

Synopsis report on the public stakeholder consultation on next phase of EU-US cooperation in eHealth/Health IT

The European Commission's DG Communications, Networks, Content and Technology (CONNECT) and the United States Department of Health and Human Services (HHS) have jointly updated an eHealth/Health IT Memorandum of Understanding (MoU) Roadmap that guides European and US cooperation on eHealth (also called Health Information Technologies/Health IT). The public consultation on the review of this new roadmap took place from 22 December 2015 to 15 March 2016 on both side of the Atlantic. This report takes stock of the contributions and trends that emerge from them, focusing primarily on the quantitative analysis of the responses.

Background and objectives of the consultation

In December 2010, the US Department of Health and Human Services (HHS) and the European Commission's DG CONNECT, signed a [Memorandum of Understanding \(MoU\)](#) on Cooperation surrounding eHealth/Health IT. The MoU was signed to demonstrate our shared dedication to strengthen transatlantic cooperation in eHealth/Health IT.

In the Spring of 2013, DG CONNECT and HHS published a [first Roadmap of specific MoU actions](#). Since then, this Roadmap has guided our activities focusing on two priority areas (work-streams):

1. Standards development to foster the uptake of internationally recognized standards supporting transnational interoperability of electronic health information and communication technology, and
2. Workforce skills to develop and expand the Health IT workforce in Europe and the US.

At the end of 2015, DG CONNECT and the US HHS agreed to add a third priority area: 'Transatlantic eHealth/Health IT Innovation Ecosystems'.

This work-stream aims at encouraging innovation in the eHealth/Health IT industry and ensuring linkages to the other two Roadmap work-streams. This was described in the draft roadmap that was the subject of this consultation.

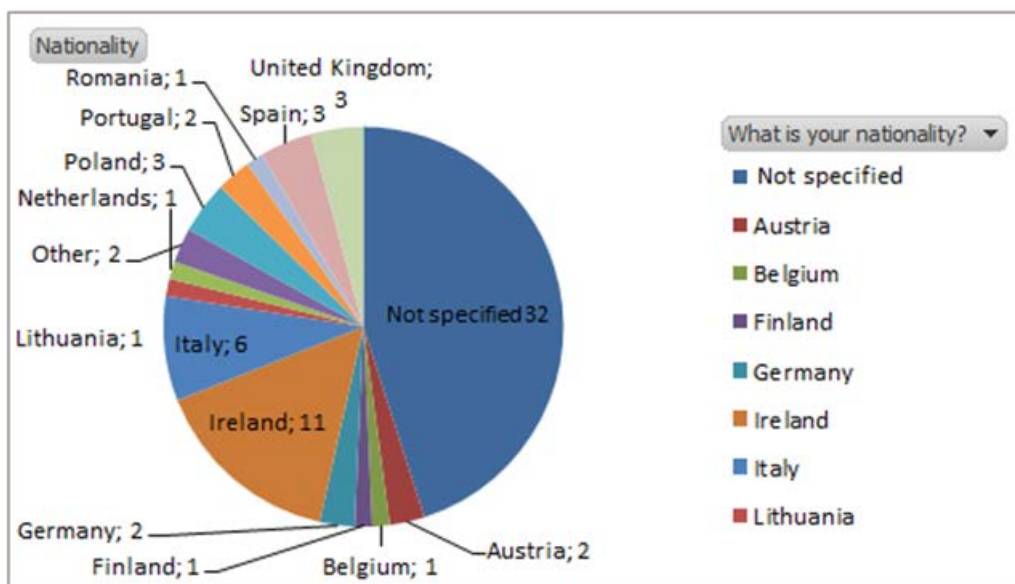
The overall objective of the draft updated MoU Roadmap document was to set out the new vision, the main challenges, the scope and description of each of the work-streams. Its updated Annex contains the specific actions and outcomes/deliverables with their corresponding milestones and due dates for each work-stream. The Roadmap activities overall will cover a longer period of time.

This consultation aimed at gathering comments and inputs to help finalise and validate the update of the Roadmap and its Annex.

Summary of EU contributions

Who replied to the consultation?

The consultation held in the EU gathered 71 replies from stakeholders. The participation per country is represented below:



Replies to the public consultation

The consultation covered three topics relevant to the Roadmap:

1. The International Interoperability Work-stream;
2. The eHealth/Health IT Workforce Development Work-stream;
3. The Transatlantic eHealth/Health IT Innovation Ecosystems Work-stream.

The next chapters objectively describe the replies per work-stream.

1. International Interoperability work-stream

Description of the work-stream:

Standards and profile developing organisations and eHealth/Health IT stakeholders should collaborate on the following items to enable a standardised international patient summary (IPS) to be in use by 2020.

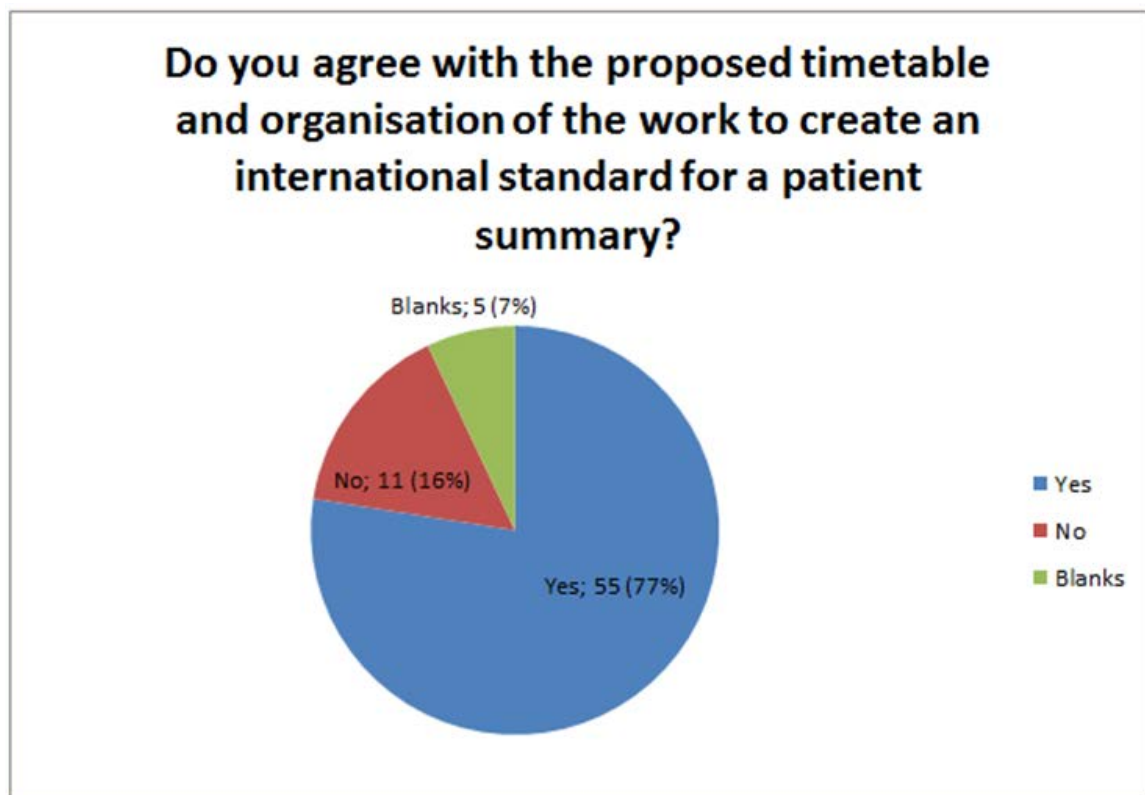
The key activities include:

1. Develop and publish an IPS 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;

2. 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 as new requirements are identified/implemented (e.g. legislation/regulation and learning from the IPS's use);
3. Target the IPS as the means for sharing a core set of clinical data for the purpose of emergency or unplanned international 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;
4. Work with producers of multi-national terminology systems to publish reliable and quality assured translations of patient summary value sets between relevant languages and cross-mappings between terminology systems; and continue collaboration on eHealth/Health IT standards work in other areas.

The part of the public consultation focussing on the first work-stream consisted of 4 questions. The results are outlined below.

- i. *Do you agree with the proposed timetable and organisation of the work to create an international standard for a patient summary?*



The vast majority of respondents defended the view that the proposed timetable and organisation of the work was adequate to create an international standard for a patient summary.

- ii. *Are there areas of technical standards work missing that would be important to the success of the international patient summary record work?*

The majority of the respondents considered that there was a need for a harmonised use of clinical terms and models. Some technical standards and terminology services should be made more easily available.

A broader adoption of existing standards along with the mapping between their deployment specifications and usages were also seen as key factors for success. The most commonly mentioned standards and terminologies were HL7, FHIR, SNOMED, IDMP, DICOM and IHE specifications. Some stakeholders mentioned e-identification and security as other key success factors.

iii. What are the best use cases for the International Patient Summary to address at a global scale (e.g., emergency, disaster, migration, tourism)?

The use cases formulated in the consultation were seen as relevant. In order of preference, the respondents suggested the following use cases: (a) Tourism, (b) Emergency, (c) Migration and then (d) Disaster. Some spontaneous use cases were also mentioned, such as short-term occupational re-deployment (e.g. for business reasons or students) or planned trans-border healthcare (e.g. for patients seeking for services offered in other countries). Other use cases included population health, with ideas related to global cohorts of patients for global clinical trials.

iv. What specific privacy and security requirements or practices could improve and allow for the exchange of health data for the purposes of clinical care across borders?

Most respondents considered that the security requirements needed to be strengthened, with systemic end-to-end security mechanisms (e.g. encryption, eID,...) to ensure confidentiality, integrity and liability while exchanging patient summaries. Legal agreements and policies would need also to be further investigated for supporting care across countries.

Although the EU General Data Protection Regulation and the Privacy Shield were seen as having a substantial impact on international data flows between both geographic areas, particular attention should be paid to health-related data.

Other suggestions to improve and allow cross-border exchange of health data included the need for an additional action to deliver data privacy and security training materials for all stakeholders involved.

2. Roadmap work-stream: IT Workforce Development

Description of the work-stream:

1. Continue to engage with EU and US eHealth/Health IT professionals and organizations to address eHealth/Health IT workforce needs and concerns;
2. Continue collaboration among US and EU stakeholders on issues and concerns surrounding the EU and US eHealth/Health IT workforce; and
3. Promote development of a global workforce professionally prepared to deploy eHealth/Health IT systems, including international use of jointly developed EU-US tools such as the Health IT Competencies platform (HITCOMP).

Roadmap action: Consult with qualified US and EU stakeholders to determine the skills and competencies required by each role in each setting, at each level of responsibility.

- i. Question 5: Which health IT competencies and other skills are important for the development of the following healthcare workers?*

Below are listed the main areas of eHealth/health IT competencies for each of the categories of healthcare workers:

a) Clinical practitioners (doctors, nurses, etc):

Many respondents highlighted the importance of having a good understanding of interoperability and standards for clinical practitioners.

Basic IT skills to ensure the best use of eHealth solutions, along with the ability to use coding systems were considered to be important competencies for clinical practitioners as well.

Several also thought that knowledge of healthcare workflows, medical device connectivity, data protection laws and data governance, and cyber security is important.

The effective use of the HITCOMP work tool, cloud computing, analytics, bioinformatics and genomics skills were also mentioned.

b) Health Informatics professionals:

25% of the survey respondents highlighted the importance of a good knowledge of interoperability standards for health informatics professionals.

Likewise, many indicated the importance of knowing the clinical practice workflows and process, along with the understanding of the user's needs.

Several respondents indicated the importance of knowledge of data protection laws, data encryption and cyber security(including Internet of Things, IoT), and the effective use of the HITCOMP work tool.

The mapping of terminology systems, health technology assessment, data governance, integration management, big data and data mining skills were also mentioned.

c) Non-clinical and administrative staff:

Many respondents were of the opinion that non-clinical and administrative staff in the healthcare workforce need to have basic IT skills to make the best use of eHealth solutions, and the ability to ensure the accuracy and the integrity of the data.

A sufficient level of knowledge of data protection laws and cyber security was mentioned by several respondents.

The HITCOMP work tool, coding basics and interoperability standards were also mentioned.

d) IT professionals coming to work in the healthcare environment:

For IT professionals coming into the healthcare sector, many respondents considered that having a good understanding of healthcare practice and workflows, and of the organisation of the healthcare delivery were essential, along with an understanding of the real needs of patients and healthcare providers, in which case interpersonal and communication skills are considered to be very important.

Several respondents highlighted the following areas as very important: ethical research protocols, interoperability standards, medical terminology and fundamentals, data protection laws, data encryption and cyber security (including IoT).

Software engineering, 3D image processing and other hard skills in software engineering were also mentioned.

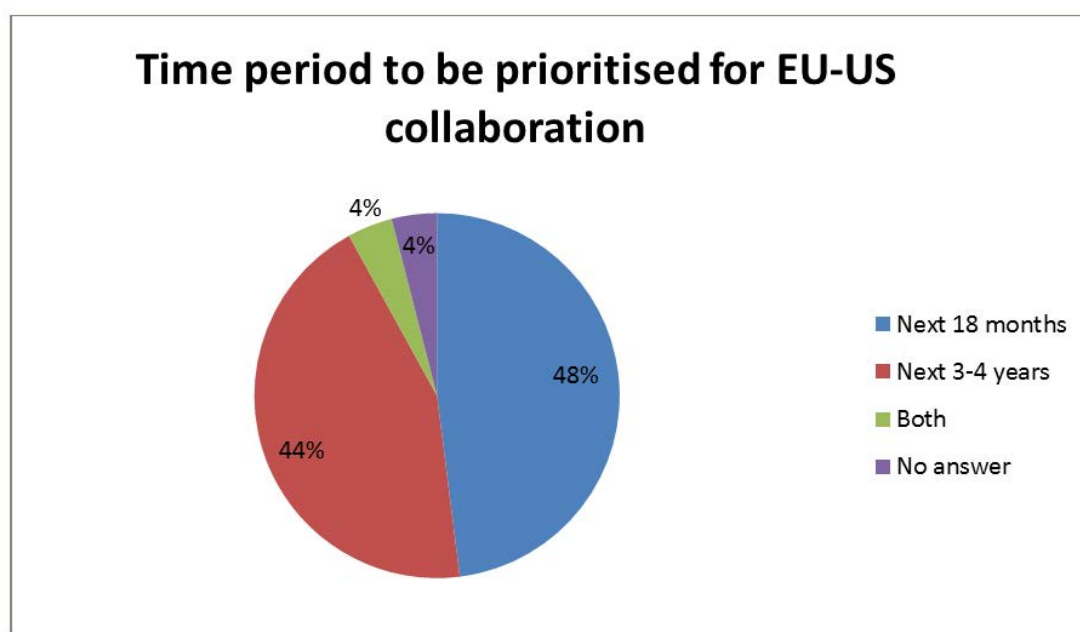
3. Roadmap work-stream: Innovation Ecosystems (for eHealth/Health IT)

Description of the work-stream:

1. The US HHS and DG CONNECT will collaborate and work together to encourage innovation in the eHealth/Health IT industry and ensure linkages to other Roadmap work-streams.
2. Key elements of this collaboration could include, but are not be limited to:
 - Identifying key EU and US stakeholders and enlisting their support;
 - Regularly take stock of the latest trends and developments in eHealth/Health IT (e.g. the growing importance of mobile Health including software and apps);
 - Building transatlantic partnerships and alliances between EU regions/cities and US States/cities that are interested in solving similar/related eHealth/Health IT challenges; and
 - Recognition of complementary EU and US strengths and business/trade opportunities (and working out how to best emphasize them in a collaborative manner).

Roadmap action: Establish an EU-US working group to identify priority areas for collaboration (in innovation ecosystems for eHealth/Health IT).

- i. *Question 6: Do you consider the next 18 months to be a higher priority for collaboration among the EU and US or the next 3 to 4 years?*



The opinions were more or less evenly divided on this: 48% of respondents considered that the next 18 months was a priority for collaboration among the EU and US and 44% thought the collaboration on this work-stream should cover a period of three to four years.

- ii. *Question 7: Which EU and US regions and cities do you consider likely candidates for building transatlantic innovation ecosystems partnerships over the next 12 to 18 months?*

States, regions and cities suggested by respondents as candidates for collaborating on innovation ecosystems included:

<i>EU Regions / Cities</i>	<i>US Regions / Cities</i>
Austria	Arizona
Belgium (Brussels)	Boston
Netherlands (Holland region, Rotterdam, Amsterdam)	California
Bulgaria	Cambridge (Massachusetts)
Denmark	Chicago
Estonia (Tallinn)	Dallas
Finland	Emory
Geneva	Minnesota
Germany (Bavaria, Frankfurt, Hamburg, North Rhine-Westphalia, Nürnberg-Erlangen, Oldenburg)	New England
Ireland (Cork, Dublin)	New York (City and State)
Italy	Pennsylvania
Latvia	Salt Lake City
Lithuania	Seattle
Norway	Stanford
Poland (Ciechocinek, Kujawsko-Pomorskie)	Washington DC
Portugal	Washington (State)
Slovenia	
Spain (Andalusia, Barcelona)	
Sweden	
UK (London, North-West, North-East, Northern Ireland, Scotland, Inverness, Wales, South-West England)	

A reply that was often noted was to start with those places that already invested in digital strategies and are more advanced in terms of information systems and interoperability standards, to demonstrate results and check difficulties in the short run. Some referred especially to the countries that already have experience in cross-border eHealth data sharing by participating in the [epSOS](#) and [Trillium Bridge](#) projects and are therefore thought to be equipped for swift action.

People also suggested the further use of existing alliances such as the TransAtlantic Business Council, the Global Health Workforce Council, TIGER, academia such as the research triangle Brussels, Amsterdam, Cork, as well as other organisations for getting further buy-in and cooperation in building, maintaining and supporting eHealth innovation ecosystems and partnerships.

Summary of US contributions

A US-organized consultation also took place in parallel with the EU consultation. It received 13 replies which contained a number of comments on the draft EU-US Roadmap. For the most part, the comments stated that the timeline under the Roadmap is too ambitious. A suggestion was for a more realistic timeline of three or more years to ensure the success of the Roadmap and to create short-term goals (with a timeline of 18-24 months).

In addition, the respondents stated that it was necessary to evaluate, align to and perhaps defer to standards work or standards bodies that have made progress in the international patient summary.

Another area that respondents provided feedback to concerned patient generated health data, mobile health capabilities and medical device data and suggested that these be included in the Roadmap. A number of respondents felt that harmonizing existing standards is necessary and could address many goals of the Roadmap, and that there is no need for additional standards. They believe there are many projects working to solve this issue, and these respondents stressed the need to collaborate and to harmonize what already exists. Moreover, the use cases must be tightly constrained and focused to ensure success.

An additional area of concern for respondents is around patient matching. Patient matching needs to be addressed for both privacy and security and reliability of the data. Overall, the topic of security and privacy is of great concern to respondents.

Patient consent and privacy needs to be addressed both technically (standards exist in both the EU and US) and with policy – the positioning of patient privacy and security will be critical for large-scale adoption.

Respondents seemed to agree that work in this area should include an analysis of existing privacy and consent standards.

There are certain regions in both the US and the EU (Northeast Europe and certain metropolitan areas in the US) that have advanced health IT capabilities, and fostering efforts among these systems should be encouraged.

Finally, the Roadmap work should be leveraged more globally so that healthcare issues such as the Syrian migration, Ebola and Zika could be used as test cases for higher priority collaboration.

With respect to the Innovation Ecosystem question, the United States Department of Health and Human Services received numerous suggestions of various US/EU regions and cities. These recommendations were based on a wide variety of reasoning, ranging from identifying those regions with “sufficient technical infrastructure, expertise, and financial resources to ensure completion of a project, and thus demonstration of its use,” to highlighting those communities with “more progressive” use of “e/tele-health for chronic disease management.” Also suggested, were regions whose “National Health Strategy is closely aligned both with the US Federal Health IT Strategy and the European Digital Agenda,” and where “there is a

tradition of collaboration with the US, NATO, and "Eastern EU-member countries" (i.e. Romania).

Selecting regions and cities based on the sufficient level of necessary diverse stakeholder engagement was also a consistent theme. In addition, a suggestion was made that "prior to identifying potential candidates for building transatlantic innovation ecosystem partnerships," research should be conducted to identify the various interoperability pilot projects that have been initiated across the US and Europe, "in order to leverage the documented work, learnings, failures, and successes of these projects."

Please see below for a full listing of EU/US Regions and Cities that have been recommended by US respondents to include in the exploration of transatlantic partnerships around eHealth/Health IT Innovation Ecosystems.

Regions / Cities Identified Through the Transatlantic eHealth MOU's Roadmap Consultation	
US Regions / Cities	EU Regions / Cities
Atlanta, GA	Austria
Boston, MA (Partners Health)	Cambridge, UK
Chicago, IL	Germany
Denver, CO	Karelian Region, Finland
Houston, TX & Dallas, Texas (UTSW, Parkland & Children's)	Munich, Germany
Los Angeles, CA	Northeast Europe (i.e. Sweden, Norway, Finland)
Madison, Wisconsin	Scotland
Maui, HI	Southern Norway
Minneapolis, MN (UHS test lab)	Spain (i.e. Catalunya, Galicia, or Aragon)
New York City, NY	Switzerland
Orlando, FL	Syddanmark, Denmark
Puget Sound, WA	Trikala, Greece
San Francisco, CA	Western European Countries
Washington, DC	

Next steps

The consultation results have shown that the foreseen roadmap activities have been widely supported by the stakeholders. European Commission and the United States Department of Health and Human Services will now implement these actions. In particular:

- As part of the Interoperability work-stream, the EU and the US will collaborate for the development of an International Patient summary taking into account the various governance challenges;
- As part of the IT Workforce Skills work-stream, the EU and the US will continue to engage with EU and US eHealth/Health IT professionals and organizations to address eHealth/Health IT workforce needs and concerns;
- As part of the new Innovation Ecosystem work-stream, the EU and the US will collaborate and work together to encourage innovation in the eHealth/Health IT industry and ensure linkages to the other Roadmap work-streams. Wherever possible, identified states, regions and/or cities suggested by the respondents will be taken into account.

The Annex to the Roadmap outlines the main activities to be undertaken in the next 18 months.

[Link to EU Stakeholder Consultation page](#)

[Link to US Stakeholder Consultation page](#)