibility analysis of the alternative scenarios and use cases. As no real pilots are foreseen within the remit of the project, resolving legal issues is out of scope. This analysis should be therefore regarded as relevant to a possible future deployment of transatlantic exchange of patient summaries.

This document is structured in parts. The next section is a review of the main legal issues encountered in cross border situations. When a transatlantic exchange takes place between the US and an EU country the national legislation of both countries must be observed. It is noted however that according to Article 168 of the Treaty on the Functioning of the European Union (TFEU) a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. However, the Treaty also requires that decisions relating to the provision of healthcare services are taken at the national or local level, and the principle of subsidiarity still applies to the organization of health services in each Member State. The EU thus has legal competency on health matters only insofar as they concern certain public health measures and when they relate to matters of the fundamental freedoms of movement of people, goods and services, such as in cross border health services. As a result, cross border health care is confronted by a great diversity such as with respect to regulations on medicinal products and prescribing, variations in terms of health professionals' duties and their roles, their work protocols and the national processes for accreditation, certification and audit of health care quality.

epSOS has focused on **EU-wide solutions** rather than bilateral scenarios. This was achieved within the constraints of existing organization eHealth systems and national legal frameworks. In doing so, epSOS

resolved, amongst other challenges issued of legal interoperability to make the pilots possible, and based on the experience gained, issued a number of recommendations for achieving legal interoperability in the deployment phase. In this respect, the transatlantic exchange may be based on this EU level agreed framework for cross border exchange within Europe, rather than dealing with the specific legal challenges for each European state separately.

The next section therefore addresses the challenge of lawful transatlantic data exchange in three ways. Firstly, the current and future prospective EU level framework is presented. Similarly, a description the US framework of Data Protection at federal level is provided. Last but not least, the legal framework that makes the transatlantic exchange legally feasible is presented.

The Last section commends on specific details of the use cases. This analysis refers to (i) national legislation (ii) current EU level legislation (iii) epSOS recommendations for sustainability of the legal conditions beyond the pilots, and (iv) current US legislation empowering the transatlantic exchange.

5.4 Cross border exchange of health data

5.4.1 Within Europe

The legal basis for cross border exchange of health data in Europe and from Europe to third countries is Directive 2011/24. The purpose is to improve continuity of care by supporting health professionals to improve patient care in cross border encounters by means of exchanging health information.

Cross-border care eHealth services have been implemented and piloted in epSOS in 15 Countries. They initially focused on accessing Patient Summaries and ePrescriptions and notifying dispensations. They were then extended to include functionalities permitting for the notification of a health care encounter in country B (HCER- Health Care Encounter Report) and the access to the PS by the patient in own language (PAC – Patient Access).

A health professional will normally access health information of subjects of care he/she has made a healthcare commitment to, in order to plan or perform clinical activities or evaluate clinical results and make clinical decisions. Such data is also sharable data e.g. in national Patient Summary repositories. He/she also contributes new data resulting from these clinical activities. epSOS use cases and their extensions make it possible to access such sharable data by a health professional in a country of treatment abroad and to return new health information created abroad for incorporation into the national repositories of sharable data.

The common EU legal basis for cross border data transfer has been Directive 95/46/EC on the protection of individuals withhttp://healthewayinc.org/images/Content/Documents/Onboarding-Artifacts/2011-05-dursa-policy-assumptions-summary.pdfh regard to the processing of personal data and on the free movement of such data.[26] Furthermore, the wider general legal basis for the processing of health data from health records as well as for electronic prescription can be gleaned from the detailed comments laid down in WP 131, which elaborates the relevant provisions of Directive 95/46/EC.

In particular, explicit consent [(Article 8 (2) (a)] and the vital interest of the data subject [Article 8 (2) (c)] have served as an appropriate legal basis for the processing of personal data in the framework of epSOS. The general principles laid down in Article 6 of the Directive have been also taken into account. These include, in particular, the purpose limitation principle, the proportionality principle, the data quality principle and the principle, which requires personal data to be kept for no longer than is necessary for the purposes for which the data were collected or further processed. Furthermore other general principles such as the information

26 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML

requirements, the data subject's right of access, rectification and deletion and security related obligations have been observed.

In order to enable the exchange of personal health related data, MS sought agreements on a number of safeguards, which were put in place for the operation of the pilots, including those for processing of health information with proper balancing of patients' interests and organizational constraints that should be guaranteed by all pilot sites. These safeguards were expressed as requirements for piloting countries in the form of clauses in a Framework Agreement (FWA). This Framework Agreement provided a blueprint for national level contractual agreements - where required[27] - to create a National Contact Point (NCP) as a legal entity entitled to process patient data in the context of the epSOS pilot. The FWA has been approved by the epSOS Steering Board composed of National Authorities representatives.

Each country is represented in epSOS by its National Contact Point (NCP). An epSOS NCP is an organization legally mandated by the appropriate authority of each country to act as an interface between the existing different national functions and infrastructures.

The NCP is legally competent to contract with other organizations in order to provide the necessary services, which are needed to fulfill the epSOS Use Cases. The epSOS NCP is identifiable in both the epSOS domain and in its national domain. It acts as a communication gateway and also as a mediator for delivering epSOS Services. As such, an NCP is an active part of the epSOS environment if it is compliant to normative epSOS interfaces in terms of structure, behavior and security policy compliance.

The common Framework Agreement (FWA) aimed to establish the epSOS Trusted Domain amongst NCPs. This domain was conceived as an extension beyond national or regional territories where healthcare services, supported by epSOS data services, are physically provided. Its function is to ensure that cross border services supported by epSOS can be delivered seamlessly to populations travelling between countries participating in the epSOS Large Scale Pilot.

All epSOS National Contact Points and Points of Care, that joined the pilot, implemented these provisions. Implementation of safeguards at the NCPs and the points of care is subject to periodic audit. According to approved PSB Audit Policy, no specific cross-border security audit is required as long as national audit is carried out by an auditor certified to international standards and accredited by national law. What is required however is that the internal audit (monitoring) should include verification of conformance to epSOS safeguards.

In case of a serious non-conformity or dispute an escalation process would include the delegation of an epSOS independent certified auditor to perform an independent audit in the country in question.

5.4.2 In the USA: DURSA agreement

The Data Use and Reciprocal Support Agreement (DURSA) is a comprehensive, multi-party trust agreement that is entered into voluntarily by public and private organizations (eHealth Exchange Participants) that desire to engage in electronic health information exchange with each other as part of the eHealth Exchange. It was first set up in 2009 and was updated in 2011[28].

The DURSA builds upon the various legal requirements that Participants are already subject to and describes the mutual responsibilities, obligations and expectations of all Participants under the Agreement. All of these responsibilities, obligations and expectations created a framework for safe and secure health information

[27] for example, the national administration provided the service itself

[28] http://healthewayinc.org/images/Content/Documents/Application-Package/2011.03.05-restatement-i-of-the-dursa-final.pdf

exchange, and are designed to promote trust among Participants and protect the privacy, confidentiality and security of the health data that is shared.

The DURSA is based upon the existing body of law (Federal, state, local) applicable to the privacy and security of health information and is supportive of the current policy framework for health information exchange. The DURSA is intended to be a legally enforceable contract that represents a framework for broad-based information exchange among a set of trusted entities. The Agreement reflects consensus among the state-level, federal, and private entities that were involved in the development of the DURSA regarding the following issues:

(1) Multi-Party Agreement
(2) Participants Actively Engaged in Health Information Exchange
(3) Privacy and Security Obligations
(4) Requests for Information Based on a Permitted Purpose
(5) Duty to Respond
(6) Future Use of Data Received from Another Participant
(7) Respective Duties of Submitting and Receiving Participants
(8) Autonomy Principle for Access
(9) Use of Authorizations to Support Requests for Data
(10) Participant Breach Notification
(11) Mandatory Non-Binding Dispute Resolution
(12) Allocation of Liability Risk

5.4.2.1 DURSA Policy Assumptions

The following outlines the key policy assumptions that underscore the agreement[29]:

- Shared Rules of the Road and Shared Governance. Common framework that binds all Participants to a set of technical requirements, testing requirements, policies, governance structure and accountability measures, including a process for adding or changing requirements.
- Representative Governance: Participants are governed by a representative group of Participants who share data in production. Additional methods for obtaining broad community input and engagement (e.g. task groups, outreach, industry collaboration, etc.) shall be supported to assure support and alignment with national policy.
- Participants in Production. Assumes that participants are in production and leverages a participant's existing end user trust agreements, policies and vendor agreements.
- Multiple Exchange Methods and Profiles. Enables Participants to declare which profiles or use cases they wish to support in production. Supports multiple exchange methods, or "Transaction Patterns", such as: push, query / retrieve and publish/subscribe.
- Privacy and Security Obligations. Defers to Applicable Law and establishes HIPAA as contractual standard of performance for those who are not governmental agencies and not otherwise subject to HIPAA. Highlights specific requirements which represent the most likely risk to the network, related to: system access policies, identification, authentication, enterprise security, malicious software, auditing and monitoring access.

[29] http://healthewayinc.org/images/Content/Documents/Onboarding-Artifacts/2011-05-dursa-policy-assumptions-summary.pdf

- Identification and Authentication. Each user who shares data as part of the eHealth Exchange shall be uniquely identified and their identity verified prior to granting access to a Participant's system.
- Permitted Purposes. Permits exchange of information among eHealth Exchange Participants for certain purposes, including: treatment, limited payment and health care operations, public health activities and reporting, any purpose to demonstrate meaningful use, and disclosures based upon an individual's authorization. These purposes may be revisited over time as additional use cases are brought forward.
- Future Use of Data Received. Through the eHealth Exchange. Data are received and integrated into end-user's system and may be reused or disclosed as any other information in its records, in accordance with Applicable Law and local record retention policies.
- Local autonomy - Each Participant shall have Participant Access Policies that establish a Participant's Users are permitted to exchange data using the Participant's system. Each Participant acknowledges that these access policies will differ among them as a result of varying Applicable Law and business practices. A Participant may not discriminate and refuse to share data with another Participant solely on the basis of differing system access privileges. A Participant is not required or permitted to release information in conflict with Applicable Law.
- Reciprocal Duty to Respond. Participants who query data for treatment purposes also have a duty to respond to requests for data for treatment purposes, either with a copy of the data or with a standardized response that data are not available. Participants may respond to requests for other purposes.
- Responsibilities of Party Submitting Data. Participants who submit data are responsible for submitting the information in compliance with applicable law and representing that the message is:
  - for a Permitted Purpose;
  - sent by the Participant who has requisite authority to do so;
  - supported by appropriate legal authority, such as consent or authorization, if required
  - by Applicable Law; and
  - sent to the intended recipient.
- Authorizations. When a request is based on an authorization (e.g. for SSA benefits determination), the requesting Participant must send a copy of the authorization with the request for data.
- Participant Breach Notification. Participants are required to promptly notify the eHealth Exchange Coordinating Committee and other impacted Participants of breaches related to the eHealth Exchange (i.e. unauthorized acquisition, access, disclosure or use of the data transmitted among Participants, which occur while transmitting the data).
- Chain of Trust. A participant's obligations to comply with the DURSA must "flow down" to users or other participating organizations that connect through a Participant's system, as well as the technology partner.
- Mandatory Non-Binding Dispute Resolution. Participants will agree to participate in a mandatory, non-binding dispute resolution process that preserves the Participants' rights to seek redress in the courts if not resolved through the dispute resolution process.
- Allocation of Liability Risk. Each participant is responsible for their own acts and omissions, but not the acts and omissions of other participants. Participants are responsible for harm caused if they breach the DURSA or if, due to their negligence, there is a breach of data being transmitted.

- Representations and Warranties:
  - Protected Health Information (PHI) may not be used in test data sets used for testing purposes. PHI may not be sent to the Coordinating Committee.
  - Participants represent that the data they transmit is an accurate representation of the data in their system at the time the data are transmitted.
  - Participants warrant that they have the authority to transmit information.
  - Participants assert that they are not subject to a final order issued by a court, regulatory or law enforcement organization, which materially impacts their ability to fulfill their obligations under the DURSA. In addition, participants represent that they are not excluded, debarred or ineligible for participating in federal contracts, or grants.
  - Participants do not guarantee clinical accuracy, content or completeness of the messages transmitted. Data transmitted do not include a full and complete medical record or history. In addition, data transmitted are not a substitute for health care providers to obtain whatever information they deem necessary to properly treat patients. Healthcare providers are accountable for treating patients. Participants, by virtue of signing the DURSA, do not assume any role in the care of an individual.
  - Participants are not accountable for failure of carrier lines (e.g. third party carriers for communications, Internet backbone, etc.), which are beyond the Participant's control. Data are provided "as is" and "as available", without a warranty of its "fitness for a particular purpose".
  - Participants are not liable for erroneous transmissions, and loss of service resulting from communication failures by telecommunication service providers or other third parties.

5.5 Enabling transatlantic exchange of health data

The European Commission Directive on Data Protection prohibits the transfer of personal da ta to non-European Union countries that do not meet the European Union (EU) "adequacy" standard for privacy protection. Since its effect in October 1998, the European Commission has assessed several national data protection schemes and has issued several Decisions about countries, projects and situations, deemed to satisfy the European data protection requirements. These decisions, however do not completely equate the respective countries, projects or situations, meaning that the European data protection framework is to be unrestrictedly applied, but attest them to comply with Art. 25 DPD, which introduces a number of principles for third country data transfer. Usually these EC Decisions include provisions allowing the competent authorities in Member States to suspend data flows to recipients resided in the country or being part of the projects or situations subject of the respective EC Decision, in case a national authority – of the country, not the Member State, concerned – has determined a breach of the data protection standards or an infringement of those standards is very likely to occur.

As of July 26, 2000, through EC Decision 2000/520/EC on the USA Safe Harbor[30] program, the US was included as one of the countries compliant with the Data Protection Directive. While the United States and the EU share the goal of enhancing privacy protection for their citizens, the United States takes a different approach to privacy from that taken by the EU. The United States uses a sectoral approach that relies on a mix of

[30] Safe Harbor refers to a framework of national and international contracts, providing for a distinct level of data protection (cf. http://export.gov/safeharbor/eu/eg_main_018365.asp, last visited: Nov. 11th 2011, for more detailed information). An updated list of the current Safe Harbor companies can be retrieved at http://safeharbor.export.gov/list.aspx (last visited: Nov. 11th, 2011).

legislation, regulation, and self-regulation. The EU, however, relies on comprehensive legislation that requires, among other things, the creation of independent government data protection agencies, registration of databases with those agencies, and in some instances prior approval before personal data processing may begin. As a result of these differences, the Directive could have significantly hampered the ability of U.S. organizations to engage in trans-Atlantic transactions involving exchange of personal data.

The U.S.-EU Safe Harbor Framework is a self-certifying mechanism, which ensures that EU organizations know that a US organization provides "adequate" privacy protection, as defined by the Directive.

It should be noted that the decision by U.S. organizations to enter the U.S.-EU Safe Harbor program is entirely voluntary. Organizations that decide to participate in the U.S.-EU Safe Harbor program must comply with the U.S.-EU Safe Harbor Framework's requirements and publicly declare that they do so. To be assured of Safe Harbor benefits, an organization must self-certify annually to the Department of Commerce in writing that it agrees to adhere to the U.S.-EU Safe Harbor Framework's requirements, which includes elements such as notice, choice, access, and enforcement. It must also state in its published privacy policy statement that it adheres to the Safe Harbor Privacy Principles.

To qualify for the U.S.-EU Safe Harbor program, an organization can either join a self-regulatory privacy program that adheres to the U.S.-EU Safe Harbor Framework's requirements; or develop its own self-regulatory privacy policy that conforms to the U.S.-EU Safe Harbor Framework.

5.6 Legal issues to be addressed in the transatlantic exchange of health data

The legal issues identified and resolved in epSOS may be found in a concise, executive level description in the epSOS Recommendations and in particular the legal sustainability chapter. The majority of them apply also to the transatlantic scenario and are briefly touched upon below:

DATA PROTECTION AND CONFIDENTIALITY: Key issues to be addressed are the legal basis for access to data between EU MS and the US; patient consent to such access to health data and information to patients. It should be noted however that while the legal rules are established and clear at national level, there is still a lack of patient knowledge of how their personal data are handled and what legal rights of access and control they have in transatlantic settings. This lack of education is well addressed through pilots such as epSOS, but it is important for Member States and the US to address the issue at local and state levels.

PATIENT CONSENT: Patient Consent is the “freely given specific and informed indication of the patient’s wishes by which s/he signifies his agreement to personal data relating to him being processed”.[31] In transposing the Data Protection Directive (DPD), EU Member States have introduced or enhanced national systems for regulating access control to patient information, as part of establishing their national trusted domain in eHealth. It is important to note however that there are some significant differences in the transpositions of the Data Protection Directive. For this purpose epSOS adopted a 2-step consent approach – prior general consent provided in the country of affiliation and specific consent provided at the point of care in the country of treatment.

For transatlantic exchange it will be important to agree on a common policy for patient consent, taking into account also organizational implications of such approach.

LEGAL ISSUES RELATED TO HEALTH SYSTEMS: Unlike other sectors, very little is regulated at EU level in terms of harmonizing health systems and healthcare services.

31 This definition is laid down in Art 2(h) of the Data Protection Directive (1995/46/EC). Given that this is a rather precise formulation which has been further clarified in the recitals of the Directive as well as in subsequent opinions of the Data Protection Working Party, the definition and handling of patient consent does not vary significantly across Member States.

It is important to note that in a usual transatlantic face to face healthcare situations local rules will apply when patients seek treatment outside their usual country of residence - therefore they may not be able to exercise rights in the visited country that they would be able to exercise at home, such as a right to mask certain information. This again calls for good patient knowledge.

LIABILITY - healthcare professionals will be called to treat foreign patients that may have an electronic Patient Summary available in their country of affiliation and which will be made available to them to consult. It is imperative that they understand that the primary application of this Patient Summary is to provide them with a data set of essential and understandable health information to deliver safer patient care. Furthermore to understand its "value" as a clinical tool i.e., what the Patient Summary is and what it is not, and how it was created.

Liability in the Trillium bridge use cases is primarily related to the processing (translation and transcoding) of the pivot MVC when converting it to local MTCs. This means that actors, whether natural or legal persons, involved in providing transatlantic PS services must assume responsibility towards each other and towards the end users and patients for the safety of the services delivered. It means also that any individual or organization that suffers a harm or loss as the result of using these services or receiving healthcare in which a health professional has made use of the services may be able to claim for compensation if the harm or losses can be attributed to a failure attributed to such processing.

In terms of liability associated with the legal responsibility for Data Protection in this is as an important part of the transatlantic security and data protection framework. It is interesting to note that although in some national environments, compensation claims due to infringements of privacy are actually close to zero, this aspect becomes very important in the cross border exchange due to the different implementation of the DPD, the Safe Harbor framework requirements and the varying security levels across EU MS and the US. Therefore, although liability concerning data protection may be of little relevance from the civil law point of view in the national context, it is a major area of concern in cross border and transatlantic eHealth context.

SECURITY: There are different security levels applied by the EU MS and the US for the protection of personal data in terms of technical and organizational measures. In relation to electronic identification it is necessary to achieve a high degree of certainly of who the person is both for the patient and for the healthcare professional. The eID Regulation in the EU sets rules only in what concerns electronic identification and authentication and it does not apply to the US. Common identification and authentication measures are expected to be adopted in the immediate future by the eHealth Network – the European policy co-ordination mechanism for eHealth. Similar agreements are likely to be needed between the EU and the US.

5.7 Critical Elements of the Use cases

5.7.1 Visualization of a printable representation of the Patient Summary

The Patient prepares a printed copy of his/her translated patient summary (paper and/or pdf) before crossing the border and brings the printed copy with him/her. The translated printed Patient Summary is shown by the patient to the physician or to other professionals that may request it (e.g. customs and border protection officers)

(1) The patient prepares in advance a translated printable representation (paper, pdf) of his/her Patient Summary.
    a. Applicable legislation is national
    b. A legal pre-requisite is that the country of affiliation has the legal framework for Patient Access to own EHRs in place. Identification, authentication and authorization issues are also handled nationally. Liability for processing (translation) of PS information lies with the service (translation) provider. The fundamental principles of tort law are to be found at

national level. Therefore a comprehensive analysis would require careful consideration of national provisions.

(2) When abroad, the patient hands the printed copy to the receiver (e.g. the foreign physician).
   a. EU Directive 2011/EU, Art 4, par. 2 lit. f
   b. "in order to ensure continuity of care, patients who have received treatment are entitled to a written or electronic medical record of such treatment, and access to at least a copy of this record in conformity with and subject to national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC". Responsibility for sharing this information is with the patient. Handing over the hard copy of the record to the physician implies informed, specific consent.

(3) The receiver reads the summary
   a. National Legislation
   b. National Legislation binds health professionals to confidentiality with respect to health information concerning their patients.

5.7.2 Patient Summary visualization using patient's device, Patient Mediated

The patient obtains access to the Patient Summary from abroad and shows a translated document on own device. This use case may include the use case #1 and implies alternative scenarios.

(1) Before leaving, the patient gets a translated copy of his/her Patient Summary.
   a. Legal basis is provided by National legislation
   b. A legal pre-requisite is that the country of affiliation has the legal framework for Patient Access to own EHRs in place. Identification, authentication and authorization issues are also handled nationally. Liability for processing (translation) of PS information lies with the service (translation) provider. The fundamental principles of tort law are to be found at national level. Therefore a comprehensive analysis would require careful consideration of national provisions.

(2) Patient shows it to the receiver(e.g. the foreign physician) using his/her device.
   a. Directive 2011/EU, Art 4, par. 2 lit. f
   b. "in order to ensure continuity of care, patients who have received treatment are entitled to a written or electronic medical record of such treatment, and access to at least a copy of this record in conformity with and subject to national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC".
   c. Responsibility for sharing this information is with the patient. Handing over the device containing the record to the physician implies informed, specific consent.

(3) The health professional reads the summary
   a. Subject to National Legislation
   b. National Legislation binds health professionals to confidentiality with respect to health information concerning their patients.

5.7.3 Patient Summary visualization using provider's device, Patient Mediated

While abroad the Patient grants access to his/her translated Patient Summary to the provider, the provider visualizes this document using own device.

(1) The patient prepares a translated (possibly transformed) version of his/her Patient Summary.
   a. Legal basis offered by National legislation
   b. A legal pre-requisite is that the country of affiliation has the legal framework for Patient Access to own EHRs in place. Identification, authentication and authorization issues are

also handled nationally. Liability for processing (translation and transcoding) of PS information lies with the service (translation and transcoding) provider. The fundamental principles of tort law are to be found at national level. Therefore a comprehensive analysis would require careful consideration of national provisions.

(2) The Summary is maintained by the patient (e.g. through a cloud).
   a. Legal basis provided by National legislation
   b. Responsibility for safeguarding this information is with the service provider.

(3) When abroad, the patient grants the foreign healthcare professional access to the translated summary.
   a. This action is understood as providing access to displayed information which the patient has accessed using his credentials. This is differentiated from the case where the health professional obtains access using his credentials and discovery information provided by the patient.
   b. Responsibility for sharing this information is with the patient. Providing access to the visual information of the electronic health record to the physician implies informed, specific consent.

(4) The foreign healthcare professional access the Patient Summary and visualizes it using own device.
   a. Subject to National Legislation
   b. National Legislation binds health professionals to confidentiality with respect to health information concerning their patients.

5.7.4 Patient Summary visualization on the provider's device, Provider Mediated

While providing unplanned care, the healthcare professional accesses the Patient Summary via own EHR-S and visualizes the translated document

(1) The patient is receiving unplanned care abroad.
   a. Subject to Directive 2011/24: This Directive applies to individual EU patients who decide to seek healthcare in a Member State other than the Member State of affiliation. There are no provisions related to EU-US. A US citizen, when receiving care in Europe will most likely "use" the cross border organizational and technical eHealth infrastructures available to EU citizens (such as the NCP of Article 5 of the Directive)

(2) The foreign healthcare professional, after having identified the patient, requests - using own EHR-S - to the patient's Country of Affiliation a Patient Summary of that patient
   a. Subject to Directive 95/46/EU: "Article 8 (7) Member States shall determine the conditions under which a national identification number or any other identifier of general application may be processed."
   b. Subject to directive 2011/24: Recital 24. Member States should ensure that mechanisms for the protection of patients and for seeking remedies in the event of harm are in place for healthcare provided on their territory and that they are appropriate to the nature and extent of the risk. Recital 49 The Member States should decide on the form and number of their national contact points. Such national contact points may also be incorporated in, or build on, activities of existing information centers provided that it is clearly indicated that they are also national contact points for cross-border healthcare…The existence of national contact points should not preclude Member States from establishing other linked contact points at regional or local level, reflecting the specific organization of their healthcare system. Recital 52: The Member State of affiliation may need to receive confirmation that the cross-border healthcare will be, or has been, delivered by a legally practicing health professional. It is therefore appropriate to ensure that information on the right to practice

contained in the national or local registers of health professionals, if established in the Member State of treatment, are, upon request, made available to the authorities of the Member State of affiliation. Article 4 maintains Information requirements: (a) Member States shall ensure that the national contact points referred to in Article 6 of Directive 2011/24/EU inform patients about the elements to be included, pursuant to this Directive, in prescriptions issued in a Member State other than the Member State where they are dispensed. (b) Article 14: The Objectives of the Network is to support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

c. epSOS Recommendations: All data contained in medical documentation, in electronic health records and ePrescriptions are "sensitive personal data" and therefore subject to Article 8 of the Data Protection Directive. MS should include cross border specific safeguards into their national information management systems and compliance requirements. Each country or region is represented in the cross border eHealth context by its National Contact Point for cross border eHealth (NCPeH) which may be a different that the NCP foreseen under Directive 2011/24/EU. A national or regional NCPeH acts as a communication gateway and maintains compliance to normative interfaces in terms of structure, behavior and security policy (epSOS). It is recommended that a platform of NCPs be established that enforce governance of the Framework Agreement, on-boarding of new PNs, periodic auditing and general operations of the epSOS infrastructure. The NCPeH is assigned the role of data controller when receiving and further processing personal data from abroad. The NCP foreseen by the Directive 2011/24/EU should include information the specific rights of data subjects, conditions and practicalities on privacy and confidentiality aspects, according to the different legislations of each Member State

(3) The remote country verifies if is entitled to fulfill such a request (correct patient identification, consent provided when applicable).

a. Directive 95/46/EU: Article 8 on the processing of special categories of data. Member States shall prohibit the processing of personal data and the processing of data concerning health or sex life. This general prohibition shall not apply where:

i. the data subject has given his explicit consent to the processing of those data, except where the laws of the Member State provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject's giving his consent; or

ii. processing is necessary to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving his consent;

b. epSOS Recommendations: The processing of healthcare data must have a clear legal basis. In the absence of other legitimate grounds, this can be the data subject's two-step explicit consent [epSOS, WP29]. MS adopt measures at the local and regional level to improve good patient knowledge and education on cross border eHealth aspects relating to their ability to exercise rights in the visited county that they would be able to exercise at home, such as a right to mask certain information rules. In the event of emergency access to health data without consent, the patient or person acting on behalf of the patient is informed about the override of consent upon leaving the PoC including details of access; privacy and confidentiality are embedded in the design of all eHealth cross border services which should include mandatory components for patient consent as well as access to audit trails and notification in case of emergency access; It is recommended that the non-

functional requirements be uplifted to form the basis for SLAs for operation of national and central services.

(4) If it is, the summary is retrieved and returned to the foreign healthcare professional in a format "suitable" for the receiver visualization, translated in the receiver language. OR If it is, the summary is retrieved and returned to the foreign healthcare professional in a "source" format (epSOS Pivot is sent to US; C-CDA ToC in sent to EU) in English.
   a. Subject to National Legislation: Liability for processing (translation and transcoding) of PS information lies with the service (translation and transcoding) provider. The fundamental principles of tort law are to be found at national level. Therefore a comprehensive analysis would require careful consideration of national provisions.

(5) The foreign healthcare professional visualizes the Patient Summary using own EHR-S. Or the foreign healthcare professional visualizes the Patient Summary using own EHR-S. Before being visualized the document is processed (transformed, translated) as needed by the EHR-S.
   a. National Legislation It is understood that no information is downloaded and stored locally.
   b. National Legislation binds health professionals to confidentiality with respect to health information concerning their patients.
   c. Liability for processing (translation and transcoding) of PS information lies with the service (translation and transcoding) provider. The fundamental principles of tort law are to be found at national level. Therefore a comprehensive analysis would require careful consideration of national provisions.

5.7.5 - Incorporating the translated Patient Summary in the PHR.

Independently on how the transformed and/or translated Patient Summary is obtained by the Patient, the document content (or part of it) is incorporated by the patient within his/her PHR.

(1) The patient is receiving care abroad.
   a. Directive 2011/EU: This Directive applies to individual EU patients who decide to seek healthcare in a Member State other than the Member State of affiliation. There are no provisions related to EU-US. A US citizen, when receiving care in Europe will most likely "use" the cross border organizational and technical eHealth infrastructures available to EU citizens (such as the NCP of Article 5 of the Directive)

(2) The foreign healthcare professional made available to the patient a transformed and/or translated Patient Summary of that patient OR The foreign healthcare professional made available to the patient a Patient Summary of that patient

(3) The patient incorporates the content of the obtained document (or part of it) within his/her own PHR.

(4) The patient uses transformation/translation service before integrating the content of the obtained document (or part of it) within his/her own PHR.

5.7.6 Incorporating the translated Patient Summary in the EHR

(1) A transformed and/or translated Patient Summary is made available to the healthcare professional.
   a. Directive 2011/EU: This Directive applies to individual EU patients who decide to seek healthcare in a Member State other than the Member State of affiliation. There are no provisions related to EU-US. A US citizen, when receiving care in Europe will most likely "use" the cross border organizational and technical eHealth infrastructures available to EU citizens (such as the NCP of Article 5 of the Directive)

(2) The healthcare professional incorporates the content of the obtained document (or part of it) into that patient's EHR.
(3) A Patient Summary is made available to the healthcare professional.

6 Comparison Between epSOS Patient Summary (PS) and Consolidated CDA (C-CDA)

6.1 General Comparison

The first comparison between the two documents, namely the epSOS Patient Summary and Continuity of Care Document used in MU-2 was performed at the macro level (data elements which were translated into sections), with the understanding that further analysis will be performed on a more refined level. At this level of analysis, correspondence is established to verify that the distinct data element exists in both documents and that they are clinically equivalent. A more detailed comparison will be performed at the entry level in order to establish the correspondence of the finer elements. The documents will also have the type of information contained in the header examined in order to complete the overall picture and to see if any other inferences can be made from this comparison (concerning legal, patient identification, etc.).

6.2 Clinical Comparison (Body)

The main purpose of this comparison is to establish a common area between the two sides of the Atlantic using coded entries and well-established value sets so that a semantic mapping can be engaged.

The epSOS Patient Summary as well as the Patient Summary of the EU Guideline specifications are compared to the CCD document. Although the comparison is clinical, the way the information is expressed in the respective documents does play a role.

The correspondence that was determined to exist between the sections is summarized in *Table* below:

epSOS/EU Directive	EU Guidelines	epSOS PS	CCD	
Section	**Optionality**	**Optionality**	**Section**	**Optionality**
Allergy	R	R	Allergies	R
Medical Alert[32] Information (other alerts not included in allergies)	R	R		
Vaccinations	O	O	Immunizations	O
List of resolved, closed or inactive problems	O	O	Problem	R
Surgical Procedures prior to the past six months	R	O	Procedures	O (R only for inpatients)
List of current problems / diagnoses	R	R	Problem	R
Medical Devices and implants	R	R	Medical Equipment	O
Major Surgical Procedures in the past six months	R	R	Procedures	O (R only for inpatients)

[32] The field “alerts” was originally defined as to include all the important and objective medical information that should be highlighted (such as allergies, thrombosis risk, immune deficit …etc.). However, when refining its content, only allergies and intolerance to drugs appear to have a common understanding and thus deemed easiest to be transferred. A lot of surveys are being made in different countries (not only in Europe) in order to obtain an evidence-based definition of what should be represented and should not by the concept “*alerts*”. As not enough information could be provided at the time to take a further decision and epSOS’s intention was not to duplicate information, this endeavour was not repeated. Alerts are difficult to represent since they are contextual. Alerts may be represented as severe or life-threatening allergies or other adverse reactions. As a general area, selected procedures and implanted devices can also be considered as “alerts”; this has its own representation in its respective section. The section *Allergies and Other Adverse Reactions* contains the medical alerts as well, based on the severity, and their representation becomes a Country B choice.

epSOS/EU Directive	EU Guidelines	epSOS PS	CCD	
Treatment Recommendations	R	O	Plan of Care	O
Autonomy / Invalidity	R	O	Functional Status	O
List of current medicines	R	R	Medications	R
Social History Observations	O		Social History	O
Pregnancy history (Expected date of delivery)	O	O	Pregnancy Observation of the Social History	O
Physical findings (Vital Signs Observations)	O	O	Vital Signs	O
Diagnostic tests (Blood group)	O	O	Results Section	R
			Advance Directives	O
			Family History	O
			Payer	O
			Encounters	O

Table 3 - A high-level Comparison between the PS and the CCD Document

Please refer to Appendix 3 for the details of this comparison.

6.3 Common Area of Intersection Between the epSOS Patient Summary and the CCD Document

Upon inspection of the sections present in both documents one can immediately conclude that although the comparison was intended as clinical, the implementation does also play a role, for example one section being expressed in free text versus coded entries. Figure 12 below illustrates the common elements of the intersections of the two representative documents. Their names are listed below in the most illustrative manner (meaning that the name describing most accurately the clinical element was used from either side i.e. *Medications vs. List of current medicines*, *Immunizations vs. Vaccinations,* etc.*)*

- Allergy
- Immunizations
- Problems
- Surgical Procedures
- Medical Devices and implants
- Treatment Recommendations
- Autonomy / Invalidity
- Medications
- Social History Observations
- Pregnancy history (Expected date of delivery)
- Physical findings (Vital Signs Observations)
- Diagnostic tests (Blood group)

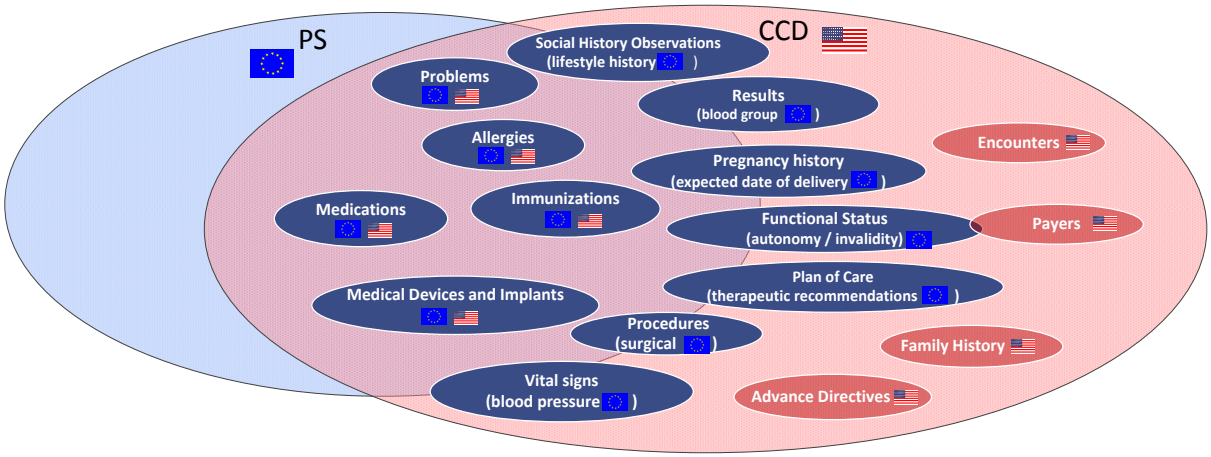


Figure 12 - Intersection of Clinical Data in the Patient Summary and the Continuity of Care Document

The *Treatment Recommendations* and *Autonomy/Invalidity* are in text format only, and the latter is not implemented in epSOS. There are four elements that are present only in CCD and not in PS. These are: *Advance Directives*, *Encounters*, *Payers* and *Family History*.

The data elements common in meaning to both documents containing both coded entries and of **equal informational coverage** are:

- **Medications**
- **Allergies**
- **Immunizations**
- **Problems**
- **Medical Devices and Implants**

The data elements that are common to both documents, containing coded entries but are **richer in content on the CCD side** are:

Social History Observation. In CCD this section contains data defining the patient's occupational, personal (e.g., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity and religious affiliation. In PS this section addresses only the lifestyle history (smoking, alcohol and diet). This section also includes the ***Pregnancy Observation,*** which contains the Estimated Date of Delivery.

Results. The Results section contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes observations such as hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, echocardiography, nuclear medicine, pathology, and procedure observations. In PS this section contains only the blood group.

- **Vital signs** section contains relevant vital signs for the context and use case of the document type, such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, and pulse oximetry.

Procedures. This CCD section defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time the document is generated. The PS Procedures section contains only the surgical procedures.

In addition to the coded entries there are two sections, which are present as free text on the *epSOS Patient Summary.*

Plan of Care section contains data that defines pending orders, interventions, encounters, services, and procedures for the patient. In PS this section contains therapeutic recommendations that do not include drugs (diet, physical exercise constraints, etc.) and it is *free text*.

Functional Status. This CCD section describes the patient's physical state, status of functioning, and environmental status at the time the document was created. In PS this section describes the invalidity status and it is *free text.*

The value sets, the associated code systems are listed in Appendix 2**.** The high-level comparison between the value set used in the coded elements can be seen in Table 3 and in more detail in Appendix 3.

At this point some high-level mapping can be asserted. They are highlighted in green in Appendix 3. For example, equivalent mappings have been identified between the value sets used in the following coded sections:

Allergies				
	Allergy/Adverse Event Type	SNOMED CT	epSOSAdverseEventType epSOSReactionAllergy	SNOMED CT
	Medication Clinical Drug Name Value Set	RxNorm	epSOSActiveIngredient	Anatomical Therapeutic Chemical
Immunizations				
	Vaccine Administered Value Set	CDC Vaccine Code (CVX)	epSOSVaccine	SNOMED CT
Problem				
	Problem	SNOMED CT	epSOSIllnessesandDisorders	ICD-10
Medical Equipment				
	n/a		epSOSMedicalDevices	SNOMED CT
Medications				
	Medication Route FDA	FDA RouteOfAdministration	epSOSRouteofAdministration	EDQM
	UnitsOfMeasureCaseSensitive	UCUM	epSOSUnits	UCUM Unified Code for Units of Measure
Vital Signs				
	Vital Sign Result	LOINC	epSOSBloodPressure	LOINC
	MoodCodeEvnInt	ActMood		

Table 4 - High-level Value Set Mapping

The comparison of value sets is strongly linked to the detailed comparison of the entries, hence at this moment this is the only equivalence that could be established. A detailed mapping of value sets is to follow in WP3.

Since the epSOS Member States have implemented the epSOS Patient Summary, that is not fully in line with with EU PS Guidelines, as for Treatment Recommendation and Autonomy coded data sets, in Trillium Bridge the piloted EU Patient Summary will be the epSOS Patient Summary.

7 Challenges of Mapping Between epSOS and C-CDA/CCD

7.1 Reference Test Data

The WP2 team, in parallel with the high level PS and C-CDA CCD models comparison, has prepared a set of reference samples (Reference Test Data – RTD) based on the user stories described in Section 4, taking in account the preliminary value set mapping activities performed by the WP3.

This reference test data (RTD), supposed to be continuously verified and improved during the project lifecycle, have been prepared coherently with the experience made in epSOS with the quality gates, where also RTD have been developed and used.

RTD produced have been built using as input the clinical content defined in Section 4 for the user stories, and they include

- A CCD representation of both Martha and Paolo scenarios. (If Paolo was a US Patient)
- A PS representation of both Martha and Paolo scenarios. (If Martha was an EU Patient). The PS RTD has been develop as PS pivot conformant samples with texts in English, without any local codes.
- A CCD representation of both Martha and Paolo scenarios, as result of a transformation of the PS format. (If Martha was a EU Patient)
- A PS representation of both Martha and Paolo scenarios, as result of a transformation of the CCD format. (If Paolo was a US Patient).

Transformations has been performed with the purpose of building documents technically compliant with the target templates, using where applicable the preliminary mapping analysis provided by WP3.

Those RTD have been and will be used by the project to:

Show how the C-CDA CCD and the PS can be used for supporting the identified user stories

Provide a first set of agreed samples for facilitating the testing activities

Have an alternative way – based on concrete use cases - for getting preliminary lessons and identifying possible transformation issues, waiting for the wider and more general analysis performed by WP3.

Provide independently developed[33], human driven, transformation samples that could be used for the quality improvement of the automated transformation service.

Those evolving documents are available in the Project Repository.
(http://www.trilliumbridge.eu/repository)

7.1.1 Issues and Lessons Learned

This section summarized some of the issues and lessons learned during this activity that have not been already mentioned in the general models comparison previously reported (like e.g. the differences in the section optionality). A more organic and wider analysis of the mapping and transformation is being performed and it will be described by WP3.

General

During the transformation all the used templates IDs have been updated for being compliant with the target template: for not all the element transformed the formal compliance with those templates has been however achieved.

[33] I.e. beside those produced by the transformer that will be developed by the WP3

The document code has been updated according to the target template, to be better understood, beside the formal compliance, if this mapping is reasonable from a semantic point of view (scope of the document).

Missing required sections need to be added: the way null flavors are used in the two cases is slightly different.

Transformation from CCD to PS

Some header data structure (like preferred HCP/ Legal Organization, or represented Organization for some of the participant used information) needs to be added for achieving the formal compliance. (Valorized with null flavors).

Not all the elements have all the attributes required by the epSOS PS template (e.g. displayName for coded elements; inversionInd for some entryRelationship).

CCD uses a wider set of information and details (e.g. qualifiers; reason for prescribing; additional section, etc. that cannot be remapped into the PS data set: they have been left unchanged and they are displayable only as untranslated text.

Allergies: although the general structure used for describing allergies is substantially the same (a concern act including allergy observations , with agents represented as participant manufactured material); the way this structure is used for conveying the type of allergy and the unknown/No information is substantially different Transformation rules seems however applicable.

Allergy Reaction, not all the concepts used in the CCD (e.g. Nausea) are present in the epSOS value set.

Medication: for filling the information required by epSOS (e.g. dose form, dosage and active ingredient), it has been assumed that they can be derived from the RxNorm drug code, this is not however always applicable. Moreover, not all the RxNorm codes used seem to be univocally mappable into the epSOS active ingredients value set (ATC).

Problem List: the CCD problem list may include both resolved and active problems, where the related PS section is supposed to include only the active one (relevant resolved problems are listed in a separate section). To be better understood if the transformation needs to process the problems and split them into the associated section, either to leave the section unchanged. This second option has been chosen for the time being for the RTD produced.

Transformation from PS to CCD

Allergies: see notes above

Agent for drug allergies: to be clarified if the ATC needs to be considered as a drug class, and then mapped into the 2.16.840.1.113883.3.88.12.80.18 Medication Drug Class (based on the NDF-RT Code system), or as a specific medication and then mapped into the RxNorm.

Medication, epSOS uses specific extensions for describing medicines, not foreseen by the CCD template: those information are left unchanged and displayable only as untranslated text (if reported in the section text).

History of past illness: the PS uses this section for listing relevant resolved problems, whereas the CCD template assume that all the problem are listed in the Problem List section. To be better understood if the transformation needs to merge the problem listed in this PS section into the CCD Problem List one, either it needs to leave this section unchanged. This second option has been chosen for the time being for the RTD produced.

Vaccination: not all the SNOMED concepts used for vaccine have a unique correspondence with the CDC vaccines (e.g. Pneumococcal vaccine)

7.2 Structural Challenges

Structural differences between the epSOS patient summary and the C-CDA/CCD presented challenges in mapping the two standards. Structural challenges include items such as differences in the granularity in how data elements are represented, differences the optionality requirements of each standard, as well as gaps in information represented by each standard.

7.2.1 Mandatory Versus Optional

There are sections common to the epSOS PS and C-CDA/CCD. In cases where a sections are either required or optional in both standards as outlined in Table 4, the mapping can be considered a ***common intersection***. A challenge arises when there are sections that are optional in one standard but are required (mandatory) by the other.

Sections that are optional in the epSOS PS but are required by the C-CDA/CCD include:

- Problem list of resolved, closed or inactive problems [34]
- Results - Diagnostic tests (optional and limited to the Blood Group for the PS)

Sections that are optional in C-CDA/CCD that are required in the epSOS PS are:

- Procedures - Major Surgical Procedures in the past six months
- Medical Equipment - Medical Devices and implants

7.2.2 Representational Gaps

Some sections are present only in C-CDA/CCD and not in the epSOS PS. These are:

- Advance Directives
- Encounters
- Payers
- Family History

7.3 Terminology Challenges

A significant aspect in the mapping of epSOS to C-CDA surrounded the choices in the value sets used by each standard.

When mapping value sets used in the epSOS PS and C-CDA/CCD certain key challenges present.

7.3.1 Like Domains, Incomplete Mappings

There are cases where value sets referenced by the epSOS PS and C-CDA/CCD clearly are intended to represent similar domain content, however very few actual concept level mappings exist across the two value sets. This is seen in the comparison between the Healthcare Provider Taxonomy (NUCC - HIPAA) value set (2.16.840.1.114222.4.11.1066) and

the epSOSHealthcareProfessionalRoles (1.3.6.1.4.1.12559.11.10.1.3.1.42.1) value sets. In this case, there are very few exact, one-to-one mappings between the two-value set. Additionally, and perhaps most concerning, is that there is no equivalent for "*medical doctor*" from the epSOSHealthcareProfessionalRolesvalue set.

[34] Please note that from the implementation point of view the CCD section that includes those past problems (Problem List) uses the same section code of the Active Problems Section required in the epSOS PS, but limited in this cases to the list of active problems.

7.3.2 Value Set Coverage Mismatch

In other cases, there is a mismatch in the intent of the value set, where a value set is used for a specific purpose to represent key concepts by one standard, but those key concepts are represented by a more encompassing value set in the other standard. This is seen when comparing the epSOSBloodPressure value set (1.3.6.1.4.1.12559.11.10.1.3.1.42.10) to the C-CDA/CCD HITSP Vital Sign Result Type value set (2.16.840.1.113883.3.88.12.80.62). In this case, there is only a small area of intersection between the two value sets as seen in the table below. Here, the HITSP Vital Sign Result Type value set is intended to represent the broader category of Vital Signs; however, the epSOSBloodPressure value set is only intended to represent blood pressure.

epSOS Code	English Display Name	CCD Code	CCD Display Name
8462-4	Diastolic blood pressure	8462-4	BP Diastolic
8480-6	Systolic blood pressure	8480-6	BP Systolic
not matched		9279-1	Respiratory Rate
not matched		8867-4	Heart Rate
not matched		2710-2	O2 % BldC Oximetry
not matched		8310-5	Body Temperature
not matched		8302-2	Height
not matched		8306-3	Height (Lying)
not matched		8287-5	Head Circumference
not matched		3141-9	Weight Measured
not matched		39156-5	BMI (Body Mass Index)
not matched		3140-1	BSA (Body Surface Area)

Table 6 – Cross Purposed Value Set

Addressing these challenges will be documented in WP3, targeted to address terminology mappings.

8 Architectural Design

8.1 The Business Architecture

The definition of the Business Architecture[35] is usually of one the first steps of an Enterprise[36] Architecture[37] development. The Business Architecture is a prerequisite for architecture work in any other domain (Data, Application, Technology), and is therefore the first activity that needs to be undertaken, if not catered for already in other organizational processes (enterprise planning, strategic business planning, business process re-engineering, etc.). A Business Architecture defines the business strategy, governance, organization, and key business processes information, as well as the interaction between these concepts and may include[38]:

- The description of the Baseline Business Architecture (sometime identified as “as is” architecture)
- The development of a Target Business Architecture (“to be” architecture) , describing the product and/or service strategy, and the organizational, functional, process, information, and geographic aspects of the business environment, based on business principles, business goals, & strategic drivers
- The analysis of the gaps between the Baseline and Target Business Architectures
- The selection and the development of the relevant architecture viewpoints that will enable the architect to demonstrate how the stakeholder concerns are addressed in the Business Architecture
- To selection of the relevant tools and techniques to be used in association with the selected viewpoints

A Business Architecture is developed to support an agreed Architecture Vision.

However, it is not in the scope of this project to formally adopt one of the existing EA (Enterprise Architecture) methodologies, although the concepts employed by these methodologies will be used as recommendations for the development of this project.

The Trillium Bridge Architecture Vision describes how the new design will meet the business goals and strategic objectives, and address the stakeholder concerns when implemented. The business Architecture Strategy describes how the goals may be decomposed into various tactical approaches so they can be more easily achieved.

Both those items are documented in the Trillium Bridge Description of Work (DOW).

The Baseline Business Architecture is depicted in this deliverable and in the Trillium Bridge Description of Work (DoW) in terms of describing the existing European and US services (Business Capabilities View), stakeholder and organization involved (Organizational View).

A key component in this project is “interoperable semantic resources” available. By semantic resources one understands the existing interoperability specifications meant to address unambiguous capturing and expression of clinical needs. To be more precise, a semantic resource (part of the semantic assets) could be

[35] For a first definition of a Business Architecture see for example http://bawg.omg.org/business_architecture_overview.htm

[36] Is the highest level (typically) of description of an organization and typically covers all missions and functions. An enterprise will often span multiple organizations. (TOGAF)

[37] In the scope of this document with Architecture is meant : a formal description of a system, or a detailed plan of the system at component level, to guide its implementation (source: ISO/IEC 42010:2007) Or “The structure of components, their inter-relationships, and the principles and guidelines governing their design and evolution over time.” (TOGAF)

[38] This description use the TOGAF methodology as reference other approaches can be used as well.

a document, section or entry templates with its accompanying value sets in use on either side of the Atlantic for a specific purpose.

The Target Business Architecture is described in this deliverable in terms of business scenarios presented as real world user stories and their corresponding patient summaries' exchange use cases in Appendix B.

Section 8.2 System Architecture describes a Target Architecture (System Architecture) in terms of logical architectural building blocks needed in covering both patient and provider mediated use cases.

8.2 System Architecture

This section describes a Target Architecture (System Architecture) as logical architectural building blocks needed in covering both patient and provider mediated use cases.

In term of layered architecture, this analysis covers only the application layer: security, organizational, business , or other layers are not subject of this section.

In the first sub-paragraphs is provided a first descriptive overview of the logical architectural components and their interactions.

A more detailed analysis of this architectural solutions has been therefore documented in the following sub-paragraphs. The analysis has been accomplished using as design principle the re-use, where applicable, of the existing components and solutions as defined by the epSOS project and by the eHealth Exchange Network.

As a consequence of this approach it has been taken in account the asymmetry of the exchange process when it is realized from EU to US and from US to EU. Therefore, for each paragraph dedicated to the identified category of data exchange (patient mediated; provider mediated) the two communication paths (EU to US and US to EU) have been explicitly considered and analyzed. That is :

- Patient Mediated
  - Document produced in US and consumed in EU (C-CDA CCD to EU PS)
  - Document produced in EU and consumed in US (EU PS to C-CDA CCD)
- Provider Mediated
  - US provider queries for Patient Summary (EU PS)
  - EU provider queries for Patient Summary (C-CDA CCD)

In case the Patient Summary is provided in the form of a CCD in US or epSOS Patient Summary in Europe this architecture can be used for covering also the inclusion of the provided data into the EHR / PHR.

8.2.1 Architectural Overview

This section provides a first descriptive overview of the logical architectural building blocks and their interactions, that may be involved in the realization of the patient and provider mediated use cases. This section extends the description provided in § 2.4 “High Level Architecture”.

In this overview it has been intentionally chosen to adopt an informal representation, where a more formal representation of the technical architecture (logical perspective) is provided in § 8.2 "System Architecture”

This overview considers three main logical architectural blocks:

- The “**EU**” node: represents the set of applications (including patient portals), National eHealth infrastructure and epSOS National Contact Point, directly or indirectly involved in the transatlantic exchange of Patient Summaries, belonging to the European Country acting as Country of Treatment or as Country of Affiliation.
- The “**US”** node: represents the set of applications and supporting infrastructure, including if present the gateway used for the business to business communication between US and EU, directly or indirectly involved in the transatlantic exchange of Patient Summaries, belonging to the US organization acting as Treatment Organization or as Organization of Affiliation.

- **"Transform"** node: represents the logical block responsible for the transformation[39] and/or translation of the exchanged Patient Summary. As logical building block there are no assumptions on how can be implemented and where can be deployed.

This choice – that is that of distinguishing between the EU and the US node – has been made in order to take in account the asymmetry between these two nodes. In fact some pilot services for supporting cross-country patient treatments - including transformation and transcoding - are currently available on some of the epSOS piloting EU countries. Following the same approach, possible interactions between these blocks for supporting specialized EU to US and US to EU use cases have been drafted in the following figures.

The figures point out the contents exchanged - EU (epSOS) PS or C-CDA CCD - and the effects of the translation process, that will act only on the coded information (labeled with 'Codes' in the figures), leaving unchanged the textual descriptions (labeled with 'Text' in the figures).

The first set of pictures draft the case of a Patient Summary produced in Europe and consumed in US (EU to US), with three options:

(1) The summary is processed using the epSOS PAC services, or the semantic services implemented in the epSOS National Contact Point, in order to obtain an English translated[40] epSOS CDA. This may reflect both the patient and the provider mediated use cases, and it is mainly applicable in the case of exchange of a printable representation of the summary or if it displayed using the patient's device.

(2) The English translated epSOS CDA is processed using an "external" *Transform* Service in order to obtain a C-CDA. This service in principle can be invoked before leaving home, or when abroad by the Patient or any other authorized user. This reflects the patient mediated use case.

(3) The summary is processed by the semantic services implemented in the epSOS National Contact Point, and then transformed into a C-CDA through the *Transform* block before being provided to the counter-party. This reflects the provider mediated use case.

Independently on the fact the CDA is displayed using the provider or the patient device a specialized CDA display (it may be a stylesheet) is required.

[39] The transformation is here intended as the capability of transforming a C-CDA Patient Summary (CCD) to and from a epSOS Patient Summary.

[40] As described for the epSOS services, with translation we consider the capability of obtaining the English translated designations for a subset of commonly agreed coded concepts. No translation of textual part (e.g., section texts) will be performed.

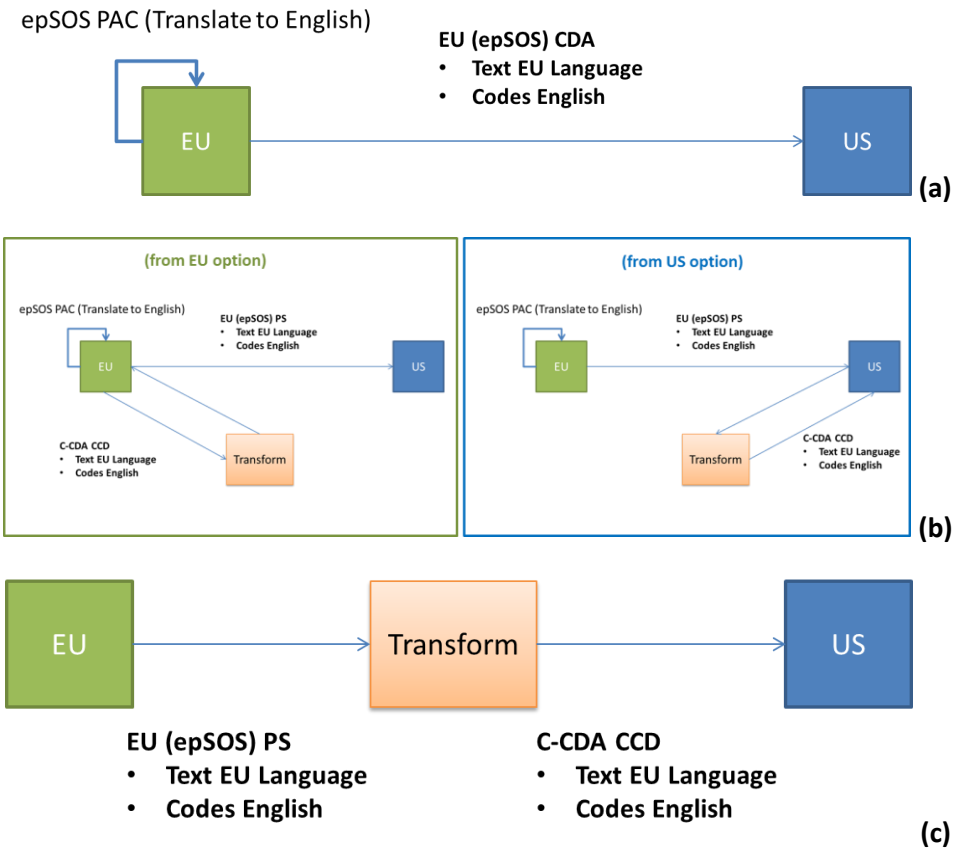


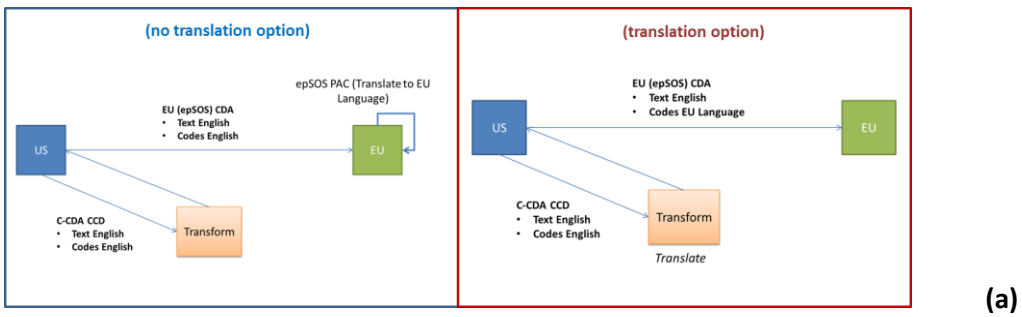
Figure 13 - Patient Summary produced in Europe and Consumed in US

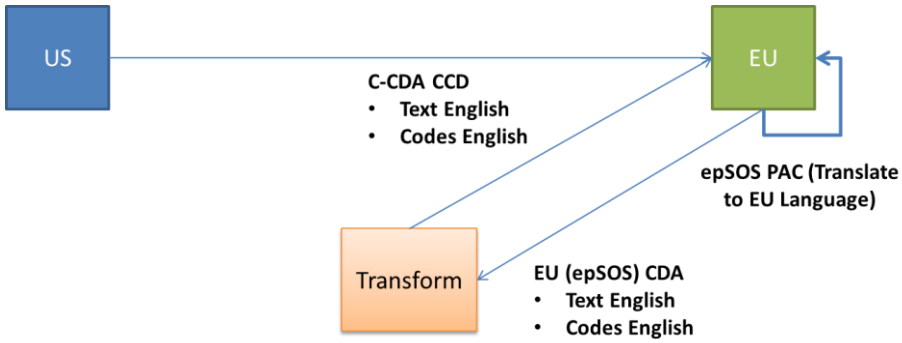
The second set of pictures drafts the case of a Patient Summary produced in U.S and consumed in Europe:

(1) The US Patient Summary (CCD) is transformed into an epSOS PS before leaving US by the patient or any other authorized user using the *Transform* component, this can be done either translating the document into the target language or requesting this task from the European Semantic components. This reflects the patient mediated use case. The second option is requested in case of visualization using the patient device, of exchange of a printable representation.

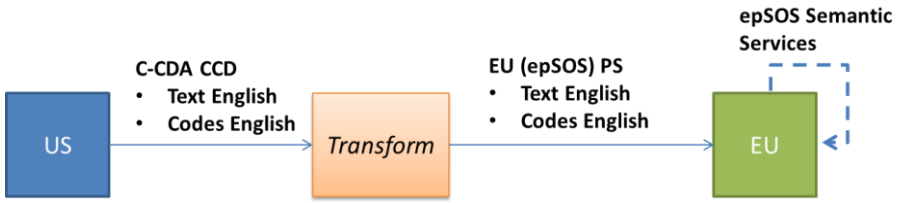
(2) The US Patient Summary (CCD) is provided "as is" to the European receiver. The *Transform* component is used for obtaining an epSOS pivot representation of this CCD and the epSOS PAC service used for translating this content. This may reflect the patient mediated use case. This might be the case of a European Patient, that received a CCD by a US physician and that wants to include it into his/her PHR or displaying it to his/her GP.

(3) The US Patient Summary is transformed by the *Transform* block before being provided to the counter-party as English translated epSOS CDA. The epSOS CDA can be processed using the semantic services implemented in the epSOS National Contact Point, in order to obtain an epSOS CDA translated in the EU target language. This reflects the provider mediated use case.





(b)



(c)

Figure 14 - Patient Summary Produced in US and Consumed in Europe

Overall, legal implications for the EU and the US were discussed in section 5. However, further discussion is called for.

8.2.2 Patient Mediated

8.2.2.1 Overview

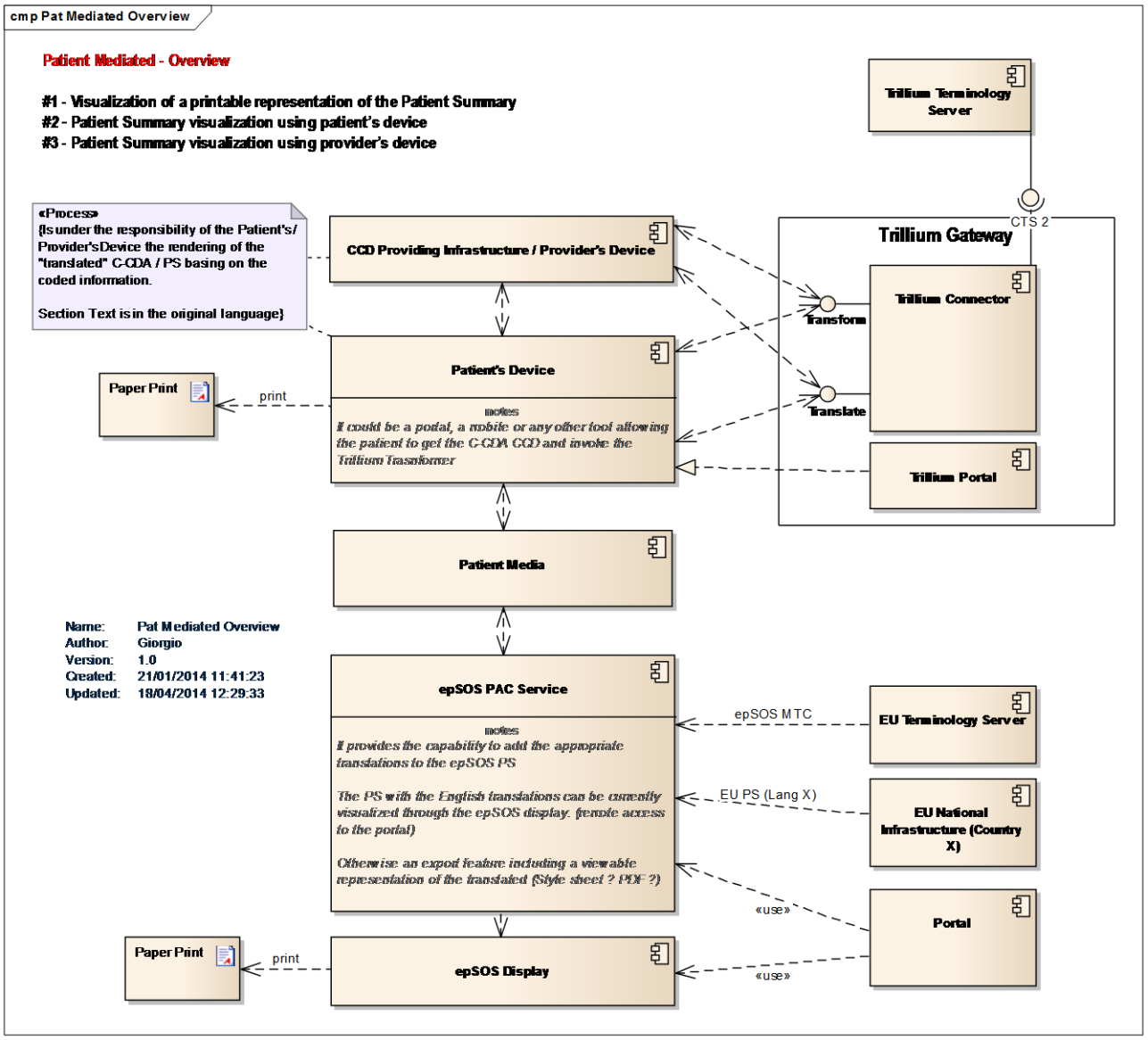


Figure 15 - Patient Mediated Use Case Logical Architecture Overview

The figure above provides an overview of the logical components involved in Patient Mediated Use Case for the exchange of Patient Summaries between US and EU.

Systems / software components realizing those logical components may implement one or many logical components, as well any logical component described can be realized by one or many software components. For example a Mobile device owned by the Patient can act as *Patient's Device* and *Media* as well; or, a PHR-S solution offering patient access capabilities via mobile App, can realize both the *CCD providing infrastructure* and the *Patient's Device*.

This architecture has been defined for maximizing the reuse of existing components and supporting different scenarios: it is not assumed that all those options will be implemented.

The *CCD providing infrastructure / Provider's Device* identifies any system, or system of systems, that manage the patient data used for generating the C-CDA CCD, and that provides capabilities for making the CCD available to the Patient. It can be a provider's organization EHR-S, a PHR-S solution, etcetera. It is also used to represent any provider's solution used for generating/exporting/visualizing the Patient Summary (CCD

and/or EU PS). It is out of the scope of Trillium Bridge to analyze and specify how the CCD is obtained by the Patient from this component: e.g., available in Personal Health System, offered by provider (tethered), brought via Blue Button, provided in a media to the patient by the care team,…..

The *Patient's Device* is the logical component that represents the solution used by the patient to obtain

- from the *CCD providing infrastructure* the Patient Summary (or the Encounter Report) in a form of C-CDA CCD and asks for its transformation in an EU PS. Depending on the patient's choice this could be a pivot EU PS (in English) or an EU PS in a chosen target language. In case, the patient can use the translated Patient Summary for generating a paper printed copy, or storing its printable representation in a media (*Patient Media*).
- From the *Patient Media* the Patient Summary (or the Encounter Report) in a form of EU PS (in English), either as viewable document (e.g., PDF, HTML) to be displayed on the device. In the first case, the patient uses this component for invoking the transformation of the incoming EU PS into a C-CDA CCD. The transformed/translated document can be therefore visualized on a *Patient's* or on a *Provider's Device*. In both cases the rendering of the "translated" C-CDA / PS basing on the coded information, is under the responsibility of the *Patient's / Provider's Device*.

This component may provide visualization capabilities allowing the Patient's to access and display the transformed/translated document during the episode of care.

A *Patient's Device* may be realized for example by a Mobile PHR App; a Web portal or other systems.

The diagram shows also a special kind of *Patient's Device:* the Trillium Portal. This component is conceived for allowing registered users to use the Trillium transformation / translation services without requiring the ownership of a specialized software component (e.g., PHR-S App).

The *Patient's Media:* represents any kind of media (removable, remote,…) through which the patient is allowed to physically exchange the Patient Summary form and to the country of affiliation and the country of treatment. In most cases the *Patient's Media* will be implemented by the same component that realizes the *Patient's Device* (e.g., a PS loaded into a patient mobile device).

The Trillium Connector is the logical component that provides services for allowing the Transformation from and to CCD and EU PS; and the Translation[41] of the EU PS into one of the EU target languages. The transformation is actually performed by the owned component *Trillium Transformer*. The translation is based on the semantic components specified in the epSOS project.

The *Trillium Terminology Server* is the component responsible for managing the mappings and the translations used for the Trillium services. Those data are made available through an HL7/OMG CTS2 compliant interface.

The *Portal* is then the abstraction of:

- the *Patient Portal* used for realizing the epSOS PAC service;
- the *epSOS portal* used by providers accessing the epSOS services.

For realizing its ends this component makes use of the:

- *epSOS PAC Service*, that allows to translate a Pivot EU PS into any of the European target languages;
- and of the *epSOS display* that is a specialized display able to provide a human readable representation of the translated EU PS.

[41] We'd like to enforce the concept that the translation is not referred to the translation of free text (like Google translator)

Through this component the patient may be enabled to print /export a printable representation of the English Patient Summary; and/or to export into the media a pivot epSOS Patient Summary (possibly with a pdf copy of the “original” national patient summary).

Additionally, the provider can import an epSOS Patient Summary, obtained as transformation of a C-CDA CCD, in order to translate and visualize it. That would to accept an incoming Healthcare Encounter Report.

This general architecture can fulfill all the different cases considered, in the following sections are specified more in details how can be realized the patient mediated use cases in the case of

- Document produced in US and consumed in EU (C-CDA CCD to EU PS)
- Document produced in EU and consumed in US (EU PS to C-CDA CCD)

8.2.2.2 Document Produced in US and Consumed in EU (C-CDA CCD to EU PS)

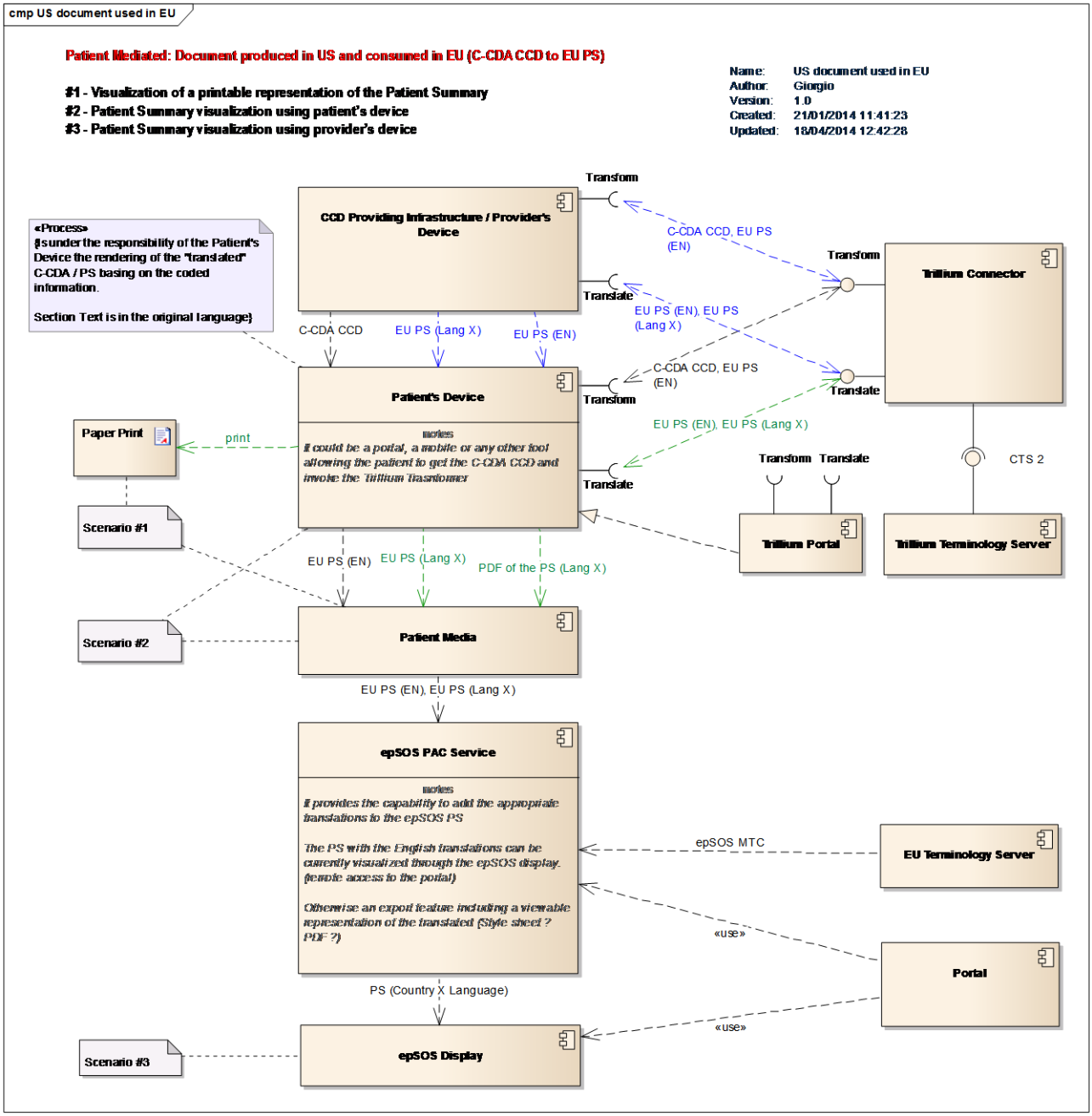


Figure 16 - Patient Mediated Use Case Logical Architecture Document Produced in US and Consumed in EU

This section describes how the logical architecture introduced in the previous paragraph can be used for supporting the case of a document produced in US and consumed in Europe. The diagram reports several possible communication scenarios that this architecture can realize, not all of them are expected to be realized. Please refer to that paragraph for the description of components.

The Patient obtains from the *CCD providing infrastructure / Provider's Device* the Patient Summary (or the Encounter Report) in a form of C-CDA CCD. He/she uses the *Patient-s Device* for asking for its transformation in an epSOS Patient Summary (in English) and optionally for its translation in one of the target European Language [Black flow]

Alternately , the US provider provides the Patient with a Patient Summary (or an Encounter Report) in form of an epSOS Patient Summary (in English) or in a target European Language [blue flow]

The Patient may use therefore the *Patient's Device* (and/or the Trillium Portal) component also to[42] :

- Generate a paper printed copy of the translated document or store its printable representation in a media (*Patient Media*) [**green flow**]. It realizes the scenario of exchange of printable representation of the summary.
- Invoke the Trillium Translation service (based on epSOS Semantic Components) for obtaining the translation of the epSOS Patient Summary in a specified target language [**green flow**].
- Display the translated content on his/her device. It realizes the scenario of the Patient Summary visualization using patient's device.
- Store on the *Patient Media* the epSOS Patient Summary [**black flow**]

As described above, the *Portal* component is the abstraction of :

- the Patient Portal used for realizing the epSOS PAC service;
- the epSOS portal used by providers accessing the epSOS services.

The *Patient Portal* can be used by the EU Patients for :

- loading the Encounter Report in form of epSOS Patient Summary
- obtaining a translated version of this document using the *epSOS PAC service* component
- visualize it through the *epSOS Display*. It realizes the visualization using the patient's device scenario.

The *epSOS Portal* can be instead used by the EU Providers for :

- loading the Patient Summary (or the Encounter Report) in form of epSOS Patient Summary
- obtaining a translated version using the *epSOS PAC service* component
- visualize it through the *epSOS Display*. It realizes the visualization using the provider's device scenario.

[42] It is not expected that the patient will accomplish all these tasks. The capabilities provided by the device will depend on the scenario realized.

8.2.2.3 Document Produced in EU and Consumed in US (EU PS to C-CDA CCD)

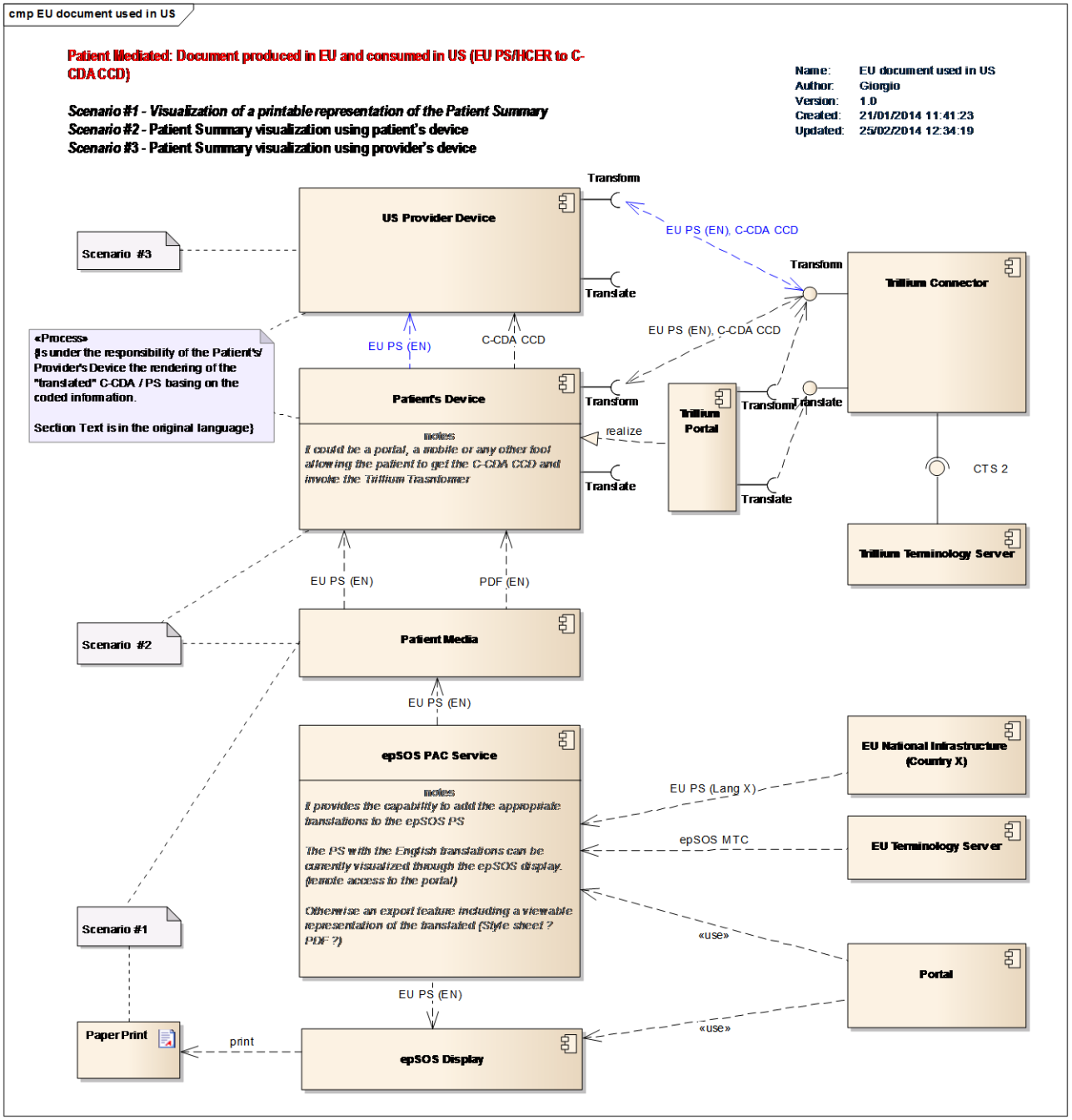


Figure 17 - Patient Mediated Use Case Logical Architecture Document Produced in EU and Consumed in US

This section describes how the logical architecture introduced in the previous paragraph can be used for supporting the case of a document produced in EU and consumed in US. Please refer to that paragraph for the description of components. For the reasons indicated in the use cases analysis section this diagram doesn't describe explicitly the sharing of the HCER for US patient. In any case the general process for the information flow for this case is the same used for the patient summary, excepting for the fact that the HCER is not obtained by the US patient from the National Infrastructure, but provided by the EU provider.

(From the bottom of the diagram)

The *Patient Portal* and the *epSOS PAC Service* can be used by the EU Patients to:

- retrieve their epSOS Patient Summary from the *National Infrastructure* and obtaining them as EU PS in English.
- visualize their patient summary through the *epSOS Display*. It realizes the scenario of the Patient Summary visualization using patient's device.
- generate a paper printed copy of the translated document or store its printable representation in a media (*Patient Media*). It realizes the scenario of exchange of printable representation of the summary.
- Store on the *Patient Media* their epSOS Patient Summary (in English)

Through the *Patient's Device and Media* the Patients are therefore allowed to:

- invoke the Trillium Transformation service for obtaining a C-CDA CCD representation of this document [**black flow**]
- display on his/her device the translated document or a printable representation of it. It realizes the scenario of the Patient Summary visualization using patient's device.
- provide the US provider with a C-CDA CCD representation of the English translated document [**black flow**]
- provide the US provider with a English translation of the EU PS. [**blue flow**]

The US Provider may finally uses the US *Provider's Device* to:

- Get the English translated EU PS and invoke the Trillium Transformation service for obtaining a its C-CDA CCD representation [**blue flow**]
- Visualize on his/her device the translated contents . It realizes the visualization using the provider's device scenario.

8.2.2.4 Implementation Notes

Among all the possible implementation options, for the piloting proposes the following scenarios will be considered.

Document produced in US and consumed in EU:

- The Trillium Portal, or a PHR APP owning a copy of the summary, invokes the transform operation
- The epSOS Patient Summary in English (obtained as transformation of the CCD) is loaded by the EU HP using the epSOS portal.
- The epSOS portal uses the epSOS semantic services (here represented by the epSOS PAC Service component) for the translation
- The translated summary is shown using the epSOS Display

Document produced in EU and consumed in US:

- The Portal uses the epSOS PAC services for having the patient Summary as epSOS Pivot
- The PS is save as PDF and epSOS Pivot on a Patient Media
- The Trillium Portal load the EU PS and invokes the Transform operation for obtaining a CCDA CCD representation of the provided EU PS
- The transformed CCDA CCD is loaded on a device and displayed using Trillium Bridge specialized stylesheets

1.1.1 Provider Mediated

8.2.2.5 Overview

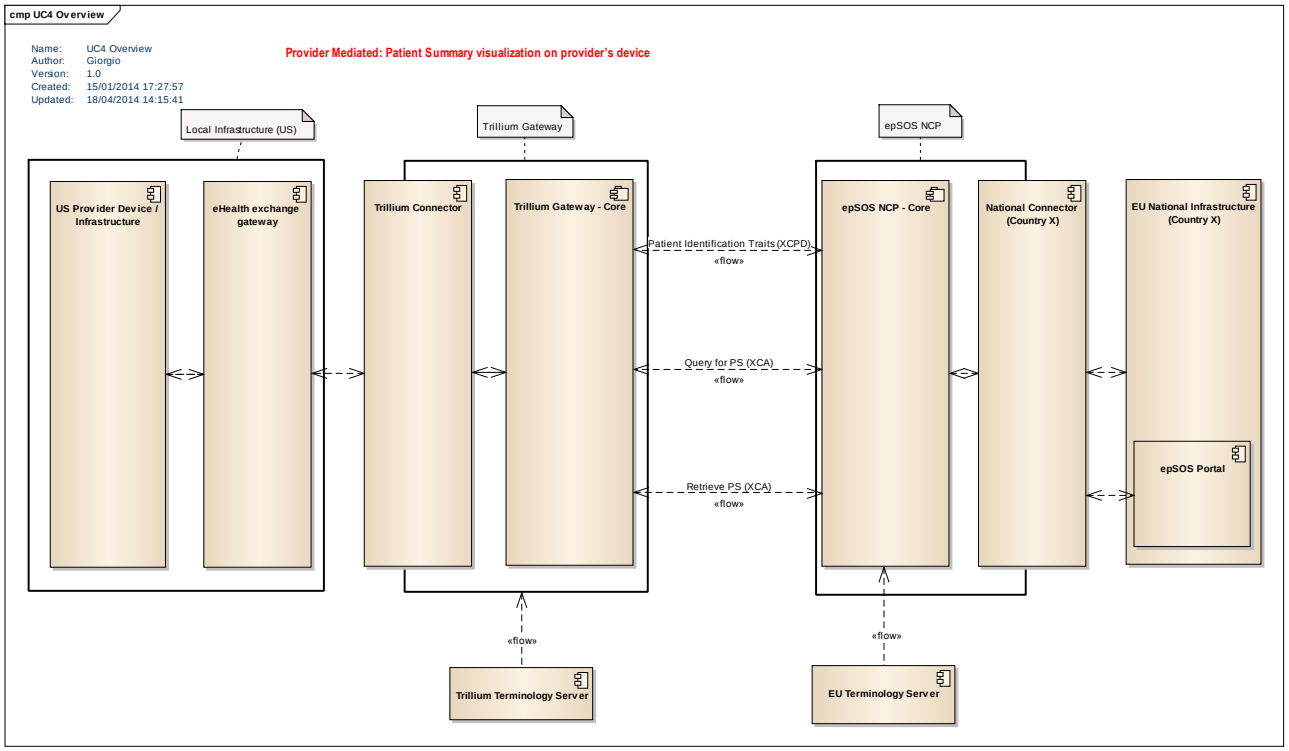


Figure 18 – Provider Mediated Use Case Logical Architecture Overview

The figure above provides an overview of the logical components involved in the provider mediated exchange of Patient Summaries between US and EU.

Systems / software components realizing those logical components may implement one or many logical components, as well, any logical component described can be realized by one or many software components. For example nothing prevents that an implementation of an eHealth exchange gateway realizes both the *eHealth exchange gateway* and the Trillium Connector components; either that the Trillium Connector is realized as composition of different software components.

This architecture has been defined for maximizing the reuse of existing components and supporting different scenarios : it is not assumed that all those options will be implemented.

In this overview can be identified four main areas

- The Local US Infrastructure
- The Trillium Gateway
- The epSOS NCP
- The National Infrastructure of a EU Country

The Local US Infrastructure includes:

- The *US Provider Device/Infrastructure* that identifies any system, or system of systems, that owns the patient data used for generating the C-CDA CCD queried by the EU providers; and/or that provides capabilities for querying the epSOS NCP for retrieving the EU PS and visualizing it. It can be an organization EHR-S, a stand-alone application used by a Provider (connected to the eHealth network); and so on …

- and the *eHealth exchange gateway* that is a gateway that allows the US providers' organizations to interact across the **eHealth Exchange Network.**

Trillium Gateway is the set of components that allows the *Local US Infrastructure* to communicate with the *epSOS network* (and vice versa) for the purpose of identifying patients and retrieving their patient summaries. It also responsible for the T*ransformation* from and to CDA CDD and epSOS PS.

Is out of the responsibilities of this project that of taking any decision about the future deployment of those gateways and about who will be accountable for them. This in fact may depend on the internal choices of each of the involved partners (US and EU) and by possible future agreements between them. That is, this architecture doesn't make any assumption about the fact either a single Trillium Gateway under the US responsibility will be deployed; or that each US organization will own its own gateway; or, finally, that a single node outside the US or EU eHealth networks (infrastructures) and under a common responsibility of both the parties will be deployed.

For the scope of the provider mediated use cases the component of interest for the Trillium Gateway are:

- the Trillium Gateway - *Core* component, that provides the common transport and transformation capabilities of the gateway towards the epSOS network , reflecting the current epSOS Open NCP core components
- the Trillium Connector that acts as mediator between the Trillium Gateway – *Core* component and the US infrastructure, and that is responsible for the transformation between C-CDA CCD and EU PS.

It has been chosen this asymmetric composition, typical of the Open NCP design, considering that the first Trillium Gateway implementation is supposed to be based on the Open NCP software components.

The Trillium Gateway acts towards the epSOS NCP as an additional NCP of the epSOS network, allowing for the patient identification and the patient summary retrieval. The epSOS NCP is composed by :

- an *epSOS NCP Core* component (that reflects the current epSOS Open NCP composition)
- and a *National Connector* that mediates between the epSOS network and the local infrastructure of Country X.

In the current version of this specification – for maximizing the reuse of existing components – the payload exchanged between the Trillium Gateway and the epSOS NCP will be an epSOS Patient Summary (pivot).

It is desirable that future operational solutions will be based on EU-US harmonized formats.

Finally the *EU National Infrastructure* that identifies the infrastructure of the European country of affiliation that owns the patient data used for generating the local Patient Summary ; or, that of the European country of treatment that provide EU providers with capabilities for querying the US Patient Summary and visualizing it.

Note: in the epSOS pilot the component used by providers for the patient identification, the retrieval of the patient summary and its visualization when translated, is realized by the epSOS portal component that includes also an epSOS display. This is part of the Open NCP package.

1.1.1.1 US Provider Queries for Patient Summary (EU PS)

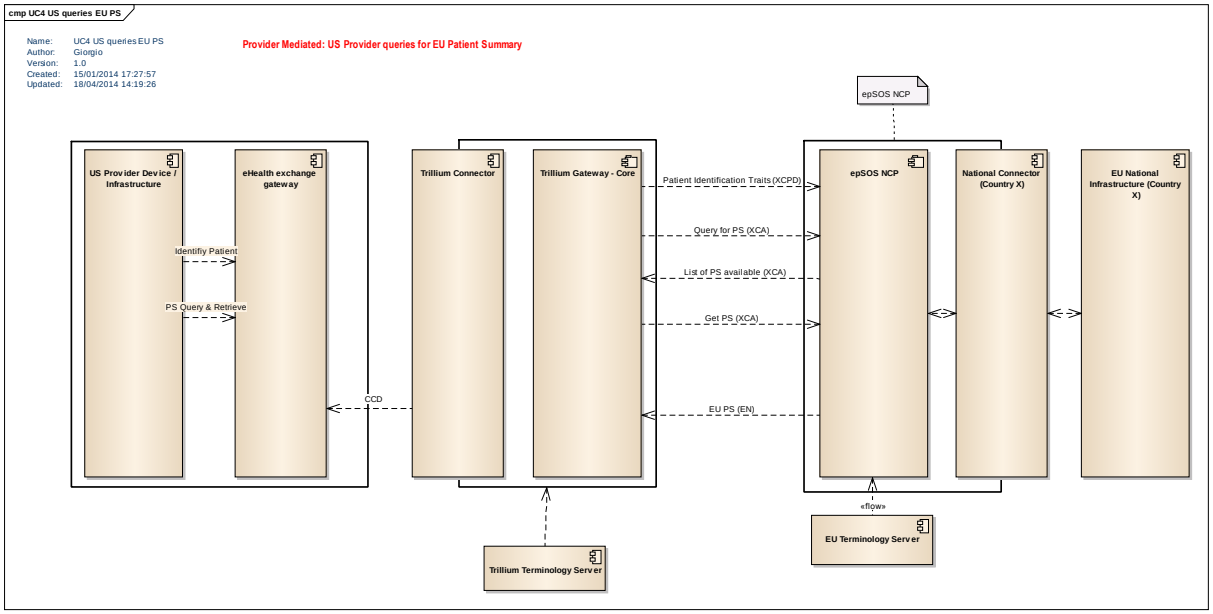


Figure 19 - Provider Mediated Use Case Logical Architecture US Provider queries for epSOS Patient Summary

This section describes how the logical architecture introduced in the previous paragraph can be used for supporting the case of a US provider that queries for Patient Summary.

The *US Provider*- authenticated in his/her organization infrastructure – uses his/her device for the:

- Identification of the Patient against the Patient Country of affiliation
- the query and the retrieval of the patient summary of that Patient from the country of affiliation [If the patient is correctly identified]
- The visualization of the retrieved document [if the document is correctly is correctly retrieved]

Those requests issued by the *US provider Device / Infrastructure* are conveyed by the *eHealth exchange gateway* to the Trillium Gateway that acts as proxy towards the epSOS NCP.

As mentioned above the Trillium Connector can be configured for transforming the returned EU PS into a C-CDA CCD before being returned to the local US infrastructure for visualization by the Provider's Device.

As alternative path the Provider's Device receives the EU PS and uses the *Transform* service for getting a C-CDA CCD representation of the EU PS.

1.1.1.2 EU Provider Queries for Patient Summary (CCD)

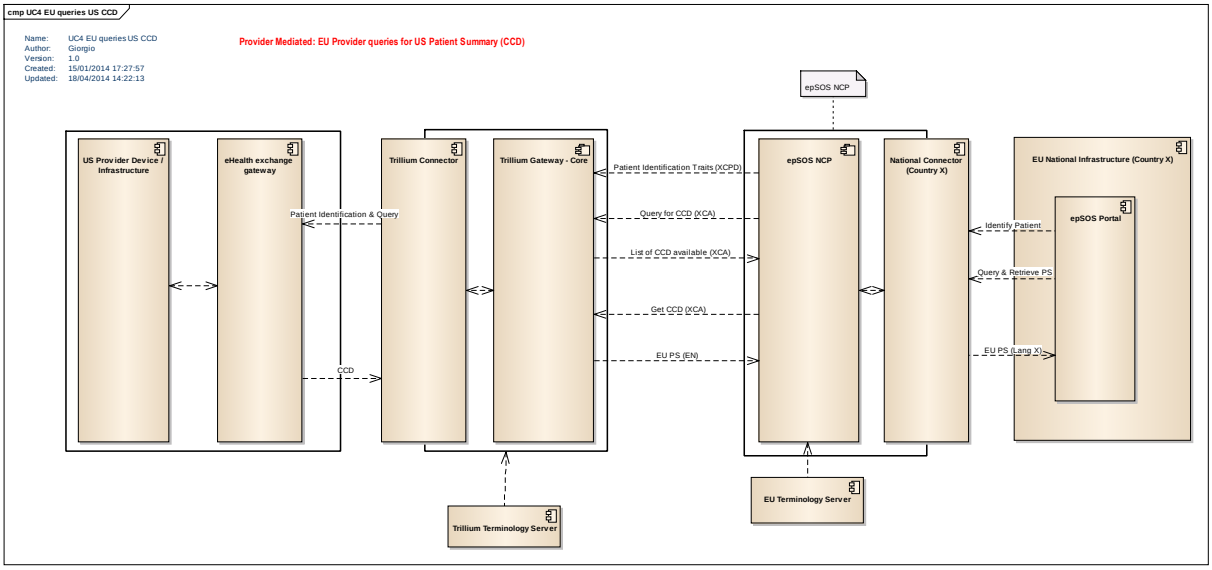


Figure 20 - Provider Mediated Use Case Logical Architecture EU Provider queries for US Patient Summary (CCD)

This section describes how the logical architecture introduced in the previous paragraph can be used for supporting the case of an EU provider that queries for Patient Summary.

The *EU Provider*- authenticated in his/her organization infrastructure – uses the epSOS portal for the:

- Identification of the Patient against the organization of affiliation of the Patient
- the query and the retrieval of the patient summary of that Patient from the organization of affiliation of the Patient [If the patient is correctly identified]
- The visualization of the retrieved document using the epSOS display tool [if the document is correctly is correctly retrieved]

Those requests issued by the *epSOS portal* are conveyed by the *epSOS NCP* to the Trillium Gateway that acts as proxy towards the *eHealth exchange gateway*.

As mentioned above the Trillium Connector transforms the returned C-CDA CCD into an EU PS before being returned to the Trillium Gateway for being sent to the epSOS NCP.

The EU PS is therefore processed by the *epSOS NCP* for being translated into the provider's language and therefore displayed by the *epSOS portal*, using the epSOS display tool.

1.1.2 Translation and Transformation (Trillium Gateway)

A core functionality of the Trillium Architecture is the capability of providing users and application services for performing the transformation from and to C-CDA CCD and EU PS, and translation of the EU PS into one of the target European Languages.

These functions are provided by the Trillium Gateway through its components :

- the Trillium Gateway - *Core* component (that reflects the current epSOS Open NCP composition)
- the Trillium Connector that acts as mediator between the Trillium Gateway – *Core* component and the local infrastructure.
- the Trillium Portal, offering to registered users a web GUI to benefit of the Trillium Transformation and Translation services.

The provided interfaces and the components involved are described in the following diagram. The diagram identifies as well which components are used for fulfilling the described use cases:

- Provided mediated scenarios: **purple** components
- Patient Mediated scenarios: **yellow** components
- Common Parts, in beige

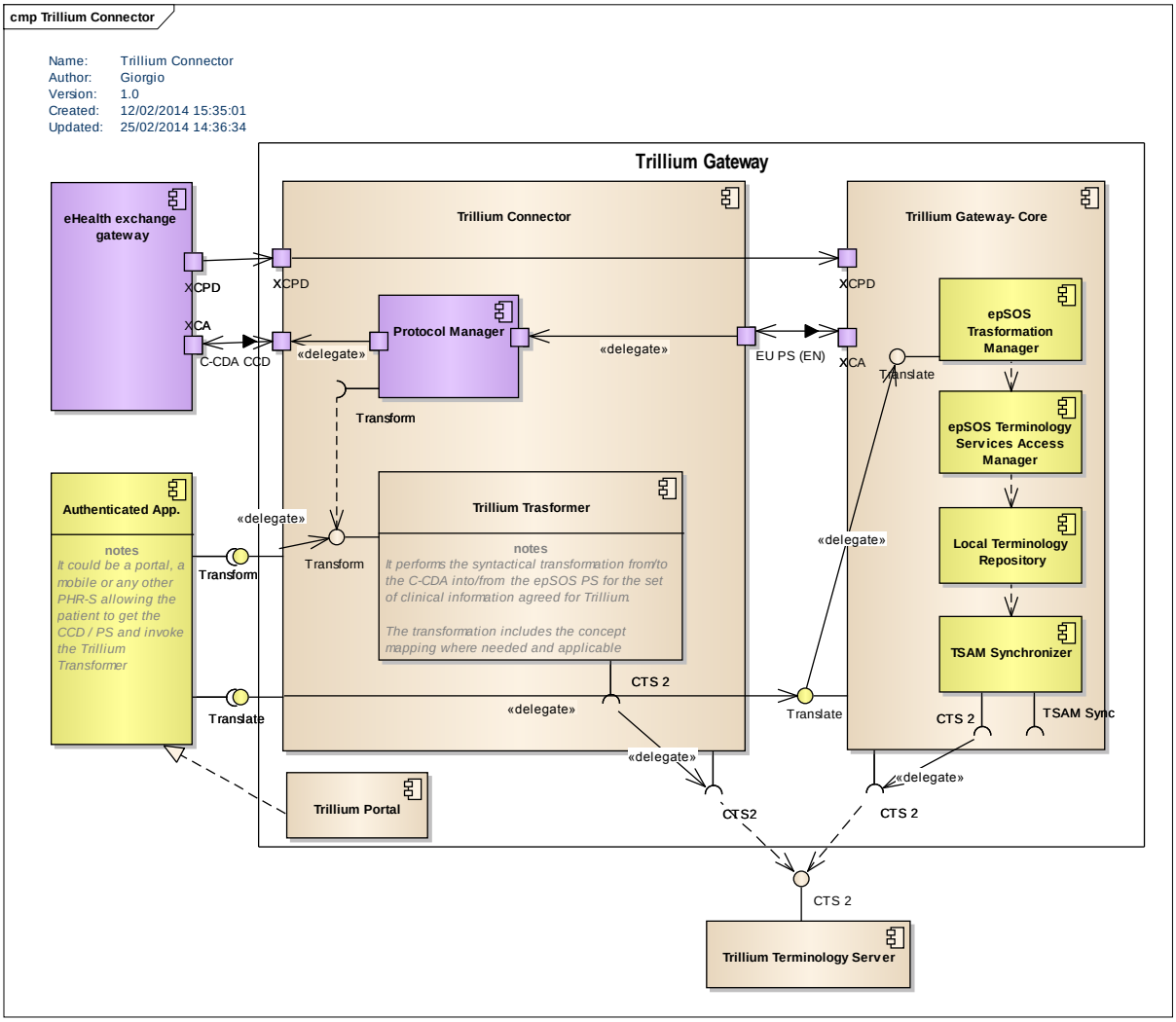


Figure 21 – Trillium Gateway**: Translation and Transformation Trillium Services**

The Trillium Connector offers/uses an "internal" interface for interacting with the Trillium Core component (whose specifications are published on https://openncp.atlassian.net)

Moreover, it exposes/consumes external interfaces for supporting:

- The identification of Patients (based on IHE XCPD profile) [used for the Provider Mediated scenarios, in **purple**]
- the retrieval of Patient Summary (based on IHE XCA profile) [used for the Provider Mediated scenarios, in **purple**]
- The T*ransformation* from and to CDA CDD and epSOS PS. This functionality is realized by the delegated component *Trillium Transformer* whose internal specification will be defined in D3.1. [used for the Patient Mediated scenarios, in **yellow**].
- The *Translation* of a EU PS into a selected European Language. This service is delegated to the *Translate* interface provided by the Trillium Gateway – *Core* component. In turn, this interface is

delegated to the Java based Public API *translate()* operation provided by the *epSOS Transformation Manager* component. The *epSOS Transformation Manager* relies on the epSOS TSAM and Local Terminology Repository components. [used for the Patient Mediated scenarios, in **yellow**]

No one of the components involved in the Transformation and Translation services stores/caches the Patient Data.

8.2.2.6 Behavior for Patient Mediated Scenarios

An *authenticated application*[43] can invoke the *Transform* service for converting a C-CDA CCD from and to a EU PS. This service is delegated to the *Trillium Transformer* component whose internal specification will be defined in D3.1.

The *authenticated application* can moreover invoke the *Translate* service for obtaining an EU PS, translated into a selected European language. This service is delegated to the *Translate* interface provided by the Trillium Gateway – *Core* component. In turn, this interface is delegated to the Java based Public API *translate()* operation, provided by the *epSOS Transformation Manager* component. The *epSOS Transformation Manager* relies on the epSOS TSAM and Local Terminology Repository components.

A kind of *authenticated application* is the Trillium Portal, that allows registered users to use the Trillium transformation / translation services without requiring the ownership of a specialized software component (e.g., PHR-S App)

8.2.2.7 Behavior for Provided Mediated Scenarios

As the Trillium Connector receives the XCA retrieve response from the *epSOS NCP,* or from the *eHealth Exchange gateway*, the subcomponent dedicated to handle the XCA protocol intercept the response and check if an EU PS or a C-CDA CCD is returned.

In case, the CDA conveyed in the response is extracted from the response and passed to the *Trillium Transformer* that converts, in the first case, the received EU PS into a C-CDA CCD; or the received C-CDA CCD into a EU PS.

The transformed document is therefore included in the XCA response and returned to the requesting component (e.g. the *eHealth Exchange gateway*).

8.2.2.8 Implementation Notes

As mentioned above the architecture for the provider mediated use case has been designed with the principle of maximizing the reuse of existing component. For the piloting proposes – that will see involved most likely Kaiser Permanente and some European partners (e.g., Portugal, Spain, Italy and likely Luxemburg) it has been assumed that a single Trillium Gateway – acting between the epSOS PPT and the Kaiser Permanente testing environments - will be deployed and it will be implemented reusing the Open NCP components. The communication between the eHealth Network and the Trillium Gateway, as well as that between the Trillium Gateway and the epSOS NCPs, will be based on the IHE XCPD and XCA interactions.

[43] Any patient's or provider's application enabled to accesses the Trillium Bridge Services.

9 Conclusions and next steps

This document reports on the work performed in WP2 (“Selecting the Grounds”) as we move forward to advance EU/US EHR interoperability, building a bridge of shared understanding and cooperation. It encompasses content from D2.1 (Inventory of Patient Summaries in the EU & US: Use Cases, Business Architecture and Data Sets) and presents concrete findings in Gap analysis between the EU and US use of HL7 C-CDA/CCD.

The Trillium Bridge team took a close look at user stories and their expressing in the patient summary specifications used in the EU (EU PS based on epSOS) and the US (HL7 C-CDA/CCD). The team also looked at the emerging eHealth infrastructure in the EU based on epSOS and in the US based on provider networks, integrated systems, and health information exchanges. We looked at the trust infrastructure in the EU and US.

Trillium Bridge Use Cases have been developed on the aforementioned bases and validated during the Initial Workshop in Boston and in subsequent interactions with EU and US Trillium Bridge participants and stakeholders.

Having established the patient summary baseline in the work presented here, Trillium Bridge will proceed to identify and deliver interoperability assets in WP3 (led by Ana Estelrich of Phast and Harold Solbrig of Mayo) to be validated in WP4 (led by Karima Bourquard IHE Europe).

The work presented here helped us understand better the way HL7 CCDA/CCD is used in the participating EU Member States and the US. We anticipate that this will help create better standards as we move towards an global standards for patient summaries that is easy and low cost to implement and maintain.

10 Glossary

This document since page 1, provides the list of the acronyms used in this document are interested in.

Acronym	Description
CDA	Clinical Document Architecture
CCD	Continuity of Care Document
C-CDA	Consolidated CDA
CDA R2	CDA Release 2
COPD	Chronic obstructive pulmonary disease
Country A	Country of Affiliation
Country B	Country of Treatment
CRL	certificate revocation list
DOW	Description Of Work
DURSA	Data Use and Reciprocal Support Agreement.
ebXML	e-business XML:
EC-HHS MoU	Memorandum of understanding between the United States Department of Health and Human Services and the European Commission on cooperation surrounding health related information and communication technologies
eHGI	eHealth Governance Initiative
EHIC	European HealthCare Insurance Card
EHR	Electronic Health Record
EHR-S	Electronic Health Record System
eID	electronic Identification.
eP	Electronic Prescription
epSOS	European Patients - Smart Open Services
GP	General Practitioner
HCER	Healthcare Encounter Report
HCP	Health Professional
HITSP	Healthcare Information Technology Standards Panel
HL7	Health Level 7
HP	Health Professional
HPO	Healthcare Organization
ICT	Information and Communication Technology
IETF	Internet Engineering Task Force
IHE	Integrating the Healthcare Enterprise
ISO	International Organization for Standardization
ITI	IT Infrastructure (The IHE Domain that supplies infrastructure for sharing healthcare information.)
MoU	Memorandum of Understanding
MRO	Medication Related Overview
MRI	Magnetic Resonance Imaging
MU	Meaningful Use
MU2	Stage 2 of Meaningful Use
MU3	Stage 3 of Meaningful Use
NCP	epSOS National Contact Point
NCP-A	(epSOS) National Contact Point of the Country of Affiliation
NCP-B	(epSOS) National Contact Point of the Country of Treatment

NHIN	Nationwide Health Information Network
OASIS	Organization for the Advancement of Structured Information Standards
ONC	United States Office of the National Coordinator for Health IT of the Department of Health and Human Services
PAC	Patient Access Service
PCC	Patient Care Coordination
PCP	Primary Care Physician
PHR	Personal Health Record
PHR-S	Personal Health Record System
PKI	public-key infrastructure
PN	epSOS Participating Nation
PS	Patient Summary
S&I	Standards and Interoperability (S&I) Framework
SOAP	Simple Object Access Protocol
SSO	Single Sign On
SBVR	Semantics of Business Vocabulary and Business Rules
SWOT	Strengths, Weaknesses, Opportunities, and Threats
Transform	Converting one xml document format into another through the application of conversion rules
Translate	Converting from one human language into another.
UDDI	Universal Description Discovery and Integration.
WG	Working Group
WP	Work Package
WS	Web Service
WS-I	OASIS Web Services Interoperability
WSS	OASIS Web Services Security
X.509	International Telecommunication Union Telecommunication Standardization Sector (ITU-T) standard for Public-key and attribute certificate frameworks
XACML	OASIS eXtensible Access Control Markup Language
XCA	Cross-Community Access
XCPD	Cross-Community Patient Discovery

Appendix A: Real World User Stories

A.1 Susie's Story: a Girl with Leukemia (provided by Elaine Blechman, Prosocial, US)

A.1.1 Overview

Susie, an 8-year old girl with leukemia, accompanied by her grandmother, travels from London to New York to spend summer vacation with her father. The grandmother carries a clinical summary including a plan of care on her mobile phone and on paper to insure continuity of care in New York.

A.1.2 Stakeholder Story

Susie is an 8-year old girl with leukemia, accompanied by her grandmother, travels from London to New York to spend summer vacation with her father. The grandmother carries a clinical summary including a plan of care on her mobile phone and on paper to insure continuity of care in New York.

- **Demographics**: Age 8 years, Gender female
- **Problems**: Acute leukemia in remission; Increased susceptibility to infection; asthma; hair loss secondary to chemotherapy;
- **Medications**: vitamins; bronchial inhaler;
- **Allergies**: peanuts, animal dander
- **Plan of Care**: monitor for symptoms of infection, prompt medical attention for potential infection

A.1.3 Starting Event

Susie complains upon arrival to New York after a flight from London.

A.1.4 Actor and Users

- Susie: girl 8 years old
- Her grand mother
- Nurse
- Oncologist

A.1.5 Goal

Susie's grandmother wishes to have readily available an up-to-date patient summary of Suzie for unplanned care events.

A.1.6 Stakeholders

- Susie
- Susie's grandmother
- Susie's father
- Admitting Nurse
- Oncologist
- PHR provider
- NYU Langone cancer center

A.1.7 Primary Scenario

On a flight from London that arrives in New York on a Saturday evening, Susie is hot to the touch and complains of joint pain. When father picks Susie and grandmother up at LaGuardia, he drives to the emergency department at NYU Langone cancer center while grandmother tries to contact the pediatric oncologist informed about Susie's case so that she can meet them at NYU.

During registration and admission, grandmother gives the admitting nurse a paper copy of Susie's clinical summary in English. To the doctor who examines Susie, grandmother shows, on her mobile phone, in Susie's PHR with CCD format, the clinical summary and data she has collected in the last 24 hours measuring Susie's temperature and pain ratings.

During discharge by the pediatric oncologist, grandmother downloads an updated clinical summary with CCD format to Susie's PHR, via Blue Button to her mobile phone.

A.1.8 SWOT Analysis

The value of this scenario for Susie and her family is high. The same is true for her providers.

This scenario is out of scope for epSOS as refers to the patient summary of a young child.

Elements of this scenario will be revisited in the context of WP5.

A.2 Martha's Patient Summary: a Traveling Corporate Executive (provided by Elaine Blechman, Prosocial, US)

Martha, a 45-year old corporate executive and breast cancer survivor travels frequently on business between the US and EU countries. She carries a clinical summary including a plan of care on her mobile phone and on paper just in case she needs to seek medical care regarding recurring symptoms.

This story has been selected for further analysis and is included in section 6.

A.3 Tom's Patient Summary: Seeking Care Abroad (provided by Elaine Blechman, Prosocial, US)

A.3.1 Overview

Tom, a 65-year old business owner, diagnosed with prostate cancer, travels to Italy for a laser ablation procedure that is five times more expensive in the US. He carries a clinical summary including a plan of care on his mobile phone and on paper to share with the surgeon in Italy.

A.3.2 Stakeholder Story

Tom, a 65-year old business owner, diagnosed with prostate cancer, travels to Madrid for a laser ablation procedure that is five times more expensive in the US. He carries a clinical summary including a plan of care on his mobile phone and on paper to share with the radiation oncologist in Madrid.

- **Demographics:** Age 65 years, Gender male
- **Problems:** Prostate cancer Stage II; hypertension; Type 2 diabetes;
- **Medications:** Lisinopril 10mg. daily; Metformin 500 mg. twice daily;
- **Allergies:** Propranolol
- **Plan of Care:** Laser ablation of prostate; monitor PSA after surgery at monthly intervals x4; if PSA less than 0.5, monitor every 3 months thereafter; daily home monitoring of blood pressure and blood glucose; monthly lab test of Hgb A2; continue moderate physical activity and follow dietary instructions.

A.3.3 Starting Event

A visit to Spain to receive an Ablation Procedure that costs less that it costs in the US.

A.3.4 Actor and Users

- Tom, 65-year old business owner.
- Radiation Oncologist
- Urologist

A.3.5 Goal

Tom wishes to ensure continuity of care among specialists and providers.

A.3.6 Stakeholders

- EHR vendors
- Health care specialists
- PHR vendors
- Radiation oncologist

A.3.7 Primary Scenario – Patient Mediated

Unplanned Care: Soon after arriving in Madrid, and before his scheduled meeting with a radiation oncologist, Tom experiences lower back pain and constipation (symptoms his US urologist warned him to monitor). The Spanish radiation oncologist will not evaluate Tom for laser ablation given Tom's current undiagnosed symptoms and refers him to a local urologist for evaluation.

During registration with the urologist in Spain, Tom gives the physician a translated paper copy of his clinical summary in Spanish. He also shows, on his mobile phone, in his PHR, the Spanish translation of his clinical summary. The urologist refers Tom for an MRI. Results suggest rapid spread of the disease since the last MRI, ruling Tom out as a candidate for his preferred focal procedures and impelling Tom to return home to the US for treatment.

During discharge from the care of the urologist, Tom downloads an updated clinical summary including information and recommendations from the surgical oncologist and the urologist, translated from Spanish to his PHR, via EPSOS transform on his mobile phone.

A.3.8 SWOT Analysis

Parts of this scenario are out of scope for Trillium Bridge. However they do reflect the complexity of ensuring continuity of care. Several questions related to the feasibility analysis of WP5.

What are the particular Security and Privacy considerations about this scenario and its variants?

Are there any legal issues that arise for the provider and patient mediated version?

A.4 Paolo Cerruti: The Story of a Retired Businessman (provided by Dipak Kalra, EuroRec, EU)

A.4.1 Overview

Paolo Cerruti is a 67-year-old retired businessman who normally lives in Boston, USA. He is generally healthy, but has long-standing hypertension. His regular physician changed his medication two weeks ago because of poor blood pressure control on his previous medication.

He is on holiday going through Italy, travelling on his own, and is presently in Lombardi. He is nearing the end of his holiday, and will be returning back to Boston in three days' time.

Unfortunately two days ago his day bag was stolen when he was in a market square. The bag included his hypertension medication, and he has therefore not been able to take his tablets for two days. He hoped that he would be fine without the tablets for a few days, and was intending to get a fresh supply from his physician immediately on his return.

However, Sunday morning he has woken up feeling dizzy and has blurred vision. The hotel is able to put him in urgent contact with a local general practitioner (Continuity of Care physician) who is able to see him that morning. Having assessed him, and noted a raised blood pressure, the general practitioner is uncertain about whether to attribute these symptoms to the raised blood pressure or possibly to a side effect of the new medication. Unfortunately Paolo does not recall the name of these new tablets, and the GP is therefore unable to look up the side-effect profile of this medication.

Feeling otherwise healthy, Paolo had not thought to request a handwritten or printed medical summary from his regular physician in advance, nor did he realize that his physician could, on request, create an online personal health summary for emergency access in Europe.

In order to manage Paolo appropriately, the GP really needs to know the name of this medication, and the last few blood pressure readings in order to determine how exceptional the present reading is, for Paolo.

Immediate access to Trillium Bridge summary would be the perfect answer.
The general practitioner is registered within the Lombardi health region, which is part of the Trillium Bridge network. This means that his region, and country, has signed mutual data-sharing agreements with other members of the network, including all of the states in the US. Patient demographic and provider directory services are accessible through search functions, and are maintained by each participating country.

The GP is able to enter demographic information about Paolo into a patient search facility, which relays his request through an Italian National Contact Point to a corresponding center in the US. Once the patient match is confirmed, Paolo is able to verify the list of health care providers linked to his record, and indicate which one is his regular treating physician. The GP can then easily request an up-to-date summary, which is generated automatically from the care center Boston as a query from his electronic health record. The credentials of the Lombardi GP are registered within the audit log at the Boston care facility, which also timestamps the export of the summary.

The summary document is relayed between the US and Italian Contact Point services, and in the process is also translated. This includes translating clinical terminology and medication codes into those which would be recognized in the Italian GP system. An audit log within the GP system also records the receipt of that summary.

The GP find that the blood pressure he has recorded on Paolo is only a little higher than his recent readings, but notes that visual disturbances are a recognized side effect of this medication. No specific treatment is indicated, and Paolo is reassured that this side effect will gradually subside, and that his regular physician can prescribe him a suitable alternative antihypertensive medication on his return to Boston.

This story was selected for further analysis and is covered in section 6.

A.4.2 Detailed Patient Summary

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**Text and SCT code**	**MANDATORY Yes/No**
Alerts	Allergies and intolerances	Allergy description	Description of the clinical manifestation of the allergy reaction. Example: Anaphylactic shock, angioedema (the clinical manifestation also gives	**Allergic rash**	**No**

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**Text and SCT code**	**MANDATORY Yes/No**
			information about the severity of the observed reaction)		
		Allergy description id code	Normalized identifier	epSOS ReactionAllergy "Atopic dermatitis and related conditions" **200769008**	**No**
		Onset Date	Date of the observation of the reaction	**1995**	**No**
		Agent	Describes the agent (drug, food, chemical agent, etc.) that is responsible for the adverse reaction	**Erythromycin**	**No**
		Agent id code	Normalized identifier	epSOSActiveIngredient **D10AF02**	**No**
History of past illness	Vaccinations	Vaccinations	Contains each disease against which immunization was given	**Pneumococcal pneumonia**	**No**
		Brand name		**Prevnar (Wyeth)**	**No**
		Vaccinations id code	Normalized identifier	epSOSVaccine "Pneumococcal vaccine" **333598008**	**No**
		Vaccination Date	The date the immunization was received	**31/10/2013**	**No**
	List of Resolved, Closed or Inactive problems	Problem Description	Problems or diagnosis not included under the definition of 'Current problems or diagnosis'. Example: hepatic cyst (the patient has been treated with an hepatic cystectomy that solved the problem and therefore it´s a closed problem)	**Fractured neck of (left) femur**	**No**
		Problem Id (code)	Normalized identifier	epSOSIllnessesandDisorders "Fracture of femur" **S72**	**No**
		On set time	Date of problem onset	**12/12/2007**	**No**
		End date	Problem resolution date		**No**
		Resolution Circumstances	Describes the reason by which the problem changed the status from current to inactive (e.g., surgical procedure, medical treatment, etc.). This field includes 'free text' if the resolution circumstances are not already included in other fields. Example: It can happen that this field is already included in other like Surgical		**No**

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**Text and SCT code**	**MANDATORY Yes/No**
			Procedure, medical device etc., e.g.: hepatic cystectomy (this will be the 'Resolution Circumstances' for the problem 'hepatic cyst' and will be included in surgical procedures)		
		Problem Description		**Migraine headaches**	
		Problem Id (code)		epSOSIllnessesanddDisorders "Migraine" **G43**	
		On set time		**1982**	
		End date		**1998**	
		Resolution Circumstances		**"No longer getting migraines"**	
	Surgical Procedures prior to the past six months	Procedure description	Describes the type of procedure	**Appendectomy**	**No**
		Procedure Id (code)	Normalized identifier	epSOSProcedures **80146002**	**No**
		Procedure date	Date when procedure was performed	**1963**	**No**
Medical problems	List of Current Problems/Diagnosis.	Problem/diagnosis description	Problems/diagnosis that fit under these conditions: conditions that may have a chronic or relapsing course (e.g.: exacerbations of asthma, irritable bowel syndrome), conditions for which the patient receives repeat medications (e.g.: diabetes mellitus, hypertension) and conditions that are persistent and serious contraindications for classes of medication (e.g.: dyspepsia, migraine and asthma)	**Hypertension**	**No**
		Problem Id (code)	Normalized identifier	epSOSIllnessesanddDisorders "Essential (primary) hypertension" **I10**	**No**
		Onset time	Date of problem onset	**2008**	**No**
	Medical Devices and implants	Device and implant Description	Describes the patient's implanted and external medical devices and equipment that their health status depends on. Includes devices as cardiac pacemakers, implantable defibrillator, prosthesis, ferromagnetic bone implants	**(none)**	**No**

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**Text and SCT code**	**MANDATORY Yes/No**
			etc. that are important to know by the HCP		
		Device Id code	Normalized identifier		**No**
		Implant date			**No**
	Major Surgical Procedures in the past 6 months[44]	Procedure description	Describes the type of procedure	**(none)**	**No**
		Procedure Id (code)	Normalized identifier		**No**
		Procedure date	Date when procedure was performed		**No**
	Treatment Recommendations	Recommendations Description	Therapeutic recommendations that do not include drugs (diet, physical exercise constraints, etc.)	**(none)**	**No**
		Recommendation Id (code)	Normalized identifier		**No**
	Autonomy/ Invalidity	Description	Need of the patient to be continuously assisted by third parties. Invalidity status may influence decisions about how to administer treatments	**(nothing stated)**	**No**
		Invalidity Id code	Normalized invalidity ID (if any, otherwise free text)		**No**
Medication Summary	List of current medicines. (All prescribed medicine whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not.).	Active ingredient	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: Paracetamol	**Metoprolol**	**No**
		Active ingredient id code	Code that identifies the Active ingredient	epSOSActiveIngredient **C07AB02**	**No**
		Strength	The content of the active ingredient expressed quantitatively per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form. Example: 500 mg per tablet	**100mg**	**No**
		Pharmaceutical dose form	It is the form in which a pharmaceutical product is presented in the medicinal product package (e.g., tablets, syrup)	**Tablets**	**No**
		Number of units per intake[45]	The number of units per intake that the patient is taking. Example: 1 tablet	**One**	**No**

[44] As there is subjectivity in the term 'relevant', the date will be used as the limit to include procedures.

[45] Posology has been defined from the functional point of view as containing these three components: number of units per intake, frequency of intakes and duration of treatment:(example: 1 unit/intake every 24 hours for a duration of 14 days

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**Text and SCT code**	**MANDATORY Yes/No**
		Frequency of intakes**Error! Bookmark not defined.**	Frequency of intakes (per hours/day/month/ week..). Example: each 24 hours	**Morning**	**No**
		Duration of treatment**Error! Bookmark not defined.**	Example: during 14 days	**Indefinite**	**No**
		Date of onset of treatment	Date when patient needs to start taking the medicine prescribed	**7/2/2014**	**No**
Social History	Social History Observations	Social History Observations related to: smoke, alcohol and diet.	Example: cigarette smoker, alcohol consumption...	**Non-smoker**	**No**
		Reference date range	Example: from 1974 thru 2004		**No**
Pregnancy History	Expected date of delivery	Expected date of delivery	Date in which the woman is due to give birth. Year, day and month are required. E.g.: 01/01/2010	**(not applicable)**	**No**
Physical findings	Vital Signs Observations	Blood pressure	One value of blood pressure which includes: systolic Blood Pressure and Diastolic Blood pressure	**130/90**	**No**
		Date when blood pressure was measured	Date when blood pressure was measured	**7/2/2014**	**No**
Diagnostic tests	Blood group	Result of blood group	Result from the blood group test made to the patient	**(not recorded)**	**No**
		Date	**Date in which the blood group test was done. This field may contain only the year if day and month are not available. E.g.: 01/01/2009**		**No**

A.4.3 Paolo's Patient Summary in EU and US Formats

Paolo's patient summary representation as epSOS and CCDA/CCD is available in the Project Repository (http://www.trilliumbridge.eu/repository) (they are one of the RTD files).

A.5 Jean's Patient Summary: a Woman with Multiple Sclerosis (*provided by Larry Garber, Atrius Health, US*)

A.5.1 Overview

Jean is a 50 year old woman from the US with Multiple Sclerosis. This illness requires treatment involving injections of Betaseron® (interferon beta-1b) every other day. In anticipation of her trip to Venice, Italy, she has her US Neurologist print out on paper a summary in English of her medical history, medications, allergies, immunizations, recent lab and brain MRI test results, as well as current functional and cognitive status.

When in Venice, Jean stands up to take a picture while in a gondola, loses her balance, and falls, banging her head. She is taken to the Ospedale Civile Strada Statale Giovanni e Paolo where an Italian physician sees her. She gives the physician a copy of her medical history on paper. The physician is able to read English, and manually enters this information into the hospital's electronic health record (EHR) system. The hospital

performs an MRI of Jean's head which reveals the same lesions that were described on the report from her US Neurologist. Reassured that there was no new brain injury, the Italian physician creates a summary record of Jean's encounter in Italian, submits it through an online system that translates it into English, and then prints it out for Jean to give to her Neurologist when she returns to the US.

A.5.2 Detailed Patient Summary

Jean Multiscler
Female
DOB: November 1st, 1963
Address:
351 Northland Ave
Worcester, MA 01605
Home Phone: 1-508-123-4567
Mobile Phone: 1-508-987-6543
Primary Care Physician:
Larry Garber, MD
Reliant Medical Group
630 Plantation Street
Worcester, MA 01605
1-508-852-0600
Neurologist:
Isa Brainman, MD
Reliant Medical Group
630 Plantation Street
Worcester, MA 01605
1-508-852-0600

Allergies
Colchicine (noted 1/17/2008) – Caused severe diarrhea

Medications
Interferon beta-1b
0.25mg SC qOD

ALBUTEROL SULFATE (PROAIR HFA) 108 (90 BASE) MCG/ACT Aero Soln
Inhale 2 puffs every 4-6 hours as needed for wheezing or shortness of breath
Start Date: 2/14/2007

Ibuprofen 200mg Tablet
2-3 PO TID prn gout

Melatonin
1 at bedtime prn insomnia or jet lag

Problems
Multiple Sclerosis - Relapsing
Dx'd 2005 by MRI following difficulty with gate with word-finding. Second episode of leg weakness. Both of which have resolved. Stable on Betaseron. Followed by Neurology

Asthma
Noted 2007. Controlled by removal of cat and albuterol prn, 1-2 times/month

Gout

Mild, controlled with NSAIDs prn

Insomnia
Reasonably good results with melatonin

Encounters
10/7/2013 – Comprehensive Physical Exam – Dr. Larry Garber – Internal Medicine, Reliant Medical Group
11/4/2013 – Office Visit – Dr. Isa Brainman - Neurology, Reliant Medical Group

Immunizations
Tdap 7/12/2009
Influenza Virus Vaccine Splt >=3yrs - 10/7/2013

Social History
Tobacco – Never
Alcohol use – rare

Functional Status – 11/4/2013
SF-12 Short-Form Health Survey

(1) In general, would you say your health is: Excellent
(2) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf: Not limited at all
(3) Climbing several flights of stairs: Not limited at all
(4) Accomplished less than you would have liked in past 4 weeks due to physical health: No
(5) Were limited in the kind of work or other activities due to physical health: No
(6) Accomplished less than you would have liked in past 4 weeks due to emotional problems: No
(7) Were limited in the kind of work or other activities due to emotional problems: No
(8) pain interfere with normal work in past 4 weeks: Not at all
(9) Have you felt calm and peaceful in past 4 weeks: Most of the time
(10) Had a lot of energy: A good bit of the time
(11) Have felt downhearted and blue: A little bit of the time
(12) Amount of time physical health or emotional problems interfered with social activities in past 4 weeks: None of the time

Physical Exam – 11/4/2013
Neurologic Exam: CN II-XII Intact. Motor 5/5 in all extremities. Sensory intact. Normal reflexes. Normal cerebellar exam.

Results
MRI Head with and without contrast – 10/30/2013
CLINICAL INDICATIONS: Multiple sclerosis follow up
FINDINGS: Comparison made to prior MRI dated March 14, 2009 , there are multiple deep white matter focal area of signal change, this has high signal intensity on T2 and FLAIR image sequence. Some of which are perpendicular to the corpus callosum consistent with patient's history of multiple sclerosis. There is there is no enhancement. The infratentorial structures are relatively spared. On T1-weighted image sequence isointense. There is approximately 16 lesion counted supratentorial brain. None of which show significant change from prior study. There are no new lesions. The centrum semiovale and falx cerebri remain symmetric and midline respectively. There is normal gray/white matter differentiation. The ventricles are symmetric.
There is normal void signal at all major vascular structures at the skull base. The cerebellum, cerebellar peduncle and pons are normal. The vestibulocochlear nerves are symmetric. There cerebellar pontine angles

are clear. The basilar cisterns are normal. The orbits and intraorbital structures are grossly intact. There is normal filling of all major vascular sinuses.
The corpus callosum and cerebellar tonsils are properly positioned. The pituitary fossa is grossly normal.
IMPRESSION: Stable approximately 16 supratentorial lesion identified consistent with patient's history of multiple sclerosis none of the lesions show significant change from prior study.

LIVER PANEL – 10/7/2013
BILIRUBIN,TOTAL = 0.40 mg/dL (Normal Range: 0.2-1.2)
BILIRUBIN,DIRECT = 0.11 mg/dL (Normal Range: 0.02-0.20)
BILIRUBIN,INDIRECT = 0.29 mg/dL (Normal Range: 0.10-1.00)
ASPARTATE AMINOTRANSFERASE = 15 U/L (Normal Range: 14.5-32.5)
ALANINE AMINOTRANSFERASE = 11 U/L (Normal Range: 13-33) (Low)
TOTAL PROTEIN = 7.0 g/dL (Normal Range: 6.6-8.7)
ALBUMIN = 3.9 gm/dL (Normal Range: 3.50-5.00)
GLOBULIN = 3.1 gm/dL (Normal Range: 1.3-3.5)
ALBUMIN/GLOBULIN RATIO = 1.3 (Normal Range: 1.5-3.0) (Low)
ALKALINE PHOSPHATASE = 66 U/L (Normal Range: 40.0-129.0)

BASIC METABOLIC PANEL – 10/7/2013
SODIUM = 140 mMOL/L (Normal Range: 136-145)
POTASSIUM = 4.4 mMOL/L (Normal Range: 3.5-5.5)
CHLORIDE = 103 mMOL/L (Normal Range: 98.0-109.0)
CARBON DIOXIDE = 29 mMOL/L (Normal Range: 22-29)
ANION GAP = 12 mMOL/L (Normal Range: 7-16)
BLOOD UREA NITROGEN = 18 mg/dL (Normal Range: 9-23)
CREATININE = 0.78 mg/dL (Normal Range: 0.37-1.12)
GLUCOSE = 91 mg/dL (Normal Range: 60-99)
CALCIUM = 9.5 mg/dL (Normal Range: 8.2-10.9)

LIPID PANEL – 10/7/2013
TRIGLYCERIDES = 176 mg/dL
NORMAL: <150 mg/dL
BORDERLINE HIGH: 150-199 mg/dL
HIGH: 200-499 mg/dL
VERY HIGH >499 mg/dL
CHOLESTEROL = 159 mg/dL
DESIRABLE: <200 mg/dL
BORDERLINE HIGH: 200-239 mg/dL
HIGH: >239 mg/dL
HDL CHOLESTEROL = 51.0 mg/dL
DESIRABLE: >60 mg/dL
BORDERLINE: 40-59 mg/dL
UNDESIRABLE: <40 mg/dL
LDL CHOLESTEROL,CALCULATED = 72.8 mg/dL
OPTIMAL: <100 mg/dL
NEAR OPTIMAL: <130 mg/dL
BORDERLINE HIGH: 130-159 mg/dL
HIGH: 160-189 mg/dL
VERY HIGH >189 mg/dL

THYROID STIMULATING HORMONE – 10/7/2013
THYROID STIMULATING HORMONE = 0.791 uIU/mL (Normal Range: 0.270-4.20)

A.5.3 Jean's Patient Summary in EU and US Formats

Jean's patient summary is available in the CCDA/CCD format in the Project Repository (http://www.trilliumbridge.eu/repository) [CCD_Jean_MULTISCLER.xml]

A.6 Logan's Patient Summary: Healthy Boy with Allergies on Vacation (*provided by Larry Garber, Atrius Health, US*)

A.6.1 Overview

Logan is a healthy 16 year old boy from the US who is traveling on vacation with his parents to Paris, France. While visiting the Eiffel Tower, he trips and injures his ankle. He is seen at the Necker-Enfants Malades Hospital, where the triage nurse asks for his medical history and in particular, if he is allergic to any medications. His parents remember that he's allergic to some antibiotic but can't recall which one. Logan takes out his Smartphone, logs into his Personal Health Record (PHR) using his US Primary Care Physician's PHR app, and identifies that he is indeed allergic to sulfa drugs. The nurse recognizes this as being "sulfamide" in French, and manually enters it into the hospital's EHR.

The French physician performs an X-ray of Logan's ankle which appears normal, and makes the diagnosis of a sprain. The French physician creates a summary record of Logan's encounter in French, submits it through an online system that translates it into English, and then prints it out for Logan to give to his Primary Care Physician when he returns to the US (after visiting the Louvre).

A.6.2 Detailed Clinical Summary

Logan Leghertz
Male
DOB: May 1st, 1997
Address:
73 Happy Mountain Ave
Worcester, MA 01605
Home Phone: 1-508-123-4567
Mobile Phone: 1-508-987-6543
Primary Care Physician:
Larry Garber, MD
Reliant Medical Group
630 Plantation Street
Worcester, MA 01605
1-508-852-0600

Allergies
Sulfa (noted 8/4/2009) – Caused hives

Medications
None

Problems
Health Maintenance
Up to date

Encounters
6/21/2013 – Comprehensive Physical Exam – Larry Garber, MD – Internal Medicine, Reliant Medical Group

Immunizations
DTaP - 7/21/1997 9/18/1997 11/24/1997 11/17/1998 5/18/2001

HPV (GARDASIL) 6/21/2012
Hep A - 12/8/2010
Hep B - 5/7/1997 6/23/1997 3/24/1998 1/7/2005
Hib - 7/21/1997 9/18/1997 11/24/1997 7/16/1998
IPV - 7/21/1997 9/18/1997 5/18/2001
Influenza (SEASONAL) - 12/11/2003 10/15/2009 12/8/2010
MMR - 7/16/1998 5/21/2002
Menactra (Meningococcal conjugate, IM) 5/30/2008
OPV 11/17/1998
Tdap - 5/30/2008
Typhoid 1/7/2005
Varicella - 5/15/2000 6/16/2009

Social History
Tobacco – Never
Alcohol use – Never

Results

A.6.3 Logan's Patient Summary in EU and US Formats

Logan's patient summary is available in the CCDA/CCD format in the Project Repository [CCD_Logan_LEGHERTZ.xml]

A.7 David's Patient Summary: Retired Man with a Clot in His Leg (*provided by Larry Garber, Atrius Health, US*)

A.7.1 Overview

David is a 55 year old man from the US who was recently diagnosed with a clot in his leg, which is causing swelling in that leg. He is currently receiving the blood thinner Warfarin each day and is traveling to Portugal. When he arrives in Lisbon, Portugal, he notices that he now has swelling in both of his legs. Concerned that he may have developed a clot in his other leg, he visits the Hospital Particular De Lisboa. He explains to the triage nurse that he has an online PHR. The nurse gives David access to a computer where he logs into his PHR and downloads a Consolidated CDA Continuity of Care Document (CCD) summary of his medical history, medications, allergies, immunizations, and recent lab and venous duplex results. The nurse uploads this CCD into an online translation system that transforms the CCD into a format that can be imported into the hospital's EHR. The hospital performs a venous duplex study on David's legs which reveals the same lesion that was described on the report from his US physician. The Portuguese physician educates him to stop eating salty peanuts on airplanes, and creates a summary record of David's encounter in Portuguese, submits it through an online system that translates it into English, and then prints it out for David to give to his physician when he returns to the US.

A.7.2 Detailed Patient Summary

David Swellercalf
Male
DOB: September 1st, 1958
Address:
153 Northville Lane
Worcester, MA 01605
Home Phone: 1-508-123-4567
Mobile Phone: 1-508-987-6543
Primary Care Physician:

Laura Bessette, MD
Reliant Medical Group
630 Plantation Street
Worcester, MA 01605
1-508-852-0600

Allergies
NKDA

Medications
Warfarin 5mg
1 Tablet every Saturday, Sunday, Tuesday, and Thursday evening
1 Tablet every Monday, Wednesday and Friday evening
Start Date: 1/10/2014

Problems
Elevated PSA
Prostate slightly enlarged without nodularity. Low risk by % Free PSA. No FHx. No symptoms. Will continue to follow.

DVT- Left Leg
s/p Left calf injury while skiing. Confirmed by duplex. Will treat with Warfarin until 7/2014, target INR 2-3

Tobacco Abuse
Not interested in quitting. Educated. Will continue to follow

Encounters
9/27/2013 – Comprehensive Physical Exam – Dr. Laura Bessette – Internal Medicine, Reliant Medical Group
1/10/2014 – Office Visit – Dr. Laura Bessette – Internal Medicine, Reliant Medical

Immunizations
Hep A - 3/6/2008 11/24/2008
Influenza (SEASONAL) - 11/17/1998 11/19/1999 12/18/2000 12/31/2001
11/9/2004 11/30/2005 11/9/2006 10/22/2009
10/12/2010 10/12/2011 11/30/2012 10/3/2013
Td - 7/2/1997
Tdap - 3/6/2008
Typhoid - 3/6/2008

Social History
Tobacco – 1 PPD Cigarettes
Alcohol use – socially

Results
Venous Duplex Bilateral Lower Extremities – 1/10/2014
HISTORY: Left leg pain and swelling
COMPARISON::None
Ultrasound evaluation of the right common femoral, femoral, and popliteal veins was performed using grayscale, color flow, and duplex sonography. There is normal flow, augmentation, and compressibility, in the common femoral vein and the femoral vein. The left popliteal vein is dilated and filled with echogenic material. It is noncompressible. Findings are consistent with left- popliteal DVT.
IMPRESSION:
1. Left popliteal DVT.

2. Findings are discussed with Dr. Bessette's office.
Approved By: MAX ROSEN MD 1/10/2014 11:05 AM
ELECTRONICALLY SIGNED BY: MAX P ROSEN MD 1/10/2014 11:05 AM

INR LOW INTENSITY ANTICOAGULATION – 1/21/2014
INR = 2.3 (Normal Range: 2.0-3.0)

INR LOW INTENSITY ANTICOAGULATION – 1/17/2014
INR = 2.1 (Normal Range: 2.0-3.0)

HEPATIC FUNCTION PANEL – 1/10/2014
BILIRUBIN,TOTAL = 0.50 mg/dL (Normal Range: 0.2-1.2)
ASPARTATE AMINOTRANSFERASE = 20 U/L (Normal Range: 14.5-32.5)
ALANINE AMINOTRANSFERASE = 18 U/L (Normal Range: 13-33)
TOTAL PROTEIN = 7.9 g/dL (Normal Range: 6.6-8.7)
ALBUMIN = 4.9 gm/dL (Normal Range: 3.50-5.00)
GLOBULIN = 3.0 gm/dL (Normal Range: 1.3-3.5)
ALBUMIN/GLOBULIN RATIO = 1.6 (Normal Range: 1.5-3.0)
ALKALINE PHOSPHATASE = 78 U/L (Normal Range: 40.0-129.0)

BASIC METABOLIC PANEL – 1/10/2014
SODIUM = 141 mMOL/L (Normal Range: 136-145)
POTASSIUM = 4.2 mMOL/L (Normal Range: 3.5-5.5)
CHLORIDE = 105 mMOL/L (Normal Range: 98.0-109.0)
CARBON DIOXIDE = 26 mMOL/L (Normal Range: 22-29)
ANION GAP = 11 mMOL/L (Normal Range: 7-16)
BLOOD UREA NITROGEN = 21 mg/dL (Normal Range: 9-23)
CREATININE = 0.9 mg/dL (Normal Range: 0.37-1.12)
GLUCOSE = 97 mg/dL (Normal Range: 60-99)
CALCIUM = 9.1 mg/dL (Normal Range: 8.2-10.9)

PSA – 9/27/2013
PSA = 4.1 ng/mL (Normal Range: 0-4.0) (High)

A.7.3 David's Patient Summary in EU and US Formats

David's patient summary is available in the CCDA/CCD format in the Project Repository (http://www.trilliumbridge.eu/repository) [/CCD_David_SWELLERCALF.xml].

A.8 Antonio's Patient summary: a Flight Attendant with Acute Motor Deficit (provided by Iciar Abad, Spanish Ministry of Health (ES))

A.8.1 Overview

Antonio, a 60-year-old flight attendant was admitted to the hospital in Barcelona (Spain) for an acute motor deficit of the four limbs. Clinical examination found a pure and severe motor deficit in the four limbs. No sensory abnormality was found. Deep tendon reflexes were abolished. Electromyography suggested the diagnosis of acute motoraxonal neuropathy (AMAN). All motor nerves were unexcitable, except for the right ulnar nerve, which evoked a compound muscle action potential reduced in amplitude and conducted at 34.5 m/s with F wave latencies not delayed. Sensitive nerve conductions were normal. Needle electromyography showed severe acute diffuse denervation. The patient was treated with intravenous inmunoglobulin. Despite the treatment, the patient continued to have profound ascending muscle weakness, eventually involving the bulbar and facial muscles. Due to respiratory distress and respiratory muscle weakness, the patient required

mechanical ventilation. Five sessions with plasma exchanges were performed without any signs of improvement. The patient continued to stay in the Intensive Care Unit. Once the patient was able to sustain spontaneous breathing, he was taken to the Neurology Department. Four months after developing the AMAN, **blood in the stool revealed anal carcinoma. The anoscopy and biopsy showed an anal squamous cell carcinoma. The tumor was classified as stage 3**. Routine laboratory data showed no abnormalities. Human papillomavirus DNA type determination was positive. Campylobacter jejuni, cytomegalovirus and Epstein-Barr virus serology were negative. CEA were normal. Cerebrospinal fluid analysis did not show any abnormalities.

The patient selected M.D. XXX Cancer Center at Houston (TX, US) to be treated, which is part of the Trillium Bridge network. This means that the particular health system has signed mutual data-sharing agreements with other members of the network, including the hospital in Barcelona where Antonio was attended. Patient demographic and provider directory services are accessible through search functions, and are maintained by each participating member. The epSOS summary document is relayed between the Spanish Contact Point and the US, and in the process is also translated. **This includes translating clinical terminology and laboratory codes into those which would be recognized in the US health record system**. The case was discussed in the multidisciplinary Gastrointestinal Tumor Board of our Center and the recommendation was to treat anal carcinoma by delivering concurrent chemoradiotherapy in order to achieve an adequate loco-regional control and motor improvement. Radiation was given to the tumor and to the pelvis including inguinal nodes, in 25 fractions over a five-week period plus fluorouracil and mitomycin. The chemoradiotherapy was well tolerated. Clinical improvement of the motor state was observed at the fourth week of the oncologic treatment.

After treatment, the patient decided to continue the follow up in his home town (Sevilla, Spain) in the Virgen del Rocío University Hospital, which is part of the Trillium Bridge network. **The Radiation Oncology Department access to the Trillium patient summary**, and studied the association of an acute motor axonal neuropathy with a squamous cell anal carcinoma. Anti-GM1 IgG antibodies were detected by an enzyme-linked immunosorbent assay method. Other antibodies, including antinuclear nucleoprotein antibody (anti-Hu), anti-Tr, anti-Ri, anti-CV2, anti-amphiphysin and anti-Yo, were negative. The antibodies in serum were analyzed by indirect immunofluorescence. The presence of anti-GM1 IgG antibodies and the clinical improvement of the motor state after concurrent chemoradiotherapy lead us to believe there is an association between anal carcinoma and this severe impairment.

Relevant information to be provided by the patient to the American hospital for treatment: diagnosis, diagnostic method and therapeutic measures applied in Spain to patient transfer.

- Medical records with medical history and physical examination, diagnosis and treatment received.
- Electromyography
- Treatment: intravenous immunoglobulin, mechanical ventilation, plasma exchanges
- Anoscopy
- Biopsy
- CT scan
- Laboratory data
- Cerebrospinal fluid analysis

Brief description of the diagnostic and therapeutic decisions taken in the American Hospital.

Treatment consisted in concurrent chemoradiotherapy in order to achieve an adequate loco-regional control and motor improvement. Radiation was given to the tumor and to the pelvis including inguinal nodes, in 25 fractions over a five-week period plus fluorouracil and mitomycin. The chemoradiotherapy was well

tolerated. Clinical improvement of the motor state was observed at the fourth week of the oncologic treatment.

Relevant information provided by the patient to continue treatment in Spain.

Medical records with medical history and physical examination, diagnosis and treatment received.

- Radiation therapy treatment planning
- Radiation therapy dose-volume histogram

A.9 User Stories Shared During the Boston Kickoff Meeting

Several stories were proposed at the Trillium Bridge kickoff meeting:

- A patient travelling from and to Europe and US is requested to have an official document that justifies the medicines that brings with him/her during the travel.
- US patient asks GP for an eHealth summary (Adverse reactions to drugs, medication, allergies, list of problems), paper or electronic before travel to one or more EU countries.
- EU patient with medication allergies and implant is admitted to US hospital on the nationwide exchange network, provider queries for epSOS PS.

As already noted, the S&I WG on EHR Interoperability have developed several use cases related to the transatlantic exchange of patient summaries. Some of these use cases are presented below as taken from the presentation in the WS on Sept 25, 2013[46]. Some of these use cases are out of scope, while others are similar to the one's already described above.

A.10 User Stories Developed by the S&I WG on EHR Interoperability, US/EU

As already noted, the S&I WG on EHR Interoperability have developed several use cases related to the transatlantic exchange of patient summaries. Some of these use cases are presented below as taken from the presentation in the WS on Sept 25, 2013[47].

A.10.1 S&I Story 1a: Family Moving Abroad: Immunization Records (Provider to Provider)

A family with three children moves to a new country. In order for the children to be admitted to their new schools they must provide a complete list of immunizations and obtain any additional immunizations needed. The family has identified a provider in the new region. The new provider needs to request the immunization records for the children to be sent to her from the previous provider.

Out of scope for epSOS due to the age of children.

A.10.2 S&I Story 1b: Family Moving Abroad: Immunization Records (Patient Mediated)

A family with three children moves to a new country. In order for the children to be admitted to their new schools they must provide a complete list of immunizations and obtain any additional immunizations needed.

[46] Meeting artefacts of the ONC S&I Framework http://wiki.siframework.org/Project+Meeting+Artifacts. User stories presented on Sept 25, 2013 http://wiki.siframework.org/file/view/Interoperability%20WG%20meeting%209-25-13%20delivered.pptx/454102790/Interoperability%20WG%20meeting%209-25-13%20delivered.pptx

[47] Meeting artefacts of the ONC S&I Framework http://wiki.siframework.org/Project+Meeting+Artifacts. User stories presented on Sept 25, 2013 http://wiki.siframework.org/file/view/Interoperability%20WG%20meeting%209-25-13%20delivered.pptx/454102790/Interoperability%20WG%20meeting%209-25-13%20delivered.pptx

The family has identified a provider in the new region. The patient accesses their PHR and sends the immunization records to the new provider.

Out of scope for epSOS due to the age of children.

A.10.3 S&I Story 2a: Traveler's Broken Eyeglasses (Provider to Provider)

A patient accidentally breaks their eyeglass while travelling abroad. They need their home provider to send their eyeglass prescription to their new optometrist. The optometrist requests the patient's prescription from their home provider.

A.10.4 S&I Story 2b: Traveler's Broken Eyeglasses (Patient Facilitated)

A patient accidentally breaks their eyeglasses while travelling abroad. They need their home provider to send their eyeglass prescription to them. The patient needs to retrieve their prescription and take the prescription to a prescription eyewear store in Europe to purchase new eyeglasses without having to have their eyes examined again by a new doctor.

A.10.5 S&I Story 3: Planned Care for Grandparents

A couple from France moved to the United States in September 2010. Their baby was born shortly after in the US in January 2011. The maternal grandparents travel to the US each year for 6 months to baby-sit. The maternal grandmother had diabetes that has been treated in Europe but needs monitoring in the US while she is living there. The grandmother has healthcare insurance in the US but she needs her US physician to interact with her provider in Europe.

A.10.6 S&I Story 4: Emergency and Inpatient Care

Patient has a heart attack and is taken to the Emergency (ER). When returning home, information from the ER must be transferred to their Primary Care Physician (PCP). Patient has information in PHR (i-phone) OR the patient may only have their insurance card in their wallet – which may be how EHR provider gets PCP information.

A.10.7 S&I Story 5: Emergency and Inpatient Care

A student is studying abroad in Italy and they are hit by a car towards the end of their stay. They are taken to a nearby hospital for treatment for head trauma. The patient is admitted and treated for approximately two weeks before they are discharged. The patient is cleared for travel back to the US, however, they will need to check in with their PCP back home for any side effects from the medication or additional treatments or radiology scans needed as a precaution. As per new policy at the Italian hospital they must send a summary of the hospitalization stay including treatment plans to the PCP identified by the patient.

A.10.8 S&I Story 6: Patient Lost Prescription Medication for BP Control and Needs a Refill

A patient is travelling through Europe and left their prescription blood pressure medication at their previous hotel in Germany. They are unable to get in touch with the hotel staff in Germany to have their prescription mailed to them. Therefore, they visit a pharmacy in Spain to see if they can request the medication from the patient's cardiac specialist back home who wrote the prescription for the medication. The pharmacy has the medication that the patient has been prescribed. The pharmacist in Spain needs to validate the prescription with the patient's cardiac specialist before they can dispense it.

A.10.9 S&I Story 7: Ambulatory (Primary Care Visit) of Diabetic Patient

A patient who has a history of poorly managing their diabetes is traveling in a different country. After hiking the Swiss Alps the patient experiences numbness and tingling in their feet. The patient disregards these symptoms attributing them to the recent hike and exhaustion from the trip. Five days later the patient steps on a nail, however, and does not realize this, until someone informs him that his right foot is bleeding. The

patient goes to an urgent care center to treat his injury and to see a diabetic counselor to determine how best to manage his fluctuating diabetes condition. The urgent care center needs to obtain a copy of the patient's medical history from the past five years including any medications the patient has been taking to manage their diabetes.

Appendix B: Appendix B: Initial Use Cases

B.1 Description of Use Cases

The description of use cases has been performed following the Use Case Framework for Concurrent Use proposed by CEN TC 251, which is also used as basis for describing use cases in other European Projects (e.g., Antilope). Through this template it was possible to collect, beside the general use case information (name, identifier, description, actors….), also the results of a first analysis expressed in term of Strength, Weakness, Opportunity and Threat associated to each use case.

This template will be gradually adopted, leaving to following project steps the responsibility to adequately complete the provisioning of the expected information at a sufficient level of detail. In that sense the cooperation with WP 5, and the collection of their inputs, is considered a fundamental step for completing this task.

This section reports a brief description of the use cases that formed the basis for the consolidated use cases UC-I (patient mediated) and UC-II (provider mediated).

B.1.1 Use Case #1 - Visualization of a Printable Representation of the Patient Summary

Reference #	Description
Use case name	*Visualization of a Printable Representation of the Patient Summary*
Stakeholder story	The Patient prepares a printed copy of his/her translated patient summary (paper and/or pdf) before crossing the border and brings the printed copy with him/her. The translated printed Patient Summary is shown by the patient to the physician or to other professionals that may request it (e.g., customs and border protection officers)
Primary Scenario	- The patient prepares in advance a translated printable representation (paper, pdf) of his/her Patient Summary. - The printed copy is maintained and transported by the patient. - When abroad, the patient hands the printed copy to the receiver (e.g., the foreign physician). - The receiver reads the summary

B.1.2 Use Case #2 - Patient Summary Visualization Using Patient's Device, Patient Mediated

Reference #	Description
Use case name	*Patient Summary Visualization Using Patient's Device, Patient Mediated*
Stakeholder story	The patient obtains access to the Patient Summary from abroad and shows a translated document on own device. This use case may include the use case #1 and implies alternative scenarios
Primary Scenario	- Before leaving, the patient gets a translated copy of his/her Patient Summary. - The document is maintained by the patient. - When abroad, the patient access the translated Patient Summary and show it to the receiver (e.g., the foreign physician) using his/her device. - The receiver reads the summary
Alternative Scenario	- When abroad, the patient accesses his/her Patient Summary and gets a translated copy of it. - The patient show the translated Patient Summary to the receiver (e.g., the foreign physician) using his/her device. - The receiver reads the summary This can be considered an enhancement of the primary scenario, since is reasonable to imagine that if the patient is able to access and obtain a translated copy of the PS from abroad, the same would apply when at home.

B.1.3 Use Case #3 - Patient Summary Visualization Using Provider's device, Patient Mediated

Reference #	Description
Use case name	*Patient Summary Visualization Using Provider's Device, Patient Mediated*
Stakeholder story	While abroad the Patient grants access to his/her translated Patient Summary to the provider, the provider visualizes this document using own device.
Primary Scenario	- The patient prepares a translated (possibly transformed) version of his/her Patient Summary. - The Summary is maintained by the patient (e.g., through a cloud). - When abroad, the patient grants the foreign healthcare professional access to the translated summary. - The foreign healthcare professional access the Patient Summary and visualizes it using own device.

B.1.4 Use Case #4 - Patient Summary Visualization on Provider's Device, Provider Mediated

Reference #	Description
Use case name	*Patient Summary Visualization Using Provider's Device, Provider Mediated*
Stakeholder story	While providing unplanned care, the healthcare professional accesses the Patient Summary via own EHR-S and visualizes the translated document
Primary Scenario	- The patient is receiving unplanned care abroad. - The foreign healthcare professional, after having identified the patient, requests - using own EHR-S - to the patient's Country of Affiliation a Patient Summary of that patient. - The remote country verifies if is entitled to fulfill such a request (correct patient identification, consent provided when applicable). - If it is, the summary is retrieved and returned to the foreign healthcare professional in a format "suitable" for the receiver visualization, translated in the receiver language. - The foreign healthcare professional visualizes the Patient Summary using own EHR-S.
Alternative Scenario	- The patient is receiving unplanned care abroad. - The foreign healthcare professional, after having identified the patient, requests - using own EHR-S - to the patient's Country of Affiliation a Patient Summary of that patient. - The remote country verifies if is entitled to fulfill such a request (correct patient identification, consent provided when applicable). - If it is, the summary is retrieved and returned to the foreign healthcare professional in a "source" format (epSOS Pivot is sent to US; C-CDA ToC in sent to EU) in English. - The foreign healthcare professional visualizes the Patient Summary using own EHR-S. Before being visualized the document is processed (transformed, translate) as needed by the EHR-S.

B.1.5 Use Case #5 - Incorporating the Translated Patient Summary in the PHR

Reference #	Description
Use case name	*Incorporating the Translated Patient Summary in the PHR*
Stakeholder story	Independently on how the transformed and/or translated Patient Summary is obtained by the Patient, the document content (or part of it) is incorporated by the patient within his/her PHR.
Primary Scenario	1. The patient is receiving care abroad. 2. The foreign healthcare professional made available to the patient a transformed and/or translated Patient Summary of that patient. 3. The patient incorporate the content of the obtained document (or part of it) within his/her own PHR.
Alternative Scenario	4. The patient is receiving care abroad.

	5. The foreign healthcare professional made available to the patient a Patient Summary of that patient. 6. The patient uses transformation/translation service before integrating the content of the obtained document (or part of it) within his/her own PHR.

B.1.6 Use Case #6 - Incorporating the Translated Patient Summary in the EHR

Reference #	Description
Use case name	*Incorporating the Translated Patient Summary in the EHR*
Stakeholder story	Independently on how the transformed and/or translated Patient Summary is obtained by the provider, the document content (or part of it) is incorporated by the provider within his/her EHR-S. This use case may extend the UC II- Patient Summary Visualization on Provider's Device, Provider Mediated and Use Case #3 - Patient Summary Visualization Using Provider's device, Patient Mediated.
Primary Scenario	1. A transformed and/or translated Patient Summary is made available to the healthcare professional. 2. The healthcare professional incorporates the content of the obtained document (or part of it) into that patient's EHR.
Alternative Scenario	1. A Patient Summary is made available to the healthcare professional. 2. The healthcare professional makes usage of transformation/translation services before incorporating the content of the obtained document (or part of it) within his/her EHR.

B.2 Correlation Between User Stories and Use Cases

The following table provides an overview of the correlation between the user stories and the use cases identified. Hereafter the legend to be used in the table to follow.

CC (Use Case is compatible with **stated** clinical requirements of User Story)
TC=Use Case is compatible with **stated** technical requirements of User Story
Bad Use Case-User Story Fit Not CC or TC
Good Use Case-User Story Fit CC + TC

User stories have been identified per Sample Name and Author; use cases per Use cases ID.

US-Ref; D2.1 p., Name (Author)	Synopsis	UC-1; Visualization of printable representation of patient summary	UC-2; Patient summary visualization using patient's device; patient-mediated	UC-3 Patient summary visualization using provider's device, patient mediated	UC-4 Patient summary visualization using provider's device; provider mediated;	UC-5 Incorporating the translated patient summary in the PHR	UC-6 Incorporating the translated patient summary in the EHR
		Fit Score=30%	Fit Score=50%	Fit Score=10%	Fit Score=20%	Fit Score=50%	Fit Score=40%
US-A; Susie Sample; (Blechman)	EU-US child traveler's caregiver wants clinical summary on phone	**CC**	CC + TC	**CC**	**CC**	CC + TC	**CC**
US-B; Martha Sample; (Blechman)	US-EU business traveler wants clinical summary on phone	**CC**	CC + TC	**CC**	**CC**	CC + TC	**CC**
US-C; Tom Sample; (Blechman)	US-EU medical tourist wants clinical summary on phone	**CC**	CC + TC	**CC**	**CC**	CC + TC	**CC**
US-D; Paolo Cheruti (Kalra)	US pt in emergency consults EU doc who requests clinical summary from Trillium network	0	0	0	CC + TC	0	CC + TC
US-E; Jean (Garber)	US pt in emergency gives EU doc paper copy of med history in English; doc enters data in Italian in EHR; gives pt summary of encounter results in English	CC + TC	**CC**	**CC**	**CC**	**CC**	CC + TC

US-Ref; D2.1 p., Name (Author)	Synopsis	UC-1; Visualization of printable representation of patient summary	UC-2; Patient summary visualization using patient's device; patient-mediated	UC-3 Patient summary visualization using provider's device, patient mediated	UC-4 Patient summary visualization using provider's device; provider mediated;	UC-5 Incorporating the translated patient summary in the PHR	UC-6 Incorporating the translated patient summary in the EHR
		Fit Score=30%	Fit Score=50%	Fit Score=10%	Fit Score=20%	Fit Score=50%	Fit Score=40%
US-F; Logan (Garber)	US pt in emergency logs in via cell phone to EHR tethered PHR and reports allergies to nurse who enters data in EHR; doc gives pt encounter summary in English	**CC**	CC + TC	**CC**	**CC**	CC + TC	CC + TC
US-G; David (Garber)	US pt in emergency logs into online PHR on hospital computer, downloads CCDA. Nurse imports CCDA to EHR exports encounter results to translation service. Doc gives pt encounter summary in English.	**CC**	**CC**	CC + TC	**CC**	CC + TC	CC + TC
US-H; Trillium Kick off (WP2)	EU-US traveler wants official med justification document	CC + TC	**CC**	**CC**	**CC**	**CC**	**CC**

US-Ref; D2.1 p., Name (Author)	Synopsis	UC-1; Visualization of printable representation of patient summary	UC-2; Patient summary visualization using patient's device; patient-mediated	UC-3 Patient summary visualization using provider's device, patient mediated	UC-4 Patient summary visualization using provider's device; provider mediated;	UC-5 Incorporating the translated patient summary in the PHR	UC-6 Incorporating the translated patient summary in the EHR
		Fit Score=30%	Fit Score=50%	Fit Score=10%	Fit Score=20%	Fit Score=50%	Fit Score=40%
US-I; Trillium Kick off (WP2)	US patient wants summary before travel to EU	CC + TC	CC + TC	**CC**	**CC**	**CC**	**CC**
US-J, Trillium Kick off (WP2)	EU pt admitted to US hospital, provider queries for epSOS PS	0	0	0	CC + TC	**CC**	CC + TC
EU-ES, Spain Min. Health (Iciar)	Planned care of oncological Spanish patient in TX	0	0	0	CC + TC[48]	**CC**	CC + TC[48]

[48] Severe limitation of epSOS PS due to lack of info requested by this user story.

The examination accomplished by the WP2 team, stakeholders and invited experts revealed the following high level use cases objectives:

(1) Support Transatlantic VIEWING of patient data
(2) Support Transatlantic INCORPORATION of patient data
(3) Support VENDORS who want International standards

And recognized objectives 1) and 3) as the primary high level objectives of the Trillium Bridge project and 2 as the holy grail.

In fact, the need was identified to select use cases that are tractable for a small pilot and based on existing epSOS CCD documents as that would increase the understanding of internationalization gaps; and that would drive towards an International Summary Document that can be realm-localized.

Whereas, the incorporation[49] of Patient Summary contents raises several issues[50], impacting on several aspects like: healthcare professionals acceptance, patient identification, quality of data, legal, semantic issues, etc. Based on the above considerations, the team evaluated the first four use cases as those potentially pilotable for this project, even if deeper analysis and evaluation need to be performed by the WP2 team. In any case, all the identified use cases and user stories will be investigated within the WP5 tasks. Therefore, only the first four use cases that consider the visualization of patient summary, were further classified according to the other dimensions, collapsing the "integration-based" use cases in just two different classes depending on weather the content – independently on how the summary is exchanged – is integrated (imported) into the Personal Health Record. The action is performed by the Patient himself. Either way, if the summary (or part of it) is integrated (imported) by the Healthcare Professional within his/her Electronic Healthcare Record System.

[49] , i.e., the capability of getting data from the documents received from external organizations, and importing this information within the receiving EHR-S

[50] Although fundamental for achieving meaningful seamless care/transition, it is indeed a critical process even when limited to data exchange within the same country.

Appendix C: Sample CCD Mapping Spreadsheet for Martha

Level	CCD	conf/card	Data	Comments
Document	patientRole	SHALL [1..1]	see below	
Document	patientRole/id	SHALL [1..1]	<!-- Generated ID using HL7 example OID. --> <id extension="998991" root="2.16.840.1.113883.19.5.99999.2"/> <!-- Generated Social Security Number using the actual SSN OID. --> <id extension="111-00-2330" root="2.16.840.1.113883.4.1"/>	Generated - not in use case
Document	patientRole/addr	SHALL [1..*]	<addr use="HP"> <streetAddressLine>1357 Amber Drive</streetAddressLine> <city>Beaverton</city> <state>OR</state> <postalCode>97867</postalCode> <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 --> <country>US</country> </addr>	Generated - not in use case
Document	patientRole/telecom	SHALL [1..*]	<!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 --> <telecom value="tel:(555)555-5555" use="HP"/>	Generated - not in use case
Document	patientRole/telecom/@use	SHALL [1..1]	see above	Generated - not in use case
Document	patientRole/patient	SHALL [1..1]	see below	
Document	patientRole/patient/name	SHALL [1..1]	<!-- L is "Legal" from HL7 EntityNameUse 2.16.840.1.113883.5.45 --> <name use="L"> <given>Martha</given> <family>XXXXX</family> </name>	
Document	patientRole/patient/name/family	SHALL [1..1]	see above	
Document	patientRole/patient/name/given	SHALL [1..*]	see above	

Document	patientRole/patient/administrativeGenderCode	SHALL [1..1]	<administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1" displayName="Female" />	
Document	patientRole/patient/birthTime	SHALL [1..1]	<birthTime value="19680607"/>	Generated - not in use case (other than year from age)
Document	patientRole/patient/maritalStatusCode	SHOULD [0..1]		don't have this information
Document	patientRole/patient/languageCommunication	SHOULD [0..*]		don't have this information
Document	patientRole/patient/providerOrganization	MAY [0..1]		Assuming this is Atrius Health which is not mentioned in the primary (patient mediated) scenario
Document	author	SHALL [1..*]	see below	
Document	author/time	SHALL [1..1]	<time value="20130329224411+0500"/>	Generated - not in use case
Document	author/assignedAuthor	SHALL [1..1]	see below	Generated - not in use case
Document	author/assignedAuthor/id	SHALL[1..1]	<id extension="99999999" root="2.16.840.1.113883.4.6"/>	Generated - not in use case
Document	author/assignedAuthor/id/@root="2.16.840.1.113883.4.6" (National Provider Identifier)	SHALL[1..1]	see above	Generated - not in use case
Document	author/assignedAuthor/code	SHOULD [0..1]	<code code="261QX0200X" codeSystem="2.16.840.1.113883.6.101" displayName="Oncology"/>	Generated - not in use case

Document	author/assignedAuthor/addr	SHALL[1..*]	<addr> <streetAddressLine>1002 Healthcare Drive </streetAddressLine> <city>Portland</city> <state>OR</state> <postalCode>99123</postalCode> <country>US</country> </addr>	Generated - not in use case
Document	author/assignedAuthor/telecom	SHALL[1..*]	<telecom use="WP" value="tel:555-555-1002"/>	Generated - not in use case
Document	author/assignedAuthor/assignedPerson	SHOULD [0..1]	<assignedPerson> <name> <given>Henry</given> <family>Oncologist</family> </name> </assignedPerson>	There SHALL be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice Generated - not in use case
Document	custodian	SHALL [1..1]	see below	Assuming this is Atrius Health which is not mentioned in the primary (patient mediated) scenario
Document	custodian/assignedCustodian	SHALL [1..1]	see below	
Document	custodian/assignedCustodian/representedCustodianOrganization	SHALL [1..1]	see below	
Document	custodian/assignedCustodian/representedCustodianOrganization/id	SHALL [1..*]	<id extension="99999999" root="2.16.840.1.113883.4.6"/>	Generated - not in use case

Document	custodian/assignedCustodian/representedCustodianOrganization/name	SHALL [1..1]	<name>Atrius Health</name>	In alternative use case
Document	custodian/assignedCustodian/representedCustodianOrganization/telecom	SHALL [1..1]	<telecom value="tel: 555-555-1002" use="WP"/>	Generated - not in use case
Document	custodian/assignedCustodian/representedCustodianOrganization/addr	SHALL [1..*]	<addr use="WP"> <streetAddressLine>1002 Healthcare Drive </streetAddressLine> <city>Portland</city> <state>OR</state> <postalCode>99123</postalCode> <country>US</country> </addr>	Generated - not in use case
Document	legalAuthenticator	SHOULD [0..1]	see below	
Document	legalAuthenticator/time	*SHALL [1..1]*	<time value="20130227130000+0500"/>	element only required if legalAuthenticator is present
Document	legalAuthenticator/signatureCode/@code="S"	*SHALL [1..1]*	<signatureCode code="S"/>	element only required if legalAuthenticator is present Generated - not in use case
Document	legalAuthenticator/assignedEntity	*SHALL [1..1]*	see below	element only required if legalAuthenticator is present
Document	legalAuthenticator/assignedEntity/id	*SHALL [1..*]*	<id extension="99999999" root="2.16.840.1.113883.4.6"/>	element only required if legalAuthenticator is present Generated - not in use case

Document	legalAuthenticator/ assignedEntity/addr	*SHALL [1..*]*	<addr> <streetAddressLine>1002 Healthcare Drive </streetAddressLine> <city>Portland</city> <state>OR</state> <postalCode>99123</postalCode> <country>US</country> </addr>	element only required if legalAuthenticator is present Generated - not in use case
Document	legalAuthenticator/ assignedEntity/telecom	*SHALL [1..*]*	<telecom use="WP" value="tel:555-555-1002"/>	element only required if legalAuthenticator is present Generated - not in use case
Document	legalAuthenticator/ assignedEntity/telecom/@use	*SHALL [1..1]*	see above	element only required if legalAuthenticator is present Generated - not in use case
Document	legalAuthenticator/ assignedEntity/assignedPerson	*SHALL [1..1]*	<assignedPerson> <name> <given>Henry</given> <family>Oncologist</family> </name> </assignedPerson>	element only required if legalAuthenticator is present Generated - not in use case
Document	legalAuthenticator/ assignedEntity/assignedPerson/name	*SHALL [1..*]*	see above	element only required if legalAuthenticator is present Generated - not in use case
Document	legalAuthenticator/ assignedEntity/assignedPerson/name/family	*SHALL [1..1]*	see above	element only required if legalAuthenticator is present Generated - not in use case

Document	legalAuthenticator/assignedEntity/assignedPerson/name/given	*SHALL [1..*]*	see above	element only required if legalAuthenticator is present Generated - not in use case
Document	documentationOf/serviceEvent	SHALL [1..1]		
Document	documentationOf/serviceEvent/effectiveTime	SHALL [1..1]		
Document	documentationOf/serviceEvent/effectiveTime/low	SHALL [1..1]		
Document	documentationOf/serviceEvent/effectiveTime/high	SHALL [1..1]		
Document	documentationOf/serviceEvent/performer	SHOULD [0..1]		
Document	documentationOf/serviceEvent/performer/assignedEntity	SHALL [1..1]		
Section	Allergies Section (entries required)	SHALL [1..1]		**Penicillin**
Entry	Allergies Section/Allergy Problem Act	SHALL [1..*]		
Entry	Allergies Section/Allergy Problem Act/Allergy - Intolerance Observation	SHALL [1..1]		

Entry	Allergy - Intolerance Observation/effectiveTime/low	SHALL [1..1]	<effectiveTime> <low value="20070501" /> </effectiveTime>	The time the allergy began Generated - not in use case
Entry	Allergy - Intolerance Observation/value	SHALL [1..1]	<value xsi:type="CD" code="416098002" displayName="Drug allergy" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"> <originalText> <reference value="#type1" /> </originalText> </value>	Allergy - Intolerance type
Entry	Allergy - Intolerance Observation/participant	SHOULD [0..1]	<participant typeCode="CSM"> <participantRole classCode="MANU"> <playingEntity classCode="MMAT"> <code code="314422" displayName="ALLERGENIC EXTRACT, PENICILLIN" codeSystem="2.16.840.1.113883.6.88" codeSystemName="RxNorm"> <originalText> <reference value="#agent1" /> </originalText> </code> </playingEntity> </participantRole> </participant>	This particpant represents the causative agent

Entry	Allergy - Intolerance Observation/Allergy Status Observation	MAY [0..1]	<observation classCode="OBS" moodCode="EVN"> <templateId root="2.16.840.1.113883.10.20.22.4.28" /> <code code="33999-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Status" /> <statusCode code="completed" /> <value xsi:type="CE" code="55561003" codeSystem="2.16.840.1.113883.6.96" displayName="Active" /> </observation>	Represents whether or not the allergy is active
Entry	Allergy - Intolerance Observation/Reaction Observation	SHOULD [0..*]	see below	Represents the reaction Generated - not in use case
Entry	Allergy - Intolerance Observation/Reaction Observation/value	*SHALL [1..1]*	<value xsi:type="CD" code="422587007" codeSystem="2.16.840.1.113883.6.96" displayName="Nausea" />	Generated - not in use case
Entry	Allergy - Intolerance Observation/Reaction Observation/Severity Observation	*SHOULD [0..1]*	<observation classCode="OBS" moodCode="EVN"> <templateId root="2.16.840.1.113883.10.20.22.4.8" /> <code code="SEV" displayName="Severity Observation" codeSystem="2.16.840.1.113883.5.4" codeSystemName="ActCode" /> <text> <reference value="#reactionseverity1" /> </text> <statusCode code="completed" /> <value xsi:type="CD" code="371924009" displayName="Moderate to severe" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" /> <interpretationCode code="S" displayName="Suceptible" codeSystem="2.16.840.1.113883.1.11.78" codeSystemName="Observation Interpretation" /> </observation>	Represents the severity of the reaction Generated - not in use case

Entry	Allergy - Intolerance Observation/Allergy - Intolerance Observation/Severity Observation	*SHOULD [0..1]*	<observation classCode="OBS" moodCode="EVN"> <templateId root="2.16.840.1.113883.10.20.22.4.8" /> <code code="SEV" displayName="Severity Observation" codeSystem="2.16.840.1.113883.5.4" codeSystemName="ActCode" /> <text> <reference value="#overallseverity1" /> </text> <statusCode code="completed" /> <value xsi:type="CD" code="371924009" displayName="Moderate to severe" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" /> <interpretationCode code="N" displayName="Normal" codeSystem="2.16.840.1.113883.1.11.78" codeSystemName="Observation Interpretation" /> </observation>	Represents the overall severity of allergy Generated - not in use case
Section	Medications Section (entries required)	SHALL [1..1]	see below	**Anastrozole 1 mg. once daily; Black Cohosh Extract herbal supplement**
Entry	Medications Section/Medication Activity	SHALL [1..*]	see below	
Entry	Medication Activity/effectiveTime	SHALL [1..1]	<effectiveTime xsi:type="IVL_TS"> <low value="20130103" /> <high nullFlavor="NA" /> </effectiveTime>	Represents medication start and stop dates Generated - not in use case
Entry	Medication Activity/effectiveTime/@xsi:type="PIVL_TS"	SHOULD [0..1]	<effectiveTime xsi:type="PIVL_TS" operator="A"> <period value="1" unit="d" /> </effectiveTime>	Represents timing such as dose frequency
Entry	Medicatoin Activity/doseQuantity	SHOULD [0..1]	<doseQuantity value="1" unit="mg" />	

Entry	Medicatoin Activity/routeCode	MAY [0..1]	<routeCode code="C38288" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="ORAL" />	
Entry	Medication Activity/Medication Information	SHALL [1..1]	see below	
Entry	Medication Activity/Medication Information/manufacturedMaterial	SHALL[1..1]	<consumable> <manufacturedProduct classCode="MANU"> <!-- Medication information --> <templateId root="2.16.840.1.113883.10.20.22.4.23" /> <id root="2a620155-9d11-439e-92b3-5d9815ff4ee8" /> <manufacturedMaterial> <code code="84857" codeSystem="2.16.840.1.113883.6.88" codeSystemName="RxNorm" displayName="Anastrozole"> <originalText> <reference value="#MedSec_1" /> </originalText> </code> </manufacturedMaterial> </manufacturedProduct> </consumable>	
Section	Problem Section (entries required)	SHALL [1..1]		**Breast cancer Stage II with no evidence of recurrence following treatment; hot flashes**
Entry	Problem Section/Problem Concern Act (Condition)	SHALL [1..*]		**Breast cancer Stage II with no evidence of recurrence following treatment**
Entry	Problem Concern Act/statusCode	SHALL [1..*]	<statusCode code="completed" />	

Entry	Problem Concern Act/effectiveTime	SHALL [1..1]	<effectiveTime> <low value="20110103" /> <high value="20130703" /> </effectiveTime>	Records the starting and ending time during which the concern was active on the Problem List Generated - not in use case
Entry	Problem Concern Act/Problem Observation	SHALL [1..1]		
Entry	Problem Concern Act/Problem Observation/code	SHALL [1..1]	<code code="55607006" codeSystem="2.16.840.1.113883.6.96" displayName="Problem" />	Represents problem type
Entry	Problem Concern Act/Problem Observation/text	SHOULD [0..1]	<text> <reference value="#problem1" /> </text>	
Entry	Problem Concern Act/Problem Observation/effectiveTime	SHOULD [0..1]	<effectiveTime> <low value="20110103" /> <high value="20130703" /> </effectiveTime>	Generated - not in use case
Entry	Problem Concern Act/Problem Observation/effectiveTime/low	*SHALL [1..1]*	see above	Represents onset date
Entry	Problem Concern Act/Problem Observation/effectiveTime/high	*SHOULD [0..1]*	see above	Represents resolution date If the problem is known to be resolved, but the date of resolution is not known, then the high element SHALL be present, and the nullFlavor attribute SHALL be set to 'UNK'. Therefore, the existence

				of an high element within a problem does indicate that the problem has been resolved
Entry	Problem Concern Act/Problem Observation/value	SHALL [1..1]	<value xsi:type="CD" code="254837009" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Breast cancer"> <qualifier> <value code="258219007" codeSystem="2.16.840.1.113883.19.6.96" codeSystemName="SNOMED CT" displayName="Stage 2" /> </qualifier> </value>	Represents the problem
Entry	Problem Concern Act/Problem Observation/Problem Status	MAY [0..1]	<observation classCode="OBS" moodCode="EVN"> <templateId root="2.16.840.1.113883.10.20.22.4.6" /> <id root="ab1791b0-5c71-11db-b0de-0800200c9a66" /> <code code="33999-4" codeSystem="2.16.840.1.113883.6.1" displayName="Status" /> <text> <reference value="#stat1" /> </text> <statusCode code="completed" /> <value xsi:type="CD" code="413322009" codeSystem="2.16.840.1.113883.6.96" displayName="Resolved" /> </observation>	Represents the status of the problem
Entry	Problem Section/Problem Concern Act (Condition)	SHALL [1..*]		**Hot flashes**

Entry	Problem Concern Act/statusCode	SHALL [1..*]	<statusCode code="completed" />	
Entry	Problem Concern Act/effectiveTime	SHALL [1..1]	<effectiveTime> <low value="20120103" /> </effectiveTime>	Records the starting and ending time during which the concern was active on the Problem List Generated - not in use case
Entry	Problem Concern Act/Problem Observation	SHALL [1..1]	see below	
Entry	Problem Concern Act/Problem Observation/code	SHALL [1..1]	<code code="55607006" codeSystem="2.16.840.1.113883.6.96" displayName="Problem" />	Represents problem type
Entry	Problem Concern Act/Problem Observation/text	SHOULD [0..1]	<text> <reference value="#problem2" /> </text>	
Entry	Problem Concern Act/Problem Observation/effectiveTime	SHOULD [0..1]	<effectiveTime> <low value="20120103" /> </effectiveTime>	Generated - not in use case
Entry	Problem Concern Act/Problem Observation/effectiveTime/low	*SHALL [1..1]*	see above	Represents onset date
Entry	Problem Concern Act/Problem Observation/effectiveTime/high	*SHOULD [0..1]*	n/a	Represents resolution date If the problem is known to be resolved, but the date of resolution is not known, then the high element SHALL be present, and the nullFlavor attribute

				SHALL be set to 'UNK'. Therefore, the existence of an high element within a problem does indicate that the problem has been resolved
Entry	Problem Concern Act/Problem Observation/value	SHALL [1..1]	<value xsi:type="CD" code="55607006" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Hot flashes" />	Represents the problem
Entry	Problem Concern Act/Problem Observation/Problem Status	MAY [0..1]	<observation classCode="OBS" moodCode="EVN"> <templateId root="2.16.840.1.113883.10.20.22.4.6" /> <id root="ab1791b0-5c71-11db-b0de-0800200c9a66" /> <code code="33999-4" codeSystem="2.16.840.1.113883.6.1" displayName="Status" /> <text> <reference value="#stat2" /> </text> <statusCode code="completed" /> <value xsi:type="CD" code="55561003" codeSystem="2.16.840.1.113883.6.96" displayName="Active" /> </observation>	Represents the status of the problem

Section	Results Section (entries required)	SHALL [1..1]	<section nullFlavor="NI"> <!-- conforms to Results section with entries optional --> <templateId root="2.16.840.1.113883.10.20.22.2.3" /> <!-- Results section with entries required --> <templateId root="2.16.840.1.113883.10.20.22.2.3.1" /> <code code="30954-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="RESULTS" /> <title>Results</title> <text>No information</text> </section>	There are no results in the use case
Section	Procedures Section (entries required)	SHOULD [0..1]		There are no results in the use case but only a SHOULD section.
Section	Plan of Care Section	MAY [0..1]		**Continue hormone medication with Anastrozole for total of 5 years; monitor for potential breast cancer recurrence.**

Entry	Plan of Care Section/Plan of Care Activity Substance Administration	MAY [0..*]	<substanceAdministration classCode="SBADM" moodCode="RQO"> <templateId root="2.16.840.1.113883.10.20.22.4.42" /> <id root="9a6d1bac-17d3-4195-89a4-1121bc809b4a" /> <statusCode code="active" /> <effectiveTime xsi:type="IVL_TS"> <low value="20130103" /> <high value="20180102" /> </effectiveTime> <effectiveTime xsi:type="PIVL_TS" operator="A"> <period value="1" unit="d" /> </effectiveTime> <routeCode code="C38288" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="ORAL" /> <doseQuantity value="1" unit="mg" /> <consumable> <manufacturedProduct classCode="MANU"> <!-- Medication information --> <templateId root="2.16.840.1.113883.10.20.22.4.23" /> <id root="2a620155-9d11-439e-92b3-5d9815ff4ee8" /> <manufacturedMaterial> <code code="84857" codeSystem="2.16.840.1.113883.6.88" codeSystemName="RxNorm" displayName="Anastrozole"> </code> </manufacturedMaterial> </manufacturedProduct> </consumable> </substanceAdministration>	

Entry	Plan of Care Section/Plan of Care Activity Act	MAY [0..*]	<act classCode="ACT" moodCode="RQO"> <!-- Plan of care activity act --> <templateId root="2.16.840.1.113883.10.20.22.4.44" /> <id root="9a6d1bac-17d3-4195-89a4-1121bc809b4a" /> <code nullFlavor="OTH"> <originalText>Monitor for potential breast cancer recurrence.</originalText> </code> <statusCode code="active" /> <effectiveTime> <low value="20130512" /> </effectiveTime> </act>	

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Appendix D: epSOS and Meaningful Use Data Sets and Code Systems

epSOS Data Sets and Code Systems

The following table summarizes the data set defined in the epSOS deliverable 3.2 table for the Patient Summary. A comparison is performed between the value sets and their respective code systems in section 5

PATIENT DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**DEFINITION AND COMMENTS**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**MANDATORY Yes/No**
Identification [51]	National Health Care patient ID	National Health Care patient ID	Country ID, unique for the patient in that country. Example: ID for United Kingdom patient	Basic	Yes
Personal information	Full Name	Given name	The Name of the patient (Example: John). This field can contain more than one element	Basic	Yes
		Family name/Surname	This field can contain more than one element. Example: Español Smith	Basic	Yes
	Date of Birth	Date of Birth	This field may contain only the year[52] if day and month are not available. E.g.: 01/01/2009	Basic	Yes
	Gender	Gender Code	It must contained a recognized valid value for this field	Basic	Pending decision by WP3.6 (in some countries 'gender' is needed for univocal identification of the patient)
Contact information	Address[53]	Street	Example: Oxford	Ext	No
		Number of Street	Example: 221	Ext	No
		City	Example: London	Ext	No
		Post Code	Example: W1W 8LG	Ext	No
		State or Province	Example: London	Ext	No
		Country	Example: UK	Ext	No
	Telephone No	Telephone No	Example: +45 20 7025 6161	Ext	No
	E-mail	E-mail	Example: jens@hotmail.com	Ext	No
	Preferred HCP/Legal organization to contact[54]	Name of the HCP/Legal organization	Name of the HCP/name of the legal organization. If it is a HCP, the structure of the name will be the same as described in 'Full name' (Given name, family name/surname)	Basic	No
		Telephone No	Example: +45 20 7025 6161	Basic	No
		E-mail	E mail of the HCP/legal organization	Basic	No
	Contact Person/ legal guardian (if available)	Role of that person	Legal guardian or Contact person	Ext	NO
		Given name	The Name of the Contact Person/guardian (example: Peter. This field can contain more than one element)	Ext	No

		Family name/Surname	This field can contain more than one element. Example: Español Smith	Ext	No
		Telephone No	Example: +45 20 7025 6161	Ext	No
		E-mail		Ext	No
Insurance information	Insurance Number	Insurance Number	Example: QQ 12 34 56 A	Pending decision by WP3.6 of including it in Basic (in some countries 'Insurance Number' is needed for univocal identification of the patient).	Pending decision by WP3.6 of including it in Basic (in some countries 'Insurance Number' is needed for univocal identification of the patient).

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PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**MANDATORY Yes/No**
Alerts	Allergies and intolerances	Allergy description	Description of the clinical manifestation of the allergy reaction. Example: Anaphylactic shock, angioedema (the clinical manifestation also gives information about the severity of the observed reaction)	Basic	No
		Allergy description id code	Normalized identifier	Basic	No
		Onset Date	Date of the observation of the reaction	Ext	No
		Agent	Describes the agent (drug, food, chemical agent, etc.) that is responsible for the adverse reaction	Basic	No
		Agent id code	Normalized identifier	Basic	No

[51] Data set that enable the univocal identification of the patient. It will be defined in WP3.6 'Identity Management'. The variable 'Birth place' (Country of birth and place of birth) needs to be evaluated by WP3.6 as in some countries it is needed for univocal identification of the patient.

[52] To be aligned with prescription minimum dataset (in D3.1.2 'Final definition of functional service requirements-ePrescription')

[53] Will be adapted due to the variability of the countries.

[54] A foreign HCP may need a contact (HCP/legal organization) who knows the patient

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**MANDATORY Yes/No**
History of past illness	Vaccinations	Vaccinations	Contains each disease against which immunization was given	Ext	No
		Brand name		Ext	No
		Vaccinations id code	Normalized identifier	Ext	No
		Vaccination Date	The date the immunization was received	Ext	No
	List of Resolved, Closed or Inactive problems	Problem Description	Problems or diagnosis not included under the definition of 'Current problems or diagnosis'. Example: hepatic cyst (the patient has been treated with an hepatic cystectomy that solved the problem and therefore it´s a closed problem)	Ext	No
		Problem Id (code)	Normalized identifier	Ext	No
		On set time	Date of problem onset	Ext	No
		End date	Problem resolution date	Ext	No
		Resolution Circumstances	Describes the reason by which the problem changed the status from current to inactive (e.g. surgical procedure, medical treatment, etc.). This field includes 'free text' if the resolution circumstances are not already included in other fields. Example: It can happen that this field is already included in other like Surgical Procedure, medical device etc., e.g.: hepatic cystectomy (this will be the 'Resolution Circumstances' for the problem 'hepatic cyst' and will be included in surgical procedures)	Ext	No
	Surgical Procedures prior to the past six months	Procedure description	Describes the type of procedure	Ext	No
		Procedure Id (code)	Normalized identifier	Ext	No
		Procedure date	Date when procedure was performed	Ext	No
Medical problems	List of Current Problems/Diagnosis.	Problem/diagnosis description	Problems/diagnosis that fit under these conditions: conditions that may have a chronic or relapsing course (e.g.: exacerbations of asthma, irritable bowel syndrome), conditions for which the patient receives repeat medications (e.g.: diabetes mellitus, hypertension) and conditions that are persistent and serious contraindications for classes of	Basic	No

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**MANDATORY Yes/No**
			medication (e.g.: dyspepsia, migraine and asthma)		
		Problem Id (code)	Normalized identifier	Basic	No
		Onset time	Date of problem onset	Basic	No
	Medical Devices and implants	Device and implant Description	Describes the patient's implanted and external medical devices and equipment that their health status depends on. Includes devices as cardiac pacemakers, implantable defibrillator, prosthesis, ferromagnetic bone implants etc. that are important to know by the HCP	Basic	No
		Device Id code	Normalized identifier	Basic	No
		Implant date		Basic	No
	Major Surgical Procedures in the past 6 months[55]	Procedure description	Describes the type of procedure	Basic	No
		Procedure Id (code)	Normalized identifier	Basic	No
		Procedure date	Date when procedure was performed	Basic	No
	Treatment Recommendations	Recommendations Description	Therapeutic recommendations that do not include drugs (diet, physical exercise constraints, etc.)	Ext	No
		Recommendation Id (code)	Normalized identifier	Ext	No
	Autonomy/Invalidity	Description	Need of the patient to be continuously assisted by third parties. Invalidity status may influence decisions about how to administer treatments	Ext	No
		Invalidity Id code	Normalized invalidity ID (if any, otherwise free text)	Ext	No
Medication Summary	List of current medicines. (All prescribed medicine whose period of time indicated for the treatment has not yet	Active ingredient	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: Paracetamol	Basic	No
		Active ingredient id code	Code that identifies the Active ingredient	Basic	No
		Strength	The content of the active ingredient expressed quantitatively per dosage unit, per unit of volume or per unit of weight,	Basic	No

[55] As there is subjectivity in the term 'relevant', the date will be used as the limit to include procedures.

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**MANDATORY Yes/No**
	expired whether it has been dispensed or not.).		according to the pharmaceutical dose form. Example: 500 mg per tablet		
		Pharmaceutical dose form	It is the form in which a pharmaceutical product is presented in the medicinal product package (e.g. tablets, syrup)	Ext	No
		Number of units per intake[56]	The number of units per intake that the patient is taking. Example: 1 tablet	Basic	No
		Frequency of intakes**Error! Bookmark not defined.**	Frequency of intakes (per hours/day/month/ week..). Example: each 24 hours	Basic	No
		Duration of treatment**Error! Bookmark not defined.**	Example: during 14 days	Basic	No
		Date of onset of treatment	Date when patient needs to start taking the medicine prescribed	Basic	No
Social History	Social History Observations	Social History Observations related to: smoke, alcohol and diet.	Example: cigarette smoker, alcohol consumption...	Ext	No
		Reference date range	Example: from 1974 thru 2004	Ext	No
Pregnancy History	Expected date of delivery	Expected date of delivery	Date in which the woman is due to give birth. Year, day and month are required. E.g.: 01/01/2010	Ext	No
Physical findings	Vital Signs Observations	Blood pressure	One value of blood pressure which includes: systolic Blood Pressure and Diastolic Blood pressure	Ext	No
		Date when blood pressure was measured	Date when blood pressure was measured	Ext	No
Diagnostic tests	Blood group	Result of blood group	Result from the blood group test made to the patient	Ext	No
		Date	Date in which the blood group test was done. This field may contain only the year if day and month are not available. E.g.: 01/01/2009	Ext	No

[56] Posology has been defined from the functional point of view as containing these three components: number of units per intake, frequency of intakes and duration of treatment:(example: 1 unit/intake every 24 hours for a duration of 14 days

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1 The following table provides a list of the Code System and Value Set of interest for the scope of this
2 deliverable as derived from the current adopted epSOS MVC version 1.8[57].

Value Set Name	Code System	Version	Coded field using value set	Description
epSOSActiveIngredient	Anatomical Therapeutic Chemical	January 2010	Active Ingredient and Allergy Agent	The Value Set is used as a mandatory code for the Active Ingredient of medications in the Medications Summary as well as the prescription Sections. Also used to code allergy agents in the Allergies and Other Adverse Reactions Section of the patient Summary.
epSOSAdverseEventType	Snomed CT	July 2009	Allergy Display Name	The value set is used to code the patient's kind of adverse reactions against substance, food or drugs.
epSOSAllergenNoDrugs	Snomed CT	July 2010	Allergy Agent	The Value Set is used to code the allergenic agents (apart from drugs) against which the patient has developed an adverse reaction.
epSOSBloodGroup	Snomed CT	July 2011	Result of blood group	The Value Set is used to code the value of patient's blood group + Rh
epSOSBloodPressure	LOINC	June 2010	Blood pressure	The Value Set is used for the observations of Blood Pressure recorded in the section for Vital Signs Observations in the Patient Summary. It codes what type of pressure (diastolic, systolic) is measured.
epSOSCodeNoMedication	Snomed CT	July 2009	Current Medication	The Value Set is used to indicate, when a patient has no medication, if it is because the treatment is unknown, or if no medication was prescribed, or if the patient doesn't take medication on his own (self-medication)
epSOSCodeProb	Snomed CT	July 2009	This is used in the problem entry.	The Value Set is used as an optional description of a problem in the patient Summary. It gives an information on the circumstances under which the problem was defined/discovered.
epSOSConfidentiality	Confidentiality	913-20091020	Confidentiality code	The Value Set is used for encoding the confidentiality level of the entire CDA. This Value Set encodes the level of access with regards to the content of the Value Set – for example N concerns all the medical team, R is restricted for specialist that take care of the patient in certain circumstances, and VIP would be for the persons that need the Privacy Officer present or other special consideration (for example a celebrity hospitalized who needs their records protected)
epSOSCountry	ISO 3166-1	2001	Country	The Value Set is used to identify the nationality of all persons and organizations.

[57] This table is valid also for the incoming MVC version 1.9

Value Set Name	Code System	Version	Coded field using value set	Description
epSOSDocumentCode	LOINC	June 2010	ClinicalDocument.code	Defines to which category the document belongs to : summary, prescription, or dispensation.
epSOSDoseForm	EDQM	2010	1)Strength of the medicinal product as in Country A 2)Pharmaceutical dose form 3)Number of units per intake	The Value Set is used for the pharmaceutical dose form. Required for ePrescriptions and optional for medication summaries
epSOSAdministrativeGender	AdministrativeGender	913-20091020	Gender	The gender of a person used for administrative purposes (as opposed to clinical gender)
epSOSHealthcareProfessionalRoles	ISCO	2008	author	The Value Set is used to code the HCP's profession (functional code). It is mandatory for each Prescriber (author) in the prescription message and optional for all other Health Care Professionals
epSOSIllnessesandDisorders	ICD-10	2008	1)History of past illness 2)Problem Description 3)Problem/diagnosis description	The Value Set is used to code illnesses, syndromes or symptoms the patient suffered in the past or is currently suffering.
epSOSLanguage	ISO 639-1	2001	languageCode	The Value Set is used to identify the language the document will be written with, as well as the patient's preferred language.
epSOSMedicalDevices	Snomed CT	July 2009	Device and implant Description	The Value Set is used for describing the patients Medical Devices and implants in the Patient Summary
epSOSNullFavor	NullFavor	913-20091020	All the data element (coded fields) which are not mandatory in the patient summary	The Value Set is used for describing why non mandatory elements throughout the entire document are not specified.
epSOSPackage	EDQM	2010	Medicinal product package	The Value Set is used to encode the Medicinal product package. Required for prescriptions and optional for medication summaries
epSOSPersonalRelationship	RoleCode	913-20091020	1) Guardian 2)Patient contact	The Value Set is used (optionally) to code the type of contact relationship between a person and the patient.
epSOSPregnancyInformation	LOINC	June 2010	Pregnancy History	The Value Set is used to determine the patient's delivery date estimation
epSOSProcedures	Snomed CT	July 2009	1)Surgical Procedures prior to the past six months 2)Procedure description	The Value Set is used to encode procedures in the section "Surgical Procedures prior past six months" in the patient Summary
epSOSReactionAllergy	Snomed CT	July 2009	reaction allergy	The Value Set is used to code the clinical manifestations of allergy developed by patient in the "Allergies and Other Adverse Reactions" section of the patient Summary (along with epSOSActiveIngredient)
epSOSResolutionOutcome	Snomed CT	July 2009	Resolution Circumstances	The Value Set is used to describe the clinical status of a problem outcome.
epSOSRoleClass	RoleClass	913-20091020	Type code of Contact	The Value Set is used to make the distinction between an emergency contact and the next of kin for a patient.

Value Set Name	Code System	Version	Coded field using value set	Description
epSOSRouteofAdministration	EDQM	2010	Route of Administration	The Value Set is used to encode the (optional) "Route of Administration" for a given medication in the Prescription section and the Medication Summary.
epSOSSections	LOINC	June 2010	Name of the sections used in the epSOS documents.	The Value Set is used for naming the sections used by the three CDA-documents.
epSOSSeverity	Snomed CT	July 2009	Allergy Display Name	The Value Set is used for all Problems and Allergies in the Patient Summary to indicate the severity of the problem (or Allergy)
epSOSSocialHistory	Snomed CT	July 2009	Social History Observations related to: smoke, alcohol and diet.	The Value Set is used to code the different elements of the patient's social history
epSOSstatusCode	Snomed CT	July 2009	Used in certain entries - see description	The Value Set is used to encode the clinical status of both problems and concerns within the Patient Summary document
epSOSTelecommAddress	AddressUse	913-20091020	Part of the description of the telecommunication description.	The Value Set is used (optionally) to code the usage of a phone number, email and all telecommunications. Can be used for all phone numbers mentioned in the three CDA-documents.
epSOSTimingEvent	TimingEvent	913-20091020	Instructions for Dispenser/Patient (Posology)	The Value Set is used (optionally) to encode the frequency of intake of medications in the Medication Summary as well as the Prescription.
epSOSUnits	UCUM Unified Code for Units of Measure	July 2009	1)Frequency of intakes 2)Duration of treatment	The Value Set is used to provide values with an international unit codification to quantify it.
epSOSUnknownInformation	Snomed CT	July 2009	Allergies, Problems, Medications, …	The Value Set is used when information about a problem or allergy is unknown or where there are no problems or allergies. This element is actually used to confirm explicitly the absence of information.
epSOSVaccine	Snomed CT	July 2009	Vaccinations	The Value Set is used to identify the patient's vaccinations in the Patient Summary

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Meaningful Use 2 Data Sets and Coding Systems

The table below lists the value sets that are present in the CCD document. A comparison is performed between the value sets and their respective code systems in section 5

CCD Section	Value Set Name*	Description	Code System Name on which the Value Set is based	Code System OID on which the Value Set is based
Allergies	Allergy/Adverse Event Type	This describes the type of product and intolerance suffered by the patient.	SNOMED CT	2.16.840.1.113883.6.96
	Medication Clinical Drug Name Value Set	Shall contain RxNorm normal forms for concepts type of "Ingredient Name" or Generic Packs. The ingredient name concepts can be found in the RxNORM file RXCONSO.RRF selecting all terms where SAB=RXNORM (selecting the normal forms), and TTY=SCD (selecting the ingredient names) or TTY=GPCK (selecting the generic packs)	RxNorm	2.16.840.1.113883.6.88
	MoodCodeEvnInt		ActMood	2.16.840.1.113883.5.1001
Immunizations	Vaccine Administered Value Set		CDC Vaccine Code (CVX)	2.16.840.1.113883.12.292
	No Immunization Reason Value Set		ActReason	2.16.840.1.113883.5.8
	Patient Education	Limited to terms descending from the Education (409073007) hierarchy.	SNOMED CT	2.16.840.1.113883.6.96
	Medication Fill Status		ActStatus	2.16.840.1.113883.5.14

	Medication Clinical Drug Name Value Set	Shall contain RxNorm normal forms for concepts type of “Ingredient Name” or Generic Packs. The ingredient name concepts can be found in the RxNORM file RXCONSO.RRF selecting all terms where SAB=RXNORM (selecting the normal forms), and TTY=SCD (selecting the ingredient names) or TTY=GPCK (selecting the generic packs)	RxNorm	2.16.840.1.113883.6.88
	UnitsOfMeasureCaseSensitive		UCUM	2.16.840.1.113883.6.8
	Body Site	Contains values descending from the SNOMED CT® Anatomical Structure (91723000) hierarchy or Acquired body structure (body structure) (280115004) or Anatomical site notations for tumor staging (body structure) (258331007) or Body structure, altered from its original anatomical structure (morphologic abnormality) (118956008) or Physical anatomical entity (body structure) (91722005) This indicates the anatomical site	SNOMED CT	2.16.840.1.113883.6.96
	MoodCodeEvnInt		ActMood	2.16.840.1.113883.5.1001
Problem	ProblemAct statusCode	A ValueSet of HL7 actStatus codes for use on the concern act	ActStatus	2.16.840.1.113883.5.14
	Problem Status	A value set of SNOMEDT-CT codes reflecting state of existence.	SNOMED CT	2.16.840.1.113883.6.96
	Problem Type	This value set indicates the level of medical judgment used to determine the existence of a problem.	SNOMED CT	2.16.840.1.113883.6.96

	Problem	A value set of SNOMED-CT codes limited to terms descending from the Clinical Findings (404684003) or Situation with Explicit Context (243796009) hierarchies.	SNOMED CT	2.16.840.1.113883.6.96
	HealthStatus	Represents the general health status of the patient. In the	SNOMED CT	2.16.840.1.113883.6.96
	Problem Severity	This is a description of the level of the severity of the problem. Specific URL Pending	SNOMED	2.16.840.1.113883.6.96
	MoodCodeEvnInt		ActMood	2.16.840.1.113883.5.1001
Procedures	ProcedureAct statusCode	A ValueSet of HL7 actStatus codes for use with a procedure activity	ActStatus	2.16.840.1.113883.5.14
	ActPriority		ActPriority	2.16.840.1.113883.5.7
	Body Site	Contains values descending from the SNOMED CT® Anatomical Structure (91723000) hierarchy or Acquired body structure (body structure) (280115004) or Anatomical site notations for tumor staging (body structure) (258331007) or Body structure, altered from its original anatomical structure (morphologic abnormality) (118956008) or Physical anatomical entity (body structure) (91722005) This indicates the anatomical site	SNOMED CT	2.16.840.1.113883.6.96
	HealthcareServiceLocation	A comprehensive classification of locations and settings where healthcare services are provided. This value set is	HL7 Healthcare	2.16.840.1.113883.6.259

		based on the National Healthcare Safety Network (NHSN) location code system that has been developed over a number of years through CDC's interaction with a variety of healthcare facilities and is intended to serve a variety of reporting needs where coding of healthcare service locations is required.	ServiceLocation	
	Patient Education	Limited to terms descending from the Education (409073007) hierarchy.	SNOMED CT	2.16.840.1.113883.6.96
	MoodCodeEvnInt		ActMood	2.16.840.1.113883.5.1001
Encounter	EncounterTypeCode	This value set includes only the codes of the Current Procedure and Terminology designated for Evaluation and Management (99200 – 99607) (subscription to AMA Required	CPT4	2.16.840.1.113883.6.12
	HealthcareServiceLocation	A comprehensive classification of locations and settings where healthcare services are provided. This value set is based on the National Healthcare Safety Network (NHSN) location code system that has been developed over a number of years through CDC's interaction with a variety of healthcare facilities and is intended to serve a variety of reporting needs where coding of healthcare service locations is required.	HL7 HealthcareServiceLocation	2.16.840.1.113883.6.259
	MoodCodeEvnInt		ActMood	2.16.840.1.113883.5.1001
Medical Equipment	n/a			

Plan of Care	Planned moodCode (Act/Encounter/Procedure)	These value set is used to restrict the moodCode on an act, and encounter or a procedure to future moods.	ActMood	2.16.840.1.113883.5.1001
	Planned moodCode (Observation)	These value set is used to restrict the moodCode on an to future moods.	ActMood	2.16.840.1.113883.5.1001
	Planned moodCode (SubstanceAdministration/Supply)	These value set is used to restrict the moodCode on a substance administration or a supply to future moods.	ActMood	2.16.840.1.113883.5.1001
	Patient Education	Limited to terms descending from the Education (409073007) hierarchy.	SNOMED CT	2.16.840.1.113883.6.96
Fictional Status	Pressure Ulcer Stage	This value set enumerates the type of a pressure ulcer.		
	Pressure Point	This value set represents points on the body that are susceptible to pressure ulcer development.	SNOMED CT	2.16.840.1.113883.6.96
	TargetSite Qualifiers		SNOMED CT	2.16.840.1.113883.6.96
	MoodCodeEvnInt		ActMood	2.16.840.1.113883.5.1001
Medications	Medication Route FDA	Route of Administration value set is based upon FDA Drug Registration and Listing Database (FDA Orange Book) which are used in FDA structured product and labeling (SPL)	FDA RouteOfAdministration	2.16.840.1.113883.3.26.1.1
	UnitsOfMeasureCaseSensitive		UCUM	2.16.840.1.113883.6.8
	Body Site	Contains values descending from the SNOMED CT® Anatomical Structure (91723000) hierarchy or Acquired body structure (body structure) (280115004) or Anatomical site notations for tumor	SNOMED CT	2.16.840.1.113883.6.96

		staging (body structure) (258331007) or Body structure, altered from its original anatomical structure (morphologic abnormality) (118956008) or Physical anatomical entity (body structure) (91722005) This indicates the anatomical site		
	Patient Education	Limited to terms descending from the Education (409073007) hierarchy.	SNOMED CT	2.16.840.1.113883.6.96
	Medication Fill Status		ActStatus	2.16.840.1.113883.5.14
	Medication Clinical Drug Name Value Set	Shall contain RxNorm normal forms for concepts type of “Ingredient Name” or Generic Packs. The ingredient name concepts can be found in the RxNORM file RXCONSO.RRF selecting all terms where SAB=RXNORM (selecting the normal forms), and TTY=SCD (selecting the ingredient names) or TTY=GPCK (selecting the generic packs)	RxNorm	2.16.840.1.113883.6.88
	MoodCodeEvnInt		ActMood	2.16.840.1.113883.5.1001
Social History	Social History Type	A value set of SNOMED-CT observable entity codes containing common social history observables. Though Tobacco Use and Exposure exists in this value set, it is recommended to use the Current Smoking Status template or the Tobacco Use template to represent smoking or tobacco habits.	SNOMED CT	2.16.840.1.113883.6.96
	Tobacco Use		SNOMED CT	2.16.840.1.113883.6.96
	MoodCodeEvnInt		ActMood	2.16.840.1.113883.5.1001
Vital Signs	Vital Sign Result	This identifies the vital sign result type.	LOINC	2.16.840.1.113883.6.1

	MoodCodeEvnInt		ActMood	2.16.840.1.113883.5.1001
Results Section	Result Status		ActStatus	2.16.840.1.113883.5.14
	MoodCodeEvnInt		ActMood	2.16.840.1.113883.5.1001
Advance Directives	MoodCodeEvnInt		ActMood	2.16.840.1.113883.5.1001
Family History	Family Member Value Set	Family Relationships record the familial relationship of a person to another person. This value set is to be used when it is necessary to record family relationships (e.g., next of kin, or blood relations). This is a subset of the value set used for personal relationships	RoleCode	2.16.840.1.113883.5.111
	MoodCodeEvnInt		ActMood	2.16.840.1.113883.5.1001
Payer	Coverage Role Type	A value set of HL7 role Codes for role recognized through the issuance of insurance coverage to an identified covered party who has this relationship with the policy holder such as the policy holder himself (self), spouse, child, etc.	RoleCode	2.16.840.1.113883.5.111
	HL7FinanciallyResponsiblePartyType		RoleClass	2.16.840.1.113883.5.110
	Health Insurance Type		Insurance Type Code	2.16.840.1.113883.3.88.12.3221.5.2
	MoodCodeEvnInt		ActMood	2.16.840.1.113883.5.1001

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