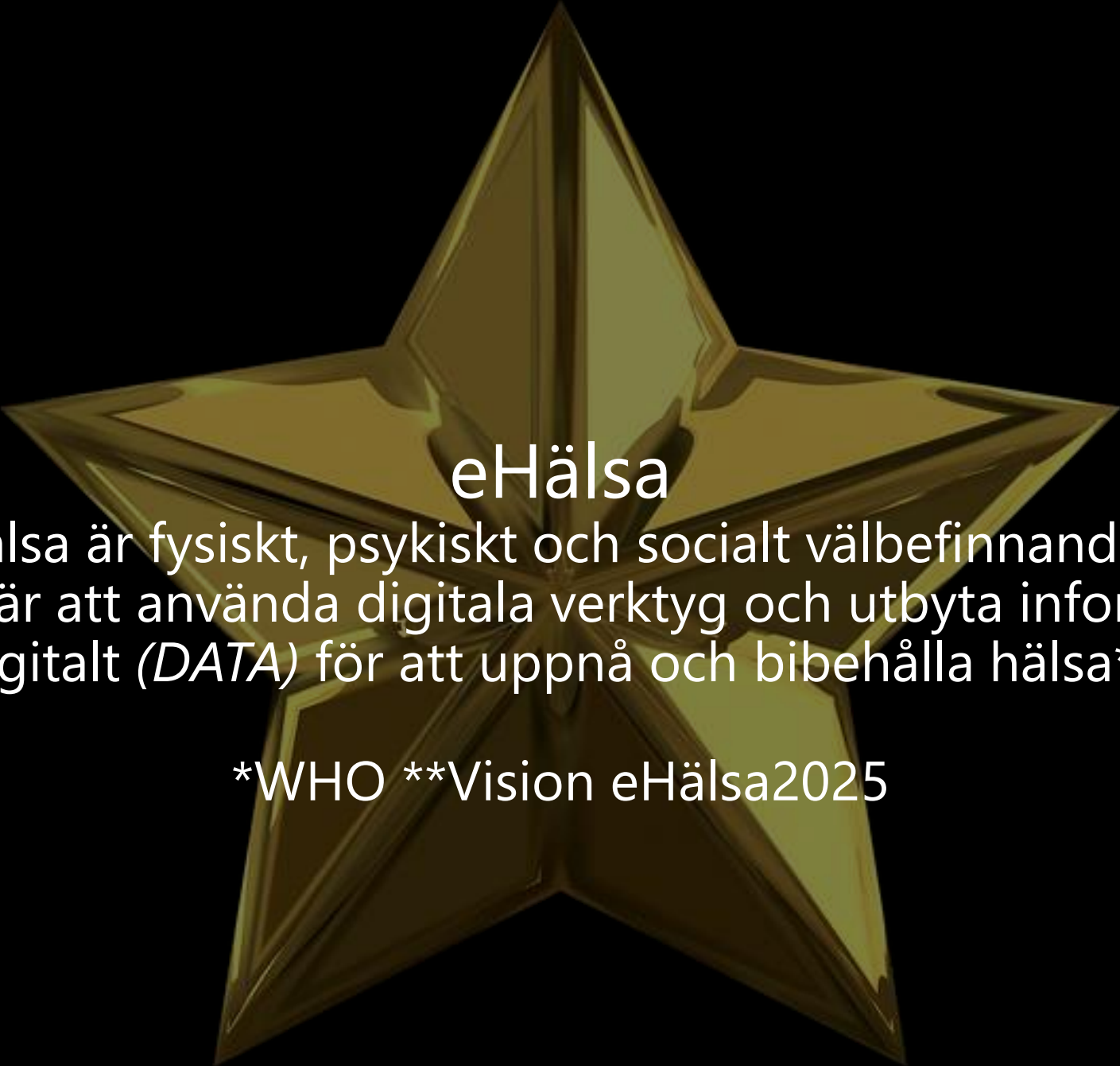


European Health Data Space (EHDS) För mer (e)Hälsa i nu och framtid.

Nasim Bergman Farrokhnia, MD PhD MBA (essentials gnm LSE)
Ordförande, Forum för Health Policys forskarnätverk
Medgrundare www.digitalcareresearch.se
Ordförande, eHälsoläkarföreningen
Hälsö- och sjukvårdschef, Microsoft Västeuropa





eHälsa

Hälsa är fysiskt, psykiskt och socialt välbefinnande*.
eHälsa är att använda digitala verktyg och utbyta information
digitalt (*DATA*) för att uppnå och bibehålla hälsa**.

*WHO **Vision eHälsa2025



Varför eHälsa?

- Bristande tillgänglighet och **ojämn kompetensförsörjning** ("medical deserts"/geografi). Ineffektivitet.* Bristfälliga IT-system.
- Demografi samt allt fler "överlevare" pga vetenskapliga/tekniska framsteg. Alltså **växande vårdbehov**.
- Globala megatrenderna urbanisering och digitalisering som också innebär ändrade beteenden och förväntningar – **förändringstrycket är högt**

* Källa: bl a Socialstyrelsens årliga väntetidsmätningar, SKRs Vården i Siffror samt OECD-rapporter

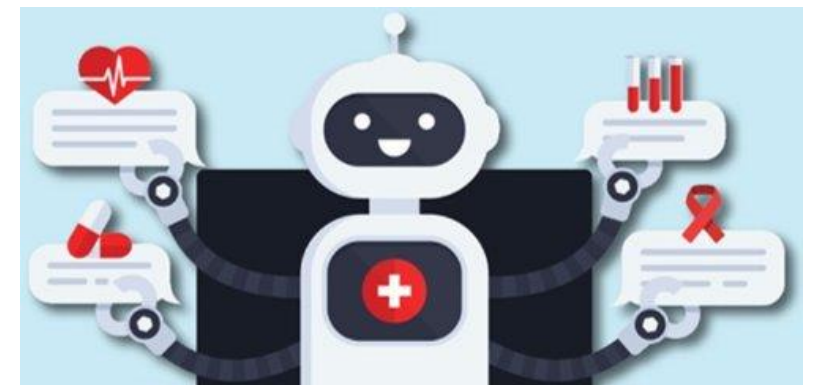
** *Hälso- och sjukvårdslagen och Patientsäkerhetslagen*



Framtidens Hälsa- och sjukvård

Preventative Förebyggande, Hälsoskapande
Co-created Sam-skapad
Precise (Gen)omics, PROM*s, PREM*s
Personalized Individanpassad, Skräddarsydd

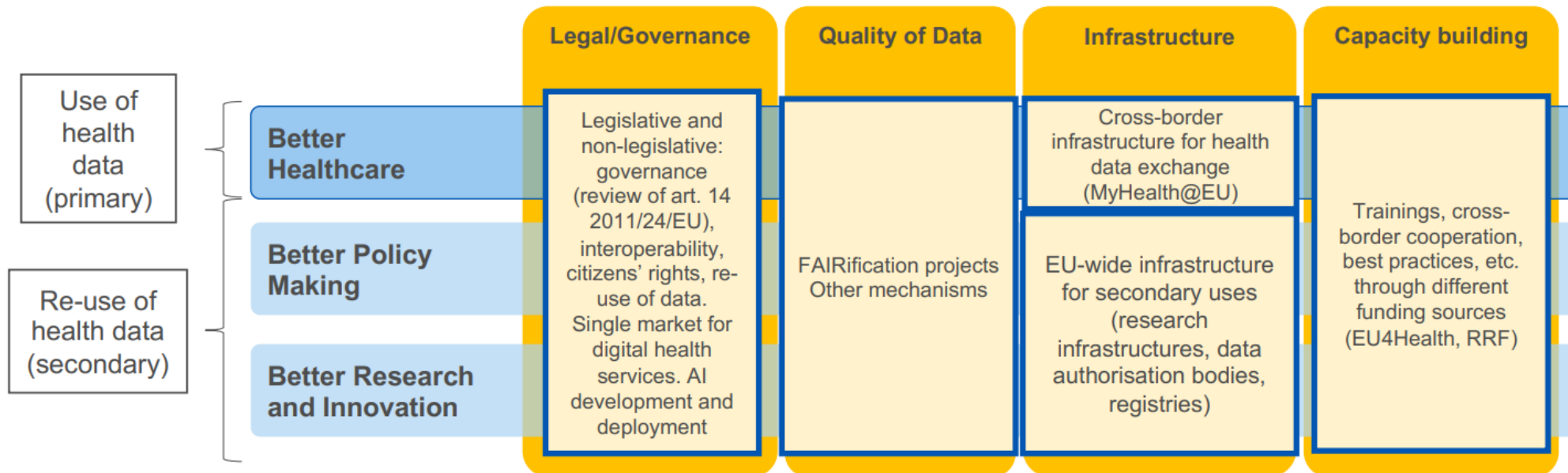
*Patient Reported Outcome (Experience) Measures
[Handlingsplan för Vision 2030 | Nordiskt samarbete \(norden.org\)](#)



European Health Data Space, EHDS

Primary and secondary uses of health data

- Timely and simplified *exchange of* and *access to* health data for different use cases:
 - Healthcare provision, access and control of patient over their data, (cross-border) exchange of health data;
 - Digital health services (including telehealth and m-health);
 - Research (eg on cancer, rare diseases, COVID-19 etc), pharmacovigilance, public health, policy making



1st sector specific European Data Space



Health



Industrial &
Manufacturing



Agriculture



Finance



Mobility



Green Deal



Energy



Public
Administration



Skills

- Driven by stakeholders
- Rich pool of data of varying degree of openness
- Sectoral data governance (contracts, licenses, access rights, usage rights)
- Technical tools for data pooling and sharing

Personal
data spaces

High Value
Datasets
from public
sector

Technical infrastructure for data spaces



Edge
Infrastructure &
Services

Cloud
Infrastructure &
Services

High-Performance
Computing

AI on demand
platform

AI Testing and
Experimentation
Facilities

Main problems

Individuals have difficulty accessing and controlling their health data



Healthcare professionals have difficulty accessing health data



Providers of digital health services and products face barriers



Policy makers and regulators cannot easily access health data



Limited innovation takes place on the basis of health data

European Health Data Space

Data Access and Fluidity to enable following objectives:

Empower individuals to
control their health data



Foster a single market for
digital health services and
products



Ensure **interoperability**
and security of health data
and a level playing field for
manufacturers



Unleash the power of the
health data economy

Ensure a consistent and efficient
framework for the reuse of
health data for research,
innovation, policy-making and
regulatory activities

European Health Data Space

Use of data for healthcare (primary)

Re-use of health data (secondary)

Sharing of health data for healthcare

Problems

- Limited control of patients over their health data
- Limited interoperability between health care providers

Areas of work

- Control of patients over their data
- Interoperability
- Role of e-health agencies
- Reinforced EU governance (eHealth Network)
- Reinforced MyHealth@EU

Single market for digital health products and services

Problems

- Uneven national legislative frameworks
- Uneven quality framework
- Uneven procedures for prescriptions, reimbursement, liability

Areas of work

- Eliminate barriers to free movement
- Labelling
- Interoperability
- Reimbursement
- Liability

Access to health data for research, innovation, public health policy making

Problems

- Low re-use of health data
- Cumbersome cross-border access to health data
- Fragmented digital infrastructures

Areas of work

- Governance and rules for access to health data
- Data FAIR-ification
- Digital infrastructure (EHDS2)

AI

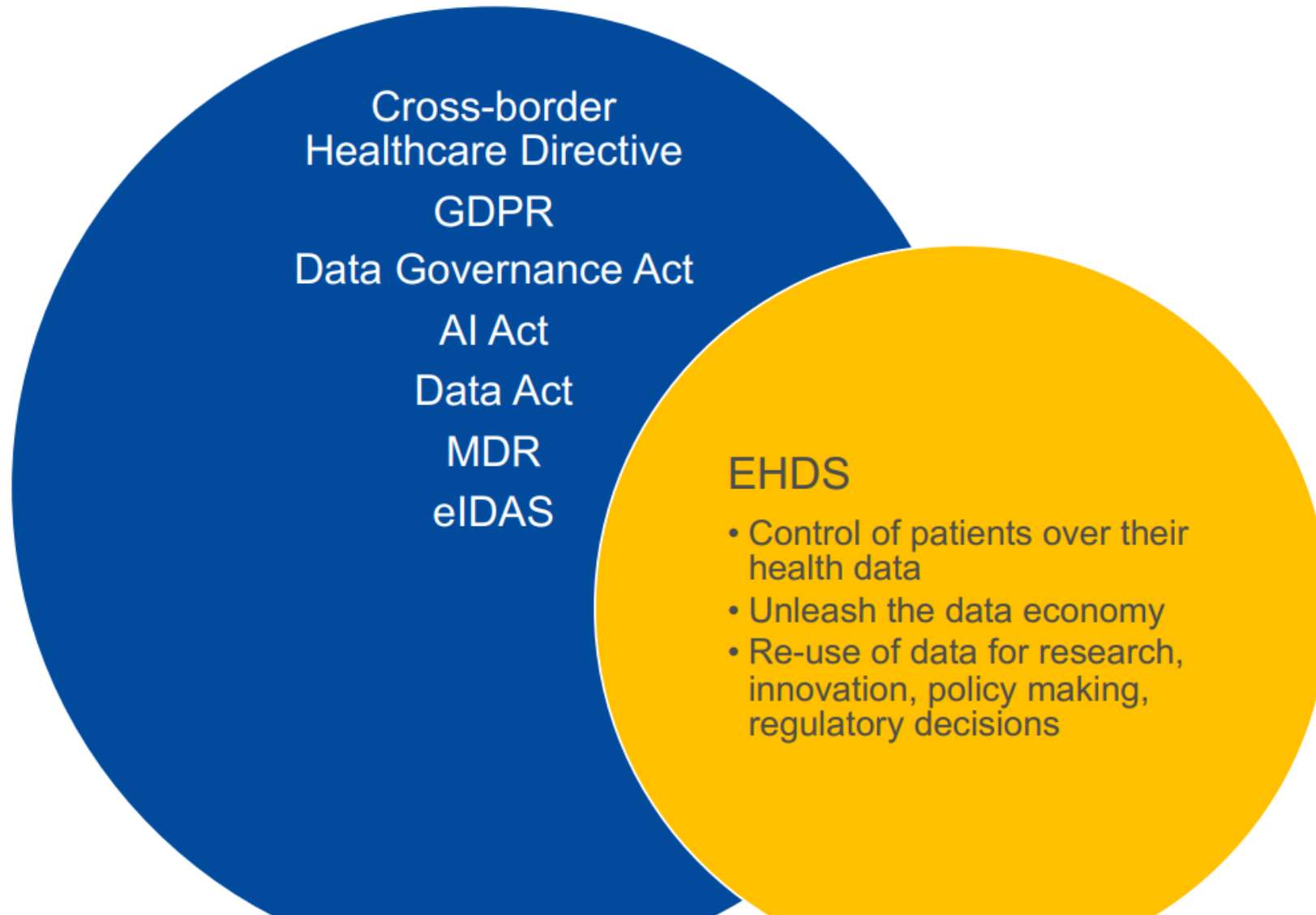
Problems

- Limited provision of data for training of AI
- Difficulties for regulators to evaluate AI algorithms
- Uncertainty on AI liability in health

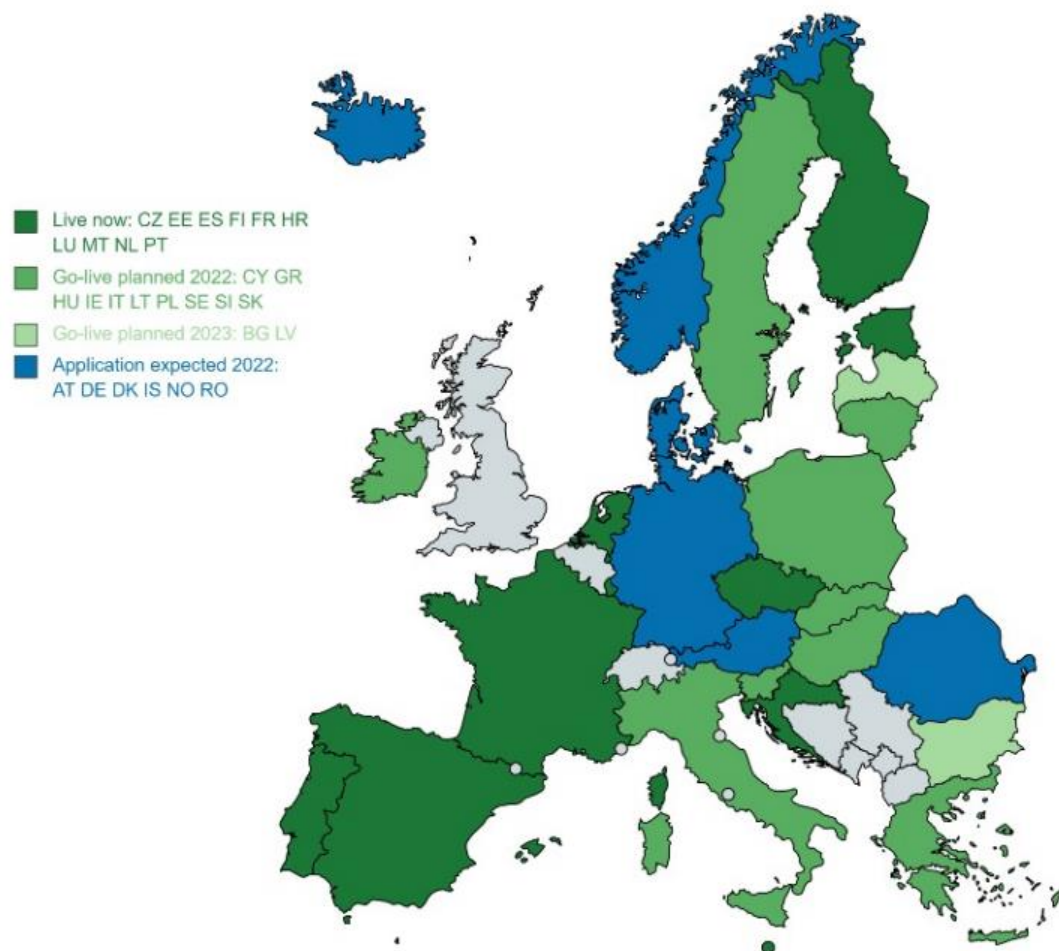
Areas of work

- Support for development and rollout of AI
- Data for AI
- Support for regulators

EHDS: articulation within EU regulatory framework



MyHealth@EU



- Currently 10 Member States are live
- The number of connected Member States will grow rapidly in the years ahead
- Currently there are 2 services: Patient Summary and ePrescription
- This is being expanded to include Medical images, Lab results, Discharge letters, Rare disease data and other health information categories
- A Pilot will explore Patient Access to their health data in MyHealth@EU

Primary use of health data

- The legislative proposal will focus on a number of areas:
- Expanding the rights of citizens to **access** and **portability** of health data
- Strengthening the eHealth **governance**
- Expanding the **MyHealth@EU** services
- Promoting **interoperability** of health software solutions (including EHR, apps, medical devices)

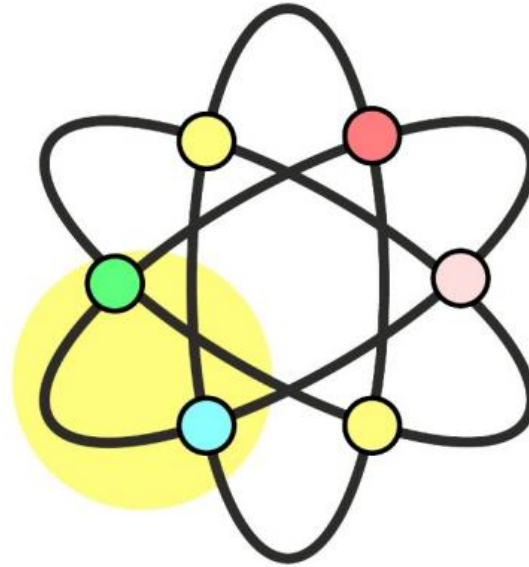
Secondary use in the EHDS



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



Rules, protocols
and governance

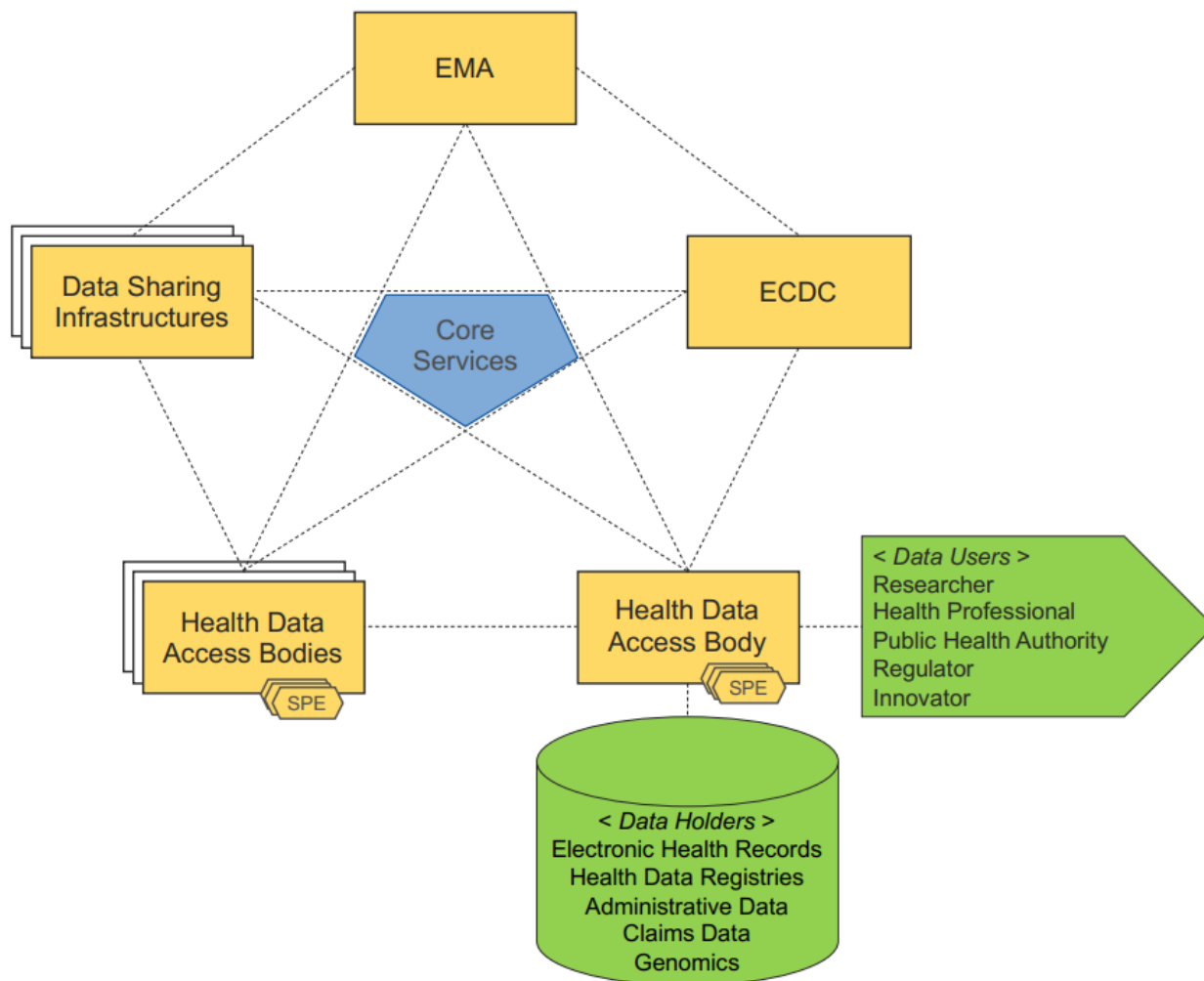


Health data from patients
and healthcare professionals



Granting researchers, policy-makers and industry access to health data across borders in an interoperable, digital format

Access to data for research, innovation and policy making



- Creating a **network of nodes** as entry points into EHDS
- Nodes can be National **Data Authorisation Bodies** or European stakeholders (EMA, ECDC, Research Infrastructures)
- Rules are in place **governing the access** to health data (interoperability, data quality, privacy, security)
- Examples at national level are established in **Finland, Denmark, France and Norway**

Towards European Health Data Space

Towards European Health Data Space or TEHDAS, is a Joint Action project being carried out by stakeholders from 25 European countries. Their goal is to develop European principles for the secondary use of health data and to advance the cross-border secondary use of health data in Europe.

TEHDAS is doing this by structuring their work in 8 different work packages.



[Project – Tehdas](#)

[TEHDAS Stakeholder forum 2022 - Sitra](#)

[FAQ in English | Health Data Hub \(health-data-hub.fr\)](#)

[Findata – Finnish Social and Health Data Permit Authority](#)



Secondary use of health data

- The legislative proposal will focus on a number of areas:
 - Expanding on the existing **infrastructure** in Member States (Health Data Authorisation Bodies)
 - Introduce a European infrastructure
 - Promoting **interoperability** and **data quality**
 - Strengthening the **legal base** for the re-use of health data
- 

Projects

EU4Health funds a number of relevant projects to further expand the European digital health infrastructure

- A pilot project to allow **patients access** their health data in MyHealth@EU
- **Expansion of MyHealth@EU**, both by allowing more Member States to establish National Contact Points and by expanding the amount of services
- A pilot project to understand the potential of a European **network of National Health Data Access Bodies** collaborating on secondary use of health data

RRF provides a further 12 Billion EUR in digital health funding

Strengthened security

Primary use

Builds upon EU-cybersecurity legislation

Security/interoperability criteria for EHR systems
+ CE marking

Security audits for the MyHealth@EU infrastructure

Strong authentication for patient
and health professionals

Only persons entitled to access the data
can get access

Secondary use

Data processed in **secure processing environments**, compliant with highest standards of privacy and cybersecurity.

No personal data can be downloaded

Users cannot identify individuals

Audits of participants in HealthData@EU

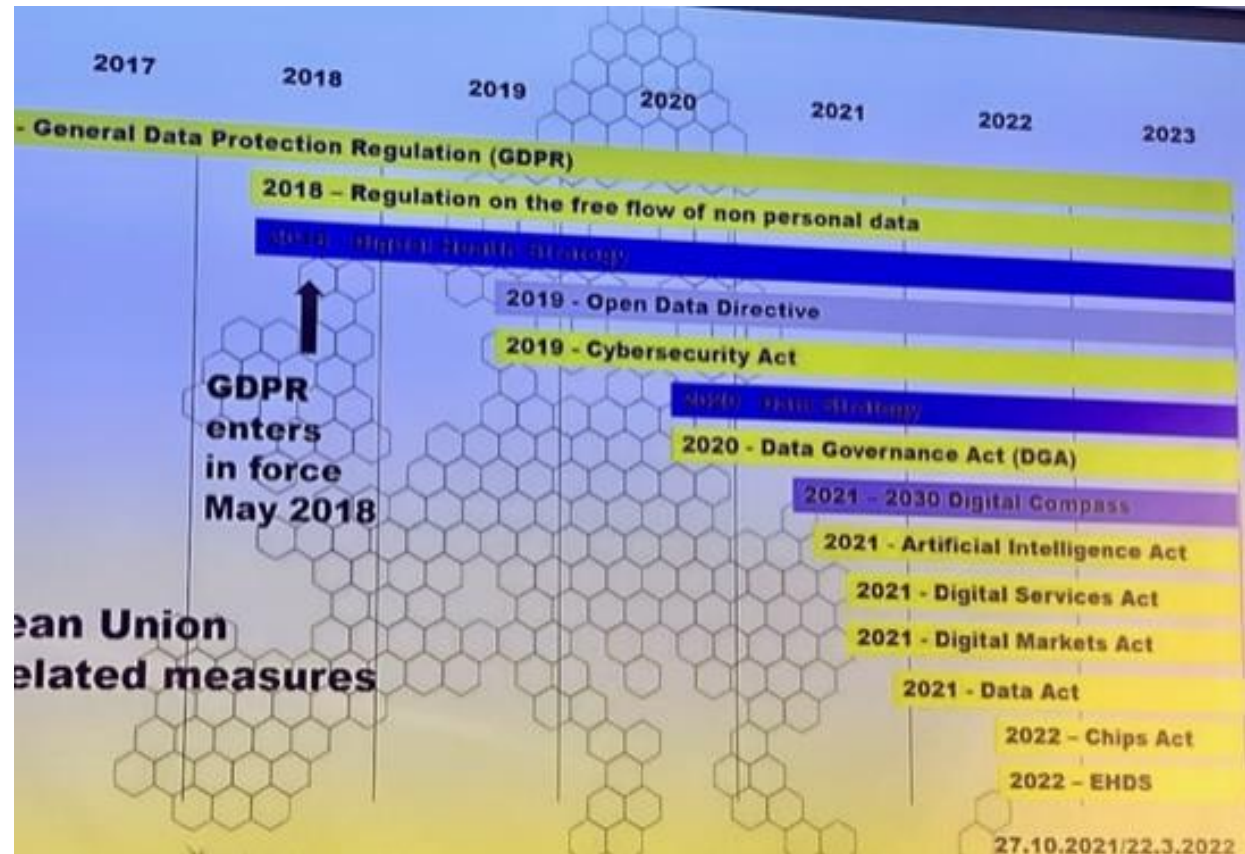
- Gemensamt personuppgiftsansvar för medlemsstaterna, med samtidig roll för kommissionen som personuppgiftsbiträde
- Betydelsen av informations- och datasäkerhet
- Kostnader och EU-finansiering
- Myndighetsorganisation för föreslagna uppgifter och ansvar
- Nätverket för e-hälsa (eHealth Network) ersätts av EHDS-styrelse (EHDS Board)
- Förordningens påverkan på olika intressenter
- Hälsoappar bör uteslutas ur förordningen.

Interoperabilitet

- Standarder
- Agilitet
- Regulation
 - Möjliggörande (*gasa*)
 - Kontrollerande (*bromsa*)



- Develops options for governance models for the exchange and secondary use of health data between European countries, based on transparency, trust, citizen empowerment and a common good.
- Provides recommendations for European countries on planning national legislation to enable cross-border exchange and secondary use of health data.



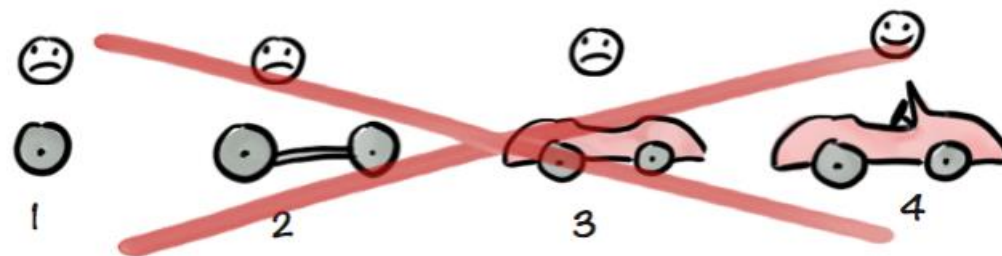
Package 5: Sharing data for health - Tehdas

🔑 Demokratiseringsverktyg
🔑 **Empowerment. Kunskap är makt.**

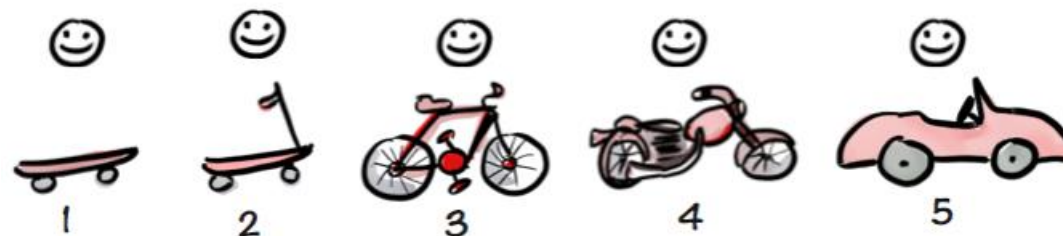
💡 Innovation > "MVP" > Piloter
💡 **Data** > Analys > Iteration > Utveckling > Support*
💡 **Skalning** och **spridning** > Ersättningsmodeller och regulation

[*At the End of the Funnel: Translation of Improvement Approaches in Healthcare \(chalmers.se\)](https://chalmers.se)
av Christian Colldén MD PhD, Sahlgrenska Sjukhuset, Göteborg

Not like this....



Like this!



SUSTAINABLE
DEVELOPMENT GOALS

Förändringsledarskap

Tekniskt
skifte

1. Att bygga förtroende för nyttan samtidigt som risker minimeras
2. Framålutad expertis och färdigheter för effektiv användning (*utbildning/träning*)
3. Anpassningar hos organization, struktur, regelverk och ersättningsmodeller

Adaptivt **skifte**
i människors
attityder och
färdigheter

Det krävs **stöd** genom alla dessa processer på alla nivåer - lokalt, regional, nationellt - till medarbetare, chefer och beslutsfattare
(ledarskap)

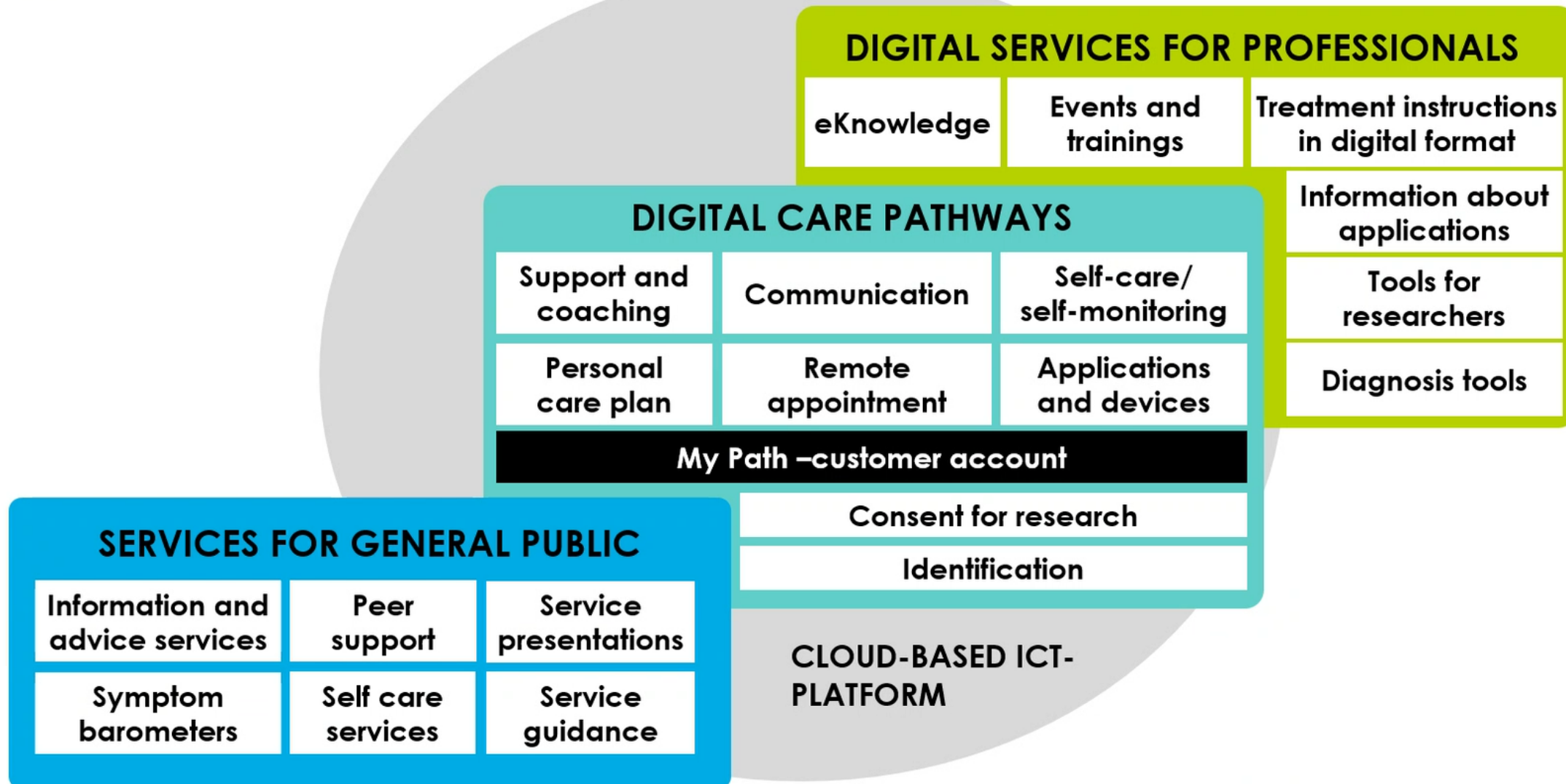
Adaptivt **skifte** i
regulation,
organisation och
arbetssätt

Empowering the **health workforce**

Strategies to make the most
of **the digital revolution**



HEALTH VILLAGE SERVICES IN FINLAND



HUS: Helsinki Universitetssjukhus har 27 000 anställda, 3000 bäddar, and är Finlands 2^a största arbetsgivare.





**Framtiden är redan här,
den är bara inte så vanlig ännu.**

Tack

Nasim.Farrokhnia@ki.se

[Nasim Bergman Farrokhnia | LinkedIn](#)

**Nasim Farrokhnia, MD PhD MBA (essential/LSE)
Hälso- och sjukvårdschef, Micorsoft Västeuropa
Ordförande, eHälsoläkarföreningen**