

EU POLICIES AND INNOVATION INITIATIVES FOR TRANSFORMATION OF HEALTHCARE SYSTEMS



**Cluj Innovation Days
Cluj-Napoca, Romania
31st March 2016**



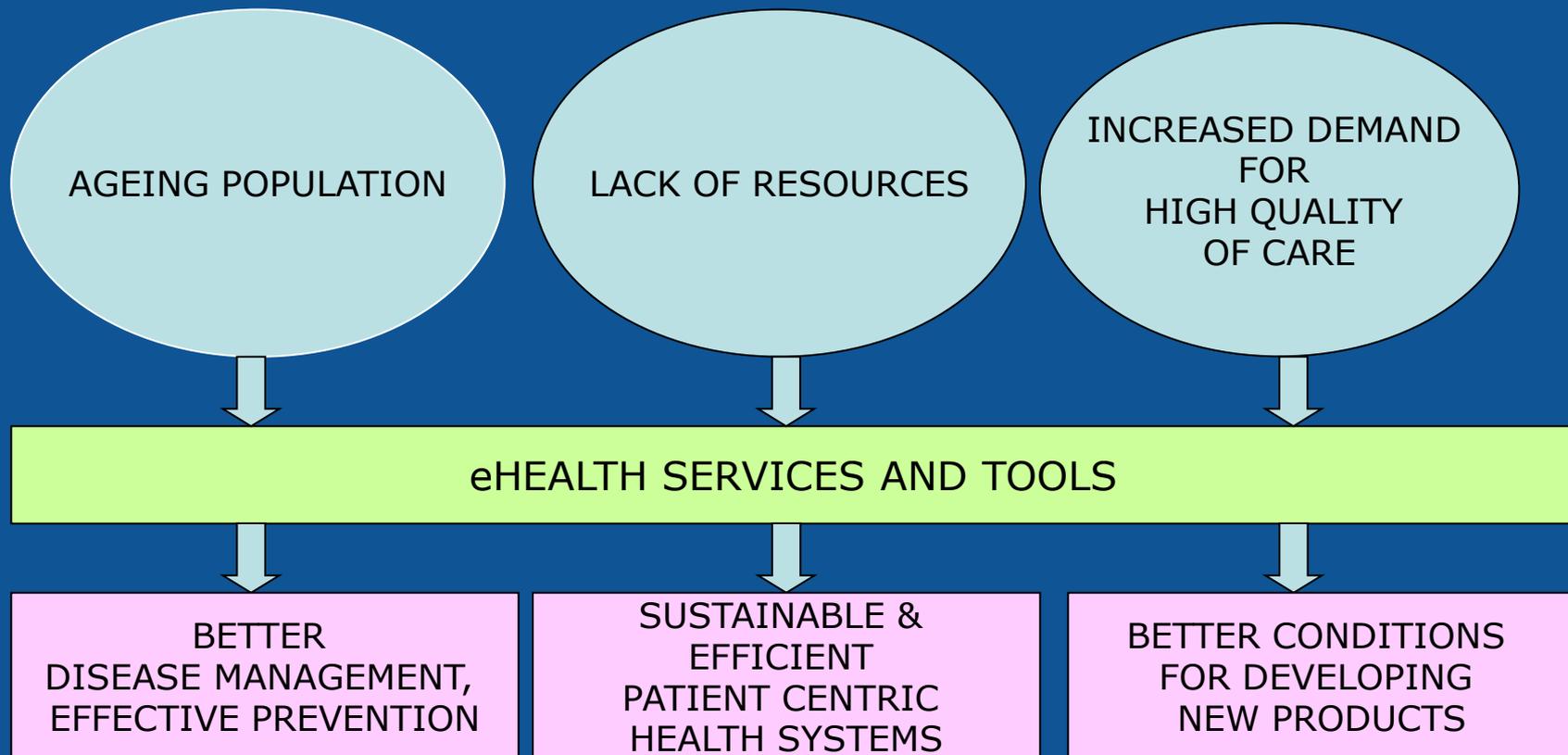
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Overview

- **eHealth Action Plan (2012-2020)**
- **Green Paper on mHealth and follow-up initiatives and actions**
- **International collaboration with the US on eHealth/Health IT including Innovation Ecosystems for Healthcare**

NEED FOR CHANGES IN HEALTHCARE



EHEALTH ACTION PLAN 2012 – 2020

OPERATIONAL OBJECTIVES



ACHIEVING WIDER INTEROPERABILITY OF
EHEALTH SERVICES



**SUPPORTING RESEARCH, DEVELOPMENT
AND INNOVATION**



ENSURING WIDER DEPLOYMENT & FACILITATING
UPTAKE



**PROMOTING INTERNATIONAL
COOPERATION**

Green Paper on mHealth

The **eHealth Action Plan 2012-2020** recognised potential benefits and challenges related to mHealth apps

European Commission Green Paper on mHealth *(10.04.2014)*

- Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps

Public consultation *(April-July 2014)*

- Summary of the results published in January 2015

Green Paper on mHealth

The Green Paper asked stakeholders for their inputs on how to overcome the main challenges to mHealth deployment, e.g.:

- **data protection**
- **the legal framework**
- **patient safety**
- **mHealth's role in healthcare systems**
- **interoperability**
- **web entrepreneurs' market access**



mobile devices



Personal Digital
Assistant (PDA)



smart watches & other body-worn devices
or implants

Legal framework

- Adjust the existing EU regulatory framework to cover safety and liability issues related to digital products
 - e-commerce, digital contracts, platforms

- Clarify the borderline between medical devices and lifestyle and wellness apps
 - update of the MEDDEV guidelines on qualification and classification of stand-alone software as medical devices

Privacy Code of Conduct for mobile health apps

- covering data protection and security principles
- voluntary instrument
- to be signed by mHealth app developers and possibly to be approved by the Article 29 Working Party

Legal basis: Article 27 of the Data Protection Directive

Objectives: Increased trust; Raising awareness and facilitating compliance with data protection rules at EU level; Competitive advantage

Process: Industry code of conduct working group with the EC as facilitator

Next steps: Finalising draft (governance) to be presented to Art 29WP

More information: <http://bit.ly/1PoVxRo>

Guidelines for assessing validity and reliability of mHealth app data

- A working group of stakeholder organisations
 - Civil society, academia, industry, public authorities
 - Stakeholders – public call for expression of interest open until **Start working in March 2016**
 - Public authorities – are invited to join the group

- Mandate
 - Draft the guidelines by the end of 2016
 - Consider and integrate input from all the stakeholders

- Process open to all stakeholders via online consultations and open stakeholder meetings

European standard on quality criteria for the development of health and wellness apps

- PAS 277:2015 on Health and wellness apps – Quality criteria across the life cycle (BSI)
 - Aims to encourage innovation in healthcare and development of safe and effective apps that are of a high quality, and that are fit for purpose
 - Does not cover requirements for apps that are classified as medical devices
- 2016 Rolling Plan for ICT standardisation

Horizon 2020 WP 2016 - 2017

- Funding of research and innovation in the fields of
 - big data
 - **digital security for healthcare**
 - patient empowerment
 - digital health literacy
- Together with WHO-ITU establish **the EU innovation hub on mHealth** to address in particular non-communicable diseases

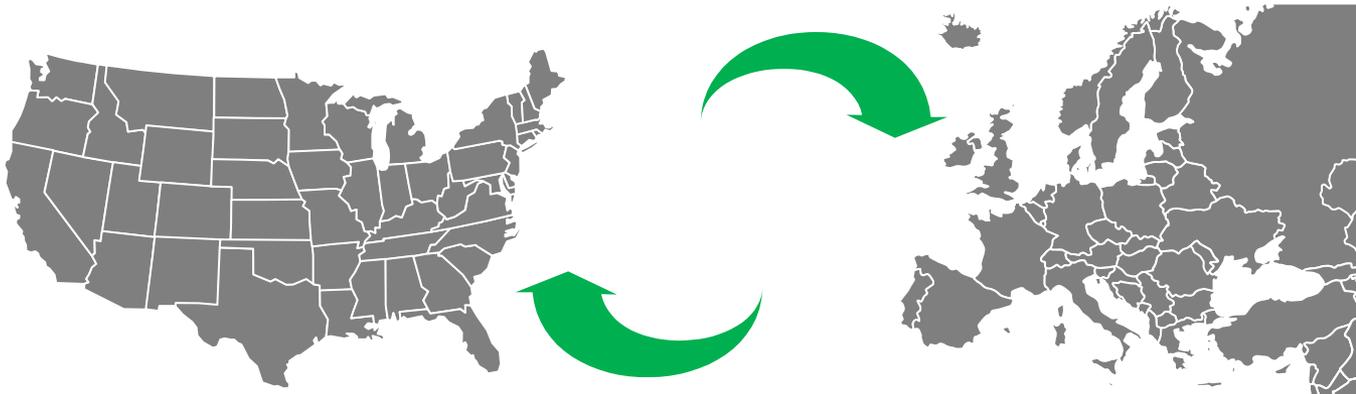
EU mHealth hub

- In cooperation with WHO and ITU (WHO-ITU Agreement)
- To support wider deployment of mHealth solutions tackling NCDs
- Exchange of best practices and innovation monitoring
- Focus on fostering research and innovation in mHealth
- **Implement mHealth strategies tailored to the needs of Member States and regions**



The European Commission (DG CONNECT) and the US Dept. of Health and Human Services signed a **Memorandum of Understanding (MOU)** to:

- Help facilitate more effective uses of eHealth/Health IT;
- Strengthen their international relationship; and
- Support global cooperation in the area of health related ICT





The vision and roadmap set the framework for progress on Transatlantic collaboration

- *To **support an innovative collaborative community** of public- and private-sector entities 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.*
- *Recognize the importance of health-related information and communication technologies (eHealth/health IT) in **promoting individual and community health while fostering innovation and economic growth***



Roadmap to achieve the vision of the MOU

- Defines a cooperative action plan to produce deliverables aligned with the goals outlined in the MoU, with a specific emphasis on the following two areas:
 - **International Interoperability of Electronic Health Records** information, to include semantic interoperability, syntactic interoperability, patient and healthcare provider mediated data exchange (including identification, privacy and security issues surrounding exchange of health data);
 - cooperation around the shared challenges related to **Healthcare Workforce IT competencies**
- In the summer of 2013 (following a '**Call to Action**') two community workgroups were launched to look at how to achieve the goals and visions of the MOU and the first phase of the work was completed in 2015.



Advancing eHealth/Health IT Interoperability Work Stream

- The first phase of the collaboration led to a successful comparison of patient summary specifications across EU and US.
- This activity mobilized resources across the Atlantic to identify gaps and assemble interoperability assets to help bridge those gaps.
- 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.



eHealth/Health IT Workforce Development Work Stream

- 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.



Innovation Ecosystems Work Stream

- At the end of 2015, it was agreed between DG CONNECT and the US HHS to add a new third work stream titled “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
- Aims to encourage innovation in the eHealth/Health IT industry and to ensure that there are linkages to the other two Roadmap Work Streams

Potential Stakeholders

- Start-up Incubators and Accelerators
 - Entrepreneurs
 - Investors / Financiers
 - Academia / Researchers
 - Advocacy Organizations
 - Government
 - Private Sector / Retail Clinics
- Suppliers of eHealth/Health IT systems
 - Products and Services (including SMEs)
 - Providers / Practitioners
 - Payers
 - eHealth/Health IT/Innovation Policy Makers
 - Non-Profits / Foundations

The Role of Governments and Public Sector Bodies

- Increase cross-border collaboration
- Promote the creation of innovation centres (as opposed to research facilities which typically lack commercial focus) that facilitate the innovations of others
- Promote the successes of domestic/local entrepreneurs to foster an entrepreneurial culture
- Lower barriers to innovation by encouraging 'balanced risk-taking' and providing financial incentives to entrepreneurialism (such as matching private investment in start-ups' research and development and providing tax incentives for funding start-ups)

- Ensure a friendly regulatory environment
- Create places where young people feel they have 'cultural self-confidence' and where they can meet face to face, as experts say that is when successful innovations emerge
- Contribute to the reform of education policies to keep pace with the knowledge and skills required for young people to participate in the emerging 'third-wave industrial revolution'
- Recognise which start-ups are more likely to succeed and channel the resources to them instead of trying to support as many start-ups as possible.



Initial Key Elements

- Identify key EU and US stakeholders and enlist their support
- Highlight latest trends and developments in eHealth/Health IT

Examples;

- **Patient Engagement / Empowerment**
 - **Patient Generated Health Data**
 - **Precision / Personalized Medicine**
 - **Privacy**
 - **Tele-Health / mHealth**
 - **Cybersecurity**
 - **Open APIs**
 - **Others tbd**
- ***Build transatlantic partnerships and alliances between EU regions/cities and US States/cities***
 - Recognize complementary EU and US strengths and business/trade opportunities (with a specific focus on SMEs)
 - Identify synergies between Innovation Work Stream, and the Interoperability and Workforce Development work streams

Three Pronged Strategy



- Webinars
- Conferences
- In-person meetings
- Online Communities
- Delegation Visits
- Trade-Missions

- Establish '*Sister Region & City Partnerships*'
- Showcase Technologies
- Asset Mapping of Current Health IT Innovation Hubs
- Provider Network & Trade Association Partnerships

- Challenges
- Pilots
- SME Opportunities
- New Programmes
- Ongoing alignment with 2 previous work streams and other EU/US initiatives



Convene (2016)

Bringing people together

Date	Event	Title	Location
Feb 25 th	Kickoff Webinar (for 3 rd work stream)	Transatlantic Health IT Innovation Ecosystems	Online
March 4 th	HIMSS Listening Session, hosted by ONC / ITA	Cultivating Health IT Innovation Ecosystems	Las Vegas, NV
May 8 th	Health Datapalooza	International Health Innovation Summit, Investors Perspectives	Washington D.C.
June 8th – 10th	US delegation to visit EU during eHealth Week	Progress update on the EU-US eHealth/Health IT MoU	Amsterdam, The Netherlands
July	2 nd Webinar (for the 3 rd work stream)	Update on Innovation Work	Online
Sep/Oct	EU delegation to visit US	Still being planned, not confirmed when/where	Chicago, IL and/or San Francisco, CA?
November	3 rd Webinar (for the 3 rd work stream)	Update on Innovation Work	Online

Collaborate

Gathering information, generating ideas

Partnerships

- Transatlantic Sister Regions / Cities
- Provider Networks (IT / Innovation Offices)
- Health IT Trade Associations

Actions - Projects

- Asset Mapping Exercise of Current Health IT Innovation Hubs (in both EU and US)
- Showcase Innovative eHealth/HealthIT Technologies
- Promote EU & US Open Data
- Mentorship Opportunities

Policy Development

- Government/Public Innovation Policy
- Hospital Innovation Policy
- Private Sector Innovation Policy
- Academic Innovation Policy

Catalyze

Turning ideas into action

- Public / Private challenges, code-a-thons, etc.
- Transatlantic healthcare system pilots
- SME business opportunities
- New public/government programmes - legislative efforts
- Ongoing alignment with 2 previous work streams and other existing EU/US initiatives





Thank you

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eHealth: <http://ec.europa.eu/digital-agenda/en/digital-life/health>

EU-US eHealth MoU Roadmap:

<http://ec.europa.eu/digital-agenda/en/news/eu-and-us-step-cooperation-ehealth-it>

eHealth Action Plan 2012-2020

<https://ec.europa.eu/digital-agenda/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century>

eHealth Week 2016

www.ehealthweek.org