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Building a path for rare diseases in the European Health Data Space

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Publisher: Geert Cami

Publication Director: Nathalie Furrer

Senior Fellow: Tamsin Rose

Programme Manager: Josephine Mosset

Editors: Anna Muizniece

Design: Lucien Leyh

Rapporteur: Louise Taylor

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Preface



Tamsin Rose
Senior Fellow at Friends of Europe

Over the past decade, the amount of data created, captured, copied or consumed has globally exploded from 1.2 trillion (tn) gigabytes to 59tn gigabytes.¹ Every aspect of our society and economy is increasingly dependent on data facilitated digital ecosystems. The field of rare diseases has a critical need for capturing and sharing data. Each rare disease affects a small number of people, who may be situated at a substantial geographical distance from one another. Of the several thousand distinct rare diseases identified to date, only 6% have a treatment available, leaving too many patients and their families with few options. The data on rare diseases are scarce and fragmented across health systems, databases and registries, many of which are created for a specific disease or research purpose.

For people living with a rare disease, it is crucial that their health data be safely connected and widely shared in order to deepen understanding, trigger medical advances, speed up the diagnostic journey and ensure that all patients – wherever they live – can benefit from the best expertise and care in Europe.

The connectivity of everyday life continues to accelerate. By 2023, there will be almost 30 billion (bn) web-connected devices, up from 18bn in 2018.² Digital tools allow huge amounts of data to be generated and collected, which can then be shared, analysed and used in many ways, from improving routine procedures to generating innovative breakthroughs. The healthcare sector is part of this rapid digital transformation. The potential of data to deliver more effective and efficient care increases the imperative to build a shared health data environment at the European level. These rapid advances in digital technology and data sharing capacity can especially benefit the field of rare diseases by facilitating shared data, interoperability and collaboration.

The creation of a European Data Space is one of the priorities of the European Commission 2019-2024. Within this, the European Health Data Space (EHDS) will promote a more robust exchange and access to different types of health data, including electronic health records, genomics data, data from patient registries, and so on, not only to support healthcare delivery but also for health research and policymaking purposes. The EHDS will facilitate the collection and sharing of data across the European Union, with benefits for patients, clinicians, researchers and health systems.

Against this backdrop, the field of rare diseases is ideally positioned to both contribute to and benefit from the EHDS. Indeed, for the estimated 30 million people in Europe living with a rare disease, the EHDS offers something even rarer — hope.

In this paper, we will delineate how the needs of people living with a rare disease could be met through the proposed EHDS and, conversely, how the long-term experience of data sharing within the rare diseases community via the European Reference Networks (ERNs) and other mechanisms can inform the governance, structure and operability of the EHDS.

The challenge in developing the EHDS goes beyond the many questions of technical interoperability to considerations around defining a governance philosophy that fosters patient trust and protects privacy. This governance framework should promote data accessibility while ensuring security. The EHDS must work within the variation and complexity of existing healthcare systems to connect the public, private and non-profit sectors.

Investment in the EHDS positions Europe as the pioneer in creating an ethical and human rights-based legal framework for digital health and data management. There will also be benefits for competitiveness by encouraging home-grown innovation that could grow to scale across the continent and maintain Europe's strength in life sciences and healthcare.

The potential benefits for the rare diseases community of a common, interoperable European space for health data were identified by the Commission in the paper on shaping Europe's digital future:

“Getting access to data, reusing and processing it will improve our daily lives: it will allow us to deliver personalised medicines and help to find cures for rare or chronic diseases because scientists can identify the best treatment thanks to having more evidence available.”³

This is a prize worth fighting for.

¹ Press, G. (2020, December 27). The state of DATA, December 2020. Forbes. Retrieved September 15, 2021, from <https://www.forbes.com/sites/gilpress/2021/12/27/the-state-of-data-december-2020/?sh=1b7bb0d43462>.

² Global mobile networks will support more than 12 billion mobile devices and IoT connections BY 2022; mobile traffic approaching The Zettabyte milestone. Cisco. (2019, February 19). Retrieved September 15, 2021, from <https://newsroom.cisco.com/press-release-content?type=webcontent&articleId=1967403>.

³ European Commission, Shaping Europe's digital future, [Data | Shaping Europe's digital future \(europa.eu\)](#)

Introduction

Accelerating the uptake of digital tools provides the essential momentum towards the development of a governance framework for health data in the European Union.

Scattered and scarce expertise in rare diseases, coupled with small, often far-flung patient populations for each disease, means that the rare diseases community is by necessity already invested in exploring digital and data sharing solutions for diagnosing, treating and researching rare diseases.

The COVID-19 pandemic has highlighted the crucial role of health data for healthcare systems in general, accelerating the uptake of digital tools. Data quickly became an essential tool in tackling the ensuing pandemic. Aggregated data on confirmed infections, hospitalisations and deaths have become key markers of the pandemic, fed into artificial intelligence (AI) tools, which were in part able to detect the spread of the virus early on and instrumental in preventing future outbreaks. Such algorithms require a vast amount of data to be operational.

There is a strong momentum around the development of a governance framework for health data in the EU. In March 2021, the European Commission launched plans for ‘the digital decade’, which included the

key target of ensuring that 100% of citizens have access to their medical records by 2030.⁴ Data governance extends beyond legal issues to address stewardship regarding the roles around data management and accountability; standards related to specifications around the creation, coding and storage of data and quality control; and policies around issues such as authentication, privacy and access rights. Governance must also take into account the varied nature of data, which may be genomic, phenotypic or clinical, for example.

Poised to be launched at the end of 2021, the European Health Data Space has three main objectives:

1. allow data sharing for the primary purpose of providing care to patients;
2. enhance data sharing for improved policymaking and health system administration; and
3. support and improve research.

The EHDS will ensure that patients from all EU member states can share their data with the healthcare professional of their choice when abroad. Being able to share medical history and records is particularly important to rare diseases patients, many of whom have conditions affecting multiple organ systems, which involve consultations with specialists

⁴ European Commission, 2030 Digital Compass: the European way for the Digital Decade, 9 Mar. 2021, <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A52021DC0118>

from different fields. These patients need a digitalised, portable format for their health data that can be easily shared with different specialists.

The EHDS also seeks to help policymakers and regulators make evidence-based decisions, while preserving the privacy of citizens' personal data. It is intended to engage all stakeholders in the health and policy fields and use many existing tools and technologies, including connectivity and open-source tools, as well as the growing range of data coming from new sources, such as wearables and health apps that monitor users' health.

Ahead of the launch of the EHDS, it is crucial to examine the health data governance challenges facing patients, clinicians, researchers, health authorities and other stakeholders, such as the pharmaceutical industry and investors, who translate data into products and services. Challenges in the collection and management of health data include a lack of institutional alignment at the EU or national levels, as well as issues of data interoperability between and across healthcare systems. Consideration is also needed around differences in the incentives and the interests among the various stakeholders regarding health data uses, which can lead to competition and create data silos.

Rare diseases: a model case for the health data governance framework

The rare diseases community has many unmet needs. The limited number of patients suffering from each of the 5,000 to 8,000 known rare diseases, alongside the scarcity of available knowledge and expertise on these diseases, make rare diseases a field that could greatly benefit from European action. Data on a national level are insufficient, but sharing data at the European level could provide the scale needed for medical research and subsequent care. Rare diseases should therefore be a priority for the new opportunities offered by the EHDS in order to improve healthcare services and evidence-based care for rare diseases patients, to monitor the public health impact of rare diseases, and ultimately to improve the lives of people living with a rare disease by enhanced access to larger amounts of data.

One of the specific challenges related to rare diseases that needs to be addressed is the near-invisibility of rare diseases in health information systems. The 10th International Classification for Diseases (ICD-10), currently in use by the World Health Organization (WHO), includes just 450 out of the thousands of rare diseases identified. Although the revised

⁵ Rare 2030 Foresight Study, 2021, pp.100-110, [Rare2030_recommendations.pdf](#)

edition, ICD-11, includes 4,500 rare diseases and was developed in 2019 by the WHO, it is anticipated that its adoption worldwide will be slow. In the United States, for example, implementation may not begin before 2027.

EU member states should move quickly to transition to use of ICD-11. With support from the European level, national authorities should implement integrated electronic health record (EHR) systems capable of capturing data on rare diseases patients at each healthcare encounter, utilising the ICD-11 along with the Orphanet nomenclature of rare diseases (ORPHAcodes) to ensure visibility of patients within national health and social systems and build a robust and accurate longitudinal care record. It should be noted that implementation of ICD-11 without the accompanying Orphacodes, designed to be complementary to the ICD, will not bring to the surface most rare diseases. The ORPHAcodes have been recognised as the

most appropriate nomenclature for clinical coding of rare diseases in Europe.

The Rare 2030 Foresight Study was initiated by the European Parliament and co-funded by the European Commission. This two-year study, conducted by EURORDIS and concluded in 2021 with over 250 experts from across the rare diseases community, resulted in seven overarching recommendations to ensure that the future of 30 million people living with a rare disease is not left to luck or chance. Rare 2030 sets out the need for a new European policy framework for rare diseases and brings together a refreshed concerted strategy across research, digital, healthcare and social welfare to complement existing legislation. It provides political momentum for the adoption of rare diseases as a use case for the health data governance framework.⁵





Four key principles

The COVID-19 crisis has brought to the forefront the importance of digital technologies for the collection and management of data in dealing with health crises. This has taken place in a more general European context that supports the development and implementation of a governance framework for data, including health data, namely the EHDS. The long-term experience of the rare diseases community's use of data and knowledge transfer into non-rare fields over the past 20+ years can serve as an important example on which to base expansion of the lessons learned.

The aim of this report is to set out principles, recommendations and guidelines on how legal and policy efforts at the EU level can support the user-friendly digitalisation of healthcare systems that leave no one behind. The principles and recommendations contained in this report address the main challenges faced in the collection, management and access to rare diseases health data by

different stakeholders, including patients, carers, clinicians, academics, researchers, entrepreneurs, industry, health authorities, Health Technology Assessment (HTA) agencies and regulatory authorities.

Four key principles have been identified to achieve the overarching objective of optimising rare diseases data in the EHDS.

The four principles are interrelated and interconnected. Each one is established on the basis of a number of recommendations and related actions for rare diseases health data users. The principles, recommendations and actions draw upon the ideas debated during three online working group sessions organised by Friends of Europe in 2021, as well as subsequent contributions to the debate from its participants.

Principles & recommendations

Principle 1

Ensure federated access to harmonised rare diseases health data in an interoperable continuum encompassing epidemiological, healthcare, research, quality of life and treatment-related data

Recommendation 1: Implement a federated, interoperable common access interface for all health data

- **Implement** the use of ICD-11 and ORPHAcodes at the member state level as early as possible.
- **Simplify** the process to access data, streamlining administrative requirements to query data across borders.

Recommendation 2: Create common rules for access to data

- **Harmonise** regulations around public and private access to data across member states.
 - **Promote** findable, accessible, interoperable and reusable (FAIR) data standards.
 - **Integrate** a wide range of data including longitudinal studies, disease burden, quality-of-life and natural history.
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Principle 2

Build partnerships for rare diseases and leverage existing initiatives such as the European Reference Networks (ERNs)

Recommendation 3: Include the European Reference Networks (ERNs) to pilot the EHDS

- **Enhance** existing rare diseases data sharing partnerships and initiatives to contribute to the EHDS.
- **Explore** the experiences of EU rare diseases data sharing experiences to inform the EHDS.
- **Capitalise** on the experience of the ERNs as a pilot for the EHDS.
- **Co-create** with EU, member states and all relevant stakeholders, a comprehensive data strategy and implementation plan, building on the Virtual Platform of the European Joint Programme on Rare Diseases (EJP RD).
- **Futureproof** the EHDS operational and governance frameworks for greater use of AI and other data tools that exploit large datasets.

Principle 3

Develop digital skills for the rare diseases community

Recommendation 4: Develop a pipeline of data specialists

- **Promote** the recruitment of trained data scientists within healthcare.
- **Create** new healthcare professions, such as digital data managers to support rare diseases patients, and data stewards to accelerate rare diseases data collection and use for research.

Recommendation 5: Support increased data literacy for healthcare professionals and the public

- **Increase** data skills training in medical school curricula.
 - **Incentivise** electronic record keeping in medical settings.
 - **Empower** rare diseases patients to make more informed decisions about their own health data and to take a larger participatory role in the use of their data.
 - **Develop** a system for the sharing of electronic health records that supports the coordination of patient care within multidisciplinary teams and across health and social care systems.
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Principle 4

Build on experiences from the rare diseases community to empower health data users through systems of trust

Recommendation 6: Build systems of trust through a clear legislative framework for health data governance

- **Cultivate** a climate of trust by fostering transparency and patient participation in governance.
- **Promote** the engagement of citizens – and particularly patients living with a rare diseases – in the EHDS via communication campaigns and ‘citizen science’ actions.

Recommendation 7: Support patients’ data custodianship

- **Demonstrate** the experience of people living with a rare disease in sharing privacy-protected data to benefit diagnostics, research and care.
- **Facilitate** rare diseases patients and patient organisations to contribute to shaping the health data governance frameworks and participate in decision-making structures.

Principle 1

Ensure federated access to harmonised rare diseases health data in an interoperable continuum that encompasses epidemiological, healthcare, research, quality of life and treatment-related data

Access to the different categories of rare diseases data should be simplified through the implementation of a harmonised, interoperable framework for all health data at the European level that caters to the diverse needs of all stakeholder groups and is integrated into the daily practice or lives of stakeholders. All European data sources relevant to addressing the challenges faced by people living with a rare disease should be federated in a continuum, encompassing epidemiological, healthcare, research, quality of life and treatment-related data, and should be linked at international levels where possible.

These data must share commonly adopted codification systems (ICD-11 and Orphanet nomenclature) along with harmonised standards and interoperability requirements. To optimise sharing of data for care and research across infrastructures and countries, cohesive data ecosystems should be developed at the national level, linking seamlessly through findable, accessible, interoperable and reusable (FAIR) data approaches to an integrated European ecosystem, positioned within the EHDS and centred on robust ERNs, the European Platform on Rare Disease Registration and other key infrastructures.

The rules around access to rare diseases health data need to be transparent, equitable and

understandable. They must also be secure, built on ethical foundations and ensure that privacy is fully respected. Legal and ethical guidelines and regulations should incentivise practices that best lead to addressing the challenges around capturing and sharing rare diseases data while respecting international, national and regional laws and conventions – particularly the preferences and privacy of people living with a rare disease and their families.

Recommendation 1: Implement a federated, interoperable common access interface for all health data

Rare diseases registries and data sets from clinical and national audits for specific conditions are scattered and scarce. They are often localised to one healthcare system or university hospital. Accessing data held in national registries through a single European level interface supporting the capture, use and reuse of data would enable a much-needed simplification of the entire process of data collection and management by providing access to datasets from across Europe. Such an approach would ensure that knowledge about rare diseases does not remain localised in a university hospital or research centre, for example, but would instead be available for access throughout the continent. The available

data would support health stakeholders in their daily practice, from more rapid diagnosis to enhanced disease management guidelines.

Hundreds of rare diseases registries have been established by dedicated experts and individual patient organisations. For some very rare conditions, they represent the sole source of data and lack sufficient financial and technical support, despite their crucial value for clinical and research purposes. Often, they fail to meet quality standards, preventing them from being used by regulators such as the European Medicines Agency (EMA) in decision-making.

A federated, interoperable common access interface would help institutions and expert groups who wish to initiate new data collections. The collection and encoding of data should be shared more widely rather than conducted in silos for specific initiatives such as clinical research projects. Collected data should be reusable and available in relatively new formats, such as patient-reported outcome measures (PROMs) and real-world evidence (RWE), which should be integrated into the EHDS as they provide essential insights to address issues, such as the off-label use of medicines, which is especially important for rare diseases.

RWE is especially valuable for rare diseases patients because it can support further research and produce deeper insights into the environmental risks that contribute to the development of non-communicable and rare

diseases. Generated from observational data gathered during routine clinical practice and outside the context of randomised controlled trials, RWE provides crucial information on health outcomes. RWE is increasingly produced by electronic health records and personally-generated health data from wearable devices, health apps and smart sensors, among others.

As health data collection accelerates, initiatives by regulatory bodies such as the EMA and the Data Analysis and Real-World Interrogation Network (DARWIN EU) are building on RWE to provide guidance on the use, safety and effectiveness of medicines, including vaccines. Including such initiatives in the EHDS will encourage increased collection of RWE to support innovations in health.

Access to data should be seamless, following common regulations regardless of the data source.

Finally, it is critically important that the EU member states move quickly to adopt the use of the 11th International Classification for Diseases (ICD-11) in tandem with the Orphanet ORPHAcodes. To rectify the quasi-invisibility of rare diseases in health information systems and accurately capture epidemiologic data on rare diseases, ICD-11, which should be ready for implementation in 2022, will increase the visibility of rare diseases in health information systems.

In the future, the core principle should be to separate the health data from the application or

programme in order to offer greater flexibility in the sharing and querying of the data. The medical community should be encouraged to agree on common European standards for data sets, data models and documentation in specific clinical areas, such as rare diseases, gradually evolving to cover the patient holistically. Supporting such activities would facilitate interoperability and data integration in the context of the EHDS.⁶

Interoperability for rare diseases requires the EU and member states to undertake the following actions: facilitate the use of coding systems by healthcare and social care providers, including those involved in the ERNs; ensure rare diseases patients' visibility in datasets, thus building robust and accurate longitudinal care records; and speed up the implementation process for interoperable coding systems, especially ICD-11 and the Orphanet nomenclature.⁷

Recommendation 2: Create common rules for access to data

The EU should adopt a harmonised regulatory framework with Europe-wide guidelines governing access to health data that also take into consideration the nuances between the various strands and purposes of health data use. In November 2020, the European Commission took an important step in this direction by proposing the so-called Data Governance Act.⁸ This proposal for regulation responds to the

need to improve conditions for data sharing in the EU internal market, through the creation of a harmonised framework for data exchange.⁹ It also foresees the development of sector-specific legislation, such as that for the EHDS.

In order to make these guiding principles functional and operational, specific forms of support are needed, such as EU-wide General Data Protection Regulation-compliant data sharing templates and tools that can be used across member states. Specific guidelines are also needed for health data access in the area of both in-person and digital cross-border healthcare. Similarly, guidance is needed to support data access and sharing around coordination of care. These areas are of particular relevance for people living with a rare disease.

The EU and member states should furthermore lay down conditions that would establish clear guidance on access to health data based on scientific relevance and public interest, including commercial operators' access. The implementation of FAIR data should be promoted to support the development of quality datasets. Particular attention is needed to support the integration of different types of data in this approach to access, such as RWE, natural history of diseases and patient reported outcomes measures.

Private research companies, including the pharmaceutical industry, play an important

⁶ COCIR, European Health Data Space, Towards a better patient outcome, November 2019, https://www.cocir.org/fileadmin/Publications_2019/19106_COC_EU_Health_Data_SPACE_web.pdf

⁷ Recommendations from the Rare 2030 foresight study, http://download2.eurodis.org/rare2030/Rare2030_recommendations.pdf

⁸ European Commission, Proposal for a Regulation on European data governance (Data Governance Act)- COM/2020/767 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020PC0767&from=EN>

⁹ Ibidem, p.24.

role in the scientific research community through the development of treatments for rare diseases. In Germany, private companies are not granted the right to apply for research data at the national data centre, whereas in France access is determined by scientific relevance of the research question. In the context of the EHDS, the French approach to accessing the data sharing ecosystem should be implemented and private stakeholders should be able to contribute to the ecosystem by sharing the data from their clinical studies. The absence of such health data users from the EHDS would be detrimental to all by slowing down rare diseases research.

Data and digitisation will radically transform healthcare and social care, with major scientific breakthroughs expected from the increased use of big data, AI and cognitive computing. New business models will emerge that create value from health data.¹⁰ The EHDS needs to support these anticipated new approaches by clarifying the rules of access for public and private actors and equitable ways to share the value created by the use of such data. This clarity in common rules about access to data could be particularly useful for start-ups, small- and medium-sized enterprises (SMEs) and spin-offs from university projects or hospital research departments,¹¹ which conduct crucial and often early-stage research and development on rare diseases.

Progress on data use and access to data at the European level should support the day-to-day lives of patients, especially those living with a rare disease. One rare disease patient may need to seek medical expertise in three or four different areas of speciality. Providing support for the portability of their data through e-medical records would ensure that healthcare providers are better informed of rare diseases patients' specific health requirements. There needs to be support and guidance for the streamlined coordination of care, which would allow each member of the patient's health and social care team to easily access relevant health data. These dynamic care pathways should gather data on patient quality of life and disease burden in addition to health data.

Finally, the EHDS should be connectable to data sets outside health systems, such as geospatial information on air pollution, socio-economic conditions and demographics. It should also interoperate with other common European data spaces via the [European digital strategy](#).¹² Such connections would support increased knowledge and awareness around the natural history of diseases and therefore lead to better health outcomes.

¹¹ <https://digital-strategy.ec.europa.eu/en/library/meetings-expert-group-business-government-data-sharing>

¹² The European strategy for data aims at creating a single market for data that will ensure Europe's global competitiveness and data sovereignty. Common European data spaces will ensure that more data becomes available for use in the economy and society, while keeping the companies and individuals who generate the data in control.



Principle 1

The recommendations below include the a number of actions to guide implementation

Recommendation 1: Implement a federated, interoperable common access interface for all health data

- **Implement** the use of ICD-11 and ORPHAcodes at the member state level as early as possible.
- **Simplify** the process to access data, streamlining administrative requirements to query data across borders.

Recommendation 2: Create common rules for access to data

- **Harmonise** regulations around public and private access to data across member states.
- **Promote** findable, accessible, interoperable and reusable (FAIR) data standards.
- **Integrate** a wide range of data including longitudinal studies, disease burden, quality-of-life and natural history.

Principle 2

Build partnerships for rare diseases and leverage existing initiatives such as the European Reference Networks (ERNs)

Data sharing should be the norm across health and social care so that the full potential for data-driven innovation can be achieved. This collaboration is especially crucial to address the 95% of rare diseases that still have unmet needs in terms of treatments. In France, the Health Data Hub has a strong focus on cancers and rare diseases. The hub has successfully demonstrated the power of data in health, especially in the rare diseases field, and could serve as a model for other countries, as well as for the EHDS, to support better health outcomes.

In the context of the launch of the EHDS, the EU and member states should exploit existing partnerships on data sharing, including the ERNs, as well as national and regional initiatives such as the French Health Data Hub and the German Medical Informatics Initiative (MII), in order to share pre-existing data within the EHDS.

To date, a number of past and current EU projects have examined creating data spaces. Examples include the European Health Data & Evidence Network, the Patient Registries of Europe (PARENT), and the GAIA-X project, led by private stakeholders to include health data from an array of sources, including apps and

wearables. Additional initiatives include the Data Analysis and Real-World Interrogation Network (DARWIN EU) led by the EMA. These initiatives can provide vital lessons about the challenges of collecting and sharing data between institutions ahead of the launch of the EHDS.

Another model to look to for data sharing is the European Joint Programme on Rare Diseases (EJP RD), which brings over 130 institutions from 35 countries to improve the integration, efficacy, production and social impact of research on rare diseases. The EJP RD fosters the development, demonstration and promotion of European and world-wide sharing of research and clinical data, resources and know-how.

Advances in the AI sector should also be incorporated into data collection, collation and cross-referencing. The EHDS should capitalise on emerging technologies such as AI to optimise its uses and interoperability. The utilisation of advanced technologies will be particularly welcome to the field of rare diseases, which is characterised by splintered and scattered research efforts and a lack of clear disease coding utilisation for epidemiological purposes. AI in clinical practice can hasten diagnostics and

¹³ <https://www.ehden.eu/>

¹⁴ Anonymous. (2021, January 4). Patient registries. European Medicines Agency. Retrieved September 15, 2021, from <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/patient-registries>.

¹⁵ Home. GAIA-X - Home. (n.d.). Retrieved September 15, 2021, from <https://www.data-infrastructure.eu/GAIA/Navigation/EN/Home/home.html>.

¹⁶ GLANVILLE, D. (2021, June 4). Data analysis and real WORLD Interrogation network (DARWIN EU). European Medicines Agency. Retrieved September 15, 2021, from <https://www.ema.europa.eu/en/about-us/how-we-work/big-data/data-analysis-real-world-interrogation-network-darwin-eu>.

¹⁷ EJP RD – European Joint Programme on rare diseases. (n.d.). Retrieved October 25, 2021, from <https://www.ejprarediseases.org/>.

enhance treatment management. However, algorithms can produce biases that are detrimental to patients. Investigation is needed to address: technical and semantic interoperability between various infrastructures and IT systems; and potential ethical and governance concerns over AI use in data management and in clinical practice.

To ensure the success of the EHDS, cultural shifts must be implemented to encourage changes in the behaviours of healthcare professionals towards their practice. Data in health systems are only as robust and reliable as the quality of the data inputted. In order to support the success of the EHDS and its widespread adoption by all health users and particularly healthcare professionals, attention must be placed on the human element. The entry and management of data must be integrated into health workers' daily practice and acknowledged as an important element of their work.

Recommendation 3: Include the European Reference Networks (ERNs) to pilot the EHDS

A relatively new structure that offers an opportunity for the innovative use of health data to improve the lives of people with rare diseases, the ERNs are expected to transform the wealth of health data and collective knowledge on rare diseases scattered throughout Europe to improve the delivery of highly specialised care and create a thriving rare diseases research landscape. The ERNs are a priority of the EU4Health work

programme, with €7.8mn allocated towards their functioning and enhancement. They offer a unique potential to consolidate and streamline a European health and research data ecosystem for rare diseases which could in turn be extended to other therapeutic areas.

The networks reveal both the promises and the challenges of connecting health data across the continent. While some of the networks have implemented successful data registries for many rare diseases, others are yet to ensure full data sharing among registered specialists, highlighting the difficulties that arise around data sharing, even among those committed to sharing it.

The EU and member states should provide financial support to co-create a comprehensive data strategy by 2030, envisaging the identified activities across a six-action architecture: cloud computing services and IT support for registries and other databases; data collection protocols; data curation services; data management tools, including services and tools to search, access and share data, tools to manage own data; data analytics tools and services; and a data governance framework.

The EU and member states should additionally leverage the ERNs as major contributors in shaping the upcoming EHDS as they bring together essential elements on which the European health data ecosystems should build upon. Firstly, the networks federate health data users, such as clinicians, patient

¹⁸ Recommendations to achieve a mature ERN system in 2030. EURORDIS-Rare Diseases Europe. (n.d.). Retrieved September 15, 2021, from <https://www.eurordis.org/maturevisionern>

¹⁹ No time to lose: Building a data strategy for the European Reference Networks, EURORDIS, April 2020, http://download2.eurordis.org.s3.amazonaws.com/ern/EURORDIS_ERN_Data_Strategy_Final.pdf#page=25&zoom=100,92,72

²⁰ Recommendation from the Rare 2030 Foresight Study. The future starts today, February 2021, pp.100-110, http://download2.eurordis.org/rare2030/Rare2030_recommendations.pdf

advocates and patient organisations, to work towards a common goal of improving care for rare diseases and advancing research. Secondly, the ERNs provide an essential wealth of data and have started building the evidence base for the natural history of rare diseases, starting with the ERN registries and disease specific health outcomes. Thirdly, clinicians and the rare diseases patient community, collaborating within the framework of the ERNs, have developed a common understanding on the importance of health data sharing and a solid degree of trust that is critical to articulate a sound health data governance framework for ethical and lawful health data sharing.

The future ERN health data strategy must be anchored to the wider European health data and IT ecosystem, driven by a concerted policy action shared across all the relevant European Commission Directorates-General and aligned with national health data strategies from the majority of member states. The networks should sit at the centre of future efforts to refine and evolve all ontologies and standards for data collection and utilisation into a common data model, including efforts to facilitate extraction and mining of meaning from real-world data.

All these decisions will affect the future rare diseases health data landscape and should have the involvement of every concerned stakeholder group, including patient organisations, some of whom curate valuable data sets.

As the structure of the ERNs serves as a model for the EHDS, so too does the rare diseases community – from patients and families, caregivers and health professionals, to researchers and academics, industry and regulators – through their proven willingness to come together and share experience and knowledge with the common overarching goal of improving life for people living with a rare disease.

Principle 2

The recommendations below include the a number of actions to guide implementation

Recommendation 3: Include the European Reference Networks (ERNs) to pilot the EHDS

- **Enhance** existing rare diseases data sharing partnerships and initiatives to contribute to the EHDS.
- **Explore** the experiences of EU rare diseases data sharing experiences to inform the EHDS.
- **Capitalise** on the experience of the ERNs as a pilot for the EHDS.
- **Co-create** with EU, member states and all relevant stakeholders, a comprehensive data strategy and implementation plan, building on the Virtual Platform of the European Joint Programme on Rare Diseases (EJP RD).
- **Futureproof** the EHDS operational and governance frameworks for greater use of AI and other data tools that exploit large datasets.



Principle 3

Develop digital skills for the rare diseases community

The EU and member states should support the expansion of data skills in the health sector by addressing both the lack of data specialists in healthcare systems and issues of literacy for healthcare professionals and patients. This is particularly key for the rare diseases community, where digital data offer many opportunities for breakthroughs in both knowledge and treatments.

Of the EU's €672.5bn post-pandemic Recovery and Resilience Facility, 20% is earmarked for digital transformation: this should be utilised to develop the skills needed across the board to make the EHDS operational. One of the EU 2030 Digital Compass targets is to have at least 80% of all adults possess basic digital skills and to increase the number of ICT specialists employed in the EU from 7.8mn to 20mn, an almost threefold increase in expertise. Some of this new IT capacity should be directed into healthcare.

Recommendation 4: Develop a pipeline of data specialists

To counter current shortfalls in data literacy, the EU and member states should support the development of pipelines of data scientists who are equipped with the skills to fully exploit the potential of the EHDS. There is a particular need to upscale the skills network in areas such as biostatistics, epidemiology, genomics, cybersecurity, AI and cloud computing. It is estimated that, by 2023, the wider public sector across the EU and the United Kingdom will need an additional 1.7mn employees

with technological skills. Of this total, the shortfall in people with advanced and complex data analytics skills is estimated at 1.1mn. Closing the gap in this skills shortfall will be challenging, as these skills are highly specialised and providing training in them will not necessarily occur rapidly. Such skills are in high demand in the healthcare industry, making it more difficult for the public sector to attract leading talents.

Health institutions need to be restructured to place a greater focus on collecting and analysing data in real time to improve efficiency. Trained data scientists should be recruited for new management posts within healthcare. New professions, such as a digital data manager, could support rare diseases patients in navigating the digital landscape and making the most use out of their data. Investment should be made to train expert data stewards able to advise rare diseases stakeholders in the national territory on FAIR-compliant data management and to support individual research projects or clinical trials in preparing relevant data from the outset, for potential secondary use in the future, capitalising on the results of the EJP RD.

Recommendation 5: Support increased data literacy for healthcare professionals and the public

Across Europe, there is an acute digital literacy deficit among healthcare professionals. According to a 2020 Deloitte report, over one-fourth of clinicians receive no formal training

in the use of digital technologies. Clinicians lack the skills, equipment and support needed to adapt to a digitally-enhanced health environment.

Basic digital health literacy and skills must be included in general education curricula and the core curricula for healthcare professionals should include medical data collection and management, as well as in their continuous professional education. The EU can foster this through the European Skills Agenda and the ERASMUS+ programme to support health literacy within citizenship education.

With the development of new digital tools, it is vital to avoid creating additional administrative burdens for healthcare professionals. Information technology (IT) should support and enable health workers by addressing difficulties in their operational reality. Some digital tools are commonly described as solutions looking for problems, specifically those developed from a ‘tech’ perspective rather than the perspective of optimising the ways that doctors, nurses or pharmacists work. To this end, the European Skills Agenda should receive a significant focus in the health sector, through support in the development of

standardised tools and facilitation of training to increase digital adoption. One solution to incentivise the use of digital tools could be to implement higher reimbursement rates for electronic documentation of a hospital visit as opposed to paper-based documentation. A key goal is to foster the emergence of ‘the health professional of the future’, who is at ease in the digital environment and skilled in using digital tools to deliver care.

There is also a need to help rare diseases patients become more digital and data literate in order to make more informed decisions about their own health data and to take a larger participatory role in the use of their data. Rare diseases patients who need to seek a variety of specialist care services should be informed on how to obtain and manage their own electronic health records (EHR) to facilitate consultations and to avoid patients having to re-explain their diagnostic and care journey to each new specialist seen. However, the burden should not rest on the patient to provide their health data and history. Each patient’s EHR must be readily accessible to all members of the patient’s care team, as well as to the patient.

²¹ Digital is here defined as electronic technology that generates, stores, and processes data in terms of two states: positive and non-positive. Positive is expressed or represented by the number 1 and non-positive by the number 0. Thus, data transmitted or stored with digital technology is expressed as a string of 0s and 1s.

²² European Commission, 2030 Digital Compass.

²³ <https://www.mckinsey.com/industries/public-and-social-sector/our-insights/the-future-is-now-closing-the-skills-gap-in-europes-public-sector>

²⁴ Digital transformation Shaping the future of European healthcare, Deloitte, September 2020, <https://www2.deloitte.com/content/dam/Deloitte/nl/Documents/public-sector/deloitte-nl-shaping-the-future-of-european-healthcare.pdf>

²⁵ Employment, social Affairs & inclusion. European Skills Agenda - Employment, Social Affairs & Inclusion - European Commission. (n.d.). <https://ec.europa.eu/social/main.jsp?catId=1223&langId=en>.

²⁶ The Future unmasked, Predicting the future of healthcare and life sciences in 2025, Deloitte Centre for Health Solutions, 2020, <https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-life-sciences-healthcare-predictions.pdf>

Principle 3

The recommendations below include the a number of actions to guide implementation

Recommendation 4: Develop a pipeline of data specialists

- **Promote** the recruitment of trained data scientists within healthcare.
- **Create** new healthcare professions, such as digital data managers to support rare diseases patients, and data stewards to accelerate rare diseases data collection and use for research.

Recommendation 5: Support increased data literacy for healthcare professionals and the public

- **Increase** data skills training in medical school curricula.
- **Incentivise** electronic record keeping in medical settings.
- **Empower** rare diseases patients to make more informed decisions about their own health data and to take a larger participatory role in the use of their data.
- **Develop** a system for the sharing of electronic health records that supports the coordination of patient care within multidisciplinary teams and across health and social care systems.

Principle 4

Build on experiences from the rare diseases community to empower health data users through systems of trust

In order to foster trust in the EHDS, the EU and member states should draw upon the experiences of the rare diseases community, which have supported the creation of specialised registries and data collection.

The success of the EHDS is contingent upon its acceptance by rare diseases patients, who expect their data to be collected, used and reused safely and according to their wishes. The EU and member states must therefore build systems of trust and support patients' data custodianship. Only then will the EHDS be able to uphold its objective of improving health outcomes.²⁷

Recommendation 6: Build systems of trust through a clear legislative framework for health data governance

Building systems of trust should extend to all health data users, including hospitals, researchers and clinicians. The EU should seek to create a system of trust among hospitals, research centres and patients based on the sharing of health data in a secure way, which protects privacy while fostering appropriate access to the data in order to deliver better care. ERNs offer experience of both the challenges in data collection and the potential value.

Examples of building systems of trust include the 2017 UK government report, 'Growing the Artificial Intelligence Industry in the UK', which presents the concept of 'data trusts' as institutions that might support data sharing in the pursuit of the public interest. The basic principle underlying the model is that there should be an independent structure for stewardship of data that can enable flexible and inclusive data governance and respect multiple interests. Data trusts are intended to act as independent and sustainable stewards of data focused on sharing data in a fair, safe and equitable way. They seek to provide inclusive, anticipatory governance of data and make trustworthy decisions about who has access to data, under what conditions, and for whose benefit.

A legal framework that provides clarity and a strong governance framework is required in order to build public confidence in the EHDS. This framework must address privacy concerns and create a trusted and secure data-sharing space.

However, legislation alone will not build the necessary patient trust. In particular, Europeans need skills and training to understand digital and data technologies, such as health monitoring and electronic records, whether in their role as patient, employee or

retiree. Currently, there are significant digital divides across Europe, which mirror and exacerbate existing inequalities. [The Digital Economy and Society Index \(DESI\)](#) shows that four out of ten adults in the EU lack basic digital skills.²⁸ This means that 75mn European adults of working age do not have the skills needed to do 90% of available jobs. Population groups that are already experiencing social exclusion or marginalisation face the greatest health challenges and are the least able to access digital tools to manage their own health.

Attention needs to be given to the potential of health IT to include patients rather than further exclude them. This includes the provision of access to infrastructure, such as reliable and fast internet, as well as the availability of simplified user interfaces that are easy to understand. Moreover, citizens should always be provided with the option to choose between digitally-enabled care and traditional face-to-face care.

Citizen engagement must be a key element of the EHDS in order to ensure that people understand its value and their own contribution to it. This is particularly important for vulnerable groups, including people living with a rare disease. Such engagement should involve transparent evidence-gathering; communication and information campaigns; and the promotion of 'citizen science' that gets people more involved in direct problem-solving.²⁹ With limited numbers of patients – as is often the case with rare conditions – it is difficult to gather information, develop treatments and conduct large clinical trials.

Healthcare systems should provide guidance on how to address the specific challenges experienced by rare diseases patients with regards to the anonymisation of their data, for example, through the adoption of solutions that federate and link rare diseases data in line with the General Data Protection Regulation (GDPR).³⁰

Recommendation 7: Support patients' data custodianship

The uses of data under unchosen circumstances are the main risks associated with sharing data. Rare diseases patients can be exemplars on how their data sharing promotes research and leads to faster diagnoses and improved treatments. Regardless of the severity of their condition or socio-demographic profile, rare diseases patients are clearly supportive of data sharing to foster research and improve healthcare and social care. A 2018 Europe-wide study by EURORDIS found that 95% of patients are willing to share their data for wider scientific interest to advance care and research not directly linked to their own disease, compared to between 37% and 80% of the general population. The EURORDIS Rare Barometer survey results indicate that rare diseases patients' willingness to share data is conditional on specific requirements, including the respect for their privacy and choices, a need for information regarding the use of their data, and their inclusion in governance frameworks around the collection and management of their data. This applies to registries, any future EU health data infrastructure and any other health database.

Patient rights logically extend to their personal health data and individuals should have rights on how such data are used. In this context, the concept of data ownership is complex. In the field of health, data are often co-created by and within health systems, and therefore, the concept of ownership is less useful. An alternative approach is that of patient data stewardship or custodianship, enabling choices about how and why data are shared.

Ensuring transparency in the collection, use and reuse of health data is essential: if they so wish, patients – whatever the type or user – should be actively notified about each use of their data, as is demonstrated by rare diseases patients, of whom 80% want to have the possibility for full or nearly full control over the data they are sharing.³¹

To support the shift from data ownership to data stewardship, healthcare systems should encourage awareness among the population of how data contribution can advance research, lead to further innovation and even create research breakthroughs in improving health outcomes. There are various ways in which healthcare systems could promote this kind of awareness-raising. One way could be through the dissemination of survey results that positively highlight patients' willingness to share data, provided that certain conditions

are met, as was achieved by the rare diseases community with EURORDIS' Rare Barometer Programme, for example. Secondly, the provision of appropriate immediate data feedback mechanisms could be constructive via patients' understanding of the useful role played by data.

Trust must be the foundation upon which everything rests: greater trust leads to successful data sharing which reinforces trust. Similarly, security breaches or abuse of data undermines trust. Transparency – clarity for communities about how data are collected, for what purposes and how data are used – acts as the guarantor of trust. Trust is built by clear and respectful communication between stakeholders at all levels, creating a chain that identifies the expectations and responsibilities for each link in the chain.

A whole-of-life perspective towards health data should also be developed, notably by supporting people's continuity of care and stewardship. This whole-of-life perspective would cover different life passages or transitions. One example of such a life transition is the passage from adolescence to adulthood. This transition period is particularly complex at the human, clinical and legal levels, among others. To ensure the continuity of care and smooth data transition, the EU and member

²⁷ A European strategy for data doc (EU COMM) <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0066&from=EN>

²⁸ <https://digital-strategy.ec.europa.eu/en/library/digital-skills-all-europeans-brochure>

²⁹ Citizen science. Shaping Europe's digital future - European Commission. (2020, October 29). <https://ec.europa.eu/digital-single-market/en/citizen-science>.

³⁰ EURORDIS, Rare 2030 foresight study, February 2021, http://download2.eurordis.org/rare2030/Rare2030_recommendations.pdf

³¹ Ibid.

³² Shaw, D. M., Gross, J. V., & Erren, T. C. (2015.). Data donation after death, *Lancet*. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(15\)61410-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)61410-6/fulltext)

states should develop a consent framework for health data sharing that includes rules to cover the handling of data as patients move out of paediatric care and into adulthood.

The issue of ‘data donation’ after death should also be addressed. One idea would be for citizens to carry a data donor card, connected to their electronic records, which would state the extent to which their data can be used for research purposes after their death.³²

Principle 4

The recommendations below include the a number of actions to guide implementation

Recommendation 6: Build systems of trust through a clear legislative framework for health data governance

- **Cultivate** a climate of trust by fostering transparency and patient participation in governance.
- **Promote** the engagement of citizens – and particularly patients living with a rare diseases – in the EHDS via communication campaigns and ‘citizen science’ actions.

Recommendation 7: Support patients’ data custodianship

- **Demonstrate** the experience of people living with a rare disease in sharing privacy-protected data to benefit diagnostics, research and care.
- **Facilitate** rare diseases patients and patient organisations to contribute to shaping the health data governance frameworks and participate in decision-making structures.

Conclusion

The creation of a common European Health Data Space (EHDS) will facilitate a more robust exchange of different types of health data to support healthcare, research and policymaking purposes. The EHDS will enhance data collection and sharing across the EU, benefitting patients, clinicians, researchers, entrepreneurs and health systems.

If the EHDS is developed with the same spirit of willingness, dedication and common purpose as is practiced in the rare diseases community, it can only be a success, despite the numerous technical, ethical and operational challenges ahead.

As much as the EHDS is expected to benefit rare diseases stakeholders by establishing a common repository for data, so too will the EHDS benefit from the rare diseases community's decades of hard-earned experience in mutual collaboration, cooperation and knowledge sharing.



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Steffen Amann

Board Member, Lead on Rare Diseases, European Association of Hospital Pharmacists (EAHP)

Alba Ancochea

Director, Spanish Federation of Rare Diseases (FEDER), Spain

Antonio Andreu

Scientific Director, European Infrastructure for Translational Medicine (EATRIS), The Netherlands

Peter Arlett

Head, Data Analytics and Methods Task Force, European Medicines Agency (EMA)

Ségolène Aymé

Vice Chair, Scientific Advisory Board, Health Data Hub, France

Benedetta Baldini

Policy Officer, European Social Insurance Platform (ESIP)

Laura Batchelor

Director, Fipra International, Belgium

Simona Bellagambi

Representative, UNIAMO – Italian Federation for Rare Diseases, Italy

Cinzia Maria Bellettato

Project Manager, MetabERN, Italy

Elena Bonfiglioli

Managing Director Healthcare EMEA, Microsoft, Belgium

Valentina Bottarelli

Public Affairs Director, Head of European & International Advocacy, European Organisation for Rare Diseases (EURORDIS)

Alina Brandes

Referent European Health Data Space, Ministry of Health, Germany

Anita Bressan

Telemedicine Platform Manager, European Reference Networks (ERNs)

Colm Burke

Member, National Parliament (Oireachtas), Ireland

Manuela Buxo

Senior Vice President, Region Head Europe, Sanofi Genzyme

Anne-Sophie Chalandon

Head of European Rare Diseases Public Affairs and Patient Advocacy, Sanofi, France

Ciara Clancy

Chief Executive Officer, Beats Medical, Ireland, and European Young Leader (EYL40)

Leucio Antonio Cutillo

Project Officer, European Commission, Italy

Nicole Denjoy

Secretary General, COCIR

Toon Digneffe

Head of EU Public Affairs, Takeda

Pavla Doležalová

Head of the Centre for Paediatric Rheumatology and Autoinflammation, Charles University, Czech Republic

Martin Dorazil

Deputy Head of Unit, European Reference Networks and Digital Health, European Commission

Bernard Durkan

Member, National Parliament (Oireachtas), Ireland

Marie-Hélène Fandel

Senior Director Corporate Public Affairs Europe, Sanofi

Wout Feitz

ERN eUROGEN Coordinator, European Reference Networks (ERNs), The Netherlands

Pietro Fiocchi

Member, European Parliament

Maciej Gajewski

Head of International Government Affairs & Policy, Alexion Pharma International, Switzerland

Elisa Gastaldi

Senior Director, Siemens

Ioana-Maria Gligor

Head of Unit, European Reference Networks and Digital Health, European Commission

Holm Graessner

Coordinator, ERN for Rare Neurological Diseases (ERN RND), University Hospital Tübingen, Germany

Julia Hagen

Director Regulatory and Politics at the health innovation hub (hih), Ministry of Health, Germany

Cécile Hemmen

Member, National Parliament, Luxembourg

Corinna Hartrampf

Senior project manager, Association Internationale de la Mutualité (AIM)

Cristina Hernández Quevedo

Research Officer in Health Economics, European Observatory on Health Systems and Policies, London School of Economics, United Kingdom

Esther Hogenhout

Adviser, Innovation in Life Sciences and Health, Embassy of the Netherlands to France

Daria Julkowska

E-Rare Coordinator, National Research Agency, France

Markus Kalliola

Project Director Health data 2030, coordinator EU's Joint Action Towards the European Health Data Space, Finnish National Fund for Research and Development (Sitra), Finland

Roman Khonsari

Medical Director, Health data platform - Health Data Hub, France

Joelle Khraiche

Associate Director Healthcare Policy & External Affairs Europe, CSL Behring

Licínio Kustra Mano

Adviser for Cross-Border eHealth Services, European Commission

Sophie Lanone

Research Director, Institut National de la Santé et de la Recherche Médicale (INSERM), France

Yann Le Cam

Chief Executive Officer, European Organisation for Rare Diseases (EURORDIS), France

Fredrik Lindén

Co-founder, MyData Global - Swedish Hub, Sweden

Peter Lindgren

Professor of Health Economics, Karolinska Institutet, Sweden

Simona Martin

Scientific Officer, European Platform on Rare diseases Registration, European Commission, Italy

Lydie Meheus

Managing Director, Anticancer Fund

Antoni Montserrat Moliner

Member of the Board of Directors, Rare Diseases Luxembourg (ALAN), Luxembourg

Benoit Mores

Advisor to the Chair of the Political Group, Chamber of Representatives, Belgium

Liuba Murauskiene

Assoc. Professor, Faculty of Medicine, Vilnius University, Lithuania

Pasi Mustonen

Health Counsellor, Permanent Representation of Finland to the EU

Jesus Olivares-Guerrero

Consultant, Fipra International

Andri Papadopoulou

Scientific Officer, European Commission, Italy

Sirpa Pietikäinen

Member, European Parliament

Frank Rademakers

Chief Medical Technology Officer, University Hospitals Leuven (UZ Leuven)

Ana Rath

Director, ORPHANET

Nina Rawal

Founder, Emerging Health Ventures, Sweden, and European Young Leader (EYL40)

Christine Redecker

Team Leader, Health in all Policies, European Commission

Vanessa Remy

Public Affairs Europe Director, Sanofi

Annika Riester

Member of Staff, Office of Dr. Katja Leikert, Bundestag, Germany, Germany

Sara Roda

EU Senior Policy Adviser, Standing Committee of European Doctors (CPME)

Dimitrios Sarikizoglou

Policy Analyst (SNE), Country Knowledge and Scientific Committees, European Commission

Maurizio Scarpa

Cordinator, European Reference Network for Hereditary Metabolic Diseases (MetabERN)

Annalisa Scopinaro

President, UNIAMO – Italian Federation for Rare Diseases, Italy

Annabel Seeböhm

Secretary General, Standing Committee of European Doctors (CPME)

Lydia Shotton

Healthcare and Life Sciences Consultant, Fipra International

Stefan Staicu

Health Attaché, Permanent Representation of Romania to the EU

Ceri Thompson

Deputy Head of Unit eHealth, Wellbeing and Ageing, European Commission

Hugo Van Haaster

Policy Officer, European Commission

Danny Van Roijen

Digital Health Director, COCIR

Bert Verdonck

Lead of Health Data Initiatives and GAIA-X, Philips

Mihaela Veringa

Global Lead Access Policy & Governmental Affairs, Sobi

Till Voigtländer

Austrian Representative to the Board of Member States, European Reference Networks (ERNs), Austria

Sarah Wamala Andersson

Professor of Health Welfare and Technology, Mälardalen University, Sweden

Diane Whitehouse

Policy Analyst, eHealth, European Health Telematics Association (EHTEL)

Petra Wilson

Director, Health Connect Partners

Wendy Yared

Director, Association of European Cancer Leagues



Square de Meeûs 5-6,
1000 Brussels, Belgium
+32 2 893 98 18

josephine.mosset@friendsofeurope.org

friendsofeurope.org