The European Health Data Space and the economics of health data

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NOVARTIS | Reimagining Medicine

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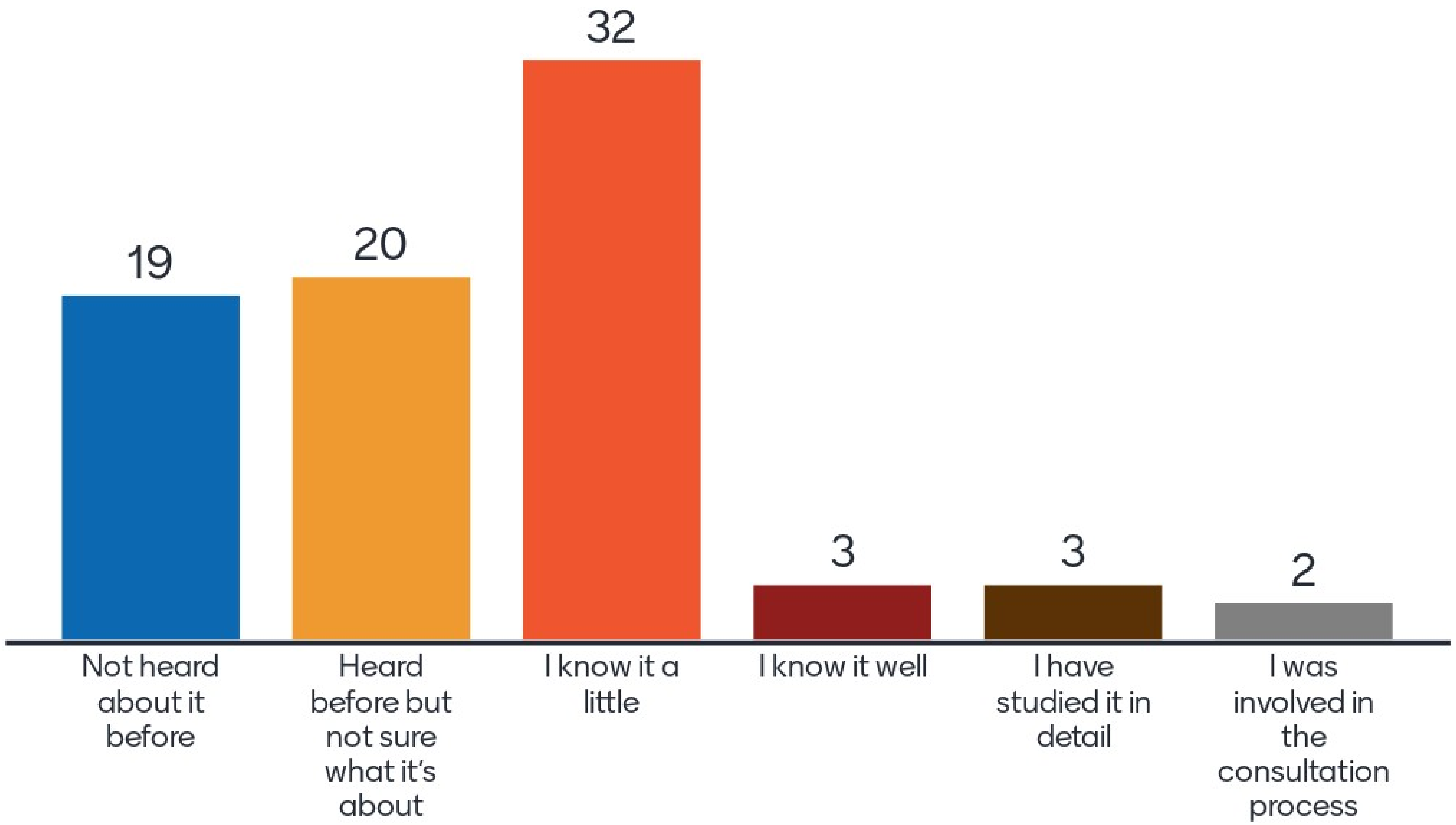
Thanks to several EHDS experts that have provided me with their insights.

How much do you know about EHDS?



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ACR Convergence
Where Rheumatology Meets
#ACR21

Early and Accurate Diagnosis of Patient With Axial Spondyloarthritis Using Machine Learning: a Predictive Analysis From Electronic Health Records in United Kingdom

Raj Sengupta[1], Shruti Narasimham[2], Borja Sepulveda Mato[3], Matic Meglic[3], Chiara Perella[3], Paula Pamies[4], Paul Emery[5]

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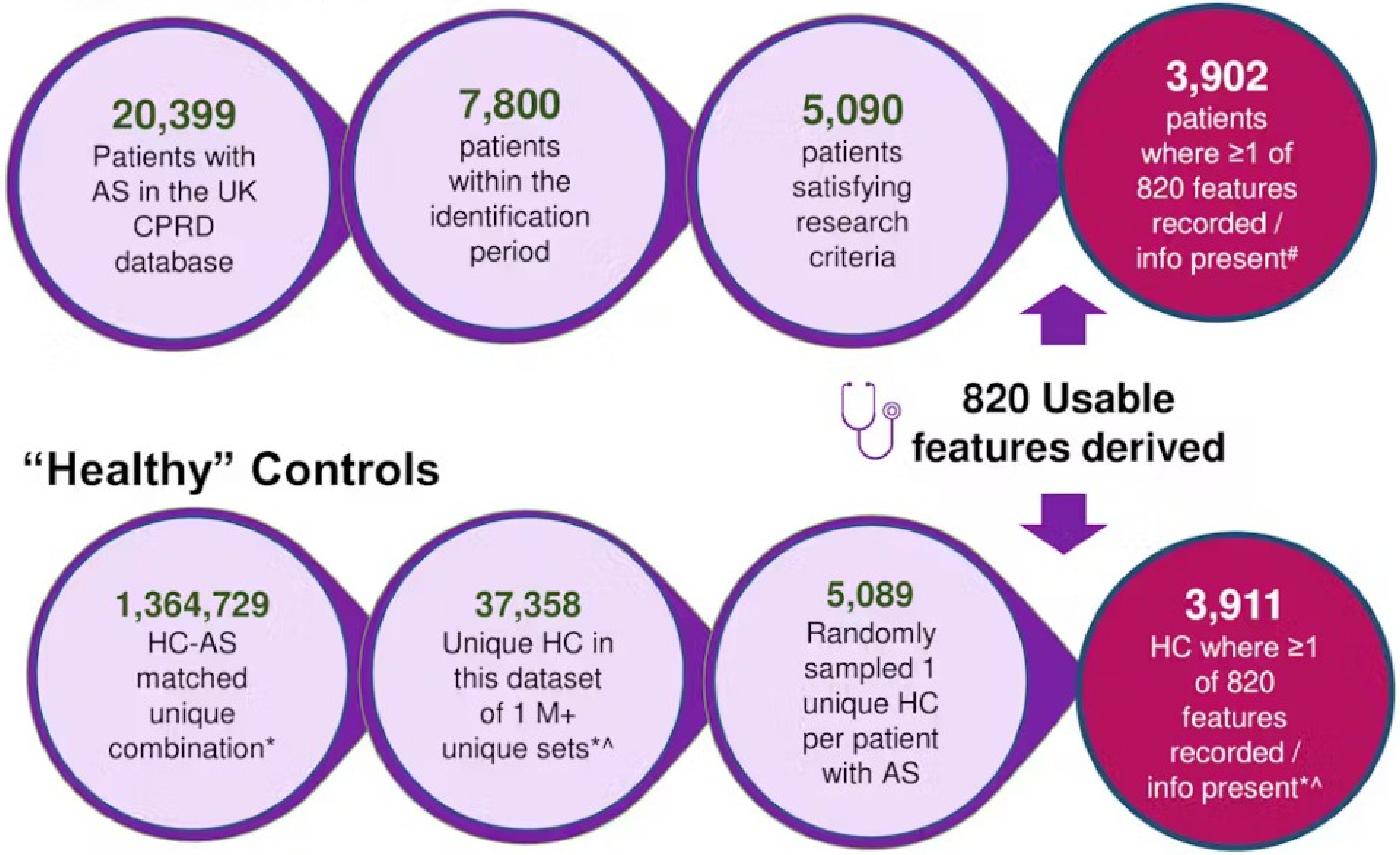
American College of Rheumatology
Empowering Rheumatology Professionals

Built a significant cohort size of AS patients And healthy controls

Cohort composition



Patients with AS

20,399 Patients with AS in the UK CPRD database

7,800 patients within the identification period

5,090 patients satisfying research criteria

3,902 patients where ≥1 of 820 features recorded / info present[#]

820 Usable features derived

“Healthy” Controls

1,364,729 HC-AS matched unique combination*

37,358 Unique HC in this dataset of 1 M+ unique sets*^

5,089 Randomly sampled 1 unique HC per patient with AS

3,911 HC where ≥1 of 820 features recorded / info present*^

Patient EMR Files

Clinical, Consultation, Referral, Test & Therapy information

820 usable **features**:

Age at symptom onset, # of axSpA symptoms, # of NSAIDs, NSAID quantity, Frequency of consultations, Lab test results, # of referrals, Referral type

AS, ankylosing spondylitis; CPRD, clinical practice research datalink; HC, healthy controls

[#] Out of 5,090 patients – 1,471 (28.9%) had ALL Data complete

*HC are patients not having AS diagnosis code in the UK CPRD data, age, and gender matched to each of the 5,090 patients with AS

^Satisfying research acceptability criteria

Predictive modelling results demonstrated high Levels of accuracy and precision

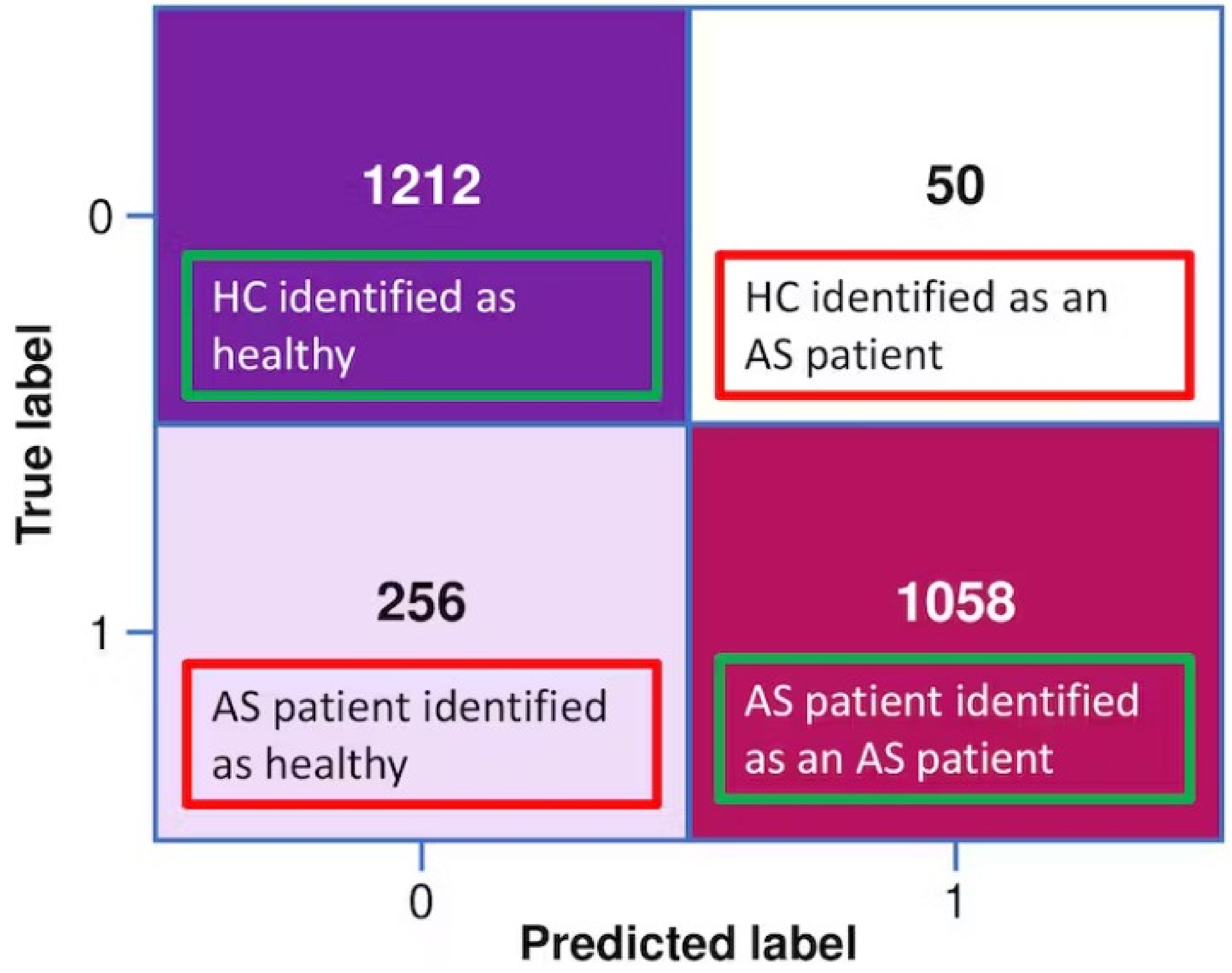
Model outcomes

- **Accuracy (88.12%)** with precision of **0.95 for patients with AS** and **0.83 for HC**
  - **Sensitivity** of the model was **0.75** and **positive predictive value** was **80.88%**
  - **Specificity** of the model was **0.96** and **negative predictive value** was **82.56%**

Total 2,576
(AS patients and controls)

1 – AS patient
0 – HC

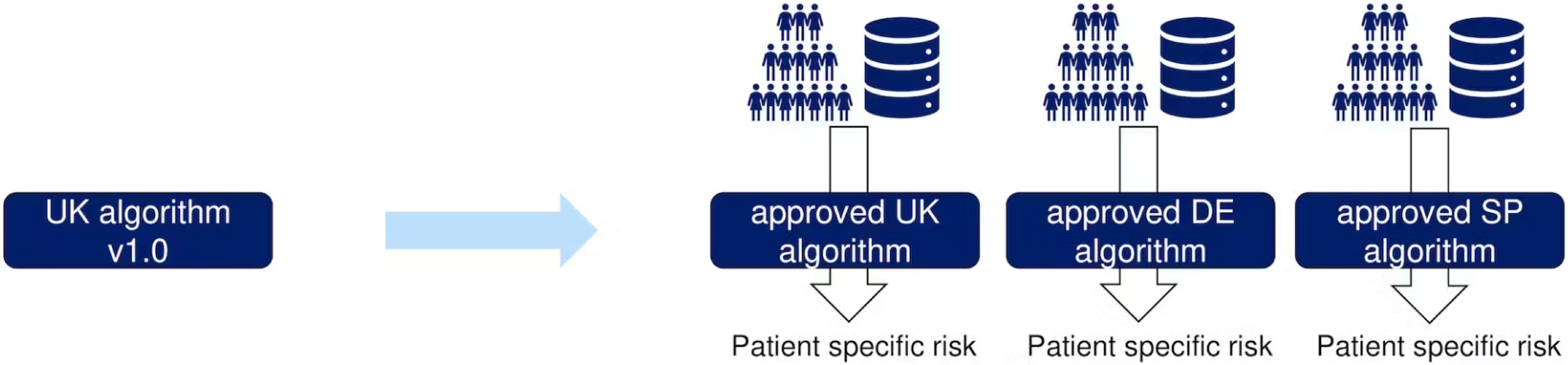
Random Forest[2]
(820 features → 89 best features)



True label \ Predicted label	0	1
0	**1212** HC identified as healthy	**50** HC identified as an AS patient
1	**256** AS patient identified as healthy	**1058** AS patient identified as an AS patient

axSpA, axial spondyloarthritis; CPRD, Clinical Practice Research Datalink; HC, healthy controls.
HCs (patients not having an axSpA diagnosis code) in the UK CPRD data, age, and gender matched to each of the 5090 patients with axSpA.
Random Forest analysis also run with no feature selection (all 820 features used) with an accuracy of 87.66% and precision: 0.82 (controls) and 0.96 (patients).

Our problem: what do you need to deploy an ML/AI algorithm at scale across Europe?



UK algorithm v1.0

approved UK algorithm

approved DE algorithm

approved SP algorithm

Patient specific risk

Patient specific risk

Patient specific risk

You have a digital solution. What do you need to deploy it at scale across Europe?

96 responses

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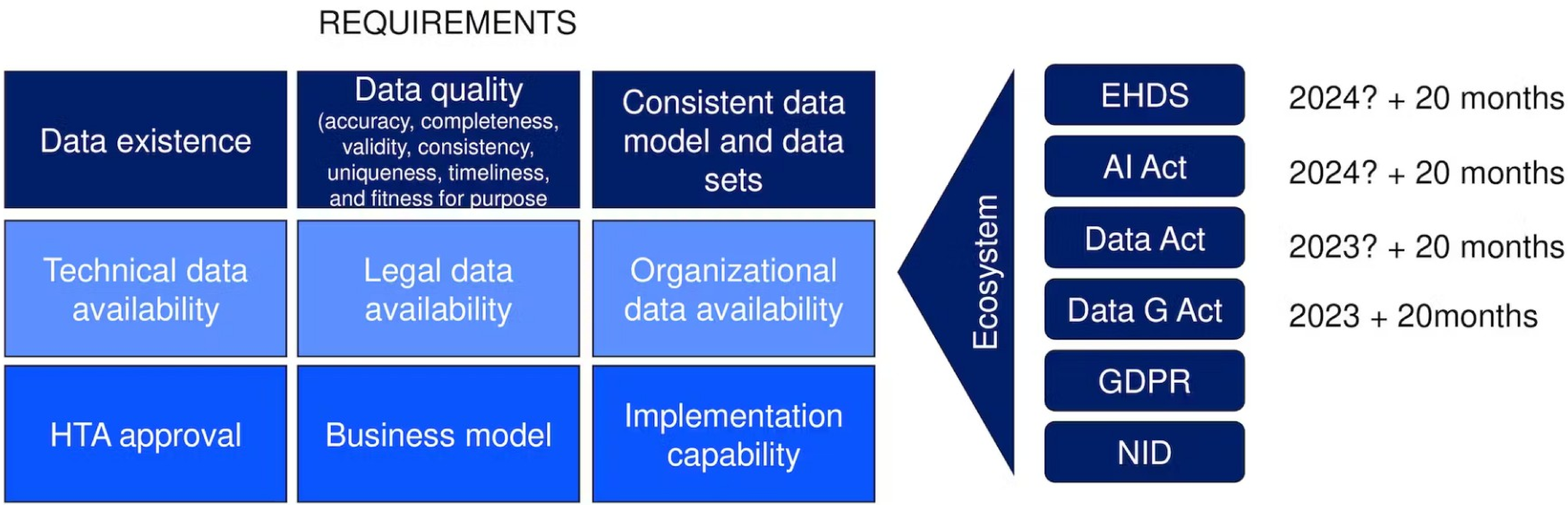
Deployment of ML/AI algorithms at scale across EU space needs a fully functioning data ecosystem



REQUIREMENTS

Data existence	Data quality (accuracy, completeness, validity, consistency, uniqueness, timeliness, and fitness for purpose	Consistent data model and data sets
Technical data availability	Legal data availability	Organizational data availability
HTA approval	Business model	Implementation capability

Ecosystem

EHDS	2024? + 20 months
AI Act	2024? + 20 months
Data Act	2023? + 20 months
Data G Act	2023 + 20months
GDPR	
NID	

These requirements also apply to most other digital health solutions e.g. Digital Therapeutics, Care Orchestration.

This legislation is a significant step towards a more unified market.

Let's talk about money to be made in reusing patient data.

NHS data grab on hold as millions opt out

A plan to share GP data was set to launch in September, but an online summer campaign has prompted widespread dissent

Chaminda Jayanetti

Sun 22 Aug 2021 09.15 CEST

'We want to see promises delivered' – privacy campaigner Phil Booth of medConfidential.

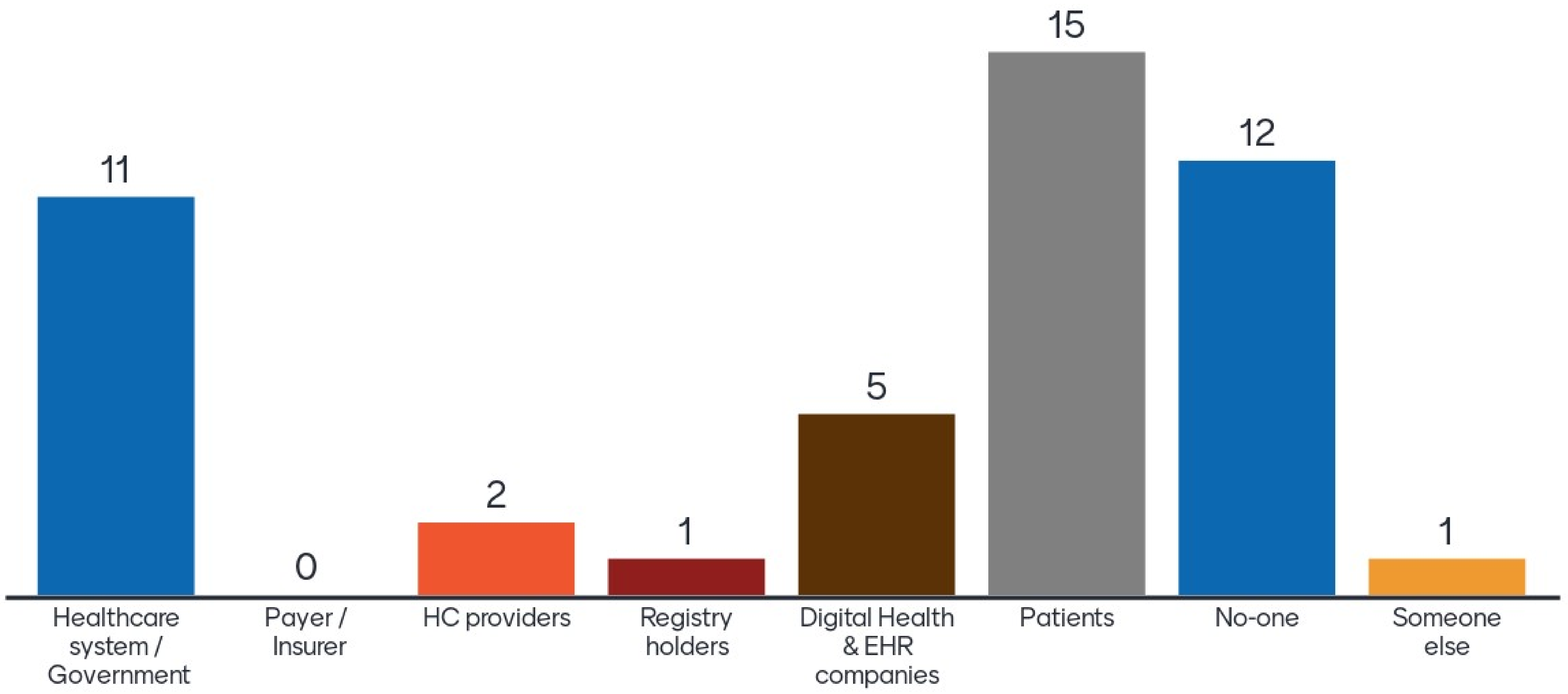
More than a million people opted out of NHS data-sharing in one month in a huge backlash against government plans to make patient data available to private companies, the *Observer* can reveal.

The General Practice Data for Planning and Research scheme is now on hold with no new date for implementation, and NHS Digital has made a series of concessions to campaigners to try to salvage it.

Under the scheme, GP health data for everyone in England, with identities partially removed, would be made available to researchers and companies for healthcare research and planning. The scheme is more extensive than

NHS data grab on hold as millions opt out | NHS | The Guardian
https://www.theguardian.com/society/2021/aug/22/nhs-data-grab-on-hold-as-millions-opt-out

Who should receive payment for secondary use of patient data?



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Experiences with data monetization models:

- **Patients**: data cooperatives

- **Patient registries** are usually struggling with funding. In 2013, we proposed a business model for registry holders to monetize data.

> Stud Health Technol Inform. 2013:192:1161.

PARENT joint action: increasing the added value of patient registries in a cross-border setting

Matic Meglič[1], Persephone Doupi, Ivan Pristaš, Yannis Skalkidis, Metka Zaletel, Andrej Orel

Affiliations + expand

PMID: 23920935

Abstract

Patient registries are poorly interoperable and as a result data exchange or aggregation across organizations, regions and countries for secondary purposes (i.e. research and public health) is difficult to perform. PARENT Joint Action aims to provide EU Member States with a set of guidelines, recommendations and tools to support setting-up, management and governance of interoperable patient registries, thus helping EU Member States to drive down cost and interoperability risks of patient registries as well as improving secondary us-age of registry data in a cross-border setting.

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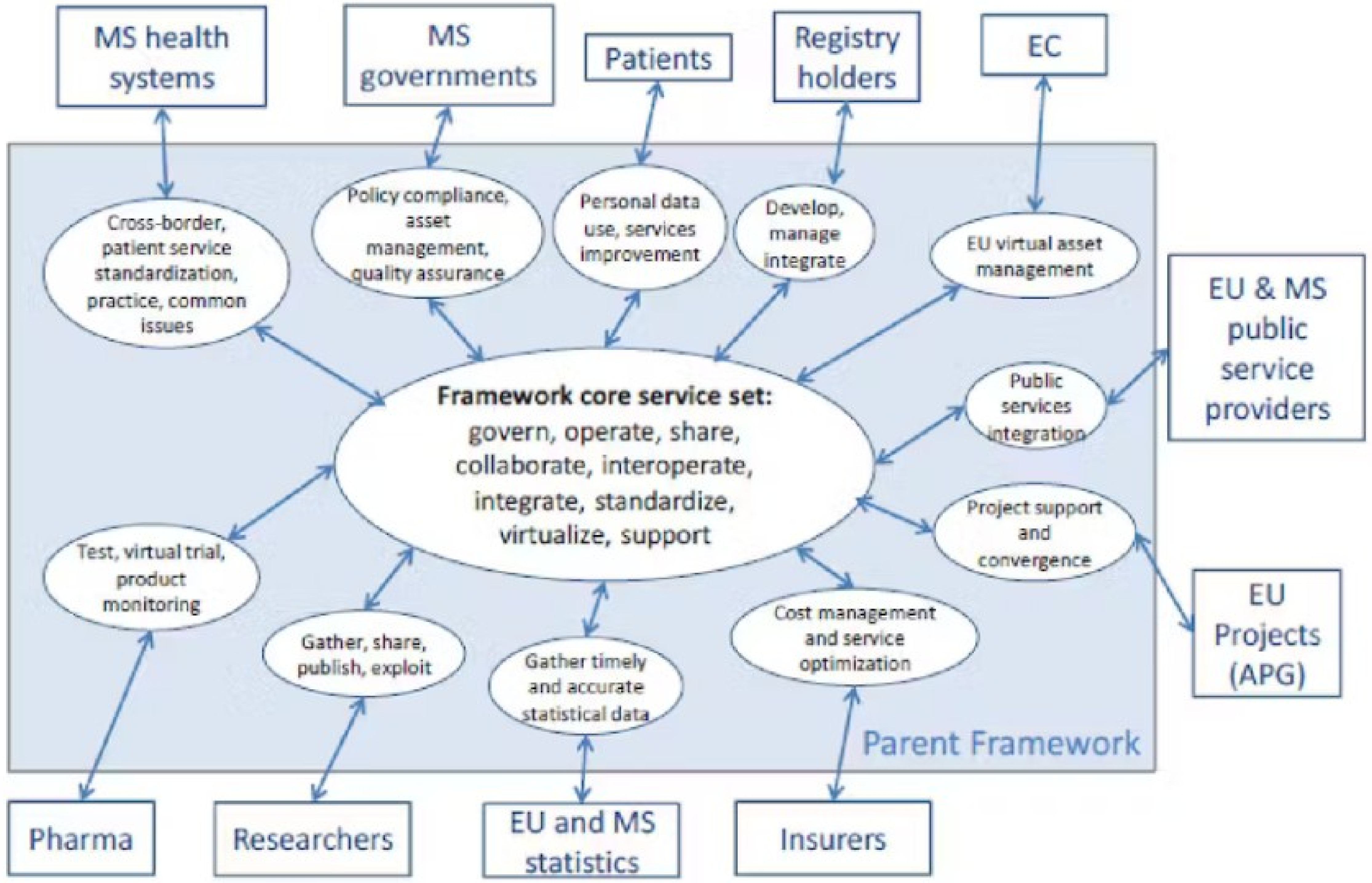
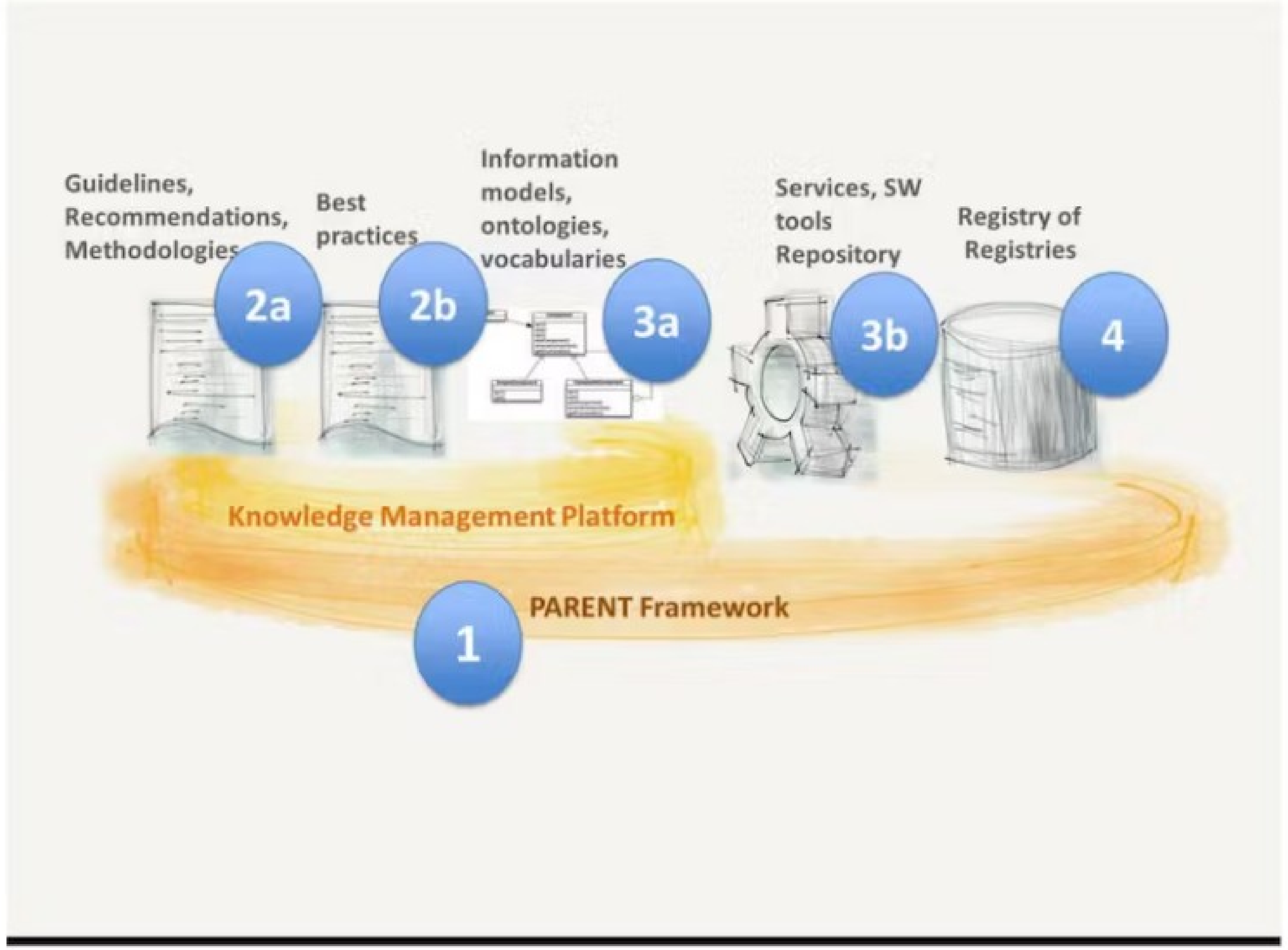
https://www.linkedin.com/company/healthbank/about/
https://pubmed.ncbi.nlm.nih.gov/23920935/

PARENT – value and commercial offer to customer segments





There were many more EC funded projects looking into secondary data reuse and value. Concepts seem to be reasonably reflected in EHDS.

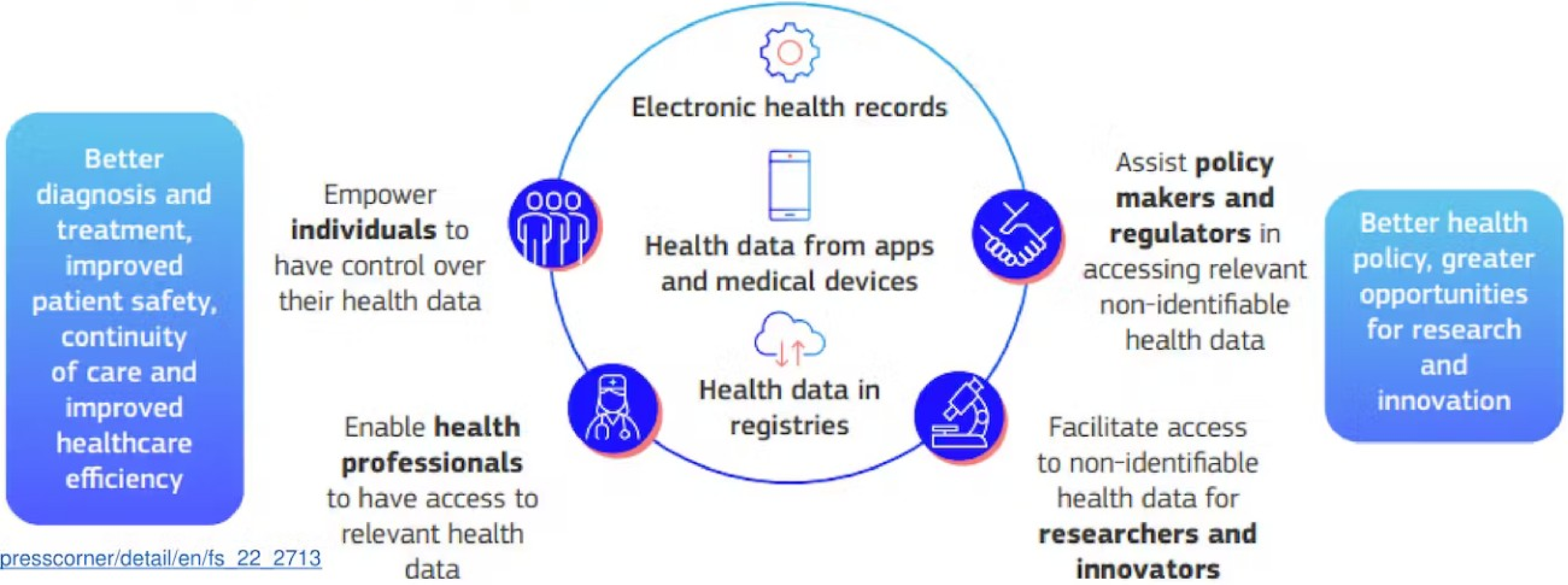
METHODOLOGICAL guidelines and recommendations for efficient and rational governance of patient registries [Electronic source] / editors Metka Zaletel, Marcel Kralj. - El. book. - Ljubljana : National Institute of Public Health, 2015
ISBN 978-961-6911-75-7 (pdf)
https://health.ec.europa.eu/system/files/2016-11/patient_registries_guidelines_en_0.pdf

EUROPEAN HEALTH DATA SPACE

#EUDigitalHealth

OBJECTIVES

- ✓ Empower individuals through better digital access to their personal health data; support free movement by ensuring that health data follow people;
- ✓ Unleash the data economy by fostering a genuine single market for digital health services and products;
- ✓ Set up strict rules for the use of individual's non-identifiable health data for research, innovation, policy-making and regulatory activities.



Better diagnosis and treatment, improved patient safety, continuity of care and improved healthcare efficiency

Empower **individuals** to have control over their health data

Enable **health professionals** to have access to relevant health data

Electronic health records

Health data from apps and medical devices

Health data in registries

Assist **policy makers and regulators** in accessing relevant non-identifiable health data

Facilitate access to non-identifiable health data for **researchers and innovators**

Better health policy, greater opportunities for research and innovation

https://ec.europa.eu/commission/presscorner/detail/en/fs_22_2713

EHDS – points to note

Patient access to own data in electronic form, free of charge

Citizens in control

Key data uses single format across EU

Interoperability and security

Cross-border digital infrastructure for primary use (MyHealth@EU)

New decentralised EU-infrastructure for secondary use (HealthData@EU)

Use of data for research, innovation, public health, policy-making and regulatory purposes.

Access to large amounts of high-quality health data (MS permit based)

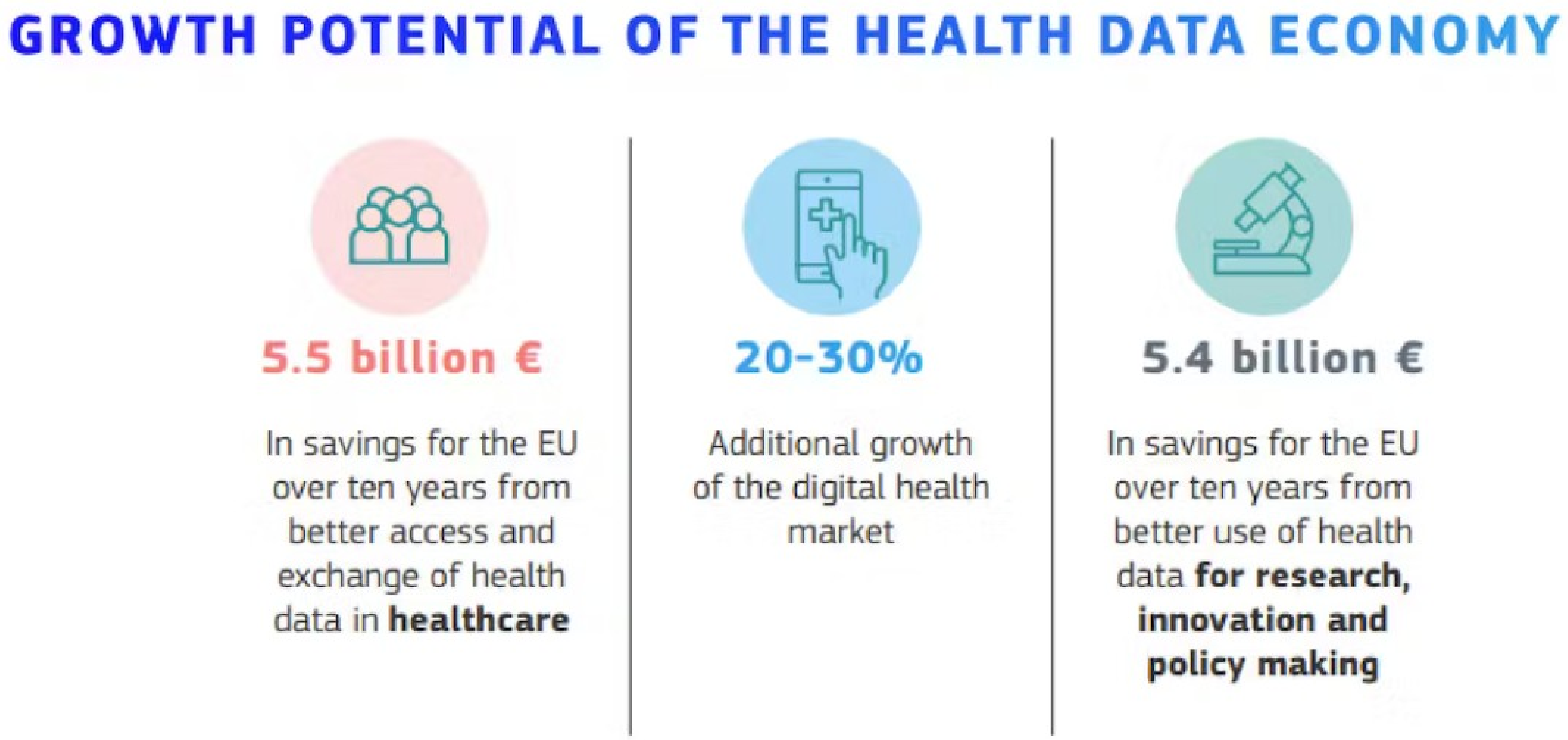
No use for detrimental decisions (designing harmful products or services; increasing insurance...)

Private & public requests have same rights of access

Data access fees proportionate to cost

Interpreted based on: [European Health Data Space (europa.eu)]()

The planned impact on economy is sizeable.



GROWTH POTENTIAL OF THE HEALTH DATA ECONOMY

5.5 billion €

In savings for the EU over ten years from better access and exchange of health data in **healthcare**

20-30%

Additional growth of the digital health market

5.4 billion €

In savings for the EU over ten years from better use of health data **for research, innovation and policy making**

https://ec.europa.eu/commission/presscorner/detail/en/fs_22_2713

EHDS and DGA concepts that spark differing opinions

Very **ambitious**; 72 implementing acts to be defined

A lot of implementation **work** for countries

Mandatory sharing of non-clinical data - could it include IP/commercially sensitive information? Who decides?

Opt-out (second. use)

Opt-in (genomic etc. data)

How to implement dynamic consent mgmt (i.e. digital wallet)

Real value for patients?

Data altruism by patients (DGA)

Conclusions

Remember GDPR? EHDS, DGA, DA, AIA etc. will significantly change markets. ▶ Big effort to implement over multiple years.

Real life value for patients, physicians? ▶ Need more use cases to fully realize its potential.

Altruism vs economic value? ▶ Be honest about value of data, who benefits and who should receive rewards for data

Catalyst – let's use it as such. ▶ Plan for it, but don't wait for it to be implemented.

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Thank you