



European Health Data Space

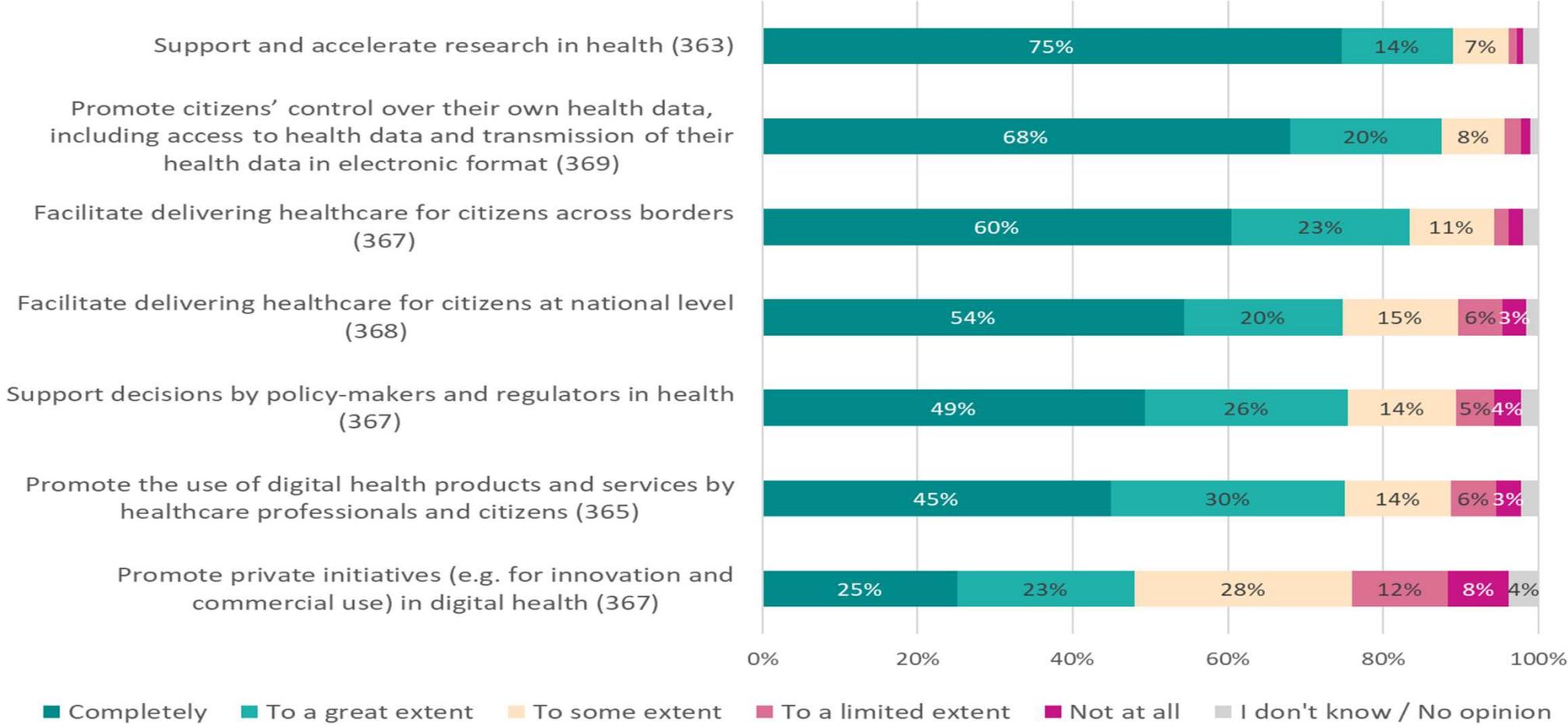
Outcome of the public consultation and key issues

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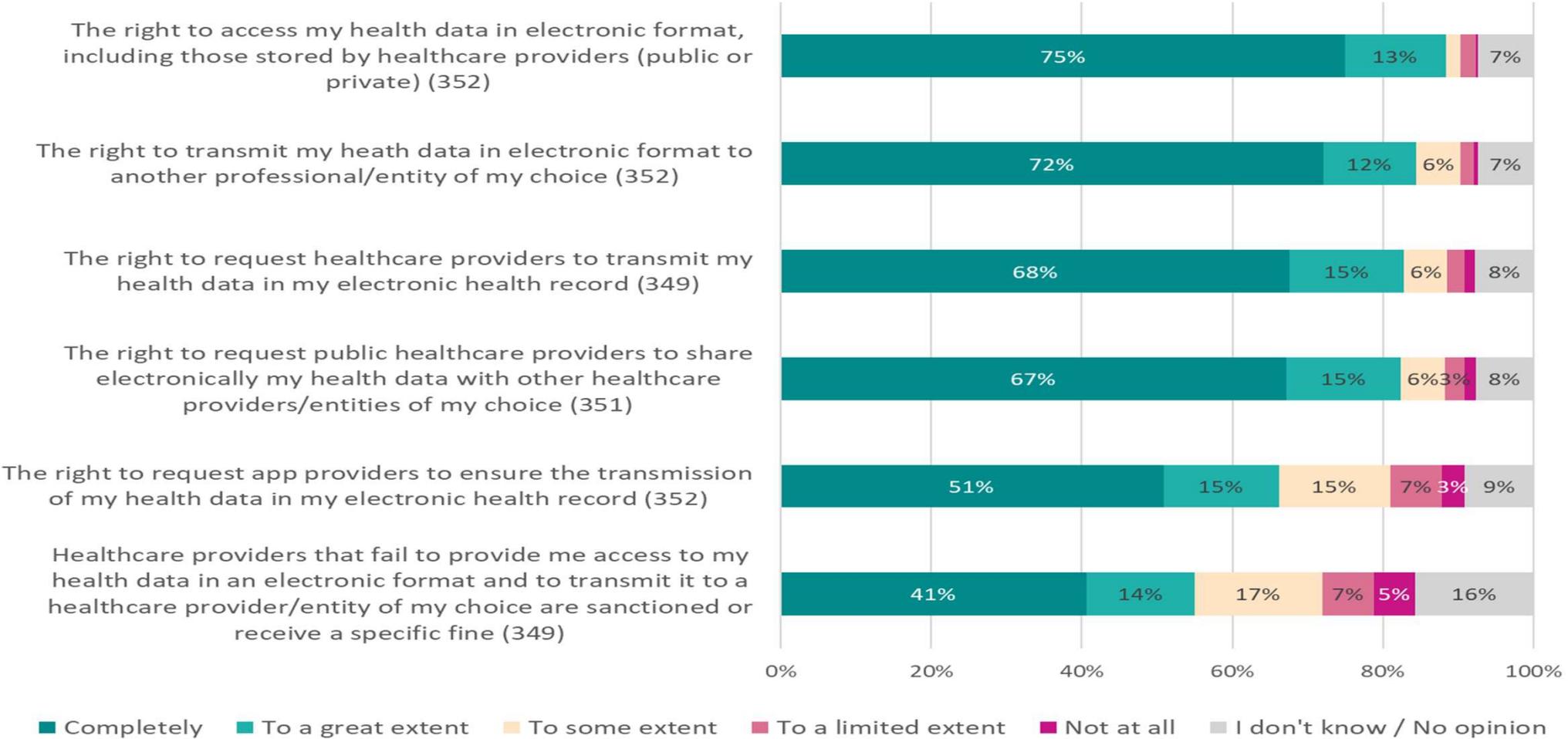


1. Key outcomes

Should a European framework on the access and exchange of personal health data aim at achieving the following objectives?

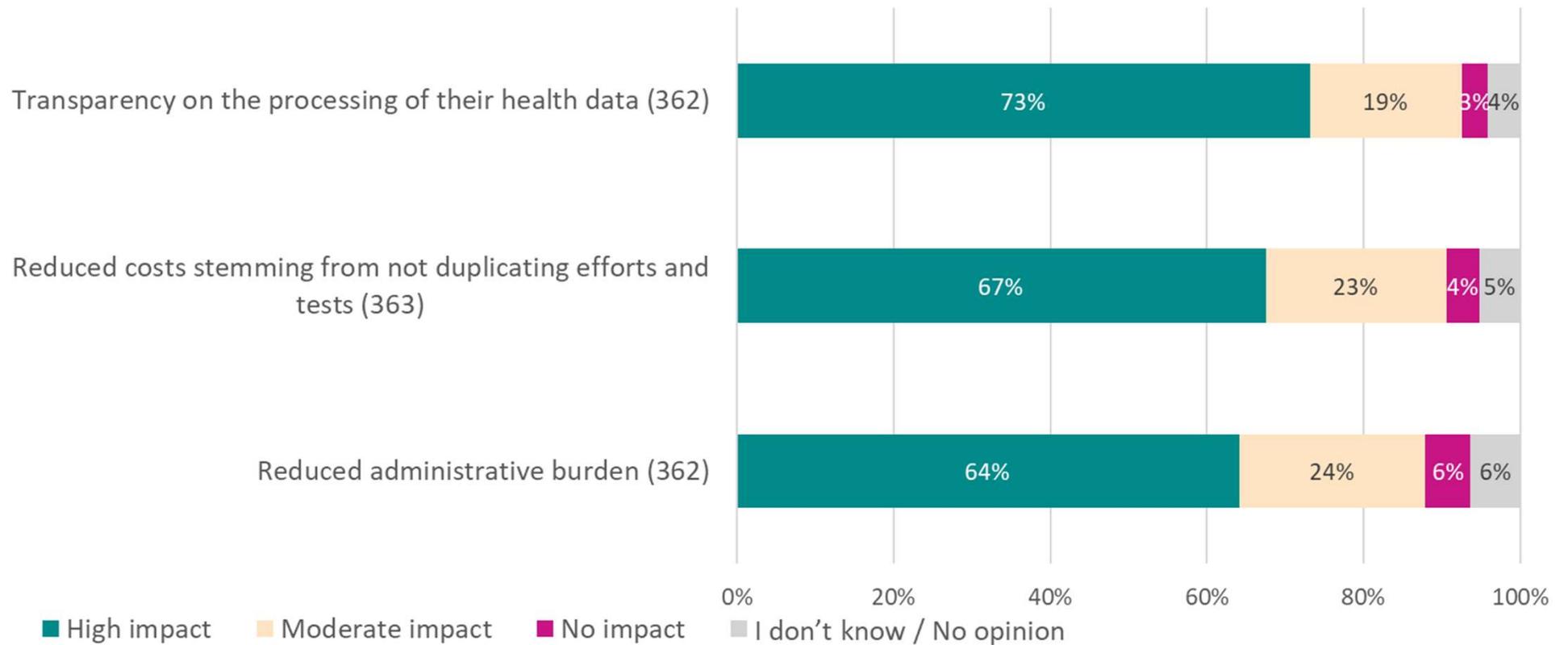


How important is it for you to be granted the following rights?



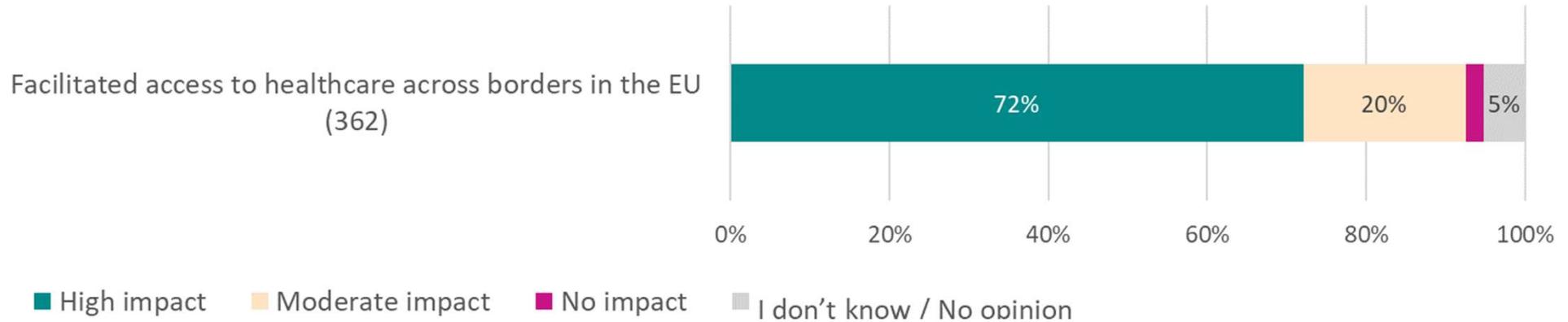
In your view, what would be the benefits for stakeholders of measures facilitating access to, control and transmission of health data for healthcare?

Benefits for patients:



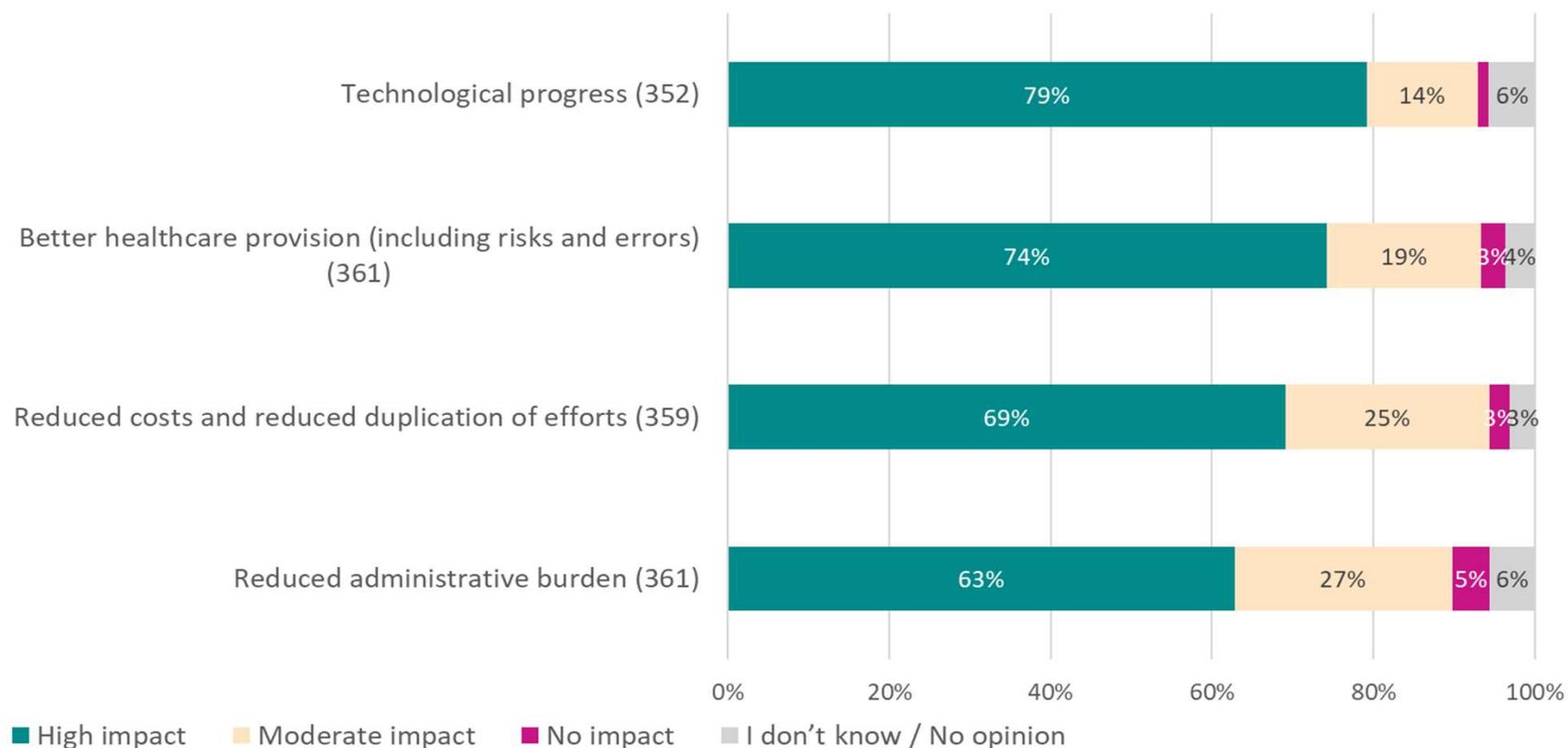
In your view, what would be the benefits for stakeholders of measures facilitating access to, control and transmission of health data for healthcare?

Access to efficient and safe care:

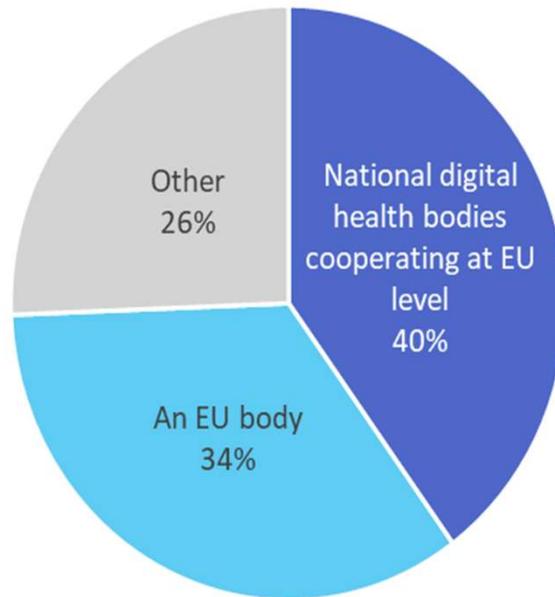


In your view, what would be the benefits for stakeholders of measures facilitating access to, control and transmission of health data for healthcare?

Benefits on healthcare systems efficiencies:



In your view, who is best suited to develop these standards and technical requirements at EU level to support exchange of data in healthcare?





2a. Use of data for healthcare

Primary use of health data (EHDS 1/MyHealth@EU)



Access to health data in digital format

Today, a large number of EU citizens and healthcare professionals cannot access health data in a **digital format**. Data are often available in paper, or only a limited set of data categories are available in digital format.

Interoperable health data

Health data is collected in such a way, that **the format is different** everywhere. This makes it impossible to understand the meaning of health data in different contexts. Therefore, interoperability standards are required to **promote wider use and understanding**.



Tools and infrastructure

Member States organise health data access through different means. Some member states have patient or professional **portals** at the level of healthcare provider, region or nation, while others have apps or **personal data space** solutions. Also, registries of who should have **access** are also local, regional or national solutions.



2b. Use of data for research, policy making and AI

Secondary use of health data

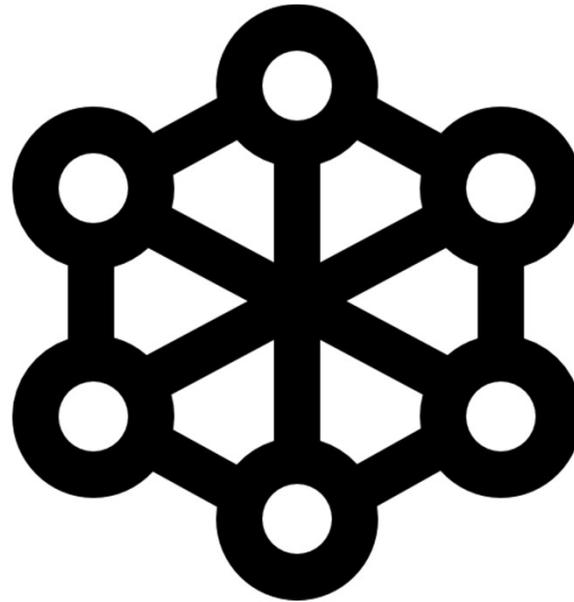
Secondary use of data in the EHDS



Reuse of health data by researchers, policy-makers and industry



Health data from patients and healthcare professionals



Other research data



Rules, protocols, infrastructure and governance



Granting researchers, policy-makers and industry access to health data across borders in an interoperable, digital format



3. Key issues and next step

EHDS: What are the problems?

Use of health data for healthcare (primary)

Sharing of health data for healthcare

- Limited control to and access to patients
- Repeated tests and high costs
- **Insufficient exchange** of health data
- **Limited interoperability** between health care providers

Single market for digital health products and services

- Uneven national **legislative frameworks**
- Uneven **quality / interoperability** frameworks
- Uneven **procedures** for prescriptions, reimbursement, liability

Re-use of health data (secondary)

Access to health data for research, innovation, public health policy making

- **Low re-use** of health data
- **Cumbersome cross-border access** to health data
- **Fragmented digital infrastructures**

Artificial Intelligence

- Limited **provision** of data for training of AI
- Difficulties for regulators to evaluate
- **AI algorithms**
- Uncertainty on AI **liability** in health

Towards a European Health Data Space (EHDS)

OBJECTIVES

Timely and simplified *exchange of and access to* health data

SCOPE & EXPECTED IMPACT

Use of health data
(primary, EHDS1)

- **Individuals to access and control their data & exchange of health data** (incl. cross-border), irrespective of source (electronic health records, tele-health, m-health, wellness apps)



Single market for data, data protection, free movement of people, digital goods and services

Re-use of health data
(secondary, EHDS2)

- **Research, innovation**
- **Policy** (incl. e.g. public health, HTA) & **Regulatory decisions**



Facilitated Research & Innovation



Better Policy Making

MEANS

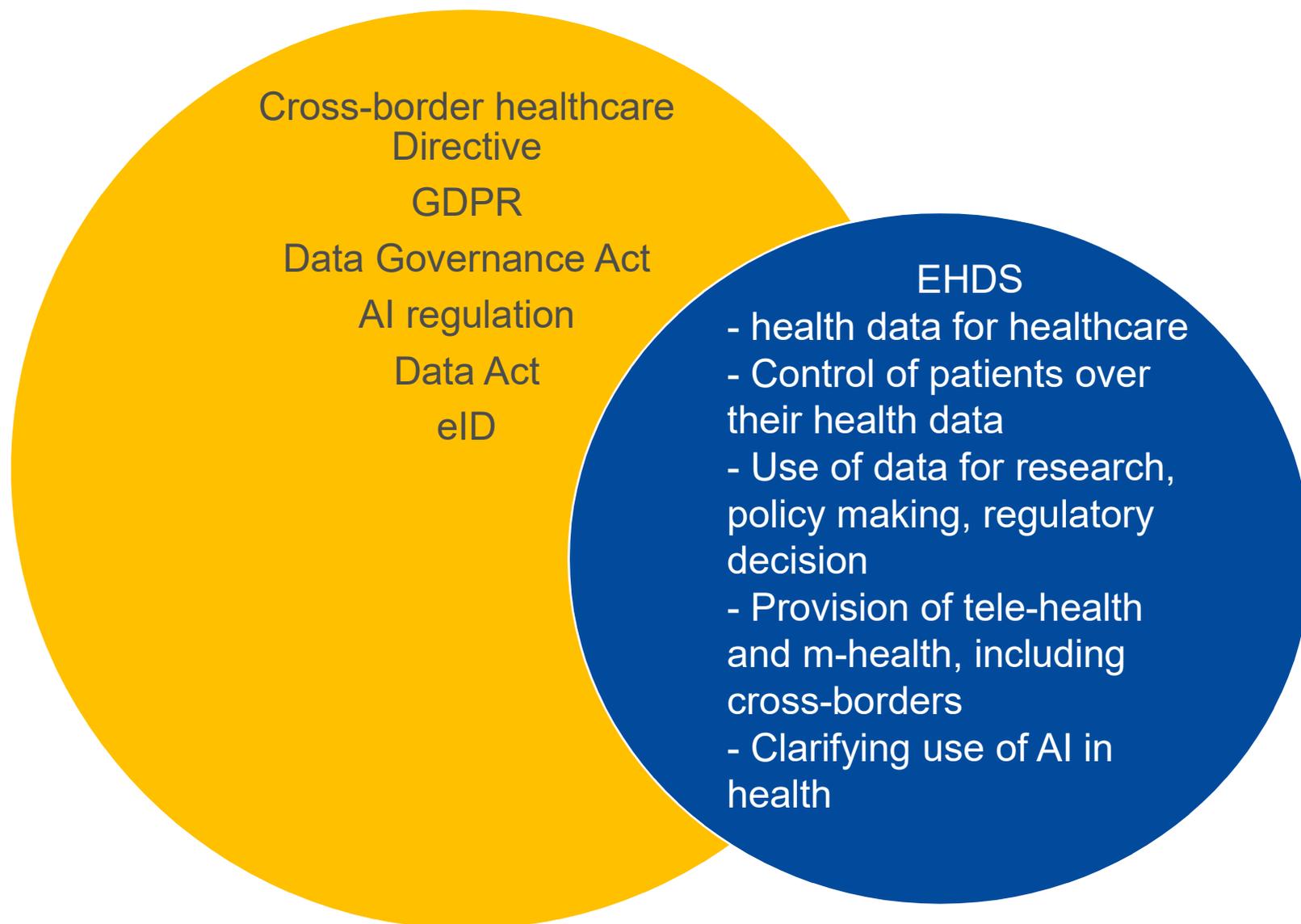
Legal / Governance

Quality of data

Infrastructure

Capacity building/digitalisation
(MFF)

EHDS: Articulation with EU regulatory framework



EHDS: next steps

Inception Impact Assessment:

<https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-A-European-Health-Data-Space>

Public consultation (3 May – 26 July 2021)

Impact Assessment (Q3 2021)

- Study on Assessment of the EU Member States' rules on health data in the light of GDPR (Q1 2021)
- Study on regulatory gaps, including evaluation D. 2011/24/EU, digital health services, AI (Q2 2021)
- Studies to support the Impact Assessment (Q3 2021)
- JA TEHDAS 2021

Consultation EDPS

Legal proposal (first part 2022)

Thank you



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