Digital Health Europe


# Digital Health Europe – Consultation with Industry on the European Health Data Space

Consensus Report

June 2020

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## Acknowledgments

We are grateful to the European Commission colleagues for their guidance and to all industry representatives (see Annex 1, List of participants) for their active participation, thoughtful input to this consultation and their continuing support.

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| **AI** | Artificial Intelligence |
| **ASEHDS** | Allied for Start-ups on the European Health Data Space |
| **CSA** | Co-ordination and Support Action |
| **DHE** | Digital Health Europe project |
| **DPA** | Data Protection Authority |
| **DPO** | Data Protection Officer |
| **EHDS** | European Health Data Space |
| **EHR** | Electronic Health Record |
| **EC** | European Commission |
| **GDPR** | European General Data Protection Regulation |
| **HCO** | Healthcare Provider Organisation |
| **HCP** | Healthcare Professional |
| **IT** | Information Technology |
| **MTE** | MedTech Europe |
| **PREMS** | Patient Reported Experience Measures |
| **PROMS** | Patient Reported Outcome Measures |
| **RWE** | Real World Data |

# DHE consultation with industry on EHDS –Consensus Report

Consolidating and synthesising discussions during the virtual focus group and questionnaire response inputs.

## Introduction and scope

### About the Consultation

DigitalHealthEurope (DHE) is a Co-ordination and Support Action (CSA) that provides support to advancing the initiatives outlined in the European Commission's Communication on the Digital Transformation of Health Care in the Digital Single Market COM(2018)233.

This consultation was undertaken under the work stream of DHE as a means of supporting the second priority of the Communication: Better data to advance research, disease prevention and personalised health and care. These issues are relevant to shaping the success of the proposed European Health Data Space (EHDS). As part of this work, a "DHE White Paper on Better Utilisation of Data Infrastructures to Support Secondary Uses of Health Data" was published in February 2020, with the aim of supporting the dialogue focusing on the needs of the health industry innovation and research sectors that complements the current scope of the EHDS outlined in the February 2020 COM(2020)66 "A European strategy for data".

### Approach

This consultation was one of a series of open DHE workshops/ webinars and surveys taking place during spring, summer and fall 2020. It is intended to lead to a common understanding of what actions are needed by the EC and other key stakeholders in order to support the implementation of a number of use cases in priority research and innovation areas, such as accelerated drug and medical device development, health services innovation, AI and predictive modelling, personalised medicine, complex process management in  such contexts as disease outbreaks and information brokering.

This document reports on the first event that involved targeted companies: large (national, EU, global) and small (SMEs, start-ups and entrepreneurs) to explore the potential industry supply and demand interest and interactions with the EHDS. It was organised as a virtual focus group. Contributions are reported here in a non-attributable form, but the list of participants is given in Annex 1.

The purpose of the focus group and this report is to present a consensus of multiple company perspectives on the EHDS to the EC. This is intended to be complementary to any direct input to the EC that individual companies may have provided, and to any inputs provided by industry-representative associations.
In fall 2020, an event will be held that will be focused on expectations on the EHDS from citizens (acting as patients and consumers of digital health services).

### Structure

The focus group was run as a series of structured moderated discussions via a combination of chat and audio. They were captured as responses to guiding questions (see Annex 2). These questions were circulated in advance of the focus group, and some initial responses from example companies were presented orally to stimulate discussion. To compensate for the limitations of a remote meeting, written inputs to the questions were invited for a time interval after the meeting. This consensus report also takes

these written responses into account. It should be noted that not all of the guiding questions were included in the virtual meeting or covered through the written feedback. At times, specific responses have been placed under the 'best fit' heading rather than the headings under which the comment was actually made.

## Participation

This DHE industry-focused virtual focus group brought together 40 experts (and 5 organisers), representing some of Europe's most competitive ICT and service innovation industrial companies from major corporations and SMEs/entrepreneurs. They covered a broad typology of players:  Health IT, 'pharma' (pharmaceuticals), medical devices, publishing, and research organizations. They also included networks and associations such as MedTech Europe (MTE) which is the European trade association for the medical technology industry including diagnostics, medical devices and digital health, and the advocacy organisation, Allied for Start-ups on the European Health Data Space (ASEHDS).

The list of participants is included in Annex 1.

# Present industry context for using health data

Participants were asked about the kinds of data they presently have access to and what uses they make of the data.

The participating organisations in the focus group typically engage in research, development, and service activities. They reflect a rich usage of health data in their daily practice and/or on behalf of their customers - healthcare providers or patients - subject to strict limitations under the GDPR. They access a broad coverage of types of health data, ranging from health data, publicly available data on health systems performance and outcomes, to non-health data relating to corporate functions, manufacturing, etc. Some health-care payers and research organisations issue devices to patients in order to support them with collecting supplementary health and wellness monitoring information.

What industry can achieve today through the use of Real World Data (RWD) is to support a broad array of use cases. The use cases range from early research such as drug discovery to clinical and to exploitation/commercial. They span a large spectrum of areas covered: understanding disease, learning health systems and reimbursement policies, safety monitoring, regulatory compliance, market surveillance, improving deep learning models, developing target hypotheses, supporting target validation, and enabling patient selection and biomarker development in clinical trials.

A big concern voiced by the industry participants is the fragmented nature of healthcare across Europe. European healthcare is a derogated competence, making European cohesion harder to achieve when it comes to data. Health data are still considered by most health and care providers, and even health systems, as a by-product of care, not an important resource for care or research. However, the continuum of care and research is very important, and our healthcare systems need to evolve towards personalisation and precision.

# Future industry ambitions for the use of health data

Participants were asked about their ambitions to access new data sources: what innovations did they foresee in the next 3-5 years that would challenge their existing availability of health data

***"Healthcare data is growing exponentially. Consumer diagnostic devices and health trackers are spearheading this growth and compounded by their increasing utilization by providers and payers for health management, [pharma] companies will have to learn to leverage these new data streams effectively. Current legacy infrastructure is not geared towards handling this incoming tsunami."***

[Participant quote]

Participants shared common visions on the potential of artificial intelligence (AI) to make health and care more personalized, precise, and predictive and to create major impacts on prevention, patient empowerment, and to support self-management. In the context of a more patient-centric health system (i.e. a shift to personalised care and prevention) transparent and non-biased AI methods can help reveal if and how healthcare practices might currently be biased with respect to gender, age, ethnicity, wealth etc. For successful adoption AI needs to be trusted and explainable to patients.

AI requires access to good quality, representative, curated health data on a large scale. In the health sector, the data strategy and the EHDS initiative will add momentum and resources to the efforts to digitally transform Europe's health systems and enable secondary use of health data. Technologies such as AI tools, machine learning, deep learning, and data analytics are some of the key instruments employed by industry to develop innovative health solutions, where access and use of data are paramount to the success of their research and products.

Access to data is restricted by legal, technical, commercial, and other barriers, which hinder the pace of innovation. The available data on clinical performance is patchy and rarely as detailed as it needs to be. There is a need for more holistic data sets that capture not only electronic healthcare records, Patient Reported Outcome Measures (PROMS), and discharge letters but also genomics, imagining, health costs, etc. Patient level data, genomic data, and specific national data (EHRs or claims, registry data depending on countries) may be difficult to access. Both aggregated data and patient-level data, including longitudinal data, is required. The need to access individual or aggregated data across continents is also important for industry. Data quality is also often an issue.

Different industries have different ambitions for their use of data.

**The ambition for the pharma industry** would be to query large networked repositories of anonymised patient-level data. This needs better data interoperability including the integration of multiple levels of phenotypic data (such as from devices/biosensors as well as laboratory measures of biomarkers) with classic clinical observations and reports. They would like access to health data in real time and to additional types of data sets and harmonized, comprehensive and longitudinal data with large and diverse cohorts to test and generate new hypotheses.

**The ambition for the MedTech industry** for research, innovation and delivery purposes is for access to the data sets from electronic health records, patient reported experience measures (PREMS) and patient reported outcome measures (PROMS), demographic, administrative and medical device data and, in some cases, genetic data.

Examples of insights that greater data access could provide across the industry sectors include: health-economic analysis; monitoring and transparency on quality, outcomes, and cost effectiveness;

advanced digital and remote healthcare services; public health monitoring and tracking of epidemics; reliability and durability claims of medical and pharmaceutical equipment; task automation/artificial intelligence and assistance with pre-market and post-market surveillance of medical devices and technologies. A better understanding of disease and treatment would also enable researchers to explore new questions, such as studying the microbiome effect on autoimmune, psychiatric and neurodegenerative diseases.

The value propositions for health and care systems to invest in insight generation are multiple and diverse. Access to new types of data has the potential to increase health economic benefits and improve the resilience of the health systems in crisis situations. Being able to generate actionable insights quickly and to react rapidly to emerging challenges (as demonstrated during the COVID-19 pandemic outbreak) are now recognised as essential. The rush to learn from pandemic-related data has highlighted long-standing data problems: missing data; the lack of ability to make decisions based on relevant data, challenges with systems around the collection and sharing of data. This kind of intelligence is needed to guide treatment protocols.

Access to harmonized, longitudinal and comprehensive European data, used with standardised analytics, can help to very quickly answer questions about disease severity associated with co-morbidities, genetics and genomics/biomarkers, and lifestyle/environmental/societal factors.

Establishing win-win relationships between health and care providers and device manufacturers would allow the manufacturers to obtain data on performance and costs collected through the clinical use of their devices, to improve efficiency in the biomedical equipment management process. Technical maintenance and quality monitoring data can also feed back into the body of scientific knowledge, to be used by innovators in the field of biomedical technologies.

**The data sources** that would provide access to the various types of health data and would facilitate research and innovation in these areas include, but are not limited to:

- → National EHR systems that host electronic health information for citizens and patients (for example in many Nordic countries, in Austria, in the Spanish autonomous regions, and being developed in many other countries).
- → Healthcare provider and other health care organisations' EHR systems that capture, store and manage data for the provision of healthcare services (i.e. in hospitals, clinics, some General Practitioners' offices) including ICT suppliers of healthcare organisations and health care providers that may be storing health data on behalf of their customers. The data storage may include registries and monitoring repositories relating to regulated goods and services supplied to the HCO and HCP.
- → Patients' and individual users' personal health systems (including portables, wearables…) and associated (vendor) IT services enable users to generate and track health data to monitor their health and wellbeing (including connected medical devices as well as fitness and lifestyle devices). An example is remote monitoring services that track health data of patients with specific chronic conditions, often on behalf of providers. The storage models vary:
  - the data may be stored on the user's own systems;
  - the data may be stored in a cloud service selected by the user;
  - the data may be stored by the provider of the personal health system.
- → MedTech companies may store health data as part of their offering of regulated products and services to HCOs and HCPs, and possibly to patients directly. Pharma regulation and medical device regulations impose extensive data collection as part of pre- and post- market clinical trial obligations, post-market surveillance obligations, and vigilance reporting obligations.
- → Registries that are set up for specific purposes and collect focused information, for example post-market follow-up.
- → Research organisations including universities.
- → Specialised provider networks for health information sharing, including regional health information exchanges or European networks for patients with rare diseases.

The richness of the contributions described by the focus group participants is indicative of the huge potential for innovation from harvesting practically all sorts of health care RWD. Likewise, the prospective value for health systems and for society is immense, not least from big data and AI.

The needed data sources largely exist; however, challenges associated with limited accessibility, data interoperability, and data quality are yet to be resolved and are not to be underestimated; the technology industry needs to also respond to and facilitate the use of interoperable data.

# Expectations from European-scale data

*Participants were asked what the added value could be to them for having European-scale data access beyond their current data resources, and how the EHDS could change the EU or global research agenda.*

Some companies stated that they already have quite good arrangements for accessing external data sets. This includes having data sharing agreements with disease, procedure or device registries, biobanks and national public data providers (such as anonymised data sets obtained from health ministries or social insurance organisations) and, in the US, the claims database providers. Some companies are investing or co-investing in the growth of federated big data networks in Europe, such as through the current IMI EHDEN and forthcoming IMI BigPicture projects, or other data networks and consortia. Some companies have formed partnerships directly with data providers, in some cases commercial ones. There was a note of concern raised that some of the data sources are not well structured, not of good quality, and that the access arrangements can sometimes be quite complicated or ad hoc. Some companies also possess internal data, which they can reuse, that has been collected from devices that they market and monitor or from clinical trials.

Companies reported that they also have plans to engage with a wider range of potential data providers, including some of the COVID-19 related data initiatives and some of the national research infrastructure programmes which are creating data hubs or data spaces. It was also noted that some countries in Asia are starting to make big data resources available as well, for example through partnerships with health ministries (which might include helping a ministry with processing and analysing the data). Several companies emphasised that they are constantly on the lookout for new data partnering and data access opportunities.

There was no indication from any of the participant companies that they have a complete enough and satisfactory network of data sources to meet their future ambitions.

The opportunity from a European Commission-backed Europe-wide health data space was regarded as offering three broad categories of valuable contribution to the challenges of data access. The first and most obvious contribution would be as a channel for accessing data from multiple European countries through a centralised access point (even if the data were themselves distributed or federated); the second is harmonised adoption of data standards; and the third is a consistent governance environment including data protection rules, data access agreements and terms.

## European-level data

Several companies emphasised the importance and value of having consistently represented data brought together at a European level, reflecting a multi-country or pan-European perspective. This would enable them to make valid comparisons across countries and health systems. Not only would the companies themselves benefit, but they would find themselves better able to work with health systems across multiple countries to promote evidence-based improvements (because of their ability to illustrate the health benefits of care innovations that had been demonstrated in other countries). The ability to compare health outcomes across countries in a robust way would act as a critical

success factor for the scaling up of value-based care models. A European perspective was also considered very important for pharmacovigilance, medical devices vigilance and post market surveillance.

Another important benefit of European-level data would be scale. Scale is particularly important for data about rare diseases, and also for conditions like cancer sub-types whose diagnosis and treatment are increasingly personalised, requiring large patient numbers to make valid scientific inferences. Many companies have restricted data access today: they perhaps only have access to what is directly relevant to their own product(s), which means that they miss the holistic patient and population views.

Facilitating access to larger pools of data powers the potential for more affordable, less invasive, and more patient-centric health solutions. Digital health start-up participants stated that being close to advances in science is necessary in order for them to develop credible and verifiable health solutions. Many start-ups carry out and publish research, hire scientists and/or collaborate with universities and research organisations.

There was a stated need for close to real time, fine grained, anonymised, multi-variate healthcare provider clinical and genomic data and to anonymised patient-generated health monitoring and lifestyle data. This data needs to be pooled or federated on a large scale: small pools of data are no longer useful. This view was endorsed as a consensus opinion by all of the industry subsectors, to track the safety and efficacy and effectiveness of treatment and to identify issues and innovation needs quickly. Longitudinal data, linked across care providers and patients, is needed for an understanding of those diseases that develop or evolve over many years. Companies are increasingly interested in having an impact on health outcomes, which are influenced by lifestyle and socio-economic situations, so they need this holistic picture in order to advance their understanding and to develop targeted innovations.

## Harmonised adoption of standards

An important added value of a European-scale data space initiative was considered to be the promotion of standards, and the potential for data to be harmonised when it is made available through the EHDS. There was a hope that cross-country data would be put into a consistent format that could be analysed as a unified resource. This was voiced as being of particular importance when companies (or other stakeholders) wish to make cross-country comparisons. Several companies supported building on the 2019 European Commission Recommendation on an Electronic Health Record Exchange Format. A parallel hope was expressed that data quality standards would also be applied, so that reliable findings could be derived.

Mechanisms that facilitate and improve access to health data and enable its secondary use for research and innovation are important to patient-centric innovation. Moreover, measures to increase cross-border interoperability of health data and electronic health records are important for the development of cross-border digital solutions for health and care. This was especially felt by digital health start-ups who frequently develop innovative solutions to address new emerging health and care challenges.

Industry could collaborate with each other and with the EC on helping to design datasets that would be of greatest value to their innovations or for future public health emergencies, on which efforts might initially be focused on data harmonisation and data quality. It was noted that the traditional boundary between treating illness and preventing illness is blurring, changing the roles of some of the traditional actors like healthcare professionals and introducing new actors such as algorithm developers into the health, care and wellness environment. This needs to be reflected in the kinds of data that are introduced, new data sources such as patients, and the actors who are able to access the data. The ability to interpret data along a patient's health and illness life course would help industry to better understand patient journeys, to guide care pathway optimisation, and to identify where the needs are for novel products and services. It is important to ensure that non-traditional actors, including patients, are equipped (trained, resourced) to interpret data such as genomic data. Feeding individual real-time data back to patients was described as a breath-taking vision.

The role of the EC and the EHDS in this area was not only seen as undertaking the data harmonisation and quality assessments, but incentivising countries and data providers to adopt standards within the systems that first capture health data, so the data are collected consistently from the start, and then made shareable. Additional investments and technical developments will be needed. The EU should promote (and enforce) the adoption of existing open technical and data (semantic) standards that are able to accommodate interoperability of all health-related data. Examples include clinical data, high dimensional data (e.g. omics) and imaging data, and patient-generated health data generated by wearables and implanted devices and apps. EHR system vendors, app and device developers also have important roles and responsibilities in this. The EC should also play a global role in this harmonisation, working internationally towards consistent data and governance rules for data access.

A combination of standardised data, consistently organised datasets, high data quality and standardised analytics would allow companies to generate evidence that would be accepted as trustworthy by regulators, payers, and clinicians. Greater interoperability, personalised medicine and the continuous generation of more "streamed data" from wearables and the Internet of Things (IoT), the wider use of Real World Data complementing Randomised Controlled Trials, leading ultimately to greater acceptability of Real World Evidence by regulators and payers.

## Consistent governance and access arrangements

There was a strong wish for the EHDS to create a unified and coherent data access scheme as opposed to having 27 different mechanisms (which seems to otherwise be the potential trajectory). However, it was also emphasised that there should be a minimum level of bureaucracy and that the centralised mechanism should simplify and standardise the process; it should not simply be an umbrella for multiple national access arrangements.

There must be clarity about the legal basis for processing any personal data held in or accessed via the EHDS. Contractual arrangements and terms for granting data access also need to be standardised. A Europe-wide code of conduct was also welcomed. Caution was raised about considering not only a formalised instrument according to GDPR Article 40, but searching for examples of codes or practice that are already operational and which could be adopted quickly.

The designers of the EHDS were urged to consider the interconnected nature of rules around privacy, AI, medical devices, and to consider how the rules apply to digital health solutions. Providing a clear pathway will allow start-ups to contribute and benefit from the EHDS as they develop user-centric innovative health solutions and begin to scale across Europe.

It was felt to be important, when accessing an integrated dataset, to be able to trace particular findings back to the source of the data. In such a way, the results could be appropriately contextualised. Possibly additional deeper dive investigations could be undertaken to clarify unexpected findings.

It was emphasised that there is much more willingness to share data, especially by patients and citizens, if the benefits are made visible.

There was also a suggestion that companies would then be encouraged to collaborate more on cross-border health and scientific research. Such collaboration might reduce unnecessary and redundant research, and therefore reduce wastage and burden on clinical and scientific resources. Early wins are needed: cross-stakeholder experiences of co-operation and data sharing in response to the COVID-19 crisis could inform priorities and data sharing practices for the EHDS.

Open data was also something that should be more widely promoted. It was expressed that data collected in EU databases and funded by public funds must be made open and available for research.

There was a consensus that, having a single access infrastructure and adhering to unified governance and data access terms to obtain standardised and high-quality European scale data, would greatly accelerate research and have an important impact on reducing costs. It could be a "a tectonic shift moment for research and innovation". This would not only benefit companies currently utilising health data but will expand the market especially for small companies to be easily able to utilise data for innovation.

# Business and governance models

Participants were asked about models they would consider for contributing financially or in kind to utilise EHDS data resources. They were also asked about what roles the EC should play in establishing governance and transparency rules that could be promoted more widely across European data ecosystems. Participants reflected on both business models and governance models related to industry access to EHDS data.

## Business models

Participants indicated that business models should be designed that consider value chains across all the players (drug, device, app and AI creators, health care organisations, payers, data providers, information brokers etc.) The party that receives the benefit may end up being the final payer. Revenue will need be distributed across the value chain according to agreed models.

Several companies indicated a willingness to pay (in cash) for European level data along the lines that had been discussed. However, willingness to pay would depend on the added value that the EHDS could offer as compared to the current data offers across EU (from both private and public data sources). It will be important to clarify if the EHDS would position itself to conflict or compete or collaborate with other private and/ or public data initiatives.

**One organisation stated:**

*"My organisation might be able to pay an annual license for access. I think that this is the most likely model that would work for all parties. I think that paying in kind would be a difficult model to make work."*

**But this view was not universally held:**

*"We would prefer services in kind, revenue sharing, or transactional options to our clients, with licensing fee being least preferred but not out of the question depending on the longitudinality of the data."*

*"If industry is to pay a fee, what is it paying for: the infrastructure? a service? the data themselves? … It is best for industry to be a partner rather than just a data user, [there is a] need to think large scale in terms of reimbursement ("it goes beyond payment for access or analysis")"*

**However, the amount to be paid should also depend on the type of data and the intended use:**

*"Depending on the type of data request (e.g. which data, from where, how much, for how long etc.) and the use purpose (e.g. product discovery and innovation, fundamental research, PPP, etc.)"*

It was also felt important to balance discussion of payment for data with data altruism or donation: efforts should be made to inspire data altruism and to define a clear and compelling quid pro quo where would-be data altruists understand how their data will be used and reused and the benefits that this would bring (and to whom). For health data, there is currently a worrying lack of mechanisms through which data can be donated (by individuals or collectively). However, it was recognised that data donation is a difficult topic and needs much more consideration and consultation in order to define a suitable model.

Companies generally accepted, and were comfortable with, contributing in return for gaining access to the EHDS. Some companies would be willing to contribute data, infrastructure support, or in-kind services to enrich the data offering to all, through a partnership model. Some companies would favour an in-cash contribution in the form of an annual licence or pay-to-use fee, although it would be difficult without further exploration to determine the basis on which such a fee should be set. Companies would also need to be clear what they are paying for: the infrastructure, a particular service, or the data.

## Governance models

Trust is key in every discussion around the use of data in healthcare. How to achieve such trust proved to be a key topic during the meeting discussions. It was recognised that a comprehensive understanding of privacy and security issues is needed across all relevant stakeholders and throughout the entire value chain. It was thought that most people would support the uses of their data if they could see the health and public benefit. One key tenet that is emerging, and increasingly gaining importance, is patient ownership of data.

Transparency towards the public is essential – citizens need to know what types of their data are available, to whom, and to understand how they are used. Giving people better access to their own data would help with that understanding. There is also a need for greater public awareness about the measures that protect citizens' privacy, from understanding the GDPR to knowing what pseudonymised and anonymised data are. However, further discussion needs to take place on how confidentiality can be maintained in those specific circumstances where the data is especially hard to anonymise.

The EC, through developing and/or proposing the governance model and practices for the EHDS, should foster a shared (multi-stakeholder) understanding and implementation of the General Data Protection Regulation (GDPR) across EU countries and healthcare organisations by, for example, developing a code of conduct for health data.

**Examples from which good practices could be drawn include:**

- → Finland's Findata
- → Estonia's X-Road
- → The German Medizin Informatik Initiative
- → IMI EHDEN
- → BBMRI-ERIC
- → Yale Open Data Access

One area of learning from these various initiatives is that federated data models help to address some of the challenges and build trust across healthcare stakeholders. Data processing and storage is increasingly performed in cloud and edge infrastructures. However, some Member States require that data be kept in their own country. These national data localisation restrictions and other country-specific regulatory requirements, coupled with the low number of providers, which limits competition could challenge the general availability and access to health data. It was suggested that the EC should promote the removal of data localisation restrictions which are not in line with EU data protection laws – whether they apply to federated data querying or to the transfer of data sets.

It was noted that, today, navigating complex regulations requires resources which could otherwise be directed towards innovation, especially for SMEs and start-ups. These small-scale companies often struggle to gain access to decision-maker contacts as well as to data within the highly specialised and regulated healthcare sector and to keep up with the evolving regulatory environment. Participants from all sizes of industry confirmed a need for authoritative guidance on the interpretation and implementation of the GDPR relating to the reuse of health data, in order to foster a common and shared view among the EC, the Member States, and key stakeholders. The GDPR provides for a public health exception to process personal data concerning health. However, the GDPR has created considerable hurdles for companies involved in cross-border research, has led to fragmentation, and has brought additional costs to ensuring compliance. The biggest negative impact from this fragmentation is that potential benefits in diagnosis, treatment and care are delayed. Legal uncertainty means that decisions are taken on the basis of interpretation and the risk capacity of companies, as well as the place of location of their main premises (and thus the interpretation by the specific country's DPA and/or by more local DPOs). Research on health data for innovative medical technologies and care pathways to improve patient's health and improve healthcare systems' sustainability (including sharing of health data for such purposes) may therefore not be used to the fullest.

The EHDS provides an opportunity to develop consistent legal framework for the ethical and compliant use of data.

**The Yale Open Data Access (YODA) principles are a useful input to ethical use conditions:**

- → Honour the people who volunteer time to participate by sharing their data for good
- → Protect privacy and confidentiality
- → Advance science by better understanding diseases
- → Generate new insights that expand knowledge to develop new treatments
- → Enable better health care decisions for patients

The meeting participants made a number of suggestions for EC action.

The EC should support Member States in establishing suitable bodies and coherent governance rules to receive and assess requests for data arising from their country. However, it was noted that many complexities exist due to different sources of data and different data needs: what may work at large-scale EU level might not work at the level of the local delivery of care. The EC should in parallel support Member States with getting the most value from their own national health data spaces.

The EC should partner with stakeholders and Member States in defining model data user agreements. More investment is needed to train personnel in the good handling of sensitive data, in the same way as they are trained in clinical practice and research conduct.

The governance of AI was also explored. The EU has led the development of ethics guidelines for trustworthy AI, and the challenge now for all stakeholders is to agree how to operationalize these principles across many different types of AI technologies and many different use cases.

The EHDS governance model and its operation should act as an enabler of safe, secure data sharing, which would empower citizens, health authorities, and companies to level up their ability to share critical insights under the highest ethical and technical standards expressed in an agreed code of conduct. Ideally, governance policies and decision making should be coordinated by an independent body.

# Potential data contributions from industry to the EHDS

Participants were asked about data resources that they might be able to contribute to the EHDS, and on what basis they would consider doing this.

Some companies have large-scale data repositories, or have access to them, which could potentially be made available for wider research or public health reuse. Some already do this, for example Johnson & Johnson via the YODA project (https://yoda.yale.edu). Others could do so under suitably agreed conditions (such as PRA with access to data on 280 million Americans contained in its integrated repository). Some companies are still determining which data resources could be made more widely accessible, and under what terms.

Companies expressed the view that sharing data (e.g. by them) should remain voluntary and not be mandatory or be a condition for EHDS data access.

Policymakers need to formulate a view on how to orchestrate an ecosystem of federated public and/or private data resources and data users. Experiences from the IMI MELLODY project might be useful to review. Competition law safeguards should be taken into account when considering how industry should contribute, so that the companies accessing data should not be required to disclose the purposes of their research project in a way that would reveal sensitive business information to their competitors. However, it was recognised that some degree of transparency as to the purpose would be appropriate.

In addition, a strong (cyber-) security framework should be in place, meeting (still to be agreed on) security standards, providing for appropriate authentication, authorization, and audit.

Some companies have large-scale data repositories, or have access to them, which could potentially be made available for wider research or public health reuse. Companies who are potential data contributors to the EHDS should be invited to contribute to formulating its governance, data access and use principles, and terms of use.

# Annex 1: List of participants and contributors

| Last Name | First Name | Country | Organisation |
|---|---|---|---|
| Aerts | Hannelore | Belgium | i~HD |
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| Blomeyer | Benedikt | Belgium | Allied for Startups |
| Bouarfa | Loubna | United Kingdom | OKRA Technologies |
| Bujok | Stefan | Germany | Forschungszentrum Jülich |
| Calini | Leonardo | Belgium | Microso |
| Christofidou | Maria | Belgium | i~HD |
| Costescu | Alexandru | Belgium | European Commission |
| Deakins | StJohn | UK | CitizenMe |
| Donay | Christina | United Kingdom | UCB Pharma Ltd. |
| Fanos | Margherita | Luxembourg | European Commission |
| Fried | Andrew | United Kingdom | IBM |
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| Gago A | Iberto | Belgium | European Commission |
| Giedraitis | Gaivandas | Belgium | Allied for Startups |
| Hajdu | Maria | Luxembourg | European Commission |
| Hughes | Nigel | Belgium | Janssen |
| Illario | Maddalena | Italy | Campania Region & Federico II University & Hospital |
| Kalra | Dipak | Belgium | EuroRec, i~HD |
| Kolitsi | Zoi | Belgium | EuroRec |
| Korwek | Justine | Belgium | ResMed |
| Kulerer C | ornelia | Belgium | Microsoft |
| Laplaza | Carmen | Belgium | European Commission |
| Malouvier | Alexandre | France | PRA Health Sciences |
| Martin | Angel | Belgium | Johnson & Johnson |
| Morlion | Birgit | Belgium | European Commission, DG CNECT |
| Pallikarakis | Nicolas | Greece | INBIT - Institute of Biomedical Technology |
| Rees | Bleddyn | United Kingdom | ECHAlliance |
| Rinne | Saila | Luxembourg | European Commission, DG CNECT |
| Romao | Mario | Belgium | INTEL |
| Rowher | Lars | Belgium | Siemens |
| Schmidtmann | Daniel | Germany | empirica |
| Stroetmann | Veli | Germany | empirica |
| Strübin | Michael | Belgium | MedTech Europe |
| Styliadou | Meni | Switzerland | TAKEDA |
| Thompson | Ceri | Luxembourg | European Commission, DG CNECT |
| Thieffry | Solène | Belgium | UCB |
| Van Roijen | Danny | Belgium | COCIR |
| Walsh | Kieran | UK | BMJ |
| Whitehouse | Diane | United Kingdom | EHTEL |
| Zilli | Veronica | Belgium | Johnson & Johnson |
| Zobell | Oliver | Germany | Forschungszentrum Jülich |

# Annex 2: Guiding questions which structured the virtual focus group and written inputs

**Present context for using health data**

1. What are the kinds of health data that you at present have access to?
   What are the main areas of insight you most use health data for?
   Which data do you need and do not have access to?
   Do you assume that all participants have already access to data?

**Your future ambitions for the use of health data**

2. What are the innovations you foresee, in the next 3 to 5 years, that will challenge your existing availability of health data?
3. What are your new data access ambitions?
4. Could you give some examples of, potentially imaginary, questions you would want answers to from new kinds of health data?
5. What are the kinds of data sources that would best fit those new research questions?

**Expectations from European-scale data**

6. Are there other data networks you are already engaging with, that would address your needs without requiring access to a European Health Data Space?
7. Are there other data networks you intend to engage with?
8. What would be the added value to you for having European scale data access versus multiple single data sources?
9. How could the common EHDS change the global/EU research agenda?
   Examples of this might include: removing barriers, access to interoperability resources, co-ordination of efforts around re-use value data sets, open access to medical device safety report data, business models supporting re-use for research and innovation.
10. Would you expect the EHDS could provide sufficiently real time, anonymised, healthcare provider data to monitor or improve the delivery and safety of care?
    Examples of this might include: data flows along patient pathways, values of the key indicators and biomarkers needed for care decision making (treatment, procedure), measures of health outcome.
11. Would you expect the EHDS could provide anonymised lifestyle data related to episodes before and after a healthcare intervention?

**Business and governance models**

12. Would you be willing to pay for accessing resources within the EHDS?
13. If so, on what criteria would you be willing to pay on…
    a. In kind, or by providing your own sources of health data
    b. In cash as an annual licence or a pay per use
    c. On the business purpose or the size of the organisation
    d. Some other determination
14. Transparency to the public and ensuring public good from the EHDS will be important.
    a. Are there any aspects of a social construct you would support?
    b. Are there any you would find challenging?
15. What role do you feel the EC, through establishing the EHDS, should play in establishing good practice governance rules that could be promoted more widely across European data ecosystems?
16. Are there good practice examples of governance rules you would recommend be considered for the EHDS?

**Contribution to the EHDS**

17. What kinds of data sources might you contribute to the EHDS?
18. What terms might you find acceptable for making your data available?
19. Would you be interested in being able to influence those terms and access rules?
20. Are there good practice examples of data access terms and rules you would recommend be considered for the EHDS?

**European value**

21. How could the EHDS ensure that European values about health data are upheld and that the value from the EHDS is delivered/deployed in Europe? For example: the use of knowledge derived from the data, access by EU citizens to products and services developed through the use of the EHDS, the creation of jobs within Europe.

**Further thoughts**

22. Do you have any other thoughts on the themes discussed during the meeting?


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