July 2016

Transatlantic eHealth/Health IT Cooperation Roadmap

Structure of Roadmap

This main Roadmap document sets out the vision, the main challenges, the scope and descriptions of each of the work-streams. The Roadmap Annex contains the specific actions and outcomes/deliverables with their corresponding milestones and due dates for each work-stream. The Annex (which will cover a 12 to 18 month timeframe) will be regularly updated to keep stakeholders fully informed of progress. The Roadmap activities overall will cover a longer period.

Vision

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

Executive Summary

Health related information and communication technology (most usually referenced as "eHealth" in Europe and "Health IT" in the U.S.) is an important and growing sector in the United States and the European Union. It is a rapidly developing and highly innovative area. It has considerable potential to promote individual and community health while fostering innovation and economic growth.

Both the United States and the European Union are currently working to encourage more effective use of information and communications technology (ICT), in particular for delivery of health services, including disease prevention and health promotion. The Transatlantic Economic Council has therefore decided to make a critical contribution to this development by promoting interoperability of health related information and communication technology (eHealth/Health IT) products and services, gaining improved mobility and consistent proficiency recognition for a professional workforce, and by helping to prevent unnecessary regulatory divergences.

Under this new version of the Roadmap, we decided to implement specific cooperative action plans for the following high-priority areas:

1. Advancing eHealth/Health IT Interoperability – The first phase of the collaboration led to a successful comparison of patient summary specifications across EU and US. This activity mobilised resources across the Atlantic to identify gaps and assemble interoperability assets to

help bridge those gaps¹. Detailed analyses of clinical and administrative components of patient summary documents used in the EU and US as well as recommendations on the structure and the content of an International Patient Summary (IPS) standard have been published in a White Paper.² Demonstrations of both the provider and patient mediated scenarios in Boston (EU/US Marketplace in October 2014), Chicago (Annual HIMSS conference April 2015), Luxemburg (IHE Connectathon April 2015), and Riga (eHealth week in Latvia as part of the EU presidency in May 2015), provided tangible evidence to the potential of a transatlantic and global exchange of patient summaries. We will continue to collaborate to accelerate progress towards the widespread deployment and routine use of internationally recognized standards. In particular, EU and US counterparts agree to promote and advance an IPS standard to enable people to access and share their health information for planned or emergency care anywhere and as needed. Health Level 7 (HL7) is currently working with Joint Initiative Council (JIC) and other standards development organizations on the design of an International Patient Summary (INTERPAS) document standard to facilitate cross-border exchange of health data.³

- 2. eHealth/Health IT Workforce Development The first phase of the eHealth/Health IT Workforce Development work-stream was successfully completed in May 2015. We were able to identify and address competency and knowledge deficiencies among staff in the eHealth/Health IT professional workforces. The next phase of this work will involve continued collaboration with the eHealth/Health IT professionals and organizations from both the EU and US communities to promote development of a global workforce professionally prepared to deploy eHealth/Health IT systems.
- 3. Supporting Transatlantic eHealth/Health IT Innovation Ecosystems. This new work-stream has been created in response to recent stakeholder consultations on the future direction of the Roadmap work and its relevance to their needs.

The cooperative action plans anticipate robust participation by relevant experts and stakeholders, across the public, private and academic sectors. The public sector participants expect to confer with private and academic stakeholders, and to convene, catalyze and support creative collaborations among capable and willing private and academic sector participants, while offering guidance consistent with their policymaking responsibilities. All participants, and particularly those in the private sector, in specific projects and initiatives under the action plans will identify solutions consistent with best practices in relevant fields (such as health informatics, workforce development, and IT-based innovation in healthcare systems).

This document represents the third version of the Roadmap (prior versions were published in 2013 and _____), and solidifies the initial phases of the cooperative activities. As technology and priorities change, we expect to periodically update the Roadmap Annex to reflect progress made and new opportunities identified in the course of their implementation. For example, the work products of the latest version of the Roadmap could feed into new activities that recognize the importance of developments such as software designed for mobile and medical devices, and those that continue to empower patients to

¹ Link to Trillium Bridge Documents

² White Paper "Comparative Analysis between HL7 C-CDA CCD and epSoS PS - v1_2.doc" was developed as part of S&I Framework EU-US initiative and can be accessed at:

http://wiki.siframework.org/Interoperability+of+EHR+Work+Group

³INTERPAS project details are available at HL7 website:

http://www.hl7.org/special/committees/projman/searchableprojectindex.cfm?action=edit&ProjectNumber=1087

contribute their own data into the healthcare ecosystem. To that end, we will continue to consult with stakeholders on how these might be included in the Roadmap.

Roadmap Challenge

To promote individual and community health in a global environment, and enable a robust and innovative ecosystem of eHealth/Health IT that supports the electronic exchange of human- and machine-readable health, clinical, medical and management information to advance the health of individuals and communities, we must maintain and enhance inter-governmental cooperation and also collaboration between governments and the private sector. The *Memorandum of Understanding between The United States Department of Health and Human Services and The European Commission, on Cooperation Surrounding Health Related Information and Communication Technologies (HHS-EC MOU)* was signed in December, 2010, to demonstrate our shared dedication to cooperation addressing these challenges. Exploration of specific activities and approaches to implementing transatlantic interoperability, consistent with the principles and vision described in the *HHS-EC MOU* require careful and inclusive analysis.

Scope Statement

This Roadmap and Action Plan in its Annex focuses on activities to advance the goals for cooperation around health-related information and communication technology, as commemorated by the HHS-EC MOU, and with a specific emphasis on three areas identified as having immediate importance and potential:

- International interoperability among Health IT systems with patient summary records, including a focus on semantic and syntactic requirements (including identification, privacy and security issues surrounding exchange of health data) for the purposes of clinical care across borders;
- 2. Cooperation and collaboration around shared challenges related to eHealth/Health IT Workforce Development; and
- 3. Supporting Transatlantic eHealth/Health IT Innovation Ecosystems.

Work-stream Descriptions

Public, academic and private-sector stakeholders from the EU and U.S. are invited to participate in this collaboration through the following work-streams.

• International interoperability Work-stream

- Standards and Profile Developing Organizations and eHealth/Health IT stakeholders should collaborate on the following items to enable a standardized international patient summary (IPS) to be in use by 2020:
 - 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.

• eHealth/Health IT Workforce Development 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).

• Transatlantic eHealth/Health IT Innovation Ecosystems Work-stream

- 1. U.S. HHS, Department of Commerce, Department of State, DG CONNECT, and other interested stakeholders 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 U.S. stakeholders and enlisting their support for greater collaboration between companies and ecosystems located in each jurisdiction;
 - 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 U.S. 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).