

101112135 - IDERHA

Integration of heterogeneous Data and Evidence towards Regulatory and HTA Acceptance

WP6 Policy recommendations to enable HTA decision making

D6.1 Analysis of current and emerging policies for data access/sharing, research use and transparency requirements

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Executive Summary

This deliverable is an early version of work being undertaken by Task 6.2 of IDERHA, whose role is to scan the European and international landscape of policy and legislative instruments that have a bearing on the ways in which IDERHA seeks to acquire, collect, process and use health data, including its intended development and use of artificial intelligence and mobile applications to be used by patients. The primary responsibility of the task is to signpost relevant instruments, or parts of instruments, to which various work packages will need to conform. Instruments in this context will not be limited to legislative instruments, but may include policies and strategies, international standards, guidelines and reports from authoritative bodies and academic publications.

The task will examine the policy and legislative landscape from the perspective of the impact that it has on the work plan, design and engineering, acceptability, sustainability and scalability of IDERHA's solutions. It will highlight whether these represent expected and good practices that the project should embrace or constraints that are not well suited to the mission of IDERHA but which we need to find appropriate ways of achieving compliance with without prejudicing the success of the project. The task will moreover highlight gaps in the current policy and legislative landscape and will co-develop strategies for addressing these with other WP6 tasks and the Integrated Data Access Governance Council (IDAGC).

It was agreed at the beginning of the project that it will not be helpful to the vast majority of internal IDERHA members and for the IDAGC for this deliverable to be a long scientific document. It has instead been decided that it will be most helpful to summarise the important implications of each instrument as an executive briefing, and to compile a portfolio of these briefs within a conceptual organisational structure that brings together related instruments under key topic headings. Task 6.2 has therefore defined, and begun to populate, a standard template for summarising each instrument and its IDERHA relevant implications. An overarching topic map was developed and will serve as the living high-level conceptual framework for a growing portfolio of executive briefing templates.

This document presents the objective of Task 6.2's first deliverable, the scoping methodology adopted, the template structure and the topic map in its present form. It includes, in Section 7, some initial populated templates, as examples of the work being undertaken. It is intended for the portfolio of templates to increase and to be maintained throughout the project as a living resource. The first deliverable is presented in a document, to be succeeded by a more complete document at month 20 of IDERHA and perhaps also an online version that is likely to be more usable by the majority of the intended readers.

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1. Introduction

IDERHA is developing a health data integration and analytics platform that combines heterogeneous health data sources including EHRs, medical images and patient collected data. It will utilise AI to develop risk stratification and prediction models that can assist in personalisation of treatment, early detection of deteriorations and recommend appropriate care pathway adaptations. Its data and analytics will deliver value across a spectrum from near patient to scientific research including the future development of innovations in medical technology and medicines. IDERHA has selected to exemplify and demonstrate this platform in the domain of lung cancer, but aims to develop components that are generic, disease agnostic and capable of application to other cancers and other short- and long-term conditions, as part of its overall scope of operation.

IDERHA will need to integrate large volumes of sensitive (GDPR special category) personal health data, perform machine learning and develop AI solutions that will be used by patients, researchers and clinicians. In order to deliver value to individual patients, some of its data flows and processing will need to retain patient identification, including collecting patient preferences and dynamic consent regarding the secondary use of their data, others will need to use pseudonymised data in order to correctly manage longitudinal linkage and multi-source linkage, and other uses can be anonymised. IDERHA will enable reuse of health data across borders, at a European scale, and reuse by industry as well as academic and health systems organisations. Its development and use of AI has to be ethical, equitable, risk managed, safe and transparent.

IDERHA's ambition will be realised in a policy and legislative context that is relatively complicated, only partially harmonised at a European level, and is rapidly evolving as the opportunity for making better use of health data is realised by decision-makers (European Commission, 2022). At the same time, legislation is becoming more stringent due to public and decision-maker concerns about the ways in which health data could be used detrimentally, inappropriately exploited, and might lead to the development of AI that harms individuals and groups (Marcus et al. 2022). There are also calls for, and potential policy movement in the direction of, greater transparency to the public, accountability to the public and greater control over the processing of personal data by individuals (TEHDAS 2023a).

Task 6.2 has been set up to scan this European and international landscape of policy and legislative instruments, to highlight those that have a bearing on the ways in which the IDERHA seeks to acquire, collect, process and use health data, including its intended development and use of artificial intelligence and mobile applications to be used by patients. The task will examine this policy and legislative landscape from the perspective of the impact that it has on the work plan, design and engineering, acceptability, sustainability and scalability of IDERHA's solutions. The primary responsibility of the task is, therefore, to signpost relevant instruments, or parts of instruments, to which various work packages will need to conform, and to highlight whether these represent expected and good practices that the project should embrace or constraints that are not well suited to the mission of the project, but which we need to find appropriate ways of achieving compliance with, without prejudicing the success of the project. Instruments in this context will not be limited to legislative instruments, but may include policies and strategies, international standards, guidelines and reports from authoritative bodies and academic publications.

A further role of Task 6.2 is to highlight policy and legislative gaps, and instruments that do not cater well for the mission of IDERHA, in order to develop recommendations for external stakeholders and policymakers. In tackling this, the recommendations arising from the task will be critiqued within the whole of work package 6 and considered as inputs to future meetings of the Integrated Data Access Governance Council (IDAGC). The council is convened and run from work package 6, and comprises internal IDERHA stakeholders and external stakeholders and thought leaders. As the project progresses, their guidance will be sought on how best to influence change in the policy and legislative landscape. How to better favour an environment that

enables large-scale learning from health data and the translation of that learning, into improvements in care pathways and clinical guidelines.

It was agreed at the beginning of the project to produce a concise document containing summarised executive briefings of salient political and legislative instruments and their important implications for the IDERHA project. In this document, we compile a portfolio of these briefings within a conceptual, organisational structure that brings together related instruments under key topic headings. Task 6.2 has therefore defined, and begun to populate, a standard template for summarising each instrument and its project relevant implications. An overarching topic map, that will serve as the living high-level conceptual framework for a growing portfolio of executive briefing templates, has been developed.

Task 6.2 has two deliverables. This deliverable, published in month 8 of the IDERHA project, presents the objective of task work, the scoping methodology adopted, the template structure and the topic map in its present form. It includes, in Section 7, some initial populated templates, as examples of the work being undertaken. It is intended for the portfolio with templates to be maintained throughout the project as a living resource, initially presented in this first deliverable, to be succeeded by a more complete deliverable in month 20 of IDERHA, containing many more templates. Moreover, the deliverable in month 20 will also draw on a broader composition of data sources, expanding the current methodology to include interviews with central stakeholders.

However, the primary repository of these executive briefings will be an internal micro-site within the IDERHA project website, as a regularly maintained library of online executive briefings, with relevant hyperlinks between them and topic related synopses. Additionally, the microsite approach will facilitate dissemination, ensuring greater accessibility to the knowledge pool produced by Task 6.2. The brief templates and synopses will later on in the process contain additional information about the approach IDERHA has taken to ensuring compliance, or mitigations it has taken in order to avoid an issue or obstacle arising from that instrument. A policy gap analysis will also be developed and maintained, alongside feedback and guidance from the IDAGC and any impacts IDERHA has had on those gaps.

2. Methodology

This first version of the Task 6.2 deliverable presents the methodology by which the task has begun its work, presenting its overall approach to collecting, synthesising, organising and sharing key insights from the relevant policy and legislative landscape.

2.1. Objective and scope

The overall task objective for examining regulations, legislation, policy, guidelines and emerging practices relevant to the IDERHA work plan, its wider adoption and sustainability, is to determine:

- to which instruments does IDERHA have to **conform**?
- which offer good approaches that IDERHA should voluntarily **adopt**?
- which might prove to be challenges that IDERHA needs to cope with by **finding mitigations**?
- on which barriers could IDERHA enlist the help of IDAGC and other external stakeholders to create calls to action and stimulate a **momentum for change**?
- to which emerging practices or in development instruments can IDERHA **contribute** our needs and insights?

The scope of Task 6.2 and its deliverables is to examine “current and emerging policies for data access/sharing, research use and transparency requirements”. This remains the primary focus of the instruments being examined, but it is necessary to take on board a slightly wider scope given that IDERHA is developing artificial intelligence solutions which are increasingly accountable, as e.g. the proposed European AI Act, to be transparent and ethical (European Commission 2021). A wider scope is also needed to consider instruments and policies that could impact on the adoption and sustainability of IDERHA-like platforms and their optimal use to benefit patient care and accelerate personalised medicine research.

The first priority for Task 6.2 was therefore to develop a topic map that scopes the possible domains of policy interest that could be relevant to IDERHA.

2.2. Development of the topic map

The starting point for this topic map was to examine the project work plan, and in particular the data acquisition, processing and sharing processes that are intended and the results outputs to be generated. IDERHA is working with multiple data providers across Europe and will also engage directly with patients at clinical sites who will collect data through apps and wearables. The data will be brought together into a federated learning platform that will serve observational study and AI development purposes. Risk stratification and prediction models will then become embedded within digital tools that incorporate AI components, for digital health trials at clinical sites. Other areas of the work plan will, for example, examine and implement topics like AI ethics and explainability, and dynamic consent. An initial topic map was drawn up reflecting these areas of work, as topics on which relevant policy and legislative instruments might have a bearing.

Next, several EU-level instruments of obvious high importance were examined in order to insert their main areas of focus. These in particular included the EU GDPR, the EHDS draft Regulation, the draft EU AI Act and the Data Governance Act (European Commission 2020). This enabled a second level of the topic map to be populated. These sub-topics can be used to map the main provisions of different instruments, and also serve as topics on which to look for other instruments and/or good practices.

The next step was to consider the challenges and strategies adopted by current and recent key European health data projects. These included IMI EHR4CR ([Weblink 1](#)), GetReal ([Weblink 2](#)), EMIF ([Weblink 3](#)),

EHDEN ([Weblink 4](#)), EU PEARL ([Weblink 5](#)), Conception ([Weblink 6](#)), H2O ([Weblink 7](#)), and Horizon 2020 projects and support actions including ValueHealth ([Weblink 8](#)), ASSESS-CT([Weblink 9](#)), eStandards ([Weblink 10](#)), DigitalHealthEurope ([Weblink 11](#)), European mHealthHub ([Weblink 12](#)), Label2Enable([Weblink 13](#)), and UNICOM ([Weblink 14](#)). Reports of well conducted multi-stakeholder consultations and engagements on health data related topics were also examined (DigitalHealthEurope 2020a,2020b; I-HD 2021a,2021b,2022,2023). The topic map was enriched to include areas on which policy, good practices or other enabling solutions exist, some of which might prove to be challenges lacking suitable policy coverage.

The resulting topic map was shared with partners in WP6, and then presented at the first meeting of the IDAGC, which is part of achieving Milestone 3 in IDERHA (IDAGC Established, due month 9). This feedback was incorporated into the map, as presented in this deliverable, in section 3. This revision process, aided by the IDAGC, constituted a central milestone and acted as a springboard for initial discussions of the council.

The topic map is not intended as a work list. It is expected that only some of the main branches and lower-level nodes will have corresponding instruments to summarise. The topic map is intended to be a conceptual model of the potential landscape that will be kept as a living model, during the IDERHA's lifetime. This is done in order to act partially as a prompt to be vigilant across these subject areas for forthcoming instruments, and partly as an organisational structure for storing and navigating the individual executive briefing summaries that are produced on an instrument by instrument basis. Higher-level topics in the topic map will also be the headings on which a synthesis of several topic maps is created, and their IDERHA implications.

2.3. Development of the policy briefing template

Having agreed that each policy instrument should ideally be summarised in a short executive style, the lead partners of task 6.2 proposed a basic set of headings that were then standardised as a Word template with guidance notes.

Each template entry must specify one or more topics to which it corresponds, from the topic map. The instrument or other resource that is being summarised is specified, preferably with a link to the original material, if it is openly accessible. The summary itself is intended only to highlight the project relevant implications. There is also a section to highlighting current gaps in the policy landscape, and a section to summarise areas in need of further exploration. It was agreed that large and complex instruments would benefit from being split into several templates in order to keep the templates short, specific and easy to digest.

The template is presented in Section 4, and initial examples of populated templates are presented in Section 7.

2.4. Collection of policy briefings

The purpose of each brief is to be concise and project relevant. It is therefore preferable that each instrument is summarised by a member of the consortium who knows that instrument well, and is also familiar with IDERHA, and therefore can create a truly expert and highly relevant summary. This contrasts from an academic style summary that would be conventionally produced through desk research.

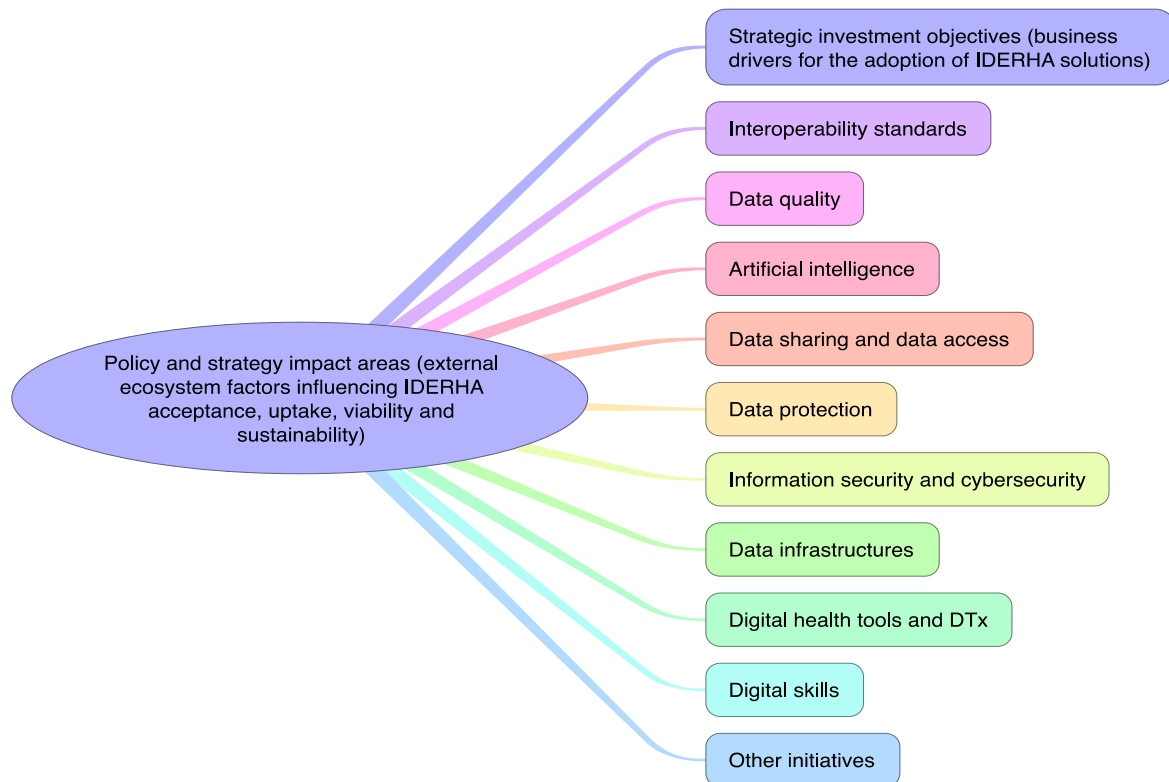
The task 6.2 leaders began this process by summarising six relevant instruments. These structured summary examples were used to define and communicate the over-arching style of summary and use of the template to other members of Task 6.2. Beside this, leaders of other relevant tasks (Tasks 6.3, 6.5, 5.1, 5.2, 5.3) and work packages leaders were included in the work. Each were identifying topics (nodes or branches) within the topic map that they could take the lead on. In this way, the portfolio of policy briefings will be populated through a distributed crowd-sourcing model, by individuals who know the instruments well. This

bottom-up content population, with editorial oversight from the task leaders, is an ongoing activity. This first deliverable contains, in Section 7, the initial examples that have been created, which should not be seen necessarily as the most prioritised and not as being complete a coverage of any individual topics.

3. The topic map

The topic map has been developed through the process described in section 2.2. It is constructed as a mind map and is presented here with an overview of the main topics. Following this, each topic tree is presented, with a short explanation and an overview of the topics it encompasses. Two of the branches, Information security and cybersecurity, and Digital skills, are not further elaborated here because further work is needed to determine what relevant sub-topics should be included that directly impact on IDERHA.

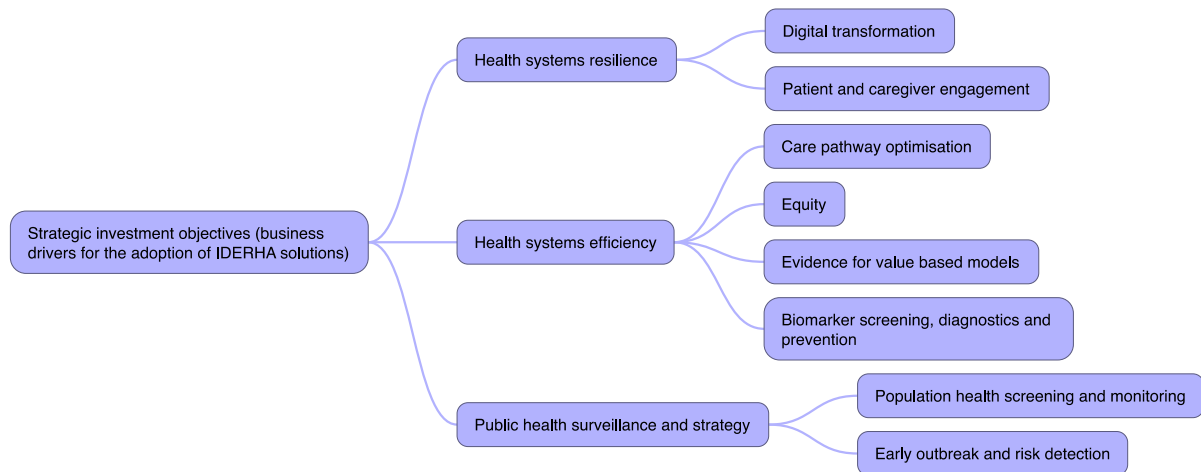
Fig 1. Topic map



3.1. Strategic investment objectives

This branch focuses on areas across the health and care and digital health ecosystems that may favour or inhibit the acceptance and rate of adoption (including investments, reimbursements) of innovations that contribute to health systems transformation, better and more equitable health outcomes and public health. Whilst not immediately impacting on the technical implementation work of IDERHA, the European digital single market, EU and national digital health policies etc. may influence the evaluation evidence that IDERHA pilots generate, and how that evidence is presented to different decision makers.

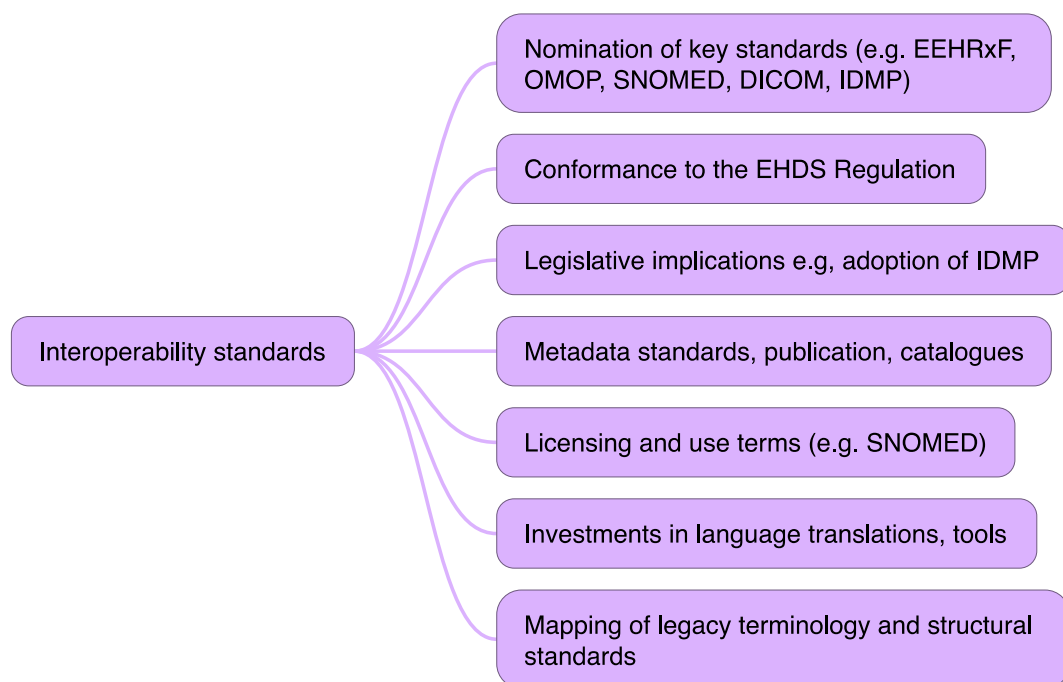
Fig 2. Strategic investment objectives



3.2. Interoperability standards

Since IDERHA is combining and co-interpreting data from multiple sources, it will need to map data from heterogeneous representations into a common one. EHR systems and countries are progressively promoting the adoption of nationally-mandated standards, and these are gradually being adopted whenever systems are upgraded. On top of this is the mandated use of the European Electronic Health Record Exchange Format by the European Health Data Space for primary data use (identifiable data). These formats will increasingly be the representation in which IDERHA receives data from its external data sources. IDERHA will also need to adopt a suitable common data model and relevant semantics for consolidating its data and acting as the master representation for machine and human learning. This should be as aligned as possible with existing observational data models. Other interoperability issues are also mentioned in this branch.

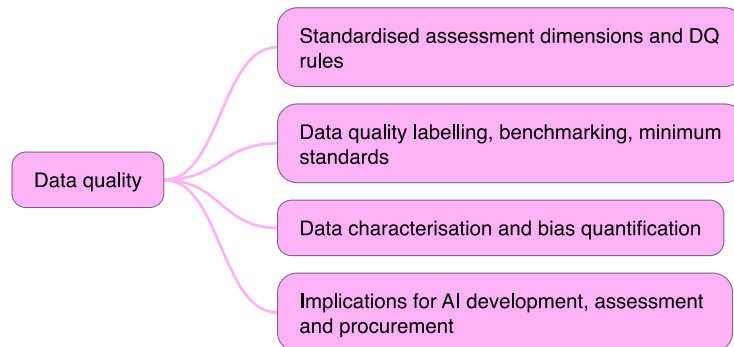
Fig 3. Interoperability standards



3.3. Data quality

It is now well recognised that data made available for reuse should be quality assessed. This has most strongly highlighted in relation to AI, but also applies to data reused for decision making evidence generation. In the near future the EHDS Regulation will give rise to a standard data quality label that IDERHA data sets should have. A new EC project called QUANTUM (2024-2026) is charged with developing this label specification and promoting its uptake.

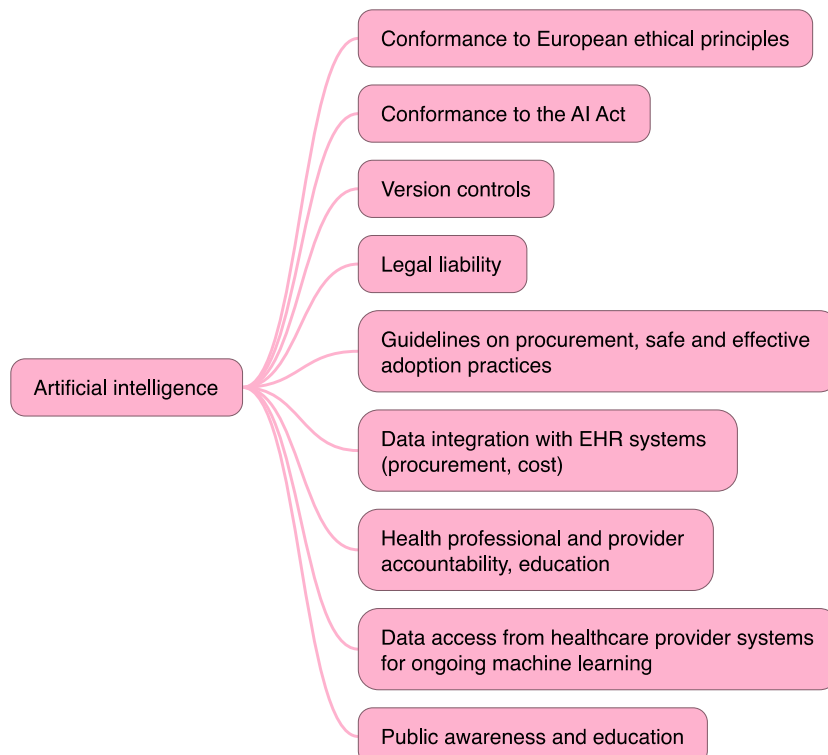
Fig 4. Data quality



3.4. Artificial intelligence

Although not strictly a data topic, the trustworthy and ethical development of AI critically relies upon the data that is used for training, as well as the quality processes that are adopted during the AI development and afterwards. This part of the tree lists a number of areas of quality and ethics, including explicitly the compliance with the European ethical principles and the proposed AI Act, that IDERHA must apply.

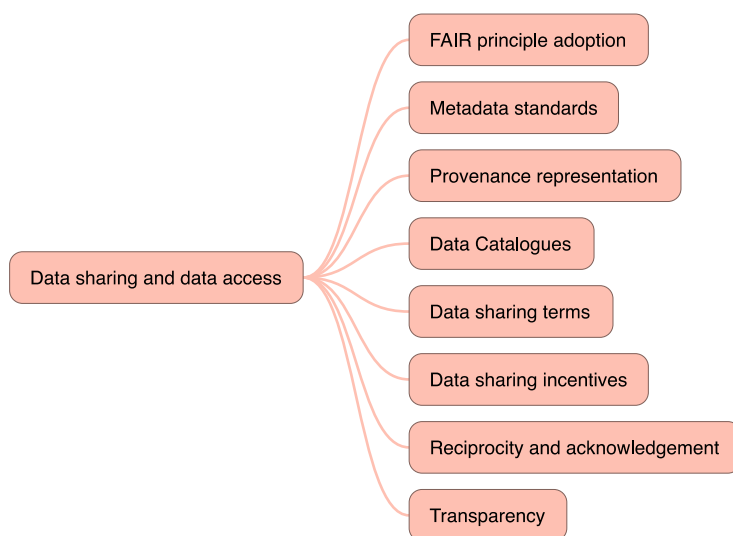
Fig 5. Artificial intelligence



3.5. Data sharing and data access

IDERHA is going to be a beneficiary of data sharing by others and may have expectations on the adherence of those data providers to good practices in the provision of data and metadata. However, probably more importantly, IDERHA expects to make at least some of the data it acquires (and which can adequately anonymised) available to other external research communities as shareable data or as data that can be queried through a federated architecture. Most of the elements of this branch are not yet reflected in formal policies or legislation, but there is mature emerging good practice that can be adopted and should be adopted, such as the FAIR principles.

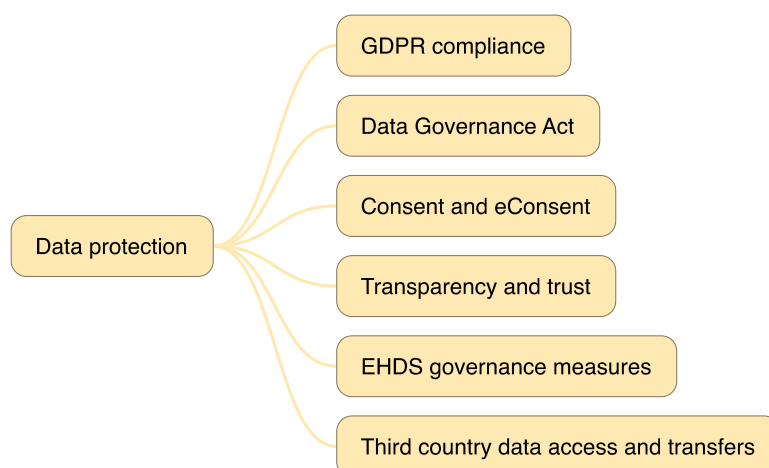
Fig 6. Data sharing and access



3.6. Data protection

Compliance with data protection legislation, in particular the GDPR, is a non-negotiable obligation on IDERHA and all of its partners. However, there are areas that are not precisely specified and not interpreted uniformly across member states, such as the adequacy of safeguards for the use of pseudonymised data. There are also complimentary areas of legislation, such as the Data Governance Act, that offer opportunities for IDERHA to consider for some of its processing activities. The EHDS Regulation draft and its stipulations to Health Data Access Bodies within Member States will also be important to monitor in collaboration with Task 6.5.

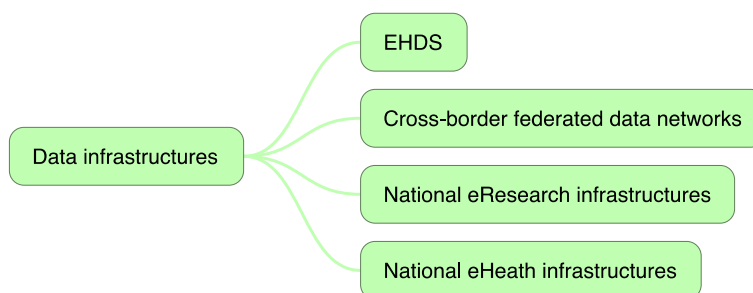
Fig 7. Data protection



3.7. Data infrastructures

Data infrastructures is a broad topic, and to some extent IDERHA is creating one itself as the IDERHA platform. In such technical framework, the IDERHA platform will act as a data source that plugs into national and European infrastructures. Whilst not directly impacting the internal workings of most work packages, it will be essential for IDERHA to monitor the regulatory and policy landscape, in particular the EHDS Regulation draft and its connections with MyHealth@EU and HealthData@EU.

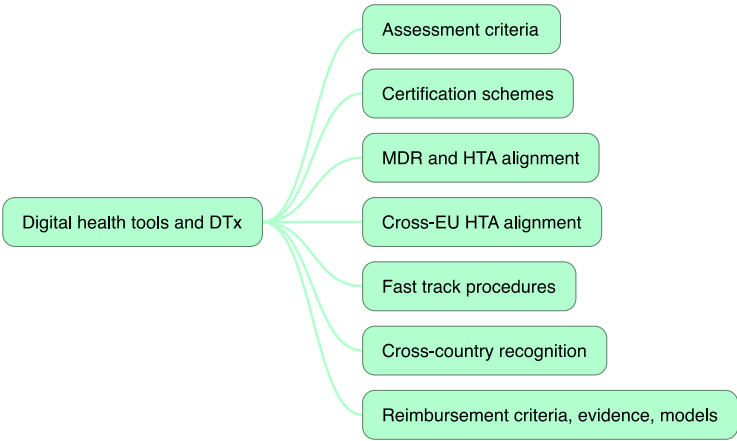
Fig 8. Data infrastructures



3.8. Digital health tools and DTx

Through its cases studies involving lung cancer, IDERHA will be creating AI solutions that will be embedded within digital health tools, to be used by patients in a piloting mode. Other digital innovations may also be developed during the project time. The sustainability strategy for these tools is still being elucidated, but if any of these have the potential to be scaled up and marketed post project, then they will need to be certified and approved at some point. Even if these assessments will take place after the project ends, many of them include formative evaluation components which means that good practices and documentation may need to be commenced during the project, at the time of development.

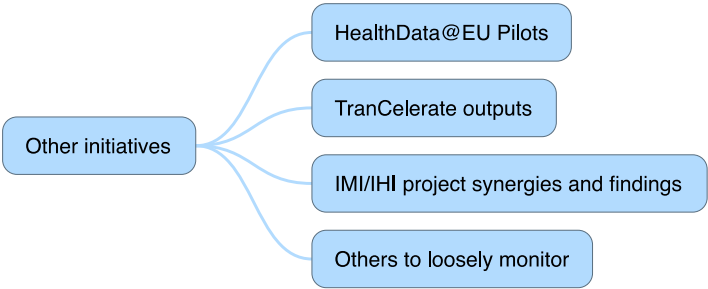
Fig 9. Digital health tools and DTx



3.9. Other initiatives

IDERHA is conducting its innovations at a time when there are other parallel initiatives that are tackling some aspects of large-scale data Reeves, and it will be of value to the project and have greater societal impact if we can establish good collaborative touch points with those projects, support each other with challenges and reinforce each other’s good practices, and lobby for change collectively. These are not examples of policy instruments or policy gaps, but channels through which we may amplify our impact.

Fig 10. Other initiatives



4. The policy briefing template

IDERHA gap analysis policy brief
Name of contributor having filled out the template:
Topic: <i>Example "Dynamic consent"</i>
Instruments or conditions that influence this topic: <i>Example – "national policies, legislation, culture etc., identified in various documents/papers etc."</i>
Insights provided by analysis/recommendations: <i>Example – "identified differences in policy, legislation, and culture between EU partners. fleshed out examples"</i>
Gaps with potential IDERHA impact: <i>Example – "Listing of crucial gaps in relation to IDERHA and suggestions for further legislative and policy development to ameliorate these potential gaps"</i>
Possible areas for further exploration: <i>Self-explanatory</i>

The presented template is a product of a pilot phase. Task 6.2 will further evaluate the template and make revisions to strengthen its meaningfulness and applicability for contributors who complete them and to ensure that the outputs presented provide maximum impact and guidance to the IDERHA project.

Additional areas to be added later, by the editors (the task leaders), will include links (hyperlinks, in the online version) to other relevant topics and policy briefs, and a summary of any actions taken within the project or in collaboration with external stakeholders on the topic of the brief.

5. Initial topics of particular interest

As presented in Section 1, Task 6.2 represents an approach to engage with the intricacies of policy gaps within the current landscape of established instruments. This investigation extends not only to those instruments that are already in place but also to those still in the early stages of development, undergoing revision, or on the brink of final implementation. The objective is to discern the nuanced influence of these instruments on the accessibility and utilization of data for secondary use, in particular for IDERHA. This influence, in turn, has far-reaching consequences, shaping the overall scope, functionality, and sustainability of IDERHA.

As emphasized the presented topic map (Fig 1.) serves as a visual guide, naming critical areas identified as focal points during the initial stages of this exploration. These critical areas have been pinpointed through an approach that includes an initial review of relevant literature, brainstorming sessions, and engaging in dialogues with experts within and outside the consortium. Therefore, each node on this topic map represents an essential aspect that requires further elaboration and critical assessment. These aspects are crucial to understanding the current landscape and pivotal in informing future developments and policy considerations within the IDERHA framework. By thoroughly examining and evaluating these waypoints, the task aims to contribute significantly to enhancing and refining the overarching initiative.

Despite still being primarily in a methodological phase aimed at building a concise approach to build a sustainable and evolving catalogue of executive briefings to inform/guide IDERHA, some salient topics are already well-known to critically influence access to the use and re-use of heterogeneous real-world data. One of these topics is consent (Fig. 7) in a broad understanding. Another topic identified as important is incentives to data-sharing (Fig.6). The latter topic has not been operationalized in template form, but the section presents insights gathered from desk research

5.1. Consent

It is well established that access, use, and re-use of data is highly dependent on the willingness of the very subjects' who have provided the data in the first place. Notable frameworks like the GDPR exist to guarantee that these processes respect and safeguard the sovereign rights of individuals who contribute their data. By emphasizing that every use of personal data must have a legal basis, and be undertaken with transparency and accountability, the GDPR establishes a formal framework ensuring that data access, use, and re-use are conducted with due consideration for the rights and autonomy of data subjects. Although the use of health data in research might be undertaken through different GDPR legal bases, discussed later in this section, informed consent is frequently used and deserves special examination in the context of IDERHA. Even if IDERHA does not collect new informed consent, some of its data sources may have collected data on that basis and may transfer some obligations in that regard to IDERHA.

The concept of informed consent is recognised as a fundamental and indispensable component practically ensuring that the access, use, and subsequent reuse of data unfolds with consideration for the individual sovereignty of data subjects. Informed consent in data processes thus ensures that vital decision-making is positioned in the hands of data subjects and promotes a data management environment based on trust and transparency. Since consent is so central in data sharing and data use, Task 6.2 has decided to have consent as one focus point in this first deliverable. In relation to the identification, comprehension, and potential alleviation of policy gaps concerning consent that may have an influence or impact on IDERHA, we here present a selected (by no means exhaustive) arrangement of pertinent consent issues identified in the early phase of the project. Each topic is presented here with a reference to the relevant template.

The analysis presented in Template 7.9–7.14 focuses on the legal framework, specifically highlighting the General Data Protection Regulation (GDPR) and the proposed Data Act. The analysis in those templates

focuses on the exchange and processing of health data in particular. The primary emphasis lies in the GDPR's Article 9.2a, which stipulates the need for voluntary and reversible informed consent. The primary identified gap relates to the issue of getting patient consent to the use of their health data.

As outlined in Template 7.9, consent must be given voluntarily and can be revoked at any time. As a result, it is crucial to ensure that the individual encounters no negative consequences in the event that they choose not to give their consent initially, or later to withdraw it. Moreover, concerns regarding the true voluntariness of consent arise from the interdependence and vulnerability inherent in the patient-caregiver relationship. Furthermore, not enough research has been done to establish the degree to which consent may be regarded as freely given in the context of the patient-caregiver relationship. According to GDPR Art. 9.2a and 9.4, consent cannot be implied; on the contrary, a more explicit declaration of consent is required, along with a more detailed description of the processing purposes, as stated in Template 7.13. The notion that there are different interpretations across the European Union complicates matters further and makes handling interjurisdictional research challenging. Moreover, in a research setting, it is impossible to determine processing purposes with the level of precision that is required. Furthermore, processing personal data requires the consent of the data owners, as per GDPR Article 9.2a. As a result, Template 7.10 emphasises the need to create a distinct connection between the act of providing consent and the particular function of data processing.

Template 7.11 emphasises the need to maintain transparency in several areas related to the processing, including recipients, cross-border transfers, purposes, and other relevant information. The degree of transparency has to correspond to the person's comprehension. Therefore, in order to ensure that everyone is aware of the terms of the data processing and can provide informed consent, it is crucial that technical concepts be explained in plain language. Additionally, the importance of Recital 33 of the GDPR concerning scientific research is emphasised in Template 7.12. It is pointed out that, in comparison to the requirements imposed for other processing purposes, the use of Recital 33 to allow Broad Consent implies a lesser degree of specificity and transparency. Broad consent is also seen as an instrument to encourage data altruism in the context of the Data Governance Act. Even though there might be less clarity and openness, it is still necessary to get someone's permission when it might not be feasible to do otherwise. Finding out what level of consent is required is crucial so that, in the event that additional requirements are not met, individuals have sufficient control over their data.

Furthermore, Template 7.14 emphasises that processing sensitive data in situations other than gaining consent is allowed under Article 9 of the GDPR. These situations include legitimate interest (9.2.d), public interest in the field of public health (9.2.h), availability of health or social care, handling or administration of health or social care systems and services in accordance with Union or Member State law (9.2.i), and public interest in scientific or historical research (9.2.j). There are significant differences in how these are applied amongst Member States. For-profit and non-profit organisations are subject to different regulations, which are best illustrated by the contrast between private practises and public institutions. Other nations have passed laws pertaining to data management, such as the necessity of obtaining consent from the applicable Data Protection Authority (France in the case of genetic data, for example). The advancement of inter-jurisdictional research is hindered by the existence of national laws that impose additional limitations. The absence of precise definitions for intermediary situations, like public-private partnerships, casts doubt on the existence of particular legal justifications, like the public interest.

5.2. Incentives and disincentives to data sharing

Meaningful incentives play a pivotal role as central engines that drive stakeholders' motivation to actively participate in various aspects of the data lifecycle, including data provision, procurement, management, analysis, and utilization. When seen as optimal, incentives may serve as catalysts, fostering a collaborative and cooperative environment where stakeholders are not only willing but also enthusiastic about contributing

to and leveraging the data ecosystem. Contrastingly, a lack of, or uncertainty about, incentives among stakeholders may act as a critical barrier to establishing productive and sustainable data-(infrastructure) and, thereby, its potential benefits. In the literature, several incentive gaps making barriers have been identified among the diverse scope of stakeholders acting in critical functions in a data-sharing ecosystem.

Among health **researchers**, current research emphasizes that willingness to share data (ultimately adhering to FAIR principles) may be hindered by a complex arrangement of disincentives: Concerns about uncertain intellectual property protection compound this reluctance, as researchers may fear losing ownership of pivotal insights and being pre-empted by academic competitors. Academic promotion is significantly based on academic publications, which require authorship; publications by others that an academic has enabled by sharing their data is barely recognised. These disincentives contribute to a reluctance to engage in transparent data-sharing practices.

Additionally, privacy and protection concerns for participants crucial to the research process act as a further deterrent. If not feeling adequately protected and accommodated, researchers may hesitate to share data that involves critical participants whose willingness to participate, or potential withdrawal, significantly influences the nature and success of the ongoing research and future projects. This is especially of concern regarding open data, which is strongly promoted within research communities across all sectors but challenging to achieve with health data due to the near impossibility of guaranteeing robust anonymisation.

Moreover, the prospect of an increased workload resulting from data sharing, coupled with a lack of adequate funding opportunities to mitigate this burden, serves as a disincentive for researchers already immersed in strenuous research endeavours. The overarching effect is a potential hindrance to the seamless exchange of data in the scientific community (Hughes et al., 2023; van Panhuis et al. 2014).

To **patients**, the active sharing of their data can be pivotal in advancing the collective understanding of various aspects, including the aetiology of diseases, the impact of different treatments, effective disease management strategies, and the optimal regulation of healthcare expenditures (Kalkman et al 2022). Motivation to participate may come from such considerations as wanting to advance health care in general acting for a the common good (see e.g. Stockdale et al. 2018; Shabani et al. 2014), return incurred benefits, or out of hope of reaping potential future personal health care benefits (Kalkman et al. 2022; TEHDAS 2023b). Nevertheless, it is well established that the lack of willingness of individuals to contribute their data may often be intricately tied to several disincentivizing conditions. These include a lack of transparency, controllability, understanding, and awareness of data use. These conditions ultimately produce a distrust that may hinder willingness to share data.

A recent report from the TEHDAS Project (2023b) provides several recommendations to support data altruism and incentivize data-sharing to counter some of the challenges described (in the context of EHEDS). These include (not an exhaustive list) on a policy level establishing and strengthening data-literacy and public awareness initiatives, identifying and adopting relevant business models, specifically for altruism organizations providing mechanisms to ensure recognition of data, providing feedback mechanisms showing how data was used and how data has resulted in benefits (for further elaboration see TEHDAS 2023b) In continuation , it is well-established that sharing data with for-profit companies or projects aimed at financial profits may act as a disincentive for some patients or citizens as they are believed to contradict personal altruistic values. Finding ways or frameworks to mitigate the conflicting values of patients may be important if health research to benefit patients and society is to include the resources and competencies of for-profit companies (TEHDAS 2023b).

A critical driver for advancing data access is to foster improved conditions for transferring knowledge and support environments for joint innovation. However, despite mutually wishing to benefit public health, **for-profit companies'** additional aims of generating profits may challenge public-private collaborations regarding how research is accessed and used (OECD 2020). Acquiring and analysing data commands significant financial investments. Financial commitments are shared among public health organizations and for-profit companies, regardless of their profit orientation. However, the landscape becomes more complex

when examining the context of for-profit companies. Much like the researchers mentioned earlier, for-profit companies face additional complexity in the form of uncertainty surrounding intellectual property protection. This uncertainty may pose a critical disincentive for for-profit companies, introducing a cloud of ambiguity that hampers the clear pathway toward profit realization commensurate with the substantial investments made. To for-profit companies, the interplay between the need for robust intellectual property protection and the imperative to share and collaborate in data-driven initiatives may result in collaborations that inherently carry a risky profile and act as disincentive. Moreover, such challenges to public-for-profit collaborations may be further exacerbated by patients views on for-profit incentives (see above).

It is, therefore, crucial to understand, accommodate, align, or even mitigate conflicting incentive structures with the various stages of the data lifecycle, cultivating a data-centric culture where stakeholders are not only willing but also eager to participate in activities related to data provision, procurement, management, analysis, and utilization. This process will, in turn, contribute to the overall success and effectiveness of the data ecosystem.

6. Conclusion and next steps

The overall method being developed and initiated through Task 6.2 has been broadly accepted as a useful approach by consortium partners and the IDAGC members. The next step, already in progress, is to expand the involvement, through the different work packages and tasks, of more consortium partners from different backgrounds and expertise areas, to contribute to policy briefing summaries. Going forward, Task 6.2 will expand the presented methodology to also include interviews with critical stakeholders to further nuance the insights to be provided in the deliverable in month 20.

The topic map will be used as the organising structure for the policy briefs, and to organise a set of web pages that contain online versions of the briefs. These online versions can contain hyperlinks to other related policy brief as well as linking together different templates that cover different areas within any large and complex single instrument (such as the GDPR). It is anticipated that the online versions will be more frequently visited and referenced by members of the project, and therefore will be the more influential format for helping the project to succeed in a policy context.

As the content grows, and the coverage per topic becomes more complete, it will be possible to produce a topic related synopsis across multiple policy briefs, which will have its own dissemination value such as through newsletters sent to the whole consortium.

As the project progresses it will be possible to update each template with how the project work plan has utilised, or found a solution to overcome a challenge within, a particular instrument.

By the time of the next published version of this content, the updated deliverable in month 20, it will have been possible to also determine and explain gaps in current policy and legislation, about which IDAGC advice will be sought.

7. Initial policy brief templates

This section contains 14 example policy briefs, covering:

GDPR: Stakeholder awareness and competencies for legal and ethical data-sharing and re-use

GDPR: Current potential gaps in cross country pseudonymisation of data

GDPR: Anonymization and new technological challenges

AI: Compliance with the AI ethics principles

AI: Regulatory gaps in the AI Act under revision - Individual rights in the use of AI for decision-making

Interoperability: Recommendation on a European Electronic Health Record exchange format

Data Provenance and Lineage (traceability)

Data Types & Formats

Consent (i): voluntary

Consent (ii): specific

Consent (iii): informed

Consent (iv): broad

Consent (v): explicit for special categories of data

Other legal bases

7.1. GDPR: Stakeholder awareness and competencies for legal and ethical data-sharing and re-use

IDERHA gap analysis policy brief

Name of contributor having filled out the template: Morten Deleuran Terkildsen, Rasmus Mølgaard Hansen, Lotte Groth Jensen

Topic: Stakeholder awareness and competencies for legal and ethical data-sharing and re-use

Instruments or conditions that influence this topic:

Data re-use may not be inherently risky, rather its risks are context-dependent. Risk associated with data-sharing and re-use may be closely dependent on several contextual factors including:

- Topical context shifts, in which ensuring that existing rights and obligations defined when data was procured (such as assumptions and expectations implicit to initial topical usage) are not explicated and carried on and therefore no longer applies in subsequent uses.
- Cultural moral shifts in context in which the procurement and processing of personal data may be legal under privacy law, yet where the shift may give rise to different moral, cultural, and social concerns, leading to potential direct or indirect adverse impacts on individuals or social groups.

Insights provided by analysis/recommendations:

- It is crucial to develop proper awareness, understanding of the context in which data re-use occurs to mitigate risks, protecting privacy, maintaining data accuracy, and ensuring legal ethical practices, and prevent challenges to data access.
- This calls for building stakeholder competencies via adopting responsible and context-aware framework approaches to allow organizations and individuals to legally and ethically leverage the benefits of data re-use while minimizing potential adverse outcomes thus paving the way for data access

Sustainability and potential IDERHA impact:

- Such framework approaches need to be developed or implemented for IDERHA to conform with existing GDPR regulation (e.g. Article 5 1.a and 2)

1a. Personal data shall be: collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with [Article 89\(1\)](#), not be considered to be incompatible with the initial purposes ('purpose limitation')

2."The controller shall be responsible for, and be able to demonstrate compliance with, paragraph 1 ('accountability')."

(e.g. Article 17 is made possible if not being the case mentioned in article 17, 3)

The data subject shall have the right to obtain from the controller the erasure of personal data concerning him or her without undue delay and the controller shall have the obligation to erase personal data without undue delay where one of the following grounds applies:

1. the personal data are no longer necessary in relation to the purposes for which they were collected or otherwise processed;

(See other Articles such as e.g. article 20 on data-portability)

- Moreover, compliance also needs to take into account the special status of health data (being sensitive data, with stricter regulation than personal data (GDPR Article 9) and have special attention to the individual regulations that further condition or limit data-use (see article 9.3)
- Needs to follow current DGA regulation (i.e. stipulating conditions for the re-use, within the Union, of certain categories of data held by public sector bodies (see. e.g. Article 5)
- Needs to comply with EHDS regulation act (e.g. Chapter IV, notably Articles 33-38)

Possible areas for further exploration:

- Explore potential framework experiences from the development of other Data-Legal- ethical frameworks (this could be such frameworks as Data ethics framework UK)

Sources

I) [Risks and challenges of data access and sharing | Enhancing Access to and Sharing of Data :Reconciling Risks and Benefits for Data Re-use across Societies | OECD iLibrary \(oecd-ilibrary.org\)](#)

II) [Data Ethics Framework - GOV.UK \(www.gov.uk\)](#)

III) [General Data Protection Regulation \(GDPR\) – Official Legal Text \(gdpr-info.eu\)](#)

IV) [EU Data Governance act](#)

V) [REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space](#)

7.2. GDPR: Current potential gaps in cross country pseudonymisation of data

IDERHA gap analysis policy brief

Name of contributor having filled out the template: Morten Deleuran Terkildsen, Rasmus Mølgaard Hansen, Lotte Groth Jensen

Topic: Current Potential Gaps in cross country Pseudonymisation of data

This topic concerns data-access to re-use of heterogeneous data, focusing on potential interpretational consistency gaps concerning common pseudonymisation standards or potential lack thereof and the implication for cross-country data re-use.

Instruments or conditions that influence this topic:

Example – "national policies, legislation, culture etc., identified in various documents/papers etc."

According to Art.4 in the GDPR 'pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person. (GDPR definitions Art4-5) Pseudonymisation is stipulated as a cornerstone practice to protect natural persons and in their right to the protection of personal data. (rewrite)

Ensuring and upholding proper jointly accepted pseudonymisation may thus act as a critical gateway to ensure data-access across member state boundaries.

a.1. GDPR - General Data Protection Regulation

<https://gdpr-info.eu/>

Current Proposal For A Regulation Of The European Parliament And Of The Council On The European Health Data Space

[EUR-Lex - 52022PC0197 - EN - EUR-Lex \(europa.eu\)](#)

Insights provided by analysis/recommendations:

Example – "identified differences in policy, legislation, and culture between EU partners. fleshed out examples"

- EHEDS proposal specifies that "Member States will have to set up a health data access body for secondary use of electronic health data and ensure that electronic data are made available by data holders for data users"
- In terms of pseudonymisation the EHEDS proposal further specifies that "Where the purpose of the data user's processing cannot be achieved with anonymised data, taking

into account the information provided by the data user, the health data access bodies shall provide access to electronic health data in pseudonymised format. The information necessary to reverse the pseudonymisation shall be available only to the health data access body. Data users shall not re-identify the electronic health data provided to them in pseudonymised format. The data user's failure to respect the health data access body's measures ensuring pseudonymisation shall be subject to appropriate penalties." (EHEDS 43) Meaning that the proposed member state health data access bodies are made responsible for adhering to proper and sufficient pseudonymisation practices.

- However, as stated by Schmitt et al. (2023) lack of consistent EU interpretation of what may constitute issues such as sufficient pseudonymisation has led to diversity and many member-states to adopt risk adverse strategies and cautious practices that may hinder data innovation.

Gaps with potential IDERHA impact:

Example – "Listing of crucial gaps in relation to IDERHA and suggestions for further legislative and policy development to ameliorate these potential gaps"

- It may therefore be profitable to develop and ensure adherence to a common interpretation of proper pseudonymisation practices across state data health access bodies to alleviate potential obstacles to cross country data access.

Possible areas for further exploration:

- Such common formal interpretation approaches could be based on existing work (i.g. ENISA Pseudonymisation techniques and best practices Recommendations on shaping technology according to data protection and privacy) but needs further exploration

7.3. GDPR: Anonymization and new technological challenges

IDERHA gap analysis policy brief

Name of contributor having filled out the template: Morten Deleuran Terkildsen, Rasmus Mølgaard Hansen, Lotte Groth Jensen

Topic: Anonymization and new technological challenges

This topic concerns current formulations in the DGA concerning anonymization practices and responsibilities that may be subject to challenge by on-going technological development.

Instruments or conditions that influence this topic:

Example – "national policies, legislation, culture etc., identified in various documents/papers etc."

As highlighted in previous templates, following GDPR guidelines (refers to pseudonymization), issues of reuse and access to data do not fall under GDPR when the data has been effectively anonymized. The DGA's stipulation for granting access to data reuse beyond the confines of GDPR's restrictions is contingent upon the thorough anonymization process. This is underscored in the DGA documentation, where it is stated that:

8) In accordance with Regulation (EU) 2016/679, the principles of data protection should not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person, or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. Re-identification of data subjects from anonymised datasets should be prohibited. This should not prejudice the possibility to conduct research into anonymisation techniques, in particular for the purpose of ensuring information security, improving existing anonymisation techniques and contributing to the overall robustness of anonymisation, undertaken in accordance with Regulation (EU) 2016/679.

In this sense, access to re-use of data falling outside the jurisdiction of the GDPR thus hinges on the provision of robust anonymization techniques (Falling under the responsibility of member state public bodies / competent bodies). So that:

Before transmission, personal data should be anonymised, in order not to allow the identification of the data subjects, and data containing commercially confidential information should be modified in such a way that no confidential information is disclosed."

Moreover Article 5 in the DGA specifies that:

3. Public sector bodies shall, in accordance with Union and national law, ensure that the protected nature of data is preserved. They may provide for the following requirements:

(a) to grant access for the re-use of data only where the public sector body or the competent body, following the request for re-use, has ensured that data has been:

(i) anonymised, in the case of personal data."

Acts and legislation influencing this topic:

a.2. GDPR

<https://gdpr-info.eu/>

DGA

[EU Data Governance act](#)

Insights provided by analysis/recommendations:

Example – "identified differences in policy, legislation, and culture between EU partners. fleshed out examples"

- The DGA states that though re-identification is prohibited, such prohibition should not hinder research and development of improved anonymization techniques.
- However, as emphasized by Ruhonen et al.(2023), examples of de-anonymization technologies and techniques already exist, and following current technological trends, the existence of such technologies is expected to increase in the near future. This development raises salient questions regarding its impact on data-access and re-use. These may include (not an exhaustive list)
 - Despite its illegality, how does the DGA propose to handle future possibilities for de-anonymization when clear examples of such techniques are on the horizon and their possibilities for compromising anonymization may bring anonymization practices into conflict with the GDPR (even though this is currently not possible as anonymization is seen as removing the opportunity for re-identification) because they can no longer ensure the rights of privacy of subjects as mentioned in the GDPR?
 - How do such future scenarios influence public trust in the use and re-use of data and thus their willingness to allow sharing of their data?

Ruohonen, J., Mickelsson, S. Reflections on the Data Governance Act. DISO 2, 10 (2023).
<https://doi.org/10.1007/s44206-023-00041-7>

Gaps with potential IDERHA impact:

Example – "Listing of crucial gaps in relation to IDERHA and suggestions for further legislative and policy development to ameliorate these potential gaps"

- Additional research might be necessary to delve into the potential void that could arise from emerging de-anonymization technologies. More specifically, further knowledge could be needed to explore the emergent gap between GDPR and the rights to privacy and formulations stipulating data-access governance and re-use in the DGA based on anonymization.

Possible areas for further exploration

7.4. AI: Compliance with the AI ethics principles

IDERHA gap analysis policy brief

Name of contributor having filled out the template: Dipak Kalra

Topic: Compliance with the AI ethics principles

Instruments or conditions that influence this topic:

- Ethics Guidelines for Trustworthy AI,” April 8, 2019, High-Level Expert Group on Artificial Intelligence, European Commission
<https://ec.europa.eu/futurium/en/ai-alliance-consultation.1.html>
- Assessment List for Trustworthy Artificial Intelligence (ALTAI) for self-assessment,” July 17, 2020, High-Level Expert Group on Artificial Intelligence, European Commission
<https://digital-strategy.ec.europa.eu/en/library/assessment-list-trustworthy-artificial-intelligence-altai-self-assessment>

Insights provided by analysis/recommendations:

The ALTAI checklist is a structured compliance-oriented representation of the Ethics Guidelines, and therefore an easier form in which to verify ethical compliance. The following is a non-exhaustive list of its main topics:

- Human interaction model and decision taking involvement
- AI user awareness
- Potential for interference with human decision making
- Oversight
- Ability to “emergency stop” the AI from proceeding and taking actions
- Cybersecurity: integrity, robustness, security., resilience from attack
- Risk management
- Reliability and stability testing, fault tolerance, failsafe mechanisms
- Accuracy of the training data, monitoring of accuracy during use, handling of uncertainty, missing data etc.
- Continual learning e.g. protection measures against risks of learning from unsuitable patterns, traceability of the learning cycles and the data inputs used
- Information governance
- Bias (mostly related to the quality and characterisation of the training and validation data)
- Accessibility
- Monitoring for negative impacts

Gaps with potential IDERHA impact:

1. At present there is no standardized way by which an AI developer would report conformance to this checklist, because it is presented as a collection of labelled paragraphs, describing each topic but without formal conformance criteria. IDERHA may therefore have to look around for emerging reporting formats or templates, or invent its own. In either case, compliance documentation could be relatively burdensome, although important.
2. The AI Regulation is now making rapid progress through the European Parliament, and a crosschecking of coverage with the regulatory requirements for the quality and safety assurance of high risk AI will be needed.

Possible areas for further exploration:

1. To identify emerging good practices in conformity checking and reporting formats, or to create one specifically for the project.
2. To consider working through IHI office to bring together projects tackling AI development in order to agree a consensus conformity checking and reporting method.

7.5. AI: Regulatory gaps in the AI Act under revision

IDERHA gap analysis policy brief

Name of contributor having filled out the template: Morten Deleuran Terkildsen, Rasmus Mølgaard Hansen, Lotte Groth Jensen

Topic: Regulatory gaps in the AI Act under revision - Individual rights in the use of AI for decision-making

This topic focuses on the rights of individuals in terms of development and usage of AI technologies for decision-making policies, as currently stipulated in the AIA, as well as identified gaps and current ongoing EU legislative work to fill such gaps.

Instruments or conditions that influence this topic:

Example – "national policies, legislation, culture etc., identified in various documents/papers etc."

The current draft of the AI Act (2021)

[EUR-Lex - 52021PC0206 - EN - EUR-Lex \(europa.eu\)](#)

A Critical Assessment by Members of the Robotics and AI Law Society (RAILS)

Ebert. et al (2021)

[J | Free Full-Text | The European Commission's Proposal for an Artificial Intelligence Act—A Critical Assessment by Members of the Robotics and AI Law Society \(RAILS\) \(mdpi.com\)](#)

a.3. Current legislative briefing - updating the AIA (2023)

[Artificial intelligence act \(europa.eu\)](#)

Insights provided by analysis/recommendations:

Example – "identified differences in policy, legislation, and culture between EU partners. fleshed out examples"

As noted by Eber. et al (2021) the initial draft of AIA did not sufficiently include provisions for individual rights. Despite its aim to safeguard fundamental rights, it fell short in offering avenues for individuals to pursue recourse in case of a violation of the regulation. A call was made to ensure that proper redress mechanisms were formulated and included in later revision.

Currently legislative work in underway seeking to strengthen citizens' rights to complain. It is currently stipulated explicitly only as concerning decisions based on High-risk systems that impact citizens' rights.

Gaps with potential IDERHA impact:

Example – "Listing of crucial gaps in relation to IDERHA and suggestions for further legislative and policy development to ameliorate these potential gaps"

Though not currently mentioned as an issue of access to data, the current legislation should be followed as issues of rights to complain could potentially come to include legislation also aimed at limiting potential threats to citizens' rights in the form of data-access legislation.

While the ongoing legislative efforts primarily target high-risk systems, closely monitoring the current legislative process could be advisable. Monitoring the process will help ensure that IDERHA remains in accordance with the civil rights requirements outlined in the legislation should it expand to cover AI technologies in additional risk categories.

Possible areas for further exploration:

Follow the development of the legislative process for the individual rights of citizens when developing new forms of AI-technology

7.6. Interoperability: Recommendation on a European Electronic Health Record exchange format

IDERHA gap analysis policy brief

Name of contributor having filled out the template: Dipak Kalra

Topic:

- The EHDS (draft) Regulation requirements for interoperability
- Recommendation on a European Electronic Health Record exchange format

Instruments or conditions that influence this topic:

The draft EHDS Regulation requires that identified patient level data, to be communicated via MyHealth@EU, conforms to the European Electronic Health Record exchange Format (EEHRxF).

https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en

<https://digital-strategy.ec.europa.eu/en/library/recommendation-european-electronic-health-record-exchange-format>

The EEHRxF is defined as a Recommendation but will be enforced through the EHDS draft Regulation. Electronic Health Record (EHR) systems will be required to be able to export patient level data in the EEHRxF Format. Member State National Contact Points will firstly be required to ensure that cross-border patient level data flows conform to the standard as well as other stipulations in the proposed EHDS Regulation, and secondly be required to oversee the conforms to the exchange of EHR systems within the Member State health system.

The EEHRxF covers the following areas of content, as technical specifications that currently utilize HL7 Clinical Document Architecture (CDA) and SNOMED, but will evolve towards the use of HL7 Fast Health Interoperability Resources (FHIR):

- Patient summary – based on the European Patient Summary Guidelines but closely related to the International Patient Summary (IPS)
- Electronic prescriptions
- Electronic dispensations
- Medical images and image reports
- Laboratory results
- Discharge reports

The EC's MyHealth@EU initiative, that Member States will be required to participate in, has largely developed the technical and governance specifications required to communicate this information between countries. Some countries see this as also useful to adopt internally.

Insights provided by analysis/recommendations:

IDERHA is primarily undertaking secondary use of lung cancer health data, constructing big data sets for federated analysis, developing AI, personalized decision making and risk stratification tools and implementing a clinical research platform. However, the source data is likely to come from EHR systems that today use heterogeneous data models and implement standards to a variable extent. If, during IDERHA's life time, conformance to the EEHRxF grows, this might become a more reliable source data format to leverage. It may therefore be valuable for IDERHA to implement an ETL process feeding its secondary use platform for EEHRxF format data.

Gaps with potential IDERHA impact:

The EEHRxF is being promoted as an EHR representation, but it is in practice limited to a patient summary and continuity of care clinical documents. The laboratory or imaging reports may be the most fruitful. We will still find we are missing some lung cancer specific data (certainly no genomics).

Possible areas for further exploration:

1. A gap analysis of data item specification may be a useful first step, in order to determine the utility of the clinical content represented by the EEHRxF to IDERHA.
2. If we find that a modest enlargement of the EEHRxF would increase its utility, this might be recommendation formalized by WP6 and presented to the Council.

7.7. Data Provenance and Lineage (traceability)

IDERHA gap analysis policy brief

Name of contributor having filled out the template: LeRoy Ruggerio

Topic: Data Provenance and Lineage (traceability)

Including:

- Origin
- Tagging
- Curation
- Mapping
- Quality/Bias
- Transformations/Linking
- Retention (Archival/Destruction)

Instruments or conditions that influence this topic:

Example – "national policies, legislation, culture etc., identified in various documents/papers etc."

Requirements to keep detailed records of data origin/provenance, cohort, bias and merging, linking, mapping or transformation, etc. of all data assets that are used to develop or that result in any research insights, conclusions or models generated.

Insights provided by analysis/recommendations:

Example – "identified differences in policy, legislation, and culture between EU partners. fleshed out examples"

Data inventory and lineage traceability is required to comply with the various terms of any data use agreements that will be in place between IDERHA (as a data processor) and any IDERHA data partners or collaborators. Some key areas of compliance that would be governed can include (with agreement metadata attributes):

- Covered Entity / Data Provider / Collaborator
- Contract Type
- Data PHI Status (Y/N)
- Legal mechanism for PHI
- Permitted Primary Use Category
- Permitted Secondary Use Category
- Verification that the source (if signing party is a non-hospital system) has the right to share data
- Data Classification (PHI/PII, Device telemetry data-low risk, Public Data)
- Data Host Platform
- Data Host Geography
- Permitted Storage Geography (restrictions for data transfer to other country/regions)
- Permitted Use Geography
- De-identification using a third party (Y/N)
- De-Identified Data - Green (Y/N)
- De-Identified Data - Yellow/Red
- De-Identification Method
- Effective Date (Agreement Expiration Date)
- Post Termination Disposition
- Retention Policy / Date

- Consent Date - Patient Consent - Primary Status - Patient Consent - Secondary Status
Gaps with potential IDERHA impact: Example – "Listing of crucial gaps in relation to IDERHA and suggestions for further legislative and policy development to ameliorate these potential gaps" Current gaps may be a general architecture/plan for the platform and a charter that would identify potential data types, data sources, initial uses anticipated, agreement terms for collaborators, permitted data uses, permitted access, etc. Some examples of industry standards and certifications are (in addition to ISO 27001:2022, NIST Cybersecurity Framework and potentially HITRUST):

Figure 11: source: LeRoy Ruggerio

National Standards- Netherlands NEN 7510	• The NEN 7510 is the official Dutch standard for setting up and implementing information security management systems for organizations working with healthcare patient data. The standard became mandatory for healthcare institutions and providers starting on January 1, 2018, offering further interpretation and accountability under Article 32 of the GDPR. • NEN 7510 is a set of standards, outlining practices and mandatory requirements for processing personal data, with an emphasis on confidentiality and accountability. The NEN 7510, 7512, and 7513 offer additional interpretation of requirements in light of the needs of healthcare providers. It also offers measures and standards to identify risks to ensure the confidentiality, availability, and integrity of secured data. The standards also ensure that data owners can decide what information can be shared, and to which providers. • Companies are required, by law, to utilize the NEN 7510 in the Netherlands. • These standards describe measures that must be taken by health care institutions and suppliers. This, in order to protect data of patients adequately. These measures will result in a monitored process concerning information security.
ISO cloud standards - ISO 270017, 270018	• ISO 27017 is the information security best-practice framework for cloud service providers and their customers. It enables them to implement information security processes and procedures to ensure information stored in the cloud is safe and secure. • ISO/IEC 27018:2019 is an information security code of practice for cloud service providers who process personally identifiable information for their customers.
Trusted Exchange Framework and Common Agreement (TEFCA)	The overall goal of the Trusted Exchange Framework and Common Agreement (TEFCA) is to establish a universal floor for interoperability across the country. The Common Agreement will establish the infrastructure model and governing approach for users in different networks to securely share basic clinical information with each other—all under commonly agreed-to expectations and rules, and regardless of which network they happen to be in. The Trusted Exchange Framework describes a common set of non-binding, foundational principles for trust policies and practices that can help facilitate exchange among HINs
ISO 31700 - Privacy by Design for	Privacy Embedded into Design, Respect for User Privacy (User Centric), Visibility and Transparency, Full Functionality (Positive-Sum not Zero-Sum), End-To-End Security (Full Lifecycle Protection), Privacy as the Default Setting, Proactive not Reactive (Preventative not Remedial)

Consumer Goods and Services	
IMDRF (International Medical Device Regulators Forum)	IMDRF is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory harmonization and convergence.
CMMC (Cybersecurity Maturity Model Certification)	The Cybersecurity Maturity Model Certification (CMMC) is the Department of Defense's (DoD) newest verification mechanism designed to ensure that cybersecurity controls and processes adequately protect Controlled Unclassified Information (CUI) that resides on Defense Industrial Base (DIB) systems and networks.
ISO 13485	ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes is a voluntary standard, published by International Organization for Standardization for the first time in 1996, and contains a comprehensive quality management system for the design and manufacture of medical devices.
ISO/IEC 27559:2022	Information security, cybersecurity and privacy protection – Privacy enhancing data de-identification framework

NOTE: There are also additional privacy related regulations around protection of data subject rights that apply to both Data Controllers and Data Processors. Depending on the charter and intended use of the data for the IDERHA program, these may also apply and would require additional traceability to comply with data subject rights (i.e.- Access and Correction, Right to be Forgotten, etc.)

GDPR Article 30 Clause 2 states:

Each processor and, where applicable, the processor's representative shall maintain a record of all categories of processing activities carried out on behalf of a controller, containing:

- (a) the name and contact details of the processor or processors and of each controller on behalf of which the processor is acting, and, where applicable, of the controller's or the processor's representative, and the data protection officer;
- (b) the categories of processing carried out on behalf of each controller;
- (c) where applicable, transfers of personal data to a third country or an international organisation, including the identification of that third country or international organisation and, in the case of transfers referred to in the second subparagraph of Article 49(1), the documentation of suitable safeguards;
- (d) where possible, a general description of the technical and organisational security measures referred to in Article 32(1).

Possible areas for further exploration:

Explore/Research potential products to help with automation of data inventory and data lineage. There are several data cataloging software products available that can help with traceability of data assets throughout the multiple phases of the data lifecycle. The specific requirements for capabilities would need to be reviewed prior to a product feature comparison. Most data cataloging systems provide the core capabilities required for proper data traceability.

7.8. Data Types & Formats

IDERHA gap analysis policy brief

Name of contributor having filled out the template: LeRoy Ruggerio

Topic: Data Types & Formats (what types and formats of data will be the focus of the IDERHA platform and research?)

- Structured Data (tabular)
 - EMR data
 - Device data (telemetry / use)
 - ePRO – patient experience data
 - Diagnosis
 - Treatment
 - Payment data
- Unstructured Data (video, images, audio)
 - DICOM
 - XRAY/MRI/Ultrasound
 - Procedure video (with or without audio)
 - OR video
- Data Transfer Protocols
 - CSV
 - HL7 (v2, v3)
 - FHIR
 - CCDA
 - XML
 - PDF
 - CDM
 - Binary files

Instruments or conditions that influence this topic:

Example – "national policies, legislation, culture etc., identified in various documents/papers etc."

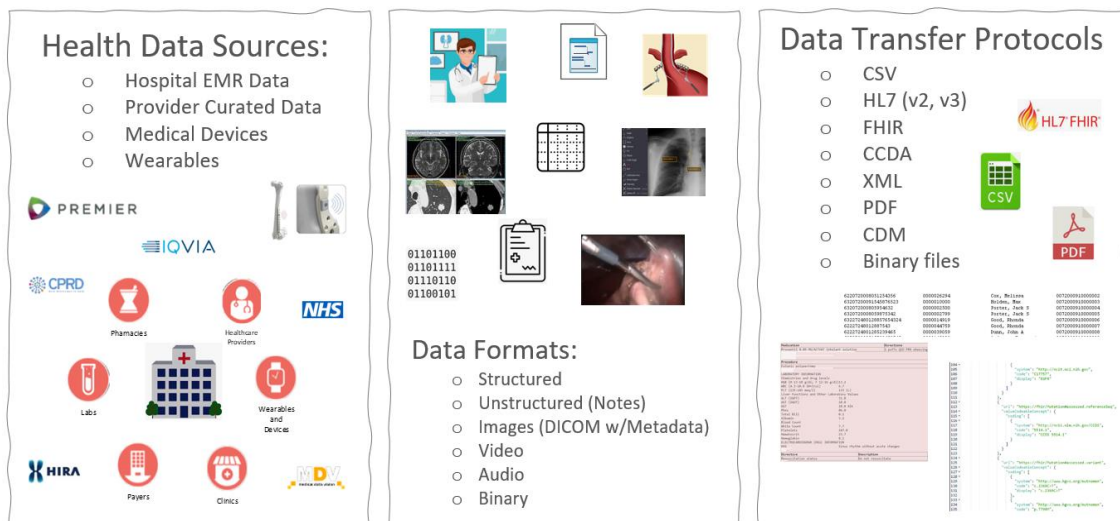
Requirements for specific research use cases to support research/analytics efforts.

Focus areas here will also guide the data use agreement terms, collaboration terms and partners, data preparation (raw, anonymized, masked, tokenized, etc.) as well as the various analytical tools required to perform the research analysis. This will also help inform the data collection and storage requirements as well as the required capacity and compute resources for the data / analytics platform.

Another requirement that will need to be addressed is that of a defined standard "Common Data Model" to be adopted by the platform for specific disease states/treatments/devices and the data associated to each. This will also need to be socialized with potential data collaboration partners to determine their willingness for adoption and transformation work toward the new CDM. This conversion can be quite complex and time/resource/effort consuming and could be a barrier to entry to the value of the data platform and analytics capabilities.

- Standards adopted by data collaborators (both in format/protocol and CDM)
- Types of data required for research efforts (structured, device, unstructured – video, images, audio)
- Data Transformation assistance – provided to collaborators that may not have adopted a standard in protocol/transport/CDM as this can be time consuming and costly.
- Types of access and use of final data – how will data be used and analyzed (analytics tools, DB, methods, etc.)
- Will there be a 3rd party integrator that will be processing data feeds and converting to a CDM ?
- What data use agreements will be in place with collaborators ?
- Will data be collected, aggregated/linked, cleaned, anonymized and transformed to CDM at source or in a central collection point within IDERHA ?
- Other decision factors will likely arise concerning legal basis, cost and size of data assets for feasibility of transfer and processing.

Real World Data Sources and Formats



Example – "identified differences in policy, legislation, and culture between EU partners. fleshed out examples"

Gaps with potential IDERHA impact:

Possible gaps would include:

- EMR systems and standards
- Data format standards
- Transfer protocols
- Anonymization methods to comply with regional requirements.
- Data Protection (access restrictions)
- Data Size and transfer methods / bandwidth requirements

Possible areas for further exploration:

Self-explanatory

Identify requirements and target profiles for Data Network Collaboration Partners and conduct interviews / Surveys to determine their systems and standards for EMR and device data including:

- EMR system(s) vendor
- Common Data Model standard
- Cybersecurity standards and certification requirements for partners (ISO, HITRUST, NIST, etc.)
- Network connectivity / bandwidth
- Supported transfer protocols/formats
- Agreement types for shared data use
- What types of procedures performed (and data available):
 1. General Surgery
 2. Gastrointestinal Surgery
 3. Orthopedic Surgery
 4. Cardiovascular Surgery
 5. Thoracic (Cardiothoracic) Surgery
 6. OB/GYN-related Surgery
 7. Neurosurgery
 8. Ophthalmological (Eye) Surgery
 9. Otolaryngological (ENT) Surgery
 10. Urological Surgery

7.9. Consent (i) voluntary

IDERHA gap analysis policy brief	
Name of contributor having filled out the template: Dominik Geller & Maria Bardaji-Cruz	
Topic Consent (I)- voluntary (1)	
Instruments or conditions that influence this topic: • Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, GDPR) ◦ Applicable National Data Protection Law (please specify) • Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on harmonised rules on fair access to and use of data (Data Act) • Other EU or National Laws if applicable (please specify)	
Insights provided by analysis/recommendations: For the analysis, please specify on what grounds health data is processed and/ or shared and what differences or inconsistencies you observe in the application of the law vs. literacy EU law, across territories and/or different organizations/ players, or whether it is Processing/ sharing shall be based on the consent (Art 9.2a GDPR), which shall be VOLUNTARY/ WITHDRAWABLE: - The consent needs to be free, i.e. the individual shall be able to grant it or not without suffering any kind of detriment - Position of weakness and dependance vis-à-vis the controller - Not dependable on other services	
Gaps with potential IDERHA impact: - Patients, as vulnerable individuals, will not always be able to choose freely whether to consent or not, hence there will likely be some considerable level of dependency.	
Possible areas for further exploration: - How much consent can be considered freely given in a patient-caregiver scenario	

7.10. Consent (ii) specific

IDERHA gap analysis policy brief	
Name of contributor having filled out the template: Dominik Geller & Maria Bardaji-Cruz	
Topic: Consent (I)- specific (2)	
Instruments or conditions that influence this topic: • Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, GDPR) ◦ Applicable National Data Protection Law (please specify) • Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on harmonised rules on fair access to and use of data (Data Act) • Other EU or National Laws if applicable (please specify)	
Insights provided by analysis/recommendations: For the analysis, please specify on what grounds health data is processed and/ or shared and what differences or inconsistencies you observe in the application of the law vs. literacy EU law, across territories and/or different organizations/ players, or whether it is Processing/ sharing shall be based on the consent (Art 9.2a GDPR), which shall be SPECIFIC: - Link between the provision of consent and the particular data processing operation - Unambiguous - Recital 33- relaxed criteria, however not applicable for sensitive data	
Gaps with potential IDERHA impact: - Defining the parameters of each processing activity within research is impracticable.	
Possible areas for further exploration: - Possibility of defining the level of specificity required in research context	

7.11. Consent (iii) informed

IDERHA gap analysis policy brief	
Name of contributor having filled out the template: Dominik Geller & Maria Bardaji-Cruz	
Topic: Consent (I)- informed (3)	
Instruments or conditions that influence this topic: • Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, GDPR) ◦ Applicable National Data Protection Law (please specify) • Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on harmonised rules on fair access to and use of data (Data Act) • Other EU or National Laws if applicable (please specify)	
Insights provided by analysis/recommendations: For the analysis, please specify on what grounds health data is processed and/ or shared and what differences or inconsistencies you observe in the application of the law vs. literacy EU law, across territories and/or different organizations/ players, or whether it is Processing/ sharing shall be based on the consent (Art 9.2a GDPR), which shall be INFORMED: - Need for transparency in all relevant aspects of the processing, e.g. recipients, cross border transfer, purposes, etc. - Adequate to the level of understanding of the individual	
Gaps with potential IDERHA impact: - Translating technical matters into lay terms to make sure the individual fully understands the parameters of the data processing	
Possible areas for further exploration: - Possibility of defining the information which shall be considered as sufficient in research context	

7.12. Consent (iv) broad

IDERHA gap analysis policy brief	
Name of contributor having filled out the template: Dominik Geller & Maria Bardaji-Cruz	
Topic: Consent (II)- broad	
Instruments or conditions that influence this topic: • Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, GDPR) • Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) • Other EU or National Laws if applicable (please specify)	
Insights provided by analysis/recommendations: For the analysis, please specify on what grounds health data is processed and/ or shared and what differences or inconsistencies you observe in the application of the law vs. literacy EU law, across territories and/or different organizations/ players, or whether it is - In respect of scientific research Rec. 33 GDPR allows for Broad Consent, which level of specificity and transparency is lower in comparison to the one required for other processing purposes. Broad consent is also considered for data altruism in the Data Governance Act. - Does not need to be explicit for sensitive data.	
Gaps with potential IDERHA impact: Although the level of specificity and transparency would be lower in this scenario there is still a need to collect a declaration of consent from the individual which in several cases is impracticable.	
Possible areas for further exploration: How much consent is equivalent to sufficient control of the individuals over their data if other considerations are not met.	

7.13. Consent (v) explicit for special categories of data

IDERHA gap analysis policy brief	
Name of contributor having filled out the template: Dominik Geller & Maria Bardaji-Cruz	
Topic: Consent- explicit for special categories of data	
Instruments or conditions that influence this topic: • Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, GDPR) ◦ Applicable National Data Protection Law (please specify) • Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on harmonised rules on fair access to and use of data (Data Act) • Other EU or National Laws if applicable (please specify)	
Insights provided by analysis/recommendations: For the analysis, please specify on what grounds health data is processed and/ or shared and what differences or inconsistencies you observe in the application of the law vs. literacy EU law, across territories and/or different organizations/ players, or whether it is Processing/ sharing shall be based on the consent (Art 9.2a, 9.4 GDPR), which shall be EXPLICIT FOR SENSITIVE DATA (SPECIAL CATEGORIES OF DATA): • Consent cannot be implied and demands a higher degree of precision in its declaration together with a more precise definition of the purposes of processing. • Member States can introduce new conditions and/or limitations when it comes to the processing of genetic, biometric or health data. • Genomic data not defined in any regulation.	
Gaps with potential IDERHA impact: - Different interpretations across the EU region, which makes interjurisdictional research complex to manage. - Level of precision in the determination of purposes of processing is not achievable in a research context.	
Possible areas for further exploration: - How to achieve harmonization in the interpretations of consent, explicit consent and conditions applicable to genetic/ genomic information across the board for research contexts.	

7.14. Other legal bases

IDERHA gap analysis policy brief	
Name of contributor having filled out the template: Dominik Geller & Maria Bardaji-Cruz	
Topic: Other legal basis	
Instruments or conditions that influence this topic: • Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, GDPR) ◦ Applicable National Data Protection Law (please specify) • Proposal for a regulation of the European Parliament and of the Council on the European Health Data Space (EHDS) ◦ Applicable National Electronic Health Record Law (please specify) • Other EU or National Laws if applicable (please specify)	
Insights provided by analysis/recommendations: For the analysis, please specify on what grounds health data is processed and/ or shared and what differences or inconsistencies you observe in the application of the law vs. literacy EU law, across territories and/or different organizations/ players, or whether it is - According to art. 9 GDPR, the processing of sensitive data can be based on legal basis different from consent, e.g. 9.2.d, legitimate interest, 9.2.h, provision of health or social care or treatment or the management of health or social care systems and service on the basis of Union or Member State law, 9.2.i. public interest in the area of public health or (.2.j, public interest, scientific or historical research. There are considerable differences between Member States in the application of these. - There are also differences in the requirements for- profit and non- for-profit organizations, e.g. private practice vs public institution. Some countries have created additional requirements in the context of processing of special categories of data, like approval of the relevant Data Protection Authority, e.g. France for the cases of genetic data	

Gaps with potential IDERHA impact:

- National Laws introducing additional conditions, including limitations hamper inter-jurisdictional research.

In-between scenarios, like public- private collaborations are not defined, which causes uncertainty in the availability of certain legal basis, e.g. public interest.

Possible areas for further exploration:

Develop standards for public- private collaborations and explore harmonization opportunities across the region

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Numbered Weblinks

1. EHR4CR <https://www.imi.europa.eu/projects-results/project-factsheets/ehr4cr>
2. GetReal <https://www.getreal-institute.org>
3. EMIF <http://www.emif.eu>
4. EHDEN <https://www.ehden.eu>
5. EU PEARL <https://eu-pearl.eu>
6. ConcePTION <https://www.imi-conception.eu>
7. H2O <https://health-outcomes-observatory.eu>
8. ValueHealth <https://digital-strategy.ec.europa.eu/en/node/3944/printable/pdf>
9. ASSESS-CT <https://assess-ct.eu/home/>
10. eStandards <https://digital-strategy.ec.europa.eu/en/library/report-eu-funded-estandards-project>
11. DigitalHealthEurope <https://digitalhealtheurope.eu>
12. European mHealthHub <https://mhealth-hub.org>
13. Label2Enable <https://label2enable.eu>
14. UNICOM <https://unicom-project.eu>