DigitalHealthEurope expert roundtables on health data sharing and use

Summary of discussions

The DigitalHealthEurope (DHE) project conducted in the first half of 2021 **three expert roundtables** (RTs) dedicated to the topics of

(1) Legal challenges in health data use (RT1),

(2) Health data standards and interoperability (RT2), and

(3) Cloud technology in health data (RT3).

Two workshops each were conducted on legal challenges and interoperability and one workshop focused on cloud technology. Each workshop was attended by experts from related fields to discuss the issues at hand, map the scene, identify crucial points and gaps and think about innovative measures to tackle the identified challenges. The experts identified, inter alia, the need to clearly define crucial terms such as health data; the importance to empower and engage citizens, to activate them as change agents and to include them in regulatory processes; and to consider common principles and enforce consistent standards.

In the following, a short introduction to the RT workshops, as well as the main findings are outlined.

1 Legal challenges in health data use

The first workshop (RT1.1) was led by Petra Wilson and opened with a presentation of the project background in the context of the three Digital Single Market priorities. The objective of the first roundtable encounter was defined as **mapping the practical experience of the implementation of GDPR and identifying possible challenges that remain in understanding the way in which health related data may be used.** The analysis centred around different contexts of health data use. Petra Wilson presented a 3x3 data governance conceptualisation model, which may be used as a simple graphical interpretation of some of the key challenges of data use governance in the health sector:

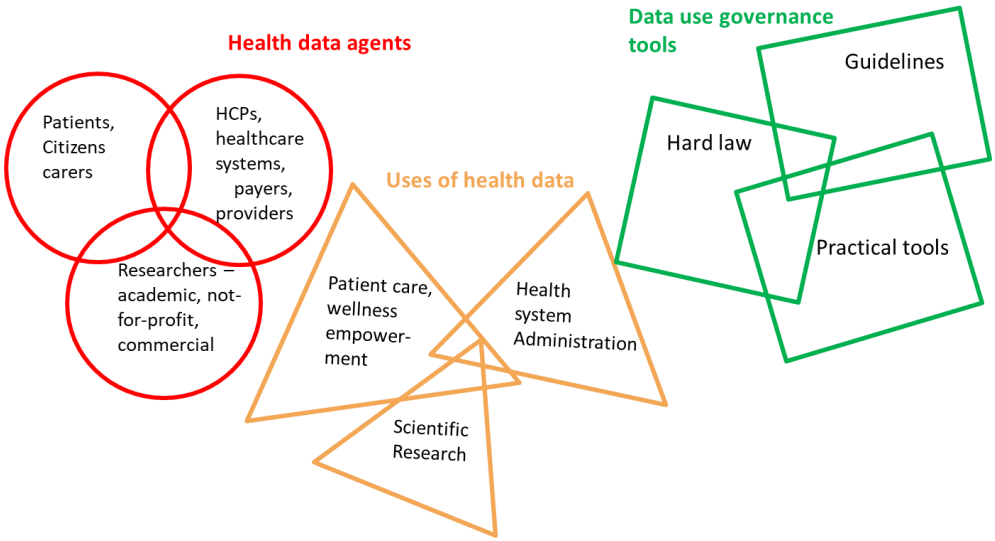

Figure 1: Health data conceptualisation model

Starting from this model, the discussion touched upon many important aspects and challenges of using health data. Five central conclusions where the main **key takeaways** from the fruitful discussion:

- The health data conceptualisation model was endorsed by the experts.
- Legal issues should consider not only data protection but citizen protection, which was an overarching topic of the roundtable.
- A central question is how to make the law an enabler instead of having a myriad of different guidelines.
- There is a human resources deficit around data protection, which should be tackled with more education for everybody handling data.
- A new kind of EU body that is responsible for data legislative needs and has the capacity to listen to citizens and the power to influence might be a good idea.

The second workshop (RT1.2) started with a short recap of the first roundtable and emphasised that **law as an enabler for the use of data**.

The experts embraced the idea of a shift to protection of citizens alongside the protection of data. Whilst data protection is important and is a legal right, it is not the only important issue. Data literacy and skills play an essential role in realising the full potential of digital health.

- Using data for protecting the health and wellness of individuals and society as a whole (shifting the focus to using data to protect citizens, rather than protecting the privacy of citizens' data, although not compromising the right to privacy)
- Generating the right data so that it can be used to protect the health and wellness of citizens (shifting the focus to include further use of data, as well as immediate use of data for care)
- Developing a data governance framework suitable for using data to promote individual and population level health and wellness (re-focussing the role of law)
- Developing a wide range of data skills amongst all data stakeholder to facilitate the objective of better use of data to promote individual and population level health and wellness.

The data conceptualisation model (Figure 1) was enhanced to incorporate a new version, focussed on law as an enabler (see Figure 2). General endorsement of the idea that **the law at the moment** (dominated by the GDPR) **does not facilitate the best possible use of data**, as it is rather focused/based on what you cannot do (data protection) instead of focusing on the use to "protect" citizens and healthcare systems. Caveat around the wording, especially "protect".

Experts want to push for whatever is adopted in terms of new governance tools (hard law, soft law or other mechanisms), to move towards **actively engaging citizens in the use of data to provide better healthcare systems for everybody**. The keywords are to **engage and to empower**. The EC should try to include as much lay opinion as possible. It is also important to include engagement of industry, especially the industry involved in creating a tool for collecting data.

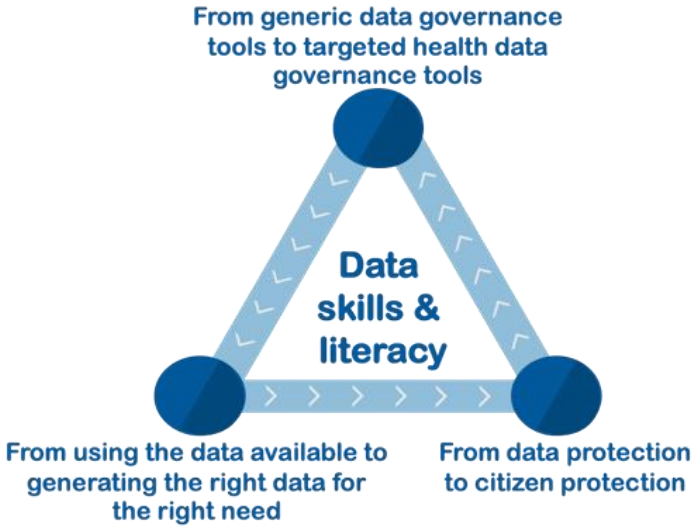

Figure 2: Key concepts from the roundtable on legal challenges

Legislation should be adopted in **plain language** to be understandable and to maximise a common understanding and make it more user-friendly for citizens.

The EC should be encouraged to dare challenge the concept of healthcare sovereignty and subsidiarity, and the idea that nothing can impinge on Member State's right to run and organise their own healthcare systems. The EC could use the newly created sense of common engagement on healthcare and collaboration (created by COVID-19) to achieve that (example is the newly proposed Green travel certificate). There is a need for **more European federated engagement on how data is collected and used**. The difficulty of not interfering too much with member states' health systems remains as a challenge.

Regarding the question what the experts want from data governance tools, the answers showed an ambivalence in the group. M**ore top-down law was not considered helpful** as it takes too long to develop and there are big problems with varying interpretation. People need to be careful that with calling for more legislation, not more problems are created for ourselves. However, there is **a feeling that the existing legislation has created a number of problems**. Therefore, it is important to send a clear message to the EC: **Before adopting more legislation** that addresses the generation, use and reuse of health data, we must **look** carefully at the **problems caused by existing legislation,** look at **gaps** that still exist and **work together** with patients, industry, researchers, etc., to develop cooperatively a possibility **to close the gaps and meet the needs**. One of the ways to do this could be to **use the soft law bodies that exist**, like the eHealthNetwork, and make sure that if new bodies, like the European data innovation board are adopted, they must develop **guidance tools** allowing data to be used to protect citizens in all dimensions recognising that protection is not a passive issue but needs engagement and empowerment. Moreover, the bodies need to make sure it is used to **create resilient health systems**.

2 Health data standards and interoperability

The roundtable on health data standards and interoperability (RT2.1) was opened by roundtable leader Henrique Martins, who introduced the **focus on the demand side of interoperability**. A quick *tour de table* followed, revealing that the session counted with experts with a background in engineering, medical sciences, law and other areas, representing research, pharma, networks, academia, think tanks, industry and the European Commission.

Henrique Martins set the scene of a demand-side approach to interoperability, pointing out that the poor extend of standard adoption was home-made, including by the experts present. Referencing a reflection paper shared before the meeting, Henrique pointed out that:

- Interoperability market can be stimulated
- Actors on the market can be both demanders and suppliers
- Citizens fulfil the double role of patients and taxpayers/insurance clients; but might not be aware that they are the demand side and can stimulate the market.

A conceptualisation of four groups of actors followed, listing individuals and collectives, either by themselves or represented by a non-human actor. Also, Henrique reminded the attendees of the concept of primary, secondary and tertiary data use. The scene setting ended with a question to stimulate expert discussion:

What are possibly motivations of existing actors? How can demand for interoperability in health data be "stimulated", "elicited", "regulated", "triggered", "empowered?

In three breakout rooms the following issues were discussed:

- The who, what and why of the demand side
- The eHealth interoperability market, a look at the demand-side
- How can we "activate" the demand site actors.

The second workshop of the roundtable (RT2.2) was opened by Henrique Martins highlighting that the challenges in this area go far beyond the technical aspects. He clarified that this roundtable was targeting the interoperability of health data and not governance or infrastructure challenges. He also introduced the emerging concepts underpinning the European Health Data Space (EHDS). Petra Wilson gave a brief summary of results from roundtable 1 on legal challenges in health data use. Dipak Kalra highlighted the possibility to harness the power of people in their role "as complainers" in order to create a higher demand for more standards adoption around health data. Particular emphasis was placed on the citizen/patient as a key game changer as illustrated in Figure 3.

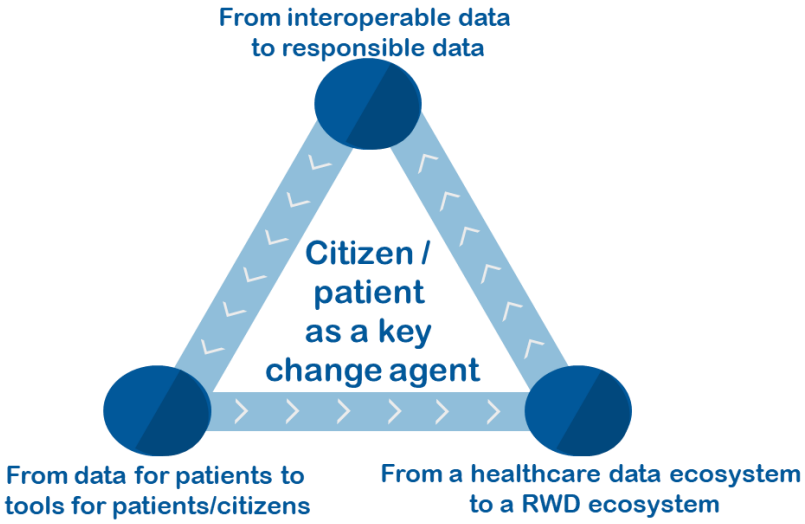

Figure 3: Citizens/Patients as change agents

In four breakout rooms regulatory as well as non-regulatory aspects were collected as recommendations for the EC/EU-level actions and recommendations targeting MS and national/regional actions:

Table 1 - Main points to be addressed regarding health data interoperability

	Regulatory	Non-Regulatory
Recommendations for EC/ EU level action	**Breakout session (Zoi Kolitsi)** • COVID-19 has shown digital health certificate as an example of data portability • Focus on using data for cross-border healthcare • Influence of cross-sectorial environment and legislation • Shift to solutions enabling citizens to use & share their data • Yes to EU level regulation as an enabler, careful selection of instruments to choose what needs to be left to be regulated flexibly **Breakout session (Petra Wilson)** • Better definition of health data – e.g., in comparison to lifestyle data • Better definition of ownership and control of data • FAIR should go beyond technical issues, towards resharing of data • Ensure that compliance with interoperability standards, in particular in procurement, is embedded in EU level legislation • Use upcoming MDR implementing legislation to support common approaches to data models and FAIR • Look for opportunities to reinforce interoperability compliance in EU level consumer protection legislation • Use EHDS initiative to support interoperable systems for ensure that data can migrate from devices in health data space	**Breakout session (Zoi Kolitsi)** • Not all aspects can be captured in legislation • Give patients access to data and enforce their right of data portability • Strengthen data quality so it is trusted at the receiving end **Breakout session (Petra Wilson)** • Everything we do regarding healthcare and regarding the legislation etc. Should be informed by the Duty of Care. • Recognise the power of the major digital health consumer ecosystems (IOS and Android eco system).
Recommendations for Member States, national and organisational level action	**Breakout session (Dipak Kalra)** • Consider regional aspect in national view • Legislation needed as much as soft law • Need for strong incentives and regulations if interoperability should work • Value of interoperability and FAIR principles, to make politicians see the use of scaling up • COVID opportunity to take stock of lessons learnt • HCP could learn from research in adoption of FAIR principles **Breakout session (Henrique Martins)** • Incentivise HCP to take up patient data and avoid "copy and respective collection" • Possibly apply "only once principle" in health • Conceive patients as a "transporter" of their data thought an APP/device • Compulsory minimum set of patient data available to all • Minimum set of "clear rules" for companies /products • Need for legacy IT "interoperability" strategy • National "Audit"/"Communication" function on what is happening with health data **Breakout session (Petra Wilson)** • Adopt MS level legislation to support realisation of the right to data portability in GDPR • Facilitate consumer device data integration through national level legislation	**Breakout session (Henrique Martins)** • Patient's double role can be stimulated both. (patient as health data source – (intermediaries of interoperability) - Patients as demand side actors) • National Government work with stakeholders (adjust to literacy level, and National Health service paradigm) • Promote health IT conformity assessment • Foster "tangible examples"/"show rooms" – making interoperability visible • Patient engagement (with data and health through use of data) strategy: use case/gamification/cocreation/ and change the focus from data to tools (useful services). • Produce procurement guidelines • Elaborate a legacy IT "phasing-out" strategy (and incentives for IT providers/HCP)

3 Cloud technology in health data

The roundtable on cloud technology in health data (RT3) was opened by a brief introduction of DigitalHealthEurope (DHE) by Veli Stroetmann. Afterwards, Zoi Kolitsi presented health data sharing initiatives that were mapped at the beginning of the DHE project. It was found that there are several initiatives to share health data for cross-border purposes (e.g., eHDSI, CPMS/ERNs, ERDRI) and sharing data for secondary use purposes (e.g., EHDEN project, French Health Data Hub). Federated infrastructure models (federation of data repositories under an overarching governance and interoperability layer) emerge as a new paradigm for sharing personally identifiable health data. Based on these insights, a first draft of what the EHDS could involve was created by DHE:

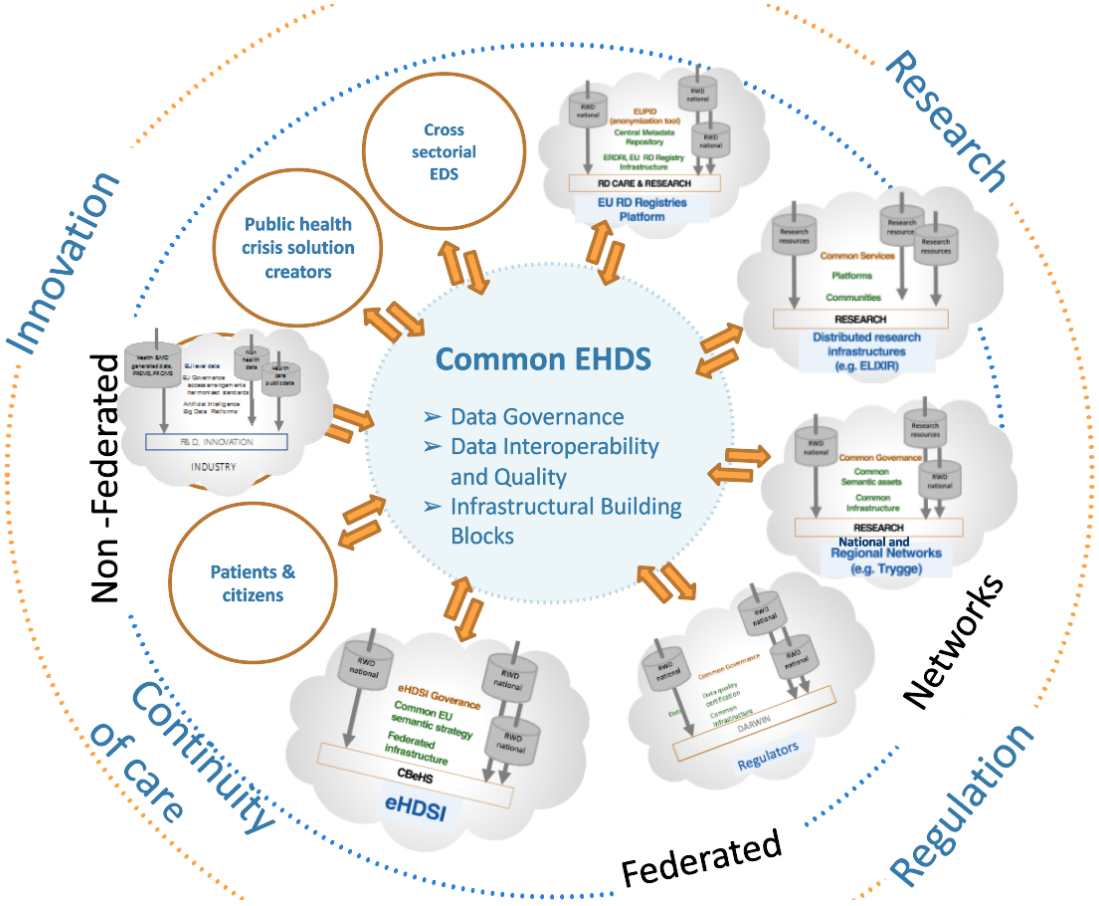

Figure 4 DHE Draft Concept of the EHDS

DHE also conducted consultations with industry and citizens/patients, as well as a large-scale citizen survey on expectations from and contributions to the EHDS and health data sharing in general.

After short inputs from selected projects, the discussion focussed on three main points:

- Leveraging promising initiatives
- Basic conditions and purposes of cloud use
- Ensuring security and privacy in the use of cloud technology in health

Francesco Torelli highlighted the need to **distinguish between requirements for infrastructure and requirements for applications as services**. This would also encompass issues such as interoperability, as discussed during the roundtable, which he would position

with the requirements needed for applications as services rather than requirements for infrastructure.

Danny Van Rojien suggested to also consider the architecture of GaiaX and what it could mean for the EHDS in further research and discussions. In particular, the documents surrounding technical infrastructure were highlighted.

Oliver Zobell put forward that some essential technical features of cloud technologies co-align with emerging technologies such as AI and sensor technologies which present a pull-effect for cloud services that are not widely adopted yet in the healthcare sector. This is something to be considered in the further analysis of the projects presented during the roundtable.

Other points named throughout the meeting include the following:

- Consider the strategic interest in having national/European cloud services.
- Have a look at which kind of data is deemed appropriate for cloud.
- Define rules regarding which cloud solutions can be part of EHDS.
- Distinguish between requirements for infrastructure and requirements for applications.
- Study which applications specifically are well suited for the cloud, e.g., through use cases.
- Have clear semantic harmonisation goals, e.g., in terminology.
- Look at procurement guides for cybersecurity, etc.
- Study anonymisation techniques.