Imagine 2029: Our data, our health, our care – 20th anniversary of EHTEL
EHTEL 2019 Symposium

11:15 – 12:30 [S8]

Breakout B: Improving Availability and Use of Secondary Health Data
Inspired by the DigiCare communication COM(2018)233 on enabling the digital transformation of health and care in the Digital Single Market, empowering citizens and building a healthier society, the workshop will focus on exploring secondary data use for improving health and care.

Session Chair: Giovanni Gorgoni, AReSS Puglia, Bari, Italy

Introduction to DigitalHealthEurope
Strahil Birov, empirica, Bonn, Germany

Data Infrastructure Platforms to Support Secondary Uses of Health Data
Oliver Zobell, FZ Jülich, Germany

Moderated Discussion Based on Three Driving Questions
Diane Whitehouse and Tino Marti, EHTEL, Brussels, Belgium

Q&A and Conclusions by the Session Chairs

#EHTEL_Symposium #EHTEL_BCN @ehtel_eHealth
DigitalHealthEurope

Support to a Digital Health and Care Innovation initiative in the context of Digital Single Market strategy

Strahil Birov
empirica Technology Research, Bonn, Germany
DigitalHealthEurope (DHE) – key facts

► **Title:** Support to a Digital Health and Care Innovation initiative in the context of Digital Single Market strategy
► **Duration:** Jan ´19 – Dec ´20 (2 years)
► **Coordinator:** empirica, Germany
► **Instrument:** HORIZON 2020
► **Type:** Coordination & Support Action
► **Grant Agreement Number:** 826353
► **Acronym:** DigitalHealthEurope
► **Budget:** €3,999,993.75
► Carried out by 17 partners supported by a Board of 50+ Associated Experts
► Partners’ members have >1,100 members, outreach to >20,000 organisations
Background: Supporting the three priorities of the EC COM 25 April 2018

Digital Health and Care

European health challenges

- Ageing population and chronic diseases putting pressure on health budgets
- Unequal quality and access to healthcare services
- Shortage of health professionals

Support European Commission:

1. Secure access and exchange of health data
   - Ambition:
   - Citizens securely access their health data and health providers (doctors, pharmacists) can exchange them across the EU
   - Actions:
   - eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and prescriptions) and cooperation between participating countries will be strengthened:
     - Proposals to extend scope of eHealth cross-border services to additional cases, e.g. full electronic health records.
     - Recommended exchange format for interoperability of existing electronic health records in Europe.

2. Health data pooled for research and personalised medicine
   - Ambition:
   - Shared health resources (data, infrastructure, expertise) allowing targeted and faster research, diagnosis and treatment
   - Actions:
   - Voluntary collaboration mechanisms for health research and clinical practice (starting with “one million genomes by 2022” target).
   - Specifications for secure access and exchange of health data.
   - Pilot actions on rare diseases, infectious diseases and impact data.

3. Digital tools and data for citizen empowerment and person-centred healthcare
   - Ambition:
   - Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (recording and providing feedback)
   - Actions:
   - Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification.
   - Support demand uptake of innovative digital-based solutions for health, notably by healthcare authorities and providers, with exchange of practices and technical assistance.
   - Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.

Potential of digital applications and data to improve health

- Efficient and integrated healthcare systems
- Personalised health research, diagnosis and treatment
- Prevention and citizen-centred health services

What EU citizens expect...

- 90% agree: To access their own health data (requiring interoperable and quality health data)
- 80% agree: To share their health data (if privacy and security are ensured)
- 80% agree: To provide feedback on quality of treatments
Overview of activities

Multi-Stakeholder Communities

- Citizen’s secure access to and sharing of health data
- Better data to promote research, disease prevention and personalised health and care
- Digital tools for citizen empowerment and for person-centred care

Digital solutions for person-centred care
Impact Assessment
Funding advice
Deployment support Capacity framework
Building blocks for scaling up

Twinning Marketplace
Twinning actions

Workshops, roundtables, stakeholder engagement at policy and expert level

Actionable recommendations
Vision of EU coordination and support beyond 2020
Twinning activities. Lead: empirica

- The twinning scheme is a mechanism for scaling up innovative digital solutions
- Funding is provided by DigitalHealthEurope to enable the transfer of innovative solutions from one European region or country to another
- 1st call for applications closed, 2nd call planned for January 2020

~€ 1 Million in funding for Twinnings on innovative digital solutions in 2019-2020

- Further support instruments provided by DigitalHealthEurope (Leads: Funka, IFIC):
  - Digital solutions for person-centred care
  - Impact Assessment
  - Funding advice
  - Deployment support Capacity framework
  - Building blocks for scaling up
Collaboration on citizens’ secure access to and management of their own health data; sharing of data across borders

- Common agenda on how to advance digital health literacy
- New ways for sharing data across borders
- Efforts towards the adoption of the European Electronic Health Record exchange format
- European guidelines for citizen-controlled data governance
Better data to advance research, disease prevention and personalised health & care. Lead: EuroRec

- Collaboration on data infrastructure; better data, personalised medicine
  - Challenges for regional, national, EU infrastructures handling personal and/or anonymous health data
  - Criteria to ensure cross-border access to genomic data
  - Business drivers for scaling up the reuse of health data
  - Business models for Real World Evidence, safeguards to ensure public trust
Citizen empowerment, interaction with health care provider. Lead: European Patients’ Forum

- Collaboration on scaling up of digital solutions for citizen empowerment and for person-centred care in Europe
  - Analysis of the experiences of European initiatives
  - Guides for successful implementation of digital solutions for citizen-health & care professionals interaction and active cooperation
  - Empowerment roadmap for healthcare providers to better engage with patients and caregivers
  - Indicators to measure Patient Reported Outcomes (PRO)
Actionable strategic vision for EU policy on digital transformation of health and care beyond 2020, incl. mobilisation of EU instruments

- Multi-stakeholder roundtable discussions on:
  - Legal challenges in using health data, privacy, GDPR
  - Health data standards and interoperability
  - Value-based care

Recommendations for future EU support to Digital Transformation of Health and Care
Get involved!

► You can get involved in DigitalHealthEurope by:

► participating in twinnings: look out for the second twinning call in January 2020

► Providing expert input to various activities of the three priorities via attending **events** (workshops, roundtables), taking part in **surveys**, validating and commenting on upcoming key reports (**white papers**, **guidelines**, **policy recommendations**)

► [https://digitalhealtheurope.eu/participate.html](https://digitalhealtheurope.eu/participate.html)
Thank you for your attention!

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How to Support Secondary Uses of Health Data

Oliver Zobell

EHTEL Symposium 2019

**Mid-Term Review** on the implementation of the Digital Single Market Strategy, COM(2017) 228


Recommendation on a European **Electronic Health Record** exchange format, C(2019) 800
Who we are

Strahil Birov
Dipak Kalra
Veli Stroetmann

Stefan Bujok
Zoi Kolitsi
Oliver Zobell
Scope of this group within the project

► Supporting the European Commission’s plan:

► Preparing within “Priority 2 - Health data pooled for research and personalised medicine”:
*White paper on better utilisation of data infrastructures to support secondary uses of health data*

Requirements for coordination + Calls to action
Secondary uses of health data

Research activities

- Basic / preclinical research data
- Research data
- Clinical trial data
- Research evidence

Healthcare activities

- Routine data
- Healthcare data
- Healthcare evidence
Secondary uses of health data

Research activities

Basic / preclinical research data

Research data

Clinical trial data

Healthcare activities

Healthcare data

Routine data

Research evidence

Healthcare evidence
“Our” problem space: Data infrastructures vs Research infrastructures

(HEALTH) Data Infrastructures
- flexible access to own health information
- Faster access to patient records by health care providers
- better longitudinal tracking of patients and patient groups
- improved standards of care and reduce the incidence of errors in clinical practice
- provide research data

Research infrastructures
- provide resources and services for research communities to conduct research and foster innovation.
- They include:
  - major scientific equipment or sets of instruments
  - collections, archives or scientific data
  - computing systems and communication networks
  - any other research and innovation infrastructure of a unique nature which is open to external users

06.12.2019
Data Infrastructures: Example infrastructures we can learn from

- EU PEARL: Reuse for clinical trials
- OHDSI: Reuse for big data research
- HEALTH DATA HUB: Reuse for digital health innovation
- Rare Diseases
- Life sciences research

06.12.2019
Better utilization of data infrastructures to support secondary uses of health data

Recommendations to policy makers on better utilization of data infrastructures for data re-use

Two topics

- What is needed in terms of data access?
  - “Can I find the data I need?”
  - “Can I connect to the data?”

- What is needed in terms of the data stewardship/governance?
  - “Are the data useful?”
  - “Am I permitted to use the data?”
  - “What are the terms, and my obligations?”
Some of the bottlenecks for **data access**

- Connecting a growing family of data catalogues
- **Interoperability**
  - standardised metadata for discovery and data set profiling
  - co-ordinated alignment of eHealth and clinical research standards
  - prioritised high value data sets to focus all efforts
  - promoting the wider adoption of standards by vendors, procurers
- **Data quality assessment, benchmarking** (minimum quality criteria)
- **Information security measures and best practices**
  - anonymisation
  - privacy protecting linkage
  - dynamic consent or other models
  - the role of Blockchain in enabling transparency and auditability
Some of the bottlenecks for data stewardship / governance

► Public engagement in understanding and supporting the data reuse ecosystem
  ▶ including mechanisms to consult with the public, take their preferences on board and provide transparency

► Respect, recognition and reward to data providers
  ▶ defining suitable (non-restrictive, but protecting) data access rules
  ▶ in return for abiding by FAIR principles

► Agreeing who are acceptable user organisations and their data reuse purposes
  ▶ including commercial and non-commercial uses
  ▶ payback (various forms) to health systems for data reuse
  ▶ including how to monitor and govern appropriate use

► GDPR compliance
  ▶ legal basis, the role of consent, data controllers and processors, pseudonymised and anonymised data, adequate safeguards, data minimisation vs big data, audit and escalation

► Business models
  ▶ attracting pump priming investments for implementation and early operation
  ▶ a medium and long-term business model for sustainability, including ROI
  ▶ investing in the data e.g. in data quality improvements, data provision resources
May 2015

May 2017
Mid-Term Review on the implementation of the Digital Single Market Strategy, COM(2017) 228

Apr 2018

Feb 2019
Recommendation on a European Electronic Health Record exchange format, C(2019) 800

Communication "Towards a common European data space", COM(2018) 125
Communication "Towards a common European data space", COM(2018) 125

“We need to make the most of the potential of e-health to provide high-quality healthcare and reduce inequalities. I want you to work on the creation of a European Health Data Space to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes. As part of this, you should ensure citizens have control over their own personal data.”
THANK YOU FOR YOUR ATTENTION!

https://digitalhealtheurope.eu

To get involved, subscribe to our mailing list at https://digitalhealtheurope.eu/participate.html

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