Public stakeholder consultation on next phase of EU-US cooperation in eHealth/Health IT

Fields marked with * are mandatory.

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The answers below such as your name and/or the name of your organisation/company/institution and email address will not be published, they are for internal use only.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

* Is your organisation registered in the Transparency Register?

- [x] Yes
- [ ] No

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

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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
- [x] European-level representative platform or association
- [ ] National representative association
- [ ] Research body/academia
- [ ] Press
- [ ] Other

My institution/organisation/business operates in:

- [ ] Austria
- [x] 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*).

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Please enter your address, telephone and email (
for internal use only).

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info@digitaleurope.org

What is your primary place of establishment or the primary place of establishment of the entity you represent? *(For internal use only).*

Brussels, Belgium

Roadmap Work-stream: International Interoperability

Roadmap Item: Collaborate with international stakeholders to develop and pilot a standardized 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?

- [x] 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?

We firmly believe that mapping and convergence of technical standards between the EU and U.S. is a valuable exercise. Standards can play an important role to the success of the international patient summary record work, but only if these standards are industry led, done at an international level, and respond to market demand rather than regulatory intervention. Many of these global standards exist today including CEN/ISO 13606, HL7, WHO (ICD10, ICF, etc.). We believe that the work brought forth by epSOS and HHS/ONC has been beneficial.

We would like to see more focus on patient generated health data (PGHD) from medical devices. The roadmap should reflect patient generated data, medical device data and remote patient monitoring technologies such as mobile health, telehealth, telemedicine, e-Care and device interoperability. Areas that should be considered are interoperability, reliability and regulatory approaches to borderline health applications. This would reflect current efforts both in Europe and the U.S.

The European eHealth Action Plan 2012-2020 addresses telemedicine and the Commission has been funding several projects on telehealth. Various countries and regions (e.g. Denmark, Basque region, Lombardy region) deployed or are

deploying telehealth systems. Equally, in the U.S. the Stage 3 of the Meaningful Use programme contemplates the inclusion of patient generated health data into the provider's EHR and HHS/ONC has planned actions to address the use of PGHD for research and care delivery.

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)?

Many countries have either implemented or have plans to develop a summary care record, primarily as a patient safety innovation. The small dataset typically used (recent medical history, known allergies and adverse drug reactions, and recent and current medications) provides a way to avoid patient harm when making treatment decisions. For this reason, the international availability of such a record should be useful in any case where the individual accesses health services, whether this involves a primary care consultation, a visit to the pharmacy, or a 'blue light' admission. When it comes to the best use cases for the International Patient Summary, we firmly believe that emergency situations are the most pressing cases for use, especially due to the immediate, dramatic, and short term demand found in such instances. When it comes to migration, we believe this is another use case for International Patient Summary's, but view this as a more continuous and long term use case due to the permanent and evolving nature of migration. For tourism, we believe this is tied closely to 'disaster' related situations as the demand for International Patient Summary's will heighten for tourists during 'disaster' related situations. ePrescription services across borders could also be considered, but not all countries have such a system in place, and this would add an extra layer of complexity.

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?

We strongly believe that the EU and U.S. should avoid an overly prescriptive approach to the identification of privacy and security requirements. Such an approach could potentially hinder the adoption of new best practices as new security solutions come to market. Consideration needs to be given to the sensitivity of data, and an evaluation of the risk of data being accessed without permission. To minimise the risk of unauthorised access we believe that the EU and U.S. should adopt a security framework that outlines categories of safeguards that must be addressed through privacy-by-design and privacy-by-default, focusing on administrative, physical, and technical safeguards that ensure the confidentiality and integrity of data. Specific safeguards could include a requirement for regular self-assessment to identify the potential risks and vulnerabilities specific to an entity and its operating environment, as well as a requirement to develop a plan to address risks and vulnerabilities. Self-assessment should focus on risks such as malware, mishandling of electronic system passwords, and use of portable

devices. Safeguards to counter these risks could include regular audits, security incident procedures, disaster recovery, workforce clearance, and business partner vetting. Continued emphasis on international cooperation is also recommended on how to ensure that security and privacy are designed into the systems that will share and view the data. Similar requirements existed for the epSOS project in Europe, and were successfully addressed.

Furthermore, when it comes to privacy, the EU could potentially explore an adequacy finding in relation to those entities which are certified under the U.S. Health Insurance Portability and Accountability Act (HIPAA). We are of the opinion that the privacy standards found under HIPAA are of a higher standard and more specific than any which can be found in the 95/46/EC Directive or the future General Data Protection Regulation.

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)

- Hard skills in cloud, analytics, mobile applications, computer literacy, forms, reports, medical device connectivity, security and social
- Soft skills in adaptability, flexibility, teaming, communications, ethics

b. Health Informatics professionals

- Hard skills in software development, 3D image processing, artificial intelligence, IoT, information security, statistics, interoperability, data privacy notions
- Soft skills in project management, leadership

c. Non-clinical and administrative staff

- Hard skills in eDocument management, ERP, information security
- Soft skills in project portfolio management and general project management

d. IT professionals coming to work in the healthcare environment

- Hard skills in software engineering, database development, 3D image processing, information security, device/wearable electronics, IoT, interoperability, data privacy notions
- Soft skills in flexibility, teamwork, communication, ethics

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?

- [x] 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?

The questions above are for your guidance. Please feel free to give other input:

Background Documents

Annex EU-US Roadmap on cooperation in eHealth/Health IT (/eusurvey/files/f3422f72-7911-4023-b829-bcdaa6df61a4)

Draft EU-US Roadmap on cooperation in eHealth/Health IT (/eusurvey/files/838baabc-6da4-45d9-922c-41bff5cf20e9)

Contact

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