Imagining 2029 webinar series:

Moving towards for European Health Data Space(s)

From the European Strategy for Data to Health Data Spaces

1st EHTEL/ELO Network Factsheet

OPENDEI
Aligning Reference Architectures, Open Platforms and Large-Scale Pilots in Digitising European Industry

InteropEHRate

EHTEL Association, a.i.s.b.l.
Avenue de Tervuren, 168, box 2 B-1150 Brussels Belgium Tel: +32 2 230 15 34 Fax: + 32 2 230 84 40 info@ehtel.eu www.ehtel.eu

This document highlights the roles of eHealth competence centres, and more broadly of Member States in Europe, on moving forward their agendas towards **European Health Data Spaces** while maintaining trust and data sovereignty for citizens and patients. It has as a starting point the **virtual ELO Network meeting** hosted by EHTEL on 20 May 2020, led by ELO Co-Chair Vesa Jormanainen of THL (Helsinki, Finland).

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Perspective of national and regional drivers towards digital health

Today, there is a drive towards implementing European Member States’ **digital health strategies** and digital health legislation. As a result, national and regional **eHealth competence centres** are instrumental in bringing digital health services to citizens and patients across Europe. These organisations convene in the **ELO Network**, one of the three collaboration platforms that are part of the EHTEL multistakeholder ecosystem. The ELO Network provides **a platform for debate** on eHealth operational activities, deployment plans and implementation, standards, interoperability, and certification. The network gathers together more then ten of these organisations, mandated by their respective national and regional governments.

European strategy for data: Opportunities and barriers

The European strategy for data[1] aims at creating a single market for data that will safeguard Europe’s **global competitiveness and digital sovereignty**. Common European data spaces will ensure that more data becomes available for use in the economy and in society, while keeping in control the companies and individuals that generate the data. These principles will apply in three areas: data flow within the European Union (EU) and **across sectors**; full respect of **European rules**, in particular **privacy and data protection** as

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[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions **A European strategy for data** - COM/2020/66 final, see https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1593073685620&uri=CELEX%3A52020DC0066

well as competition law; and making sure that the **rules for access and use** of data are **fair, practical and clear**.

Establishing **transparent, fair and interoperable connections** is likewise one of the key objectives being pursued by eHealth competence centres that gather together in the ELO Network. Accordingly, their activities match a number of the implementation targets mentioned by the European Commission in the European Strategy for data. It has been announced that these will be funded in support of the **establishment of EU-wide common, interoperable data spaces** in strategic sectors. It is important to look at both the opportunities (facilitators) and the barriers.

In particular, **facilitating data spaces** will include:

- Deployment of data-sharing tools and platforms
- Creation of data governance frameworks
- Improving the availability, quality and interoperability of data.

Moving towards implementing the European data strategy, some **barriers** need to be overcome**:**

- Not enough data available for reuse
- No real user empowerment / imperfect data portability mechanisms
- Skills shortages and low data literacy
- Fragmentation of the single market
- Lack of European data processing and storage solutions
- Absence of comprehensive data governance approaches.

Data spaces and data sovereignty of persons and organisations

A specific example of today's focus on data spaces lies in the work of the International Data Spaces Association (IDSA).

Over several years, IDSA has established a number of approaches to sharing data across industry sectors; examples include **smart health**, the smart home, and smart industry. The health sector is one of these.

In the age of digitisation, health data is the "new blood". It enables the facilitation of powerful tools and methods for personalised precision (P4) medicine. P4 approaches are largely data-driven and are thus in need of privacy-preserving methods capable of processing highly sensitive, re-identifiable data and yet maintaining **data sovereignty**.

Data sovereignty can be defined as a natural person's or a corporate entity's capability of being entirely self-determined with regard to its data. This implies in practice (in healthcare) that each user (citizen/patient) decides for her/himself where her/his data is stored, as well as who may process it and for what purpose, based on the user's (citizen/patient) own data classifications and assignments.

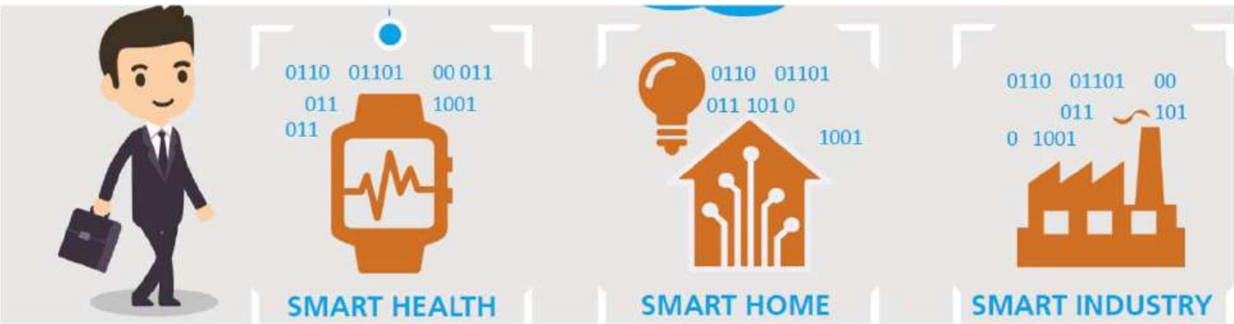


Figure 1: DAWID - a cross-sector, data-centred value creation platform for interactive-assisted service systems (Fraunhofer)

Meta-consent enhances data sovereignty: To empower a person for the **control of data flows**, meta-consent and data usage, means actively identifying the purposes for which data are to be used and not used. In this report, the concept of meta-consent uses healthcare data as an example. Data is assigned to classes for this purpose and, for every class, a **user** can define whether he or she wants to be informed of data usage requests or whether a set of standard rules will apply (see also factsheet 2 in the ELO series of factsheets).

For IDSA, **users** can be either individuals, companies, or complete ecosystems of companies. **Digital eco-systems** are composed of several components, such as service platforms and data sharing infrastructures – see figure 2 for a generic model proposed by IDSA. Digital eco-systems are related to two sets of services: one based on trust; the other ('base services') founded on up to 12 core services. **Essential trust services** include a clearing house, certification bodies and authorities, and dynamic trust management. **Base services** involve access, encryption, governance, and interoperability. This is just one of the many models developed by IDSA.

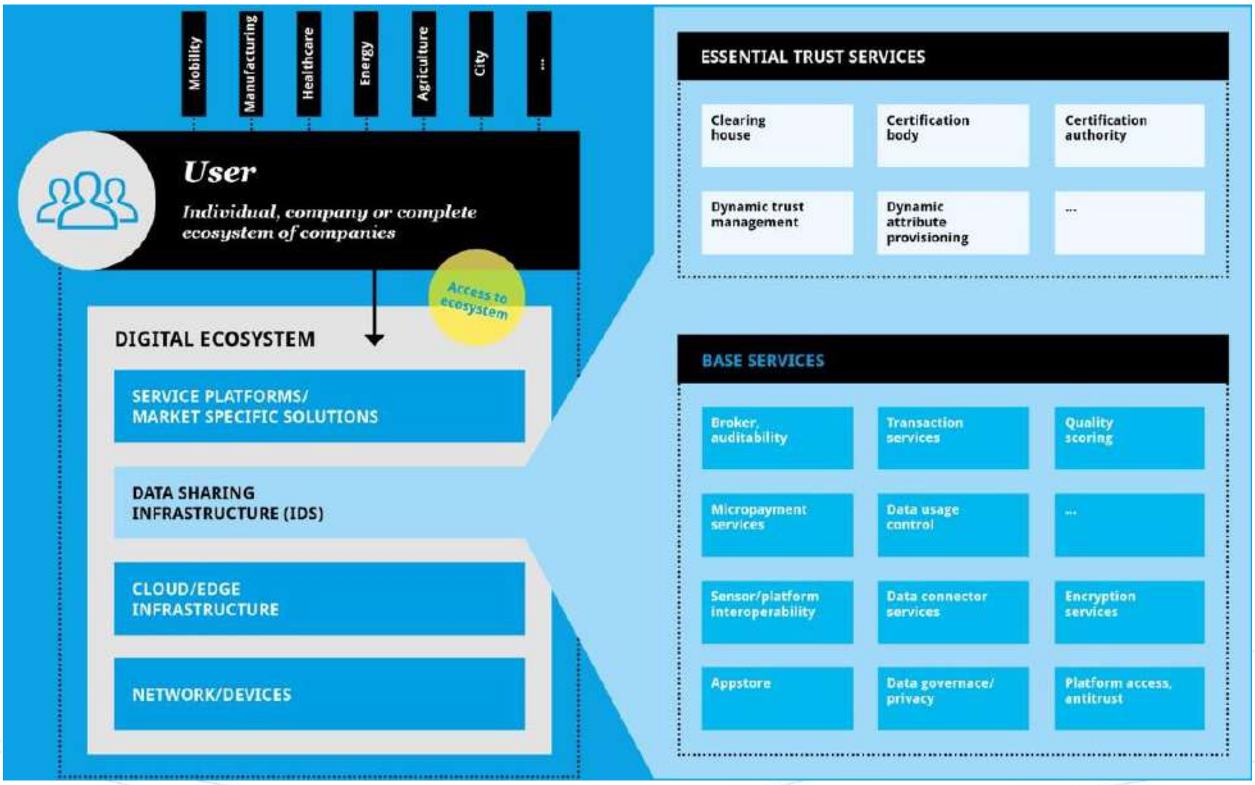


Figure 2: An overview of the digital ecosystem, trust, and base services proposed by IDSA

The principles and digital ecosystem **models** developed by IDSA are powerful tools to maintain health data sovereignty and to have decentralised medical data spaces. Hence, the essential elements of the IDSA architecture have already been successfully deployed in the health sector. In one use case of drug development, companies like Boehringer Ingelheim, B. Braun and SAP are actively participating in a Medical Data Space on the basis of IDSA rules. This space is suitable for providing trustworthy access to research and personal data given the certification of participants. This guarantees a common understanding and a highly ethical and legal standard when sharing and using data (see Use Case Overview International Data Spaces, 2018 Edition at https://www.internationaldataspaces.org/use-cases-downloads/).

Learning from its cross-sectoral projects and its dialogue with stakeholders, IDSA has made four major observations on data sovereignty that:

- Current **national eHealth infrastructures** are often “closed” infrastructures which are not open for all involved stakeholders. In particular, important industry stakeholders are often excluded.
- Medical dataspaces need to evolve using more and more **decentralised approaches (data hubs)**.
- Personalised health treatment and efficient health delivery are the main expected added values.
- To assign a value to data, it must be possible to determine **a comparable and reproducible value** according to accepted rules.

Given the recent importance of **data sovereignty**, the IDSA models have been implemented in the European GAIA-X initiative, which was initially started by France and Germany and meanwhile convenes 300 organisations from all over Europe.

Looking forward to European Health Data Spaces

European Health Data Space(s) (EHDS) are foreseen by the European Strategy for Data as offering opportunities for **better healthcare based on better research**. The aims of global competitiveness and data sovereignty pursued through Europe’s generic strategy for data are also valid in health. Sector-spanning rules for access and use have to be adopted for key use cases in health and care so as to arrive at a **domain-specific action plan** towards a European **Health** Data Space.

> “We need to make the most of the potential of e-health to provide high-quality healthcare and reduce inequalities. I want you to work on the creation of a European Health Data Space to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes. As part of this, you should ensure citizens have control over their own personal data.”
> Ursula von der Leyen
> Mission letter addressed to Stella Kyriakides, Commissioner for Health and Food Safety

These actions are built on **research of the use of personal health data** in Member States. They will be the results targeted by a soon-to-start Joint Action dedicated to health data and the General Data Protection Regulation (GDPR), funded by the EU Health programme (2020-2023):

- Develop sector-specific legislative and non-legislative measures for the **European health data space, complementing the horizontal framework of the common data space**.
- Take measures to **strengthen citizens’ access to health data and the portability of these data** and tackle barriers to **cross-border provision of digital health services** and products.

- Facilitate the establishment, in accordance with Article 40 of the GDPR, of a **Code of Conduct for the processing of personal data in the health sector**.

Making Electronic Health Records fit for data re-use in health systems

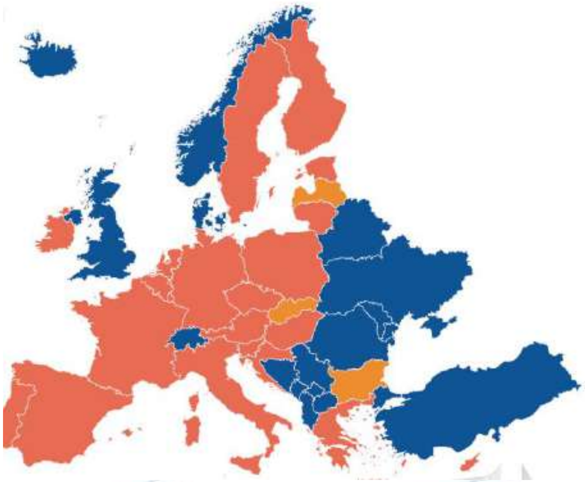
Electronic Health Records (EHRs) connect people (citizens/patients), health professionals and provider organisations, leading the way towards ubiquitous digital health services. Given the impact of COVID-19 as a digitisation "booster", the speed of digital health and care transformation will increase in European Member States. Thus, **sharing digital health data** between patients, healthcare institutions and **researchers** is rapidly **becoming real for national and regional platforms**. In most Member States, patients have gained full access to their personal health data. Yet so far, across borders, use cases often exclude citizens/ patients from having direct access to their data. Moreover, linking clinical routine care and data insights remains a complex challenge. To implement a **flexible flow of digital health data** from clinical practice (i.e., real-world data) to research (governed by GDPR-compliant policies) is the next step needed for up-to-date healthcare.

To **move forward on the pivotal role of EHRs in data use and re-use**, the European Commission – in the annex to the European strategy for data (see footnote 1) – proposes to:

- Deploy the data infrastructures, tools and computing capacity for the European health data space, and more specifically support the development of national EHRs and interoperability of health data through the application of the **Electronic Health Record Exchange Format**.
- Scale up **cross-border exchange of health data**; link and use, through secure, federated repositories, specific kinds of health information, such as EHRs, registries, genomic information (for at least 10 million people by 2025), and digital health images, in compliance with the GDPR.

To share EHRs across borders, the **eHealth Digital Service Infrastructure** (**MyHealth@EU**) – jointly with the Member States – will be **developed** to:

- Enable the exchange of electronic patient summaries and ePrescriptions between 22 Member States participating in the eHealth Digital Service Infrastructure (eHDSI/MyHealth@EU) by 2022
- Start cross-border electronic exchanges through eHDSI of medical images, laboratory results and discharge reports
- Support prevention, diagnosis and treatment (in particular for cancer, rare diseases and common and complex diseases), research and innovation, and policy-making
- Enhance the virtual consultation model and registries of European Reference Networks
- Support big data projects promoted by the network of regulators.



Use cases from Europe on steering / practicing health data re-use

Beyond operational objectives and activities focused on standardisation, interoperability and certification, Member States are reorienting their digital health strategies towards **building integrated health data ecosystems**, enabled by seamless, interoperable data flows in support of (primary) data use and (secondary) re-use. This remarkable paradigm shift in national digital health strategies was evident at a series of stakeholder workshops organised under the auspices of the European Art. 14 eHealth Network by the eHAction project (a European Joint Action)[2]. Member States like Austria, Denmark, Finland, and France are working on the basis of national strategies covering the complete data value chain including primary and secondary use of health data. A fifth example sets the European scene more generally in relation to a research infrastructure for population health.

Finland: GDPR-compliant legislation enabling a unique contact point for data re-use

In Finland, the government has issued forward-looking legislation enabling the secondary use of health data in compliance with the GDPR. By implementing this legislation, FINDATA has been set up as a central access point for requesting data from a multitude of data controllers.

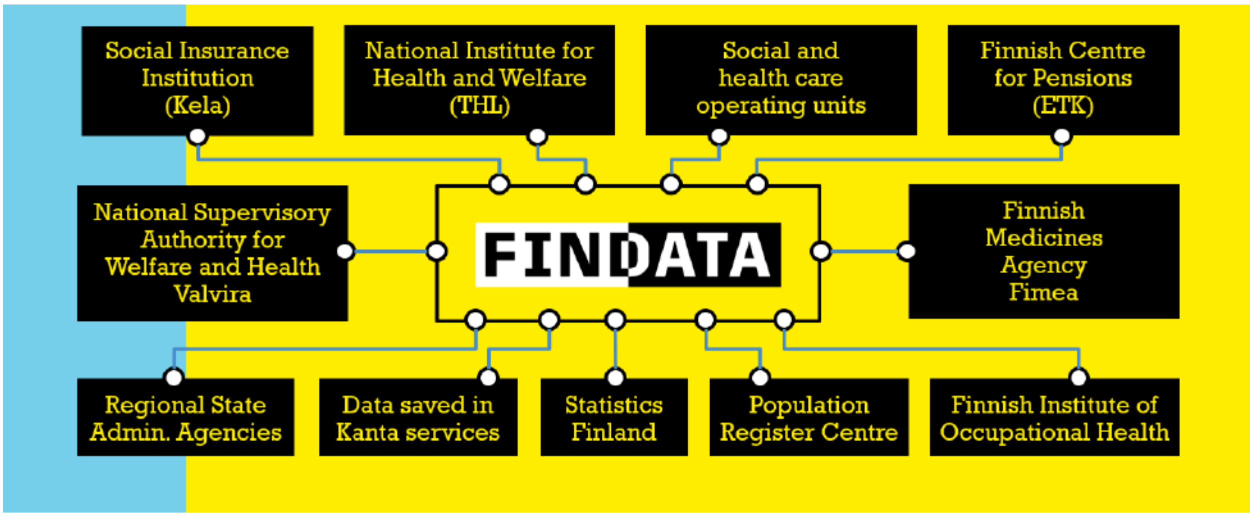


Figure 3: FINDATA as the unifying entry point for institutions and researchers engaging in health secondary data use

Denmark: Secondary data use in responding to COVID-19

Health data re-use relies on meaningful digital health services enabled by interoperable infrastructures. This is where operational activities, focused on standardisation, interoperability and certification come into play. An example of this is provided by MedCom in Denmark, one of the eHealth competence centres that is a member of the EHTEL ELO network. Here, the specific example refers to the country's response to the COVID-19 crisis.

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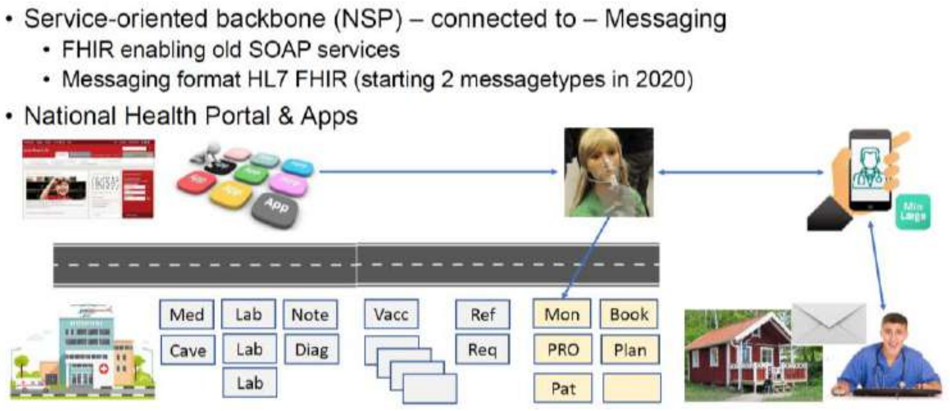
[2] On 23rd, 24th and 25th June 2020, work package 5 "Innovative use of health data" of the European Union (EU) eHAction project, the Joint Action supporting the **eHealth Network**, held six virtual focus group meetings on common governance principles for the re-use of health data. The six events were joined by 101 participants from 26 European countries.

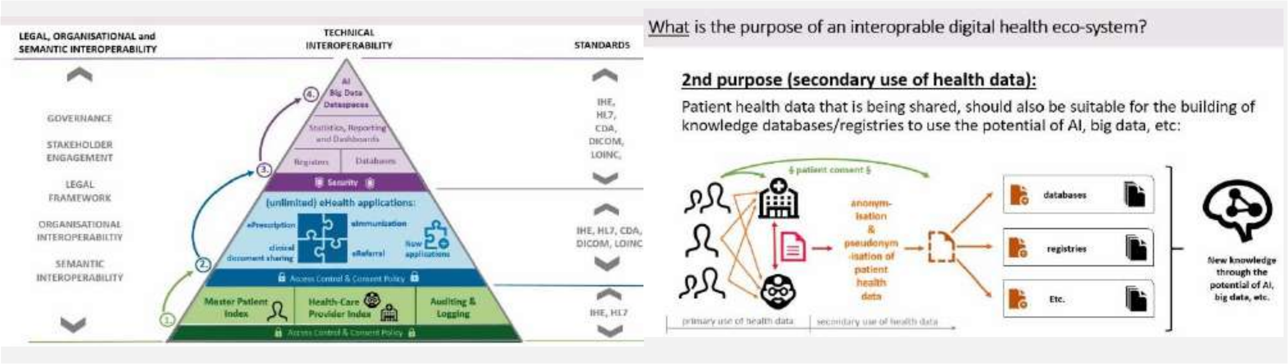


- Service-oriented backbone (NSP) – connected to – Messaging
  - FHIR enabling old SOAP services
  - Messaging format HL7 FHIR (starting 2 messagetypes in 2020)
- National Health Portal & Apps

Figure 4: Secondary data use in responding to COVID19 in Denmark

Austria: Interoperable digital health eco-system

Austria has **a digital health eco-system**. The aim of the Austrian digital health eco-system is to enable the exchange and sharing of health data of all patients within the health system. The universal use of health data leads to improved and faster availability of medical information. In turn, it contributes to higher quality in diagnostic and therapeutic decision-making and treatment, as well as to an increase in the process and performance quality of health services.



What is the purpose of an interoprable digital health eco-system?

2nd purpose (secondary use of health data):

Patient health data that is being shared, should also be suitable for the building of knowledge databases/registries to use the potential of AI, big data, etc:

Figure 5: Austrian integrated data strategy spanning primary and secondary data use

Patient data is generated by all health care and nursing providers and it should always be sharable nationally and cross-border for the continuity of care. The **eco-system** also spans registries and data bases to enable research and artificial intelligence (AI) applications. The eco-system starts from a shared strategic and political understanding about interoperability in digital health. The interoperability framework for digital health is demonstrated in figure 5 (left-hand side image of the triangle). Interoperability does not stop at national borders, the scope of the eco-system is global.

France: Health data hub

The **Health data hub** is part of the French government's strategy to accelerate the digital health shift and the national plan for AI. The hub guarantees a transparent, easy and unified access to health data to improve the quality of care and patient support.

- Health data hub consists of a unique entry point facilitating access to health data for research projects contributing to public interest respecting patient rights and ensuring transparency with civil society. It complies with the GDPR and the guidelines set by the French government.
- A state-of-the-art platform at the highest level of security, offering storage, computing, reconciliation and data analysis capacities. It allows the development of innovative research projects.
- A documented data catalogue built in a progressive manner to make priority data (historic data, cohorts, registers, hospital data, available to the scientific community).
- A range of tools to promote networking and to bring together key stakeholders.

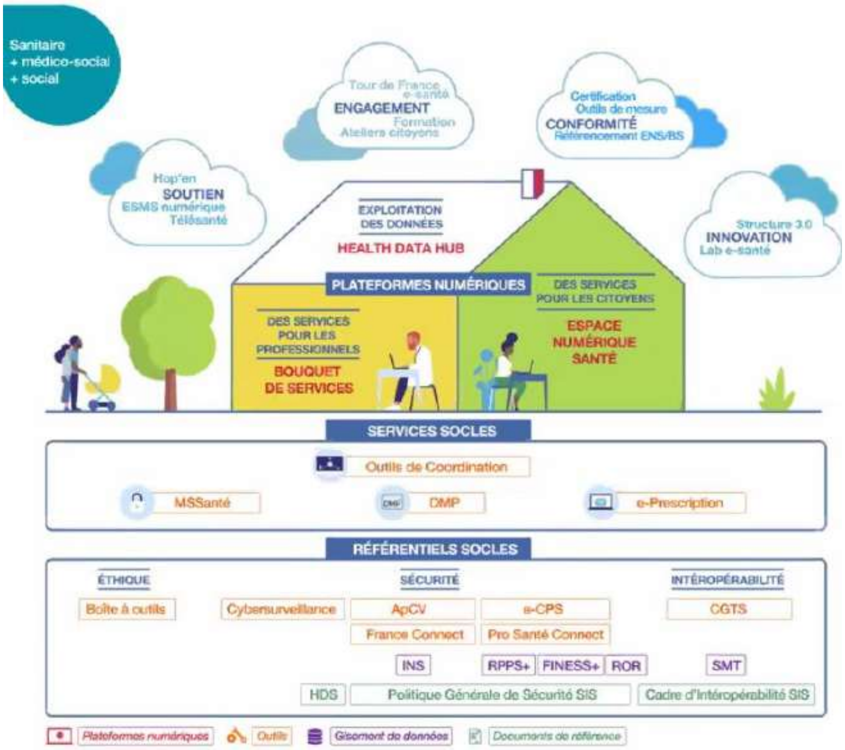
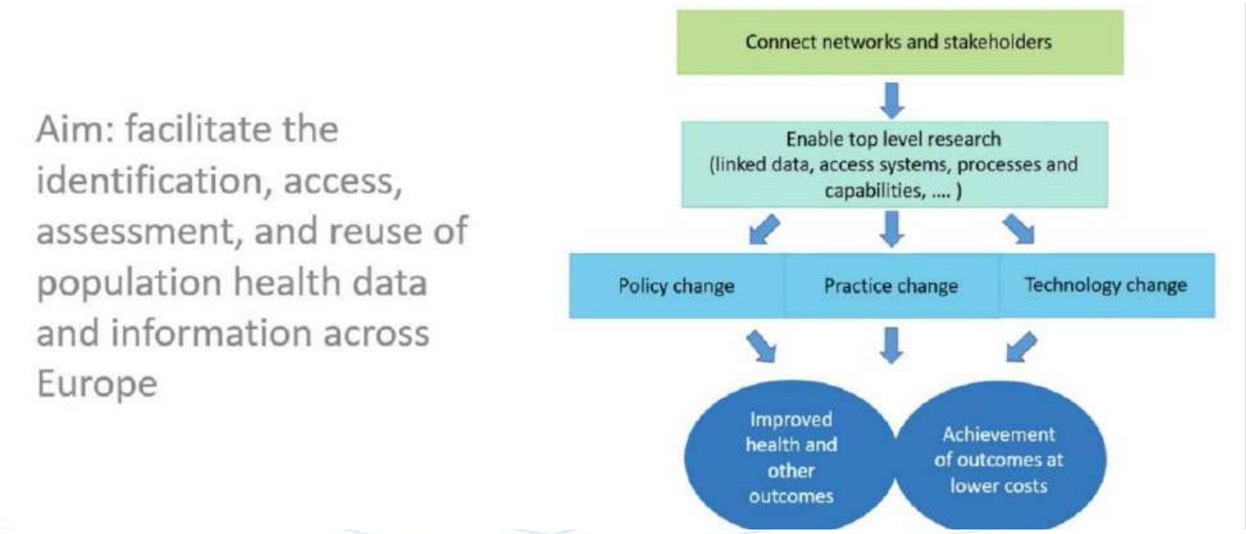


Figure 6 Health Data Hub, France

Europe: DIPoH Joint Action

The Member States' **research infrastructure** (DIPoH), which is **a distributed infrastructure** on population health, will support high-level health research by facilitating the identification, access to, assessment of, and re-use of data. DIPoH combines a central coordination office, national nodes across European Union (EU) countries, and pan-European research networks on specific **population health** topics. DIPoH provides a one-stop shop to gather population health data, develop innovative methods, build capacity, and develop knowledge translation research.



Aim: facilitate the identification, access, assessment, and reuse of population health data and information across Europe

Figure 7: DIPoH Joint Action (Member States distributed infrastructure supporting population health secondary data use)

European Commission's next steps towards the EHDS

To establish **a dedicated European data space for health and care**, specific rules and measures are needed. These actions can be grouped into four domains. They cover data governance, data quality and interoperability, infrastructure and technology, and capacity-building/digital skills. They are proposed as ways to leverage the benefits of **better health care**, **better policy making** and **better research and innovation**.

Data governance and rules

- ✓ Measures on governance and rules for primary and secondary use of data, respecting the GDPR
- ✓ Free movement of digital health services
- ✓ Regulatory framework for AI (including safety and liability)

Data quality and interoperability

- ✓ Increase uptake of and further development of the EEHRxF(framework for interoperable EHRs)
- ✓ FAIR-ification of health data for primary and secondary use
- ✓ Measures on governance and rules for primary and secondary use of data, respecting the GDPR

Infrastructure and technology

- ✓ eHealth Digital Services Infrastructure
- ✓ European Reference Networks
- ✓ Link different repositories in Europe, e.g. cancer registries, clinical reference networks, transplantation etc.
- ✓ Link the data permit authorities

Capacity building / Digital skills

- ✓ Support for digitisation of healthcare systems
- ✓ Support for national eHealth contract points
- ✓ Foundational and advanced digital skills
- ✓ Skills for graduates, health professionals
- ✓ Training options, support mobility health professionals

Figure 8: Four proposed domains of action on the EHDS

EHTEL ELO recommendations for future directions towards the EHDS

The EHTEL ELO Network came up with **a set of ideas** that its members believe fulfil priority purposes and priority recommendations for data re-use in health and care. These were submitted to a consultation organised by the European Commission (see website article and Position Paper 1).

The ideas have been used by EHTEL to focus on **key messages** on patient safety, services, open and available data, promotion of information sources, and citizens' need to be in control of their own data through fine-grained, dynamic consent. EHTEL ELO Network members believe that concrete points of **guidance** are needed for the EHDS.

- **Data use and re-use are vital, including for patient safety.** Among the important diseases and conditions where data could be appropriately re-used are infectious diseases and complex chronic conditions (such as cancer treatment and cancer research). **Healthcare organisations can benefit from data re-use in many ways**: these involve public health, personalised medicine, organisational and management purposes, as well as research, development, and innovation.
- **AI-enabling technologies are key to services.** Among these technologies are machine learning and AI for the personalised promotion of healthier lifestyles. Investment in public infrastructures and technology is thus urgent to enable health data, as much as possible, to be captured and made machine-computable. Along these lines, data-capturing technology at the point of care is a pre-requisite.
- **Data need to be made more open and available to every stakeholder.** Examples include industry, governments at national and regional levels, and hospitals – citizens/patients too, of course. Obtaining the full benefits of health data re-use is reliant on meaningful real-world data sources and Europe-wide interoperability.

- Sources of information are really important. General **public awareness on the social benefits of data re-use** needs to be developed. Existing sources of open data should be better promoted.
- **Citizens need to maintain control about the stakeholders with whom they want to share data.** Citizens should be able to manage consents on their own with the help of easy-to-use applications and an integrated infrastructure. **In turn, third parties should be able to request access to data for re-use purposes, and citizens should get feedback on the actual use of their data**. Incentivisation schemes for citizens to agree on data re-use should be developed, on the grounds that this would be a contribution to social, public and community-based objectives.

Outlook: Health data ecosystem – integrated re-use of real-world data

To be "Fit for EHDS", data quality and flexible consent processes need to be in place.

As a preliminary sketch, figure 9 (below) demonstrates an overarching perspective on how real world data – from clinical encounters (Electronic Health Records - EHR), registries and wellness Apps – can "flow" across domain, institutional and country borders supporting, for example, the MyHealth@EU cross-border use cases and feeding secondary data use for research and innovation (both are examples of initiatives already discussed in this report). Moreover, the EHDS enablers depicted in the figure comprise data transport, data interoperability, legal/policy and governance enablers.

Furthermore, the figure extends the infrastructure and basic operations for **health data processing and research** potential of the ELO Network organisations. These eHealth Competence Centres can contribute as enablers of real-world health data-sharing for the purposes targeted by the European Strategy for data in the health domain, often through the provision of infrastructure and/or data handling.

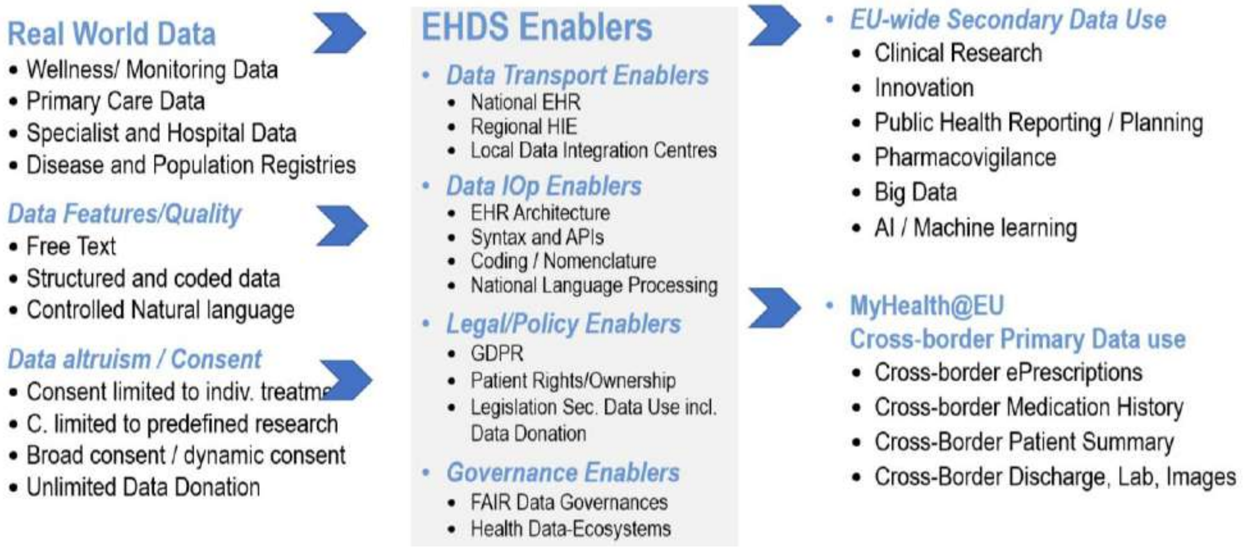


Figure 9: "Fit for EHDS" / EHDS data flows and enabling factors – the pivotal role of consent dynamic / broad consent

Future EHTEL webinars will lead to the production of more factsheets and briefing papers. In the field of "Getting ready for European Health Data Spaces", the next Imagining 2029 webinar in this workstream is entitled "**Towards European data spaces for medicines: Semantic interoperability for patient safety**". It took place on Monday, 21 September 2020, 14:00 – 15:30 CET. Among other related topics are health data ecosystems for integrated care, and digital therapeutics and AI.

Acknowledgements

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For more information about EHTEL's ELO Network of eHealth Competence Centres' work on EHDS:
Contact the EHTEL Secretariat - **communication@ehtel.eu**.

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