

WEBINAR

28 APRIL 2020 / 14:00 -15:30

The role of a health Data Space in a pandemic

Moderated by **Cecilia Bonefeld-Dahl**, Director General of DIGITALEUROPE



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European Health Data Space & COVID-19

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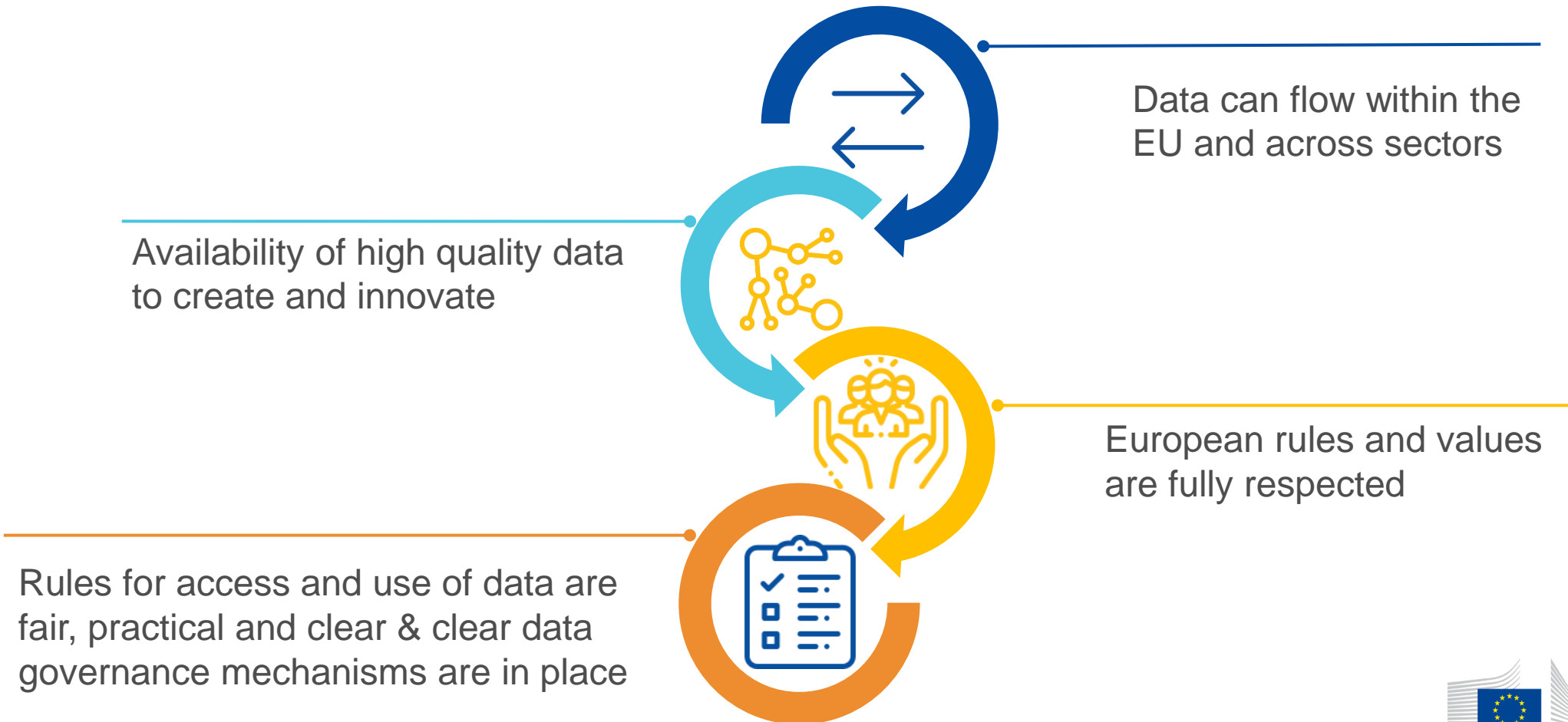
Head of Unit European Reference Networks and Digital Health, DG SANTE

Content

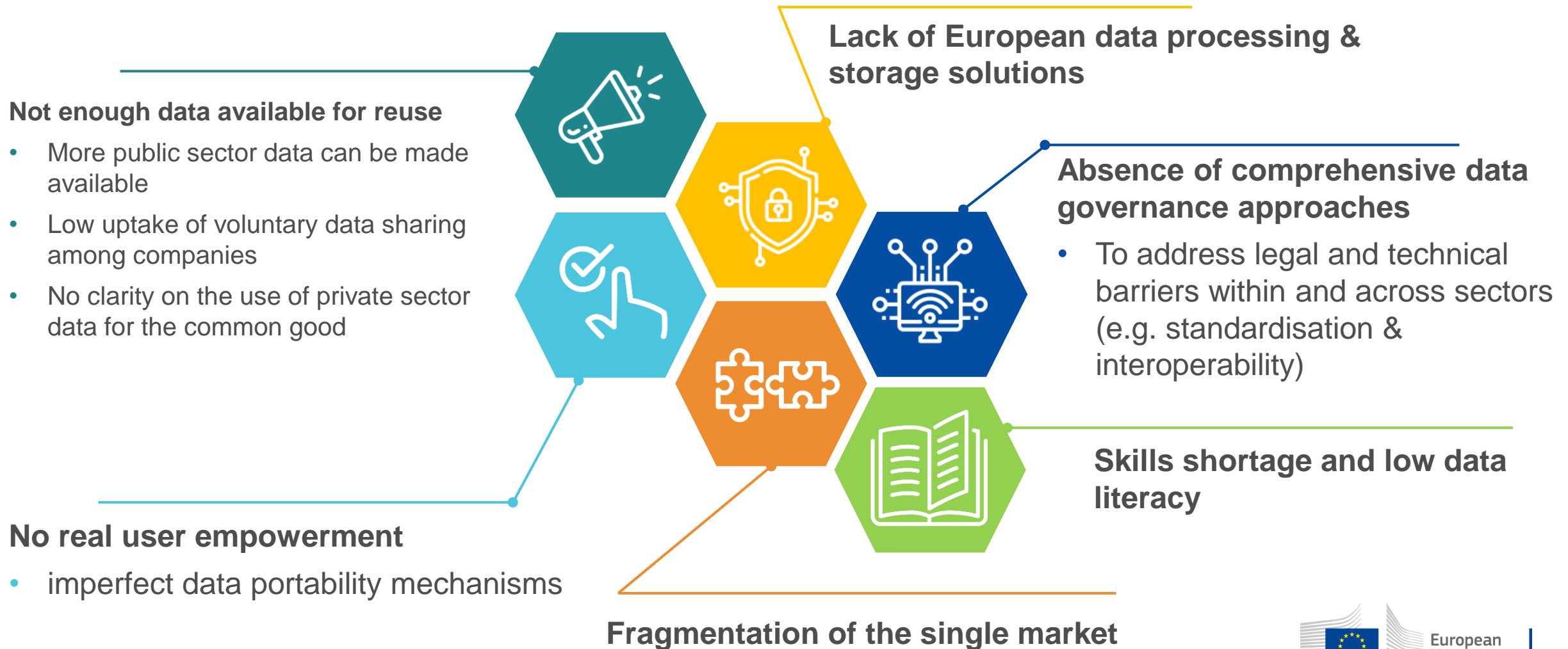
- Data strategy and European Health Data Space
- Actions against COVID
- Questions

European Strategy for Data

A common European data space, a single market for data



What are the problems?



Deploying the strategy through 4 Pillars



A cross-sectoral governance framework for data access and use

including a legislative framework for the governance of European data spaces and other cross- sectoral measures for data access and use



Enablers

Total investments of € 4-6 billion in a High Impact Project on European data spaces and federated cloud infrastructures



Competences

Empowering individuals, investing in digital skills & data literacy and in dedicated capacity building for SMEs.



Rollout of common European data spaces

in crucial economic sectors and domains of public interest, looking at data governance and practical arrangements.

International Aspects

Common European data spaces

Rich pool of data
(varying degree of
accessibility)

Free flow of data
across sectors and
countries

Full respect of GDPR

Horizontal
framework for data
governance and data
access



Health



Industrial &
Manufacturing



Agriculture



Finance



Mobility



Green Deal



Energy



Public
Administration



Skills

- Technical tools for data pooling and sharing
- Standards & interoperability (technical, semantic)

- Sectoral Data Governance (contracts, licenses, access rights, usage rights)
- IT capacity, including cloud storage, processing and services

Public Online Consultation

open until 31 May 2020

<https://ec.europa.eu/digital-single-market/en/news/online-consultation-european-strategy-data>



*“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**.”*

*Mission letter of Stella Kiyriakides
Commissioner for Health*

European Health Data Space

What?

Use of health data for:

- Better healthcare
- Better policy making
- Better research and innovation

How?

3 pillars of action:

- Data governance and rules
- Data quality and interoperability
- Infrastructure and technology

Matrix of the EHDS

	Governance	Quality of Data	Infrastructure
Better Healthcare	Legislative and non-legislative measures on governance and rules for primary and secondary use of data, respecting GDPR (data for healthcare, policy making, research and innovation)	Uptake and develop the EHRxF	MyHealth@EU ERN-CPMS 1+mil genomes Access of regulators to data
Better Policy Making		FAIR-ification of health data for primary and secondary use	Linking repositories in MS, including data permit authorities, registries and other databases
Better Research and Innovation	AI framework (incl AI&liability)		Images database Research infrastructures

Governance – preparatory work

Workshops & study on primary and secondary use of health data (2020: 29 Jan, 16 Mar, 28 Apr) DE EPSCO Council and Council Conclusions

- Mapping of GDPR implementation
 - Access of citizens to health data and portability of data, including rules and governance structures
 - Use of data for policy making and regulatory purposes, access of regulators to health data: rules and governance structures
 - Use of data for research and innovation: rules and governance structures
- What **EU action**?

Study on regulatory gaps in cross-border digital healthcare – *digital healthservices, AI (including AI&liability, evaluation of article 14 of the Directive 2011/24)*

Joint Action on European Health Data Space, (to be signed in Q3 2020)

Support for a **Code of Conduct** on secondary use of health data (to be launched in 2020)

- build upon the workshops

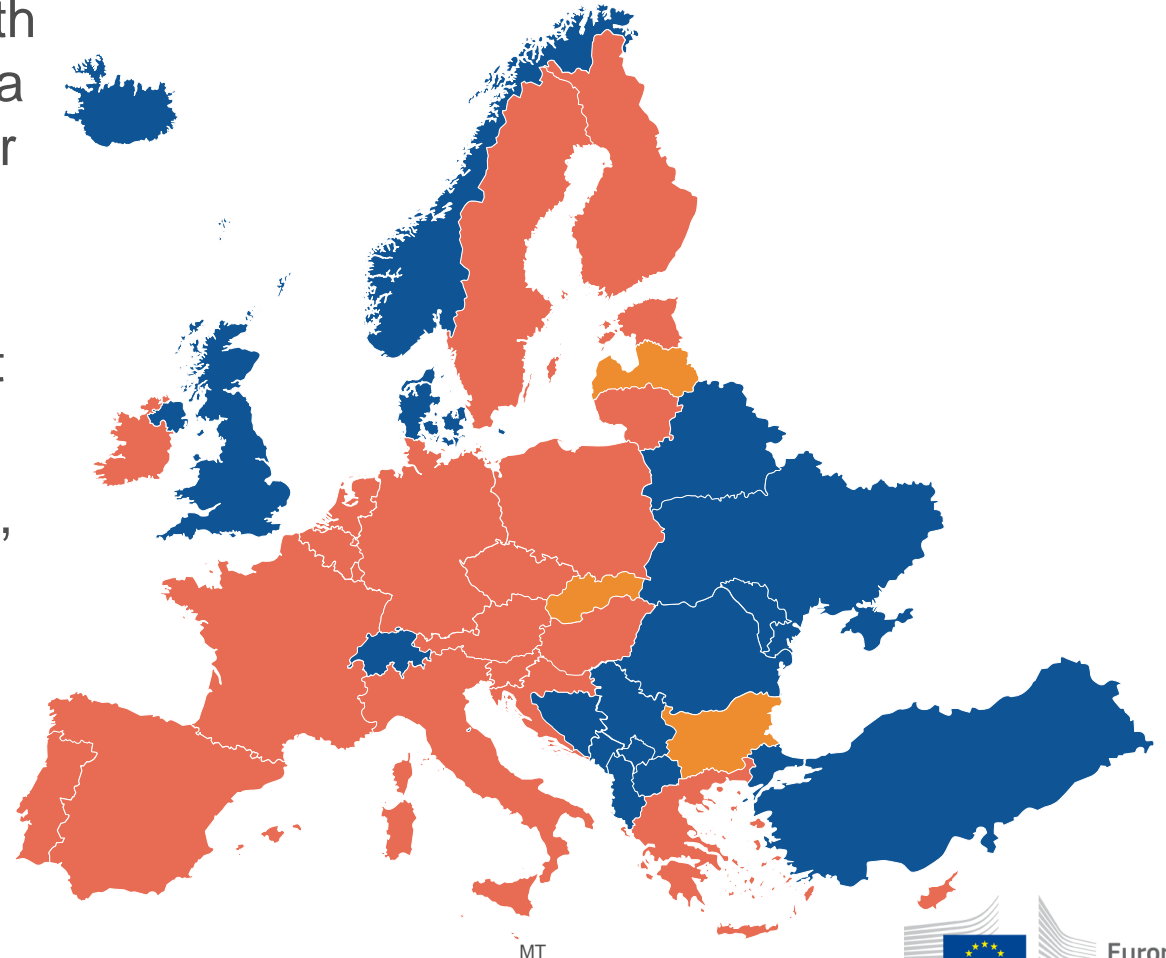
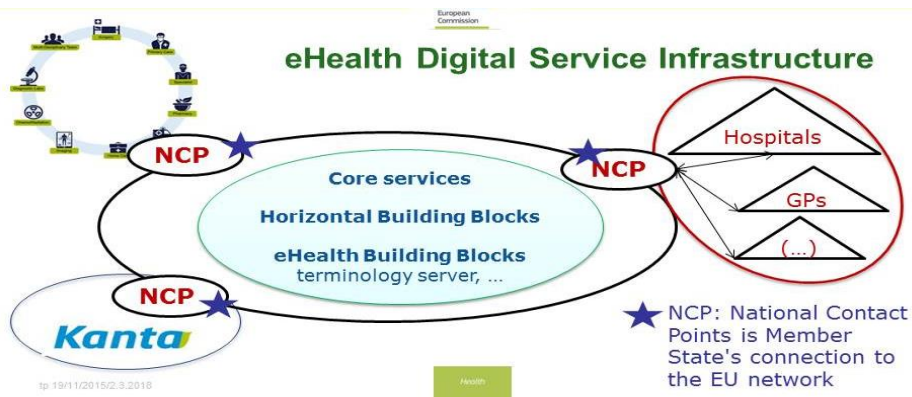
Data quality

- Joint action
- Projects for FAIR-ification of data
 - Electronic health records
 - Data for research

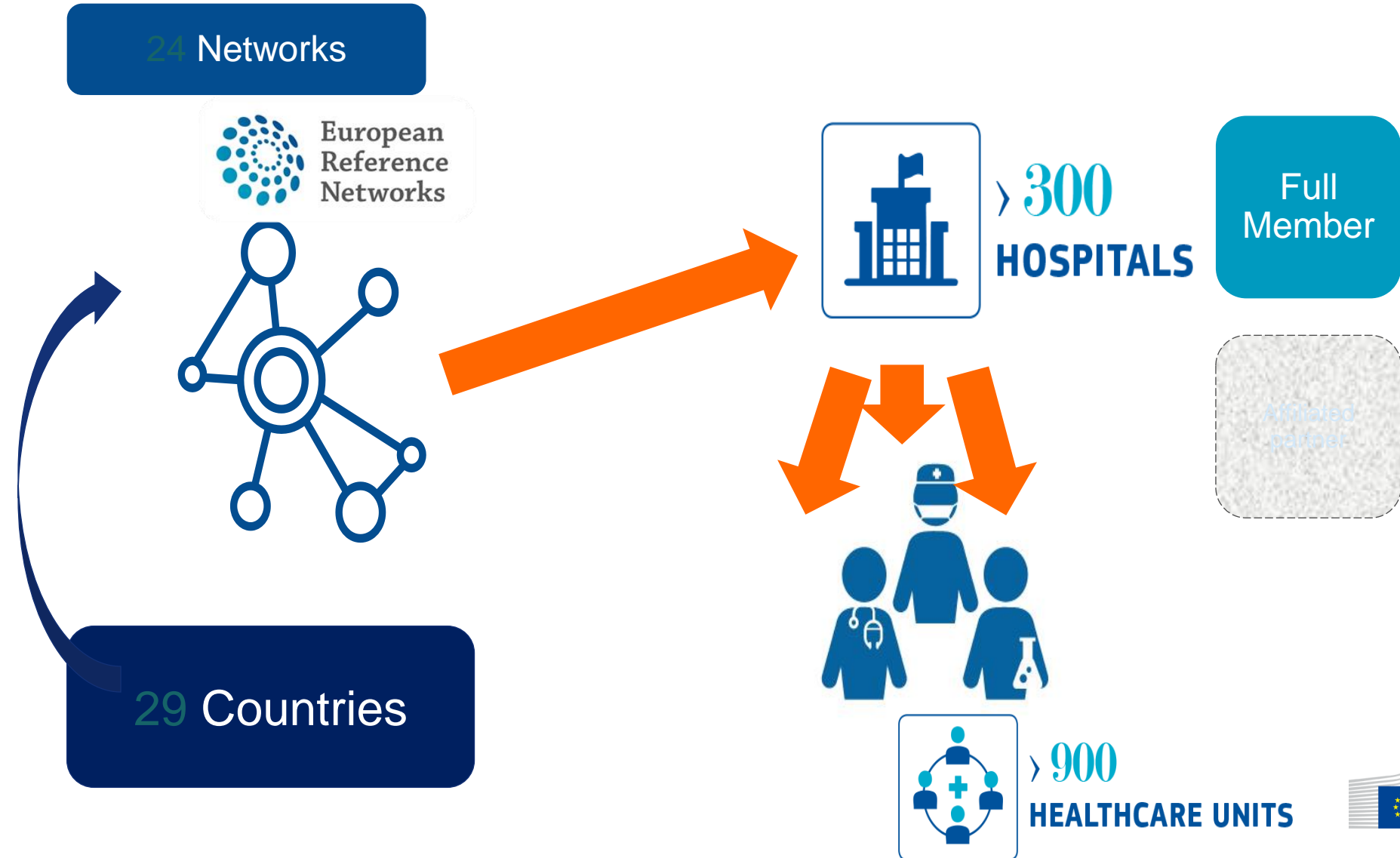
Infrastructure: My Health@EU/eHDSI

MyHealth@EU enables exchange of patient data across borders

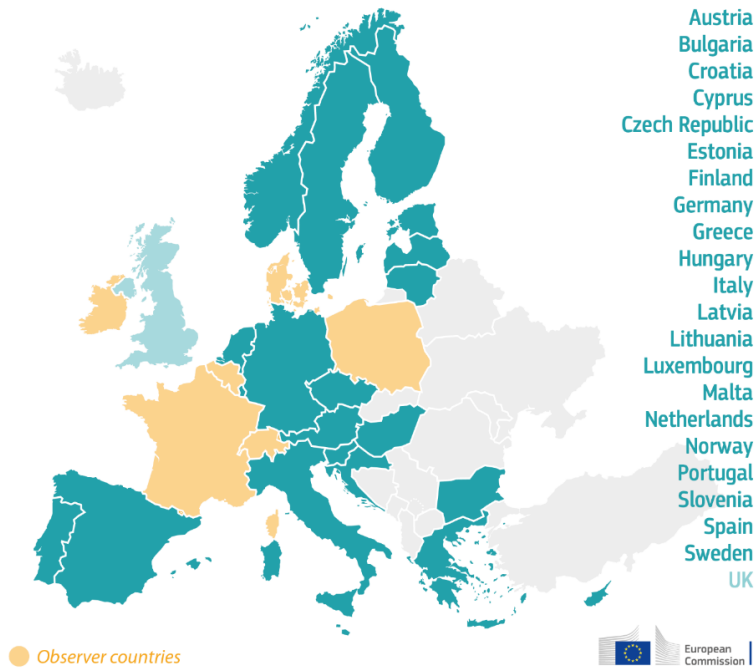
- **Patient Summary** provides access to health professionals to verified key health data of a patient during an unplanned care encounter while abroad
- **ePrescription** enables patients to receive equivalent medication while abroad to what they would receive in their home country
- New services to be added: **images**, results, **laboratory discharge** reports



Infrastructure: ERN- CPMS



EU countries agreed to cooperate in linking
genomic data across borders



2018 Declaration "Towards access to at least 1 million sequenced genomes in the EU by 2020"

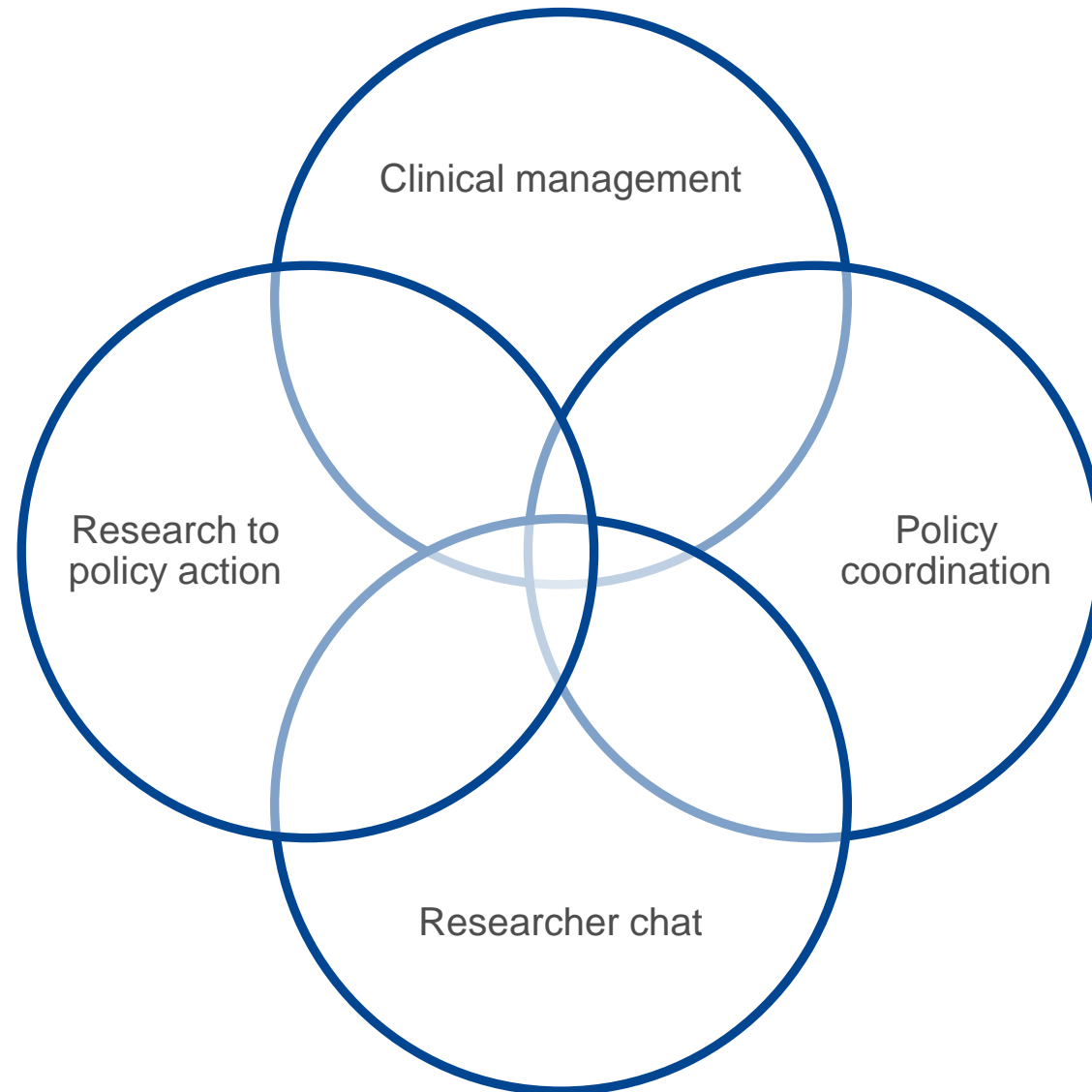
- cross-border access to genomic databases in the EU
- for a sufficient scale for clinically impactful research
 - in full compliance with data protection rules
 - Member States driven initiative
 - EC facilitating the progress

Infrastructure

- Linking MS data sources cross-border
- Technical interoperability guidelines/agreements to enable European Health Data Space services

COVID activities

COVID-19 communication platforms



Work on COVID

- Cooperation between clinicians
- Transfer of patients data between hospitals and MS
- COVID registries: Leoss, semantics (eHN)
- Tracing apps (eHN + COM):
 - COM Recommendation
 - Toolbox
 - Interoperability

Questions:

- In the context of COVID, what is your experience with special systems/rules that have been put in place to **facilitate patient access to care** (eg through telemedicine, telemonitoring), but also to data concerning them and data portability? Did you see any **problems in cross-border context** in these areas? What **action do you believe is needed at EU level** in this area?
- Where do you see the main challenges for the use of data that are collected in the context of care provision for secondary purposes of **public health management**, including the planning of care provision, resources management and the evaluation of care protocols, medicines and devices? Do you see any need for any **EU level guidance or legal action** could be useful now and in preparing for future epidemics?
- Some MS have created systems for citizens to provide access to their data so that it may be shared for research purposes – this is known variably as **data donation, data altruism or data solidarity**. We are keen to hear **your views** about MS who have adopted such systems or are in the process of doing so and if you see any need for **action in this area at EU level**.
- Where do you see the main challenges for the use of data that are collected in the context of care provision for **secondary purposes of scientific research**?
- We would like to hear from your **experience** with countries that have created **special systems or organisations for providing access to health data for research purposes** (eg data permit authorities, data hubs etc.) We are keen to hear about the governance of such secondary use in 'normal' situations and now in the context of a public health crisis.
- What **actions do you believe are necessary at EU level** to support access to data for research purposes across EU borders? Should this be addressed through **hard law or soft law measures such as a Code of Conduct**?

Thank you for your attention!

Questions?

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