WHY IS HEALTH DATA ACCESS IMPORTANT TO R&D?

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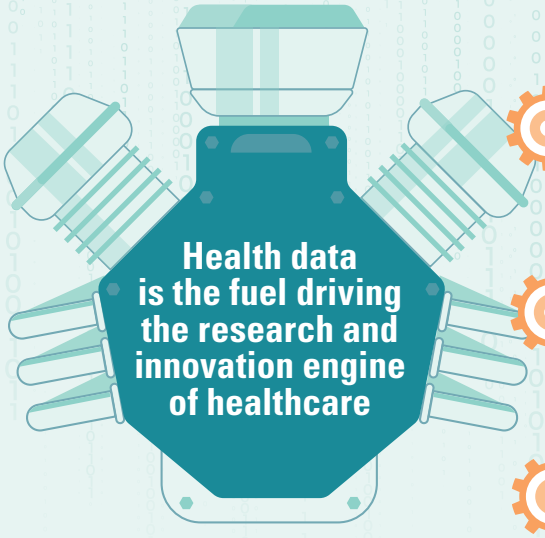

- Leads to the development of **new medicines and vaccines.**
- Drives **population health studies** that compare health nationwide to identify problems and plan additional services.
- **Enhances monitoring and tracking of diseases** to target therapies where they are most needed.
- Identifies individual and community trends in order to target and **develop personalized medicine, better treatment plans** or **predict at-risk patients.**
- Allows for greater application of **digital health technologies like AI** which has the potential to revolutionise healthcare.
- Leads to a better **understanding of disease biology** which led to the development of innovative treatments such as cell and gene therapies, RNA therapeutics.

Some Examples of the Benefits of Collaborative Research using Health Data:

During the pandemic, the sharing of:

13,612 protein structures[1]

Over **13.5 million** genomic sequences[2]

Over **356,000** papers on COVID-19[3]

Led to the rapid development of:

33 vaccines and **32 therapeutics** which received regulatory approval (and **521 vaccines and 1,630 therapeutics** are currently being researched) for COVID-19 over the course of **3 years** instead of the average development time of 10 years[5].

Advances in healthcare are fueled by data:

95% of the 15 million European Hepatitis C patients can now be cured[4]

94% reduction in age-standardised death rates for patients living with HIV in France, between 1991 and 2016[4]

21% reduction in mortality rates from all cancers between 1991 and 2016[4]

37% reduction in the death rate from cardiovascular disease in the EU5, between 2000 and 2012[4]

(1) https://www.rcsb.org/
(2) https://gisaid.org/
(3)https://outbreak.info/resources/search?q&filter=%40type%3APublication&page=0&size=10&sort=&dateMin=2020-03-02&dateMax
(4) https://www.efpia.eu/about-medicines/use-of-medicines/value-of-medicines/
(5) https://efpia.eu/media/636989/efpia_vaccines-europe_covid-19-lessons-learned_may-2022.pdf

However, significant barriers hinder data-availability and the development of a digital health ecosystem in the EU.

What are the challenges facing data sharing?

- **Unclear & un-harmonised data privacy and protection rules** in the context of existing (GDPR) and emerging (EHDS, Data Act) initiatives.
- **Data is fragmented and in silos as result of a lack of interoperability and standards** across health data systems.
- **Limited awareness** of the benefits for sharing citizens' data.
- **Lack of data authorities** that can guide harmonised data access rules.
- **Lack of consistent understanding and standardised approaches** to health data anonymisation techniques and standards.
- **Lack of skills in health data** management and culture of sharing.

For data to drive better health outcomes, Europe must seek to have a harmonisation of rules, the clarification of standards, and a legal framework for data transfers that is based on the accountability of data controllers rather than unrealistic restrictions.

THE PHARMACEUTICAL INDUSTRY IS ALREADY SHARING ITS CLINICAL DATA IN MANY WAYS

Clinical Study Data Request is a voluntary data-sharing platform that allows researchers to request, access and analyse clinical trial data from multiple organisations.

Voluntary data sharing with academics and researchers is already possible via global **clinical research data sharing platforms such as "Vivli" or "YODA"** which enable access to anonymised patient-level clinical trial data.

Aggregated data is shared and publicly listed on the **EMA's website** in line with existing EU regulations and policies.

Regulators & public sector already gain access through regulatory science initiatives.

EFPIA has published their **Principles for Responsible Clinical Trial Data Sharing** to enhance research and scientific knowledge, advance patient care and improve public health. EFPIA has a **Clinical Trial Data Portal Gateway** which lists companies' online portals for voluntary clinical trial data sharing data[2].

(2) https://gisaid.org/

Through these data-sharing practices, the innovative pharmaceutical industry is supporting scientific and health innovation throughout Europe and beyond.

EFPIA supports digital transformation of healthcare.

Supporting the advancement and application of a **common data model through the IMI EHDEN** (European Health Data Evidence Network) project[1] and amplifying patient voice in their own healthcare and in healthcare systems more broadly in the IMI H2O (Health outcomes observatory) project.

Engaging with **EMA** to drive broader acceptance of the RWE in decision making.

Helping to **develop Codes of Conduct for Data** to harmonise the rules and rights across Europe and reduce the complexity of cross-border projects.

Working with patient organisations, healthcare professionals, and Member States as they develop their roadmaps for digital health[1].

(1) https://www.rcsb.org/

The innovative pharmaceutical industry, together with regulators and researchers, have established a robust clinical data-sharing ecosystem, which should be regarded as the basis for the data-sharing system in Europe. By complementing this system with other health datasets like RWD and EHRs, the European Health Data Space could drive research into new treatments and ultimately improve health outcomes.

To unlock its full potential, we must share broader types of data internationally.

Allows the comparison of determinants and outcomes of diseases in different settings to assess whether findings and treatments are compatible in other countries.

Development of new methodological areas to facilitate health research such as Artificial Intelligence.

Improved continuity of care and efficiency due to the elimination of unnecessary medical tests and procedures.

Pooling of data from rare disease patients to create samples large enough to perform research that can inform the development of treatments.

RWD: real world data; EHR: electronic health record

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HOW HEALTH DATA ACCESS CAN TRANSFORM HEALTHCARE

There are barriers to international data sharing in Europe:

Health Data Generation

Benefits of Data Availability in Europe

- **Unclear & un-harmonised** data privacy and protection rules.
- **Data is fragmented and in silos as result of a lack of interoperability and standards across** health data systems.
- **Regulatory and legal fragmentation,** include differing definitions of anonymisation.
- **Limited knowledge** of the benefits for sharing citizens' data.
- **Lack of skills in health data** management and culture of sharing.

The EHDS has the potential to revolutionise how data is used in the EU and lead to improvements in the prevention and healthcare delivery, in our health systems' sustainability, and in the development of innovative treatments for patients. The following aspects are fundamental to its successful set up:

Enhance rights

Strengthen the rights of natural persons in relation to the availability and control of their health data.

Create standards

Lay down **standards for data,** outlining which data must be published and supporting capacity building in Member States to strengthen their digital systems.

Establish cross-border infrastructure

Establish **cross-border infrastructure** for the primary and secondary use of data and provisions for sharing with third countries.

Provide governance

Provide governance through the creation of the EHDS Board and ensure Member States have bodies responsible for facilitating access to secondary data.

Set clear rules for data holders and users

Provide clarity on the type of data in scope and accountability for privacy protection, data misuse, and unfair competition.

There is significant scope for the EHDS to improve data sharing in the EU. By doing this, the EU could strengthen public health, deliver better health outcomes for citizens and promote their well-being. To unleash the power of health data and fine-tune the first sectoral data space proposal, EFPIA believes that the following factors are essential:

Support of **Member States**, including investing in their digital healthcare infrastructure.

Strong **privacy frameworks** and data literacy to build trust amongst citizens.

Legal harmonisation to address alignment between EHDS and GDPR and to foster uniform interpretation of GDPR.

Standardised data which includes ensuring data is high quality and that relevant data has been collected.

Framework that provides **clear rules for stakeholders** to access data to conduct research.

Coordination of all of **other existing digital legislative** frameworks (such as the GDPR, DGA, Data Act, AIA act, Cyber resilience Act).

Foster innovation by **respecting and preserving** existing IP protection.

The majority of health data in Europe is held unconnected. This data could complement the small amounts of structured data already generated through clinical trials. Together this may bring new insights ultimately leading to better health outcomes.

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