

EHTEL Thought Leader Symposium
28th November 2022

Summary of the
*European Health
Data Space
Regulation*

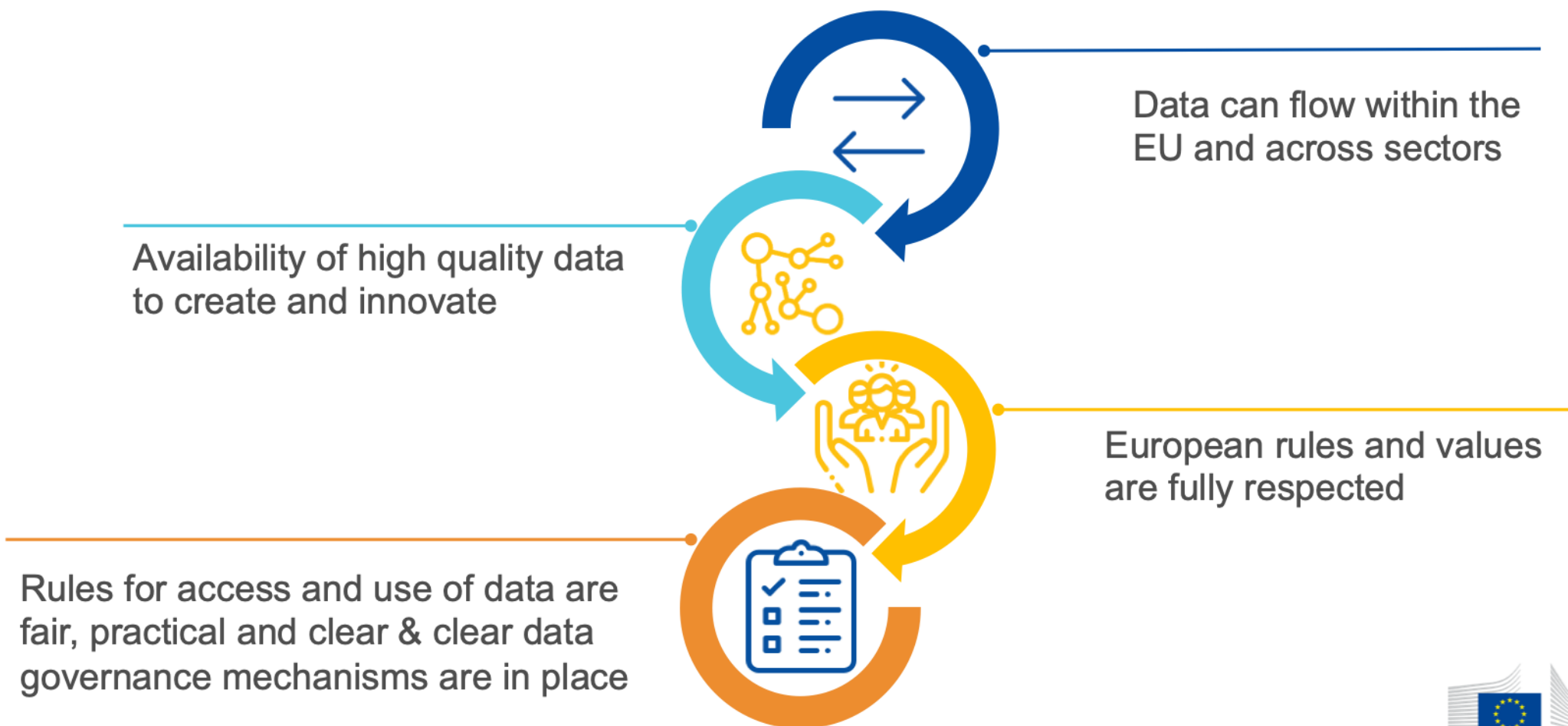


Health data drives innovation

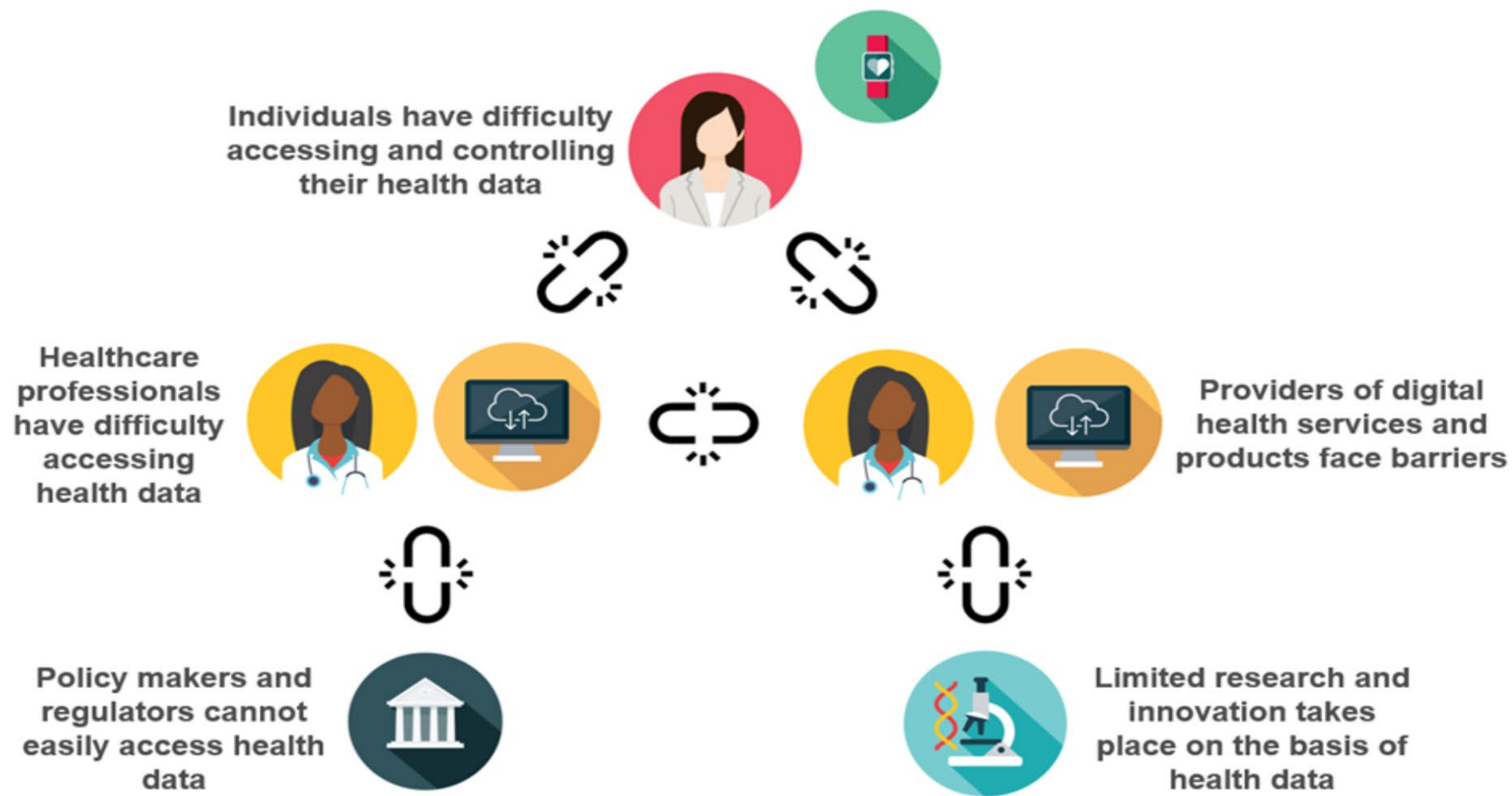
Dipak Kalra
President of i~HD

European Strategy for Data

A common European data space, a single market for data



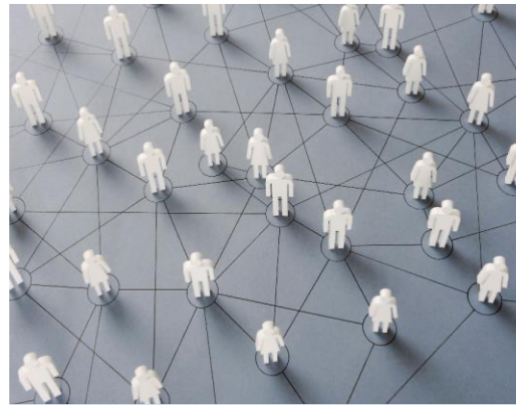
Main challenges in harnessing the power of health data



Proposal for a Regulation on the European Health Data Space

It sets out rules, common standards, infrastructures and a governance framework for the use of electronic health data for healthcare, research, innovation and policy making

Empower individuals to access and control their personal health data

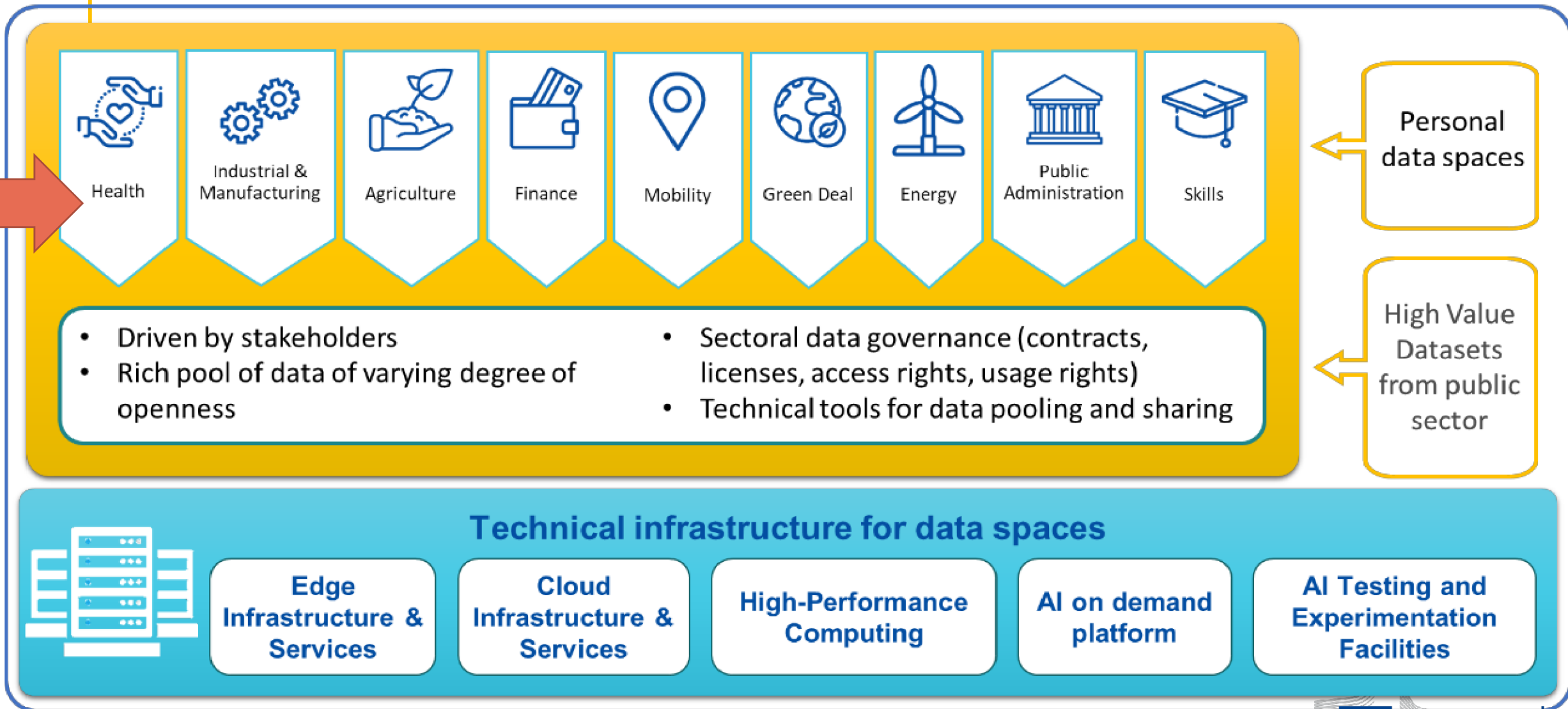


Ensure a consistent framework for the use of individuals' health data for research, innovation, policy-making and regulatory activities

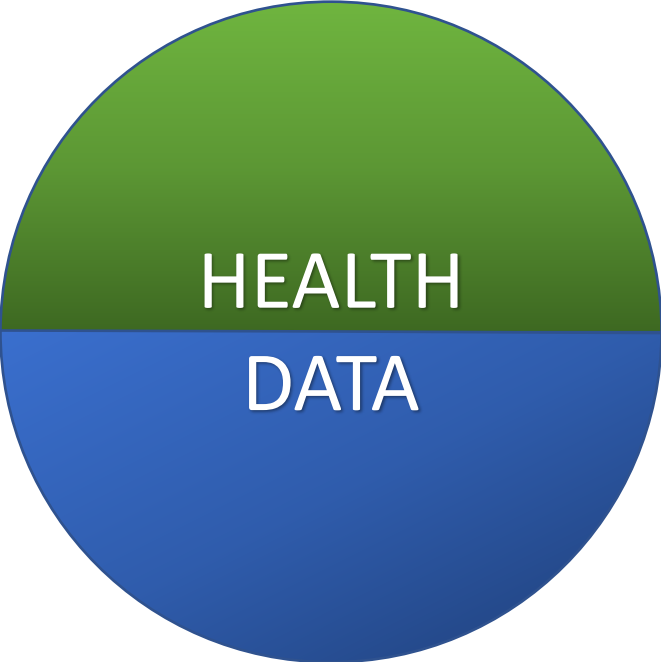
Unleash the data economy by fostering a genuine single market for digital health services and products (EHR systems)



EHDS – the first sector specific European Data Space



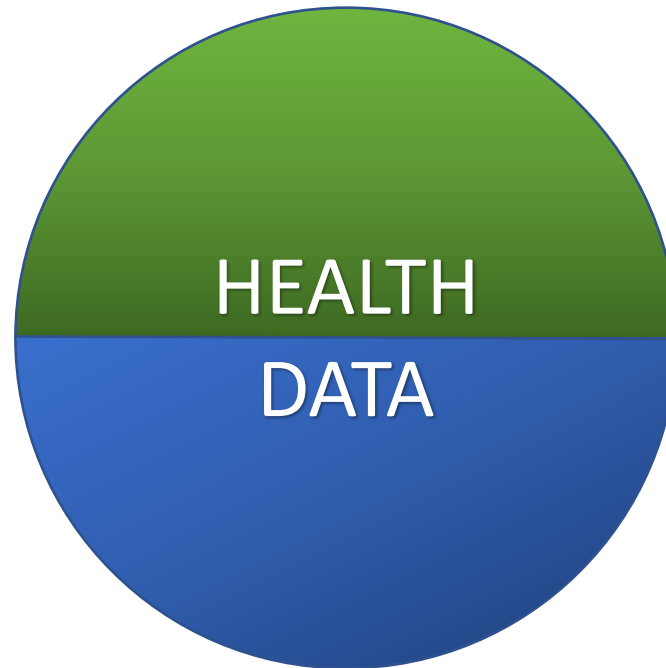
Primary Use
For health, care, wellness



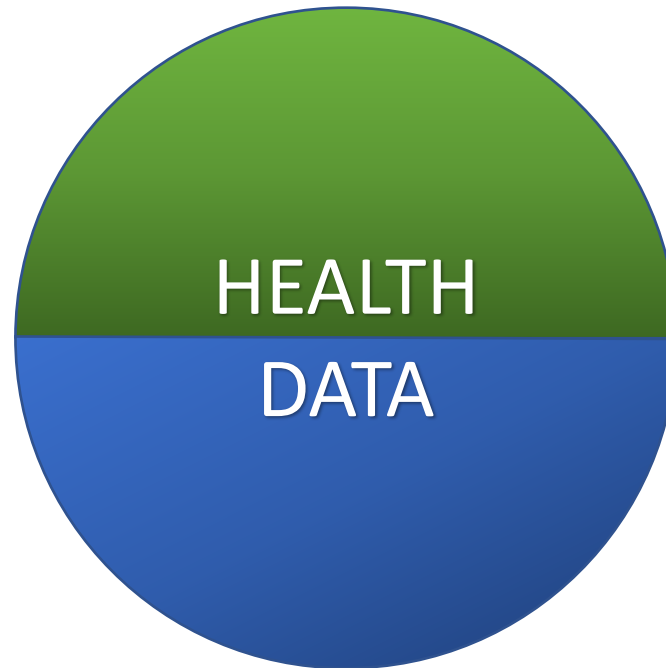
Primary Use

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- Aims:
 - Natural persons in the EU have increased control in practise over their electronic health data
 - Better exchange and access to different types of electronic health data, including electronic health records, genomics data, patient registries etc. to support healthcare delivery



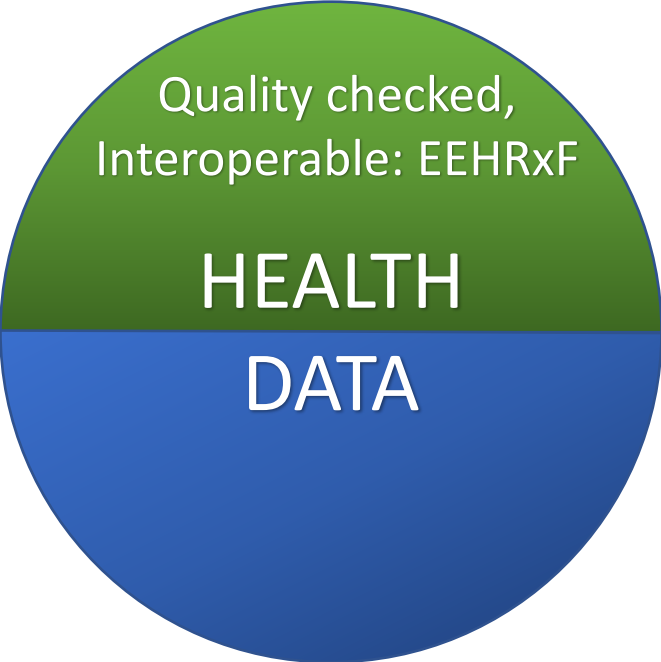
Primary Use
For health, care, wellness



Secondary Use
For research and strategy

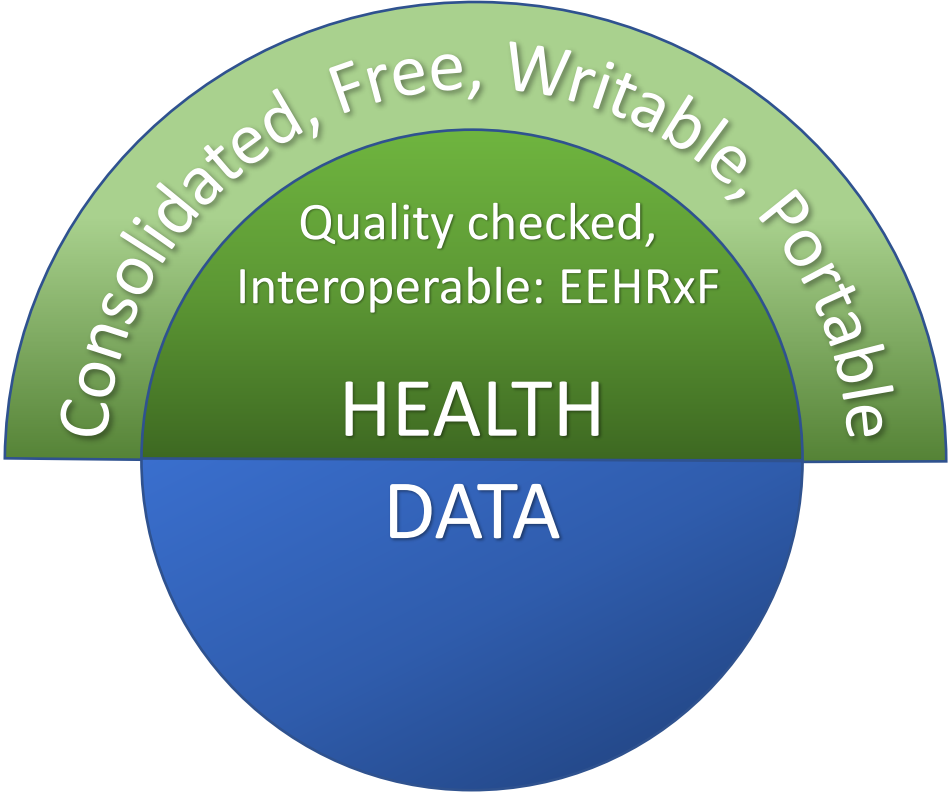
- Aims:
 - Researchers, innovators, policy- makers and regulators at EU and Member State level to access relevant electronic health data to promote better diagnosis, treatment and well-being of natural persons, and lead to better and well- informed policies
 - Support health research, innovation, policy-making, regulatory purposes and personalised medicine purposes

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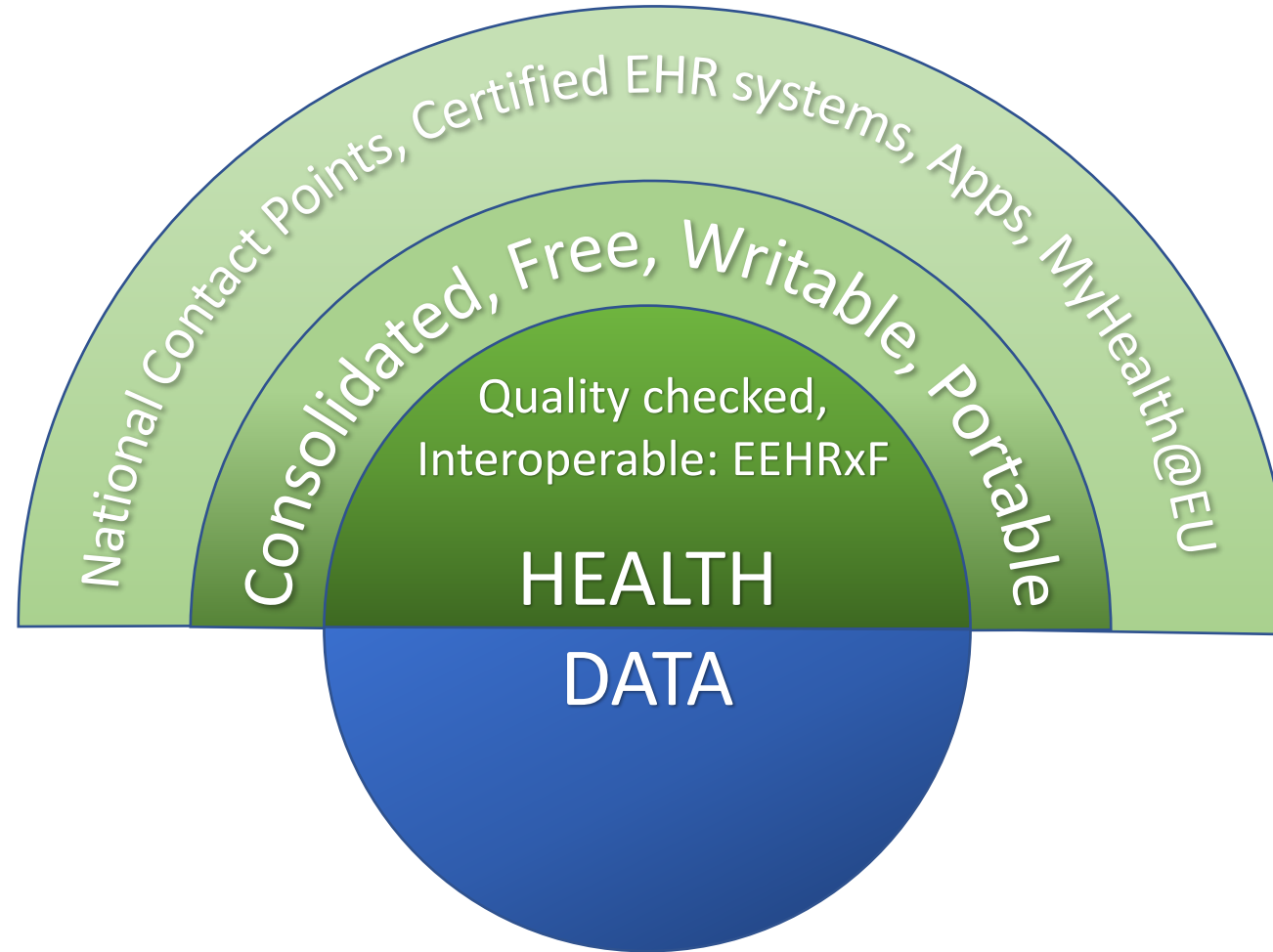
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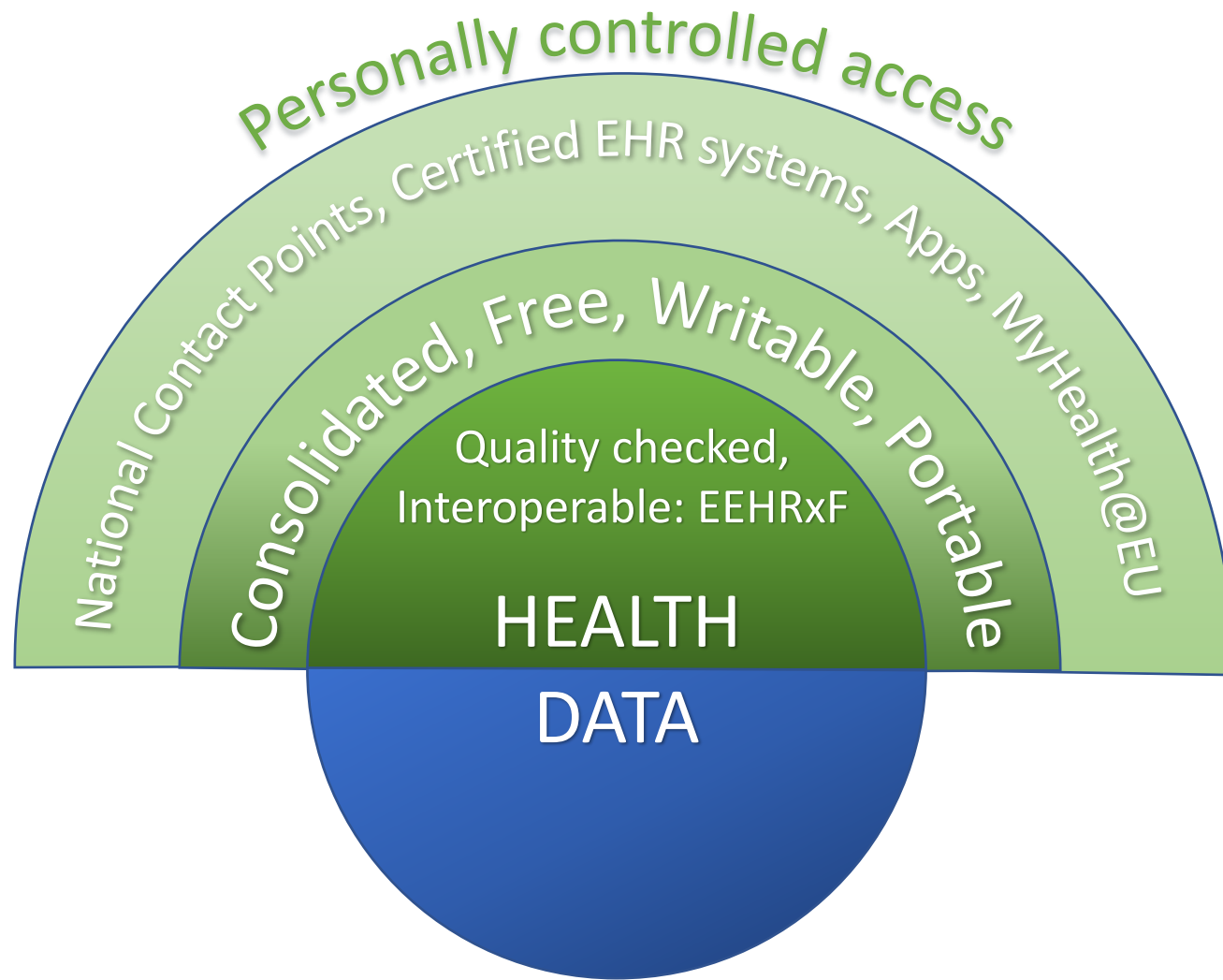
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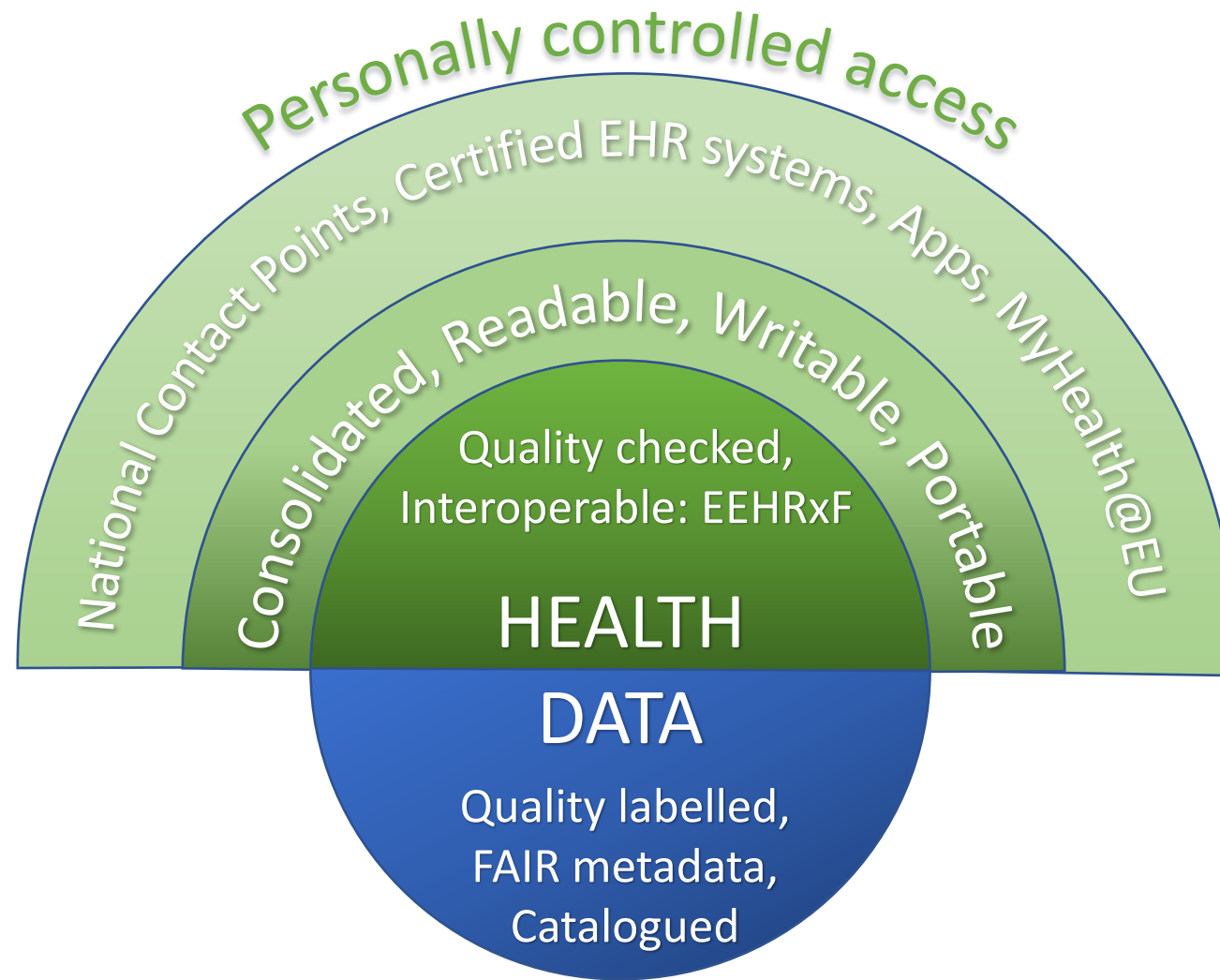
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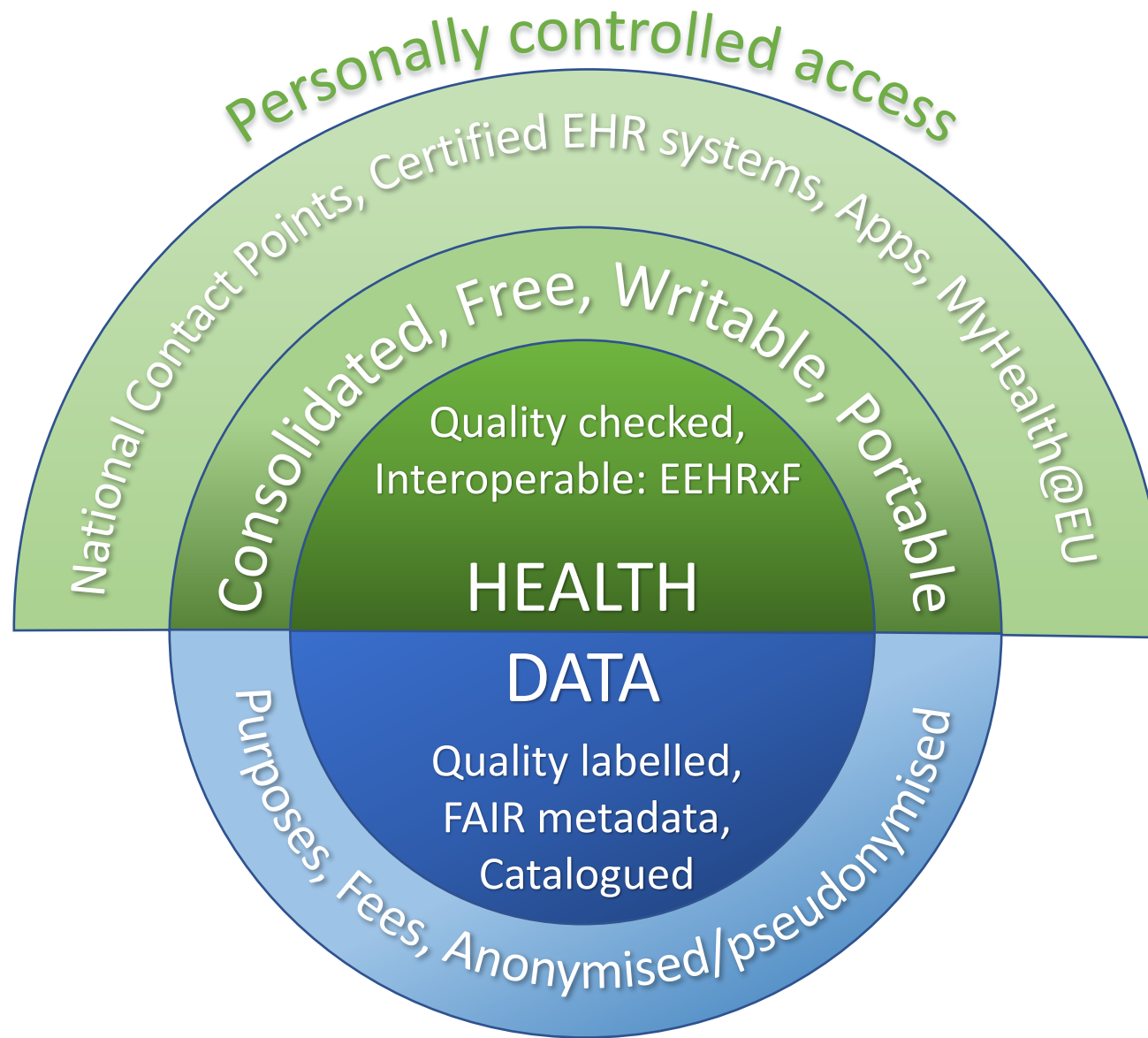
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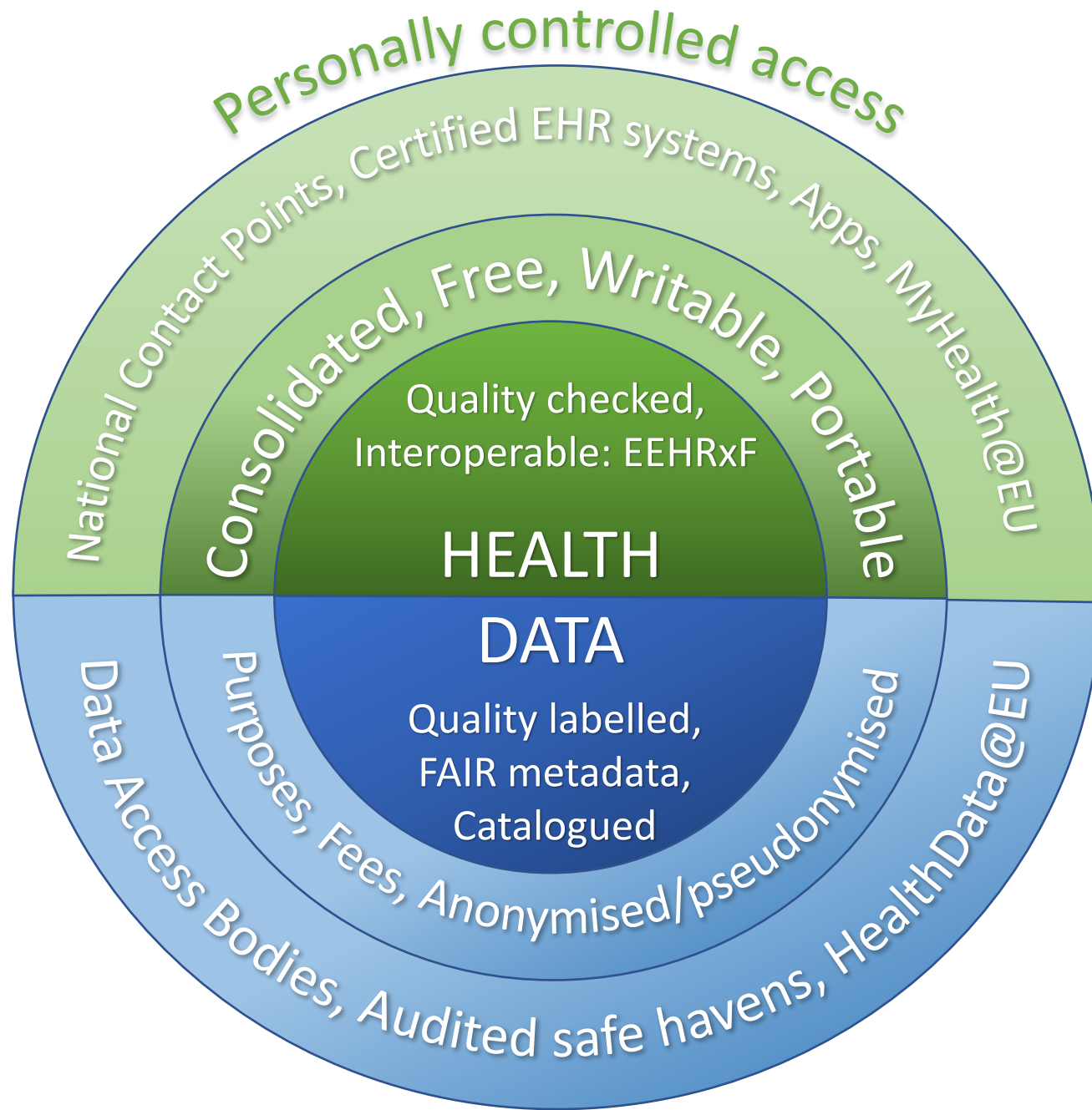
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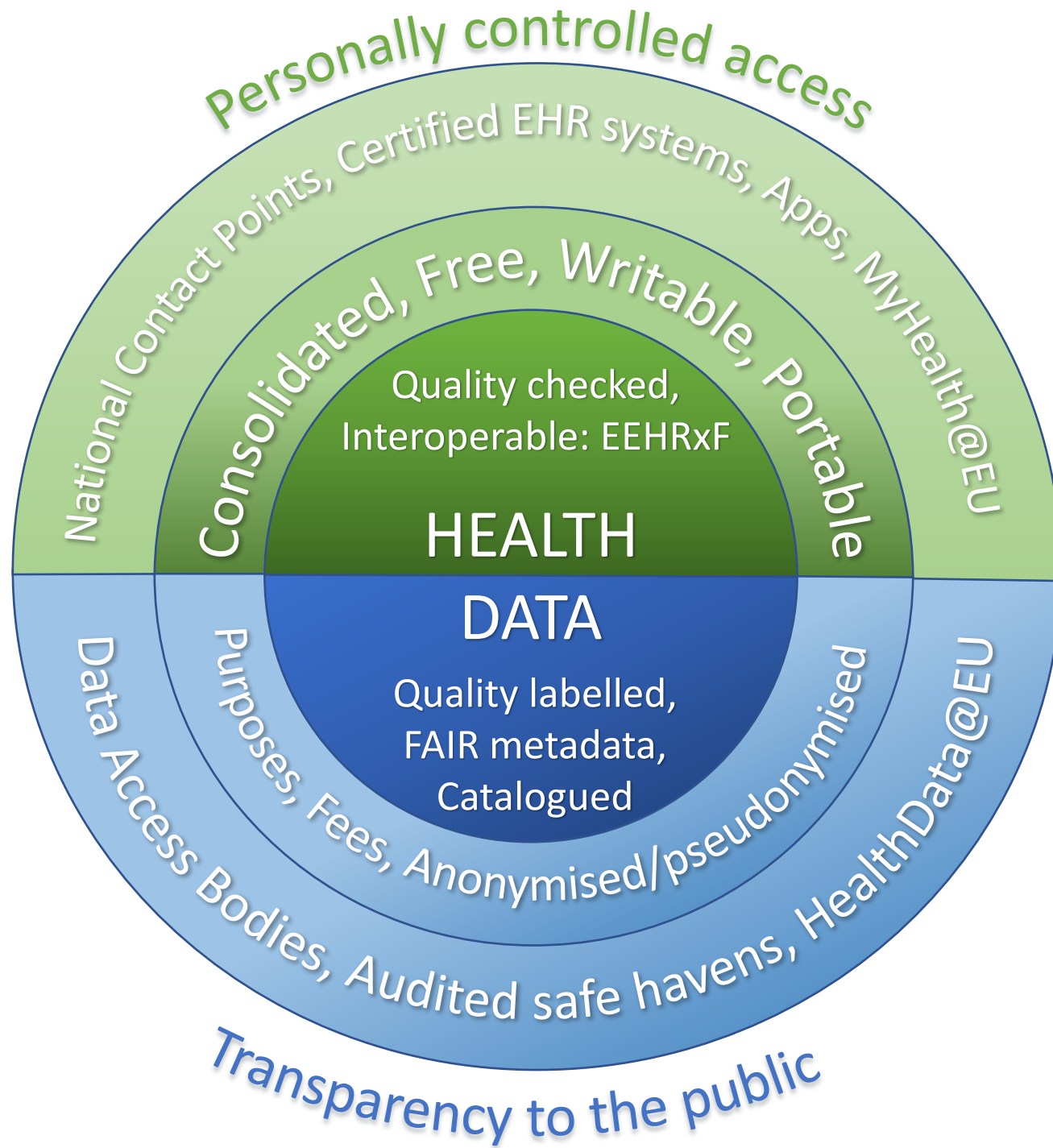
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The EHDS Regulation, May 2022

- The EHDS Regulation has been broadly welcomed by many stakeholder representative bodies and associations, and by multiple European initiatives
- Some of its provisions are expressed at a high level (e.g. citizen control over data access for primary use, the certification of EHR systems, decision making by data access bodies) and will need more detailed work
- It has an ambitious time line for implementation of many of its provisions, which some Member States may find challenging
- **However, it provides a much valued direction of travel for the landscape of health data access and use across Europe, and is already stimulating a powerful momentum and commitment towards achieving its vision**