



# TRILLIUM II

Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient Summary

## FINAL REPORT



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## List of Acronyms

- CDASH: Clinical Data Acquisition Standards Harmonization defines basic standards for the collection of clinical trial data.
- CDISC: Clinical Data Interchange Standards Consortium
- CEN TS17288: The International Patient Summary: Guidance for European Implementation
- CEN EN17269: The Patient Summary for Unplanned, Cross-border Care
- CoP: Community of Practice
- EHN: eHealth Network established under article 14 of the EU directive to patients’ rights to cross-border care (2011/24).
- EHR: Electronic Health Record
- eEHRxF: European Electronic Health Record Exchange Format
- eHDSI: eHealth Digital Services Infrastructure
- EFMI: European Federation for Medical Informatics
- FHIR: Fast Healthcare Interoperability Resources
- FAIR: Findable Accessible Interoperable Reusable
- GPS: Global Patient Set: free set of terms by SNOMED CT
- HHS-ONC: Health and Human Services, Office of the National Coordinator
- HSPC: Healthcare Services Platform Consortium
- HL7: Health Level Seven
- IHE: Integrating the Healthcare Enterprise
- IPS: International Patient Summary
- JIC: Joint Initiative Council of Global Health Informatics Standardization
- KPI: Key performance indicator
- MOOC: Massive Open Online Course
- NCP: National Contact point
- RWD: Real World Data
- SME: Subject Matter Expert
- SME: Small to Medium Enterprise
- SNOMED CT: Systematized Nomenclature of Medicine -- Clinical Terms
- SDO: Standard Developing Organization



## Executive Summary

The Trillium II consortium comprises 4 Standards Developing Organizations (SDOs) (HL7 Foundation as scientific coordinator, NEN/CEN TC 251 Health Informatics, IHE Europe, and CDISC Europe), 10 health systems and eHealth competence centres from 6 Member States (MedCom, Denmark as Coordinator; Lombardy, Italy; THL, Finland; eSante Agency, Luxembourg; TicSalut, Catalunya, Spain; SPMS, Portugal) and the United States (Reliant Medical Group -500 GP offices in Massachusetts, US; HSPC - Association of health systems; Kaiser Foundation Hospitals; Sequoia Project/Carequality - Network of Health Exchanges), and 7 research and development, ecosystem networking and evaluation partners in Europe and the US (I<sup>2</sup>HD, empirica, Gnomon, ECHAlliance, DHACA, PHAST, SRDC, Offis, Lantana, ProSocial). With broad support from the US Department of Health and Human Services, Office of the National Coordinator in the US (HHS-ONC) and the community of Trillium Bridge already established, Trillium II set out to implement the EU-US roadmap action plan of 2016 and advance standardization and Electronic Health Record (EHR) interoperability globally.

Following the mission of the EU-US roadmap, the aim was to support an innovative collaborative community of public and private sector entities working towards developing, deploying, and using eHealth science & technology to empower individuals, support care, advance clinical outcomes, enhance patient safety, and improve the health of populations using as critical levers international interoperability, workforce development, and innovation ecosystems.

Focusing on concrete actions raising awareness of the International Patient Summary (IPS) standards that targeted established networks, projects, and ecosystems, the Trillium II project contributed to nurturing digital health innovation by making standards and associated tools available to a wide audience and to lowering trade barriers by accelerating development and consensus on IPS standards. Trillium II also engaged soft power to bridge the gap between strategic intent and capability to act on the adoption of IPS standards by linking the IPS narrative to the needs of citizens for trusted access to their health data for safe care and research in specific circumstances identified in use cases.

Trillium II relied on the vibrant community and recommendations of Trillium Bridge (Bridging Patient Summaries across the Atlantic, 2013-2015, GA610756) which were reflected in the EU-US Roadmap action plan. It also adopted the framework and roadmap methodology set up by eStandards (eHealth Standards and Profiles in Action for Europe and Beyond, 2016-2018, GA643889) highlighting the eStandard's lifecycle and the co-creation, governance, alignment approach to standardization. Support from US partners and HHS-ONC, the HL7 FHIR framework, and links to other health informatics standards organizations through the Joint Initiative Council on Global Standardization helped Trillium II contribute to accelerated IPS standards development and alignment. Moreover, it helped create momentum behind the IPS through workshops, demonstrators, and synergies with health professional organizations and large initiatives.

Thus, Trillium II contributed in various degrees to guiding, bridging, harmonizing, and evaluating patient summary specifications such as eHDSI PS, HL7 FHIR IPS, the CEN IPS, as well as national, regional, and domain specific initiatives in which patient summaries had a role to play: 1) Home based records and vaccination cards for children (in collaboration with the MOCHA project); 2) frailty assessment and monitoring for the elderly (in collaboration with the FrailSafe project); 3) monitoring hypertension apps (in collaboration with the European Society of Hypertension); 4) personalized care plans based on professional guidelines (C3Cloud project); 5) evaluation of mobile patient summaries in emergency care and disaster management (European Society of Emergency Medicine and EUModex exercises).

Several activities like the use of IPS in childhood cancer survivor passport (initial contacts), rare disease passport, clinical research or precommercial procurement will no doubt continue after the end of Trillium II.



A common element of these efforts is understanding and responding to the needs of patients with the patient summary. Therefore, questions like who, when, what, where, and how in workflows speak to access, trust, and provenance of high-quality data in the health ecosystem.

Specific and measurable objectives articulated in the Trillium II description of action were pursued relentlessly exploring the networks available and opportunities as they materialized. Specifically:

- *Highlight the social value of IPS standards:* worked with the World Health Organization (Health and Safety Network and Emergency Medical Teams) and with the World Economic Forum (Value in Healthcare activity). As a result, patient summaries and associated standards were mentioned in reports generated by the [WHO Executive director to the WHO Assembly](#) and the [WEF Value in Health Care Project report](#) to Davos in 2019, linking IPS to measuring clinical outcomes.
- *Bridge IPS initiatives with validated interoperability assets, sharing lessons learned with SDOs:* Trillium II through specific activities, contributed to development of tools, examples, and educational material to accelerate implementation of IPS. While in the Trillium II description of action the objective was to support the implementation of the IPS within a week, the Trillium II tools used in the MIE2018 Datathon, Hacking Health Athens, and the EU Modex exercise showed we can accelerate implementation of IPS standards, in mobile apps from week (our ambition), to 2 days (MIE2018 Datathon), 36 hours (Hacking Health Athens), and allow modifications in a few hours. Nevertheless, much more is needed to accelerate adoption of IPS standards and tools by start-ups and Trillium II proposes development of a start-up kit, perhaps within the context of EHRxF activities.
- *Contribute to IPS Standards Governance under the JIC:* Trillium II contributed to IPS Standards Governance by engaging all SDO members of the JIC and supporting the release of the Global Patient Set of free terms by SNOMED. Trillium also contributed to the development of a governance methodology which was tested with several projects and initiatives in Europe and globally to reveal that many initiatives fell short in engaging all IPS stakeholders and do not anticipate and plan for sustainability and change management. The relevant work has been published in [Stud Health Technol Inform. 2019 Jul 4;262:202-205](#). Related to that is the effort to adopt a harmonized evaluation framework and scoreboard that would measure the level of adoption and identify levers and roadblocks. A gap analysis for IPS/Argonaut was funded by the HHS-ONC and a similar one more recently for IPS/eHDSI reflect the spirit of co-creation governance and alignment.
- *Develop, Collect and Assess IPS Learning resources:* Trillium II developed IPS educational resources and created translations in 6 languages, double the Key Performance Indicator (KPI) of 3 noted in the Description of Action. Additional learning resources were developed for the 17 workshops that were organized or co-organized in the course of the Trillium II project and made available on the website. Trillium II recognized that there is a large gap between knowledge and expertise available and the skills required to advance interoperability and quality of health data. Much more is needed to cater to the needs of different stakeholders and develop high quality interprofessional training modules and resources for high quality data sets. Thus, Trillium developed a syllabus and learning objectives that educational bodies, possibly with support from EFMI, can implement to further support adoption of patient summary standards among patient advocacy groups and health professionals.
- *Engage mobile Health companies and app developers with IPS standards:* Trillium II used the business model canvas to frame the parameters of viable business models for mobile health companies to implement IPS. The relevant work was considered by the EU innovation radar. With the initiative of



ECHAlliance, a panel was organized at the Mobile World Congress 2018 and an article on IPS business models has been published in the [Journal of Aging and Innovation](#). A second paper on business models is currently under review. Trillium II contributed to the development of several resources to assist IPS developers, that are now available online:

1. Datasets, scenarios and value sets are available in Art-Decor:
    - <https://art-decor.org/art-decor/decor-datasets--trilm2->
    - <https://art-decor.org/art-decor/decor-scenarios--trilm2->
    - <https://art-decor.org/art-decor/decor-valuesets--trilm2->
  2. Source files and examples are available in GitHub:
    - <https://github.com/gcangioli/trilliumII>
    - <https://github.com/gcangioli/trilliumII/tree/master/examples>
    - <https://github.com/gcangioli/trilliumII/tree/master/IG>
  3. FHIR Implementation Guidelines are available at HL7 or Trillium II website:
    - <http://hl7.eu/fhir/build/trillium2>
    - <http://hl7.eu/fhir/ig/trillium2>
    - <https://trillium2.eu/fhir/>
- *Foster innovation & inform health policy sharing IPS:* Trillium II promoted the concept of patient summaries as a “window to a person’s health information.” Numerous presentations in Europe, the US, and Asia, highlighted the ability of IPS standards to deliver patient summaries in interoperability, safety, and trust. Trillium II also provided presentations and slides to speakers that wished to speak about the IPS in their own community and language. The results of this active engagement and awareness raising, is reflected in the submissions to the Trillium Award, which includes entries from North and South America and organizations unknown to Trillium-II partners. An international jury (Elaine Blechman, CEO, Prosocial Applications, Inc. & Professor Emerita, Univ. of Colorado, Christopher Chute, Chief Research Information Officer for Johns Hopkins Medicine, Gora Data, Group Chairman, CAL2CAL Corporation, Dee O’Sullivan, Director, myhealthapps.net at PatientView, Mike Short, Chief Scientific Adviser, Department for International Trade, UK, Jeremy Thorp, Director of Business Architecture, NHS UK, Patricia Van Dyke, Past Chair HL7) agreed that the Trillium Award was to be shared by two initiatives fostering innovation. These initiatives showed how IPS standards can support incremental innovation (extending a medical service to include additional IPS components i.e. problem list, allergies, etc.) and disruptive innovation (CAPABLE – citizen centred services combining IPS with nutrition data). Finally, the work of Trillium II with vaccination cards and home-based records for children created a bridge to primary care and public health and resulted in thematic workshops at CEN/CENELEC and WHO Europe. The relevant results are reported in the [European Journal of public health](#).

Trillium-II reached out to workforce actions, SDO platforms in Europe and United States, large scale eHealth deployments, and emergency readiness exercises in Bucharest, Romania and Saaremaa, Estonia. The aim was to use IPS standards to increase actionable interoperability of health systems in Europe, the United States, and globally, nurturing innovation and fuelling creativity with effective use and continuous improvement of interoperability standards.

Trillium II activities and achievements pave the way towards a global IPS Community of Practice (CoP) that fosters the practice of digital health innovation with robust widely-used interoperability standards and supporting tools for implementation, education, evaluation and monitoring. This global IPS CoP is central to building capacity in interprofessional education and leading the transformation of health and care with trust, quality, and safety as the overarching principles underpinned by broad adoption of IPS standards. The work



of Trillium II is also critical to the further development, refinement, and implementation of the European Electronic Health Record Exchange Format (EEHRxF) in ways that improve European competitiveness, facilitate the defragmentation of digital health services market, and advance the safe, trusted, and productive use of data. Looking forward, we expect the global IPS CoP to play a strong role in Digital Health Europe, the mobileHealthHub, cross-border eHealth Services in Europe (eHDSI), work on the EEHRxF, genomics, AI, and their connections to projects with similar scope in other parts of the world. For that, Trillium II recognises that interprofessional education is key, along with shifting our mentality from data exchange to data sharing and making decisions by asking the patient, to use reliable high-quality interoperable data. This may require a profound change in the culture of health and care but is at the same time is key to the transformation of health and care in ways that ensure benefits from digitization and the emerging data economy.



## 1 Introduction

International Patient Summary (IPS) standards consistently adapted and localized to serve the needs of specific use cases are essential to attaining of vision of the patient summary as a social good and a human right. The Trillium Bridge project (2013-2015) compared Patient Summary standards and specifications in Europe and the United States and demonstrated the technical feasibility of exchanging electronic health record summaries across the Atlantic in the context of emergency or unplanned care abroad. Reflecting on its results, the Trillium Bridge consortium reached a broadly endorsed recommendation: “Advance an International Patient Summary standard to enable people to access and share their health information for emergency or unplanned care anywhere and as needed starting with immunizations, allergies, medications, clinical problems, past operations and implants.”

Trillium Bridge II - Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient Summary (referred to as ‘Trillium II’) is a partnership comprising organisations from 14 countries (Europe and the United States), 7 different health systems, SDOs, SMEs, healthcare providers, companies, competence centres and non-profit associations. Trillium II builds on the recommendations of Trillium Bridge and aims to bridge, harmonize, evaluate existing patient summary initiatives and guide emerging ones, leading the way toward one IPS standard by establishing a global community fostering the practice of digital health innovation with robust widely-used interoperability standards, activities targeting capacity building, and joint pilots.

The Final Report reports on the 30-month workplan of Trillium II and comprises a description of the work carried out by Trillium II in order to meet the project objectives, while at the same time adapting to political change and benefiting from opportunities as they emerged in the project lifetime.

*Firstly*, the report presents the project’s objectives, accounting for what has been done to achieve them and describing what the result has been. It also states the achievements made beyond state-of-the-art. *Secondly*, the report conducts an overall assessment of Trillium II’s qualitative and quantitative results. *Finally*, the report proposes next steps for follow-up initiatives and concludes summarizing the results and achievements of the Trillium II project.



## 2 Technical Report

Trillium II builds on the community established in the Trillium Bridge project to: 1) improve international interoperability of eHealth Systems in Europe, the United States and globally; 2) accelerate establishment of interoperability standards in eHealth with validated open source interoperability assets and sharing lessons learned with SDOs; and 3) facilitate secure, seamless patient summary sharing offering clarity and oversight.

### 2.1 Project Objectives and Results

#### Establish a Global Community for Digital Health Innovation Practice (GC-DHIP) or Global IPS CoP

**Objective:** Trillium Bridge recommended that we advance sharing of patient summaries starting with **clinical problems, allergies, past procedures, medication, vaccinations, and implantable devices**. To advance this objective, Trillium-II established a Global Community for Digital Health Innovation Practice, later renamed IPS Global Community of Practice (GC-DHIP or Global IPS CoP), as we call it henceforth.

The purpose of the Global IPS CoP is to identify use cases of interest to validate and promote the use of IPS standards in demonstrations, readiness exercises and other pilot projects. The target for **Global IPS CoP is 1000 members** by the end of the project with **at least 2 pilot projects of sharing patient summaries in the context of specific use cases**, supported with interoperability assets to be evaluated and promoted. The final deliverable of Trillium-II is lessons learned and recommendations for the long-term sustainability and further growth of the Global IPS CoP.

The objective of Trillium-II has been to join forces with health professional organizations, patient advocacy groups, emergency response organizations and the eHealth and pharma industry to discuss and pilot patient summary extensions serving specific population needs. Through this engagement, the hope was to further expand the reach of the Global IPS CoP.

**Result:** The GC-DHIP was announced in MedInfo2017, Hangzhou China, in August 2017. One of the first IPS workshops was hosted in Beijing in HL7 China. After 30 months of supporting standardization in the technical committees of HL7 and CEN TC251, providing regular progress reports to the JIC, liaising with potential users of the IPS to understand their information needs and work processes, developing training material to accelerate implementation of IPS standards, and providing feedback to SDOs from users, GC-DHIP was relaunched as the Global IPS CoP at HIMSS Europe 2019. Right after the announcement of the Trillium Prize winners, the Global IPS CoP launch framed IPS standards as infrastructure for innovation, safety and quality, in a society that increasingly depends on data and knowledge. Global IPS CoP builds on learning communities of knowledge, mentoring, and accelerated adoption of IPS standards.

It is difficult to estimate the number of the people associated with the Global IPS CoP. With 17 workshops organized by Trillium II alone, participation in more than 4 eHDSI bootcamps, 2 IHE Workshops at the Annual Connectathons 2017 and 2019, and several third-party workshops, the number of people and organizations that interacted with IPS development or use, directly or through partner networks is quite high. Counting only those that participated in Datathons, Hackathons, and Connectathons, or those that attended smaller events, training seminars, and workshops of 20-25 people, we can easily reach 780 people that were directly engaged. On the other hand, including all outreach activities mentioning the Global IPS CoP and urging groups to build their own IPS CoP in the local ecosystem, the audience becomes much broader, extending to more than 5500 people. The audience is even bigger, reaching tens of thousands of people, when we consider the networks of networks effect of partners connecting people in at North and South America, Asia, Europe, and the Middle East, as indicated in the dissemination report.



Looking forward, we expect the Global IPS CoP to play a strong role in Digital Health Europe, the mobileHealthHub, cross-border eHealth Services in Europe (eHDSI), work on the EEHRxF, genomics, AI, and their connections to projects with similar scope in other parts of the world. What we can say with reasonable confidence is that with more the **five Memorandums of Understanding that have been signed, numerous organizations have been exposed to the work of Trillium II and the role IPS standards**. This number corresponds to pilot projects and reflects the extend of Trillium II project resources. The exploitation potential of the HL7 FHIR IPS resources is quite significant, especially when considering the EEHRxF.

For more information, please consult our deliverable: D7.6 Recommendations for a global community of digital health innovation practice.

### Highlight the social value of the International Patient Summary Standards

**Objective:** Trillium-II will liaise with WHO and other United Nations agencies to identify the context, role, and adoption of the IPS in the global ecosystem. Particular emphasis will be placed on disaster management and emergency response, as well as quality and safety. The main instrument for this effort is consultations and stakeholder meetings.

Thematic EU/US consultations with health professional associations, patients and the industry, grounded in the recommendations of Trillium Bridge, will identify concrete steps.

Trillium-II will investigate the potential of endorsement and action from UN agencies on the social value of health data and patient summaries as a fundamental right to safe care, so that people can access and share their patient summary in a secure and trustworthy manner.

**Result:** Trillium II has through its work and collaboration with stakeholders highlighted the social value of accessing to one's IPS positioning health data as a common good.

**WHO:** Trillium II has liaised with WHO Headquarters (Geneva) and WHO Europe (Copenhagen) to promote adoption of the IPS in the global ecosystem, seeking clarification of its role and context of use. In WHO Headquarters in Geneva, we liaised with two groups:

- Emergency Medical Teams (EMT) under WHO Humanitarian Health Action and followed up with the disaster medicine exercises to highlight the importance of the IPS in disaster situations.
- Integrated Health Services Division of Universal Health Coverage and Life Course to illustrate the role of IPS in safe care with and across borders and jurisdictions.

These liaison activities contributed to the recognition of the IPS priority by the WHO Director General to the 77nd World Health Assembly A71/20 of March 26, 2018 in his report of "[mHealth: Use of appropriate digital technologies for public health](#)" noting: "The spread of digital technologies and global interconnectedness has a significant potential to accelerate Member States' progress towards achieving universal health coverage, including ensuring access to quality health services: ... (e) *by increasing the safety and quality of care*. The concept of making international patient summary data available through mobile technologies will increase the safety and quality of care by providing secure access to the information needed by the attending physicians at the time of care."

In two EUModex humanitarian aid exercises, Trillium II evaluated the value of scenarios where EMTs had access victims' IPS, against the alternative of EMT's making clinical decisions without having access to the victims' medical history. WHO EMT was interested in actively engaging with IPS standards and indicated how



impressed they were by the experiments: they would very much like to receive and study the evaluation report of Trillium II (D6.2) and considered the use of IPS as part of the EMT training scenarios.

In the WHO Europe regional headquarters in Copenhagen, Trillium II was invited to participate in the WHO Europe Conference, “Digital Health Systems of the Future” on February 6-8, 2019 and engaged with the mhealthHub project which restarted in July 2019 with the participation of several Trillium II partners, WHO and the ITU. WHO Europe also hosted one of our workshops with MOCHA on IPS for Child Health in November 2018. The relevant results are reported in [European Journal of public health](#).

**Health Professional Associations:** The Trillium II project has been a connector of IPS standards development teams at HL7, CEN, SNOMED, CDISC and IHE, with emergency organizations of Physicians (e.g. EUSEM and its national member societies) European member states’ associations of physicians (invited from the first workshop on February 7, 2017), European Society of Cardiology (hosted our consortium meeting in Brussels on February 8, 2017), the European Society of Hypertension (signed an Memorandum of Understanding and hosted a Trillium-II workshop at their annual conference in June 2018), as well as to the eHealth Stakeholder Group (2015-2018) established by the European Commission.

**Citizens, Patients and other stakeholders:** Project activities concentrated on use cases that make a difference in a patient’s life. While in the case of hypertension our work concentrated on health professionals (i.e. European Hypertension Society) following up patients taking Hypertension medication, in the case of childhood cancer survivors, children with complex needs, vaccination, chronic disease patients or rare disease patients, we were in contact with multiple stakeholders and flagship activities in this area (see D5.1, D4.1). Additional project results in this area are:

- 1) Gap analysis indicated how patient summaries are used in practice (D2.1). The work was published in MIE2018 (Kai U. Heitmann, Giorgio Cangoli, Marcello Melgara, Catherine E. Chronaki: Interoperability Assets for Patient Summary Components: A Gap Analysis. MIE 2018: 700-704, 2017).
- 2) Building on the work of previous project situation of using patient summaries for patient safety and quality of care were identified and prioritized (D3.1). Some of these cases were analysed in detail (D3.2) and presented in MedInfo2017 (Catherine E. Chronaki, Robert A. Stegwee, Anne Moen: In Search of a Digital Health Compass to Navigate the Health System. MedInfo 2017: 30-34, 2016).
- 3) Citizens and health data: task force of the eHealth Stakeholder Group (eHSG) set up by the European Commission and was mirrored in a newly created WG of the European Federation for Medical Informatics, supported by more than 10 members of the eHSG.
- 4) Cooperation with project Frailsafe.eu (signed MoU and joint pilot) and FOCUS (joint workshop MIE2017) on Frail patients, working with their technical partners but linking to the whole ecosystem of prefrail and frail aging patients.
- 5) Cooperation with C3Cloud.eu (signed MoU and joint pilot) allowed to work on the constructing a care plan from the IPS of chronic diseases patients based on professional guidelines by NICE for people with multiple chronic diseases.
- 6) Cooperation with MOCHA project (signed MoU and pilot activity for SPMS and e-Sante) on children with complex needs and vaccinations.
- 7) Participation in the [WEF WG on value-based care](#), which highlighted the role of standards, recognized the importance of the IPS and the link to clinical outcomes.



There has also been communication and discussions with European Rare Disease Networks and the association of rare disease patients (EURORDIS) towards the development of rare disease passport based on the IPS. Some of this work may be handed off to future use cases of eHDSI and to the RCODE project. Trillium II has also explored cooperation with Survivor Passport (SurPass), a patient summary like construct created by the SIOPE and PANCARE associations advocating for childhood cancer survivors and their families. Due to time and resource constraints aligning SurPass to IPS was not part of the Trillium project. Partners expect to take up this line of work in a follow-up project.

**Industry:** Trillium work with the industry focused on Pharma, EHR vendors, Small to Medium Enterprises (SMEs) and start-ups:

- worked in the EU-US context with the Argonaut project to align HL7 IPS with Argonaut specs and US-Core. There has been significant progress and there is more to do as Argonaut moves to FHIR R4.
- Worked with partner CDISC to align HL7 IPS with the CDASH standards for regulatory submissions and the work will continue 2020.
- SMEs and start-ups: presented at the Mobile world congress in Barcelona in February 2019, carried out a Datathon in MIE2018 and actively participated in a Hackathon in February 2019 (see D6.1).

For more information, please consult our deliverables: D4.1 Social value of IPS standards in United Nations Agency contexts; D5.1 Recommendations for the EU/US eHealth interoperability roadmap – Open Innovation in digital Health: the case of the international patient summary, and D6.1 Report from Testing Events, Demonstrations, Pilot projects, and Readiness Exercise. Trillium II used the business model canvas to frame the reasons why mobile health companies should engage with IPS, and the relevant work was selected for the EU innovation radar. With the initiative of ECHAlliance, a panel was organized at the Mobile World Congress 2018 and an article on IPS business models has been published in the [Journal of Aging and Innovation](#).

From the average 371 recorded views per month recorded in the Trillium II website (well in excess of the KPI target of 250), we observe that the social value of the IPS summary was significant, with people from around the world accessing it, particularly for the Trillium Prize where entries came from as far away as southern South America. Furthermore, access to the Trillium II website is not the only site to present results of the project. Having adopted a network of networks approach to dissemination, partners and third-party collaborators have contributed to strong awareness of the work of the Trillium II project.

Project partnerships also exceeded expectations. The original proposal mentioned 2 partnerships, Trillium signed five MoUs and collaboration plans. Each MoUs was concrete noting the benefits to both parties in each partnership. Another impressive metric was the number of speaker invitations - 15 in total - from prestigious conferences (note this figure does not include those events where Trillium presenters were speaking anyway and included a reference to the project). Trillium II IPS Ambassadors (i.e. Petra Wilson, Silvia Thun, and Mike Short), have been an important resource to the project, since they served as spoke persons for the IPS. In hindsight, we feel that we were a bit late in engage the Ambassadors. We were waiting for the IPS standards version 1 to be ready. However, it would be better, if we brought them on board earlier. Thus, we would advise follow-up projects (for example on the EEHRxF), to engage Ambassadors early and selecting them wisely based on their capacity to speak to the heart and mind of stakeholders. That would increase the impact of the work of Trillium II. Finally, the number of workshops - 17 overall - far exceeded the original commitment of three and demonstrate the keenness of others to participate in this most exciting project.



## Bridge patient summary initiatives and provide feedback to SDOs

**Objective:** Trillium-II supports the recommendation of Trillium Bridge to work with SDOs and provide feedback from implementation: *“to collaborate on developing and adopting the patient summary standard to enable the interoperable representation and communication of information about a patient’s immunizations, allergies, medications, clinical problems, past operations and implants, building on reusable interoperability assets and tools;”*

Several standardization initiatives related to patient summaries that are in progress, can provide input to Trillium-II. Besides national initiatives, there is the JIC Standard Set for Patient Summary, the HL7 InterPAS project, the ISO Standards Reference Standards Portfolios, the ISO/EN 13606 revision, openEHR archetypes, CIMI models, FHIR profiles, the EU patient summary guideline revision, etc.

Trillium-II will support standardization with interoperability assets and tools that build and validate the results of these initiatives. For each of the main components of the patient summary, an open source library with software components, data sets, information structures and value sets will be validated in testing events, pilots and demonstrations. Already potential extensions (e.g. labs and imaging results, prior encounters, etc.) have been identified based on the ONC interoperability roadmap and the Meaningful Use stage III.

In addition, Trillium-II with support from GC-DHIP, will elaborate use cases of sharing patient summaries to inform SDOs work and relevant EU guidelines updates.

Selected standards or profiles and interoperability assets will be validated in testing, demonstrations, pilots and readiness exercise and lessons learned will be shared with SDOs.

**Result:** IPS standards development work was accelerated by the Trillium II project, resulting in reducing the typical length of standards development from 3 to 2 years. Resources, software tools, libraries, examples, and mobile health apps were developed and validated for the demonstration of the main components of the IPS (WP2 and WP3 deliverables D2.3 [Medications and implantable devices], D2.4 [Vaccinations], D2.5 [Allergies and Intolerances], D2.6 [Problems and Procedures], D3.3 [lab results], D3.4 [encounter report], and D3.5 [imaging results]). Moreover, in D2.7 Patient Summary Implementation guidance, IPS implementation guidance is provided with links to the prior content deliverables.

Collaboration and alignment of HL7, CEN/TC251, and IHE with the eHDSI and eHAction in the frame of HL7 FHIR IPS and HL7 CEN IPS revealed that it is extremely helpful to create a common joint logical model for the IPS to facilitate discussion of use cases. This logical model has helped extend alignment to other standards, such as: the ISO/EN 13606 revision, openEHR archetypes, CIMI models, and soon the EU patient summary guideline revision.

Several hands-on events, targeting developers and in some cases also business analysts have accelerated the implementation of IPS for the pilot use cases and improved the tools available adding to the IPS examples. On all of these occasions, Trillium II partners collaborated with other projects and initiatives that are external stakeholders of the IPS promoting alignment and creating value:

- HL7 FHIR IPS Connectathon in Baltimore with participation of partners SRDC, GNOMON, and collaborator U of Leipzig (under MoU with EUMFH), and HL7
- MIE2018 Datathon with participation of SMEs (MIE2018 was organized in Gothenburg in cooperation with Vitalis) along with seminars, in collaboration with the European Federation for Medical Informatics (EFMI) and the European Society of Emergency Medicine (EUSEM).



- Hacking Health Athens 2019 where mostly young attendees participated eager to create their startup, implementing ideas that involve health data and IPS standards.
- IHE Connectathons 2019, IHE Connectathon 2018
- eHealth Portugal in 2017, 2018, and 2019.

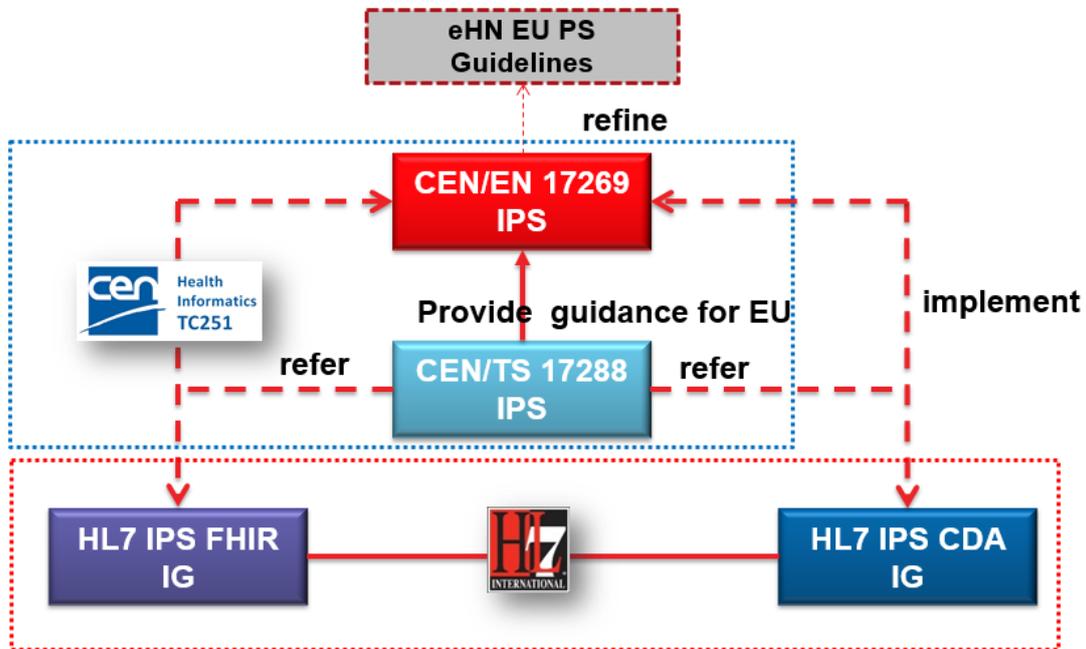


Figure 1: Relation between IPS standards and implementation Guides.

### Contribute to International Patient Summary Standards Governance under the JIC

**Objective:** This objective that embodies one of the proposed actions in the Annex of the EU/US MoU roadmap, originally proposed by Trillium Bridge aims to connect the standards developing organizations to implementers following the practice of open innovation. “..work closely with clinician and patient associations in the EU, US, and globally to define, refine, and validate the IPS standard, and establish with them a standing governance process under the Joint Initiative Council of SDO Global Health Informatics Standardization to maintain it in the light of updated requirements, legislation and learning from use of the IPS.”

Trillium-II through WP6 and its Global Community will support the JIC and SDOs in validating and receiving endorsements on the accuracy of cross-border clinical information structures and associated terminology value sets.

In addition to the patient summary standard sets, and as part of the evolution of the EU/US eHealth cooperation roadmap, several topics related to the operationalization of standards will be raised in the context of further areas of cooperation including the licensing and accreditation supported by conformance testing that has been highlighted by Trillium Bridge in its recommendation: “licensing and accreditation schemes that demonstrate competence and commitment to accurate and complete clinical documentation that enables the creation, maintenance, and communication of patient summaries in the IPS standard.”



Bridging the gap between standardization and adoption, steps will also be taken in the direction of innovation in the management of information in view of the perceived value and the questions raised in our increasingly **data-driven economy**, namely: *“review models of comprehensive person-centered health information stewardship, supporting the patient summary standards.”* These areas of work reflected in WP4 and WP5, will be actioned in consultations and workshops that will be organized by Trillium-II with collaborating projects and initiatives in Europe and the United States. The advisory group of Trillium-II will be enabling liaison activities.

**Result:** Trillium II partners have been working across:

- 1) the HL7 FHIR IPS project (previously HL7 InterPAS) with one of the co-leads being HL7’s WP3 Lead and the other being the United States HHS ONC consultant.
- 2) The CEN IPS project with HL7, IHE Europe, Nictiz (eHDSI), under the leadership of NEN (all with representatives who have been deeply involved in Trillium II WP2.6 work), in an effort to accelerate standards development and consistency across HL7, CEN and eHDSI. Furthermore, a steering committee led by project representatives from CEN/TC251, IHE Europe and HL7 addressed communication issues.

HL7 and CEN coordinated across the Joint Initiative for Global Health Informatics Standardization i.e. HL7, CEN, ISO, PCHA, DICOM, CDISC, GS1, which has created the Patient Summary Standards Set resource.

Partners HL7 and CEN/NEN engaged with the Argonaut project in the United States and HL7 affiliates throughout the world to promote alignment of patient summary efforts. A gap analysis of Argonaut and the HL7 FHIR IPS was sponsored by HHS-ONC and has helped align the two initiatives highlighting the role of HL7 IPS and its components as the payload in the Argonaut transactions. The upgrade of the Argonaut to HL7 FHIR STU4, is an opportunity to further this alignment.

Partner CEN/NEN coordinated interviews on governance structures and processes for patient summary specifications among the known patient summary initiatives and provided recommendations on Governance for IPS specifications (see D5.1 Recommendations for the EU/US eHealth interoperability roadmap – Open Innovation in digital Health: the case of the international patient summary) and the Governance Framework has been published in [Stud Health Technol Inform. 2019 Jul 4;262:202-205](https://doi.org/10.1016/j.jheale.2019.07.005).

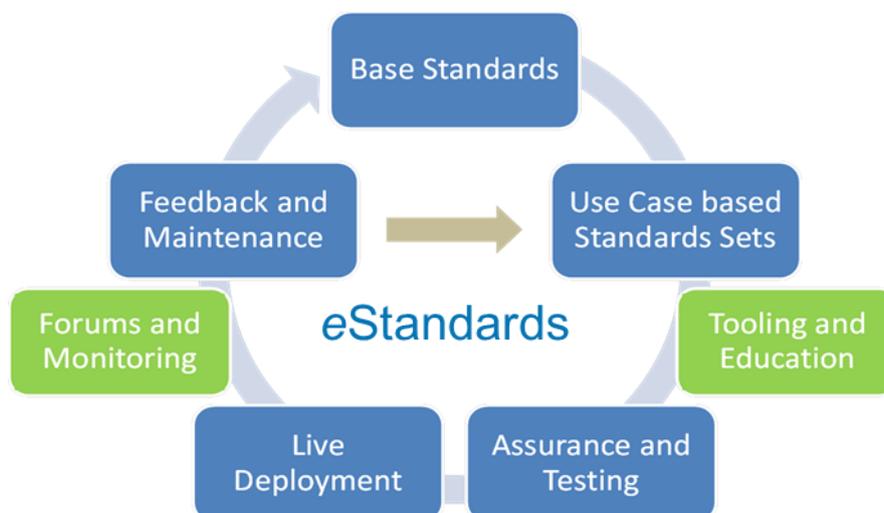


Figure 2: the eStandards lifecycle model. Trillium II tried to address every step of the cycle.



The standardization work carried out has been unique in that it engaged proof of concept implementation, validation, tools development, alignment of efforts with standards development across SDOs following every step of the lifecycle model introduced by eStandards (see figure above). The Trillium II project partners were initially optimistic about the start date of the CEN IPS project which was delayed almost six months but, in the end, the two standards were approved within two years, a record for standardization work items. Trillium II was also optimistic about the exchange of patient summaries, but that also had not picked up by the end of the Trillium II project. Despite these set-backs, the work embraced and aligned stakeholders from Member States through joint actions funded by the European Commission (eHaction and JAVac, as well CEF eHDSI). The relation of the patient summary related standards appears in the figure below:

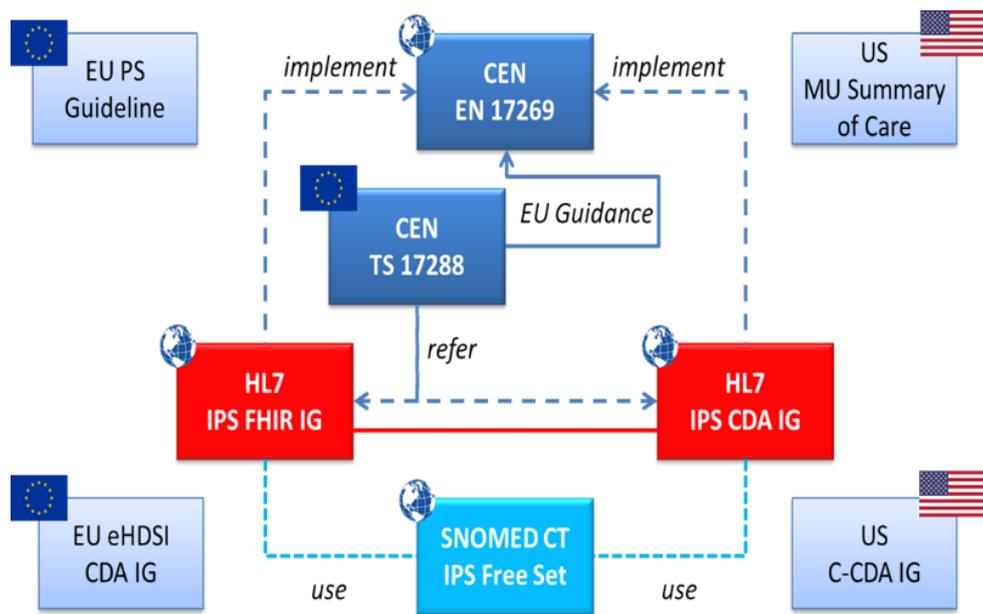


Figure 3: IPS standards work items that have been aligned and related.

### Develop, Collect and Assess Learning resources for the international patient summary

**Objective:** Trillium Bridge recommended that EU and US policy makers with support from educators, health professional and provider associations, patient advocacy groups and developers of eHealth/health IT solutions should *“promote the development of guidance and training for all healthcare professional disciplines and specialties, and patients, about creating, maintaining and using high quality health records, including the appropriate use of patient summaries in the IPS standard to inform clinical decision-making;”* and *“foster initiatives that motivate and equip patients to maintain and harness their own health summary information in the IPS standard for better health and the self-management of health conditions.”*

Trillium-II will assemble a transatlantic team to collect, assess, and adapt **learning resources for the international patient summary** standards. Potential topics to be included are: *“What makes a good patient summary?”* and *“How can we validate the quality of patient summary?”* An educational strategy will be compiled based on existing resources. In this context, the topic of incentives will be also raised addressing the question *“What should be the rewards and incentives for health care providers to maintain complete, up-to-date health records that enable the generation and sharing of accurate patient summaries in the IPS standard.”*



**Result:** An **educational strategy** has been compiled. Learning resources have been assembled and translated. Additionally, **educational webinars** were organized prior to Hacking Health Athens and for Canada Infoway (the Canadian standards competence center). The presentation on the IPS has been translated in **Danish, Italian, English, French, Spanish and Catalan**, well above our commitment of 3 languages. Additionally, slide decks from 20+ presentations that touch upon IPS have been delivered at various venues are offered on the website.

Concerning available learning resources from third parties the available material was less than expected. Very few countries have chosen to invest in publicly accessible educational material for patients and for health professionals about their strategy for shared patient summaries, the information contained in them, how to access this information, how to make corrections, etc. There were almost no cases to be reported in which there have been investments in education to the public about how they could use their own patient summary information to track and improve their own health and management of their conditions.

The desk research carried out looked for material in English and in national languages used the networks of CEN and ECHA. Copyright-protected course material or printed materials, unless available online were not considered. Deliverable D4.3 includes the small number of examples identified in this way. These resources were neither sufficient to create a collection, nor to identify best practices. There was no information available on the learning objectives, use or impact of these resources. This has to change if policy makers want the exchange of patient summaries cross-border or the use of patient summaries to integrate care across organizations to become part of the practice of safe health care.

**Trillium II offers syllabus and learning objectives that could be taken forward by anyone wishing to develop a public or professional educational programme to address the needs of patients or health professionals.** We also created quality resources about IPS standards and translated them into six languages including English with voice narration.

For the future we suggest engagement with educational bodies, such as universities across Europe to determine whether courses within existing Masters' programmes in medical informatics, include education about patient summaries or more broadly information resources to support safe continuity of care. If as we suspect, there is insufficient material available, we would recommend development of a Massive Open Online Course (MOOC) or a portfolio of educational resources offered by universities to national contact points (NCPs), health professional associations and patient advocacy groups, to help scale up public and professional awareness about the IPS, the benefits of IPS and how they could use it. The European Federation for Medical Informatics may have an important role to play in this space.

The Trillium II Learning Resources are available on the project website and have since their publication been viewed 198 times, mostly strongly at the time we published the resources on what the IPS is in 6 languages and when the CEN TC 251 presentation with voice-over explaining the IPS standard was made available. The Learning Resources are still being accessed as analytics show there is constant activity on the page, even if at small scale in terms of views (average of 10,5 per month in the last 6 months).

For more information on this topic, please consult our deliverable: D4.3 Education and training material for IPS and associated standards in three languages.

### Engage Mobile Health Companies and App Developers with Patient Summary Standards

**Objective:** The visibility of patient summary standards in the mobile health community will increase with a **patient summary interoperability award** planned for 2018. Trillium-II will thus support the actions of the EU/US roadmap including alignment of IHE profiles, FHIR resources, and open APIs, in mHealth pilots,



demonstrations, and competitions supported by reusable interoperability assets with computable information structures and value sets that are openly available to stimulate broad adoption. At the same time, Trillium-II will connect with ad hoc groups like the Argonaut project, to test and demonstrate use cases of common interest.

Furthermore, activities in WP7 which address market outreach will look into **procurement, business models, and licensing trends** of interoperability assets related to patient summaries supporting the recommendation of Trillium Bridge to *“stimulate the market for the adoption of the IPS standard by lowering trade barriers and supporting entrepreneurs working with eHealth/health IT systems and mHealth applications to capture and deliver patient summaries in the IPS standard, and by encouraging novel business models.”*

Workshops associated with demonstrations of mobile apps will be also used to discuss “quality criteria on maintaining accurate health records in the appraisal of healthcare professional staff and other relevant care givers to support effective exchange of patient summaries in the IPS standard.” This activity will be linked to the EC guidelines to improve quality of mHealth apps<sup>12</sup>. Relevant activities are in WP4, WP6, and WP7.

**Result:** Significant effort has been invested in engaging mHealth companies. Specifically, Trillium II explored:

- a) the role of standards in innovative procurement has been reviewed identifying state of play and future prospects;
- b) business models for mHealth were reviewed and we encouraged companies to invest in the implementation of IPS standards considering them infrastructure for innovation (D7.4); a journal publication has been submitted.
- c) the status of licensing and the deployment of information structures and value sets (D7.5), supported the delivery of the Global Patient Set (GPS) by SNOMED international and proposed a governance structure for its update (D5.1);
- d) multiple prizes and awards were bestowed: (1) MIE2018, HL7 FHIR IPS Datathon; (2) HIMSS & Health 2.0 European Conference, Trillium Prize. (3) Innovation prizes were offered in Hacking Health Athens, in a competition that also engaged IPS.

Based on this experience, Trillium II concluded that further targeted action is required to make standards accessible to health start-ups and more investment is needed to connect standardization to mHealth companies and app developers. Trillium II has reasons to be optimistic: as IPS standards mature, the tools become more intuitive and easier to use. With the resources of Trillium II, it was possible to implement a proof of concept with the IPS within a business day. This is less than what we originally anticipated. At the same time, we have reasons to believe that further improvements are feasible.

The technical resources developed by Trillium II are freely available. HL7 FHIR IPS resources and examples are available to mobile health app developers and we do hope that future projects will be able to further shorten implementation effort and thus increase the availability and uptake of apps with IPS inside.

Trillium II contributed to the development of the following resources:

1. Datasets, scenarios and value sets are available in Art-Decor:
  - <https://art-decor.org/art-decor/decor-datasets--trilm2->
  - <https://art-decor.org/art-decor/decor-scenarios--trilm2->
  - <https://art-decor.org/art-decor/decor-valuesets--trilm2->
2. Source files and examples are available in GitHub:
  - <https://github.com/gcangioli/trilliumII>
  - <https://github.com/gcangioli/trilliumII/tree/master/examples>
  - <https://github.com/gcangioli/trilliumII/tree/master/IG>
3. FHIR Implementation Guidelines are available at HL7 or Trillium II website:



- <http://hl7.eu/fhir/build/trillium2>
- <http://hl7.eu/fhir/ig/trillium2>
- <https://trillium2.eu/fhir/>

In addition, the Trillium II FHIR IPS components are available in Simplifier, the global FHIR collaboration platform. Engagement with mobile health companies and app developers is ongoing and will continue after the end of the project embedded in the daily activities of the partners.

### Foster innovation & inform health policy sharing patient summaries in various settings

**Objective:** Trillium Bridge recommended that the IPS standard should be targeted *“the IPS standard as the means for sharing a core set of clinical data for the purpose of emergency or unplanned patient care, aligning it with other relevant existing standards, and incorporating where possible the needs of public health and other secondary uses of aggregated health summary data.”* Trillium Bridge also recommended under cross-vendor integration promoting *“the capability to generate and export patient summaries in the IPS standard, as well as import and integrate patient summaries in the IPS standard with locally-held EHR data,”* and *“advance conformity assessment methods and tools that verify the robustness and quality of vendor implementations of the IPS standard, including the ability to generate and exchange patient summaries conforming to the IPS standard from / between EHR systems.”*

WP2 and WP3 will develop interoperability assets and tools for the core and extended components of the patient summary standards, WP4 and WP6 will review the output, creating compelling demonstrations and proposing attractive pilot projects. In an effort to draw attention to the **quality and safety** of patient summaries expressed in international patient summary standards, Trillium-II will liaise with initiatives for developing appropriate metrics and will explore them in demonstrations to indicate their potential value and impact on improving patient safety and continuity of care, with efficient emergency diagnosis, reduced adverse drug events and reduced duplicate investigations.

**Security and Privacy** emphasis will be placed in the demonstrations, readiness exercise and pilot projects with particular attention to the context of use to trigger productive dialogue. Cooperation with the winning proposal under the DS-03 call will be sought. There will be vigilance as to the progress on the legal framework to enable the safe and secure global exchange of patient summaries in the IPS standard, starting with the EU/US privacy shield<sup>13</sup>. The *“organisational and security safeguards needed to underpin global exchange of patient summaries in the IPS standard between providers”* and *“the policies specifying the safeguards and measures needed to protect citizens in the cross-border exchange of patient summaries in the IPS standard including, but not limited to, identity management, access controls and audit trails”* are addressed in WP3.

Trillium-II will showcase the value of IPS standards in pilots and high visibility events: competitions, awards, testing, and global athletic events, as well as readiness exercise with selected use cases from health emergencies, travel, medical tourism, telehealth, epidemics, disasters, immigration, etc. In this way, it will be possible to identify the limitations of technical and semantic standards underlying pilot activities with concrete impact assessment strategies.

**Result:** Trillium II broke new ground with demonstrating how IPS standards could be part of the trusted infrastructure and training for humanitarian aid. This was achieved in Bucharest during the EUModex-Ro and in Saaremaa Island during EUModex-EE, where we tested in near real-life time the benefit of using the IPS. Particularly important was the exercise in Saaremaa, where some actors had an IPS on their phone and some did not, demonstrating clear benefits associated with the group that did have the IPS on their phones. The actors/victims were handing their patient summary to the EMT personnel, who were able to find additional information and make better clinical decisions about the management of the victims.



Trillium II project has followed OASIS PMRM methodology and ENISA ‘Privacy and Data Protection by Design’ guidelines and has examined several IPS exchange use cases (namely Unplanned care, Emergency and Disaster Management, and Chronic Disease Management) to provide guidance about the Security and Privacy Enhancing Technologies that need to be implemented by the implementers of the use cases in order to protect personally identifiable information of citizens in the light of the legal requirements derived from the EU General Data Protection Regulation (GDPR) and Health Insurance Portability and Accountability Act (HIPAA). This guidance is delivered as part of deliverable 3.6 Catalogue of Security and Privacy Controls and Methods for mitigating the security and privacy risks associated with use cases<sup>1</sup>. Part of this deliverable were published in ICIMTH2019 ([Gokce Banu Laleci Erturkmen, Ezelsu Simsek, Giorgio Cangioli, Catherine E. Chronaki: A Privacy Management Analysis \(PMA\) of Exchanging International Patient Summary](#). ICIMTH 2019: 19-22). The presentation was very well received, and people made sense of the old and new ways.

Trillium II Project has collaborated with H2020 Project Confido through joint partner MedCom and H2020-72730-SHIELD – European Security in Health Data Exchange Project, through T3.6 leader Dr. Gokce B. Laleci Erturkmen, who acted as the Advisory Board Member of Shield project. We have exchanged ideas and shared our approaches in the analysis of security and privacy of IPS use cases. Both consortiums have attended and contributed to the dedicated workshop about the GDPR and its impact on IPS organized by the CEN IPS project.

## 2.2 Achievements beyond State-of-the-art

Trillium II was able to carry out an ambitious program of supporting development and adoption of IPS standards, while looking into governance and alignment issues across SDOs. It succeeded to accelerate delivery of the HL7 FHIR standard aligned with the CEN IPS standards and eHDSI within 2 years, a year less than the time foreseen for a CEN standard.

Trillium II brought several innovative elements in its results. Some highlights are identified below:

- Configuration canvas for the patient summary component libraries has been identified by the innovation radar (see D2.2 Configuration Canvas for patient summary component libraries<sup>2</sup>).
- Open source tools, example and servers to test against has been very useful for developers of mHealth apps available in parallel to the standards development process.
- Development of a syllabus along with learning resources to directly engage educational institutions in teaching IPS standards, implementation, deployment in value added services.
- Direct engagement with user groups in a co-creation spirit, addressing also aspects of digital health service design.
- Engaged with the World Economic Forum linking patient summaries with clinical outcomes and value-based care.
- Initiated a structured dialog with the WHO integrated person centered care initiative and the associated safety network that identified patient summaries as the first step in the standardization of Electronic health data narrative for low income countries.

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<sup>1</sup> <https://trillium2.files.wordpress.com/2018/08/d3-6-v2018-03-26-catalogue-of-security-and-privacy-controls-and-methods-for-mitigating-the-security-and-privacy-risks-associated-with-use-cases-wp3-srdc.pdf>

<sup>2</sup> <https://trillium2.files.wordpress.com/2018/08/d2-2-v2017-10-13-configuration-canvas-for-patient-summary-component-libraries.pdf>



- Influenced the initiation of gap analysis studies between IPS, Argonaut (US) and eHDSI (Europe), which include impact assessment for adoption of the standard by member states.
- Introduced IPS standards in disaster medicine and opened the discussion of training emergency worker in EU module exercises, on how to use patient summaries.

### 3 Overall Assessment

#### 3.1 Methodology

Assessment of the results of the Trillium II project is divided into qualitative and quantitative results, i.e. what came out of the project based on the work performed by the project partners. The method for assessing qualitative results is often interpretive, where on the other hand it is measurable for quantitative results. That is not exclusively the case however, as quantifiable measures also exist for some of the qualitative results. Nevertheless, the qualitative results are mostly presented as the project’s own assessment and interpretation of the situation, whereas the quantitative results are assessed against pre-defined criteria such key performance indicators, milestones, deliverables etc.

#### 3.2 Qualitative Results

The qualitative results are categorised according to four overall themes:

1. Project Management and Coordination
2. Collaborations and Demonstrations
3. The Trillium II IPS Prize
4. EU/US dimension

##### 3.2.1 Project Management and Coordination

The focus of project management and coordination including project administration and scientific coordination, has been on achieving the objectives and assuring quality – in this case defined as the activities and processes performed to ensure that the efforts put in to the project and the results that came out are at the required quality level, fulfilling the obligations of the Grant Agreement, which outlines the objectives and tasks to be achieved.

The project management team, consisting of the administrative coordinator and scientific coordinator, comprised:

- ❖ MedCom, who performed the administrative and financial coordination of the project and were responsible for the daily management of the project.
- ❖ HL7 Foundation, who has been the scientific coordinator of the project with responsibility for operation and strategic direction of the project.

The collaboration has worked very successfully, and the roles were well assigned in terms of experience and expertise.

The project management and coordination efforts have consistently followed some principles and goals for ensuring progress and quality. These constitute:

Principle/goal	Method	Tools
Effective quality control	Monitoring progress and status of tasks and deliverables in respect to content and timing and ensuring quality in outputs	Project Handbook QA process



		Guidelines for financial reporting
Achieving the project objectives, incl. mitigation of risks	Applying a process-driven approach of a planning-performing-monitoring through the operation of the Project Executive Committee (PEC), which monthly plan the coming activities per WP and across WPs, carry out the actions agreed, follow-up on progress at the next meeting and check if the outcome has been achieved.	Risk log PEC meetings (monthly and fixed agenda) WP alignment meetings (virtual and f2f)
Effective communication internally	Timely and open dialogue with consortium members	Collaboration site (SharePoint) Meeting minutes Email groups Meetings (virtual and f2f)
Effective communication externally	Timely and open dialogue stakeholders, incl. EC	Website Emails Social media Events (conferences, workshops, webinars etc.)

*Table 1 Principles and goals for project coordination*

**We monitored progress and applied a quality assurance system.**

- ✓ A Project Handbook was produced from the project outset and contained all the practical information for beneficiaries and third parties in relation to the processes for the work ahead.
- ✓ The process was established for quality assurance including quality and ethical review and was well implemented and incorporated in the work processes of the consortium members.
- ✓ Approximately 75% of deliverables were delivered at the time planned. For the remaining, these were completed within 1-2 months after agreement with the EC. The deviations from the original time plan were attributed to tasks and deliverables taking additional time to complete due to the necessity to align with other tasks and deliverables and add further content, all in order to provide outputs (deliverables) of high quality and with content that reflect the current situation in the best possible manner.

**We managed to mitigate risks so that it remained possible to complete all the tasks we had identified where necessary to achieve the project objectives.**

- ✓ A risk register was used to log and maintain the risks. It was monitored by the Project Executive Committee. In each monthly meeting, the log was updated with respect to the status of each risk, its likelihood and impact, as well as the best mitigation strategies.
- ✓ Approximately half of the identified risks materialised throughout the project and were managed by putting in place the proper mitigation activity. None of the risks reached a stage that posed an overall risk for the project not to reach its objectives. In situations where either pre-identified risks or circumstances occurred that were not in advance identified as a risk, these were managed effectively by the consortium members and especially through the coordination in the Project Executive Committee.

**We ensured effective communication outside and inside the project by setting up proper mechanisms and channels.**



For internal communication:

- ✓ A SharePoint site for all beneficiaries and third parties contained all project information (templates, minutes, deliverables, contractual documents, dissemination material, dissemination activity log, risk log etc.).
- ✓ Project email groups were established and centrally managed, making it easy to communicate internally.
- ✓ Regular contact between beneficiaries and third parties took place through emails and meetings so that ongoing activities and priorities were clear to all.

For external communication:

- ✓ A public website, which contains general information about the project was our principal “shop window”. It also contained IPS learning resources, public material, incl. accepted deliverables and other material such as presentations, articles, brochures and also the HL7 FHIR IPS implementation guide developed by the project.
- ✓ For other communication activities, KPIs were identified to measure progress. The outcome is listed in section 3.3.4 and 3.3.5.
- ✓ The engagement with the European Commission through the Project Officers was constructive and valuable to the project’s advancement and achievements.

### 3.2.2 Collaborations and Demonstrations

For Trillium II, the foundation of our project and work has been to bridge and harmonize between existing European and US IPS projects and standards to the extent possible, to inspire and guide the implementation of HL7 FHIR IPS standard and to test and evaluate the IPS in a range of use case scenarios.

For this purpose, Trillium II has worked with five projects and organisations, where a Memorandum of Understanding was signed. This has enabled us to work with:

- European Medicine Field Hospital on disaster medicine
- The MOCHA project on policies for child health (focus on home-based records and vaccination);
- The C3Cloud project on using IPS to develop care plans for chronic diseases base on guidelines;
- The FrailSafe project on assessing frailty in the elderly
- The European Society of Hypertension on certifying apps for monitoring hypertension.

One of the main goals of Trillium II has been to test, pilot and demonstrate the applicability of IPS in different scenarios and ways. This has been possible through a range of different events such as:

- European Civil Protection Readiness Exercises (ModEX) (Romania, October 2018 and Saaremaa, Estonia, in April 2019), where we applied 5 scenarios:
  - Import /export from remote EHR into the Mobile Field Hospital Patient Record.
  - Patient mediated provision of patient summaries, using four different mobile health applications.
- Implementation and demonstration of two scenarios for vaccination at large events.
- Testing events and feasibility demonstrators, incl. Datathon, Connectathons and Hackathon.

As the visibility of Trillium II and IPS increased the number of initiatives that could use the IPS components increased. At the end of the project, an ecosystem approach building on learning communities i.e. IPS CoP appears essential for sustainability of the project.



### 3.2.3 The Trillium II Prize

The project launched the Trillium Prize competition for most innovative idea or use of the IPS standard in order to further promote the use of IPS, raise awareness and encourage innovation in the field.

Among nine finalists from Europe, Canada and Latin America, an international and independent jury ultimately selected two IPS initiatives as the winners, as they reflect the transformative power of the IPS in health and care, show how standards can serve as infrastructure to innovation both incremental building on existing solutions and disruptively challenging the status quo:

- ❖ Trifork (Denmark), which proposes to extend the nationally operational Danish Shared Medication Record service, funded by the Danish Health Data Authority to provide Danish citizens with their patient summary information when abroad.
- ❖ CAPABLE (Norway), which proposes to provide citizens a tool to empower them to active use of personal health information in the IPS to make healthy nutritional choices being mindful of food and medication combinations.

It is possible to read more about the winning initiatives here: <https://trillium2.eu/trillium-ii-prize/>

Information on all the finalists can be found here: <https://trillium2.eu/2019/06/10/the-trillium-ii-prize-finalists-and-award-ceremony/>

The Prize winners were announced at the HIMSS & Health 2.0 European Conference in June 2019 at a public ceremony and were interviewed for HIMSS TV.

### 3.2.4 EU/US dimension

An EU/US Memorandum of Understanding on Cooperation Surrounding Health Related Information and Communication Technologies was signed 2010 to: *“support an innovative collaborative community of public- and private-sector entities working toward developing, deploying, and using eHealth science & technology.”* This laid the foundation for the Trillium Bridge project, where the key recommendation was: *“to advance an international patient summary standard to enable people to access and share their health information for emergency or unplanned care anywhere and as needed. At a minimum the IPS should include immunization, allergies, medications, clinical problems, past operations and implants.”*

This recommendation and associated action plan have been guiding of the work the Trillium II project, enabling us to advance the use of IPS and to coordinate the cross-Atlantic IPS standardisation activities. In the FHIR Developer days organized in the Microsoft campus in Redmond, the topic of IPS received a lot of attention. Interest has been also registered by AIRA, the association of immunization registries in the United States. More information on this topics can be found in Deliverable 5.1.

## 3.3 Quantitative Results

The quantitative results are listed according to:

1. Deliverables
2. Milestones
3. Meetings
4. Publications
5. Other dissemination and outreach activities



### 3.3.1 Deliverables

The project has in total produced 30 deliverables, of which 27 are public reports and, thus, publicly available on the Trillium website: <https://trillium2.eu/deliverables/>.

Some deliverables are building on opportunistic data collection such as questionnaire, survey, interviews etc. for the purpose of gaining better insights on the actual use of patient summary like structures as well as potential new use cases. Please refer to paragraph 3.1.1 for methodological limitations.

Deliverable	Due delivery	Actual delivery	Dissemination level
<b>WP1 Management &amp; Administration, Communication and Liaison Activities</b>			
D1.1 Project Management Handbook	M3	M3	Confidential
D1.2 Report from Advisory Board and Steering Committee of GCDHIP	M30	M30	Confidential
D1.3 Communication and Visibility Plan	M3	M3	Public
<b>WP2 Assembling Interoperability Assets for Patient Summary Components</b>			
D2.1 Patient Summary services – gap analysis	M6	M6	Public
D2.2 Configuration canvas for patient summary components	M8	M8	Public
D2.3 Medications and Implantable Devices libraries: data sets, information structures, value sets, and tools	M12	M12	Public
D2.4 Vaccinations Library: data sets, information structures, value sets, and tools	M12	M12	Public
D2.5 Allergies and Intolerances Libraries: data sets, information structures, value sets, and tools	M12	M12	Public
D2.6 Problems and procedures Library: data sets, information structures, value sets, and tools	M12	M12	Public
D2.7 Patient Summary Implementation Guide	M24	M24	Public
<b>WP3 Extending the Scope beyond Emergency and Unplanned care</b>			
D3.1 Use case selection and analysis of patient summary use cases beyond emergency or unplanned care	M12	M13	Public
D3.2 Implementation libraries for the selected Patient Summary Use cases	M30	M30	Public
D3.3 Laboratory results library: data sets, information structures, value sets and tools	M14	M14	Public
D3.4 Implementation libraries for Encounter Reporting	M18	M18 M24	Public
D3.5 Imaging Results Library: data sets, information structures, value sets and tools	M16	M16	Public
D3.6 Catalogue of Security and Privacy Controls and Methods for mitigating the security and privacy risks associated with use cases	M15	M15	Public
<b>WP4 Context, role and adoption of the International Patient Summary in the Global Ecosystem</b>			
D4.1 Social value of IPS standards in United Nations Agency contexts	M21	M24	Public



D4.2 Impact, success factors, recommendations on the wide-scale adoption and use of an international patient summary standard	M21	M24	Public
D4.3 Education and training material for the international patient summary and associated standards in three languages	M24	M24	Public
<b>WP5 EU/US eHealth Interoperability Roadmap, Open innovation and International Patient Summary Standards Governance</b>			
D5.1 Recommendations for the EU/US eHealth interoperability roadmap - Open Innovation in digital Health: the case of the international patient summary	M26	M28	Public
D5.2 Towards an international patient summary standards Governance Framework: managing requirements, intelligence gathering, and updates	M26	M27	Public
<b>WP6 Making it Real: Engaging with the practice of Digital Health Innovation</b>			
D6.1 Report from Testing Events, Demonstrations, Pilot projects, and Readiness Exercise	M28	M31	Public
D6.2 Establishing the value case for the international patient summary: indicators and results	M30	M30	Public
<b>WP7 Dissemination, Market Outreach and Sustainability</b>			
D7.1 Stakeholder analysis and dissemination plan	M4	M4	Public
D7.2 Market outreach & patient summary implementation Prize	M20	M20	Public
D7.3 Patient Summary standards in Innovative procurement	M20	M22	Public
D7.4 Business modes for Patient Summary standards in mHealth apps	M24	M24	Public
D7.5 Outlook on licensing and deployment of information structures, tools, and associated value sets for patient summary components	M24	M24	Public
D7.6 Recommendations for a global community of digital health innovation practice	M29	M30	Public
<b>WP8 Ethics Requirements</b>			
D8.1 GEN – Requirement No. 3	M6	M6	Confidential

Table 2 List of Deliverables

### 3.3.2 Milestones

Milestones	Due date	Achieved by
MS1 Project Start	M1	M1
MS2 Trillium II live in social media and web	M3	M3
MS3 Stakeholder analysis and dissemination plan	M4	M4
MS4 Analysis of selected uses cases for patient summaries beyond emergency or unplanned care	M12	M13
MS5 Libraries for patient summary components, implementation guidance, business models	M14	M14
MS6 Laboratory Results libraries	M14	M14



MS7 First Periodic Report	M15	M15
MS8 Catalogue of security controls; imaging results library; encounter reporting use cases; Interoperability assets of extended use cases	M18	M18
MS9 Patient Summary interoperability Award	M20	M20
MS10 Formulation of the social value of international patient summary: educational strategy	M24	M24
MS11 Outlook on licensing trends for information structures and value sets	M24	M24
MS12 International Patient Summary Governance Framework	M26	M27
MS13 Completion Pilot projects and readiness exercise	M29	M30
MS14 Recommendations for a global community of digital health innovation practice	M29	M30
MS15 Second Periodic Report	M30	M30
MS16 Project End	M30	M30

Table 3 List of Milestones

### 3.3.3 Meetings

Meeting	Attendees	When	Method
Kick-off meeting	All partners	7-8 February 2017	F2f
PEC*	WP and Task leaders	Every 4 weeks - Jan '17 to Jun '19	Virtual
PEC*	WP and Task leaders	28-29 Nov '17	F2f
PEC*	WP and Task leaders	23 <sup>rd</sup> Nov '18	F2f
Advisory Board	WP leads and AB members	3 meetings in Feb '19	Virtual
WP1	WP members	Frequently, as needed	Virtual
WP2	WP members	= 48 (Feb '17-Jan '19)	Virtual, f2f
WP3	WP members	= 79 (Feb '17 - Mar '19)	Virtual, f2f
WP4	WP members	= 25 (Jan '17 - Dec '18)	Virtual
WP5	WP members	= 10 – (May '17 - Feb '19)	Virtual
WP6	WP members	= 25 (Mar '17 - Jul '19)	Virtual, f2f
WP7	WP members	= 14 (Jan '17 - May '19)	Virtual

\*Project Executive Committee

Table 4 List of Meetings

The number of meetings per WP reflect all meetings that have been registered. However, these meetings did not always include every WP member. One-on-one meetings between members of the consortium are also reflected in part, since communication to coordinate activities was frequently direct, impromptu, and thus unofficial.

Trillium II has been a complex project that required a lot of alignment and coordination between WPs and individual tasks. For that reason, in some cases there have been joint meetings particularly for WP2 and WP3.

Trillium II has found it beneficial to conduct very frequent meetings at both WP and Project Executive Committee (PEC) level in order to achieve quick progress and alignment in activities due to the high dependency of tasks in e.g. WP2, WP3, and WP6. We have, therefore, found it unnecessary to conduct frequent f2f consortium meetings as the interaction between project beneficiaries.



## 3.3.4 Publications

KPI	Goal	Realisation
<b>Publication in academic journals</b>	3	<ol style="list-style-type: none"> <li>1. Carina Dantas, Valentina Tageo, Catherine Chronaki, Charles Lowe, Alexander Berler: A review of successful initiatives and models on Patient Summary standards in mHealth apps, Volume 8, Edition 2 – August 2019, Journal of Aging and Innovation, <a href="http://journalofagingandinnovation.org/">http://journalofagingandinnovation.org/</a></li> <li>2. Michael J Rigby, Catherine E Chronaki, Shalmali S Deshpande, Peter Altorjai, Maria Brenner, Mitch E Blair, European Union initiatives in child immunization—the need for child centricity, e-health and holistic delivery, <i>European Journal of Public Health</i>, ckz199 <a href="https://academic.oup.com/eurpub/advance-article/doi/10.1093/eurpub/ckz199/5603534?guestAccessKey=585ce3fb-b840-4a8a-b2ea-eeae8a247e11">https://academic.oup.com/eurpub/advance-article/doi/10.1093/eurpub/ckz199/5603534?guestAccessKey=585ce3fb-b840-4a8a-b2ea-eeae8a247e11</a></li> <li>3. Valentina Tageo, Carina Dantas, Catherine E Chronaki, Charles Lowe, Alexander Berler, Federica Porcu: Business model canvas for adoption of International Patient Summary standards in mHealth industry (submitted for publication)</li> </ol>
<b>Scientific Publications</b>	2 papers in pubmed indexed conferences	<p>Published conference papers – full paper reviewed: 5</p> <ol style="list-style-type: none"> <li>1. Gokce Banu Laleci Erturkmen, Ezelsu Simsek, Giorgio Canglioli, Catherine E. Chronaki: A Privacy Management Analysis (PMA) of Exchanging International Patient Summary. ICIMTH 2019: 19-22</li> <li>2. Robert A. Stegwee, Hans Gille, Catherine E. Chronaki: IPS Governance Framework: Current Practices in Specification Use and Updates. ICIMTH 2019: 202-205</li> <li>3. Aikaterini Kolokathi, Arie Hasman, Catherine E. Chronaki, Inge Madsen, Anne Moen, Rebecca Randell, John Mantas: Education in Biomedical and Health Informatics: A European Perspective. MedInfo 2019: 1951-1952 2018</li> <li>4. Kai U. Heitmann, Giorgio Canglioli, Marcello Melgara, Catherine E. Chronaki: Interoperability Assets for Patient Summary Components: A Gap Analysis. MIE 2018: 700-704, 2017</li> <li>5. Catherine E. Chronaki, Robert A. Stegwee, Anne Moen: In Search of a Digital Health Compass to Navigate the Health System. MedInfo 2017: 30-34, 2016</li> </ol>
<b>Press release</b>	1-2 every year	<p>5 (2-3 per year)</p> <ol style="list-style-type: none"> <li>1. Compete for the Trillium-II prize, October 19, 2018, <a href="https://ec.europa.eu/digital-single-market/en/news/compete-trillium-ii-prize">https://ec.europa.eu/digital-single-market/en/news/compete-trillium-ii-prize</a></li> <li>2. Trillium II - Using the international patient summary in a disaster situation, November 9, 2018, <a href="https://ec.europa.eu/digital-single-market/en/news/trillium-ii-using-international-patient-summary-disaster-situation">https://ec.europa.eu/digital-single-market/en/news/trillium-ii-using-international-patient-summary-disaster-situation</a></li> <li>3. Congratulations to the Trillium II Prize Award Winners, June 12, 2019, <a href="https://ec.europa.eu/digital-single-market/en/news/congratulations-trillium-ii-prize-award-winners">https://ec.europa.eu/digital-single-market/en/news/congratulations-trillium-ii-prize-award-winners</a></li> </ol>



		<p>4. IPS Global Community of Practice for Digital Health Innovation, June 12, 2019</p> <p>5. <a href="https://www.himsseuropeconference.eu/helsinki/2019/news/ips-global-community-practice-digital-health-innovation">https://www.himsseuropeconference.eu/helsinki/2019/news/ips-global-community-practice-digital-health-innovation</a></p>
<b>Newsletter</b>	No target identified	<p>&gt;8</p> <p>HL7 Europe Newsletter, 2019 <a href="http://www.hl7.eu/download/eun-09-2019.pdf">http://www.hl7.eu/download/eun-09-2019.pdf</a></p> <p>HL7 Europe Newsletter 2018, <a href="http://www.hl7.eu/download/eun-08-2018.pdf">http://www.hl7.eu/download/eun-08-2018.pdf</a></p> <p>HL7 Europe Newsletter 2017 <a href="http://www.hl7.eu/download/eun-07-2017.pdf">http://www.hl7.eu/download/eun-07-2017.pdf</a></p> <p>HL7 international news Jan 2019 <a href="http://www.hl7.org/documentcenter/public_temp_7456A81C-1C23-BA17-0C654588C82DD1C9/newsletters/HL7_NEWS_20190114.pdf">http://www.hl7.org/documentcenter/public_temp_7456A81C-1C23-BA17-0C654588C82DD1C9/newsletters/HL7_NEWS_20190114.pdf</a></p> <p>HL7 International news May 2017 <a href="http://www.hl7.org/documentcenter/public_temp_7456A81C-1C23-BA17-0C654588C82DD1C9/newsletters/HL7_NEWS_20170505.pdf">http://www.hl7.org/documentcenter/public_temp_7456A81C-1C23-BA17-0C654588C82DD1C9/newsletters/HL7_NEWS_20170505.pdf</a></p>
<b>Poster</b>	No target identified	<p>Total: 3</p> <p>eHealth Portugal 2018; Digital Agenda 2018; IHE Connectathon 2019;</p>

Table 5 List of Publications

### 3.3.5 Other dissemination and communication activities

The dissemination and outreach activities carried out in the Trillium II Project are listed according to the key performance indicators (KPI) that the project established to reach the identified stakeholders.

The list excludes publications, which are listed above in 3.3.4.

KPI	Goal	Realisation
<b>New website story</b>	1 every month	On average 3 posts per month.
<b>Target website users</b>	250 views per month	On average 371 views per month
<b>LinkedIn Group</b>	200 members	118
<b>Twitter followers</b>	150 followers	154
<b>Tweets</b>	100 per year	434
<b>Ambassadors</b>	3 ambassadors	3 Ambassadors
<b>Project partnerships</b>	2 partnerships	5 partnerships
<b>Professional societies</b>	2 agreements	2 agreements
<b>Global IPS Community of Practice</b>	1000 members outreach	>1000
<b>Presentations</b>	10 per year	+10 per year
<b>Opinion Editorials/ Blog posts</b>	2 per year	6 in total
<b>Webinars</b>	2 webinars	2
<b>Workshops</b>	3 workshops	17

Table 6 List of Dissemination KPI

In addition to the KPI targets, Trillium II conducted a range of other activities that again help reach the diverse group of stakeholders that are important to reach the project's objectives.



Activities	Realisation
<b>Invited Presentations in Conferences*</b> <small>*this does not include all events in which Trillium II has presented, but where the project has been specifically invited by the organisers to give a presentation</small>	15
<b>Awards</b>	3
<b>Testing Events</b>	4
<b>Disaster Exercises</b>	2
<b>Validated IPS Use cases</b>	4
<b>Tutorials / Masterclass</b>	3
<b>SlideShare</b>	1 <sup>3</sup>
<b>TV interview</b>	1

*Table 7 List of Other Dissemination Activities*

### 3.3.6 Impact

As previously discussed, Trillium II adopted a network of networks approach to raising awareness of IPS standards. Trillium II partner organisations have engaged in extensive outreach activities which have been partly captured by the KPIs above. Partner activities promote the project either generally or more frequently in relation to specific outcomes and events that related to the priorities of the specific partner. Therefore, the channels as presented above, e.g. website, newsletters, social media, events etc, only some of the media engaged, since Trillium II has been promoted through the project partner organisations’ own channels and media and in their name. This brings the amount and outreach of the dissemination activities to a much higher level. An indication of the impact achieved can be witnessed by searching “Trillium patient summaries” in google.

The total number of attendees, subscribers, followers etc. to whom project results has been disseminated at various events and conferences through social media, newsletters and websites etc. by the Trillium II consortium members can be estimated at >38,000 people. This number covers an international audience including North and South America, Asia, Europe and the Middle East. Potentially, the number is even bigger if the networks of our project partners are taken into account, but this figure cannot be easily estimated. That is not to say that Trillium II has reached all these people directly. However, the number of subscribers and followers that can be reached in social media is high. This complements a conference where it is unlikely that a presentation will reach the full list of attendees unless it is a keynote speech. Some partners have very strong social media presence and large group of followers. The events on the other hand often target a very specific group of people that represent Trillium II’s stakeholders. In combination, the outreach activities combining social media and conference presentation reach a high number of people but also the “right” people.

What is not directly evident from the total number of people reached through our dissemination activities, is the more specific IPS community we have collaborated and engaged with in the America (North and South), Africa, Australia, Asia Pacific, and China. With the number of workshops, bootcamps etc. that Trillium II has either organized or participated in, the interaction with those developing the IPS directly or through partner networks is quite high. Counting just key events such as Datathons, Hackathons, and Connectathons etc. the number is close to 800 people from that community. If we consider, the outreach activities referring to the IPS Global CoP and urging groups to build their own local CoPs, then the audience is much broader reaching out more than 5500 people.

<sup>3</sup> <https://www.slideshare.net/TrilliumIIHorizon>



## 4 Next steps – suggested activities beyond the project

Trillium II has been true to the spirit of a Support and Coordination Action. Although, use of patient summaries is not yet part of the daily practice of medicine, self-care, or health monitoring, Trillium II engaged in developing scenarios, which matched stakeholder needs to the IPS standard and its components, highlighting the importance of structured data and coded information in the process of continually improving interoperability standards. Trillium II has throughout its lifetime carried out an open engagement process in Europe, the United States and beyond, which has laid the foundation for the establishment of a worldwide IPS CoP. As described in the objectives, the Global IPS CoP is the culmination of 30 months' work of supporting standardization in Europe, Asia, Americas, and Australia, liaising with potential users of the IPS, developing training material to accelerate implementation of IPS standards, and providing feedback from users.

At the time of this writing, the number of patient summaries exchanged in the European cross-border setting is limited. We do think that this situation is bound to change. Multiple projects and initiatives are contributing to the AI initiatives to support the EU Cancer mission, the pledge of Genomics, and last but not least, further development, refinement, and adoption of the EEHRxF.

Moving forward, more systematic efforts are needed. In the course of the Trillium II project, our search for evidence was not easy. Looking at the patient summary as a window to a person's health information, has been ahead of what is supported by current IPS standards. However, it does establish a mission, a digital health compass, to engage in iterative cycles of co-creation, governance, and alignment. Looking at the IPS standards aligned across HL7 CDA (clinical document paradigm) and HL7 FHIR (IPS components as a collection of FHIR resources) helps engage across the three pillars of the EC communication on the transformation of health and care. Already, a number of projects benefit from the Trillium II work: (a) FAIR4Health on creating high value data sets based on the FAIR principles using HL7 FHIR resources including those developed in Trillium II; (b) UNICOM looking to update the HL7 FHIR IPS resources to incrementally incorporate elements of the ISO IDMP standard in the IPS medication component; (c) Digital Health Europe, looking again at high value data sets from the perspective of integrated care – how does the IPS support typical lifestyle scenarios in integrated care, how does it improve care, clinical outcomes, empowerment; (d) mHealthHub, developing assessment criteria and policies for mobile health across Europe; (e) Gatekeeper investigating the role of patient summaries in IoT scenarios; (f) HSMonitor, which is a PCP procurement action for hypertension monitoring, (g) European vaccination card; (h) PAN CARE/SIOPE on SurPass the survivor passport of childhood cancer survivors; (i) RDCODE for better coding of Rare Diseases also in the IPS, and many more.

This extensive list illustrates that IPS standards are becoming part of the eHealth ecosystem, and there is increasing need to deliver robust tools and data sets for implementation of IPS. Horizontal activities are also needed to support these and many more project that can benefit from high-quality patient summary data:

- (a) Education, training and mentoring
- (b) Improved open source tools and data
- (c) Synthetic data for researchers and developers to experiment
- (d) Cross-SDO alignment and information sharing, e.g. CDISC and HL7 FHIR IPS in iterative cycles of IPS standards improvement and refinement.
- (e) Monitoring and evaluation services that follow implementation and use of patient summaries.

Educational networks and other stakeholders including NCPs for eHealth may support Massive Open Online Course (MOOC) or a portfolio of educational resources so that no health professional or citizen is left behind



unable to ripe the benefits of value added services that use the patient summary. The European Federation for Medical Informatics may have an important role to play in this space targeting continuing education.

A synthetic mass of IPS data that simulates the population structure of an area in Europe would help illustrate in virtual space the value of IPS data across the community tackling organizational, semantic, and legal interoperability issues.

Different projects and funding streams can contribute to these actions to support local activities and at the same time align at regional, national, European, or global level. Critical lever in this effort is the global IPS CoP which will be the sustainability mechanism to follow Trillium II bringing together interoperability standards, workforce development, and innovative ecosystems, while at the same time building capacity on CDA on FHIR and HL7 FHIR IPS, and the EEHRxF.

Additional potential/future areas of adoption beyond development and adoption of the EEHRxF are:

- Specific tenders related to interoperability published by the European Commission
- Transatlantic secure access to trustworthy health information
- Risk management of access to patient summaries in different settings
- Design of the next generation health services (online/offline)
- Linking patient summaries to clinical and patient reported outcomes
- Monitoring the quality of information in IPS for new domains
- Capacity building for patient summaries in clinical practice
- Evaluation by design of patient summary initiatives
- Initiatives linking Clinical Decision Support to IPS
- Support of FAIR data sets, using HL7 FHIR interfaces to access data
- Regulatory support to deployment of IPS apps in view of the Medical Device Directive.

Trillium II activities and achievements pave the way towards a global IPS CoP that fosters the practice of digital health innovation with robust and widely used interoperability standards and supporting tools for implementation, education, evaluation and monitoring. This global IPS CoP is central to building capacity in interprofessional education and leading the transformation of health and care with trust, quality, and safety as the overarching principles underpinned by broad adoption of IPS standards. Trillium II recognises that interprofessional education is key, along with shifting our mentality from data exchange to data sharing and making decisions asking the patient, to use reliable high-quality interoperable data. This may require a profound change in culture but is at the same time key to the transformation of health and care to benefit from digitization and the emerging data economy.

## 5 Conclusions

The overall aim of Trillium II was to progress on the recommendations of the predecessor project Trillium Bridge as reflected in the EU/US MoU action plan and to “advance an International Patient Summary standard to enable people to access and share their health information for emergency or unplanned care anywhere and as needed starting with immunizations, allergies, medications, clinical problems, past operations and implants.” To achieve this objective, Trillium II has bridged, harmonized, evaluated existing patient summary initiatives and guided emerging ones in order to lead the way toward one IPS standard by establishing a global community fostering the practice of digital health innovation with robust widely used interoperability standards and joint pilots.



Trillium II identified seven objectives that it would spend 2.5 years working together towards: the partnership of 25 organisations from Europe and US has been strong enough in its composition and experience to achieve the following results:

- ✓ We have established a Global Community for Digital Health Innovation Practice (GC-DHIP), now renamed to Global IPS Community of Practice.
- ✓ We have highlighted the social value of the International Patient Summary Standards through our work and collaborations.
- ✓ We have bridged patient summary initiatives and provide feedback to SDOs.
- ✓ We have contributed to International Patient Summary Standards Governance under the JIC.
- ✓ We have developed, collected and assessed learning resources for the IPS standards.
- ✓ Developed an evaluation framework for the adoption of IPS standards
- ✓ Delivered a syllabus and learning objectives for an IPS module addressing health professional associations and patient advocacy groups, without forgetting citizens, patients, and their families.
- ✓ We have engaged mobile health companies and app developers with IPS standards, and this work has to continue building further moment, perhaps in collaboration with projects as InteropEHR and Smart Health to select two.
- ✓ We have fostered innovation & informed health policy sharing patient summaries in various settings.

Trillium II operated in a dynamic environment strongly dependent on external factors, activities, and time plans of bigger initiatives such as eHDSI or Argonaut (US Core). However, ultimately the Trillium II project has succeeded in delivering beyond the initial KPIs. Trillium has succeeded in making the patient summary feel real: assess and use of the IPS has been tested and validated in a range of settings and scenarios in close collaboration with relevant projects and organisations. The next goal is to make the Global IPS CoP sustainable so that Trillium II's work and results develop further and we build the human capacity needed to engage and work together with people, organisations and communities to advance the IPS standards, building learning health systems and communities for the benefit of citizens and patient across the world.