IDERHA Task 6.3 Data stakeholder workshop 31/10/2023- Executive summary

Participants

The IDERHA project's multi-stakeholder workshop on the 31st of October 2023 gathered 10 experts from different initiatives regarding data access, sharing and integration, such as DARWIN EU®, EHDEN and Gaia-X.

Aims

The workshop aimed to provide insights into barriers and challenges to data access and sharing, their sensitivity to policy change, and discuss those most impactful and feasible for IDERHA to address. This is the first of several data stakeholder workshops seeking to incorporate lessons learned from similar projects for the development of policy recommendations related to health data access and sharing.

Conclusion

- The most frequently cited challenges to data access and sharing were:
  - Interoperability
  - Uncertainty over legislation and governance
  - Lack of a data sharing culture/lack of trust to share data.
- Legislation/governance issues and interoperability were perceived to be more sensitive to change through policy than attempting to enact culture change.
- When considering impact and feasibility, however, incentivisation, patient/citizen consent to data access, and increasing public spending on data sharing and access were prioritised.
- It will be important to consider the wider context of the European Health Data Space (EHDS) and previous lessons learned when considering areas for policy development.

Key recommendations and priority areas

- IDERHA should explore policy recommendations for creating standardised incentives, promoting data altruism, and establishing clear governance procedures including appropriate consent mechanisms. This includes incentivising public and private entities to share data while ensuring transparent and ethical practices.
- IDERHA should assess the feasibility of implementing policy recommendations and seek to tackle areas where this is most likely. These recommendations should emphasise harmonisation at EU, national, and organizational levels.
- IDERHA should establish and maintain strong links with the EHDS, to ensure ongoing work is complementary and avoids duplication of efforts. Exploring involvement in

the EHDS2 Board and pilot and leveraging their reusable building blocks will enhance the project's impact and contribute to the broader European health data landscape.

IDERHA Task 6.3 Data stakeholder workshop 31/10/2023- Full report

Introduction

Following the launch of a series of multi-stakeholder workshops, with the first workshop focusing on the patient's perspective, the IDERHA project held its third multi-stakeholder workshop on 31st October 2023. The online workshop gathered 10 key stakeholders from the health data ecosystem, see appendix 4, focussing on the areas of data access, sharing, and integration. The primary objective was to highlight the necessities for developing new policies and frameworks to support better health data integration across Europe. The workshop aimed to hear the perspectives of stakeholders already engaged in the data sharing and integration space, seeking to understand what IDERHA is best placed to deliver in terms of building policy recommendations for supporting data sharing and integration. Specifically, the aims were:

- To explore differences, synergies, and interconnections of IDERHA with other data projects
- To understand gaps or challenges in policy requiring consensus building
- To identify areas with existing best practices or relevant consensus on guidance around data sharing and integration
- To explore what needs to be done to ensure the successful sustainability of policy recommendations

Methodology

During the workshop, participants received an introduction to the IDERHA project, gaining insights into how the project aims to change how health data can be used, accessed, and shared. Workshop participants were encouraged to discuss their experiences and lessons learned from similar projects that could be helpful for IDERHA.

To facilitate the discussion and for visualisation, Miro board was used (https://miro.com). In the first of three tasks, workshop participants were asked to identify their top barriers and challenges to data access and sharing. Subsequently, participants were asked to place their virtual sticky notes on a scale allowing for the visualisation of which identified barriers and challenges were more or less likely to be affected by policy change (Appendix 1). Participants were then asked to move their sticky notes on to a quadrant chart, providing a visualisation of which of their barriers and challenges were both feasible and impactful (Appendix 2).

Top barriers and challenges to access and sharing of data

To begin the discussion, participants were asked to share their top barriers and challenges to access and sharing of data that they have identified from working in this area. The identified barriers and challenges included:

- Harmonisation and interoperability
    - Lack of shared terminology e.g., for pseudonymisation, clinical definitions and analytical definitions
    - Limited interoperability/lack of resources to achieve interoperability
    - Lack of interoperability standards
    - Cloud solutions owned by third parties (outside of EU[1])
- Culture
    - Lack of data sharing culture i.e., people want access but are not willing to share - particularly at the organisational level
    - Distrust around data sharing across stakeholders especially for citizens
    - Lack of or non-standardised incentives to share data and/or setting up infrastructure
    - Lack of reuse/cooperation across European Union (EU) funded research projects
- Legislation & governance
    - Lack of harmonisation of legislation and governance procedures at an EU, national and organisational level
    - Differences in interpretation of legislation including General Data Protection Regulation (GDPR) and national policy
    - Challenge to international data flow
    - Management of granular on-going consent for primary and secondary usage of data
- Data access
    - Short timelines for procedures and processes to access data
    - Lack of clarity on requirements and decision-making in data access applications
    - Lack of realism when defining project goals - not aligned to the data access situation “on the ground”
    - Access to decision-makers who have the power to share data
- Data quality
    - Limited quality/completeness of data sets
    - Bias within data sets

[1] Third-country: A country outside of the EU. This can have an impact on data-flows especially in the context of the General Data Protection Regulation Data protection adequacy for non-EU countries (europa.eu)

Interoperability, culture change/trust building, and legislative and governance uncertainty issues were the most frequently mentioned topics.

Peter Rijnbeek, executive director of the DARWIN EU® Coordination Center, and coordinator of European Health Data and Evidence Network (EHDEN), emphasised the importance of improving interoperability, standardisation of analytical pipelines and phenotypes of certain diseases, and aligned definitions of study types. While most analytics are done using aggregated data, rare diseases may require specific policies, constraints, legal, and ethical considerations. He also emphasised the importance of a "research memory" to avoid repetition.

Christian Buggedei from Charité working on the project Gaia-X, highlighted problems in maintaining the infrastructure, but felt this could be easily solved through policy. However, a complex infrastructure involving multiple actors, costs effort and money and may need incentives to be maintained in the longer term.

Harald Wagener, also from Charité working on the project Gaia-X, stated that while there is consensus on the importance of sharing data by clinicians and researchers, there is also hesitancy in sharing these data and felt that this cannot be easily solved with regulations.

Shahid Hanif, Managing Director of the GetReal Institute, highlighted that the IMI GetReal project experienced a number of challenges accessing data for a variety of reasons, including the complexity of the process to access research-ready data in a timely manner as one significant barrier. Establishing a clear and reliable process regarding the request and timely provision of research-ready data is of importance.

Niklas Hedberg, who is involved in the project EUnetHTA-21, highlighted that decision makers mostly put emphasis on the risks rather than on the benefits of data sharing, since there are very few successful examples and pilots of use cases, that would ease trust building. Shahid Hanif added that decision makers must be clearly informed about strategies for risk minimisation. Christian Buggedei stated that data sharing through citizen consent is encouraged, ensuring that people consent before data is transferred or processed. However, the challenge of this approach is that the data owners need to be contacted and it might be difficult to find them. He states that the German Health Minister introduced the term "Study Tinder", which could be used to allow people to choose whether and in what study they would like to participate by contributing their data. Harald Wegener added to this, that the goal should be to make it easy for end users to understand the types of studies, the data needed, and the reasons for participating in such studies.

Dipak Kalra, President of the i-HD, added that educating the public about the value of using health data for the benefits of patients remains an activity undertaken by bodies with limited budgets.

Rada Hussein, Principal Investigator at Ludwig Boltzman Institute, stated that data and data ownership is currently discussed in Europe with a similar focus as in the United States. Depending on who owns the data, incentives to share data should not only be given to patients, but also to hospitals and healthcare providers. She referred to the health data governance principles (https://www.healthdataprinciples.org/) that were used in creating the governance model of HL7-Patient Contributed Data.

Sebastian Gerbholz, from Atos working on the Gaia-X project, mentioned the need for small pilot projects, that enable to get to the big picture in the end, such as the Gaia-X reusable blocks that will be used in the ambitious European Health Data Space (EHDS) pilot project.

Barriers and challenges that could be most influenced by policy change

Participants were asked about which of the identified barriers and challenges they felt could be most influenced by policy change. They were asked to place these on a scale from 'Can't be influenced by policy change' to 'Can be influenced by policy change' on an online Miro board. A summary of the key results can be seen in figure 1; the full results can be found in appendix 3.

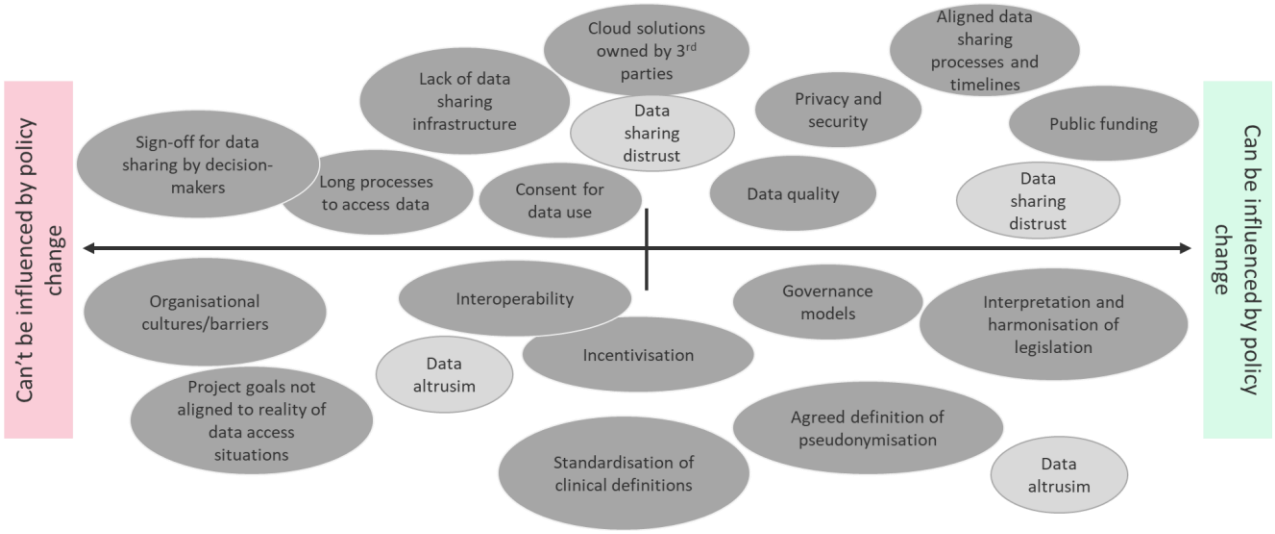


Figure 1 - Summary of key results of likelihood of barriers to be influenced by policy change. Light grey circles indicate key differences in participants' opinions on placement.

Issues surrounding legislative and governance rules and procedures, generally tended to be classed as having a higher likelihood of being influenced by policy change. Whereas, creating culture change to one of greater openness to data sharing, was generally felt to be less policy sensitive. It should be noted that this was a subjective exercise, meaning there were some discrepancies in participants' perceptions of how much certain topics could be influenced by policy change, such as hesitancy of data holder to share their data.

Other issues that were perceived to be likely to be impacted by policy change include the limited quality and completeness of data sets, lack of data availability, and public funding.

The lack of interoperability and data standards, and the complex application process of data access were perceived as problems that legislation was unlikely to solve.

Michel Silvestri, Head of Unit of the Swedish eHealth Agency, pointed out that the legal uncertainties are likely to be solved by policy. As some EU Member States may have additional legislations on top of the GDPR that could restrict cross-border health data exchange, the EHDS legislation could remove those barriers once it is implemented.
To enhance lack of trust of citizens and data holders, Shahid Hanif mentioned that transparency is needed from the bodies aiming to access and process the data.

Barriers and challenges that would be most impactful and feasible for IDERHA to address

Participants were asked to assign the identified barriers and challenges according to the impact they might have for the IDERHA project and according to the feasibility that they can be addressed within the IDERHA project. The key results are summarised in Figure 2.

Most of the challenges were classed as impactful with the majority being also perceived as feasible. Again, as a subjective task there was some disagreement, for example lack of trust, data altruism, data quality and interoperability, were all placed as different levels of feasibility and impact by different participants. This is perhaps reflective of the different experiences of the participants, and their general outlook on what is achievable. It is perhaps unsurprising, however, that most of the challenges were seen as impactful, as they had already been identified by the workshop participants as being their top perceived key challenges.

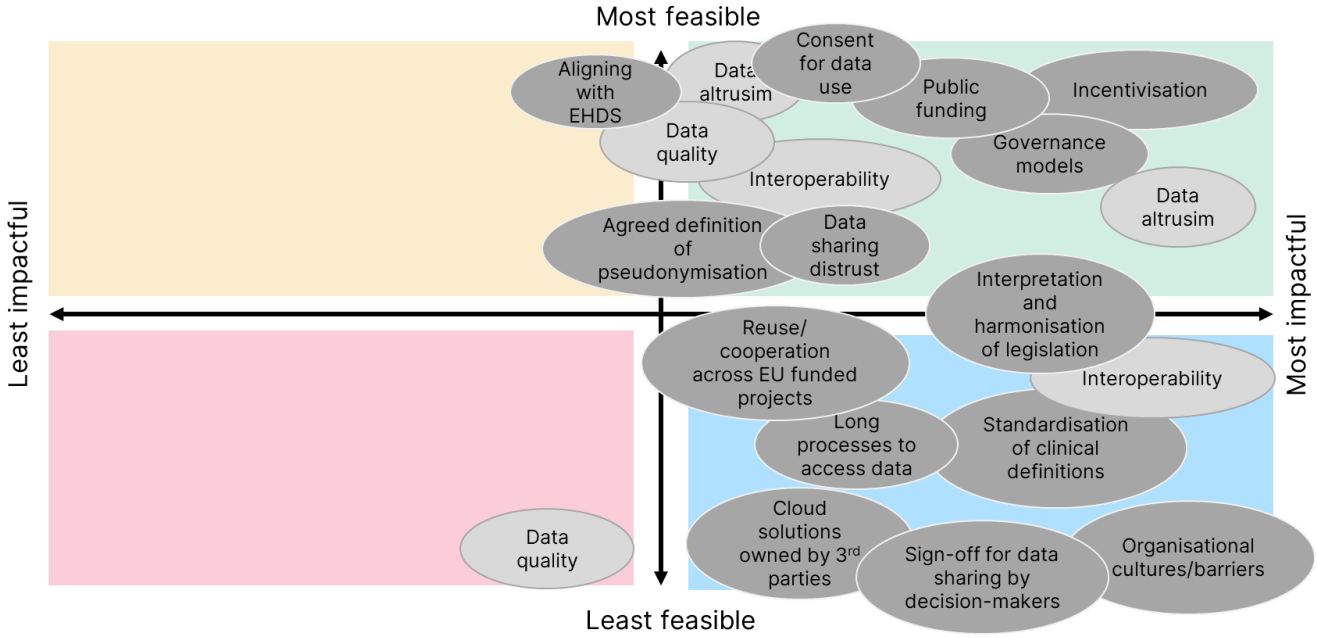


Figure 2 - Summary of key results of activity rating feasibility and impact of addressing barriers. Light grey circles indicate key differences in participants' opinions on placement.

Some of the barriers/challenges classed as most impactful and feasible to address included:

- Incentivisation for data sharing
- Consent by citizens/patients for primary and secondary data use
- Governance models
- Increasing public funding on data sharing and access

Some of the barriers/challenges classes as impactful but with lower feasibility included:

- Different organisational cultures and barriers
- Cloud solutions owned by third parties
- Standardising clinical definitions across databases
- Getting decision makers to sign off data sharing

Shahid Hanif stated that the challenge lies in identifying the key policy focus areas that can be impacted within the time frame of IDERHA. The focus could be on a whole range of policies with regards to different stakeholders or specifically on e.g. the EHDS. For enhancing the effectiveness of the work in IDERHA, Sebastian Gerbholz mentions the importance of reusable building blocks and cooperation across different projects.

Advice for the IDERHA project

To close the discussion, the participants were asked about advice they would give to themselves if they were undertaking a project like IDERHA, for example regarding actions or considerations at the earliest stages of the project to ensure best chances of policy recommendations being actionable.

Shahid Hanif suggested that it may not be enough to simply publish policy recommendations without laying out a path for others to follow. The policy recommendations should be addressed to specific target groups to be feasible. It is important to define and prioritise specific tasks focusing on impactful changes. He highlighted the importance of understanding previous political recommendations, important key drivers of change, identification of stakeholders, and failure-prone experiences to avoid repeating previous mistakes. Regarding this, Niklas Hedberg stated the importance of learning and analysing the reasons behind decisions that agencies did or did not make.

Shahid Hanif also mentioned the importance of communicating with the broader community and to actively ask for feedback.

Phillip Gribbon, IDERHA project leader, pointed out that the policy recommendations should be annotated with concrete examples of the use cases. Use cases and policy recommendations should align and should have a solid basis.

Sebastian Gerbholz mentioned that IDERHA might think about how to position the project regarding the upcoming EHDS regulation. He emphasised that the reuse of existing resources and cooperations across existing research projects should be strengthened, as there is no need to re-invent the wheel. He encouraged the IDERHA project to explore involvement in the EHDS2 Board and pilot.

Conclusion

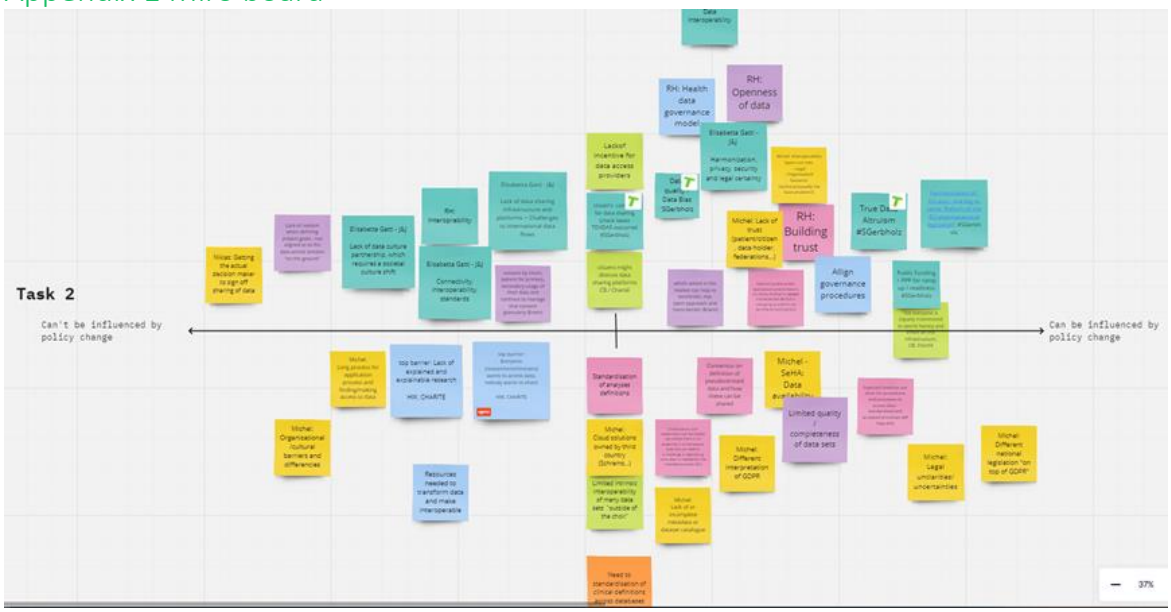
There are a wide range of key barriers and challenges to current data sharing and access. These encompass attitudinal barriers such as a lack of altruism in data sharing, governance barriers in the form of lack of harmonisation across international, national, and organisational policies, and more technical barriers such as interoperability. The most frequently cited challenges to data access and sharing were interoperability, uncertainty over legislation and governance, and the lack of a data sharing culture or lack of trust to share data. Legislation/governance issues and interoperability were considered more sensitive to change through policy than attempting to enact culture change, however, the feasibility of addressing some of these challenges were unclear. Three of the barriers and challenges considered most impactful and feasible to address were incentivisation, patient/citizen consent, and increasing public spending on data sharing and access. It will be important to consider the wider context of the EHDS and previous lessons learned when considering areas for policy development.

Recommendations

- IDERHA should explore policy recommendations for creating standardised incentives, promoting data altruism, and establishing clear governance procedures including appropriate consent mechanisms. This includes incentivising public and private entities to share data while ensuring transparent and ethical practices.
- IDERHA should assess the feasibility of implementing policy recommendations and seek to tackle areas where this is most likely. These recommendations should emphasise harmonisation at EU, national, and organizational levels.
- IDERHA should establish and maintain strong links with the European Health Data Space (EHDS), to ensure ongoing work is complementary and avoids duplication of efforts. Exploring involvement in the EHDS2 Board and pilot and leveraging their reusable building blocks will enhance the project's impact and contribute to the broader European health data landscape.

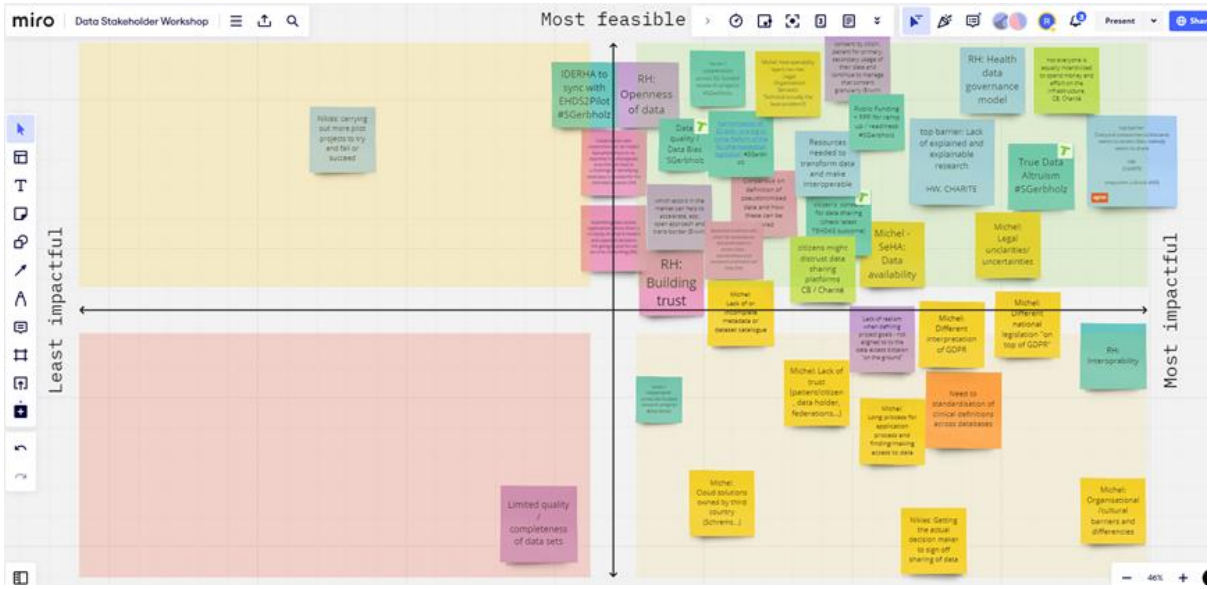
Appendix

Appendix 1 Miro board



Appendix 1 - Example of Miro board activity looking at likelihood to be impacted by policy change

Appendix 2 Miro board



Appendix 2 - Example of Miro board activity looking at feasibility and impact of addressing barriers

Appendix 3: Miro Board Results: perceived policy sensitivity of identified barriers and challenges

Barriers and challenges identified by participants listed in order they were placed on the scale of 'can't be influenced by policy change' (indicated by red) to 'can be influenced by policy change' (indictaed by green). Colour strength indicates proximity to the midline. Those in yellow indicate those placed on the midline between the two points.

Can't be influenced by policy change
Getting the actual decision maker to sign off sharing the data
Organisational/cultural barriers and differences
Lack of realism when defining project goals – not aligned to the data access situation "on the ground"
Long process for application process and finding/making access to data
Lack of data culture partnerships which requires a societal culture shift
Top barrier: lack of explained and explainable research
Resources needed to transform and make interoperable
Connectivity, interoperability standards
Interoperability
Everyone (researchers/clinicians) wants to access data. Nobody wants to share.
Lack of data sharing infrastructure and platforms and challenges to international data flows
Consent by citizen, patient for primary, secondary usage of their data and continue to manage that consent granularity
Lack of incentive for data access providers
Citizens might distrust data sharing platforms
Citizen's concerns for data sharing (check latest TEHDAS outcome)
Standardisation of analyses definitions
Need to standardisation of clinical definitions across databases
Cloud solutions owned by third country
Limited intrinsic interoperability of many data sets "outside of the choir"
Data quality Data Bias

Health data governance model
Lack of or incomplete metadata or dataset catalogue
Collaboration with researchers can be helpful but where there is no example in a therapeutic area this can lead to a challenge in identifying what data it needs for the intended purpose
Which actors in the market can help to accelerate, esp. open approach and trans-border
Harmonisation, privacy and security and legal certainty
Consensus on definition of pseudonymised data and how these can be shared
Openness of data
Different interpretation of GDPR
Lack of trust (patient/citizen. Data holder, federations....)
Submitting data access applications where there is no clarity of what is needed and expected decisions - the going to and from can be time-consuming (SH)
Legal, Organisational semantic, Technical (usually the least problem?), Governance
Building trust
SeHa: Data availability
Limited quality/completeness of data sets
Align governance procedures
True data altruism
Expected timelines are short for procedures and processes to access data- standardised and accepted processes will help
Public funding = PPP for ramp up/readiness- extension of direct grants to MS for initial setup of NCP2/HDAB services, expansion of grants for initial implementation of MyHealth@EU eHDSI, offering secure processing environment as a service (esp. initially and for smaller countries)
Not everyone is equally incentivised to spend money and effort on the infrastructure
Legal uncertainties/unclarities
Harmonisation of EU acts - one big to come 'Reform of the EU pharmaceutical legislation' - common European goals of EU Health Union, Digital Society, along with harmonization of EU acts national implementations. EU Acts (AI Act, Data Act, Data Governance Act, revision of the EU general pharmaceuticals legislation) interrelate

with multiple EU programs (Building resilience for future public health crisis / Rules on Cross Boarder Health Threats; OneHealth; ...
Different national legislation “on top of GDPR”
Can be influenced by policy change

Appendix 4: Workshop Attendees

The data stakeholder workshop consisted of 10 participants that were/are involved in different projects aiming to facilitate data access, sharing and integration:

Name	**Organisation**	**Relevant projects involved in**
Professor Peter Rijnbeek	Erasmus University Medical Centre, Department of Medical Informatics	EHDEN, DARWIN
Niklas Hedberg	Dental and Pharmaceuticals Benefits Agency	EUnetHTA-21
Shahid Hanif	GetReal Institute	GetReal Institute
Rada Hussein	Ludwig-Boltzmann Institute	IDERHA
Erwin Dijkstra	Atos	Gaia-X
Sebastian Gerbholz	Atos	Gaia-X
Harald Wagener	Charité, Berlin Institute of Health	HEALTH-X dataLOFT
Christian Buggedei	Charité, Berlin Institute of Health	Gaia-X
Michel Silvestri	Head of Unit, Swedish eHealth Agency	TEHDAS
Elisabette Gatti	Johnson & Johnson	

The IDERHA members in attendance were:

Name	**Organisation**
Phillip Gribbon*	Fraunhofer Institute for Translational Medicine and Pharmacology
Lotte Gorth	DEFACTUM
Morten Deleuran Terkildsen	DEFACTUM
George Kolostoumpis	ECPC
Dipak Kalra	i-HD
Monica Brand	Johnson & Johnson
Heather Colvin	Johnson & Johnson
Ravinder Claire*	National Institute for Health and Care Excellence
Katharine Cresswell*	National Institute for Health and Care Excellence

Rebecca Lumsden*	Sanofi
Nataliya Kemenyash	Takeda

*Speaker

Appendix 5: Workshop agenda

Topic	**Lead**
Welcome and introductions	Ravinder Claire
IDERHA introduction	Phillip Gribbon
Audience Q&A	All
Miro board activity 1 – barriers and challenges	Katharine Cresswell
Miro board activity 2 – likely impact of policy change on barriers/challenges	Katharine Cresswell
Miro board activity 3 – Impact and feasibility of addressing barrier/challenge	Rebecca Lumsdon
Closing question - advice for the project	Katharine Cresswell
Next steps	Katharine Cresswell

IDERHA Task 6.3 Data Providers Workshop 20/06/2024 - Executive summary

Participants

The IDERHA project's multi-stakeholder workshop on the 20th June 2024 gathered seven data protection officers (DPOs), information governance officers and people working in associated roles from across healthcare sector organisations in Europe that hold health data.

Aims

The workshop aimed to:

- understand more about the challenges in assessing data access and sharing requests for research faced by those directly responsible for data protection in their role i.e. DPOs
- understand both potential pragmatic and aspirational solutions to the challenges DPOs face, both now, in the mid-term (~next 5 years) and long-term after the implementation of proposed plans such as the European Health Data Space (EHDS).
- understand possible nuances in challenges and solutions to data sharing in different countries, organisation types (e.g. hospital vs. consultancy, for profit vs. not for profit)
- get feedback from the DPOs on the proposed principals of the data management plan in IDERHA

Key Findings

The greatest challenges facing DPOs and people working in associated roles are around ensuring correct interpretation of the legislation. There is a need to support and promote harmonisation of interpretation of the GDPR, and this will be even more important as new EHDS legislation comes into force.

Recommendations

Based on the discussions held in this workshop, the following recommendations could be made:

1. **Provide greater support in interpreting how best to comply with the GDPR, especially with regard to anonymisation**
2. **Ensure new EHDS legislation does not conflict with GDPR and clarify the interplay between EHDS and GDPR. Since EHDS will give rise to new scenarios requiring new GDPR interpretations, this would represent new challenges for the work of the DPOs. Provide training and support on EHDS for DPOs rather than just providing information to raise awareness of impacts on their job – this needs to be easily understandable, with relevant examples/case studies for their work and not burdensome as many DPOs and people in associated roles are already overstretched**
3. **Create opportunities for DPOs and people in associated roles to be able to connect to discuss problems and understand solutions others have taken.**
4. **Existing engagement opportunities should be promoted, since they are not well known or not widely used due to limited resources from the DPOs side. Hence, organizations should also provide resources (dedicated time and funding) for DPOs to take part in these opportunities.**

IDERHA Task 6.3 Data providers workshop 20/06/2024 - Full report

Introduction

On 20th June 2024, the IDERHA project held its fourth multi-stakeholder workshop. The online workshop gathered seven data protection officers, information governance officers and people working in associated roles from across healthcare sector organisations in Europe. The workshop aimed to hear the perspectives of stakeholders already engaged in the data sharing and integration space, seeking to understand what IDERHA is best placed to deliver in terms of building policy recommendations for supporting data sharing and integration. Specifically, the workshop aimed to:

- understand more about the challenges in assessing data access and sharing requests for research faced by those directly responsible for data protection in their role i.e. DPOs

- Understand both potential pragmatic and aspirational solutions to the challenges DPOs face, both now, in the mid-term (~next 5 years) and long-term after the implementation of proposed plans such as the European Health Data Space (EHDS).
- Understand possible nuances in challenges and solutions to data sharing in different countries, organisation types (e.g. hospital vs. consultancy, for profit vs. not for profit)
- Get feedback from the DPOs on the proposed principals of the data management plan in IDERHA

Methodology

Data providers were identified from projects such as EHDEN, DARWIN, and HARMONY, from the HMA-EMA Catalogues of Real-world Data Sources[1] and also Biobanks and University Clinics. Both profit and not-for-profit healthcare data organisations were approached. We contacted the respective organizational contact person and/or DPO, if known, via e-mail, explained the aims of the workshop, and invited them to take part. Eight people confirmed their attendance, with one person withdrawing before the workshop took place. During the workshop, participants received an introduction to the IDERHA project. They were then asked to describe what they felt the role of a DPO/their role was within their organisation. This was followed by a discussion on the current barriers and challenges to health data sharing and access, prompted using an image from the EIT Health Think Tank report (2024): Implementing the European Health Data Space Across Europe (Appendix 1). Participants were then asked to complete a polling question on their familiarity with the European Health Data Space (EHDS), before being given a short overview of the EHDS and some of the key concepts that interplay with the existing General Data Protection Regulation (GDPR). Finally, an overview of the IDERHA Data Management Plan was provided.
To facilitate the discussion and for visualisation, Miro board was used (https://miro.com). Workshop participants were asked to identify their top barriers and challenges to data access and sharing and the potential solutions to these using virtual sticky notes.
The workshop agenda can be found in Appendix 2.

Role of a DPO/Information Governance Officer

It was felt that the focus of the role of DPO was on trying to support compliance with all relevant data protection laws, in particular GDPR, within the organisation. The challenges of doing this as an individual or a small team were acknowledged, as was the need to work and have support across the organization.

"The reality if you're a part of a big organisation...the idea of one person guaranteeing compliance is obviously impossible, but I can inform the policies, the procedures and also it takes a bit of a village... it'd be fair to say most people aren't doing this job solo"

It was noted that the acceptable decisions, processing actions and safeguards to be compliant is not always clear cut and so the DPO role is often to provide interpretation to the applicable privacy rules and regulations and then determine the most appropriate approach to take.
DPOs are expected to maintain their knowledge on all relevant legislations to be able to act as an 'expert' or adviser on such matters, ensuring organisational policies are kept up to date.
Additionally, the role involves raising awareness and conducting training among staff and stakeholders on relevant data protection regulations, compliance requirements and important updates to these.

Participant quotes on role of a DPO
"Act as the single contact point for supervisory authorities and DPOs at customer and vendor companies; oversee compliance with data subject requests; early involvement in DPIAs and privacy policy and procedures development, staying engaged with EU privacy forums and continuous GDPR training – basically "stay an expert" so when consulted on escalated privacy issues, I am able to determine the correct / most appropriate approach under GDPR / the applicable privacy rules and regs."
"In my view, a DPO should ensure that an organization complies with data protection laws and regulations, particularly GDPR when dealing with data from the European Union. I see some basic roles and responsibilities for a DPO such as advising on policies and monitoring processes to ensure compliance."
"Act as an advisor to the organisation on the protection of personal data it processes, including in relation to legal obligations under applicable data protection law, but also to operational and practical issues concerning protection of personal data. Overseeing data protection across the organisation, including risk assessments (DPIAs), and training and awareness. In reality, the role often involves acting as a 'critical friend' to the organisation, in terms of informing them of the data protection risks of proposed processing activities, while also recognising the benefits to the organisation's strategic objectives. Acting as a senior, central point of contact for staff, customers, individuals, regulatory bodies and other stakeholders seeking to raise concerns. This also includes acting as an advocate for individuals who may not have a single voice, such as patients."
"Provide advice, make sure to comply with different laws"
"My role is to guarantee GDPR compliance in the organisation by data process review and training and raising awareness among staff and stakeholders."
Participants quotes on role of an information governance officer
"Establishing and overseeing processes for the safe and appropriate handling and sharing of personal and sensitive information relating to patients & health service users. Balancing the need to facilitate use while limiting the risks involved in management of data and ensuring regulator compliance. Key to this is engaging key stakeholders DPO/legal/public to build solutions!"

Table 1. Participant quotes about purpose of DPO/their job role

Current barriers and challenges to access and sharing of data

The following barriers and challenges were identified and/or acknowledged by the participants:
Heterogenous interpretation of the GDPR – different organisations/countries will take different approaches based on their own perceptions of what is compliant

Lack of dedicated resources i.e. protected time, travel budget to engage within the network of DPOs to grow consensus on challenging topics contributes to differing interpretations

"So yes, there's certainly awesome networks. And again, it does come down to resource. You know, there ends up being lots of different sort of meetings we should be attending to and we can't"

"Individual Players following an unilateral maximum approach, thereby further enhancing the cross-sectoral and cross-jurisdictional gaps"

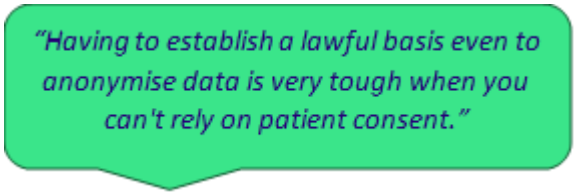
- **Legal basis fragmentation**

- **Determining the relevant legal basis e.g.** will consent be needed or will a different GDPR legal basis be more suitable?

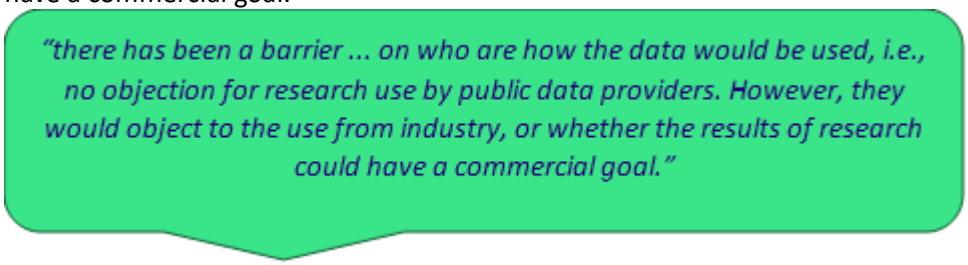
"The GDPR itself is very principles based. It tells you what you must do. In order sets out the obligations, but it doesn't really tell you how to comply with them

- **Concerns around anonymisation**
    - Ensuring anonymisation of health data and preventing indirect identification of patients, e.g. when linking the data with other data sources
    - Lack of standards on anonymization/ pseudonymization in research contexts
        - What these terms mean
        - Whether anonymised or pseudonymised data should be used

"Different institutions have different understanding of of what is Pseudonymous data or what is anonymized data. We have the same contract framework agreement...and there are a different interpretations of the same article for at least 50% of the of the different institutions, depending on the countries."

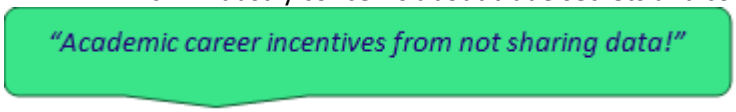


- **Transparency and trust on purpose of data use**
  - Understanding public value of use of data - to feed into risk balance assessment
  - Maintaining public trust in the appropriate use of health data e.g. the research must visibly be to benefit public health and/or patient care
  - How data would be used, i.e., no objection for research use by public data providers, however objection to the use from industry, or whether the results of research could have a commercial goal.



  - Lack of transparency and visibility for patients

- **Disincentives for data sharing**
  - Lack of return (not necessarily economic, but information on data use, acknowledgement, reciprocity etc.) to the data provider
  - Academic career incentives are often greater from not sharing data (publications, grant applications, reputation) may rely on not sharing primary data sources
  - Industry concerns about trade secrets and commercial IP protection



- **Technical barriers**
  - Unstructured formats in Electronic Health Records (EHRs) means data not easily searchable and is therefore unused and some sources of EHR are not easily accessible e.g. primary care
  - Unharmonised data models and data dictionaries
  - Lack of interoperability of EHR and other health data systems

> *"..the way electrical records, which are something that is gonna be used more and more in Federated networks. They are so different even within the same country... They don't talk between them. So if you go from Spanish health record and try to compare it with the German one. It is totally impossible."*

- **Cost and resource use**
  - Maintaining accuracy EHRs costly / time-consuming
  - The costs of data documentation and support of data sharing (advising both potential users and organisations) cannot be covered by grants or core organisational funds

> *"The requirements to be a data a data provider are not very clear. And for some organisations, for big organisations it's OK, but for instance for non-profits like us. We are fearing that the requirements might require an investment that we cannot afford so that we don't have the resources."*

- **Knowledge gaps**
  - Lack or trust due to lack of understanding of concepts and emerging technology

Introduction of the EHDS

Most participants rated their familiarity of the EHDS as 3 or below, (Table 2) when asked to rate from 1 to 5, where 1 was not at all familiar and 5 was very familiar. This lack of familiarity meant that most participants were unable to consider potential policy recommendations at this time, however, it was clear that there is concern that existing issues with heterogenous interpretation of the GDPR could be maintained or exacerbated with an additional set of legislation being added. It was stressed that getting the information and training on the different legislations, such as the EHDS was not the main concern, but rather the practical interpretation of different legislations in place and the question what legislation and law would apply under what scenarios. One participant mentioned the concern that especially small organisations might not be well be equipped for implementing the EHDS and for meeting the requirements a data provider would have to fulfil within the EHDS framework.

Participant No.	**Rating**
Participant 1	3
Participant 2	3-4
Participant 3	2
Participant 4	1-2

Participant 5	3
Participant 6	2

Table 2. Participant ratings on familiarity with EHDS where 1 was not at all familiar and 5 was very familiar.

Suggested solutions

Participants suggested a number of solutions to address the barriers that had been described:

- Harmonisation of GDPR interpretations for health data use
- Lobbying for reform of local laws governing health data processing, i.e. to allow processing to anonymise data without requiring patient consent (where public interest is not available, for example)
- Harmonising data models
- Data access via Secure Processing Environments/Trusted Research Environments, rather than traditional data sharing models
- Use of synthetic data for AI/Machine Learning (BUT synthetic data may still be considered personal data under existing legal frameworks, so more specific regulation is likely to be required)
- Clarification of the practical requirements/risk mitigations for cross-border transfers where data are hosted in the EEA, but accessed from a third country
- 1-1 conversations between DPOs rather than forwarding information. Calls better than lengthy emails.

In addition, during the workshop a small number of IDERHA participants suggested the following solutions upon hearing the discussions:

- Approach as to data sharing framework, based on efficiency risk mitigation (lose redundancy where possible)
- Cross-country agreements on the adequacy of information security safeguards for pseudonymised data
- Consensus on acceptable standards for adequate anonymisation, for different categories of data and scales of data sets
- Clarity on the granularity and specificity of broad consent that is still considered to be consistent with the GDPR

Conclusions and Recommendations

The greatest challenges facing DPOs and people working in associated roles are around ensuring correct interpretation of the legislation. There is a need to support and promote harmonisation of

interpretation of the GDPR, and this will be even more important as new EHDS legislation comes into force.

Based on the discussions held in this workshop, the following recommendations could be made:

1. **Provide greater support in interpreting how best to comply with the GDPR, especially with regard to anonymisation**
2. **Ensure new EHDS legislation does not conflict with GDPR and clarify the interplay between EHDS and GDPR. Since EHDS will give rise to new scenarios requiring new GDPR interpretations, this would represent new challenges for the work of the DPOs. Provide training and support on EHDS for DPOs rather than just providing information to raise awareness of impacts on their job – this needs to be easily understandable, with relevant examples/case studies for their work and not burdensome as many DPOs and people in associated roles are already overstretched**
3. **Create opportunities for DPOs and people in associated roles to be able to connect to discuss problems and understand solutions others have taken.**
4. **Existing engagement opportunities should be promoted, since they are not well known or not widely used due to limited resources from the DPOs side. Hence, organizations should also provide resources (dedicated time and funding) for DPOs to take part in these opportunities.**

However, additional work is needed by IDERHA to further develop these recommendations to ensure effective implementation and impact:

- How/if should these recommendations be promoted by policy? There is an urgent need for policy makers to address these issues, but at the same time, policy makers work slowly and therefore may not be able to address every issue in time
- Who should be responsible for providing such support, training, opportunities?
- What level should these recommendations be targeted?
    - National
    - International
    - Organizations
    - Funders
    - DPOs

Appendix

Appendix 1 Current Data Sharing Barriers and Challenges Discussion Prompt

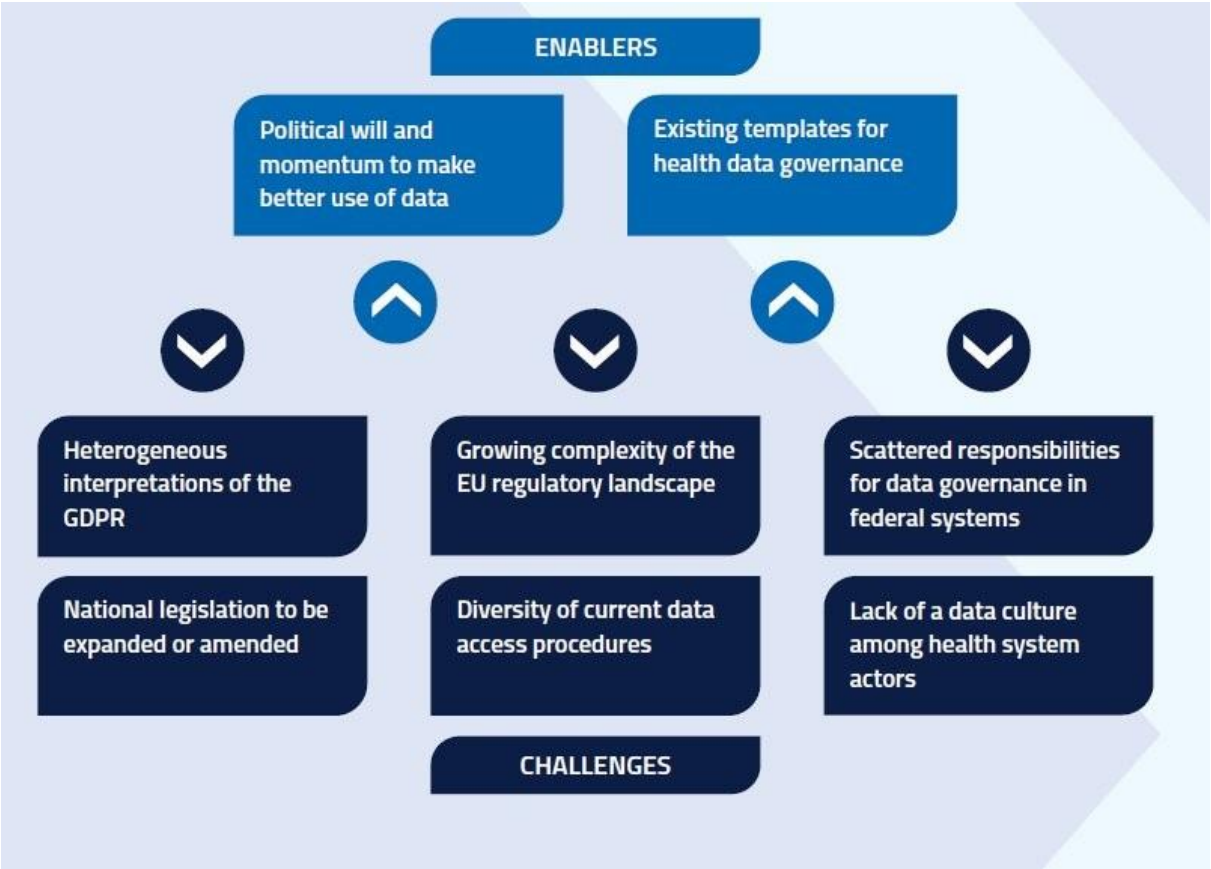


Image from: EIT Health Think Tank (2024): Implementing the European Health Data Space Across Europe

Appendix 2: Workshop agenda

Item	Timing
Welcome and introductions	10 mins (12.00-12.10)
Introduction to IDERHA	10 mins (12.10-12.20)
Role of a DPO	10 mins (12.20-12.30)

Key barriers & solutions – short to mid-term	35 mins (12.30-13.05)
Developing solutions – looking to the future (EHDS)	25 mins (13.05-13.30)
Developing solutions – IDERHA proposal	25 mins (13.30-13.55)
Next steps	5 mins (13.55 - 14.00)