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**TIC | Salut Social**  
Technology, innovation  
and digital transformation.

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

## EHTEL 2019 Symposium

11:15 – 12:30 [S8]

**Aula 0**  
Ground Floor

### 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



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#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



## Digital Health and Care



TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET - Harnessing the potential of data to empower citizens and build a healthier society

### European health challenges

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

### 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

### Support European Commission:

#### 1 Secure access and exchange of health data

**Ambition:**  
Citizens securely access their health data and health providers (doctors, pharmacies...) can exchange them across the EU.

**Actions:**

- eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and ePrescriptions) 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.



Updated 24/04/2018

#### 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 (receiving and providing feedback).

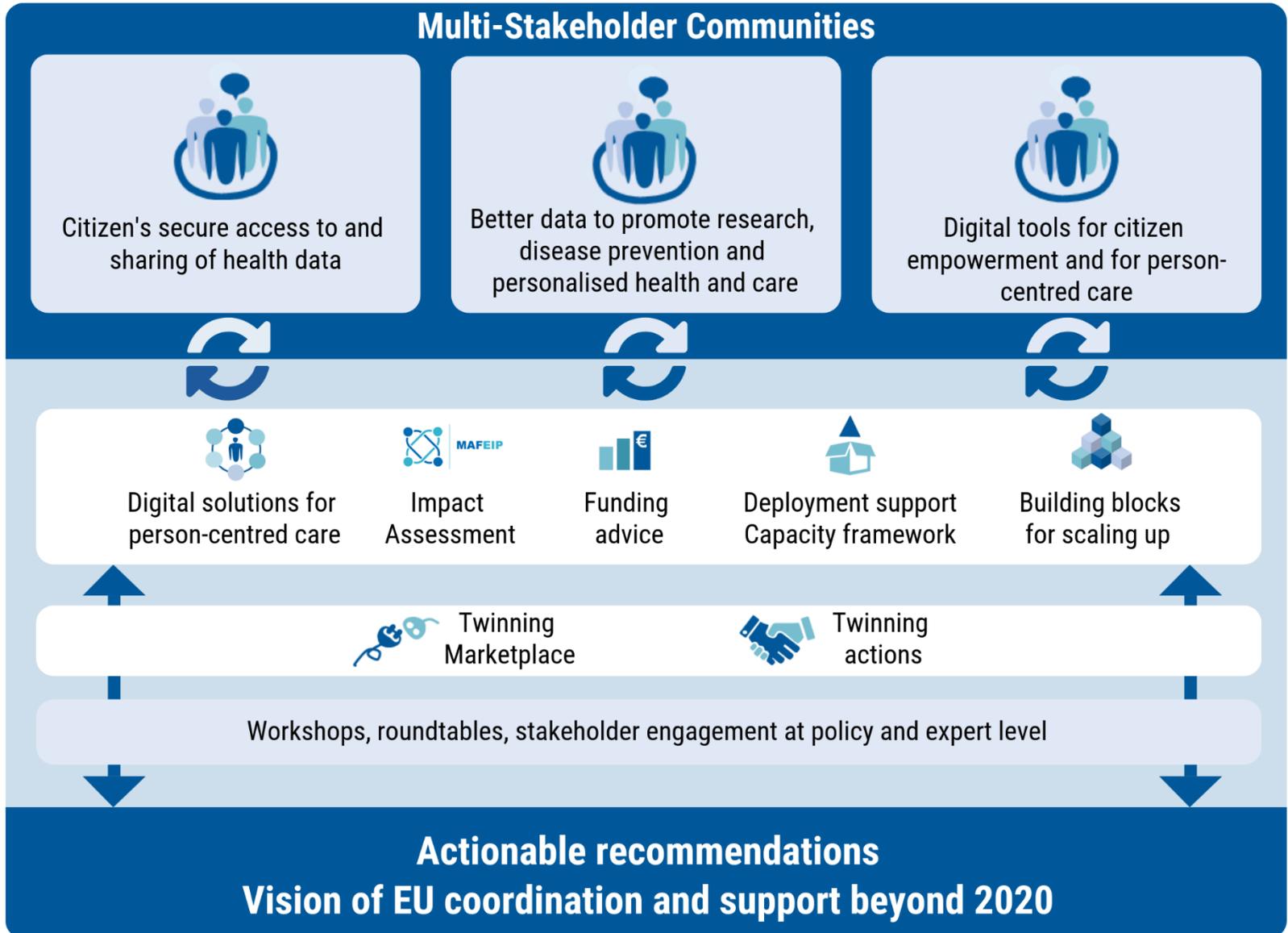
**Actions:**

- 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.



#DigitalSingleMarket #DigitalHealth @eHealth\_EU @EU\_Health

# Overview of activities



## 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
- ▶ 1<sup>st</sup> call for applications closed, 2<sup>nd</sup> call planned for January 2020

**~€ 1 Million in funding for Twinning 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



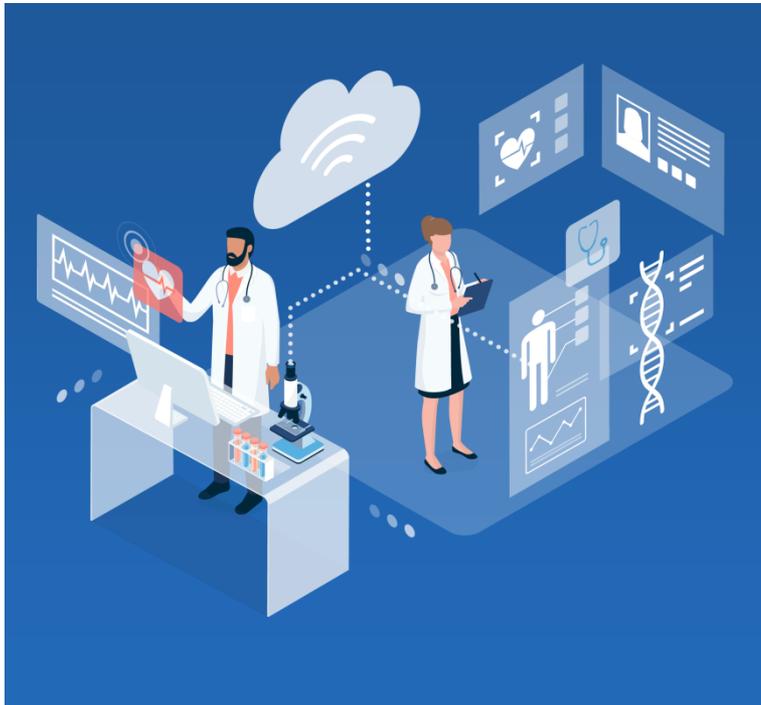
Building blocks for scaling up

## Citizens' secure access to & sharing of their data across borders. Lead: SPMS, Portugal



- ▶ 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

- ▶ You can get involved in DigitalHealthEurope by:
  - ▷ participating in twinings: 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>



**Thank you for your attention!**

Contact

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[DigitalHealthEurope@empirica.com](mailto:DigitalHealthEurope@empirica.com)



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

## How to Support Secondary Uses of Health Data

Oliver Zobell

EHTEL Symposium 2019

May 2015

A **Digital Single Market** Strategy for Europe, COM(2015) 192

May 2017

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

Apr 2018

Communication on enabling the **digital transformation of health and care** in the Digital Single Market; empowering citizens and building a healthier society, COM(2018) 233

Feb 2019

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



**2** Health data pooled for research and personalised medicine

*Ambition:*

Shared health resources (data, infrastructure, expertise...) allowing targeted and faster research, diagnosis and treatment.

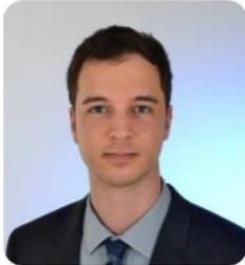
*Actions:*

- 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.



## Who we are

Strahil Birov



Dipak Kalra



Veli Stroetmann



Stefan Bujok



Zoi Kolitsi



Oliver Zobell



- ▶ Supporting the European Commission's plan:

*Digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, COM(2018) 233*



- ▶ 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*



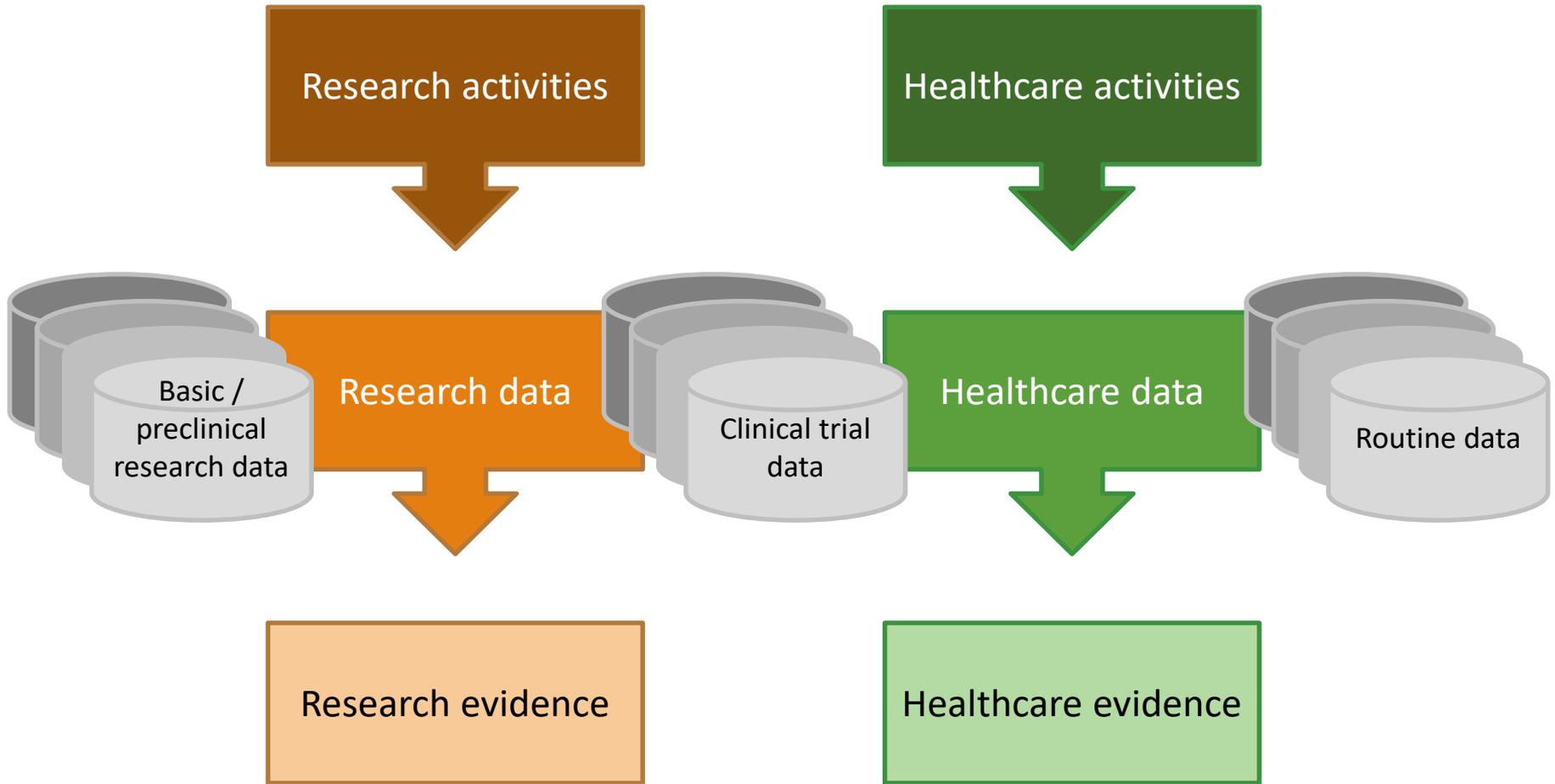
Requirements for coordination

+

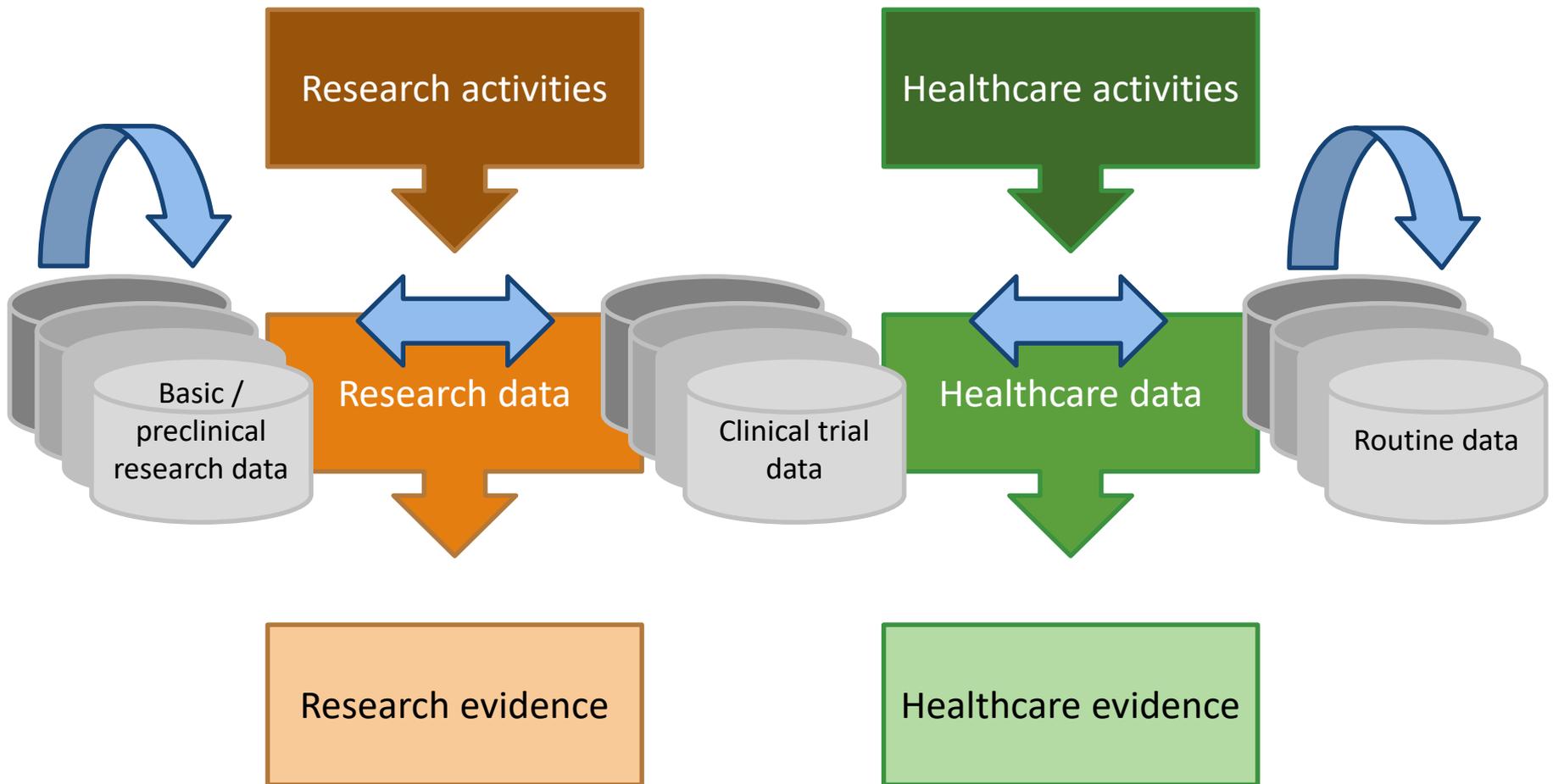
Calls to action



# Secondary uses of health data



# Secondary uses of health data



## (HEALTH) Data Infrastructures

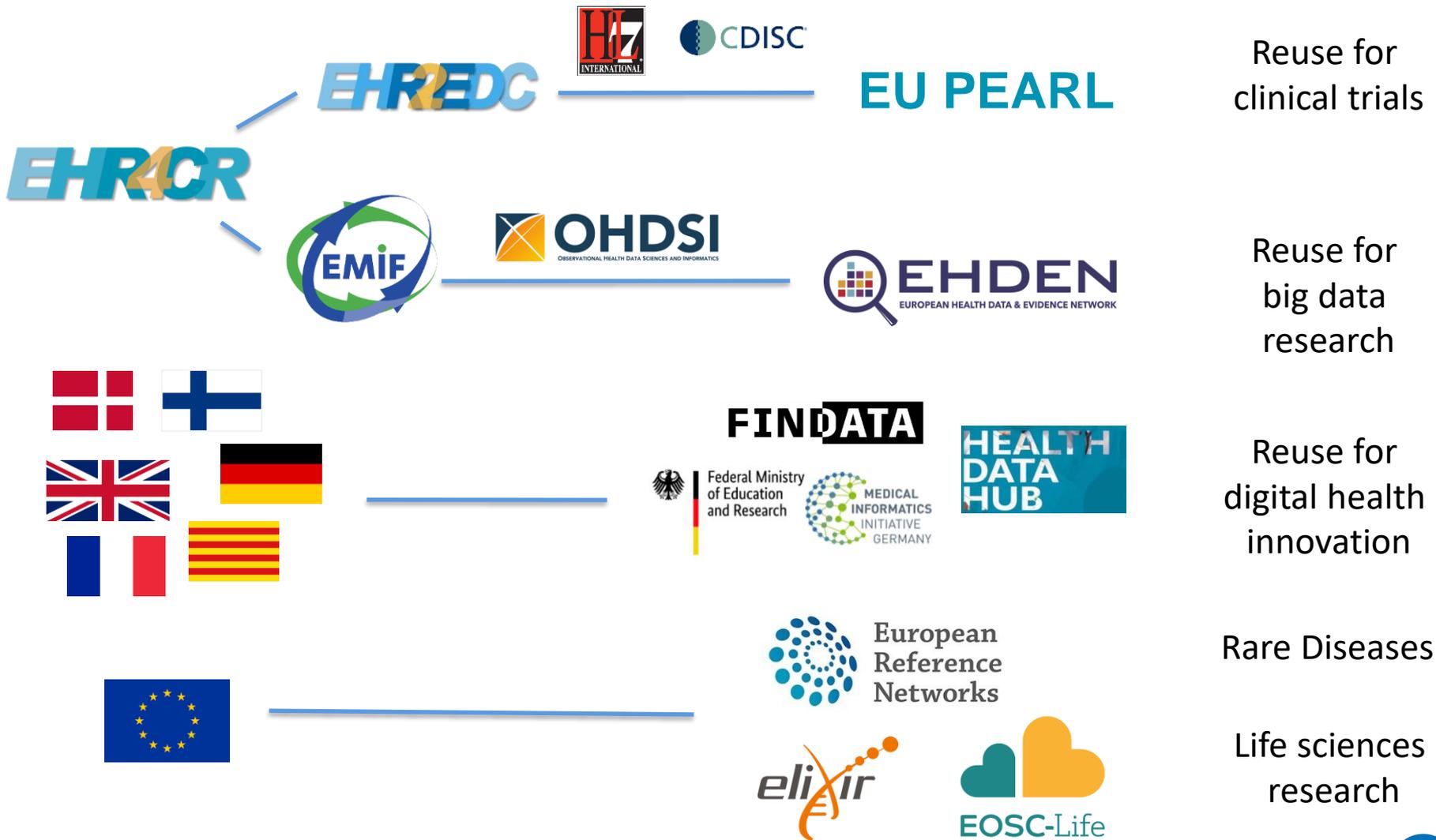
- flexible access to own health information
- Faster access to patient records by health care providers
- better longitudinal tracking of patients and patient groups
- improved standards of care and reduce the incidence of errors in clinical practice
- provide research data

"Our"  
problem  
space:  
Better  
data for  
re-use

## 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

# Data Infrastructures: Example infrastructures we can learn from



- ▶ 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?"*

- ▶ 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

- ▶ 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

A **Digital Single Market** Strategy for Europe, COM(2015) 192

May 2017

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Apr 2018

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Feb 2019

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



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



Stella Kyriakides

Commissioner-designate for Health

Brussels, 10 September 2019

Dear Stella,

Earlier this year, the people of Europe made their voices heard in record numbers at the European elections. They presented us with a mission to be decisive and ambitious on the big issues of our time that are shaping the future of our society, economy and planet.

Changes in climate, digital technologies and geopolitics are already having a profound effect on the lives of Europeans. We are witnessing major shifts all the way from global power structures to local politics. While these transformations may be different in nature, we must show the same ambition and determination in our response. What we do now will determine what kind of world our children live in and will define Europe's place in the world.

Our job as the European Commission will be to lead, to grasp the opportunities and to tackle the challenges that these changes present, working hand in hand with people from across Europe and with the governments, parliaments and institutions that serve them.

This is the guiding principle behind my Political Guidelines for the next European Commission 2019-2024, which I presented to the European Parliament on 16 July 2019. I outlined six headline ambitions on which I want the European Commission's work to focus. These priorities are interlocking and are part of the same picture. In this spirit, I have put together a College in which we will all work, decide and deliver together.



## 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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