



# The European Health Data Space and Cancer

## Applying Lessons Learnt for Successful Implementation

ACTION REPORT



## Digital Health Network



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The Digital Health Network is one of the European Cancer Organisation's Focused Topic Networks, established as part of our Strategy for 2020-2023. The Digital Health Network was launched in July 2020.

More information is available on our website.

If you would like to find out more about the Digital Health Network, please contact us at: [info@european-cancer.org](mailto:info@european-cancer.org)

### Member

SOCIETY OF THE  
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ORGANISATION

### Patient

ADVOCACY GROUP OF  
EUROPEAN  
CANCER  
ORGANISATION

### Community 365

INITIATIVE OF THE  
EUROPEAN CANCER  
ORGANISATION

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# Acknowledgements

This report was produced by the European Cancer Organisation and is based upon the Community 365<sup>a</sup> Roundtable Meeting on the topic of the European Health Data Space (EHDS) and Cancer on 23 June 2022.

Its content and arising recommendations have been produced in line with the European Cancer Organisation's Policy Approval Pathway process.<sup>a</sup> The decision to initiate a Community 365 Roundtable on this topic was taken in the context of the recent publication of the EHDS legislative proposal by the European Commission and considering the strong focus that the ECO Digital Health Network places on the potential of digitalisation in cancer care. The Digital Health Network comprises representatives drawn from the European Cancer Organisation's Member Societies, Patient Advisory Committee members, Community 365,<sup>b</sup> and other invited stakeholders.

We thank all those who provided their time and expertise for the roundtable, gave comments and suggestions towards the completion of this summary, and who continue to support the work of the European Cancer Organisation in achieving high-level discussions and actions on digital health and cancer.

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## Contributors

Thanks are due to all who participated in the European Health Data Space and Cancer 2022 Roundtable, including speakers and those providing comments during and after the discussions. We also thank all member societies and patient organisations who contributed to the review of this paper during the Policy Approval Pathway process.

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- a. European Cancer Organisation's Policy Decision Making Process. <https://www.europecancer.org/2-uncategorised/24-policy-decision-making>
- b. Community 365 is a group of charity, philanthropy, and industry contributors to the Focused Topic Networks of the European Cancer Organisation. Community 365 provide ideas, guidance, practical support, and resources for our work in convening stakeholders and building consensus in the European cancer community. Community 365 contributors do not have a decision-making role in our policy work. Rather, policies of the European Cancer Organisation, such as those represented in this document, are agreed by our Board after consultation with our Member Societies and Patient Advisory Committee, via our Policy Pathway process. More information here: [www.europecancer.org/community-365](http://www.europecancer.org/community-365)

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## Executive Summary

This meeting brought together leading policy-makers, politicians, oncology experts, and patient advocates to discuss EU policy developments related to the ongoing digital transformation of cancer care, with a special focus on the opportunities and challenges associated to the creation of a European Health Data Space (EHDS), and its potential impact for the improvement of cancer care across Europe.

The Community 365 Roundtable Meeting on the European Health Data Space and Cancer aimed to:

- Increase awareness on what data can do for cancer, and what the European Health Data Space means for the oncology community,
- Identify lessons learnt from pre-existing EU-wide projects on data sharing,
- Explore European Health Data Space implementation challenges, including those related to GDPR and data interoperability,
- Provide political understanding and suggest next steps for the EHDS.

This roundtable was organised by ECO in collaboration with the Digital Health Network, one of the ten ECO Focused Topic Networks, and the Community 365 group of charity, philanthropy, and industry contributors to the Focused Topic Networks.

### Main outcomes from the roundtable include:

1. **Data silos:** Data silos should be torn down to improve cancer care, for example, by developing data translators, and taking a citizen-focused data sharing culture.
2. **Trust:** Data security, trust, respect for privacy, and transparency of the use and access of health data is key. Citizens and patients need to know how they can engage in the digital transformation of healthcare. There should be a harmonised, fit-for-purpose ethical approval process for secondary use across Europe.
3. **Applications for oncology:** The implementation of the EHDS can have positive implications for strengthening research and innovation in cancer care, and should actively complement Europe's Beating Cancer Plan<sup>1</sup> and Cancer Mission.<sup>2</sup>

4. **Multi-stakeholder collaboration:** Multi-stakeholder collaboration is key to ensuring the success of the EHDS. Collaboration between different stakeholders, and co-design by end-users will be critical for the successful development and implementation of the EHDS.
5. **Applying lessons learnt:** Lessons learnt from pilot projects in the secondary use of health data should be applied to maximise the success of the EHDS. Consideration should be given to deploying Federated Data Spaces using FAIR principles to overcome barriers to accessing health data. Similarly, experience with real-world data and real-world evidence initiatives point to the need to link data sets with a common data model / format, and thus ensure they are interoperable.
6. **Implementation:** Implementation guidelines should be drafted to support the roll-out and implementation of the EHDS at Member State level.

# Introduction

Wim Oyen, Co-Chair, Digital Health Network, European Cancer Organisation and Carlo Catalano, Co-Chair, Digital Health Network, European Cancer Organisation

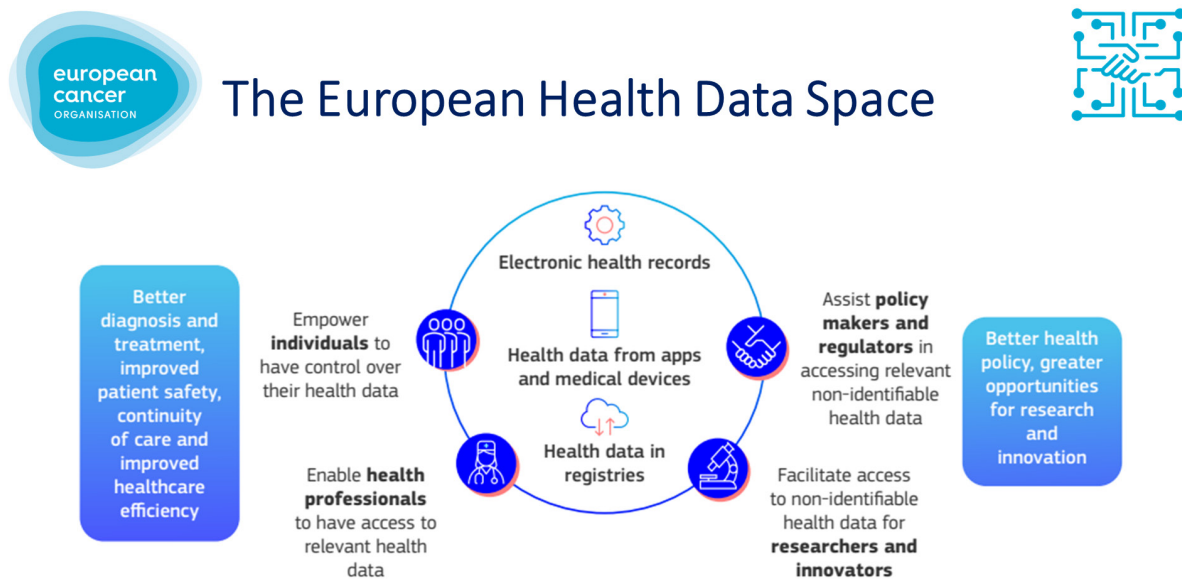
Digital transformation will play a key role in meeting the post-pandemic world's challenges related to healthcare. However, achieving this will require implementation of relevant policies to address critical challenges around accessibility, data interoperability, and digital literacy to ensure that no one is left behind during this digital transition. A successful digital health transition requires empowering patients, rethinking education and life-long training, and bringing about strong governance models that inspire and sustain public trust.

The oncology community is at a critical juncture in the digital health transition. There is a shared understanding by all stakeholders of the power of data and digital health solutions to advance cancer care. However, known obstacles remain.

It is therefore time to be precise about these, to prioritise, and take pragmatic and achievable actions.

The European Health Data Space Regulation (Picture 1), published in May 2022 by the European Commission, is expected to support such a successful digital health transition by promoting better exchange and access to health data, not only to support healthcare delivery, but also for research, regulatory, and policy-making purposes. Looking ahead at inter-institutional negotiations, as well as implementation, this Roundtable aimed at providing targeted feedback on the EHDS to the European institutions.

Picture 1. The European Health Data Space



# What Is the European Health Data Space, and What Does it Mean for Cancer Care?

## SUMMARY

- Academics, healthcare professionals, patients and leading policy-makers at the European Commission provided perspectives and context on how better use of oncology data can drive improvement in cancer care.
- The roundtable examined the level of readiness in Europe for the kind of enhanced cooperation on health data envisaged by the EHDS and provided an understanding of key concepts and measures including in the current EHDS proposal.
- Main conclusions included:
  - » Like many other types of ‘silos’ across healthcare, health data silos exist preventing sharing and pooling of data that otherwise could be useful in cancer care and research.
  - » Citizens and patients often lack the knowledge on how to effectively navigate and utilise emerging digital health technologies.
  - » Experience with the GDPR has left many stakeholders wondering how aspects related to data security, trust, respect for privacy, and transparency will be addressed within the EHDS.

**This session was chaired by Carlo Catalano, Co-Chair, Digital Health Network, European Cancer Organisation and Greg Rossi, Senior Vice President Head of Oncology Europe and Canada, AstraZeneca.**

### Participants

- **Mark Lawler, Board Member, European Cancer Organisation and Professor of Digital Health, Queen’s University Belfast (QUB)**
- **Kjeld Hansen, Chair, European Lung Foundation (ELF)**
- **Jerome de Barros, Policy Officer, European Reference Networks and Digital Health unit, DG SANTE, European Commission**

The audience was polled to reveal their perspectives on the EHDS and cancer care (Picture 2, 3 and 4).

Greg Rossi, Senior Vice President Head of Oncology Europe and Canada, AstraZeneca, opened by describing how digital technologies are being used to improve patients’ outcomes and how it will play an ever-increasing role in cancer care. For this to

work in practice, a trusted, interoperable framework is required to help accelerate wider roll-out and uptake.

### Tear Down the Data Silos

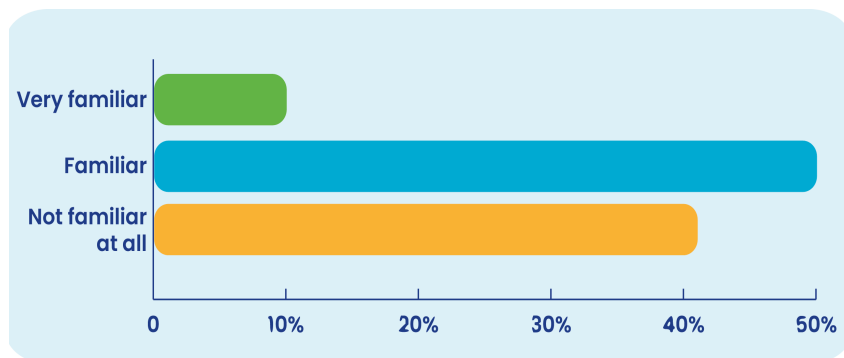
*What can data do for cancer care?*

Mark Lawler, Board Member, European Cancer Organisation stated that a digital health transition agenda goes hand in hand with improving patients’ outcomes in cancer care. Such an agenda is comprised of three elements: Breaking down the silos; learning from the data; and big data for better health.

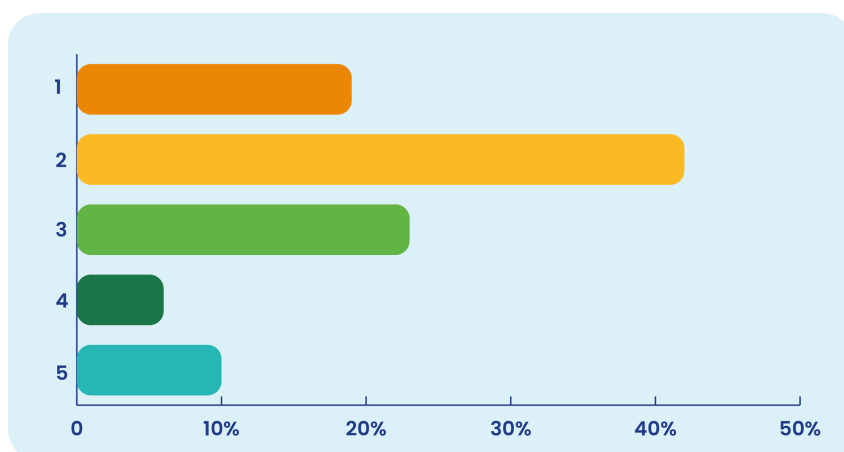
Mark Lawler made references to several recent initiatives related to digital health and cancer.

The European Cancer Patient’s Bill of Rights<sup>3</sup> has been driving policy, empowerment, and change. Empowering a citizen-centred data-driven ecosystem is key to driving R&D, enabling more effective prevention and early diagnosis, facilitating data-enhanced discovery, nurturing recovery and rehabilitation, and underpinning industry partnerships and innovation.

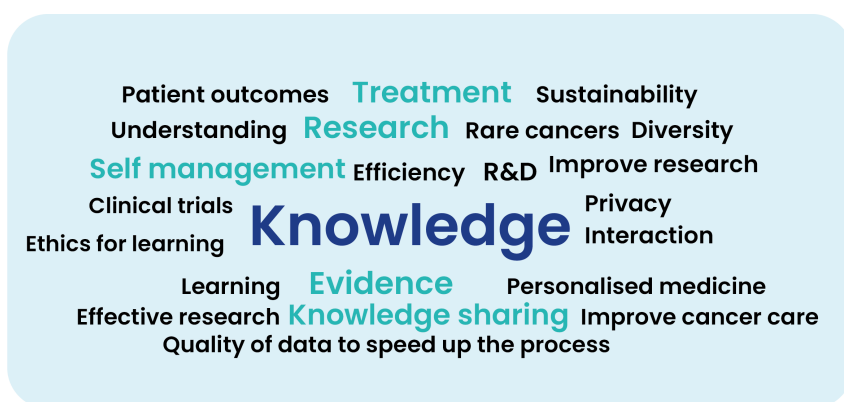
Picture 2. How familiar do you feel with the European Health Data Space?



Picture 3. On a scale of 1 to 5 how well do you consider your country is achieving the full benefit of data-sharing in cancer care?



Picture 4. Why do you feel that better sharing of data is important to improve cancer care?



Championing a citizen-focused data sharing culture will help facilitate access to data to enable innovative research, establish a Cancer Data Knowledge Network<sup>4</sup>, and move away from a closed, 'selfish silo' culture to a more open source 'collaborative culture'. In this respect, there is a need to establish and maintain public trust in the use of big data to ensure a citizen-focused perspective.

Another pivotal action is the need to transform the data landscape by transcending disciplines. Lawler

cited over 25 different professionals that could be considered to help maximise the power of data for the cancer community. Overall, patients need to be at the heart of this, such as in the DATA-CAN project - an example of best practice for patient involvement. (Picture 5)

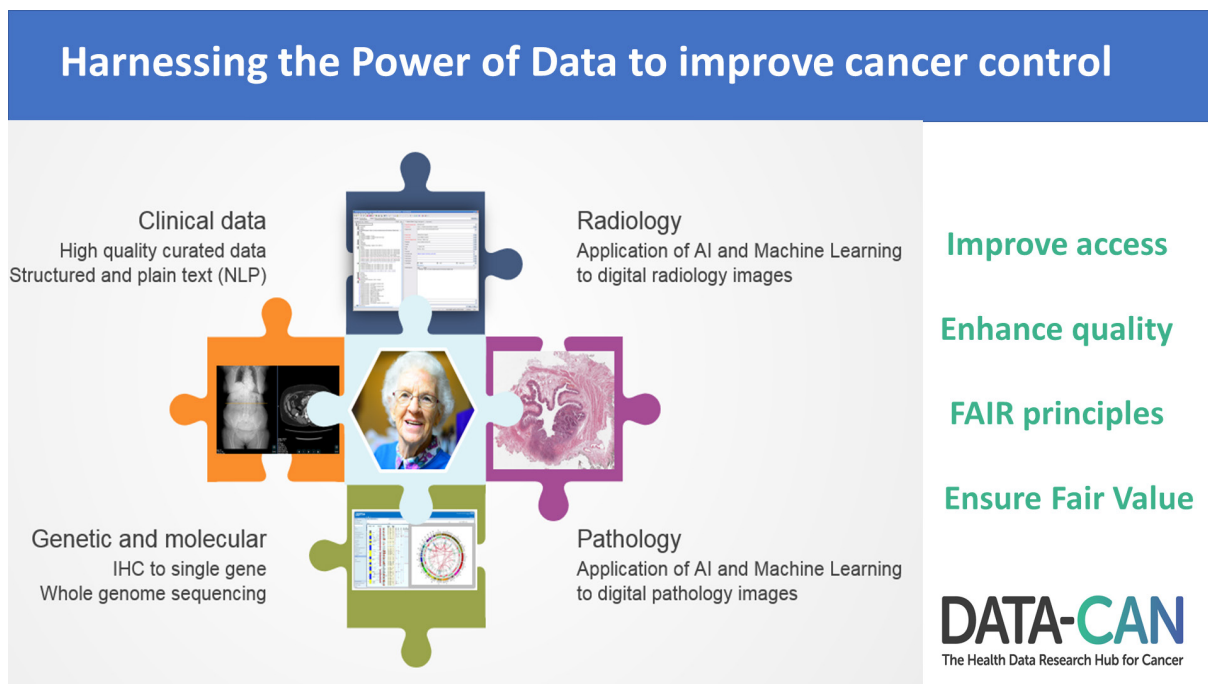
Additionally, one way of breaking down the data silos is to create a 'data translator' for enhanced cancer care. An example of this is the Variant Interpretation for Cancer Consortium (VICC).



## DATA-CAN – The Health Data Research Hub for Cancer

DATA-CAN is the UK's Health Data Research Hub for Cancer. DATA-CAN's aim is to make high quality health data more accessible for cancer researchers and health professionals, and to help improve cancer services and patient outcomes. Patients are involved in decisions at all levels for DATA-CAN, for example, on the Steering Board, Management Group, and specific projects.

Picture 5. Harnessing the Power of Data to improve cancer control



The VICC 'Meta-Knowledgebase' aggregates all known information about gene mutations and variants of uncertain significance into a single searchable resource for the cancer community.<sup>5</sup>

*Cancer must not become the forgotten "C" in the fight against Covid-19.*

The world changed as a result of the Covid-19 pandemic. This in turn led to the creation of the ECO Special Network on the Impact of Covid-19 on Cancer, and the development of a 7-Point Plan to build back better using data. For this, a data intelligence study was conducted at EU level that revealed Covid-19's impact on cancer screening, diagnosis, and on cancer patients and professionals. Ultimately, this allowed ECO to develop and launch the Time To Act campaign and Data Navigator, which uses data to drive policy, and to unite cancer patients, citizens, HCPs, policy-makers, and health system leaders.<sup>6</sup>

In conclusion, tearing down the data silos will

improve cancer care across Europe.

### What Does Digitalisation Mean for Patients?

Kjeld Hansen, Chair, European Lung Foundation (ELF) provided the patient perspective on data-sharing, with critical areas of concern including privacy, patients' participation, data rights, data issues, diversity, and inclusiveness.

Considering the growing importance of digital health and the need to include patients, the ELF has recently launched a new initiative, the ELF's European Patient Ambassador Programme (EPAP), which is a free, online self-learning programme that introduces patients and carers to some of the basic skills and knowledge needed to represent themselves and others successfully on digital health issues. ELF has also developed Factsheets in Telemedicine and Data Sharing in Healthcare.

The Covid-19 pandemic forced both healthcare providers and patients to make rapid adaptations to how they provide and access healthcare. For lung

patients, digitalisation meant that in many settings, patients were able to speak with HCPs via telephone and video calls and this is expected that a mix of face-to-face and virtual engagements will become the norm in the future. However, more research is still needed to understand the effectiveness of such services.

There are several additional digital tools that patients are using to manage their condition, including sharing photos or videos, virtual wards and home monitoring, health apps, online journaling and questionnaires, online rehabilitation and activity sessions, and wearable devices. Perceived benefits of these digital interventions include: a reduced need to travel; a more relaxed setting; infection control; improved access to specialists; and improved collaboration and empowerment. However, the challenges that need to be addressed include changes in structures in healthcare settings; access and education; data security; and medical ethics and relationships. In addition, patients are also expressing concerns about their data security and are therefore seeking guidelines on data sharing, on data security, and their rights under GDPR.

From the patient perspective:

- Meaningful use of digital health is motivating, liberating, and inclusive
- Use of digital health services and health data must have a clear purpose. Patients need to know how they can engage, and for what purpose their data will be used for
- Feeling safe and having a sense of trust is critical, including understanding who will have access to patients' data
- There is still a lot to do to help patients realise, learn, and manage digital health systems and their digital self.

## Discussion

Carlo Catalano, Co-Chair, Digital Health Network, European Cancer Organisation (ECO), and Professor, Department of Radiological, Oncological and Pathological Sciences, Diagnostic Radiology, Sapienza University of Rome, opened the discussion by asking what the expectations are from HCPs and patients for the European Health Data Space.

There are big expectations, but also big challenges. While this is a huge opportunity to work together, concerns were expressed over various national

interpretations and the need to explore the issue of underserved communities.

The EHDS will allow researchers to collect much more data related to quality of life (QoL), survivorship, and follow-up. With the expansion of data repositories and AI, this information will improve treatments and medication, and it will also facilitate bringing in expertise at the right time and place, and with patients being able to participate. Digital health innovations will also allow healthcare professionals to reach out to more patients than before, and in enhanced ways.

Lessons learnt that can be applied for the implementation of the EHDS include on the one hand, working with linked datasets of a whole country, and on the other hand, recognising the critical importance of patients and citizens' involvement.

## What Is the European Health Data Space?

Jerome de Barros, Policy Officer, European Reference Networks and Digital Health Unit, DG SANTE, European Commission, provided an overview of the EHDS proposal.

In order to unleash the full potential of health data, the European Commission has presented a regulation to set up the European Health Data Space, which:

- supports individuals to take control of their own health data
- supports the use of health data for better healthcare delivery, better research, innovation and policy-making
- enables the EU to make full use of the potential offered by a safe and secure exchange, use and reuse of health data.

The Covid-19 pandemic has clearly demonstrated the importance of digital services in the health area. The uptake of digital tools increased significantly during this time. However, the complexity of rules, structures and processes across Member States makes it difficult to access and share health data, especially cross-border. In this context, the EHDS builds further on the GDPR, proposed Data Governance Act, draft Data Act and NIS Directive. It complements these initiatives and provides more tailor-made rules for the health sector. Ultimately, the EHDS is one of the central building blocks of a strong European Health Union. The EHDS will help the EU to achieve a quantum leap forward in

## THE EUROPEAN HEALTH DATA SPACE

The European Health Data Space legislative proposal, published in May 2022, is a health-specific ecosystem comprised of rules, common standards and practices, infrastructures, and a governance framework that aims to:

- empower individuals through increased digital access to, and control of their electronic personal health data, at national and EU-wide levels, and to support their free movement,
- foster a genuine single market for electronic health record systems, relevant medical devices, and high-risk AI systems (primary use of data),
- provide a consistent, trustworthy, and efficient set-up for the use of health data for research, innovation, policy-making, and regulatory activities (secondary use of data).

the way healthcare is provided to people across Europe. It will empower people to control and utilise their health data in their home country or in other Member States. It fosters a genuine single market for digital health services and products. And it offers a consistent, trustworthy and efficient framework to use health data for research, innovation, policy-making and regulatory activities, while ensuring full compliance with the EU's high data protection standards.

### Putting people in control of their own health data, in their country and cross-border:

- Thanks to the EHDS, people will have immediate, and **easy access to the data** in electronic form, free of charge. They can easily **share** these data with other health professionals in and across Member States to improve healthcare delivery. Citizens will be in full control of their data and will be able to add information, rectify wrong data, restrict access to others and obtain information on how their data are used and for which purpose.
- Member States will ensure that patient summaries, ePrescriptions, images and image reports, laboratory results, discharge reports are issued and accepted in a common European format.
- Interoperability and security will become mandatory requirements. Manufacturers of electronic health record systems will need to certify compliance with these standards.
- To ensure that citizens' rights are safeguarded, all Member States have to appoint digital health authorities. These authorities will participate in the cross-border digital infrastructure (MyHealth@EU) that will support patients to share their data across borders.

### Improving the use of health data for research, innovation and policy-making:

- The EHDS creates a strong legal framework for the use of health data for research, innovation, public health, policy-making and regulatory purposes. Under strict conditions, researchers, innovators, public institutions or industry will have access to large amounts of high-quality health data, crucial to develop life-saving treatments, vaccines or medical devices and ensuring better access to healthcare and more resilient health systems.
- The access to such data by researchers, companies or institutions will require a permit from a health data access body, to be set up in all Member States. Access will only be granted if the requested data is used for specific purposes, in closed, secure environments and without revealing the identity of the individual. It is also strictly prohibited to use the data for decisions, which are detrimental to citizens such as designing harmful products or services or increasing an insurance premium.
- The health data access bodies will be connected to the new decentralised EU-infrastructure for secondary use (HealthData@EU) which will be set up to support cross-border projects.

### Discussion

The EHDS will help research and innovation by facilitating the secondary use of data, with direct implications for the research and innovation in the oncology community. Under the proposal, any data

holder should make it known that they have data, via a dataset description. There will be a common procedure across Member States for a data permit for researchers to help identify relevant data for their research. This permit will allow access in a secure way.

Data holders will be limited to the health and care sector, and the system will be focused on categories of data. There will also be a data quality and integrity label. Linking with the GDPR, the European Commission is proposing the EHDS as a Regulation,

which will not modify the existing legal framework, but will add-on, and complement it.

## Concluding Remarks

The EHDS has direct and relevant implications for Europe's Beating Cancer Plan and the oncology community. A significant amount of progression has already been made across EU countries in the digital transformation of care, with key implications for the oncology community – as will be explored in the next section of the report.

## KEY POLICY RECOMMENDATIONS

- Data silos should be torn down to improve cancer care by developing data translators and taking a citizen-focused data sharing culture
- Citizens and patients need to know how they can engage in the digital transformation of healthcare
- Data security, trust, respect for privacy, and transparency of the use and access of health data are key
- The implementation of the EHDS has implications for strengthening research and innovation in cancer care and will complement Europe's Beating Cancer Plan and other data legislations such as GDPR

## FIND OUT MORE

- **DATA-CAN – The Health Data Research Hub for Cancer.**  
data-can.org.uk
  - » See also BMJ Opinion piece on DATA-CAN  
bit.ly/BMJ\_DATACAN
- **VICC – Variant Interpretation for Cancer Consortium**  
cancervariants.org
- **ECO Special Network on the Impact of Covid-19 on Cancer and 7-Point Plan**  
bit.ly/Covid19\_Network  
bit.ly/7\_Point\_Plan
- **ECO Time To Act campaign and Data Navigator**  
europeancancer.org/timetoact  
europeancancer.org/data-navigator
- **ELF – European Lung Foundation**  
europeanlung.org/en
- **EPAP – European Patient Ambassador Programme**  
bit.ly/ELF\_EPAP
- **EHDS – The European Health Data Space: Proposal for a Regulation**  
bit.ly/EHDS\_Proposal
- All.Can International Report 'Harnessing Data For Better Cancer Care'  
bit.ly/AllCan\_Report
- **Data Saves Lives**  
datasaveslives.eu

# How can we leverage lessons from European data initiatives for the European Health Data Space?

## SUMMARY

- Experts from leading EU supported health data projects provided their insights and experiences on the development of a shared infrastructure between countries for data sharing
- Experience has shown that as technology has evolved in the digital age, there has been development of different data models and formats, which makes it time consuming and resource intensive to connect the different datasets
- However, there are several successful examples related to the design and implementation of future-proof digital health data projects, and lessons should be learnt from them for the design and implementation of the EHDS

This session was chaired by Wim Oyen, Co-Chair, Digital Health Network, European Cancer Organisation and Richard Price, Head of Policy, European Cancer Organisation.

### Participants

- **Juan Abellan, Data Analytics and Methods Task Force, European Medicines Agency (EMA)**
- **Bertrand de Meulder, Senior Researcher, European Institute for Systems Biology and Medicine (EISBM)**

Wim Oyen, Co-Chair, Digital Health Network, European Cancer Organisation, and Professor, Diagnostic Imaging and Radiotherapy at Humanitas University in Milan, Italy, explained that this session's objective was to learn lessons from existing EU data projects ahead of the implementation of the EHDS.

Richard Price, Head of Policy, European Cancer Organisation introduced the following two exemplar initiatives in respect to sharing health data.

## DARWIN EU: A Federated Network to Support Better Decision-Making

Juan Abellan, Data Analytics and Methods Task Force, European Medicines Agency (EMA), and DARWIN EU Data Analytics and Methods Task Force presented the DARWIN EU initiative in the context of the European Medicines Regulatory Network (EMRN) Strategy 2025, which aims to enable Real-World Evidence (RWE) and the value established across the spectrum of regulatory use cases by 2025. According to the Heads of Medicines Agencies / European Medicines Agency Big Data Steering Group (HMA/EMA BDSG) Workplan 2021/2023, one of the 11 recommendations was to create a platform for collecting RWE databases, which ultimately became the DARWIN EU initiative.

DARWIN EU aims to:

- provide scientific expertise in formulating and executing studies and analyses
- maintain a catalogue of known, relevant data holders, continually ensuring the discoverability and quality held by data holders

## DARWIN EU

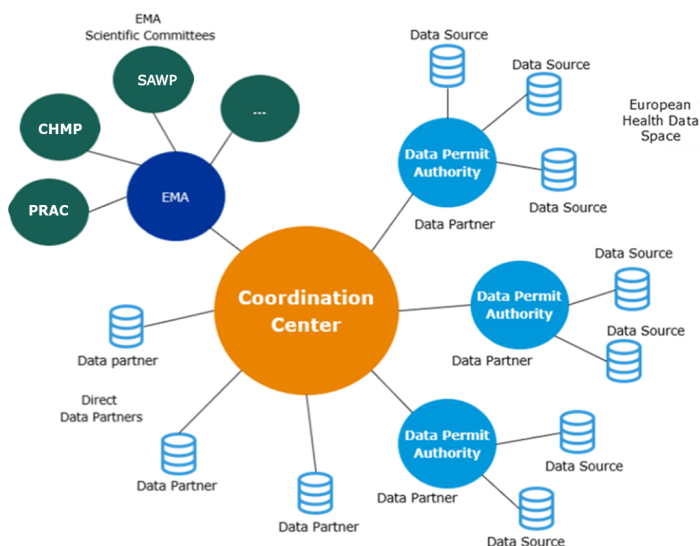
The Data Analysis and Real World Interrogation Network for Europe (DARWIN EU) is a federated network of data, expertise, and services that supports better decision-making throughout the product lifecycle by generating reliable evidence from real world healthcare data (Picture 6).

Picture 6. DARWIN EU

DARWIN EU® is a federated **network of data, expertise and services** that supports better decision-making throughout the product lifecycle by generating reliable **evidence from real world healthcare data**

**FEDERATED NETWORK PRINCIPLES**

- Data stays **local**
- **Use of Common Data Model** (where applicable) to perform studies in a timely manner and increase consistency of results



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- maintain and expand the federated network of data partners, assisting new data holders in conforming with required standards for usage in the regulatory context
- conduct scientific studies and analyses on behalf of the EMRN and EMA scientific committees
- deliver training, governance, support of business services
- enable the EMRN, EMA, and the scientific committees to make use of the EHDS in the context of medicines regulation, acting as the EHDS ‘pathfinder’.

Data sources for DARWIN EU will comprise those from general practitioners (GPs), medical specialists, electronic health records (EHRs), and insurance claims databases, and will cover a wide geographical area, including beyond the EU. For data sources containing patient-level data, there will be a unique identifier linking all the records relating to a given patient, but the patient will not be identifiable. Additionally, data on medicines prescribed or dispensed will also be included. Clinical events will be formally coded, and data will be converted into a common data model.

The beneficiaries of DARWIN EU will include EU patients and HCPs, the European Commission, National Competent Authorities, HTA bodies and payers, EU and international health agencies,

academia and research organisations, and industry (Picture 7).

While the needs and use cases of medicine regulators and decision-makers are driving DARWIN EU’s development, DARWIN EU will also contribute to developing the EHDS and the joint action to deliver European principles for the secondary use of health data (TEHDAS). Indeed, acting as an early flagship ‘pathfinder’ for the EHDS, DARWIN EU enables the exchange of healthcare data for use in healthcare delivery, policy-making and research across Europe, while fully complying with data protection requirements.

**OPTIMA: Tackling Cancer Through Real-World Data and Artificial Intelligence**


Bertrand de Meulder, Senior Researcher, European Institute for Systems Biology and Medicine (EISBM) provided an overview of the Innovative Medicines Initiative (IMI) OPTIMA project – Tackling cancer through real-world data (RWD) and artificial intelligence. The OPTIMA project currently has 36 partners across nine countries and is still growing.

The objectives of OPTIMA are:


- to establish a data catalogue by harmonising large-scale, structured, and unstructured real-world datasets from EHRs and other types of RWD
- to develop a secure and interoperable platform to host harmonisation tools, federated learning



Picture 7. Who will benefit from DARWIN EU?


  
 EUROPEAN MEDICINES AGENCY








## Who will benefit from DARWIN EU®?



### EU medicines regulators

- **Drug development** – disease epidemiology, unmet need, historical controls, planning
- **Authorisation** – contribution to benefit-risk, controls, extrapolation to general and/or special populations
- **Post-authorisation** – benefit-risk monitoring, extension of indication, risk minimisation measures

DARWIN EU® will **increase the capacity** of the EMRN to undertake high-quality observational studies based on RWD and **reduce the time** per study

- 
**EU patients and healthcare professionals**  
 Faster access to innovative medicines and safe and effective use
- 
**European Commission**  
 Key use case for the European Health Data Space
- 
**National competent authorities**  
 Support health policy and delivery of healthcare systems
- 
**HTA bodies and payers**  
 Support better quality decisions on cost-effectiveness
- 
**EU and international health agencies**  
 Use cases specific for other EU Agencies such as ECDC
- 
**Academia and research organisations**  
 Increase use of RWE, methodology development, and better data quality
- 
**Industry**  
 Enable better evidence supporting decision-making, increase receptiveness for RWE in MA submissions, and reduce time & cost of drug development

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## OPTIMA

The Innovative Medicines Initiative OPTIMA project aims to ensure that every patient has access to the most up-to-date individualised treatments and innovative therapies. By strengthening shared decision-making through dynamic computer-interpretable guidelines (CIGs), innovative access to broad data sets, and AI-driven technology and tools, OPTIMA envisions revolutionising oncology care in Europe (Picture 8).

tools and AI algorithms, and guideline-based decision support tools

- to develop a scalable and regularly updated guideline decision-support toolset as part of the platform for three indications: prostate, breast, and lung cancer
- to drive new knowledge generation through advanced analytics and AI-models
- to ensure the sustainability of OPTIMA's platform by supporting business models based on commercial uses.

The OPTIMA project has a specific focus on breast, prostate, and lung cancer; however, the intention is to extend the project to other cancer types in the future. OPTIMA is a platform with AI to plug gaps in the system, and is a federated, hybrid data system. The platform can help all users see data relevant to them, as well as in a format that is understandable to them.

Critical to the success and functioning of

such a project is the data mapping to 'OMOP' (Observational medical outcomes partnership). OMOP is an open community data standard to structure observational data and enable efficient analyses by for example, standardised vocabularies for medical terms (Picture 9).

Several lessons learnt can be headed from the OPTIMA project:

- The Healthdata@EU list of datasets that are already available will save time and resources (as finding datasets is resource intensive).
- Standardisation and mapping of data to OMOP is crucial, and resource intensive.
- Collaboration between all stakeholders is key. It takes time and resources to bring patients and clinicians onboard. Co-designing the programme is encouraged. It should be noted that this process is significantly different from randomised-controlled trials.
- Federation (privacy by design) has advantages, but there is also a value to centralisation (as

not all stakeholders have access to the same technology to read data).

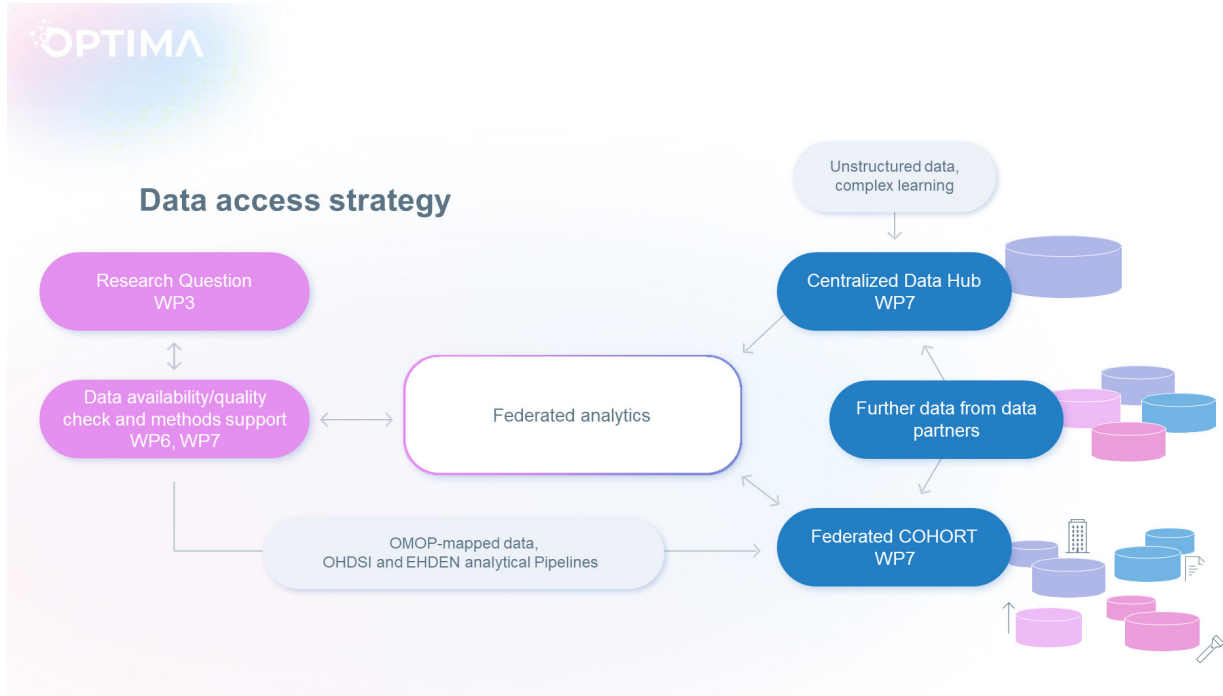
harmonisation of different vocabularies for diseases has proven useful.

**Discussion**

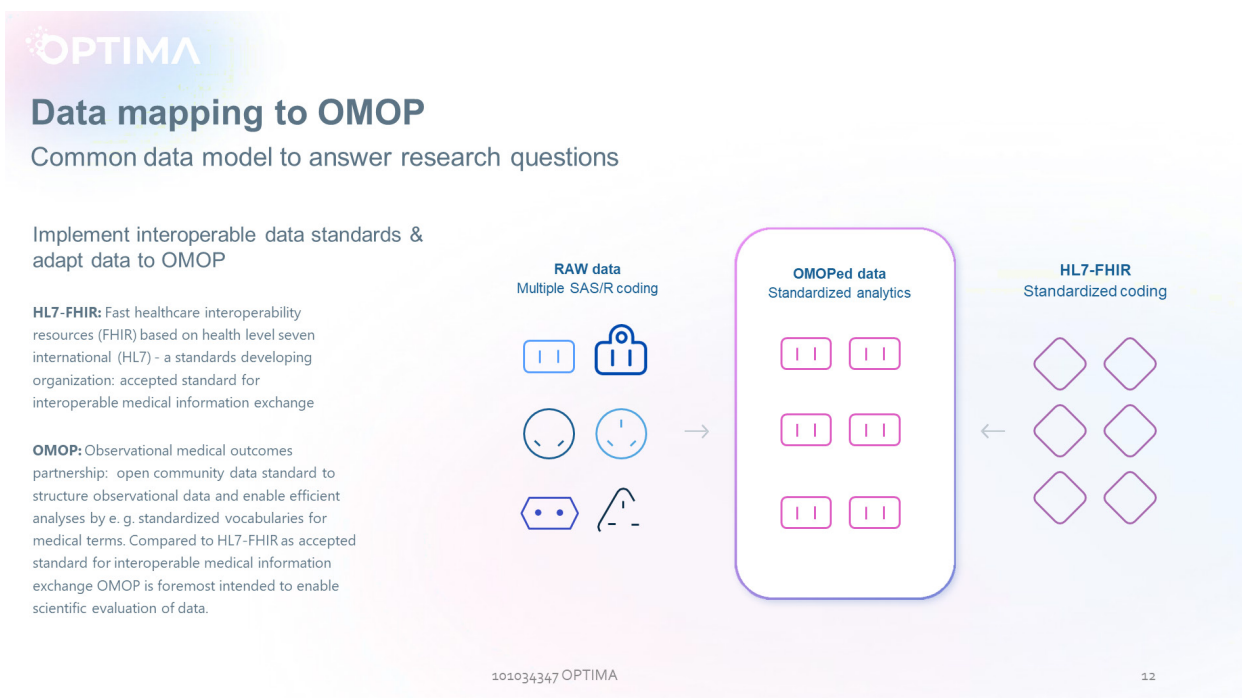
In the discussion, comparisons were drawn between the successes and pitfalls from establishing DARWIN EU, and the impending implementation of the EHDS. Conversion to a common data model/ common data format has been critical. Additionally,

The discussion moved on to whether there is any risk of large-scale EU data projects potentially operating in silos from each other, and how, for example, could DARWIN EU and OPTIMA connect with the EHDS. This could be possible so long as it is done with the right standards, for example, OMOP by default. DARWIN

**Picture 8. OPTIMA – Data access strategy**



**Picture 9. OPTIMA – Data mapping to OMOP**





EU and OPTIMA both use OMOP, and therefore are interoperable. In the case of the OPTIMA project, the tools are being developed 'disease-agnostically', meaning the platform can be plugged-in to every

clinical and research centre. It is hoped that OPTIMA and DARWIN EU will inspire the EHDS when it comes to the use of standards analytics.

## KEY POLICY RECOMMENDATIONS

- Experience with real-world data and real-world evidence initiatives point to the need to link data sets with a common data model / format to ensure their interoperability. As such, in order to further boost interoperability of health data exchanges, this is recommended that EU targets/indicators for interoperability of health data exchanges be committed to in the EHDS legislation, mainly in the form of guidance on standards, leveraging the learnings from previous EU projects.
- Collaboration between different stakeholders, and co-design by end-users, will be critical for the development and implementation of the EHDS. Stakeholder engagement should be fundamentally integrated into the governance of the EHDS with specific provisions, ensuring that health data exchange in Europe is based on the core principles of openness and transparency.
- Traditional centralised architectures for health data sharing have shown their pitfalls and building the EHDS on a federated structure might be a solution to the most common health data sharing challenges.

## FIND OUT MORE

- **DARWIN EU – Data Analysis and Real-World Interrogation Network**  
[bit.ly/DARWIN\\_EU](https://bit.ly/DARWIN_EU)
- **EMRN Strategy to 2025 – European Medicines Regulatory Network's (EMRN) Strategy to 2025**  
[bit.ly/EMRN\\_Strategy](https://bit.ly/EMRN_Strategy)
- **OPTIMA – Tackling cancer through real world data and artificial intelligence**  
[optima-oncology.eu](https://optima-oncology.eu)
- **OMOP – Observational medical outcomes partnership**  
[ohdsi.org/omop](https://ohdsi.org/omop)
- **European health Data & Evidence Network**  
[ehden.eu](https://ehden.eu)

# How Can We Address Implementation Challenges for the EHDS?

## SUMMARY

- Interoperability and data standardisation are long known challenges to overcome in respect to achieving enhanced health data sharing. Experts highlighted the opportunities, approaches and case studies that demonstrate how such obstacles can be overcome.
- Key challenges for the EHDS are: misinterpretation of data rules and regulations, fragmentation of health datasets across the global and multiple administrative, ethical, political, and technical barriers to access data.

This session was chaired by **Carlo Catalano, Co-Chair, Digital Health Network, European Cancer Organisation** and **Sabine Dörhöfer, Standard Domain Lead, Roche Diagnostics International.**

### Participants

- **Andre Dekker, Professor of Clinical Data Science, Maastricht UMC+**
- **Linda Abboud, Researcher and project manager- EU health information system, Sciensano**
- **Sarah Collen, EU Policy Manager, European Association of Urology (EAU)**

## Multiple Implementation Challenges for the EHDS

Linda Abboud, Researcher, and project manager- EU health information system, Sciensano, provided an overview of the TEHDAS Joint Action.

A literature review was performed in order to look for barriers to cross-border healthcare data sharing as part of a prioritisation exercise for TEHDAS. The categories of barriers identified included those related to infrastructure, legal, data, and trust issues. The review found that most barriers are legal and result from misinterpretation, or misalignment of implementation of data sharing rules.

With respect to legal barriers, while the General

Data Protection Regulation (GDPR) is a much-appreciated piece of legislation, variations in the implementation of the law have led to a fragmentation of approach which makes cross-border cooperation for care provision, and research difficult. Reported problems include a lack of guidance on what constitutes anonymisation and pseudonymisation of health data. Many suggest it is also contributing to a risk-averse culture which further hampers the environment for cross-border cooperation in data sharing for research purposes.

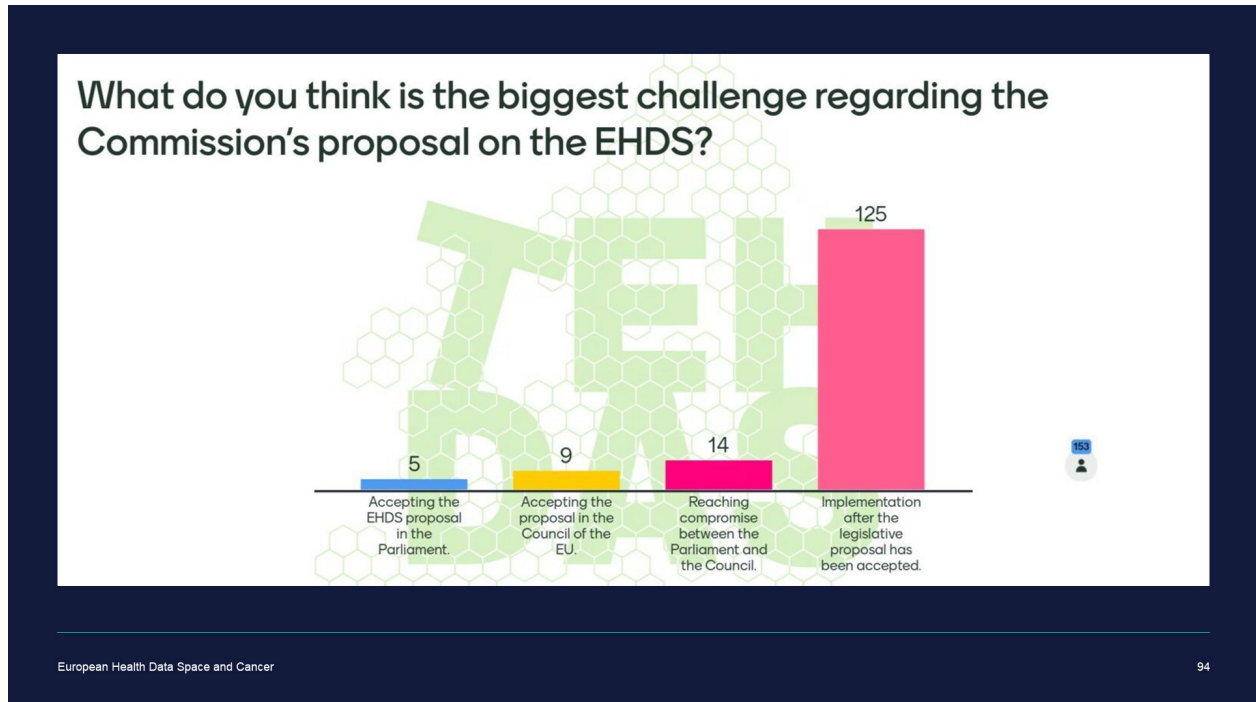
Additionally, the review identified inconsistencies with the definition of secondary data. There is no common European interpretation of what is, and what is not, 'secondary use' of data. This European level definition of the secondary use of health data, especially the lack of clarity around consent, is a barrier to research. As a result, certain research studies cannot be conducted due to unclear definition of what is secondary use of health data, its purpose and whether it is compatible with what is allowed. As such, it is crucial that the EHDS includes specific provisions outlining the definitions and addressing this lack of alignment. An alternative option could be to produce a reference document at EU level.

During a related piece of research within TEHDAS, participants were asked the following question: *What do you think is the biggest challenge regarding the Commission's proposal on the EHDS?*

## Joint Action Towards the European Health Data Space – TEHDAS

The TEHDAS Joint Action project aims at developing European principles for the secondary use of health data. The results of the TEHDAS project are providing input into the European Commission's legislative proposal for a European Health Data Space and are also supporting the pan-European dialogue that follows the proposal.

Picture 10. What do you think is the biggest challenge regarding the Commission's proposal on the EHDS?



In response, 125 out of 153 respondents replied: *Implementation after the legislative proposal has been accepted.* As such, TEHDAS is drafting an implementation document to address these concerns.

### Personal Health Train: A Federated Data Network to Overcome Barriers to Health Data Sharing

Andre Dekker, Professor of Clinical Data Science, Maastricht UMC+, presented proposals to overcome data sharing obstacles, including FAIR data principles, a Federated structure for the EHDS, and aspects of data quality. A significant problem with health data is the fragmentation of the health data landscape. Additionally, there are multi-factorial barriers to sharing data such as administrative, ethical, political, and technical obstacles.<sup>7</sup>

Modern health research generates and requires vast amounts of data captured and stored at different locations. Managing these data in a centralised database is hardly feasible. The Personal Health Data Train was designed to enable healthcare innovators and researchers to work with health data from various sources. It can give controlled access to data, while ensuring privacy protection and optimal engagement of individual patients and citizens. This can be achieved via a Federated Data Infrastructure, being an example of a multi-country federated data set comprising over 37.000 NSCLC patients.<sup>8</sup>

The essence of the Personal Health Data Train approach is that the research question travels to the data source 'stations' rather than data from various sources having to be transported to the research question. So, sensitive data remains where it is. The Personal Health Data Train can transport 'workflows' for complex research questions. The Personal Health Data Train connects different data 'stations'. Stations can range from very large databases to small personal lockers containing the data of one person. Each station has its own set of house rules describing what a visiting 'train' is allowed to do with their data.

The following lessons learnt can be taken from the Personal Health Data Train:

- It is recommended that the EHDS takes a federated approach, as health data often comes from multiple (non-health) sources. A federated approach ensures that data access/permit is controlled by the data holder (assuring control and sovereignty), and that data quality is dealt with at the source. With a federated data approach, the focus is on the question, rather than on the data, which helps to determine the data elements that need to be made FAIR, as well as the required quality of data. Furthermore, the question can be used to estimate cost/payments/fees and can be evaluated by Data Access Bodies.



## Discussion

The importance of secondary use for both patient outcomes and diagnostics alike was stressed. Additionally, being as flexible as possible was noted as a critical factor, as the data structure is not necessarily the same everywhere.

## MyHealth@EU

MyHealth@EU is an EU-wide system to ensure access to electronic cross-border health services (ePrescriptions and Patient Summaries) in the event of a health emergency during a stay in another EU country.

## KEY POLICY RECOMMENDATIONS

- Produce implementation guidelines to support the roll-out and implementation of the EHDS at Member State level.
- Advance interoperability of health data through federated data networks by establishing a clear governance framework for federated data networks within the EHDS.
- Develop a harmonised, fit for purpose ethical approval process for secondary use of data across Europe.

## FIND OUT MORE

- **TEHDAS – Joint Action Towards the European Health Data Space**  
[tehdas.eu](http://tehdas.eu)
- **Personal Health Data Train**  
[pht.health-ri.nl](http://pht.health-ri.nl)
- **MyHealth@EU**  
[bit.ly/MYHEALTH\\_EU](https://bit.ly/MYHEALTH_EU)

# In Conversation With the Policy-Makers

## SUMMARY

- A legal proposal can set out what the law should be on a certain topic, and, in the case of the European Health Data Space, underpin its operation with a strong legal foundation. However, ultimately, the real test of implementation will be at the national level. National experts looked beyond the passage of EHDS legislation and examined the perspectives of those in-country with future responsibilities for EHDS implementation.
- There are multiple challenges for implementation of the EHDS across Member States. However, there are also several examples of pilot projects and pathfinder initiatives that can provide stakeholders and policy-makers with valuable lessons learnt for the EHDS implementation at the national level.

This session was chaired by Wim Oyen, Co-Chair, Digital Health Network, European Cancer Organisation and Bartek Madej, Head of Digital and Innovation, Southern Europe Russia Ukraine CIS Central Europe, Novartis Oncology.

### Participants

- Tilly Metz MEP, Representative, Greens/EFA Group, Committee on Environment, Public Health and Food Safety (ENVI)
- Maria Hassel, Senior Advisor and International Coordinator, Swedish eHealth Agency
- Mélodie Bernaux, Project Director, eHealth Delegation, French Ministry of Health and Prevention

### The French Health Data Hub: A Pathfinder for the EHDS

The intervention for Mélodie Bernaux, Project Director, eHealth Delegation, French Ministry of Health and Prevention, was added to this report post-event.

The European Health Data Space proposal was published under the French Council Presidency, and to coincide with this, the French Presidency published the European principles for ethics in digital health in February 2022, containing 16 ethical principles for digital health. These 16 principles

reflect European values and are divided into four areas: Base digital health on humanistic values; Enable individuals to manage their digital health data; Make digital health inclusive; and Implement eco-responsible digital health. This supportive document can pave the way for the EHDS implementation to ensure that the EHDS is built on citizens' 'trust.

### Save Lives: Share Your Health Data

Bartek Madej, Head of Digital and Innovation, Southern Europe Russia Ukraine CIS Central Europe, Novartis Oncology opened the next part of the session.

Maria Hassel, Senior Advisor and International Coordinator, Swedish eHealth Agency provided an overview of the Swedish government's Vision for eHealth 2025, which is an agreement between the government and the regions. It aims at ensuring that in 2025, Sweden will be best in the world at using the opportunities offered by digitisation and eHealth to make it easier for people to achieve good and equal health and welfare, and to develop and strengthen their own resources for increased independence and participation in the life of society.

This strategy proved to be successful. During the pandemic, it was found that the services already in place, such as telemedicine, have been increasingly

## French Health Data Hub

The French Health Data Hub, is a pilot project for the EHDS and the secondary use of health data. The objective of the French Health Data Hub is to enable project coordinators to easily access data in order to improve the quality of care and patient support. The French Health Data Hub features non-nominative data which is hosted on a secure platform, in compliance with regulations and citizens' rights.

taken up. However, regulatory challenges were still identified, resulting in the need to review current regulations to support this digital transformation.

Trust and willingness to share data go hand in hand. The Swedish public is already positive about sharing their health data for research and health promotion purposes, as this is built on a solid and robust foundation. It was noted that 95% of rare disease patients are willing to share their data, compared to 37% of non-rare disease patients. In the context of the upcoming EHDS implementation where a European level of trust is being added, it is necessary to build this trust by handling health data safely and securely.

*Would you be willing to share your health data if it could help save someone's life?*

### Improving Patient Care Should Be Our Guiding Objective

MEP Tilly Metz, Member of the European Parliament (Greens, Luxembourg) emphasised her considerations about the importance of the EHDS finding the right balance between promoting innovation for better patients' outcomes, and the protection of patients' privacy.

The use of data has been, and still is, an area where policy-makers must scrutinise and regulate. The point was made about the need to manage patient data ethically, and to keep in mind that improving patient care should be the guiding principle

when developing the EHDS. Health data can be used for research purposes such as personalised care, clinical trials, screening, risk strategies, and development of new therapies. As such, it is necessary to establish relevant safeguards. Patients should be the first beneficiaries of the EHDS, and therefore should be co-creators in its development.

Digital literacy will be key to the success of the EHDS, for example, in ensuring patients are aware of the uses of their health data and what their options are. This requires training for healthcare professionals and providers, including in respect to data ethics.

The question on how and where health data will be stored was also raised.

### Discussion

Oyen opened the discussion by stating that the EHDS is setting ambitious targets for implementation at national level. Considering that there are important differences when it comes to digitalisation and digital readiness across Europe, the question was raised as to whether these targets were reachable, and how to avoid the creation of further inequalities across Europe. The timeframe to implementation and large differences between, and within the Member States, were both identified as issues. It is important to develop EU guidelines to support the exchange of best practices (such as toolboxes, training materials, etc) across Europe to support the EHDS implementation.

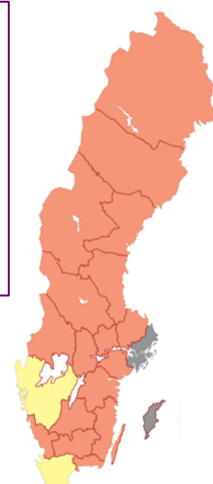
Picture 12. Vision for eHealth 2025

## Vision for eHealth2025



Working with the Vision:

- Current status
- Level of digitalisation in Swedish healthcare
- Challenges





## KEY POLICY RECOMMENDATIONS

- Lessons learnt from pilot projects should be applied to maximise the success of the EHDS.
- The potential benefits of the secondary use of health data should be better communicated to citizens to ensure that citizens will be willing to share their data.

## FIND OUT MORE

- **European Principles for Ethics in Digital Health**  
[bit.ly/European\\_Ethical\\_Principles\\_Digital\\_Health](https://bit.ly/European_Ethical_Principles_Digital_Health)
- **French Health Data Hub**  
[health-data-hub.fr](https://health-data-hub.fr)
- **Swedish Vision for eHealth 2025**  
[bit.ly/ehealth\\_2025](https://bit.ly/ehealth_2025)

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## Concluding Remarks

**The Roundtable was closed by Wim Oyen and Carlo Catalano, Co-Chairs, Digital Health Network, European Cancer Organisation.**

From this Roundtable meeting, stakeholders have clearly agreed that there is still a significant amount of work for all parties to ensure we arrive at the right situation for the implementation and use of the EHDS. Several key recommendations will be

brought forward from this Roundtable to ensure the most effective implementation of the EHDS for the oncology community.

The full potential of the EHDS can only be harnessed by collaboration with all of the relevant stakeholders coming together to ensure the sharing of high-quality, harmonised, and interoperable data.



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# Digital Health Network Participants

## Member Organisations Part of this Network



## Patient Organisations Part of this Network



To view the latest list of the Digital Health Network participants, visit our website.

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As the not-for-profit federation of member organisations working in cancer at a European level, the European Cancer Organisation convenes oncology professionals and patients to agree policy, advocate for positive change and speak up for the European cancer community.

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