AmCham EU's response to the public stakeholder consultation on the next phase of EU-US cooperation in eHealth/Health IT

CONSULTATION RESPONSE

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled €2 trillion in 2014 and directly supports more than 4.3 million jobs in Europe.

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General information

What is this survey about?

The European Commission's DG CONNECT and the United States Department of Health and Human Services (HHS) have jointly updated a Roadmap that guides European and US cooperation on eHealth (also called Health Information Technologies or Health IT).

The objective of this consultation is to gather comments and input which will be used to validate and to finalise the update of the Roadmap and its annex.

Recommended reading: the draft Roadmap and its annex.

Information about respondents

The answers below such as your name and/or the name of your organisation/company/institution and email address will not be published, they are for internal use only.

*** I'm responding as:**

- An individual in my personal capacity
- The representative of an organisation/company/institution

*** Is your organisation registered in the Transparency Register?**

- Yes
- No

*** Please indicate your organisation's registration number in the Transparency Register:**
526578050997

Please tick the box that applies to your organisation and sector:

- National administration
- National regulator
- Regional authority
- Non-governmental organisation
- Small or medium-sized business
- Micro-business
- Large business
- Healthcare professionals
- European-level representative platform or association

- National representative association
- Research body/academia
- Press
- Other

My institution/organisation/business operates in:

- Austria
- Belgium
- Bulgaria
- Czech Republic
- Croatia
- Cyprus
- Denmark
- Estonia
- France
- Finland
- Germany
- Greece
- Hungary
- Italy
- Ireland
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Spain
- Slovenia
- Slovakia
- Sweden
- United Kingdom
- United States
- Other

*** Please enter the name of your institution/organisation/business (for internal use only).**
American Chamber of Commerce to the European Union (AmCham EU)

Roadmap Work-stream: International Interoperability

Roadmap Item: Collaborate with international stakeholders to develop and pilot a standardised approach for an international patient summary that can be exchanged internationally.

Question 1: Do you agree with the proposed timetable and organisation of the work to create an international standard for a patient summary?

- Yes
- No

Question 2: Are there areas of technical standards work missing that would be important to the success of the international patient summary record work?

AmCham EU welcomes the approach outlined in the draft Roadmap and believes that technical and regulatory cooperation across the Atlantic is necessary not only for maintaining a strong transatlantic economy but also for harmonising global eHealth/Health IT. AmCham EU believes a timely agreement on standards is critical and should be prioritised. However, keeping to a designated timetable can be difficult. Standardisation work requires consensus, which is hard to plan top-down. AmCham EU is committed to contributing to a focused development process in an effort to deliver market-driven standardisation in a timely fashion.

AmCham EU believes that the new version of the Roadmap should consider not only basic patient summaries across the Atlantic, but also full-blown interoperable Electronic Health Records (EHRs). This should also include the ability to upload patient-generated data or data from nonclinical settings, as provided for in Stage 3 of the Meaningful Use Requirements in the US, so as to offer citizens complete and secure access to their health information and associated services on mobile devices.

Looking at eHealth from a broader perspective, one of the most promising developments for future work will arguably lie in the emergence of the Internet of Things (IoT) paradigm, of which health services and applications such as mHealth will be a key component.

To drive clinical and operational improvements, real-time medical device data (physiologic data, therapeutic device settings and device alarms) increasingly needs to be provided to systems beyond the patient record, such as alarms management, patient surveillance, clinical decision support and asset management. AmCham EU envisages dramatic changes in the way healthcare is delivered over the coming decades, both in and outside the hospital. This is due to a broader societal transition towards value-added services empowered by expanded connectivity and technological convergence. Patient summaries will also need to be part and parcel of the IoT (and eventually 5G). They will need to communicate with many disparate services and applications (e.g. vehicles and smart cities) beyond the traditional care environment, as well as with medical devices and pharmaceuticals to deliver personalised treatment. From this standpoint, it will be increasingly difficult to consider eHealth-specific requirements individually from other similar IoT applications that will require robust security, privacy, authentication, coverage, bandwidth, quality of service and horizontal interoperability.

In this context, we applaud the public-private dialogue initiated by the Commission under the 5G Infrastructure Public Private Partnership (5G-PPP) as well as the Alliance for Internet of Things Innovation (AIOTI) to develop innovation and standardisation policies that can respond

to IoT use cases such as eHealth. We believe that the Roadmap would benefit from further coordination with these initiatives to set out priorities on future standards and obtain relevant business input for successful bottom-up standardisation work based on market needs.

Question 3: What are the best use cases for the International Patient Summary to address at a global scale (e.g. emergency, disaster, migration, tourism)?
AmCham EU believes that tourism could be the best use case. This will be particularly useful from a Transatlantic angle, as in 2012 alone tourists from the US spent 54.8 million nights in tourist accommodation in the EU Member States and tourists from the EU took 9 million trips to the US.[1] AmCham EU believes that the tourism use case will be able to provide cross-industry insight from a banking and insurance transactions point of view into how healthcare payers and providers will use eHealth to create both revenue opportunities and cost savings.

Roadmap Item: Identify and understand current privacy and security laws and practices surrounding the exchange of health data for the purposes of clinical care across borders.

Question 4: 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?
AmCham EU believes that robust data protection and security will be fundamental requirements to ensuring a successful and widespread deployment of an eHealth ecosystem. As outlined in AmCham EU's response to question 2, AmCham EU believes that eHealth security will need to be considered in the larger context of IoT and 5G development and deployment, to the extent that many requirements will be similar to other applications and can largely build on similar legal and technical (including standards) solutions.

Moreover, AmCham EU welcomes EU initiatives to develop industry-led, EU-wide codes of conduct such as the ongoing work to create a privacy code of conduct on mHealth apps and the recently launched working group to develop guidelines for health apps data to be reliably linked to EHRs. AmCham EU also welcomes the development of certification mechanisms that can enhance citizens' trust in eHealth services and applications and facilitate their effective uptake in clinical practice, including across borders.

[1] http://ec.europa.eu/eurostat/statistics-explained/index.php/The_EU_in_the_world_-_industry,_trade_and_services#Tourism

Roadmap Work-stream: IT Workforce Development

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

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

a. Clinical practitioners (doctors, nurses, etc.)
No response.

b. Health Informatics professionals
No response.

c. Non-clinical and administrative staff
No response.

d. IT professionals coming to work in the healthcare environment3
No response.

Roadmap Work-stream: Innovation Ecosystems (for eHealth/Health IT)

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

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 next 18 months
- The next 3 to 4 years

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?
AmCham EU believes that in order to achieve the greatest impact, partnerships for transatlantic ecosystems should be established in the 20 most populous US and EU urban areas.

The questions above are for your guidance. Please feel free to give other input:
No further comments.