European Health Data Spaces

Fostering medical research, safeguarding patient interests

Contents

Part 1

Building a secure, integrated data space

What is the EHDS?

The European Health Data Space (EHDS) concept is one of the most ambitious initiatives ever taken in the field of public health.

- It is broad in scope (covering everything from delivering better health outcomes for patients to enhancing general medical research).
- It covers a huge geographic area (with the vision of providing a common space for exchange and use of data across the entire European Union), and…
- It is technologically ambitious (deploying advanced tools and methods to create potentially the most effective, integrated data environment for healthcare in the world).

The strategic objective of EHDS is to make it possible for healthcare data, including patient data, to be safely and consistently used across the whole of the European Union, while respecting the individual policies and health frameworks of individual member states. This will then enable Europe to use its scale as a source of benefit in everything from original research to care delivery.

There is a major challenge, of course, in balancing the need for an integrated, obstacle free environment of this kind with a scrupulous respect for privacy and data integrity, based on the regulatory approach developed by the EU for use of data more generally. This is why the role of advanced technology in realising the EHDS vision is so important.

Structure and scope of EHDS 1 & 2

The strategy is based on two distinct initiatives:

- Primary, which focuses on healthcare delivery, management and patient care. Known as EHDS1, this is already partly operational in the market using the brand name: MyHealth@EU.
- Secondary, which is designed to support research and is targeted largely at Research Organisations (RESOs). Known as EHDS2, this is at an earlier stage of development, but is starting to become operational using the brand name: HealthData@EU.

The Primary version of EHDS is largely focused on exchange of health data across national borders through Cross-Border eHealth Information Services. At this moment, EHDS1 is primarily focused on patient summary data, which relates to initiatives for electronic prescriptions and dispensing (ePrescription, eDispensation), while making short-form summaries of patient data available under controlled conditions to healthcare providers.

EHDS1 is governed through a single point of contact in each member state (known as the National Contact Point for eHealth- NCPeH) and is entirely separate from Secondary EHDS.
The Primary version is designed to ensure that patients are followed by their own data as they move from place to place across the EU, with healthcare providers having access to the knowledge needed to deliver top quality care. This approach also means that provider and payment systems can be kept up to date, with insurance and state related benefits and costs always aligned to the care provided.

The Secondary version of EHDS (EHDS2) is designed for a different purpose and has its own objectives, related to different kinds of research (which can cover scientific research, policy-making, regulatory management and surveillance), development of new treatments and sharing of data at the Research Organization level. Governance and management are carried out on via peer-to-peer interaction between national Health Data Access/Authorisation Bodies (HDAB) responsible for actions within their own jurisdictions, with EU level oversight provided by a separate European Health Data Authorisation Body.

Two distinct governance regimes

The development of EHDS1 & 2 as two distinct and separate entities reflects the differing roles of data in healthcare.

Primary data is used for improving care to a specific individual, that is its core purpose. Data related to this purpose is thus managed by healthcare providers and professionals, and should be limited to actions that affect quality of care for an individual patient.

Secondary data is designed for broad use by researchers and planners of many different kinds. As noted above, researchers may be engaged in work related to medical treatments, policy making, regulatory management or surveillance.

There can be a cross-over with Primary data, as well, by offering clinicians and healthcare managers information related to capacity planning, decisions about the numbers and categories of healthcare professionals to be trained and managed, gaining insights to trends, or enabling use of successful treatments to patients with similar issues. The key point to remember here is that, once data has more generic usage (not only for a specific individual) then it is automatically classified as Secondary.

In the medical research field, Secondary data can also be used for identifying emerging issues and pathogens and, most clearly, for the development of new treatments, from medical research to building and testing innovative new treatments. This can also cover actions to foster and implement effective preventive measures.

Research can therefore be integrated into practice, with studies done at secondary data level, but with AI algorithms then potentially deployable for Primary use, as well.

It was recognised from the start that interface between Primary and Secondary areas would be vital, but that the differences between needs and structures were significant enough to require separate governance methods and authorities. The strategy for EHDS always envisaged a high level of harmonisation and data interoperability between Primary and secondary areas, but negotiating these points of connection is not always easy. As we shall see, this is where integrated solutions can prove extremely important.

Strategy and balance

The EHDS strategy can therefore be seen as a cautious but effective way to ensure that a pan European approach is taken to healthcare data that:

- Keeps patient care and the interests of individual citizens at the centre of every action.
- Ensures that the right balance is achieved between the desirability of providing access to data (so that healthcare providers can deliver the best care and researchers can develop novel treatments efficiently) and the need to comply with privacy regulations at all times.
- Preserves a clear distinction between Primary and Secondary so that the two major strands of data use (provision of treatment and research) are each given their own focus and priority, with air-gaps in place to ensure that data does not “leak” across from one system to the other.
- Enables the EU to create a continent-sized environment that delivers economies of scale, while maximising the potential for original research, while preserving the non-negotiable rights of member states to control the own assets and safeguard the rights of their own citizens.

This is a requirement of exceptional complexity and sensitivity, with close connections matched by strict governance provisions. Figures 1 and 2 below show how the two forms of EHDS differ from each other, with their own governance and “consumers”. At the same time, it is possible to see the synergies and close connectivity that enables EHDS1 and EHDS2 to add value to each other under controlled conditions.

Figure 1 below shows EHDS1 in schematic form, with national hubs in place and a connecting point for data transfer provided by the CBeHIS.

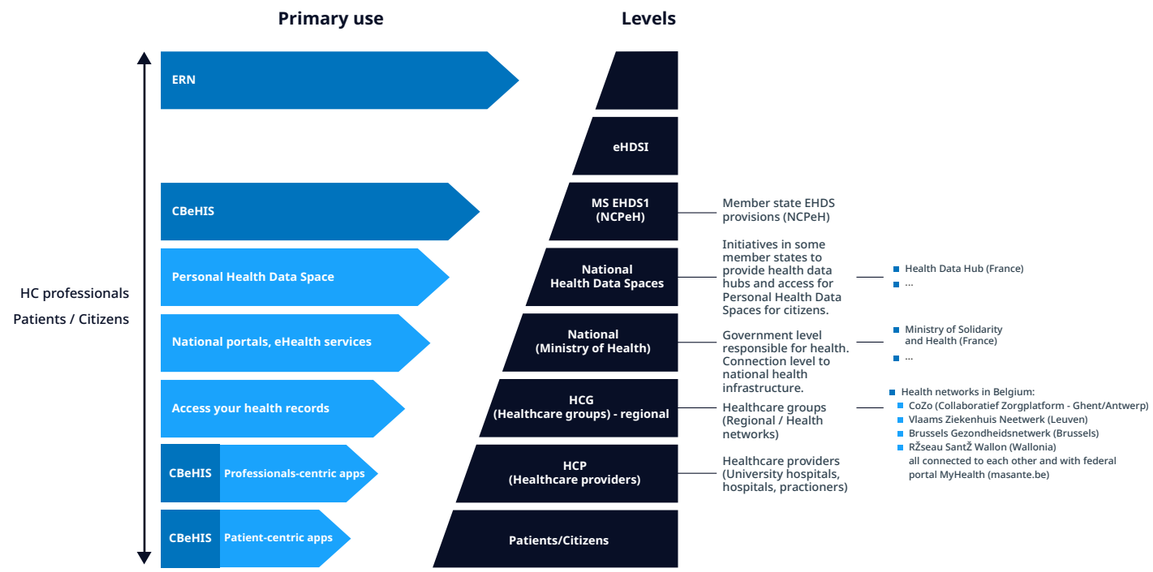
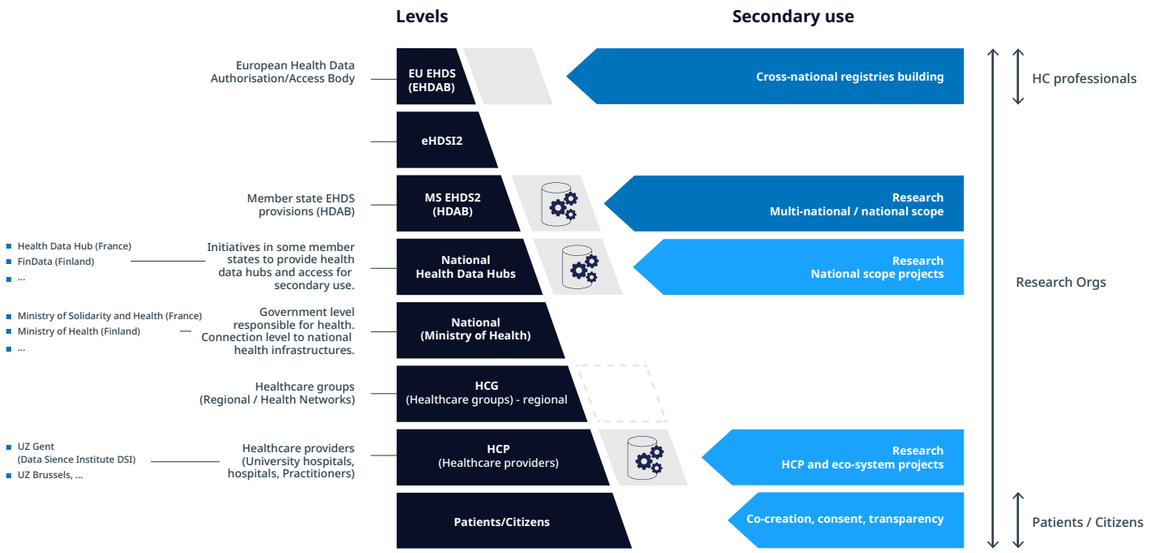


Figure 2 below shows the same form of layout for EHDS2. Each Member State must establish its own Health Data Authorisation Body (HDAB), which is the lead authority for EHDS in that particular Member State. National HDABs will liaise with the European Health Data Hub (EHDH), which provides guidance, advice and support as needed, especially when it comes to cross border contacts between hubs for multi-national projects.



A federated approach to data

A decision was made early in the development of EHDS to avoid applying high granularity data models onto either Primary or Secondary versions of the environment. Governance is also managed through local leadership, using a federated model. This means that participants, from national governments and ministries through to individual healthcare related organisations and their partners, can apply their own methods and tools, while remaining able to collaborate effectively.

The federated approach formally operates in two ways. First, it is based on peer-to-peer communication between National HDABs, with light-touch guidance from the EHDAB. Member states can manage data and functionalities in the way that suits their own needs best. A typical federated model will incorporate national, regional and local integrated joint working.

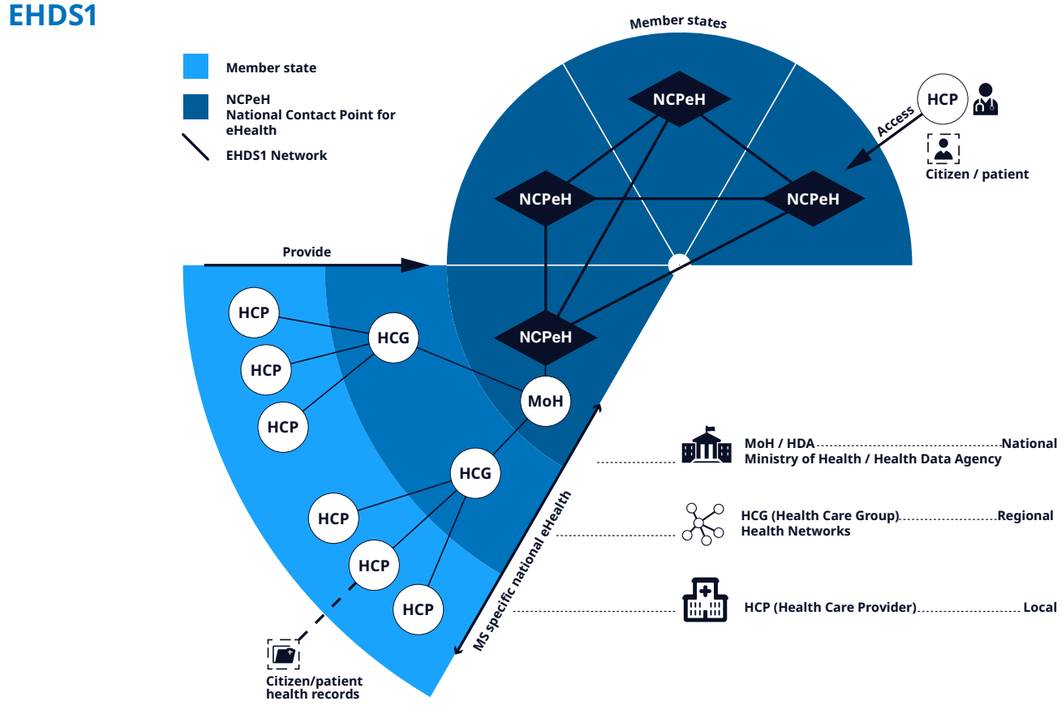


Figure 3 shows the structure of EHDS1, the provision of data from the MS national infrastructure, and the access to health records in a cross-border context.

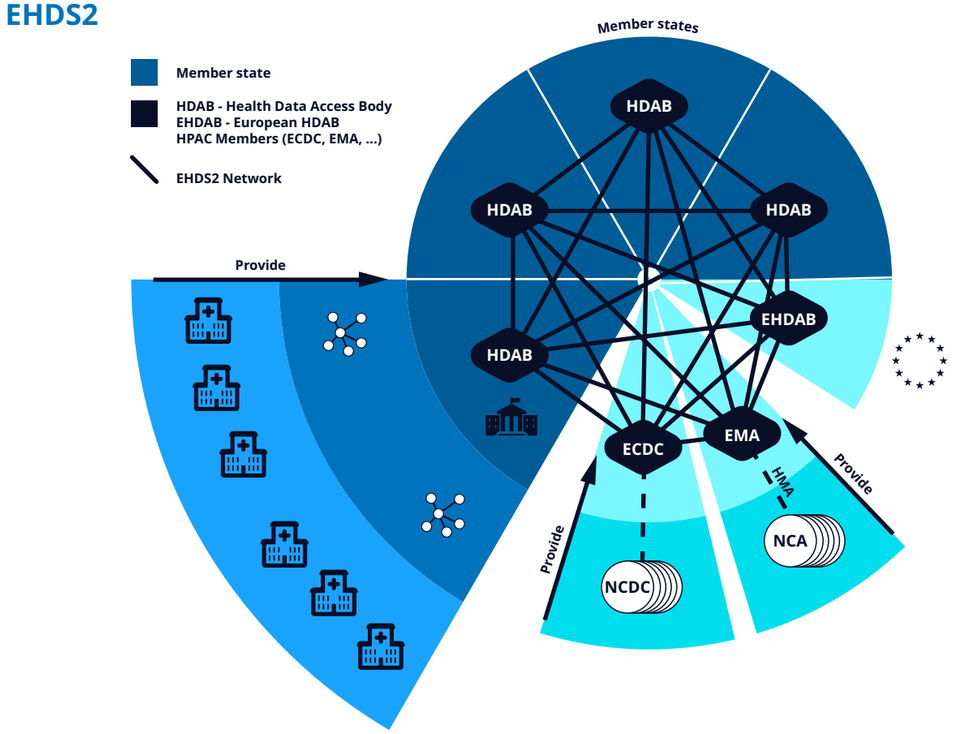


Figure 4 shows the structure of EHDS2, with the HDABs for each member state, and agency nodes for EMA and ECDC.

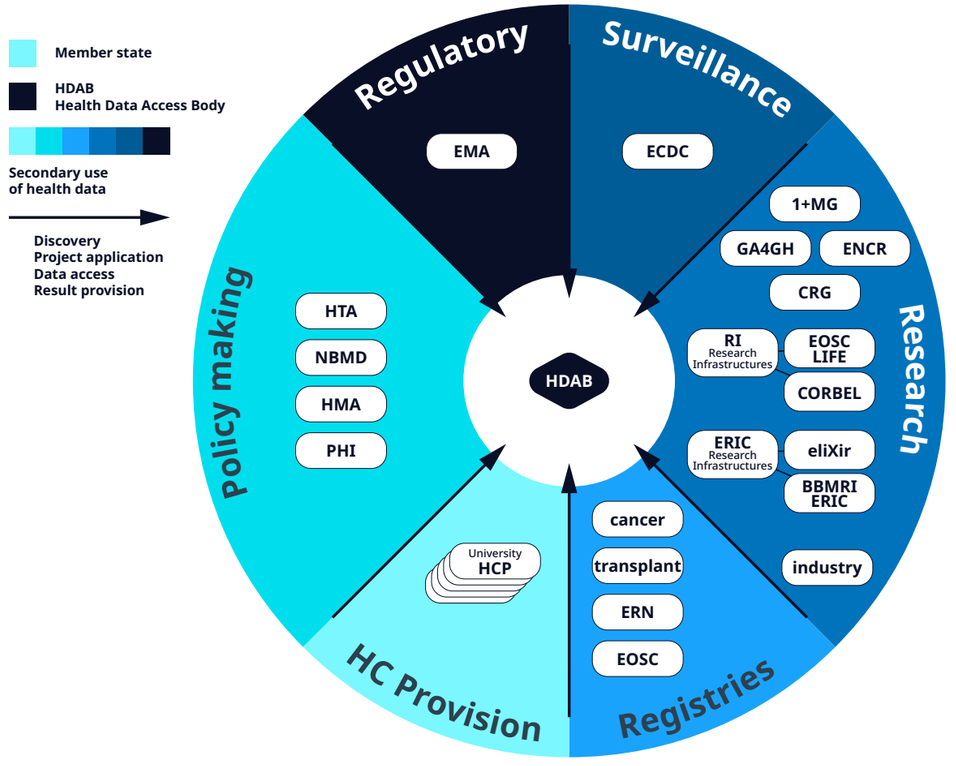


Figure 5 shows the consumption of EHDS2, with types of secondary use of health data and respective example actors.

This complex arrangement makes it possible to source data for specific groups of researchers (in the Secondary area), while maintaining privacy, legal controls and full regulatory compliance.

In the Primary space, the flow of data between healthcare providers (HCP, as shown on the diagram) is managed through a jointly developed and therefore always consistent software gateway forming the National Contact Point for eHealth (NCPeH). By developing one software solution on a Europe-wide basis, harmonisation is made simpler and faster, while maintaining national level control over which data can be shared and under what conditions. Interface between EHDS1 & 2 is managed through a single node for each member state.

The design approach can be summarised like this.

- Where the same generic methods and processes are required, the EU has chosen to manage such activities on a European level to ensure easy interoperability, while keeping costs and the potential for errors to a minimum.
- Where management control is required (use of patient data, rules governing research…) individual member states are given maximum discretion to manage their own processes, ensuring these are best suited to the priorities and conditions in their own territories.

For those businesses, institutions and collaborative bodies wishing to provide high quality services into this entire vast marketplace for healthcare and treatments, the key requirement is to navigate complexity without wasting time and resources and while always staying compliant.

The creation of a single data space for healthcare, despite all the compromises and areas of fragmentation in structure and governance, is a potential source of immense benefit to European citizens and the entire health economy. Our task is to build solutions and services that can navigate the complexities and deliver the benefits.

Part 2

Creating an integrated service strategy

Permitted usage models

Data within both EHDS1 & 2 are subject to tightly defined usage restrictions. These are complex and full understanding requires in depth study. To illustrate some of the issues involved in developing effective services, we will focus on a limited number of examples.

Data within the EHDS fits normally into one of three distinct categories:

- Data that can be transferred. This is normally permitted due to anonymisation, to the point where data cannot be connected to any individual. This can be extremely difficult where genetic data is involved (which is increasingly the case), or where rare diseases in small population groups makes it too easy for individuals to be identified. In all such cases data may be pseudonymised or used as the basis for synthetic data, which may become especially important to researchers as LLM-based AI assumes a higher importance in research.
- Models that can be transferred. In these cases, data remains where it is but the analytical functionality for a particular requirement is taken to the data, rather than vice versa. This is essential where specific and easily identifiable data (such as home addresses) may be needed to draw research conclusions about types of treatment or pathology. Output takes the form of federated, anonymised data suitable for use in research activities, but without the risk of breaching privacy law.
- Data that cannot be transferred under any circumstances. In such cases, we create a Trusted Research Environment (TRE) which enables remote interaction with data under very strictly secured and controlled conditions. Such environments will normally operate under the rules set by a national body, such as the UK NHS or the Finnish FINDATA (to give just two examples).

Data management also takes place in the context of strict control for access to data and the ways in which it is legally permitted to use it.

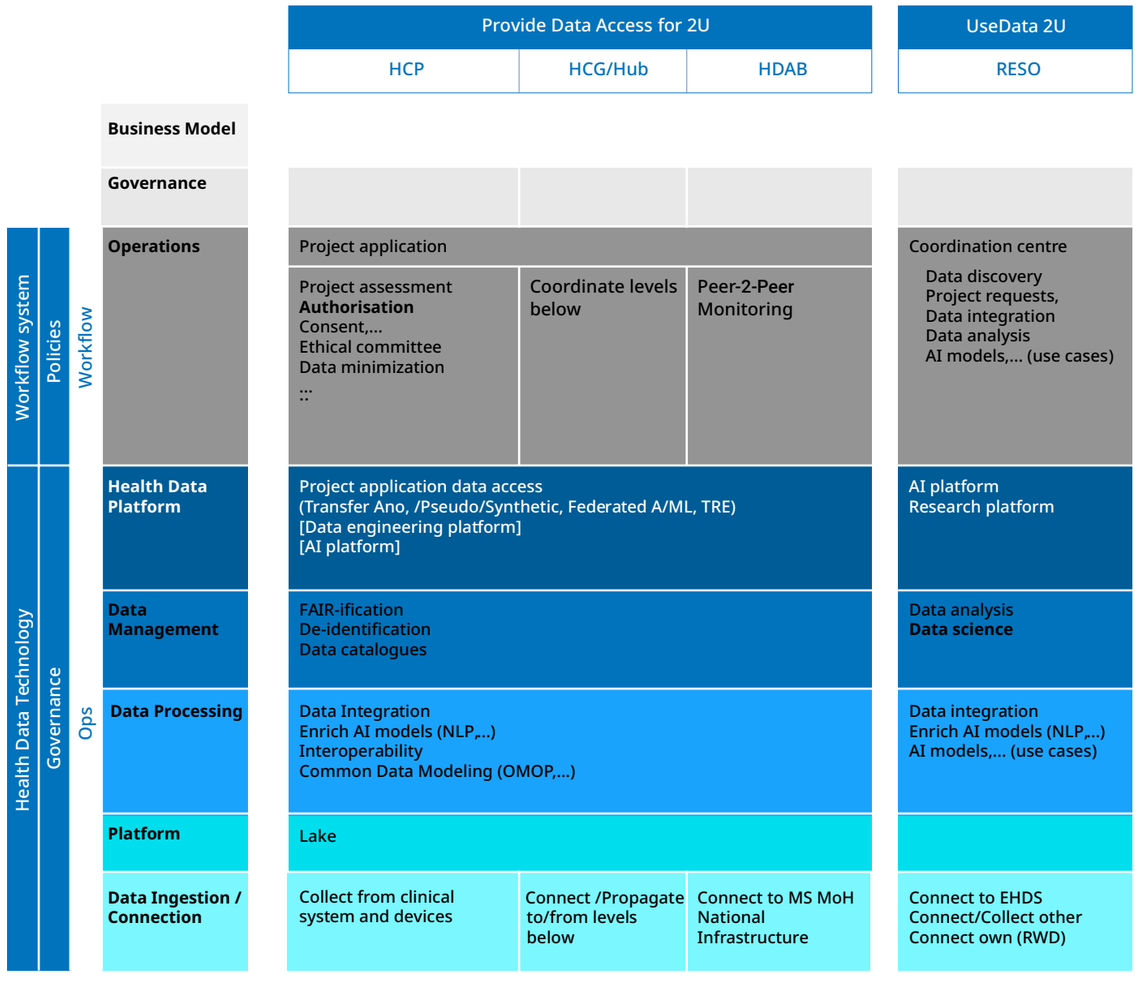


Figure 6.

All projects require authorisation, ethical evaluation, consent and agreement on data minimization, with healthcare providers (and specifically through the operation of their ethical committees), always having the final say in data use. Data must then be managed in the correct way: de-identified, categorised (for data transfer, for model transfer, use of TRE), before we move onto the practical issues of access to data storage platforms and processing.

The stages involved here include workflow, policies, governance, operations and technology. The processes of ingestion, control, oversight, analysis, review and publication are all part of the same, carefully designed and integrated process. This is the environment in which all participants and service providers must operate. It is in place to provide confidence and enable buy-in from national governments and supra-national bodies, alike.
It is the necessary foundation for everything we do in our objective of improving and accelerating quality and innovation in the health economy across Europe.

The service models

To deliver effective outcomes both for consumers and providers of key services, it is essential to understand how such services can be constructed in the EHDS environment. A simple overview of the different service models available is provided in figure 7 below.

Service model	Service model type
D	Analysis and design, including initial and repeated maturity assessments, business model definition and design, governance model design and workflow definition.
A	Solution Architecture definition on technical, operational, process and workflow.
G	Services on 1) definition, including governance definition, policies definition (e.g. data management/governance, project application/authorisation policies, data minimization principles, TRE policies etc.) and 2) operations, including both the governance/compliance operations and the overall operations (e.g.operations of coordination centre models to perform research on secondary use with data discovery, data modeling, mapping to common data models, MLOps, etc.).
B	Bulding solutions, ranging over buid/buy, development and co-development, integration, providing assets, extending or integrating present cliente assets in solution (e.g. extending client data lake environments with TRE layer functionality).
R	Resource services provinding skilled resources/teams such as data engineers, data scientists in a shared service model.
M	Managed service model where the solution is serviced as an outsourced managed service.

Figure 7 shows the different forms of service that can be built, packaged and delivered to EHDS1 & 2 participants. It begins with analysis (pure consultancy) and ends with comprehensive managed services, delivered on a partnering or outsourcing basis.

These models for the context for the services that can be developed and provided to the wider marketplace across the EU. At this moment, NTT DATA has identified over 30 different “Service Packages” for use as packaged options, that can be taken in their generic form and then rapidly adapted for use by specific organisations and groups. Based on these different service models and packages, it is possible to create customized solutions for each different user group, simply by selecting and reconfiguring a number of standard packages.

Using the catalogue

To make these packages easily available to a wide user base, NTT DATA has built a catalogue of solution components, based on four main layers or groupings:

Platform layer. This is the foundation for all services, and covers...

- **Architectural design**, which begins with consultancy input and collaborative working lead to development of the core structure, roadmap to implementation and gap analysis. We then move onto developing the transformation plan and set up of data management and governance arrangements.
- **Platform delivery**, which starts with the fundamental decision about location for the solution, which is increasingly likely to be the cloud but can include on-premise options, as well. The next stage is gathering and ingesting data, modelling the to-be structures, together with meta data repository creation and implementing a quality management regime for all data used in the solution.
- **Platform automation and monitoring**, covering key operational requirements (DataOps, Machine Learning Ops, FinOps and DevSecOps), together with all functions related to auditing, health of the system and security management.

Health data layer. This brings together a complex blend of packages and capabilities related to all aspects of managing interaction with and operations in the EHDS. Individual elements include:

- **Operational and organizational model,** which includes such key data requirements as de-identification and pseudonymisation, together with data policies and coordination of processes within these policies. Also included here are core data-related operational functions, such as interoperability and security, with mapping of data and management of data lifecycles.
- **Data services** covers everything from analytics supporting visualization and user self-service, through management of master data and overall data quality, up to validation of data, while keeping it current.
- **Data space** is where we manage most aspects of user access. This includes managing and federated data catalogue, together with visualization and access within the EHDS marketplace. This is also where we establish the access portal and associated tools.
- **Governance** is a broadly based set of processes, procedures and tools responsible for compliance, privacy, ethics and certification, while also overseeing the specific services designed for RESOs.

Health data value creation layer. This is where we base the capabilities and functions needed to enable authorised users to use catalogue items as a source of business value. This layer includes:

- **Data strategic consulting**, which is the primary design and build space in the environment. Here external bodies can scope use cases, put together potential ecosystem alliances, develop and test strategic transformation plans for data and carry out information governance maturity assessments.
- **Advanced analytics** provides a growing repository of advanced tools and templates. It enables users to test designs, use federated analytics and begin the process of using AI within their approach.
- **Data sharing and ecosystems** enables development of a clear strategy for data sharing, including security procedures, surveillance and designation of open data.

Overall management. In this top layer we place the capabilities needed for client interaction, reporting and relationship management, including:

- **Demand and quality management** covers everything related to talent and resourcing, market intelligence and knowledge, with request management and market strategy.
- **Integration** is critically important to management, not just of the catalogue but all services delivered to end users. This is where we enable capabilities from different partners across the industry to be brought together for rapid fulfilment of service requests, thereby maximising the value users receive from the EHDS.
- **Innovation**, reflecting the fact that EHDS and the services it supports are innovative of their nature. In this set of components we provide capabilities designed to guide research, manage transformational change and provide effective management of the whole innovation space.
- **Project and service management** is where we locate the tools and functions needed to manage risk, project scope, financial controls and planning.

The components within the catalogue represent a major resource for end users of every kind, from research organisations (EHDS2) to care delivery organisations, including hospitals and other practitioners (mainly within EHDS1) and the technology or consultancy partners that work with this community of key data users across the whole landscape.

Building solutions and use cases

Use of a term like “catalogue” may give users a slightly misleading view of how a complex subject like the Health Data can be managed. We do not as yet provide a consumer-type “customer portal”, with click and drag functionality as the key to rapid configuration of composable solutions. The reason for this is less to do with basic technology and more to do with regulatory compliance, rules for data access and the need to introduce new use cases in a measured way.

Yet even with these provisos, it is possible to move rapidly and with low risk to establish use cases ready for testing and implementation. Most important, it is possible to do this by using a proven model, which ensures effective governance, compliance and a high level of operational efficiency. Let’s take a look at two use cases, one for EHDS1 and one for EHDS2, analysing how the service catalogue and implementation models interact to deliver low risk, high quality outcomes.

Use case 1: building an interface between EHDS1 and any national infrastructure

This is likely to be a very typical, “normal” and early-stage requirement. As we have seen, EHDS1 & 2 operates on a pan-EU basis. Yet the autonomy of member states and their designated healthcare management bodies is guaranteed as a basic design feature. The added complexity here is caused by the fact that not all national bodies are participating in this system and the scope for participation varies from state to state.

The solution defined by the EHDS architecture is not to provide variations within the EU-level design but rather to permit national bodies to consume services from EHDS based on their own policies and requirements.

Target bodies here are the National contact points in each participating member state (NCPeH) and the relevant Ministries of Health.The different model components mobilised to deliver the right outcomes are solution architecture, governance, build and resourcing.

The solution packages used here include:

- Integration of EHDS1 common services.
- Linking network/messaging infrastructure, supporting EHDS1 messaging.
- Identification/authentication services, security protocols and related services.
- Translation and mapping of EHDS1 to/from target content and formats.
- Establishment of a new NCPeH for participating Member States, including governance and operational models, NCPeHs portals and other requirements.
- Connection of Member State Ministry of Health governance protocols, with a link to national infrastructure in support of use cases.

Combining these packages in different combinations makes it possible to deliver a single use case (integration of national infrastructure with the pan-national EHDS) but to create the formula that works best for each individual country and its Ministry of Health. It therefore combines a high level of standardisation (in technologies, architecture and process) with the ability to deliver a unique, customized solution.

Use case 2: connecting an EHDS2 user (RESO) with EHDS2

We have already noted the differences between EHDS1 & 2, and in particular the fact that EHDS2 is mainly designed for Secondary users: research organizations and those that use research data in their product development work. In order to make use of the data within EHDS2, individual RESOs must connect as “consumers” to the data space, connecting as a “user node”, and following a common formula for project scope, data discovery and data access.

Data models used for this activity include Architecture, Build and Resourcing, leading to two key actions:

- Integrating EHDS2 common technical services, complying with security practices, registering as an EHDS2 client node (both on technical authentication level and on governance information level). This analyses and interprets the overall RESO business model to provide extra safeguards for data use.
- Implementing these services could include connecting/ interfacing the RESO internal standards, systems and formats on multiple areas such as user management (mapping active directory information to EHDS user registries), data catalogue queries (translating internal query formats to EHDS2 data discovery queries), and potentially other factors, as well, depending on the nature of the organisation.

Apart from the RESO itself, there will be active participation at EU level (from the EU Health Data Access Body) and at national level from the relevant HDAB within each individual RESO’s home territory.

These two use cases are at the very heart of the EHDS environment. So far, however, NTT DATA has identified 37 different work packages across both EHDS1 & 2, covering requirements as diverse as building user portals, data or compliance management, strengthening national or regional health infrastructures or solutions to link high performance computing infrastructures.

By establishing a large and growing portfolio of service packages, it is possible to simplify usage and accelerate time to value, while reducing risk at every stage of the journey.

The service packages available today are extremely varied in their nature, and can be reviewed in headline terms within the two tables below:

#	Service packages	Targets	Models
Sevice packages for EHDS1 infrastructure and common services			
I.1	Strengthen/build out the national/regional digital health infrastructure to support primary use cases. (driven by new CBeHIS services or national/regional services)	MS MoH, HCG, HCP	DAGBR_
I.2	Support to interface the national infrastructure with the EHDS1	NCPeH, MS MoH	_AGBR_
I.3	EHDS1 (MyHealth@EU) infrastructure and common services.	[eHDSI]	_A_B__
#	Service packages for EHDS1 use cases.	Target	Models
II.1	Implementation of EHDS1 use cases.	NCPeH, MS MoH, HCG, HCP	DA_B_R
II.2	Implementation of EHDS1 extended (new) use cases. (in context of CBeHIS services or solely without EHDS scope on national/regional level.		DA_B_R
Sevice packages for EHDS2 infrastructure / infrastruture and common services			
III.1	EHDS2 (HealthData@EU) infrastructure and common services.	eHDSI2	(_A_BR_)
III.2	Services to connect EHDS2 governance actor (EHDAB, HDABs) with EDHS2 infrastructure	EHDAB, HDAB, [Hub, HCG, HCP]	DA_B__
III.3	Services to connect EHDS2 consumer (RESO) with EDHS2	EHDAB, HDAB, RESO	_A_BR_
III.4	Services to connect EHDS2 producer with EHDS2	RESO	DAGBR_
Service packages for EHDS2 provisions			
IV.1	Technical data provisioning (for HDAB from national infrastructure layers)	HDAB, MS MoH, Hub, HCG, HCP	DA_B__
IV.2	Data discovery provisions by HDABs for RESOs	EHDAB, [Hub, HCG, HCP], and RESO(*)	DA_BR_
IV.3	Project application and authorisation by HDABs for RESOs	HDAB, [Hub, HCG, HCP]	DAGB__
IV.4	Data access platform by HDABs for RESOs		DA_B?_
IV.5	Data integration (HDAB internal)		DA_BR_
IV.6	Data management/governance (HDAB internal)		DAGBR
IV.7	Portals	HDAB, EHDAB, [Hub, HCG, HCP]	DA_B_
IV.8	Compliance management services		
IV.9	Registry services	EHDAB, [HDAB, HCG]	DA(G)BR_
IV.10	Other EHDAB related service packages		
IV.11	Other HDAB related service packages		
IV.12	Analytics/Data Science platform	HDAB, [Hub, HCG, HCP] or RESOs	DA_BR?
IV.13	Data engineering / FAIR-ification platforms		

Table 1: service packages list 1.

#	Service packages	Targets	Models
Sevice packages for RESOs			
V.1	Analytics/Data Science platform	RESO	DA_BR?
V.2	Data engineering / FAIR-ification platforms		DA_BR?
V.3	Data science model development		DAGBRM
V.4	Coodination Centre Services		DA_BR_
V.5	RWD collection and processing	RESO, [EHDAB, HDAB, Hub, HCG]	DA(G)BR_
V.6	Health applications deployment	RESO, [HCP]	DA_BR_
Sevice packages for EHDS2 infrastructure / infrastruture and common services			
VI.1	Capability mapping and uplift analysis on core capabilities	HPACK,...	DA_BR_
VI.2	Digital transformation of data collection, data integration and data management	HPACK,...	DA_BR_
VI.3	Digital transformation of data processing, scientific analysis and dissemination platforms	HPACK,...	DA_BR_
VI.4	Common Data platforms and/or exchange functions to expose key data catalogues across agencies	HPACK,...	DA_BR_
VI.5	Solutions for exchange of aggregated, analysed or environmental data (within EU and international)	HPACK, WHO,...	DA_BR_
VI.6	Solucions to exchange data on international level (analysed, aggregated or environmental)	HPACK, DG-ENV, WHO, International	DA_BR_
VI.7	Solutions to link High Performance Computing Infrastructures	RESO, Hub, HCG, HCP	DA_B__
Sevice packages for computing infrastructure			
VII.1	Solution design on computing infrastructure optimization for EHDS	HDAB, Hub, HCG, HCP, (RESO).	DA_BR_
VII.2	Solutions to link High Performance Computing Infrastructures	RESO, Hub, HCG, HCP	DA_B__
VII.3	Option on Computing infrastructure at EHDAB level	EHDAB	DA_B__

Table 2: service packages list 2.

These tables show the titles, targets and service models used for implementation of each one. As described above, end users of every kind will need to begin their engagement with EHDS via one of this existing list of service packages, which have been structured and formulated with input from the regulatory and political bodies, as well as the EC Directorate responsible for IT infrastructure and policy.

Using these standardised packaged as a starting point, however, customers have broad scope to personalise, fine-tune and optimise the basic formulae to suit their own precise needs. This is where collaboration with a capable and expert partner is of key importance.

NTT DATA point of view

NTT DATA is one of a small group of elite specialists in both healthcare and IT trusted to deliver innovation and long-term vision in this essential field. We partner with the European Medicines Agency (EMA) one of the world's two leading health regulators, and ae helping to roll out a new and accelerated approach to medical testing across Europe right now. Our work on patient-centred treatments is also breaking new ground for medical practitioners and is helping to change key research practice across the wider health, monitoring and medical device markets.

By helping some of the same players to make best use of EHDS, we are simply following a single strategic vision, which is to build stronger, more capable methods for delivering better health outcomes, serving individual human beings and their nations equally well.

Maximising the potential of EHDS

We believe EHDS1 & 2 represent a major opportunity for all participants in healthcare, from care provision to original research. The potential impact of the new strategy can be seen in figure 8 below: the Impact Assessment for each part of the strategy.

Figure 8: impact "heat map" on different aspects of the health economy.

The impact on both producers (care providers) and data consumers (RESOs and treatment designers) is obvious. Access to richer data sources under controlled conditions, exactly as needed, has the potential to transform their practices. We can also see improved working practices and collaboration methods across the entire data field, for which this will be a vital new resource.

Yet the most interesting advances may be seen further down the stack. In patient centric care, for example, it should now become easier to design individualised treatment regimes that involve clinicians (care management and design), device companies (wearable technology, connected at the Edge) and IT providers (continuous monitoring, alerts and support).

We have always known that effective patient centred care must depend on close interaction between these different disciplines and capabilities. EHDS does not in itself make this possible, but it does make solution design and delivery much easier by providing a well-governed, compliant and open method for managing data within such solutions, and between solutions and care providers.

Similarly, at the “crossroads” between Primary and Secondary data use, we see major opportunities for improved preventive treatments through creation of registries and short-cycle research options. This is where EHDS1 & 2 intersect, and also where major delays and discrepancies are likely to occur. By managing these interfaces much more smoothly, through standard service registries, it is possible to speed interaction, identify potential policy improvements and continuously contribute to better health outcomes.

How to start
How to continue

Any potential player in this field must respect the processes and frameworks set in place by the EU, after long deliberation with and the agreement of Member State healthcare and political leadership.

The environment has areas of complexity but the need for fool proof governance and compliance makes this inevitable. A key benefit of the EHDS is an enhanced level of public confidence and belief in the system, itself, and this must be defended by every player.

As an acknowledged expert in this field, NTT DATA can help providers and RESOs maximise the benefits to them of participating in the EHDS through a proven engagement model, based on a simple discovery – design – build – implement – manage workflow.

We will work with clients to understand the vision and objectives for engagement with the EHDS at this stage, and will then:

- Discover current state of readiness, capability gaps, need for expert input from external partners, likely timeline for development.
- Design the solution, using standard elements from existing service packages, with a minimum level of customised components, consistent with highly targeted delivery.
- Build the solution iteratively as part of a high performing collaborative team formed by client, NTT DATA and partner resources as needed.
- Implement the solution as defined by the design (cloud based, on-premise…) with all EHDS interfaces managed and assured compliant.
- Manage the early stages to ensure optimal performance, continue management if required.

Solutions are likely to reflect the cloud-based, networked intelligence method that we use in other industries for rapid configuration of network elements to launch highly individual solutions at speed.

NTT DATA is fully at home in the emerging world of networked cloud (indeed, we are responsible for much of the IP that is creating this concept), so building composable solutions fast is part of our normal working methods.

Our goal is to bring as much of this simplicity and speed as possible to clients in the wider health economy, while remaining compliant with the restrictions placed on data usage by the EU. This safeguards the interests of data owners (citizens for the most part), ensures that companies taking part in the EHDS remain compliant and safe from the possibility of legal action, while delivering targeted, effective solutions at low risk and high speed.

NTT DATA

The European Health Data Space (EHDS) is one of the most important initiatives taken to date in the European Union. It is designed to help care providers, researchers and regulators to work more effectively than before, while clarifying and simplifying the regulatory frameworks in which they operate. The structures set up under the EHDS will bring significant benefits to citizens and businesses across Europe, but the new regime is complex and requires deep understanding from everyone involved.

NTT DATA works closely with the European Commission and European Medicines Agency (EMA), and has a strong track record in helping its client navigate the complexities of pan-European operations, maximising potential while staying compliant. Our new white paper gives a definitive introduction to the EHDS, together with insights and guidance as to future operations.

About NTT DATA

NTT DATA a part of NTT Group is a trusted global innovator of IT and business services headquartered in Tokyo. We help clients transform through consulting, industry solutions, business process services, IT modernization and managed services.

NTT DATA enables clients, as well as society, to move confidently into the digital future. We are committed to our clients' long-term success and combine global reach with local client attention to serve them in over 50 countries.

Visit us at es.nttdata.com