



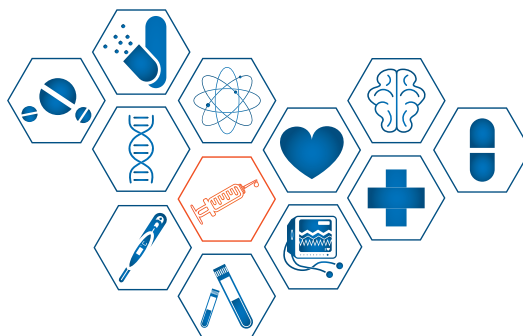
EUROPEAN HEALTH DATA SPACE:

TOWARDS A BETTER PATIENT OUTCOME

November 2019

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INTRODUCTION

The emergence of new technologies and enhanced connectivity have spurred the exponential growth of health data. Unfortunately, a vast quantity of this remains hidden in private or proprietary and project specific registries. Organisations face hurdles in their efforts to construct large-scale data bases. Pooling data would increase the efficiency with which we gather and access data. This will stimulate further research while providing equal opportunities of access for all actors, including small and medium enterprises.

Within healthcare, the first steps are being taken in the area of health imaging¹ with a primary focus on cancer, as laid out in the EU's Coordinated Plan on Artificial Intelligence (AI)². In addition, by June 2019 20 EU Member States and Norway have already signed the Declaration for delivering cross-border access to a genomic database that will make more than 1 million genomes accessible in the EU by 2022³.

Greater ambition is needed to develop further initiatives on an even broader scale, with the goal of strengthening the EU's position of furthering AI development in a way that reflects and accords with EU values. We should look to build longitudinal datasets, integrate a wider range of data sources, such as lab results and hospital data and consider the value of other real-world data.

We are pleased that the European Commission has identified the need and importance of data spaces, initially mentioned in the 2018 Communication "Towards a common European data space".⁴ More recently, the then President-elect of the European Commission Ursula von der Leyen made this objective even more explicit for the healthcare sector in her Mission letter⁵ to Ms. Stella Kyriakides, Commissioner-designate for Health.

"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."

In this paper, COCIR outlines why it supports a European Health Data Space, sets out how it would like to see data access managed and who can contribute, as well as how this Data Space should be governed and executed.



¹ Horizon 2020 Call "AI for Health Imaging" (DT-TDS-05-2020) - <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/dt-tds-05-2020>

² Coordinated Plan on Artificial Intelligence, 7 December 2018 - <https://ec.europa.eu/digital-single-market/en/news/coordinated-plan-artificial-intelligence>

³ European '1+ Million Genomes' Initiative - <https://ec.europa.eu/digital-single-market/en/european-1-million-genomes-initiative>

⁴ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "Towards a common European data space" - <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2018:0232:FIN>

⁵ Mission letter to Stella Kyriakides, Commissioner-designate for Health, 10 September 2019 - https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf



EXECUTIVE SUMMARY

Technology is viewed as a powerful enabler and positive gamechanger in the healthcare space. Access to data has a critical role in filling the data pipeline that fuels innovation.

We see considerable benefits from the use of Real-World Data, genomics information, high-performance computing and other resources for AI. There are challenges; limitations and obstacles created by interoperability and the differing legal regimes within the EU that govern the access and right to process health data for research purposes, a lack of high-quality data, organisational and structural barriers and the need for a highly ethical approach essential to build trust with individuals and strives to use the data for the greater good.

All actors in the healthcare ecosystem can make a genuine contribution to the European health data space. Ideally, a trusted independent party should be charged with balancing the interests of the data subjects, data providers and data users. Access to, and use of, the available data need careful consideration. In support of existing business practice, a series of templates and guidelines could be developed to assist organisations in drawing up robust data-sharing agreements that would ensure a fair, balanced relationship between the involved parties.

There should be clear rules defined to allow for qualitative data. Providers and users of data should adhere to the FAIR principles of being Findable, Accessible, Interoperable and Reusable. Interoperability should be embedded into the procurement process by default.

In order to provide a level playing field, access to data should be fair, transparent and non-discriminatory. By extension, it should be the same for access to basic and common AI technology. There should be no exclusivity granted that would monopolise data or technology.

COCIR RECOMMENDS THAT THE EUROPEAN COMMISSION AND MEMBER STATES SHOULD:

- 1. Mobilise** funds, using the programmes available programmes under the Multiannual Financial Framework effectively, to allow increasing and structural investment in education and skills.
- 2. Invest** in pan-European technical infrastructure to provide the technical backbone of a Health Data Space to enable pooling of health data for research.
- 3. Create** a trusted framework with clear governance, which defines how to use and manage health data while taking into consideration the rightful purposes and the adequate protection of individuals' rights and privacy.
- 4. Support** a cross-sectorial Public-Private Partnership in healthcare to promote the pooling, integration and sharing of high-quality, harmonised, interoperable data with documented provenance.
- 5. Encourage** the medical community to agree common European standards for data sets, data models and documentation in specific clinical areas. This should evolve to cover citizens/patients holistically, to facilitate interoperability and data integration.

1. WHY DOES THE HEALTHCARE SECTOR NEED ACCESS TO DATA?

There are high expectations for technological developments in big data analytics and AI. While there has been an abundance of health data – estimated at more than 1100 terabytes generated over a person's lifetime⁶ - this data is usually unstructured and non-harmonised. Thus a great deal of resources need to be directed to preparing data to an acceptable level of quality and robustness if it is to permit meaningful outcomes.

Typically, an AI process requires the following steps:

- Collecting; gathering data and/or making it accessible
- Organising; structuring, cleaning and labelling the data
- Analysing; understanding the context of the data

Access to data and the right to use, data plays a critical role in building the data and evidence pipeline. However, data is not an end in itself. Ultimately, the objective is to improve health outcomes throughout the care pathway, trying to shift the focus from a curative approach to a preventive one.

There are some particular opportunities and challenges capable of affecting - positively or negatively - the level of technological progress and outcome, which we need to take into account.

OPPORTUNITIES

Real World Data (RWD) provides valuable information on health outcomes and brings deeper insights into lifestyle patterns and environmental risks that contribute to prevalence of chronic and/or non-communicable diseases. We will see an increase in RWD, both from electronic health records and from personally-generated health data, for example from wearable devices, smart sensors and health apps.

Concerted efforts on creating **large cohorts of genomic information**, such as through the European 1+ Million Genomes Initiative will open new possibilities in the field of personalised healthcare and precision medicine.

In addition, the European **High-Performance Computing** Joint Undertaking (EuroHPC⁷) will pool resources to develop a European supercomputing ecosystem, to make computation time available to public and private users, including SMEs. This access to state-of-the-art technology for all actors will support research and innovation.

Furthermore, in its European approach on AI and the coordinated plan on AI, the European Commission has set out supporting actions to make the technology and knowhow available to all actors, creating an **AI-On-Demand platform**⁸ and providing **Digital Innovation Hubs**⁹ and legal sandboxes.

CHALLENGES

Interoperability has been one of the weaknesses in the healthcare ecosystem. There are gradual steps forward on the political and execution levels. Although there are generally available and accepted standards, there is still a strong need to accelerate these efforts, particularly at Member State level, if health data sharing is to become more meaningful.

High quality data remains vital to ensuring the robustness and reliability of the health data. There are certain key conditions for determining the validity and trustworthiness of the available data. As context is important, there needs to be special attention paid to data provenance and a common understanding of definitions and ontology. Furthermore, to avoid any potential bias, sources and selections of data should be carefully considered to ensure sufficient diversity.

⁶ Cavlan O., Chilukuri S., Evers M. and Westra A. (May 2018), Real-world evidence: From activity to impact in healthcare decision making, Retrieved from <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/real-world-evidence-from-activity-to-impact-in-healthcare-decision-making>

⁷ EuroHPC - <https://eurohpc-ju.europa.eu/index.html>

⁸ AI4EU - <https://www.ai4eu.eu/>

⁹ Digital Innovation Hubs - <https://ec.europa.eu/digital-single-market/en/digital-innovation-hubs>



At present, EU **data protection** legislation and the various national implementation acts governing the right to use health data for research purposes pose significant challenges for the access and use of health data. Whilst the privacy rights of the data subjects need to be considered, there also needs to be an appropriate balance with the interests such as the improvement of healthcare outcomes.

Barriers to data sharing and data transfers also exist beyond the purely regulatory and technical levels. **Organisational and structural processes** may keep data in siloes, hampering new models of cooperation.

Finally, the data economy has surged dramatically, driven by new business models seeking to monetise the collected data to improve. A **highly ethical approach**, one that can be trusted by individuals and strives to use the data for the greater good of society.

2. WHO SHOULD SHARE DATA?

All actors in the healthcare ecosystem can make a meaningful contribution to creating health data spaces

- Public Sector – population health data
- Research centres and biobanks – research data and registries
- Healthcare providers and professionals – electronic health records, hospital information, lab reports, real-world data
- Industry – registered information, clinical trials information
- Payers – health outcome information, cost/reimbursement information
- Citizens and patients – real-world data, electronic health records, hospital information

There should be efforts to create awareness on how these contributions can advance research and lead to further innovation, even breakthroughs, in improving health outcomes. Direct feedback may also motivate people to share data more routinely and altruistically.

To ensure trust, data sharing should always be transparent and strong measures should be put in place to protect the personal data and mitigate privacy risks for individuals. Industry should promote de-identification standards for research purposes and legislators should endorse best practices and standards.

3. HOW TO MAKE DATA AVAILABLE?

Discussions on data sharing are dominated by issues of data ownership and monetisation. Yet access to data is vital to facilitate innovative research. Different groups of stakeholders may be swayed by different incentives, including non-commercial or altruistic.

The healthcare landscape is diverse, with data being exchanged between public authorities, healthcare providers and professionals, manufacturers of medical devices and software, payers and patients. Within each of these relationships, there may be different power and leverage at play between the organisations involved that can significantly affect the level of data sharing.

This makes a clear governance structure essential. Ideally, this should see a trusted independent third party capable of balancing the interests of the data subjects, data providers and data users. This third party should recognise the importance of federated sources and coordinate the integration of existing and new data spaces on a European level. As well as the input side, access and use of available data also needs careful consideration. Different data governance models should be developed to address different research purposes. This would also require an appropriate privacy framework, for example through dynamic consent management systems or de-identification techniques.

From a technical perspective, there needs to be infrastructure to facilitate and manage identity and consent. This will also need to govern access to data appropriately. Some of these elements are already defined or works-in-progress as blueprints at the EU level

The platform should be technology-agnostic and provide a general framework to which new collections of data can be connected via APIs. This way, the system could be more modular and take advantage of those systems already in place.

4. CURRENT STATUS

To date, a number of past and current EU projects have already looked into creating data spaces:

- Patient registries of Europe (PARENT)
- European Health Data & Evidence Network
- Big Data and B2B platforms: the next big opportunity for Europe

Finland has also played a pioneering role, issuing a legal act¹⁰ to facilitate the secondary use of health data. Similarly, the UK is investigating this type of use as part of the ICO's regulatory sandbox¹¹. In Germany, meanwhile, there is an ongoing Medical Informatics Initiative¹² with the goal of establishing data spaces for medical research. In Belgium, the healthdata.be platform makes health data available for research.

Other grassroots organisations have been working on data sharing by patients for the purpose of research, such as:

- **MIDATA Coop:** a non-profit cooperative that focuses on health data and smartphone app-based services. Data account owners may choose to actively contribute to medical research and clinical studies by granting selective access to their personal data.
- **Salus coop:** a citizen health data cooperative aiming to legitimise the rights of citizens to control their own health data while facilitating data sharing to accelerate research innovation in healthcare.
- **Data for Good Foundation:** a data foundation and a public health project that aims to allow citizens to exercise the right to control their own personal data.
- **Digi.me:** a private sharing platform which seeks to empower patients by giving back their data and providing the opportunity to share their health data with third parties.
- **Data4life (formerly Gesundheitscloud):** initiated as a project by the Hasso Plattner Institute, the platform allows people to store and improve use of their health data on a secure platform.
- **Usemydata.org:** founded by patients, relatives and carers following a cancer research project, this platform supports the effective use of patient data for research.

Last, academia and NGOs are also looking into the practical and ethical implications of data sharing. One of the authorities in this area is the Open Data Institute, which has undertaken in-depth research into data trusts.

These initiatives, notwithstanding, we should not be blind to developments in other geographical regions, where different contexts mean less friction in building large-scale datasets for research purposes. It is important that we continue to ensure the high quality of care within Europe.

¹⁰ <https://stm.fi/en/secondary-use-of-health-and-social-data>

¹¹ ICO selects first participants for data protection sandbox - <https://ico.org.uk/about-the-ico/news-and-events/news-and-blogs/2019/07/ico-selects-first-participants-for-data-protection-sandbox/>

¹² Medical Informatics Initiative Germany - <https://www.medizininformatik-initiative.de/en/start>



5. HOW DO WE REACH A EUROPEAN HEALTH DATA SPACE?

The first step should be to establish a trusted framework with clear governance. Linked to this is the need for a secure technical infrastructure, one which respects the privacy of citizens while providing them with the tools to exercise their individual rights and consent.

There should also be tools and incentives to encourage the pooling of data through different means, addressing the various data streams. For example, this could be done by making full use of the competences provided under the Public Sector Information Directive, or by appealing directly to patients or population groups to share data.

In addition, existing business practice 'building blocks' could be developed to help organisations draw up robust data-sharing agreements that would ensure fair and balanced relationships between the parties involved.

There should be clear rules to allow for qualitative data. Providers and users of data should adhere to the FAIR principles of being Findable, Accessible, Interoperable and Reusable. To encourage interoperability, this should be linked more closely to procurement, as proposed for example, in the eHealth Network's investment guidelines.

Access to data should be fair, transparent and non-discriminatory, creating a level playing field. By extension, this should be the same for access to basic, common AI technology. There should be no exclusivity granted that would monopolise data or basic technology.

6. RECOMMENDATIONS

COCIR recommends to the European Commission and to the Member States to:

- 1. Mobilise funds**, making effective use of the programmes under the Multiannual Financial Framework (Digital Europe, Horizon Europe, Cohesion Fund) **to allow increasing and structural investment in education and skills**. There should be an emphasis on data science, needed to build the health data space and new data models for data compilation and sharing to spur innovative research.
- 2. Invest in a pan-European technical infrastructure** as the technical backbone of a European Health Data Space. This will **enable pooling of health data for research** purposes from different European sites, based on the trusted framework with clear governance previously described.
- 3. Create a trusted framework with clear governance** that defines how to use and manage health data, while taking into consideration the rightful purposes and the adequate protection of individuals' rights and privacy.
- 4. Support a cross-sectorial Public-Private Partnership in the healthcare area** under Horizon Europe to **promote the pooling, integration and sharing of high-quality, harmonised, interoperable data** with documented provenance that can be shared. This will provide research and innovation funding for collaboration between different stakeholders (competent authorities, healthcare system providers, industry, patients).
- 5. Encourage the medical community to agree common European standards** for data sets, data models and documentation in specific clinical areas, e.g. stroke, cancer, diabetes, cardiovascular diseases, gradually evolving to cover the citizen/patient holistically. Supporting such activities **will facilitate interoperability and data integration** throughout Europe.

ANNEX - REFERENCES

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[Towards Integrated Care Workflows](#) (December 2016)

OTHER PUBLICATIONS

OECD [Recommendation](#) of the Council on Health Data Governance

Science Business - [The Life Savers : The Value of Medical and Digital Health Technology in Breast Cancer Care](#) (September 2019)

High Level Expert Group on Artificial Intelligence – [Policy and Investment Recommendations for Trustworthy AI](#) (June 2019)

EU Health Coalition – [A Shared Vision for the Future of Health in Europe](#) (November 2018)

EU COMMISSION LINKS

[Communication “Towards a health data space”](#) (April 2018)

[Commission Communication – Digital transformation of Health and Care](#) (April 2018)

[Patient Rights Directive](#) (April 2011)

[eHealth Network](#)

[European Reference Networks](#)

EU FUNDED PROJECTS

[EHDEN – European Health Data & Evidence Network](#) (ongoing)

[Big Data and B2B Platforms](#) (ongoing)

[PARENT – Patient Registries Initiative](#) (closed)

GENERAL INFORMATION ABOUT COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

Our focus is to open markets for COCIR members in Europe and beyond. We provide a range of services in the areas of regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs.

COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (www.globalditta.org).

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