



# European Health Data Space

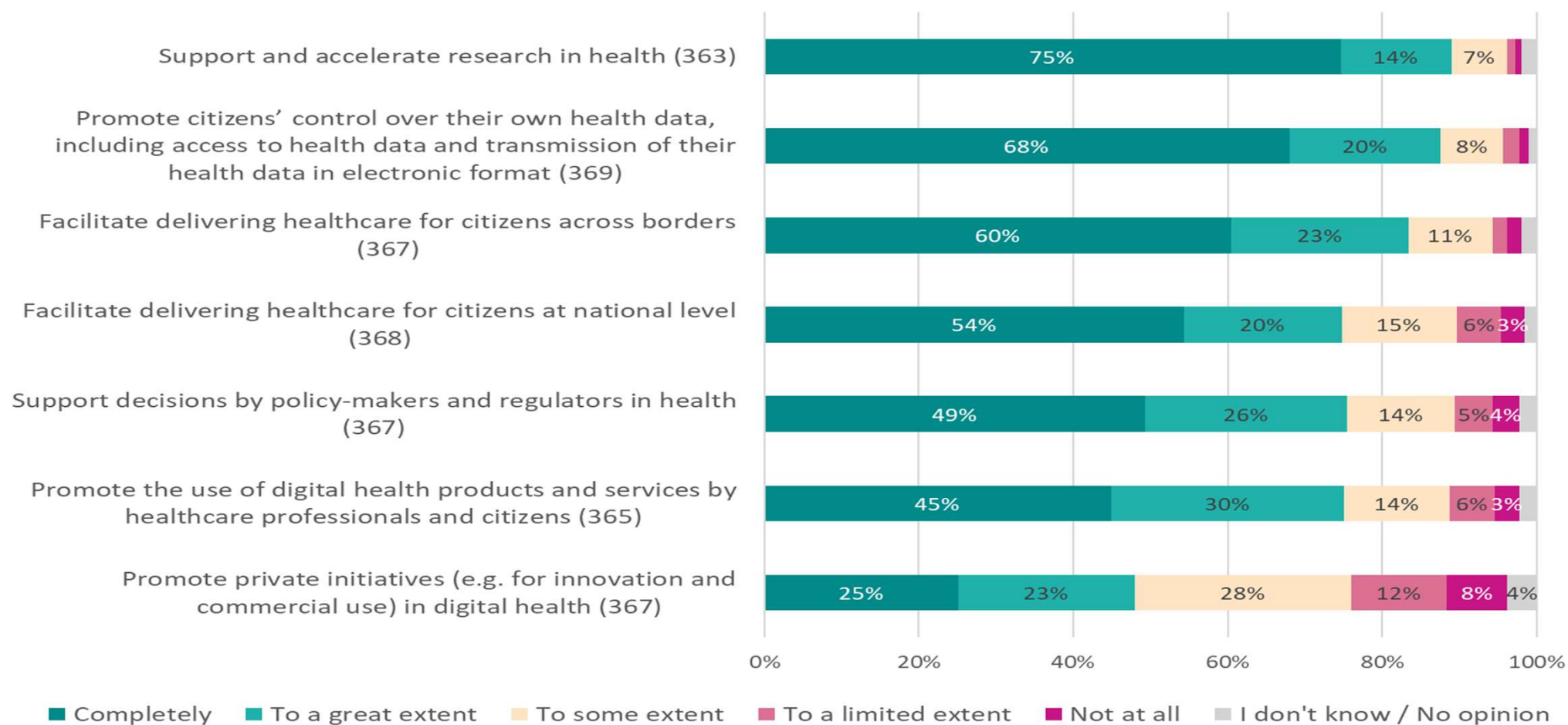
## Outcome of the public consultation and key issues

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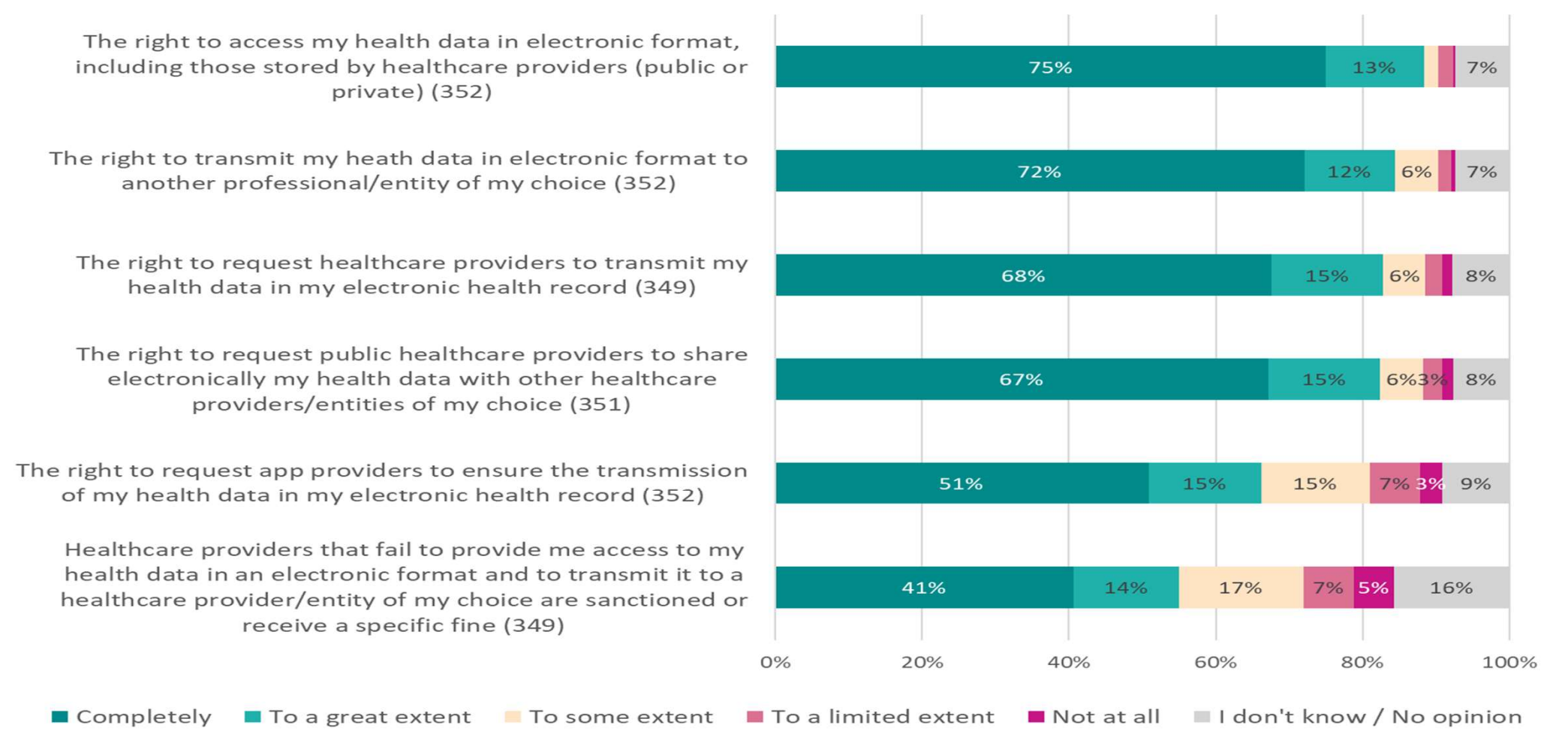


# 1. Key outcomes

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

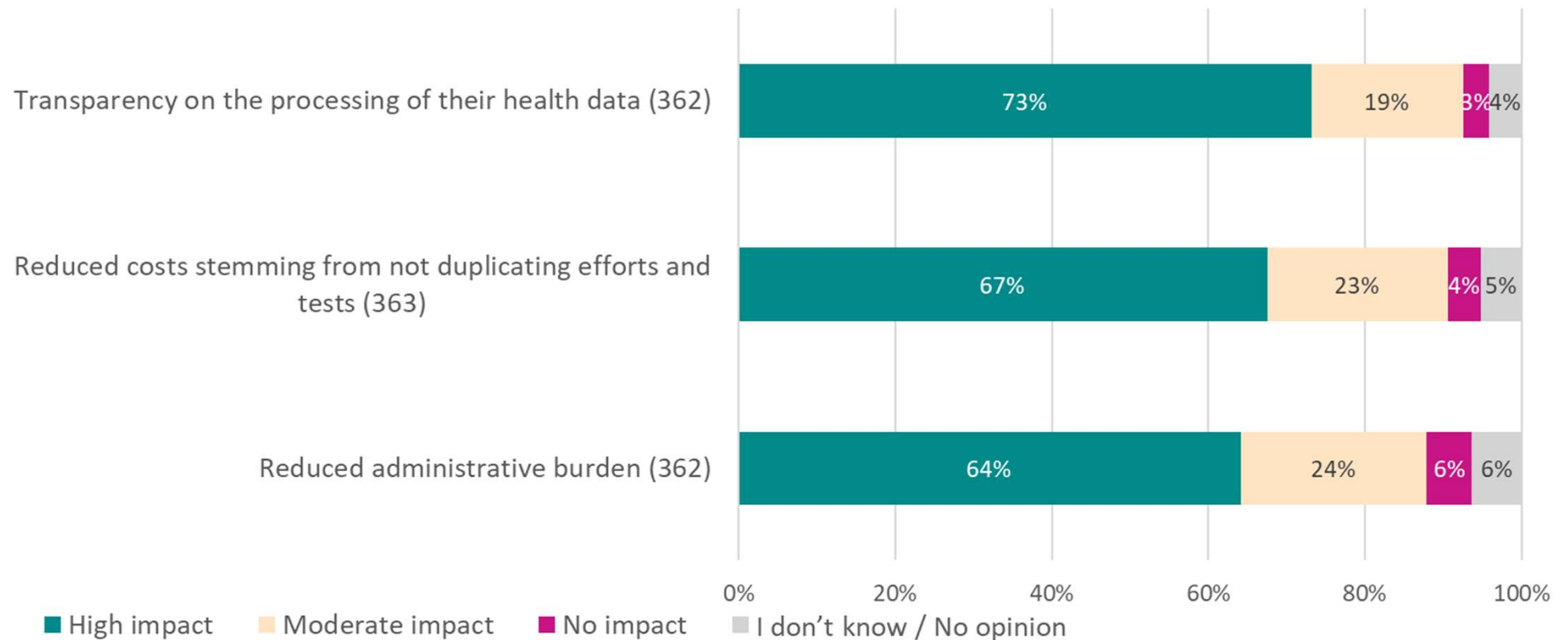


# How important is it for you to be granted the following rights?



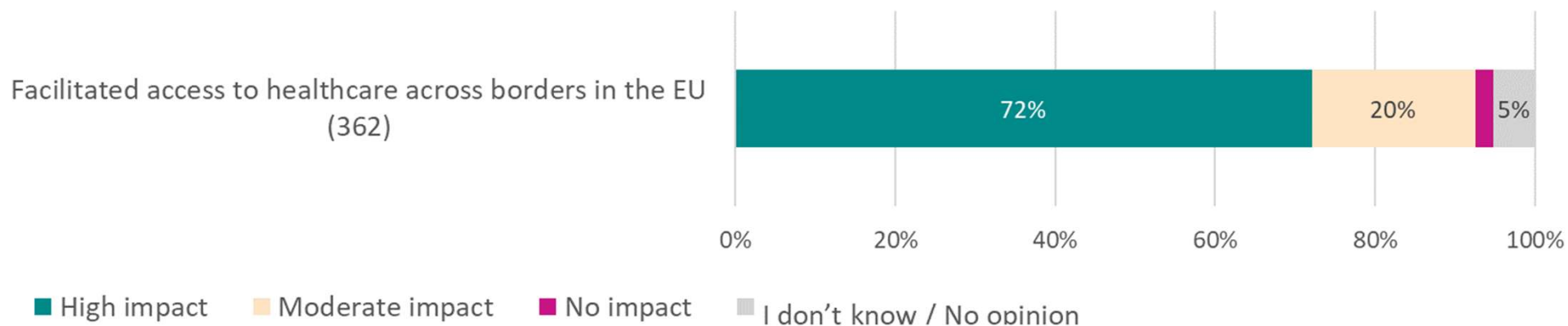
# In your view, what would be the benefits for stakeholders of measures facilitating access to, control and transmission of health data for healthcare?

## Benefits for patients:



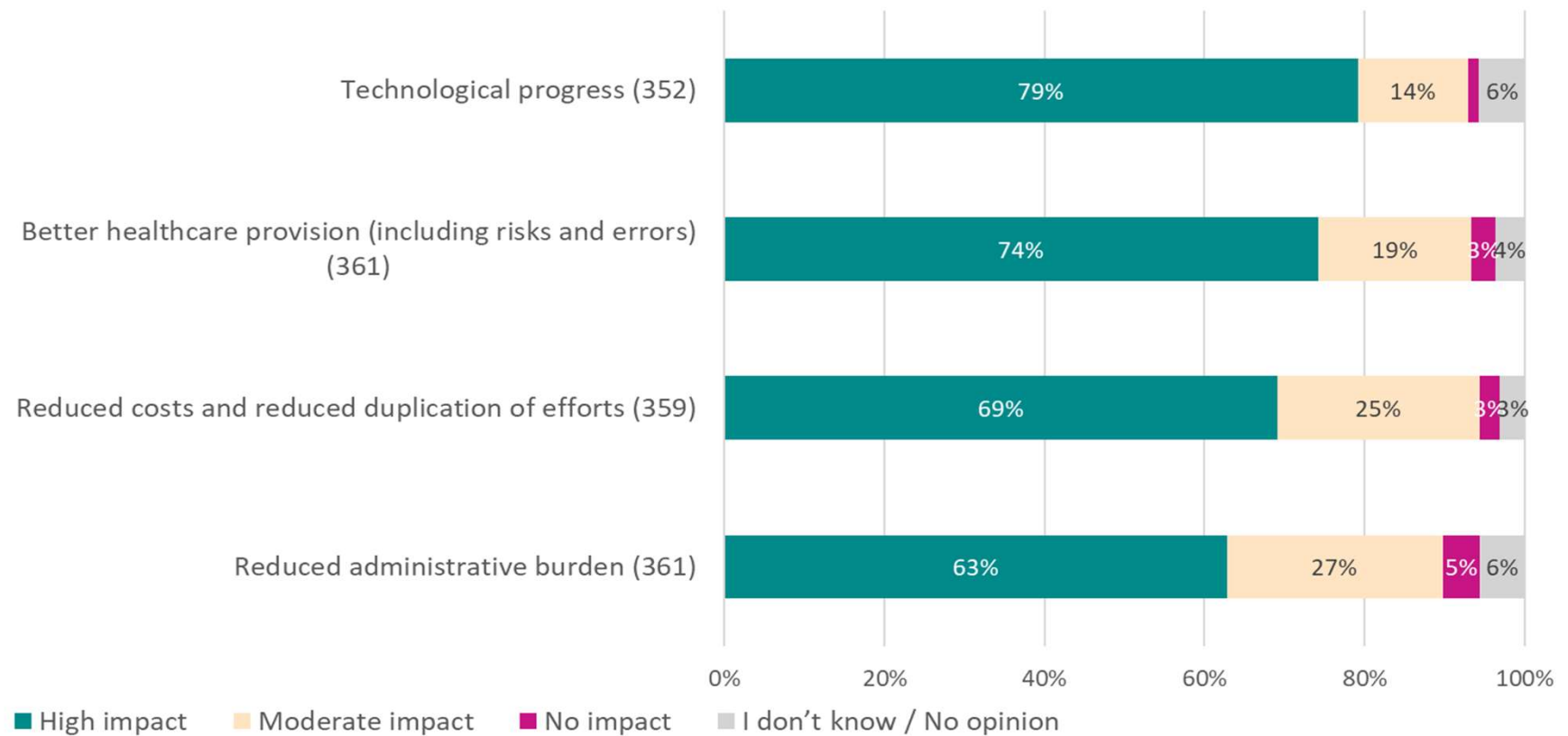
In your view, what would be the benefits for stakeholders of measures facilitating access to, control and transmission of health data for healthcare?

Access to efficient and safe care:

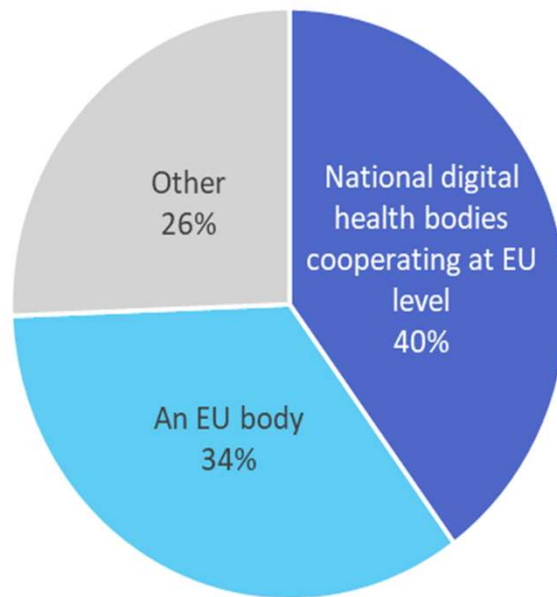


# In your view, what would be the benefits for stakeholders of measures facilitating access to, control and transmission of health data for healthcare?

## 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.



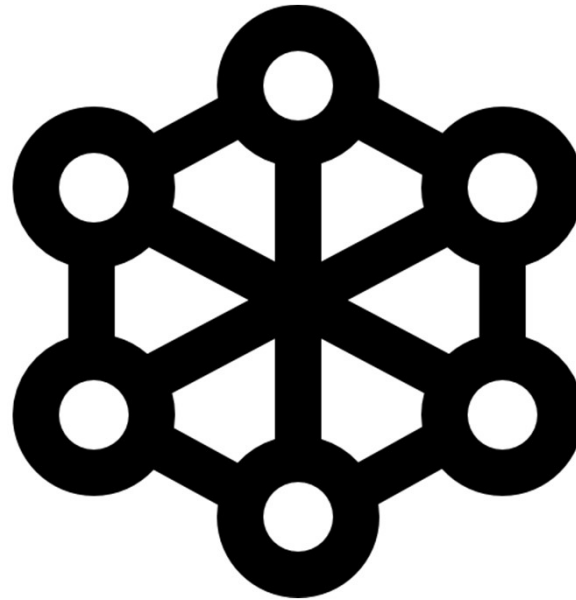
# 2b. Use of data for research, policy making and AI

Secondary use of health data

# Secondary use of data in the EHDS



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

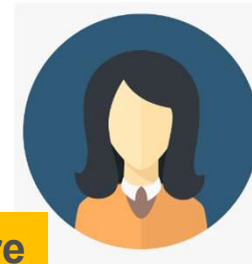


Health data from patients and healthcare professionals

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

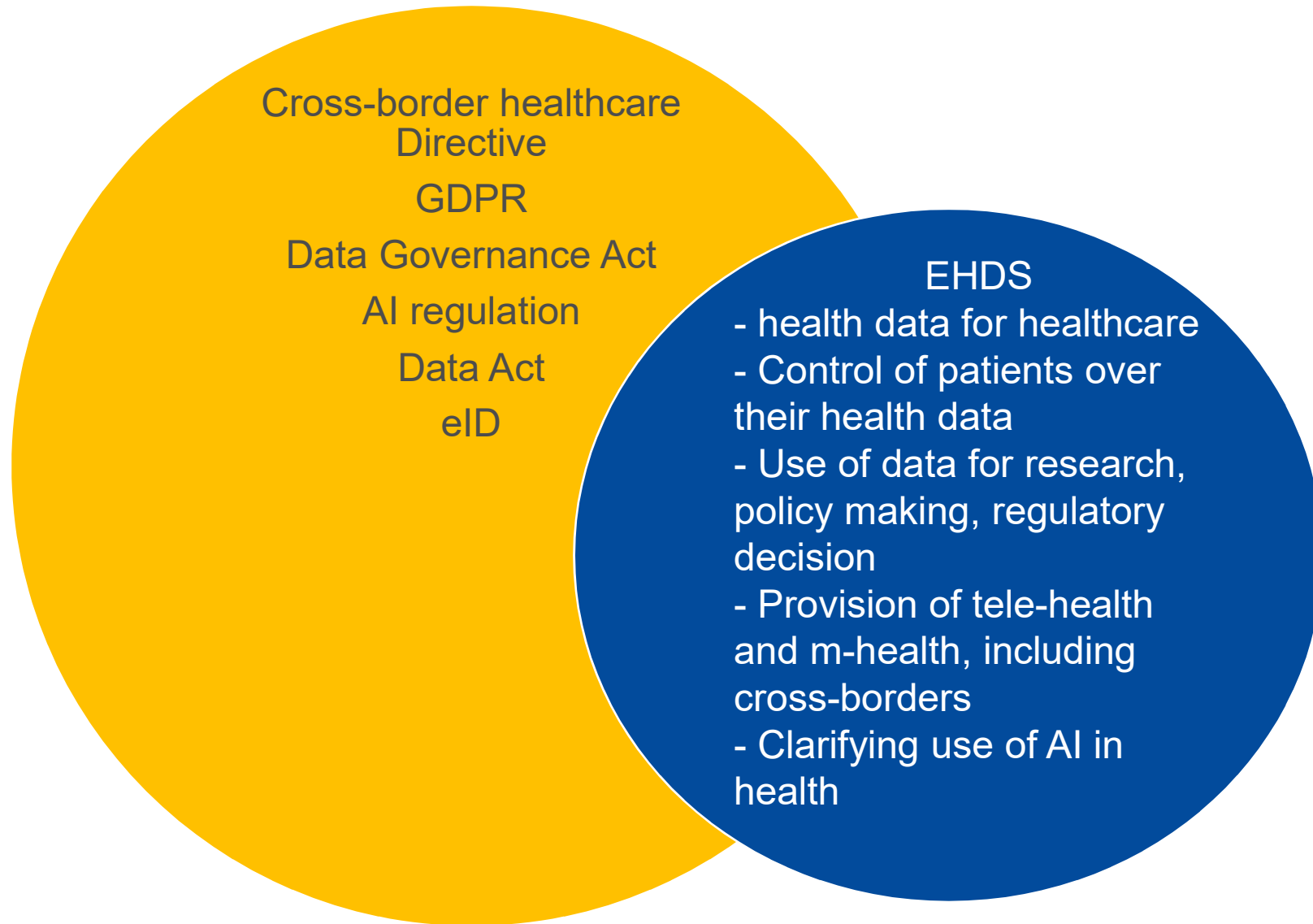
Infrastructure

Capacity building/digitalisation (MFF)



European  
Commis

# 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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