



*i~HD BeMedTech Breakfast workshop
on Health Data Quality
17th May 2022*

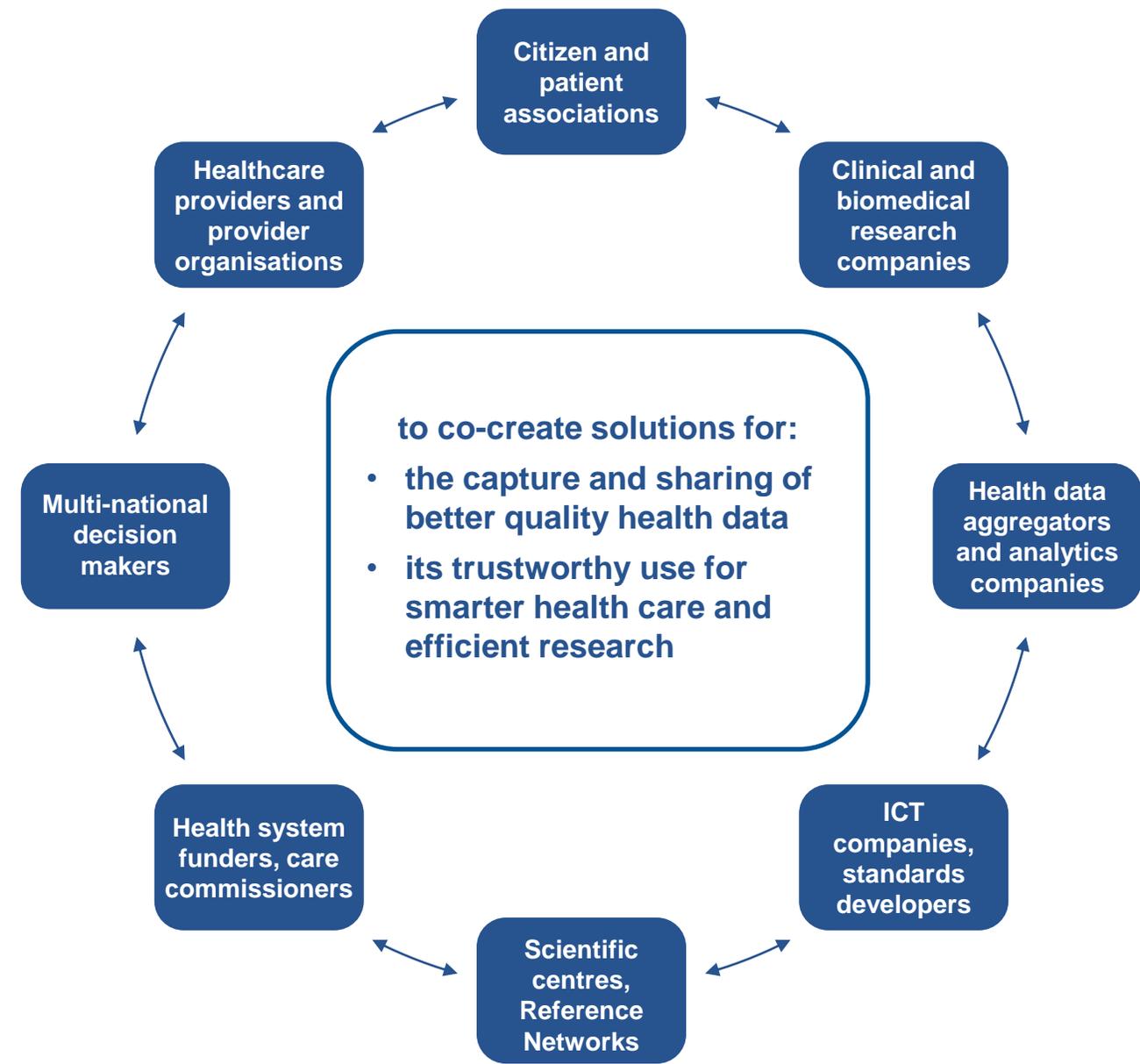
*Why do we need good
quality health data?*



Health data drives innovation

*Dipak Kalra
President of i~HD*

iHD is a neutral, not-for-profit, European institute uniting stakeholders



Clinical Research needs

Healthcare needs



INFORMATION
GOVERNANCE



QUALITY OF
HEALTH DATA



TRUSTWORTHY
HEALTH ICT SYSTEMS



DATA
INTEROPERABILITY
STANDARDS

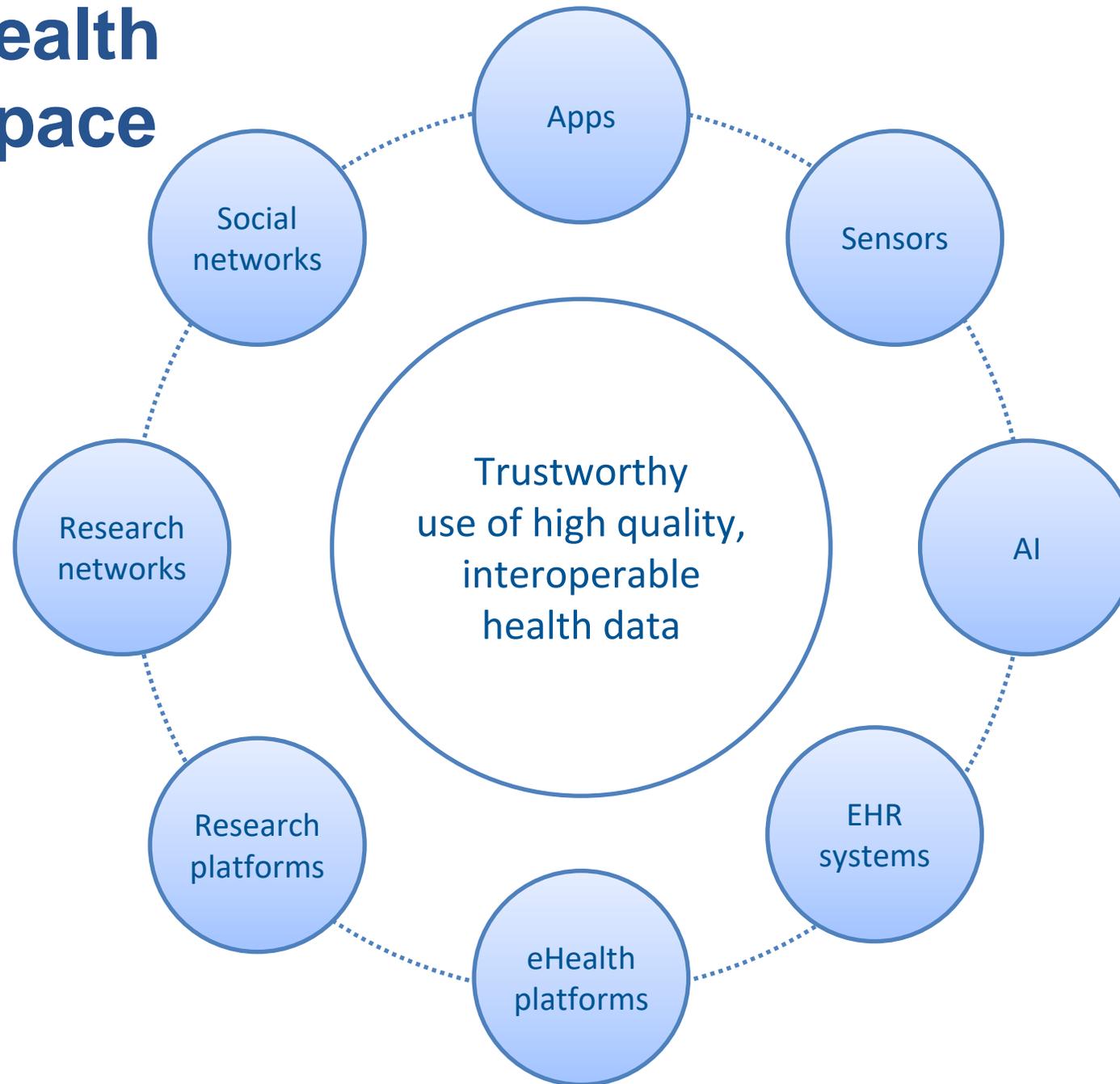


QUALITY LABELS:
CERTIFICATES & SEALS



SCALING UP
THE HEALTH
ECOSYSTEM

The digital health innovation space



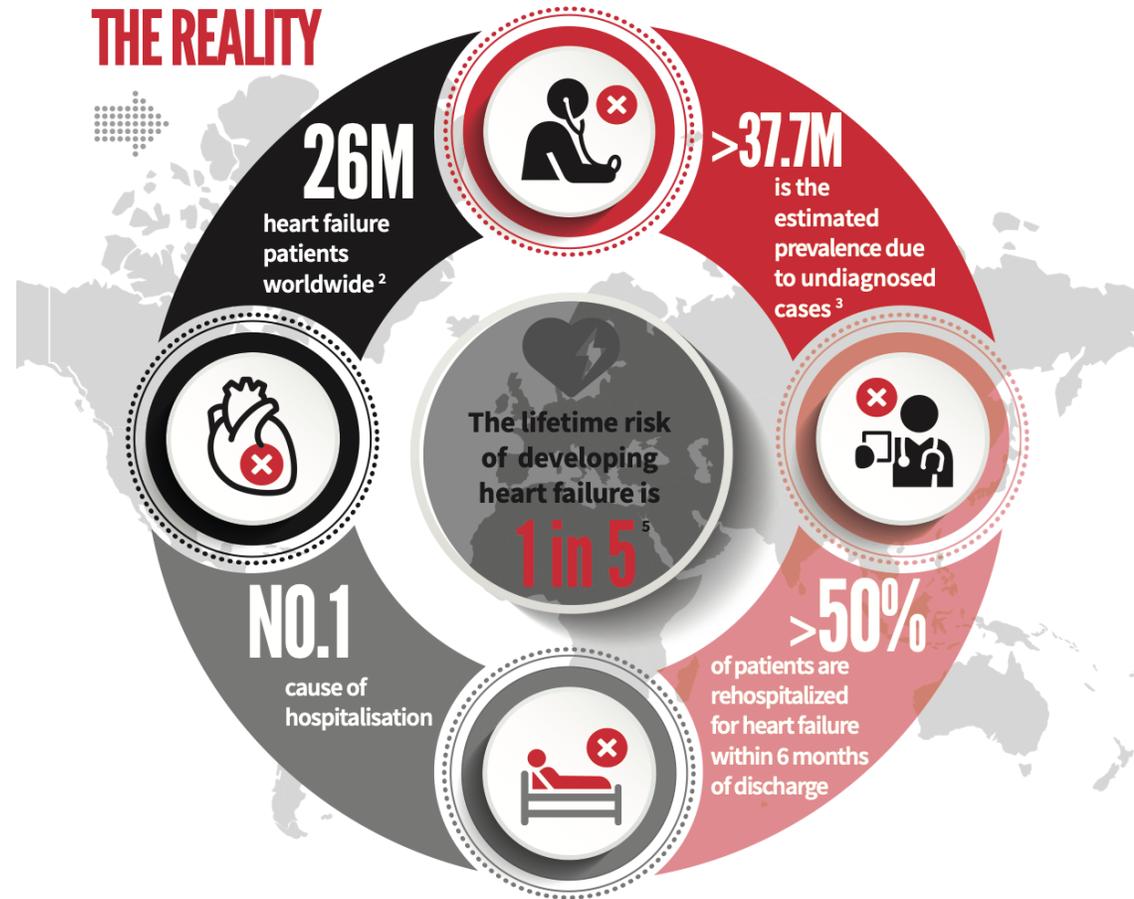
The massive challenge of heart failure



PEOPLE WITH HEART FAILURE ARE MORE VULNERABLE TO COVID-19

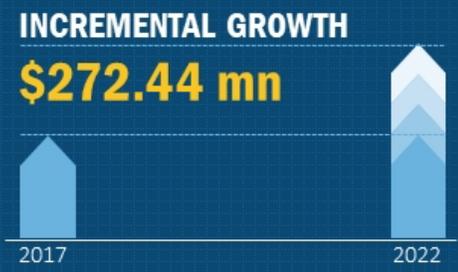
WHAT IS HEART FAILURE?

Heart failure is a severe failure of the heart to pump enough blood around the body
Symptoms include breathlessness, fatigue and swollen limbs



Cardiac monitoring market - an opportunity for innovators

The market will be **ACCELERATING** growing at a **CAGR** of over **5%**



The **EMEA REGION** has a **HIGHER** incremental growth than the **APAC REGION**

One of the **KEY TRENDS** for this market will be the **DEVELOPMENT OF NEW PRODUCTS**

READ THE REPORT:
GLOBAL AMBULATORY CARDIAC MONITORING DEVICES MARKET 2018-2022

10,000+ reports covering niche topics
HEALTHCARE AND LIFE SCIENCES
Read them here:
www.technavio.com



<https://www.businesswire.com/news/home/20180717005566/en/Global-Ambulatory-Cardiac-Monitoring-Devices-Market-2018-2022-Development-of-New-Products-Technavio>

mHealth is effective in heart failure

- Remote tele-monitoring of patients with heart failure improves cardiac function, reduces heart failure severity and improves patients' physical and emotional well-being, improves quality of life and reduces future hospitalisations
 - 26% reduction in hospital days per patient
 - 10% overall cost savings through nurse remote support
 - 15% improved survival rates



How do patients want to use digital health?

Learn about health conditions, treatment options

Track health state

Compare with others

Set personal goals

Track progress towards targets

Track bodily function

Adjust dosage to fit lifestyle

Personalise prevention and wellbeing

Monitor symptoms

Assess impact of treatment

Share clinical decision making

Monitor activity, sleep, diet

Document side effects

Contribute their own collected data to research

Know what to discuss with clinical team

Allow their clinical data to be used for research

90% of the data in the world today has been created in the last 2 years

Population registries,
Clinical trials databases

Care pathways,
decision support,
trends and alerts

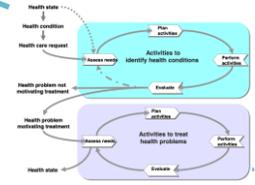
There will soon be almost as many personal assistant bots on the planet as people

Genomic data



Environmental data

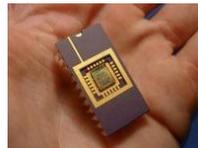
The Digital Citizen



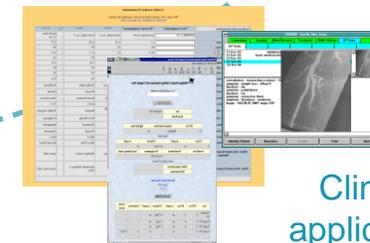
Mobile devices

> 1 billion people have access to mobile broadband internet

Personal sensor data is expected to grow to 90% of all stored information within the next decade



Bio-sensors



Clinical applications

Social networks



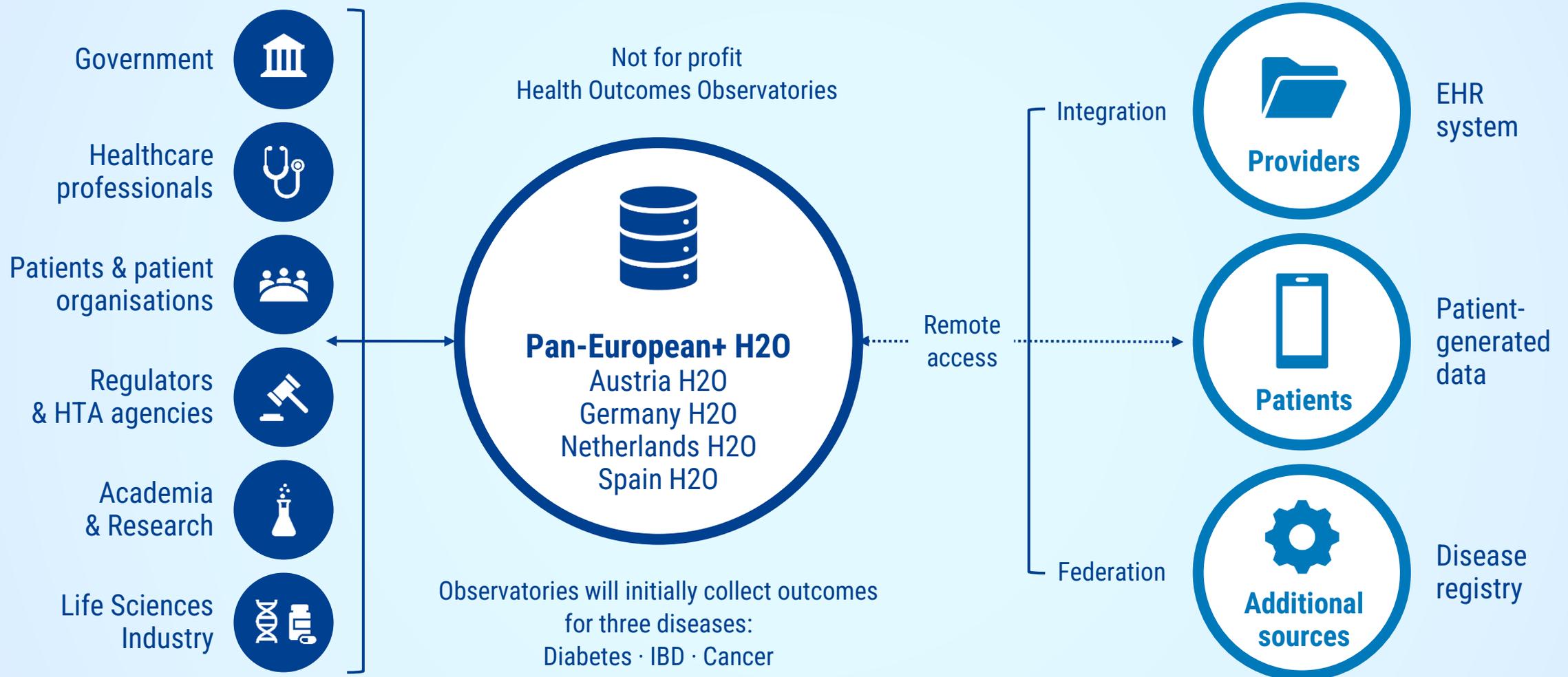


H₂O

First European scale network for health outcomes data



innovative medicines initiative



IMPACTS



Patients : improve dialogue between patient and clinician to receive better care



Health care professional: better access to data to inform and enhance clinical decisions



Patient
organisations

Patient organisations: assess the status and dynamics of their patient population



Regulators &
agencies



Government

Health authorities, providers and payers: improve the quality and sustainability of care through better and more transparent evidence of patient measures and outcomes

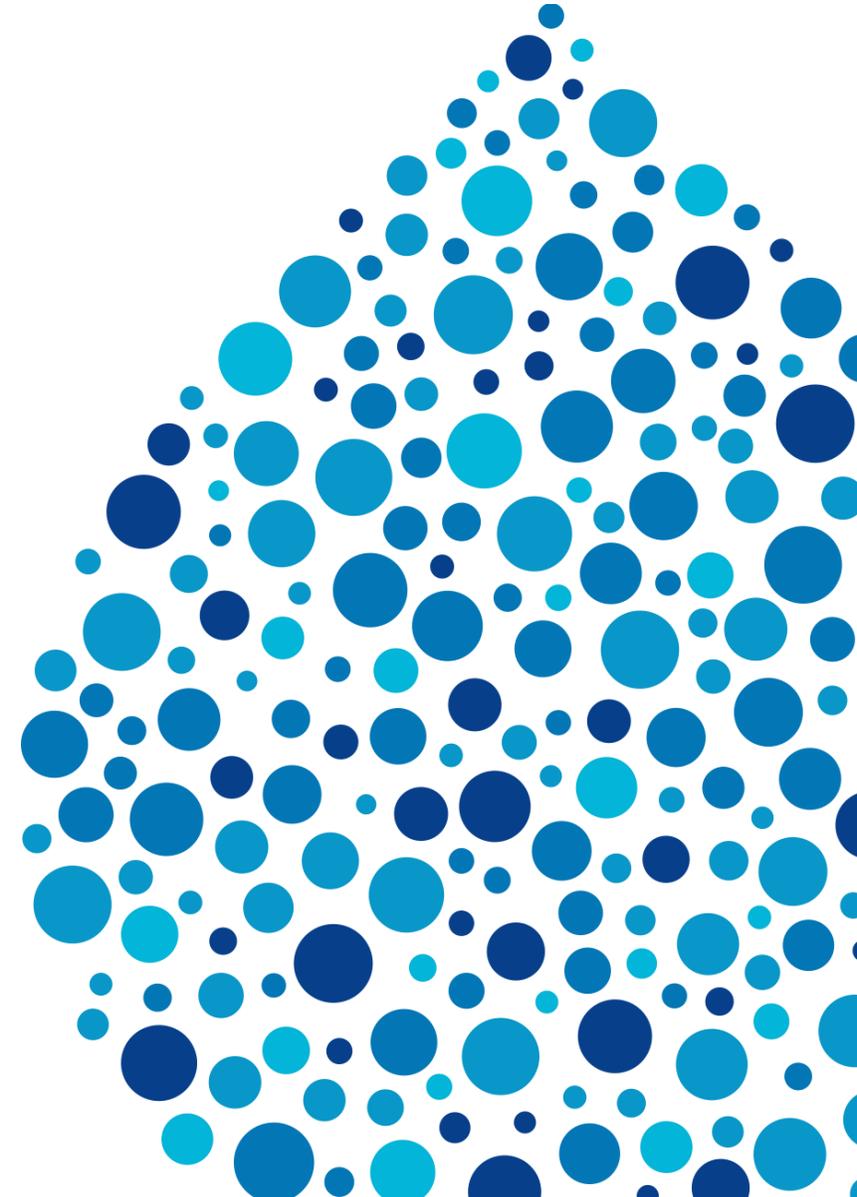


Academia &
Research



Industry

Researchers and pharma companies: generate insights that can be used to support the design and direction of the development of new treatments



How has “big” EHR data been used by health services?

- Demonstrated health improvements through using data in one **Learning Health System**

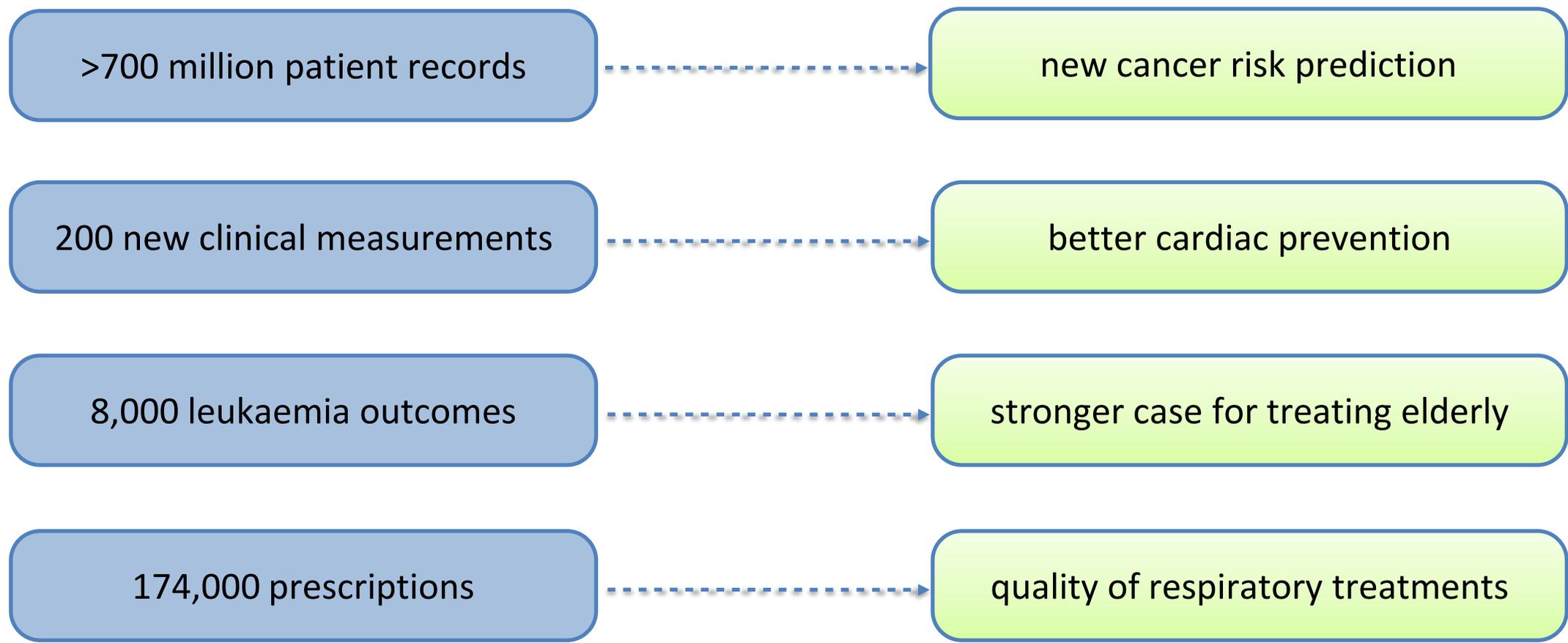
33% decrease in heart disease deaths

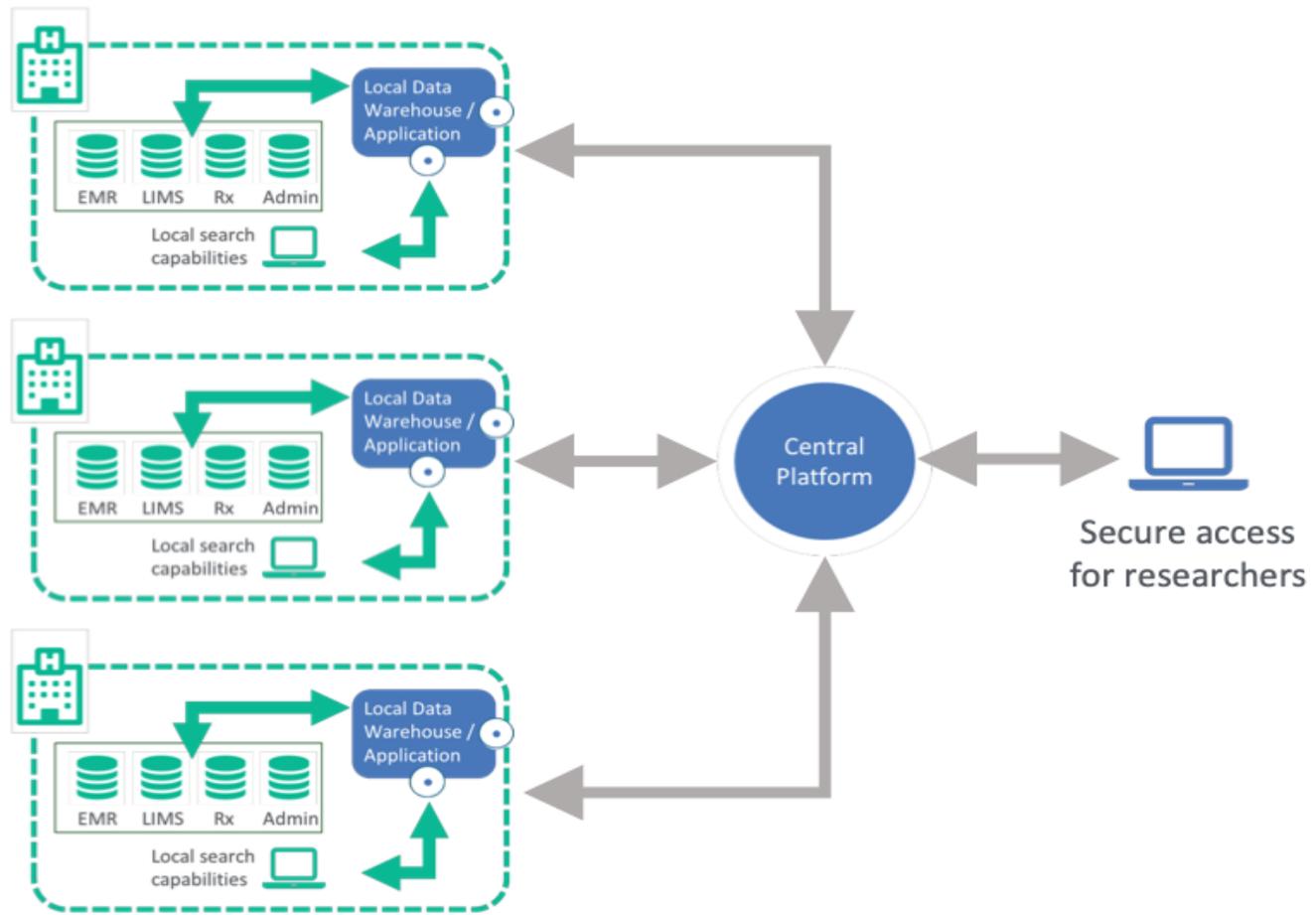
50% decrease in HIV deaths

50% decrease in septicemia deaths

67% decrease in pressure ulcers

Some other research findings from “big data” research

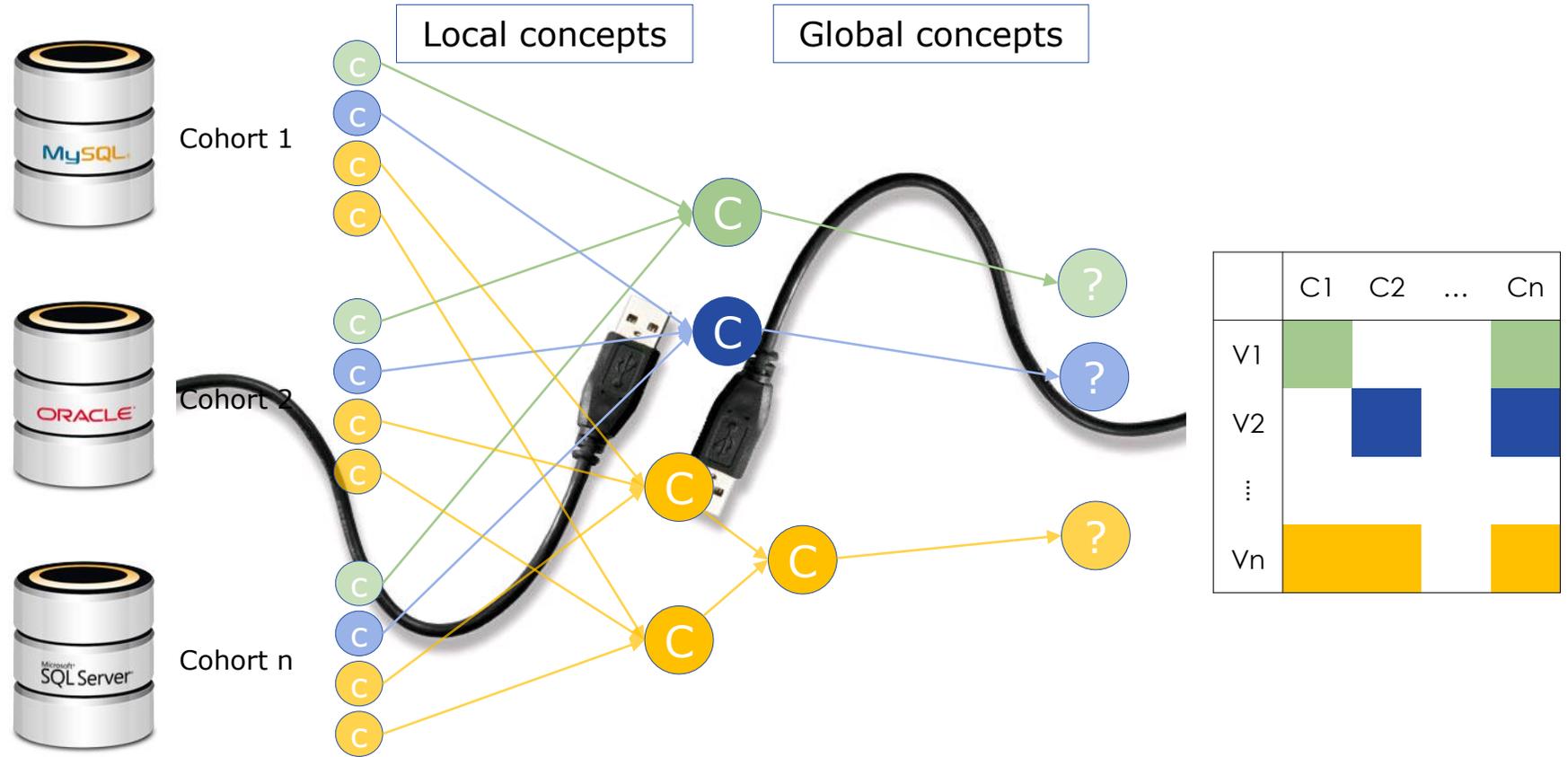




Benefits of federated networks

- Data remains under the control of the data owner
- Locally required legal and ethical approvals apply
- No patient level data leaves the owner's site, only aggregated counts, thereby ensuring patient privacy
- GDPR – '*Privacy by Design*'
- Analysis is "brought to the data" rather than creating central data repository
- Use of common data model allows for efficient search / analysis across multiple data sets
- Requires close collaboration with data owners which builds trust





	C1	C2	...	Cn
V1				
V2				
⋮				
Vn				

Data custodians

- Identify local concepts
- Specify mappings
- Define security

Community

- Specify global and derived concepts
- Define research groups

Example interoperability standards relevant to the EHR

Business requirements and functions	ISO 18308 EHR Architecture Requirements HL7 EHR Functional Model ISO EN 13940 Systems for Continuity of Care ISO EN 12967-1 HISA Enterprise Viewpoint
Information models	EHR Reference Model <i>openEHR</i> and EN ISO 13606-1 HL7 Clinical Document Architecture Clinical content model representation <i>openEHR</i> and EN ISO 13606-2 archetypes ISO 21090 Healthcare Datatypes ISO EN 12967-2 HISA Information Viewpoint
Clinical knowledge and content models	Terminologies: SNOMED CT, LOINC, etc. Clinical models: Archetypes, Templates, etc. Ontology standards... Genomic standards... Metabolic standards....
Computational services and message models	EHR Communication Interface Specification ISO/EN 13606-5 ISO EN 12967-3 HISA Computational Viewpoint HL7 SOA Retrieve, Locate, and Update Service DSTU HL7 FHIR
Privacy and security	EHR Communication Security ISO/EN 13606-4 ISO 22600 Privilege Management and Access Control ISO 14265 Classification of Purposes of Use of Personal Health Information ISO 27789 EHR Audit Trails

Scaling up International Patient Summaries



**Great potential for care co-ordination,
for innovation and learning health systems**

- Patient summaries
- Electronic prescriptions
- Electronic dispensations
- Medical images and image reports
- Laboratory results
- Discharge reports

To trust data in a shared data environment we also need to know:

- Provenance
 - robust patient identification, handling duplicates, reliable cross-provider linkage
 - authorship and author credentials
 - date and time, date formats and time zone
 - data integrity: units of measurement, term lists and terminology systems, drugs databases...
- Traceability
 - version history: confirming the latest version
 - reasons for changing records: typo correction, update, change of clinical opinion, disproved...
 - system, sub-system and repository history, system updates, roll back
- Security
 - access controls
 - indelible and inspectable audit trails
 - adequate protection and backup, ransomware resilient

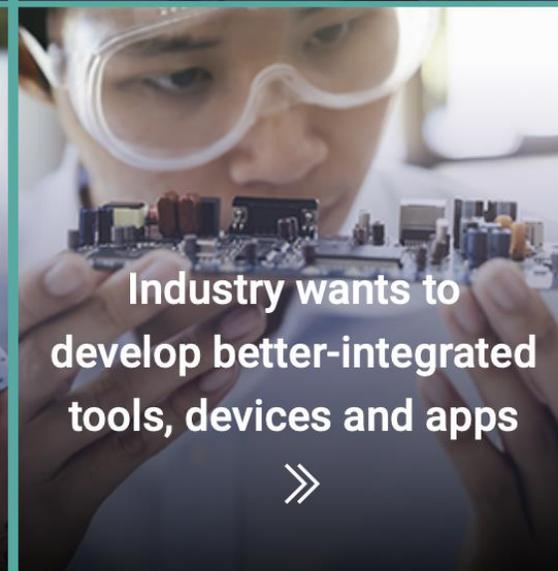
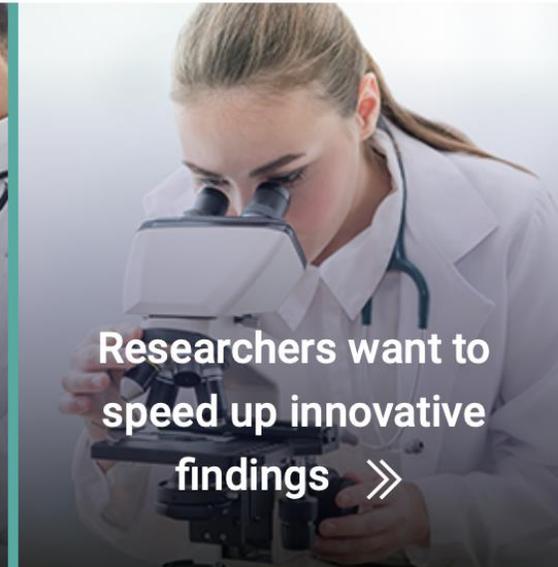
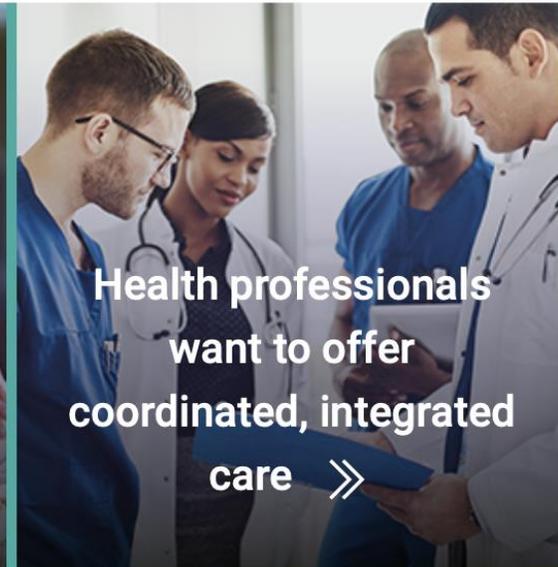
The FAIR principles: a commitment by data sources

- Data must be **Findable**
 - a searchable method to discover resources, with standardised metadata and a repository identifier
- Data must be **Accessible**
 - retrievable metadata, and potentially retrievable data via appropriate protocols and controls
- Data must be **Interoperable**
 - metadata is standardised, data conforms to relevant published standards
- Data must be **Reusable**
 - there is transparency about the terms under which the data may be reused

Health data is more and more collected and stored electronically, often through a variety of digital technologies, devices and apps.

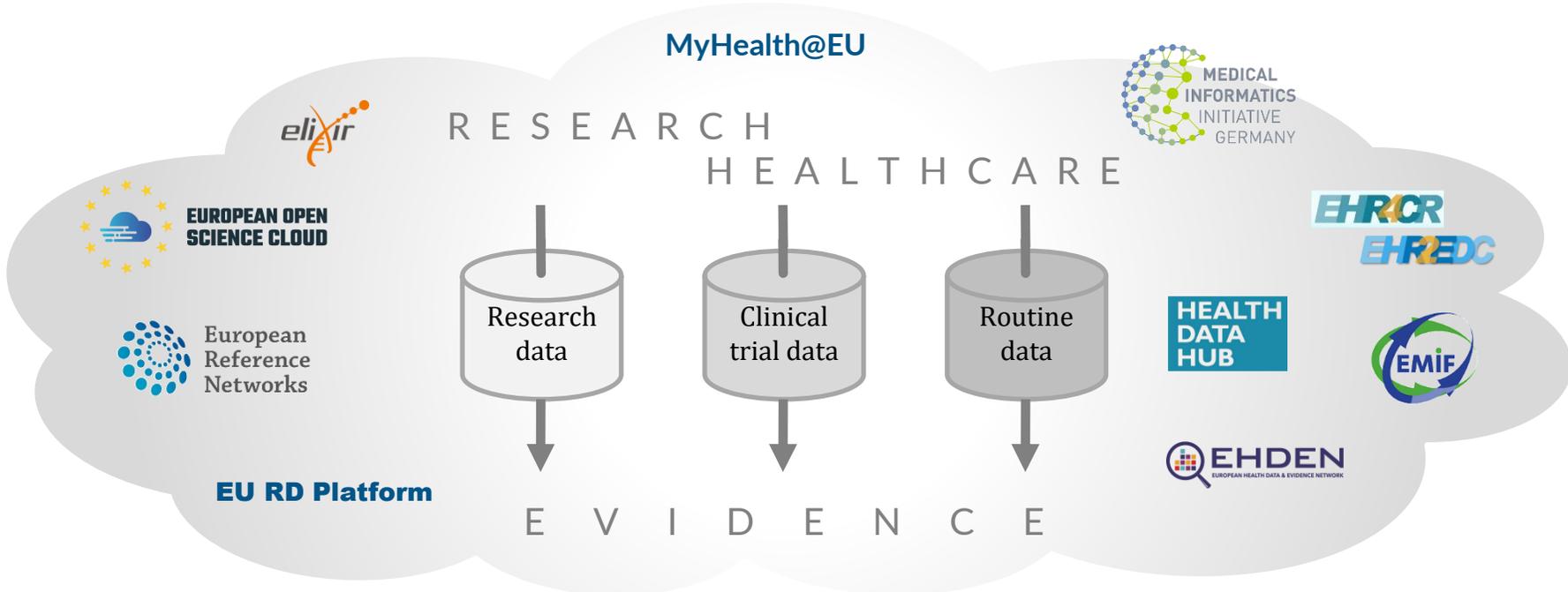
The diversity of health information technologies means that data is often collected in separate, unconnected silos.

We need to connect health data sources, for many reasons.



Big health data sharing initiatives

- Myriad of initiatives to share health data across jurisdictional, institutional and domain borders:
 - Sharing data for cross-border care or for research
- Emerging paradigm for analysing personally-identifiable health data:
 - federated infrastructure model: network of repositories with an overarching governance and interoperability layer



Some key provisions in the proposed EHDS Regulation (1)

- Mandating free access and portability for persons to their own EHR data, in a consolidated and readable form compliant with the EEHRxF
- Mandatory Member State participation in MyHealth@EU
- Data to be collected and processed in quality assured and certified EHR systems
- Patients will be able to add content to their EHR
- Increased personal control over who can access their health data

Some key provisions in the proposed EHDS Regulation (2)

- Health Data Access Bodies to be set up across Europe, to make consistent decisions relating to national public data sets
- Single application principle across countries, aiming for a level European playing field
- Published lists defining the scope of health data, permitted secondary use purposes, prohibited purposes
- Access to data for re-use is not limited by the type of user, public or private, but based on the purpose
- Data normally to be provided in an anonymised form, pseudonymised if necessary
- Published information about data access conditions, requests, decisions, and uses made
- European and national data source catalogues
- **Data quality and metadata labelling**

Data quality and metadata labelling Article

- FAIR: Findable, Accessible, Interoperable and Reusable
- Data documentation: meta-data, support documentation, data model, data dictionary, standards used, provenance
- Technical quality, showing the completeness, uniqueness, accuracy, validity, timeliness and consistency of the data
- Data quality management process: level of maturity of the data quality management processes, including review and audit processes, biases examination
- Coverage: representation of multi-disciplinary electronic health data, representability of population sampled, average timeframe in which an individual appears in a dataset
- Access and provision: time between the electronic health data being collected and added to the dataset, time to provide electronic health data following electronic health data request approval
- Linkages: ability to link with other datasets

ISO/TS 82304-2:2021 Health and wellness apps: Quality and reliability

Flag or logo **Health app quality label**

App icon **App name**

Platform icons

Name app manufacturer

Benefit of the app
 With this app [intended users] can [intended use] / With this app [x in 10] [intended users] [health effect] [if use]
 ⚠️ Check [here] when app requires approval from a health professional before use.

Healthy and safe

	B	A
--	---	---

Easy to use

	D	C	B	A
--	---	---	---	---

Secure data

	E	D	C	B	A
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Robust build

	A
--	---

↓

Overall health app quality score

C	B	A
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App checked on [date]

CEN-ISO/DTS 82304-2

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CEN-ISO/DTS 82304-2

Healthy and safe

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Robust build

	A
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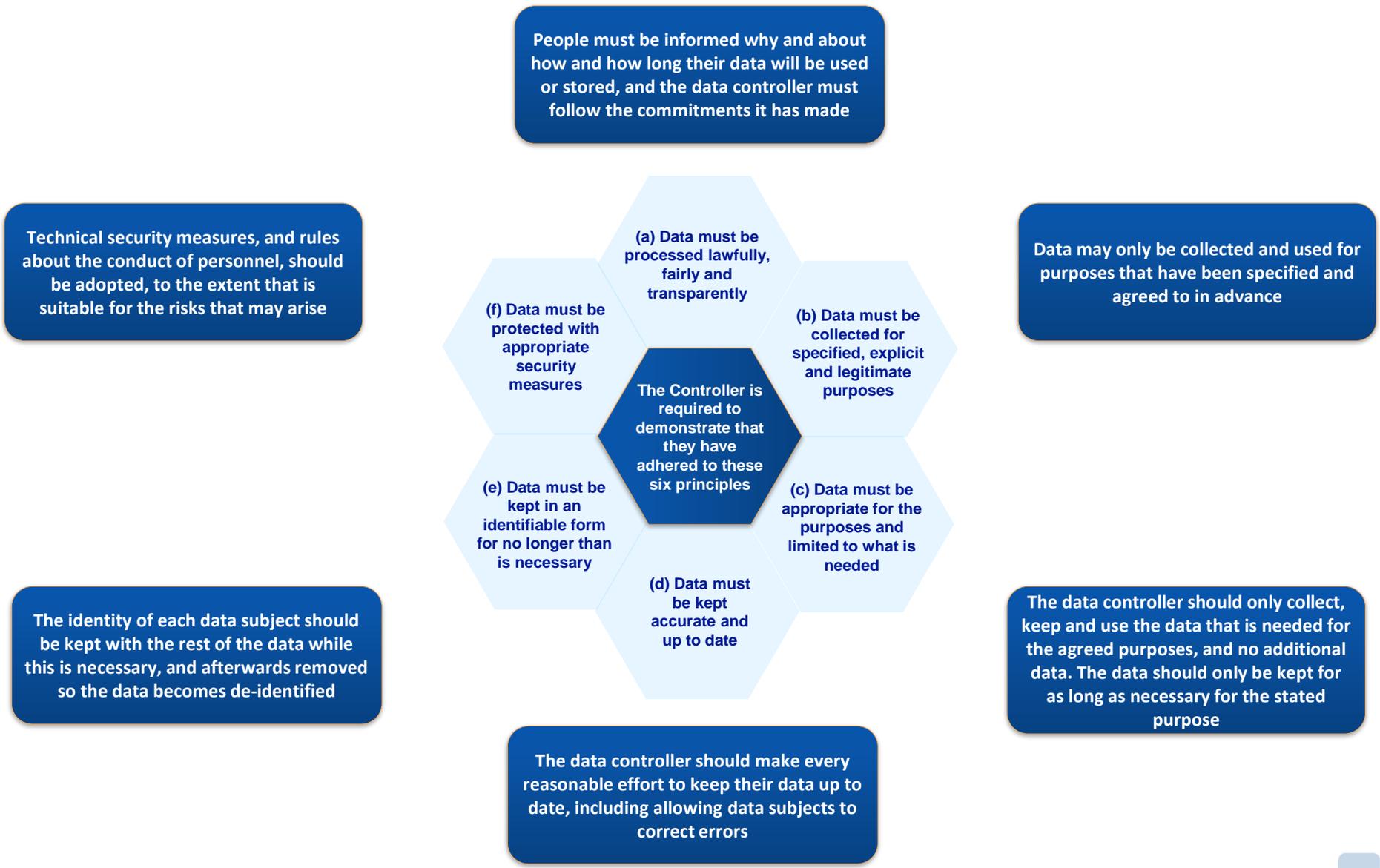
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Overall health app quality score

C	B	A
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App checked on [date]

What is required of data “controllers” (who collect, hold and use data)



There is a need for education - across all stakeholders



How GDPR applies to health data

Setting up a GDPR-compliant data collection and processing pipeline

Patient & participant consent

Real World Evidence and GDPR

Regulatory Framework, GDPR and RWE

Accountability, Threats, Security and Breach Management

Transparency and Rights

Extra-EU Transfers and Operations

Exploring Breaches and Prosecutions

Anonymity and Pseudonymisation

Data Protection Impact Assessments and organisational templates

Regulatory compliance for AI development

Case Studies

Panel Discussions

i~HD is contributing towards consensus on strategies and solutions



DigitalHealth Europe project:
European Health Data Space:
Policy White Paper, industry consultation, patient and citizen consultation 2020



Multi-stakeholder consensus events and reports 2020-21, joint with DHS, sponsored by MS, J&J and MSD



Your health **connected**

NEW

Experiences of Integration of mHealth into health systems

SEE MORE



<https://mhealth-hub.org>



SITRA

WORKING PAPER

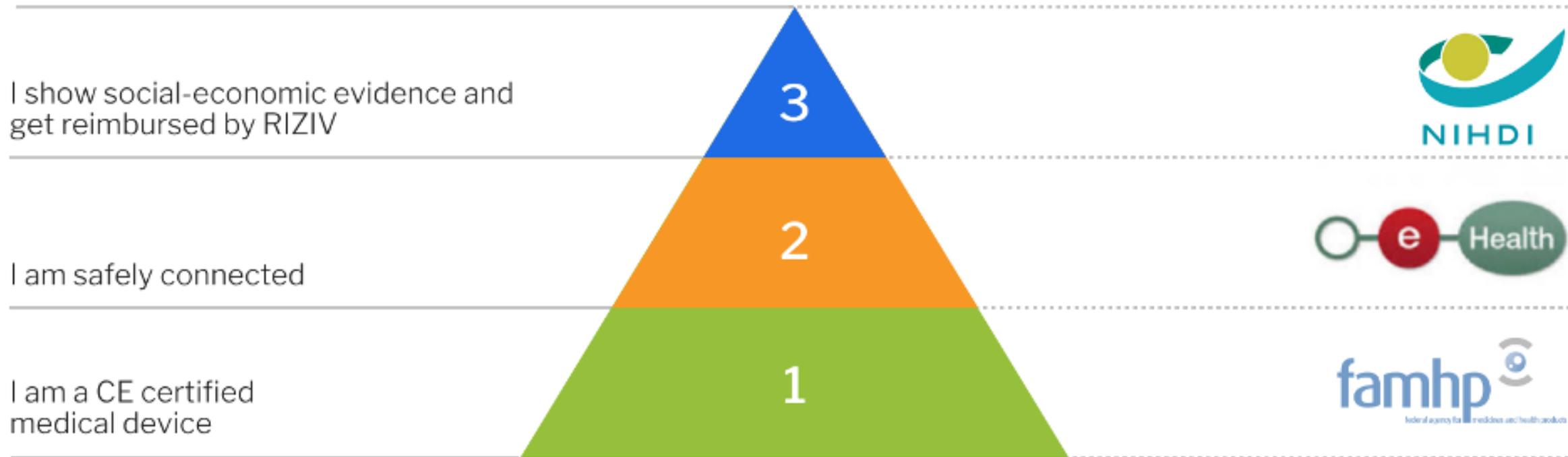
24.11.2021

HOW CAN

DIGITAL THERAPEUTICS

HELP EUROPE?

App approval pyramid, Belgium





- Arrhythmia detection
- Early detection of heart failure
- Cardiac function monitoring



Uptake issues in Europe

- Challenging to become incorporated within health systems
- Compiling the approvals evidence dossier for each EU country separately
- Limited cross-recognition between countries
- Who pays?
- Who takes clinical responsibility?

Success factors for scaling up the adoption of digital therapeutics

- National strategies must be inclusive of DTx
- Better balance regulation and innovation
- Share the burden of evidence generation
 - make national health and socio-economic data available
 - enable incremental evidence generation
 - recognise studies across Europe
- Provide clear assessment, certification and reimbursement criteria
- Support health systems change management and capacity building
- Plan for the reuse of DTx data
- Foster innovation with the DTx industry

Take home messages for digital health innovators

- Target health outcomes and health systems needs
- Document requirements and reference them
- Define and follow formalised quality processes
- Be interoperable, collaborative, data protecting, by design
- Rapidly consolidate on a Minimum Viable Product
- Develop a business model for the MVP
 - work out who will gain
 - work out who will pay
- Plan ahead for assessments, certification, approvals
- Maintain evidence of value