



ERICA

European Rare Disease Research
Coordination and Support Action

Using primary health data for clinical research: Directions and Barriers

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Udine - Italy

Primary Health Data: Definition and Sources

GDPR: Health data defined as “all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject.”

Data derived from:

- medical examinations
- lab tests
- genetic data
- medical devices
- mobile apps, wearables, etc.



Prerequisites for Research Use of Primary Health Data

- **Technological Infrastructure**
Comparable digitalization level between HCPs
- **Interoperability**
Use of common standards and ontologies
- **Data Relevancy**
Focus on real-time relevance – up-to-date and actionable data
- **Compliance**
Legal frameworks

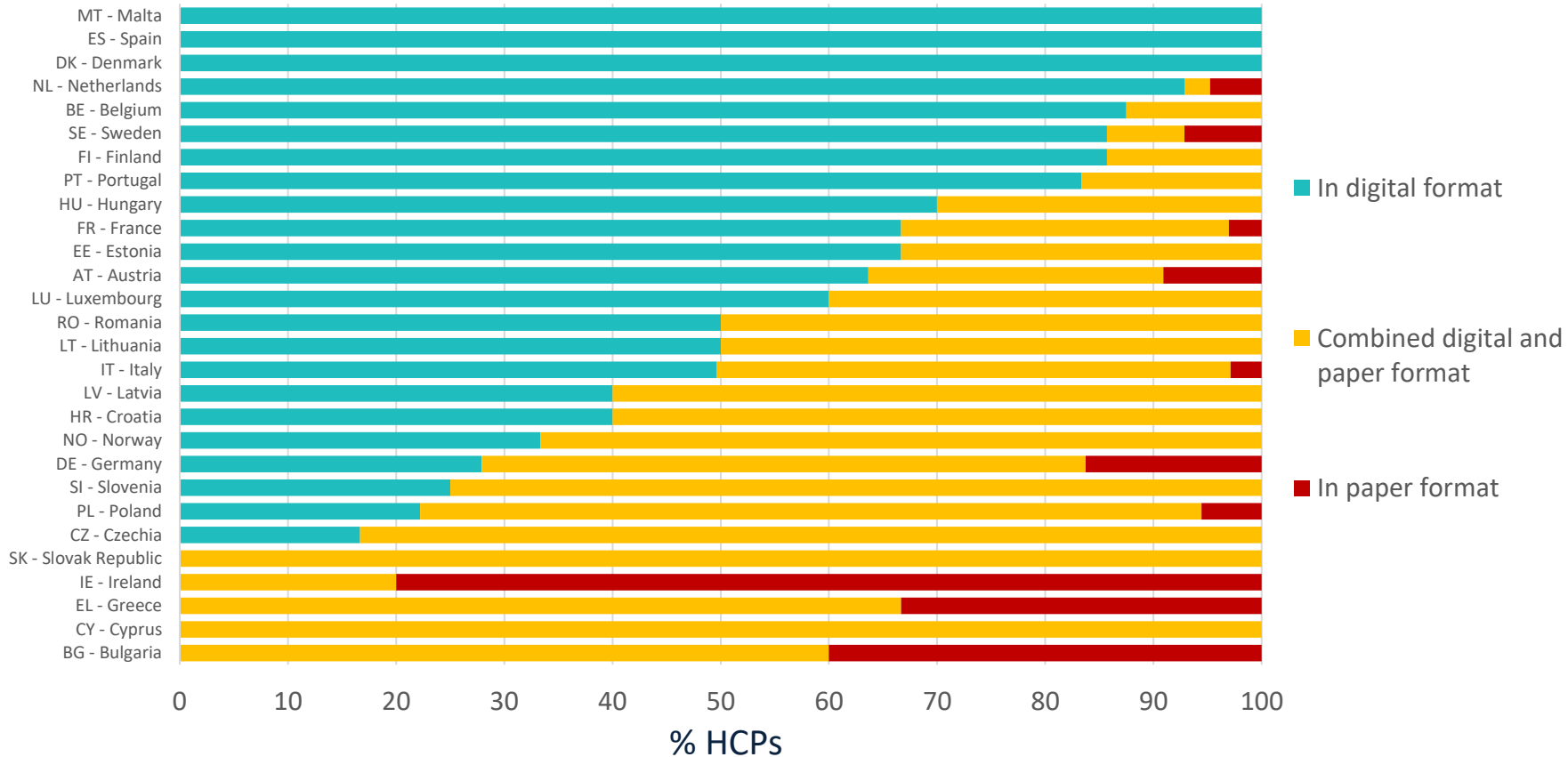
Barriers to the Use of Primary Health Data for Research

- **Infrastructure limitations**
- **Data Quality**
- **Interoperability**
- **Legal and Ethical Challenges**
- **Behavioural Barriers**

Barriers to the Use of Primary Health Data for Research

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- Incomplete health data digitalization
 - High proportion of unstructured data
 - Immature EHR semantic search algorithms

Primary Health Data Capture by ERN HCPs



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Data Quality Issues with EHRs

Incomplete or inaccurate documentation

- Lack of trained, committed staff
- Manual collection processes
- Poor documentation of research-relevant data items

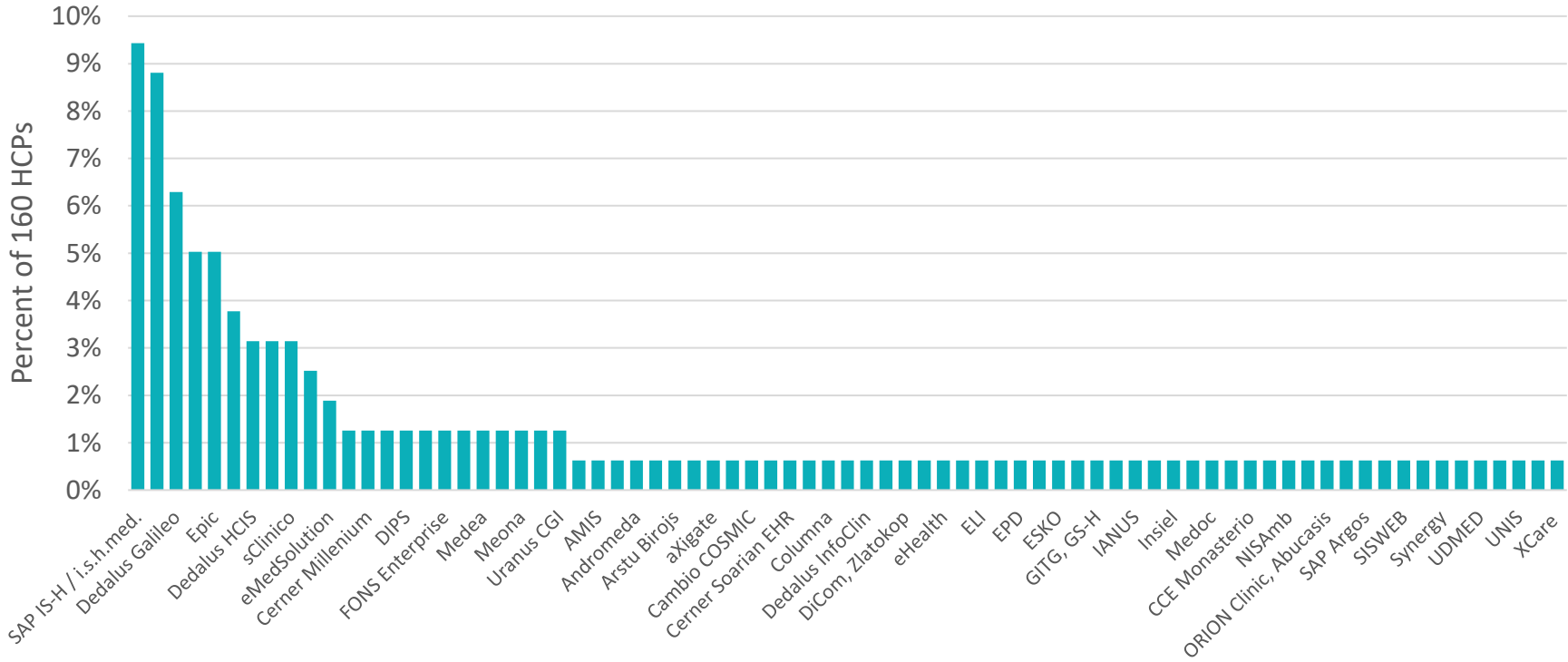
Technical barriers

- Incomplete/delayed digitalization
- Diverse data entry formats

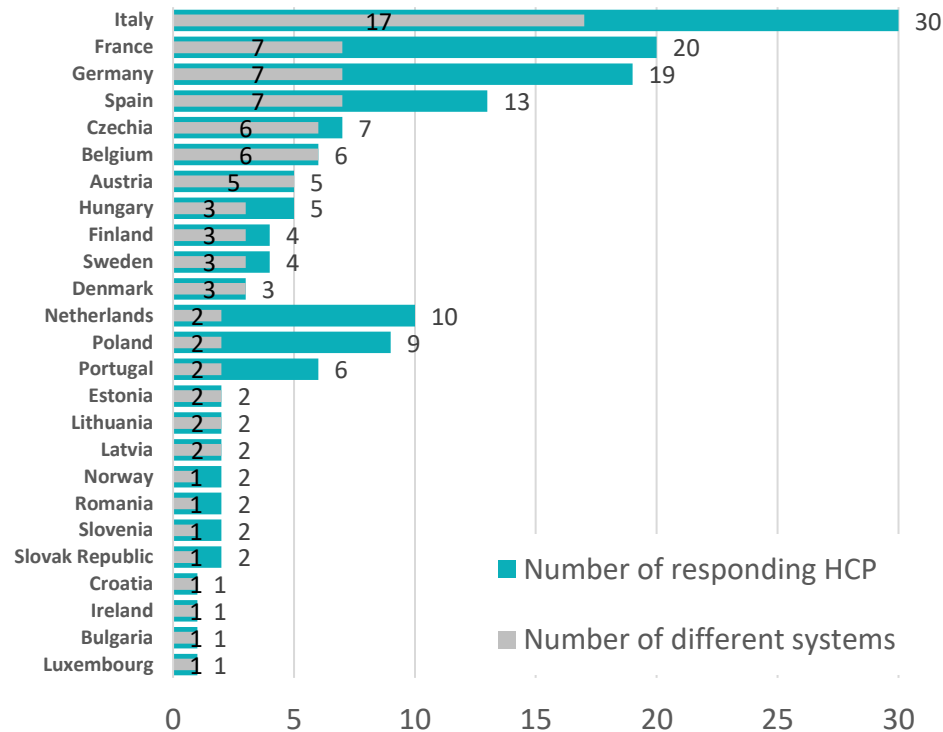
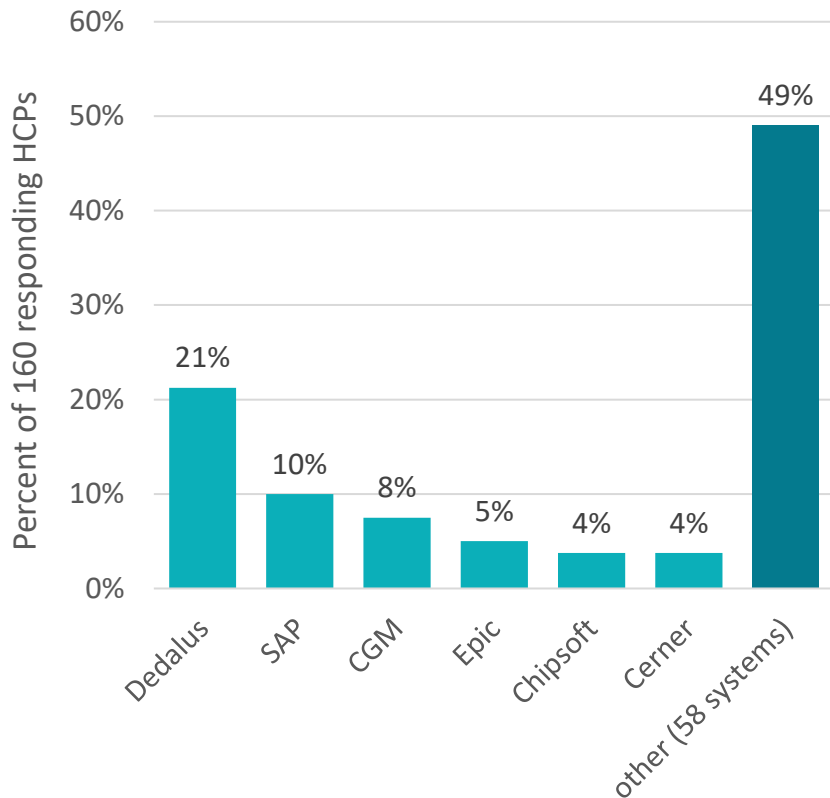
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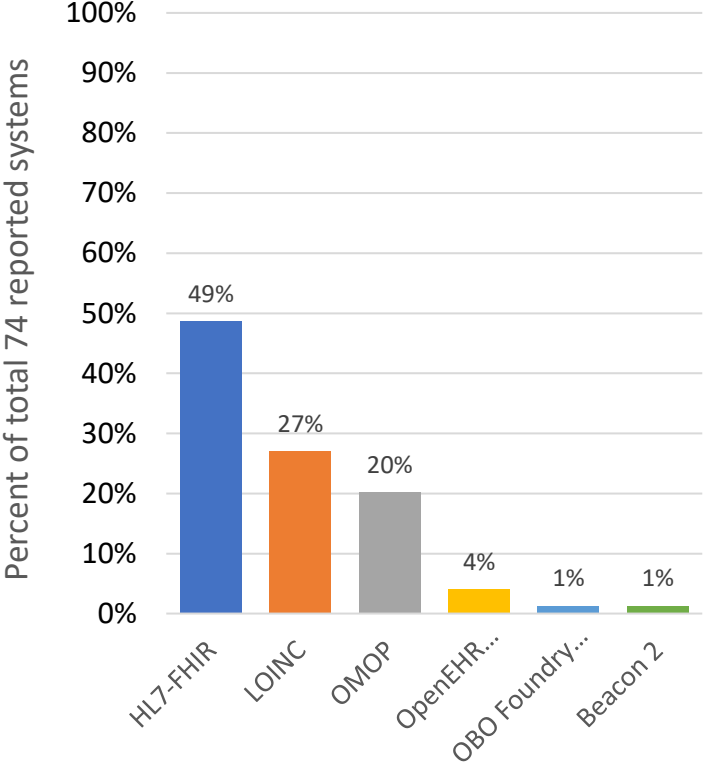
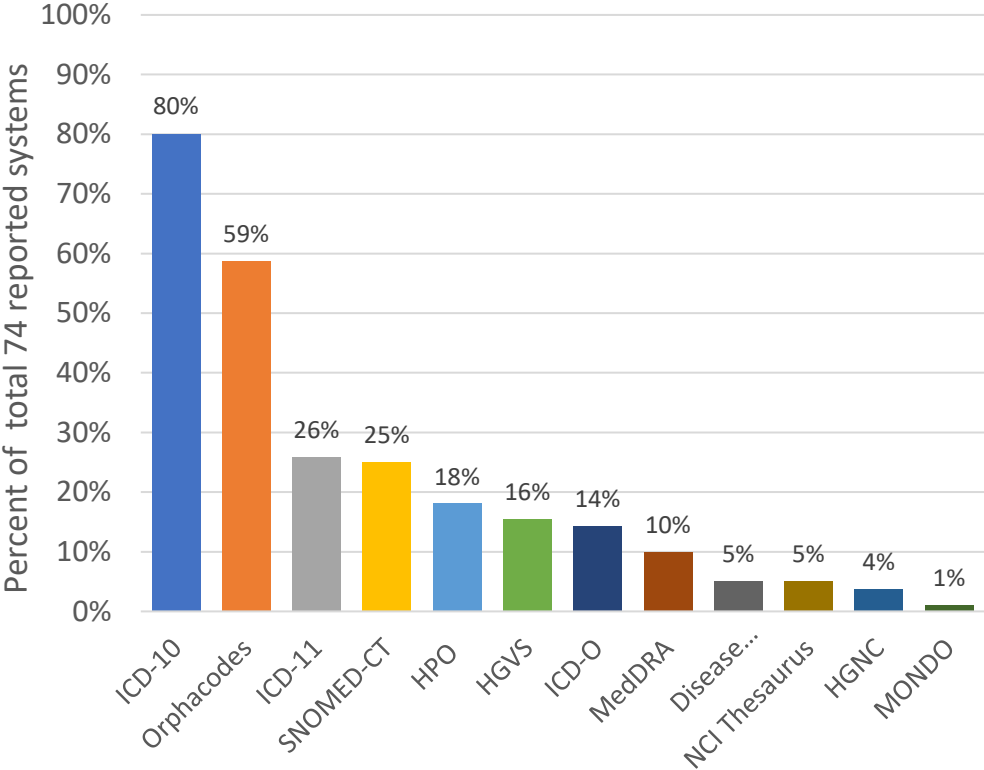
75 Different EHR Systems Used in 160 ERN Centers



Fragmentation of EHR Systems Across ERN Hospitals



Ontologies and Data Exchange Standards Used in EHRs



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Legal and Ethical Challenges

- Restrictive HCP data privacy rules
- Complex and diverse data access regulations: GDPR + national + local (EC+DPO) frameworks

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Behavioural Barriers

- Lack of awareness among healthcare professionals about importance of accurate and complete data entries
- Low willingness of patients (and healthcare professionals) to share data for research purposes

Health data sharing attitudes towards primary and secondary use of data: a systematic review

Fidelia Cascini,^{a,d,} Ana Pantovic,^b Yazan A. Al-Ajlouni,^c Valeria Puleo,^a Lucia De Maio,^a and Walter Ricciardi^a*

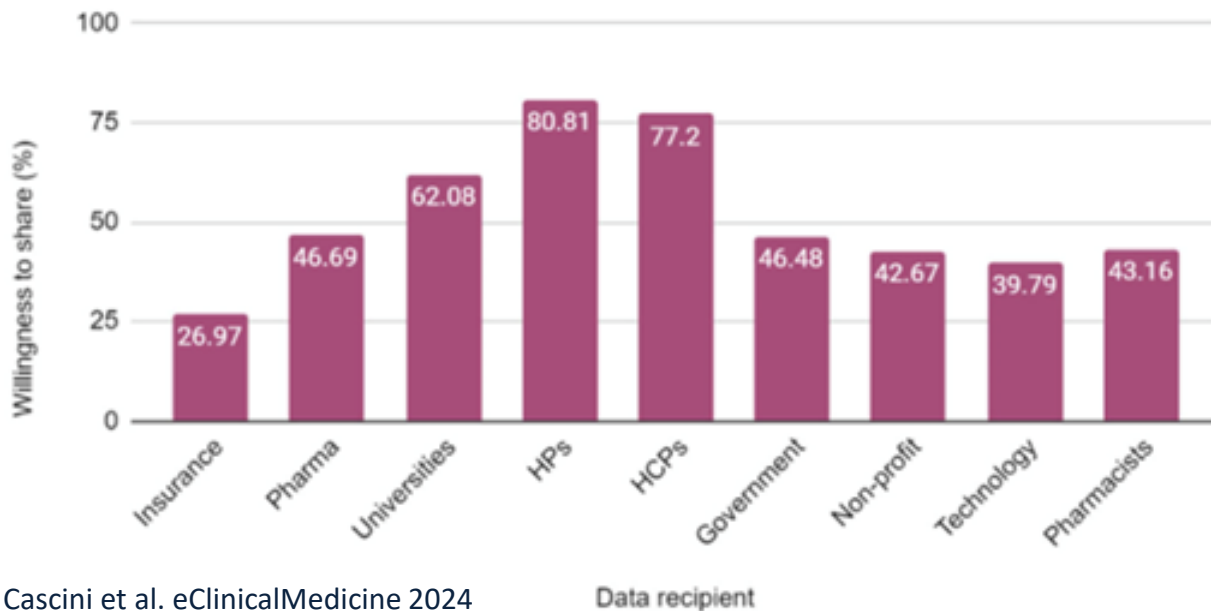
*eClinicalMedicine
2024;71: 102551*

Systematic review of 116 studies

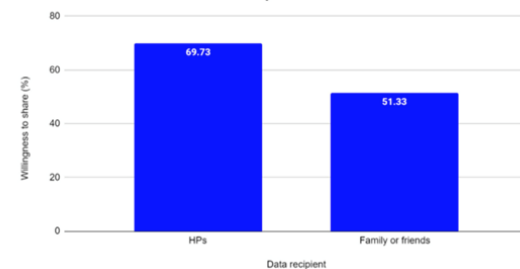
Personal health data in general:	69 studies, 117,054 participants
Person-generated health data:	17 studies, 10,771 participants
Genomic data:	13 studies, 54,716 participants
Biobank data:	7 studies, 27,073 participants

Patient Willingness to Share Health Data

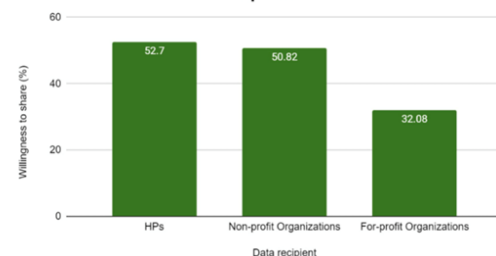
Willingness to share personal health data and information with different data recipients



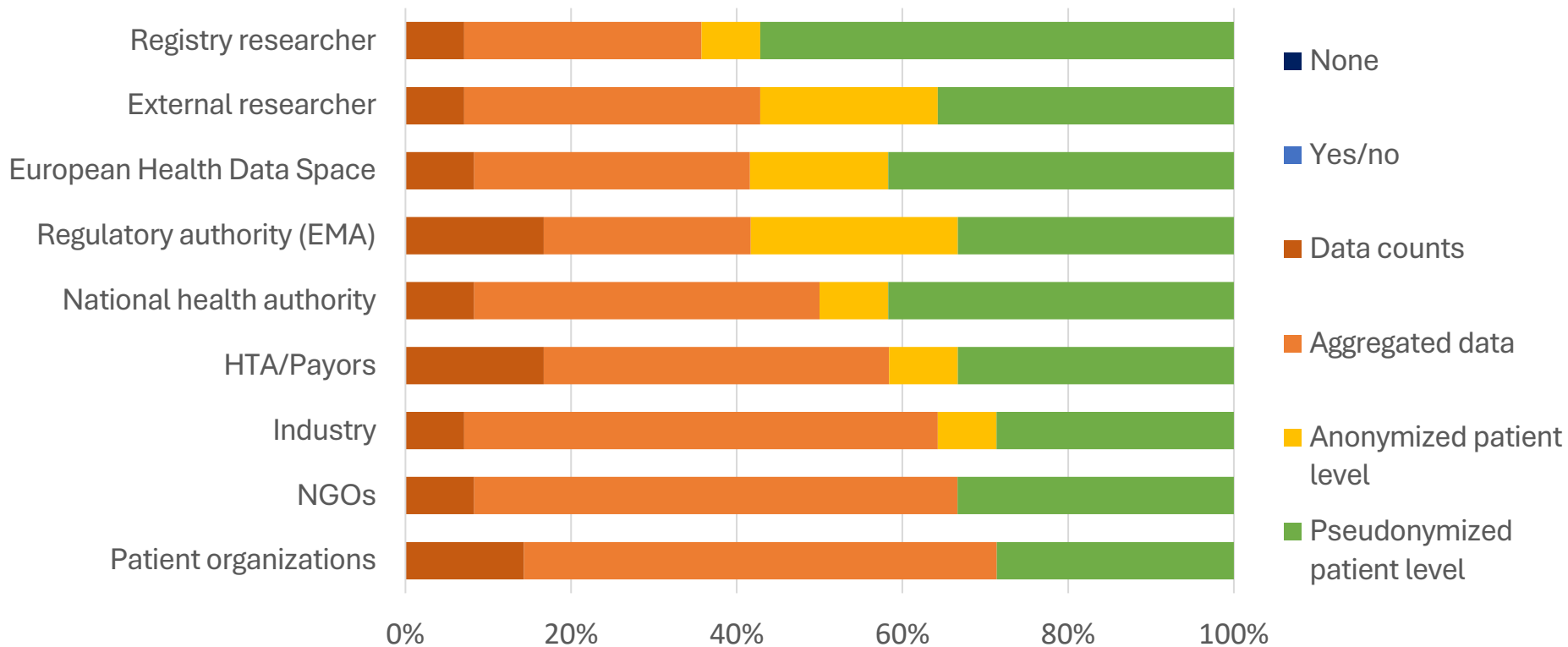
Willingness to share person-generated health data with different recipients



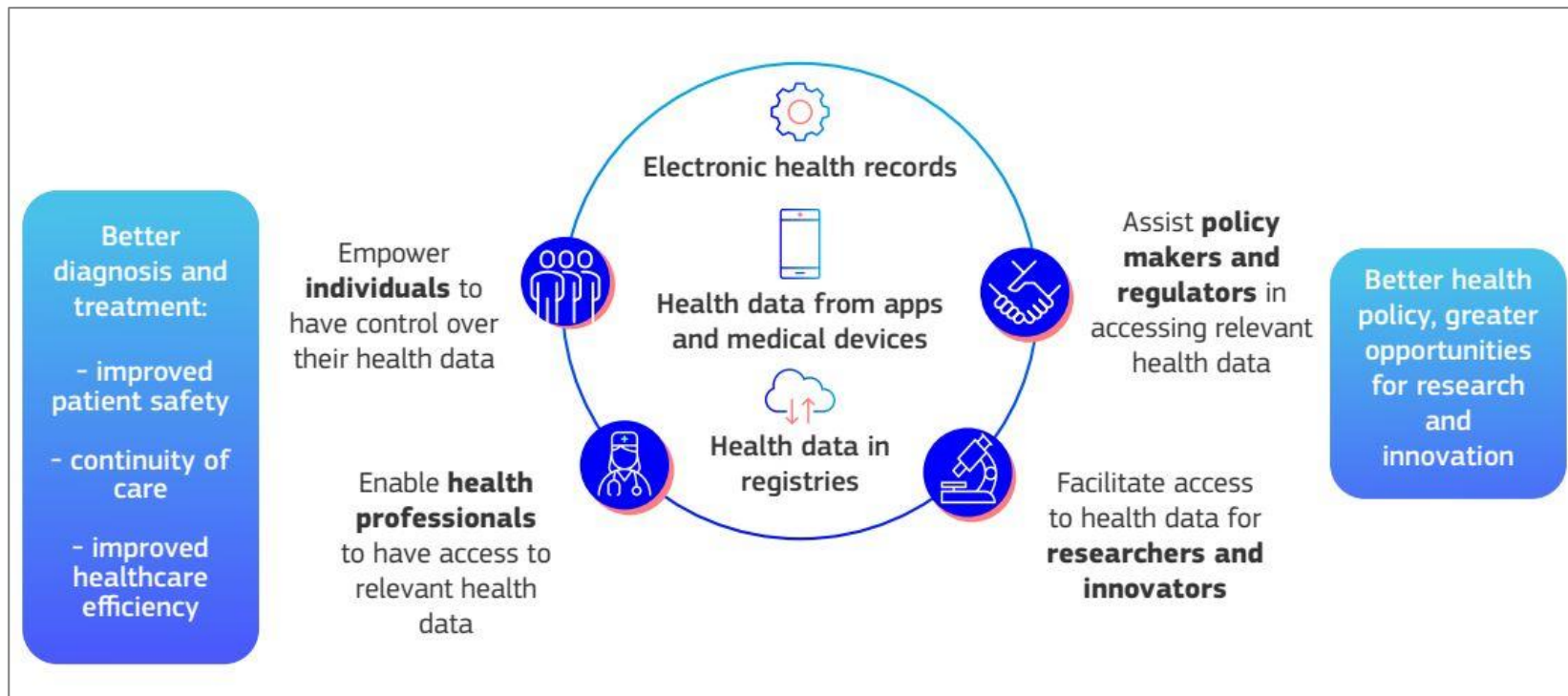
Willingness to share genomic data with different data recipients



Willingness of ERN Registry Researchers to Share Data with Third Parties



Long-Term Solution: The European Health Data Space



The European Health Data Space

- Access to **anonymized EHR data** for research purposes
- Mandatory adoption of **uniform European EHR Exchange Format** by all EHR systems, apps, devices, AI systems
- Data sharing **mandatory**.
Individual **opt-out option**, can be overridden by member states for public data usage
- Data access controlled by national authorities
(supported by trusted third parties)
- Stepwise implementation over 10 years

EHDS – Overall timeline

