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# Digital Transformation and Interoperability in Healthcare



The impact that information technology has had in healthcare in Europe in the past decades has been impressive. Nevertheless, much of the investment has gone into isolated projects that benefit a hospital or region but with little consideration of whether they help Europe advance towards a coordinated and integrated healthcare system.

The problem is often due to a lack of interoperability that makes it difficult for health data to be easily shared across between different equipment, systems and organizations, as well as the challenges professionals may have understanding that data.

This issue of interoperability has acquired a new urgency now with the growing interest in using health data and new digital technologies to solve challenging problems in health and boost the effectiveness and efficiency of healthcare.

Digital transformation needs to transcend mere process automation, despite the obvious benefits of leveraging automation technologies to increase productivity and optimize processes in healthcare.

By leveraging advanced technologies such as artificial intelligence (AI), machine learning (ML), predictive analytics and synthetic data, the industry is now in the position to create proactive support decision, intelligent, and predictive environments.

By enabling healthcare professionals to make more accurate decisions using data-driven insights across all levels of the system, these “smarter” environments can better address the big challenges facing the sector today, such as personalizing care, anticipating health issues, and improving resource management.

## The Importance of Data Interoperability

Despite the impressive advances in how data is processed, stored and analyzed, achieving true interoperability for health data remains a significant challenge in the healthcare sector.

In recent decades, a large number of new and increasingly complex diagnostic tests, techniques, methods and protocols have been created, which require the collaboration of various professionals, units and organizations with a clear tendency towards specialization.

The effective participation of many different players and systems within a healthcare process requires them to be able to easily access, share.

And understand data, irrespective of who created it or where it originated.

Interoperability involves the ability to exchange information between systems while maintaining its meaning and context, ensuring that all parties understand the shared data.

This is of critical importance in healthcare, as it can directly impact patient health and even save lives.

## Benefits of Interoperability

### Enhanced Decision-Making

**Sharing meaningful and contextual data across isolated systems increases the efficiency and impact of intelligent algorithms used in healthcare, enhancing collective intelligence at hospital, regional, national, and international levels. This leads to better population and patient care, earlier disease detection, speedier drug development and it helps advance research.**

### Improving Care and Outcomes

**Each day, hospitals and other points of care generate a vast amount of clinical information. Without interoperability practices and standards, this information cannot be effectively shared with other hospitals, primary care centers, national health systems, or international research organizations. This results in missed opportunities to improve patient care and health outcomes by sharing data.**

### Semantic and Technological Integration

**The full integration of systems like Electronic Health Records (EHR), departmental systems, Hospital Information Systems (HIS) or remote monitoring devices, among others, into interoperable systems allows for comprehensive data sharing. For example, the use of electronic prescriptions sent to pharmacies reduces errors and ensures safer medication management, while shared medical images aid in quicker diagnoses.**

## Barriers to Interoperability

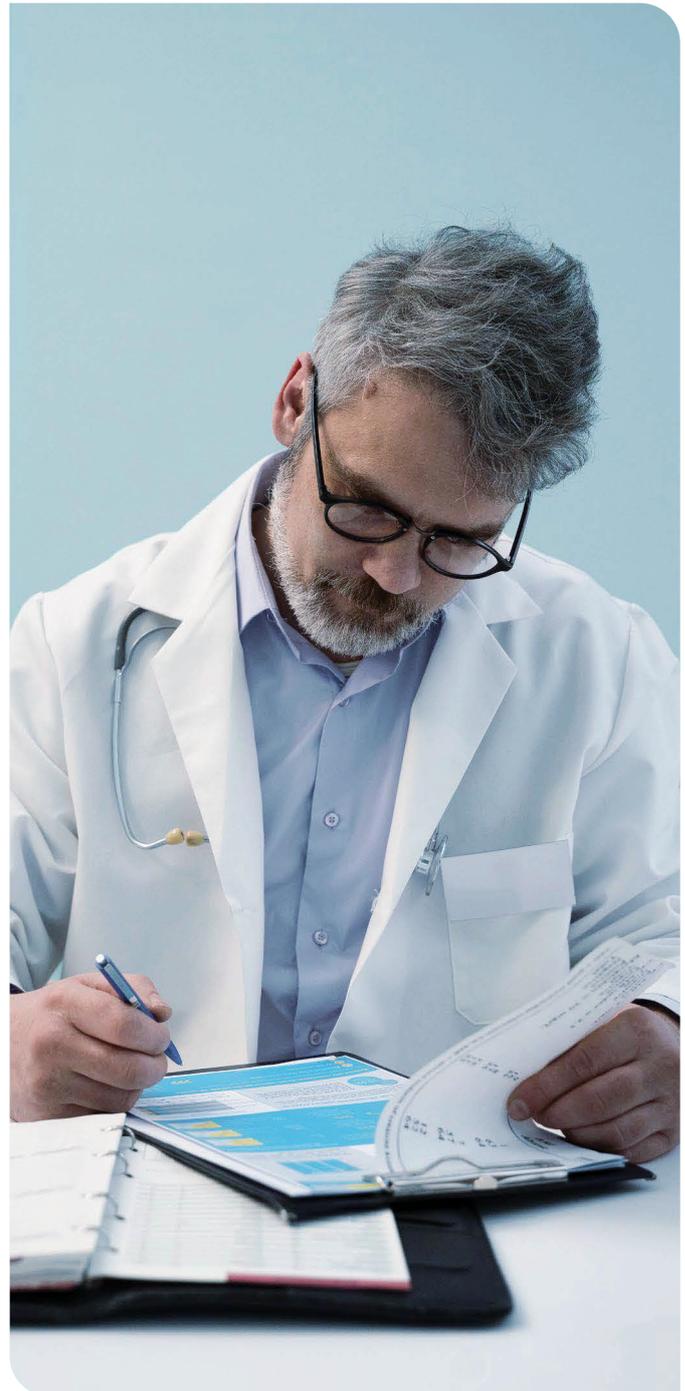
The widespread adoption of EHRs in recent years has meant that great amounts of data are now captured across the care continuum. But the data may be distributed across different systems in proprietary and unstructured formats, making it difficult and costly to extract meaningful information.

Health professionals may use different terms to describe the same illness or diagnosis – “hypertension” instead of “high blood pressure” – or use abbreviations such as MI for Acute Myocardial Infarction, for example. That can lead to misunderstandings and increase the risk of errors if another professional has to intervene in the treatment and the information they share is not standardized at a semantic level.

The risk of the message being “lost in translation” obviously multiplies if the health data has to be shared with professionals that use different working languages.

Therefore, the use of standard information models, the creation of a common archetype base and the use of standard clinical terminologies and information classification systems is one of the major challenges facing healthcare in order to be fully interoperable and make effective use of information.

Another challenge lies in the area of data governance and regulation. Privacy laws and data protection regulations complicate data sharing, requiring robust governance frameworks to be created.



Health systems are increasingly the target of cyberattacks such as the recent data breach in France that affected two companies that provide healthcare payment services. The cyberattack exposed sensitive data of over 33m people, although the companies do not store health-related data.

## The Journey Towards Standardization

Achieving health data interoperability is a slow process involving foundational legislation, development and adoption of standards, regulatory mandates, and international cooperation.

In Europe, the first steps were taken in 2012 with the launch of the European Commission's eHealth Action Plan. This established the foundation for eHealth infrastructure, encouraging the adoption of electronic health records (EHRs) and cross-border health services.

In 2015, countries began adopting the Systematized Nomenclature of Medicine - Clinical Terms (SNOMED -CT), which standardized clinical terminology across healthcare systems, so improving data interoperability.

The EU's General Data Protection Regulation (GDPR), which came into force in 2018, standardized data protection across the EU, which is crucial for secure health data exchange and interoperability.

The following year, the European Commission proposed a common EHR exchange format to enhance interoperability by standardizing the data formats in EHRs across member states.

In 2021, the European Health Data Space was proposed to create a cohesive framework for health data sharing across the EU to improve healthcare delivery and research.

Alongside these European initiatives, there are broader actions at the international level such as openEHR, an organization created 20 years ago to promote standards for creating electronic health records over a common information model.



## The Current State of Play

Today, activities in the area of interoperability seek to drive greater adoption of standards like openEHR and FHIR, a common set of archetypes, SNOMED CT, LOINC and other terminologies which aim to separate data from applications, so ensuring data can be accessed and used independently from specific applications to enable better interoperability.

Updating privacy regulations and creating frameworks that allow for secure and compliant data sharing will be necessary steps towards achieving effective interoperability.

The ultimate goal is to build information systems that offer built-in interoperability using standard information models and terminologies.

By embedding interoperability into the design of healthcare systems, organizations can leverage the full potential of their data to improve patient health outcomes, increase operational efficiency, and drive innovative healthcare solutions.





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# Information Models and Standards



The main objective of an interoperability initiative should be to provide a health organization with a set of solutions adapted to its characteristics that allow the implementation of any healthcare process that requires the intervention of various agents, equipment and systems, associated with different care levels as well as other health organizations.

NTT DATA believes interoperability must be approached holistically by first developing an overarching strategy following **international regulations and standards**, then examining how to best **model, define and exchange** meaningful and contextual information, and finally through the use of **technological tools**.

The main objective of interoperability is to distribute and use the information in the correct way, and this cannot be done with technology alone, as early initiatives that put too much emphasis on the selection of an EHR platform have discovered.

It is necessary to define **information models based on standards** while ensuring that **meaning** and **context** of the data is maintained. That may involve changing the way systems are built so that data can flow horizontally rather than, as is often the case now, be confined in vertical silos.

Finally, it is essential to have an **effective governance of all elements involved** (processes, data, APIs, services and systems) so as to ensure compliance with the strategy.

When talking about interoperability, it is important to realize that the concept needs to be applied at five different levels within a healthcare system: legal, organizational, semantic, syntactic and technical.

## Legal Interoperability

Legal interoperability involves ensuring compliance with the relevant regulatory frameworks, policies, and strategies. Different regulations, policies, and strategies apply to each area and work together at international, macro-national, national, regional, or local levels.

When defining strategies, data models, information flows, and how data is implemented and used, it is essential to consider the relevant regulatory framework in each case to ensure compliance with legal and regulatory requirements.

## Organizational Interoperability

Organizational interoperability in healthcare is essential when defining clinical, logistical, administrative, and management processes. It ensures that these processes and their associated information flows align with the organization's interoperability strategy.

Organizational interoperability is also necessary to meet the information needs of users by making information available, accessible and user-centric.

To achieve a comprehensive and unified view, organizational processes must be reviewed and validated to ensure that they support continuity of care across systems, including quality measurement and risk management.

A team must be in place to monitor and coordinate the interoperability demands of the organization and ensure that its objectives are met.

## Semantic Interoperability

Semantic interoperability means ensuring that when information is exchanged between information systems or applications, they share knowledge through the use of the same concepts, identifications and codifications.

This can be either done by using a single standard or by establishing automatic conversions (semantic mediator) between the different standards used – “high blood pressure” is converted automatically to “hypertension”, for example.

The semantic level is achieved by means of **reference models** that represent the clinical data that will be used by the information systems that support the EHRs. In short, we create a model that represents a common data model and vocabulary.

There are four fundamental aspects to achieving semantic interoperability within an organization:

**Definition of information models** representing existing concepts in the organization based on archetypes. For this purpose, the use of international standards such as **OpenEHR** or **HL7 FHIR** is recommended.

1.

**Semantic standardization** of the concepts, archetypes and data existing in the organization. It is necessary to gradually standardize the different information systems by adapting the existing models to the archetypes defined.

2.

**Management of terminologies** that give meaning to the defined information structures. The most widespread terminologies are **Snomed CT** and **LOINC**, but there are others such as **ICD NANDA**, **NIC**, and **NOC**. NTT DATA recommends the use of **Snomed CT** as a base terminology combined with terminology servers that allow conversion to any other terminology necessary for interoperability.

3.

The **management and governance** of the semantic resources generated in the organization. It is essential that the defined models and regulations are extensible throughout the organization and their use generalized to achieve full interoperability.

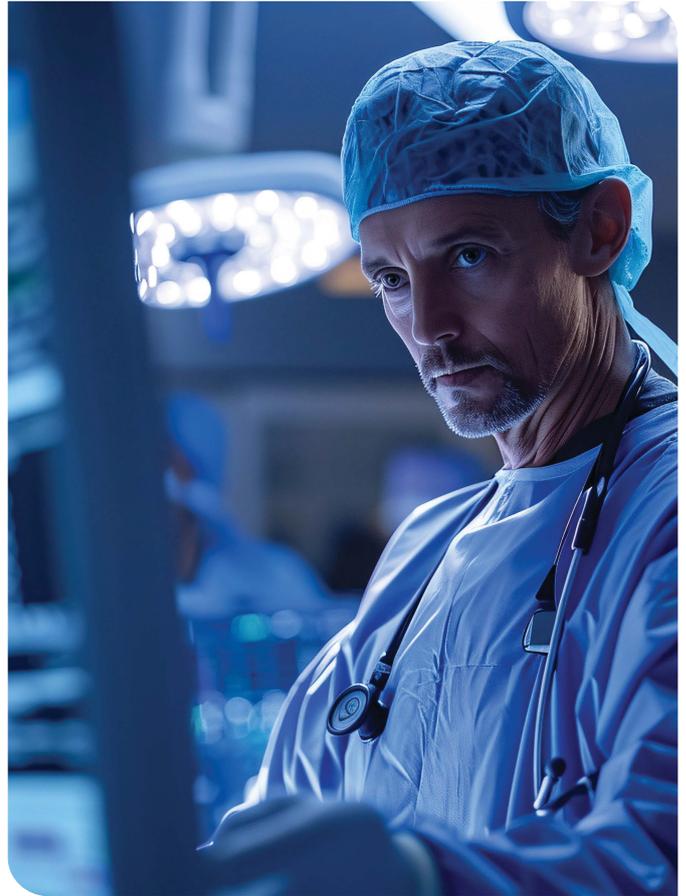
4.

## Syntactic Interoperability

Syntactic interoperability guarantees the delivery of messages with the appropriate structure, but this level does not guarantee the content of the messages, nor that the message exchange protocol is correct and expected.

We need to define and standardize the structure of the messages based on international standards but adapted to the needs of the organization.

The most widespread structures in the healthcare environment are:



- **FHIR** is the latest standard published by HL7 focused on the REST API paradigm and is also compatible for the exchange of clinical documents or events;
- **HL7 v2.x** for the exchange of events between information systems, widely used internationally;
- **HL7 CDA** for clinical reports being the standard used in epSOS and European Patient Summary (EUPS);
- **DICOM** for sending and retrieving image objects;
- **ASTM** for laboratory systems (no longer in use)

Each of these standards establishes a catalogue of messages or resources associated with specific actions along with the rules that guarantee the delivery of messages at the logical level.

# Technical Interoperability

Technical interoperability is responsible for providing the technological architecture that enables the management of business processes, events and the exchange of information.

This can be achieved through different architectural models.

Key elements of these models are services, APIs, and events, which act as software components published on a network (whether enterprise or global). These components handle specific business logic or data and are essential in business processes. They are consumed through a simple contract (interface) based on open standards.

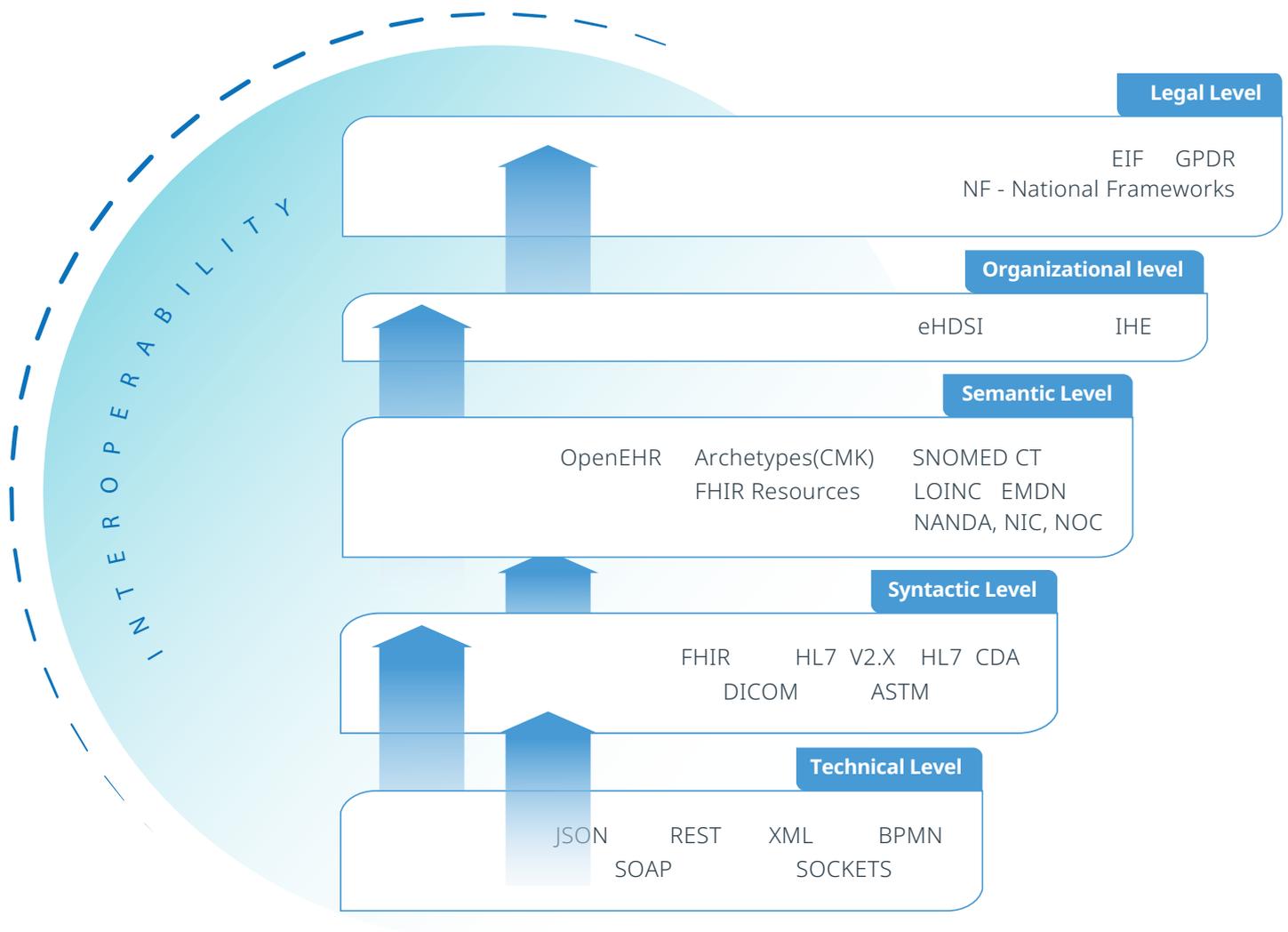


Figure 1 The Levels and main standards of interoperability for Health Data

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# Innovatrial Project Enhances Medical Research in Spain

Clinical trials play a key role in advancing medical research as they enable pharmaceutical companies to objectively demonstrate the effectiveness and safety of new treatments. As such, clinical trials are a critical component in the development of evidence-based healthcare, which seeks to encourage informed decision-making and optimize patient care.

However, conducting clinical trials is time-consuming and involves challenges in areas such as data management and patient recruitment, necessitating innovative approaches.

To improve the way clinical trials are run, NTT DATA, recently launched the Innovatrial initiative, which is developed in collaboration with the Consellería de Sanidade de la Xunta de Galicia, the public health authority for the Galicia region of Northern Spain.

Galicia participates in 23% of the approximately 900 clinical trials for drugs that are authorized annually in Spain.

The regional health body also participates in other studies in the field of biomedicine and health sciences such as observational studies with drugs, studies with biological samples or epidemiological studies with health data.

At the core of Innovatrial lies a sophisticated platform that leverages the experience and resources of the NTT DATA Center for Excellence in Interoperability and is designed to seamlessly integrate clinical research data with healthcare activities in Galicia.

This integration facilitates comprehensive analysis and informed decision-making, leveraging advanced tools such as AI to derive insights and enhancements in medical research.

By integrating accelerators and technological assets, the platform offers a highly scalable solution that can support the needs of health researchers in all aspects related to data storage, interoperability and analysis of clinical information.



The platform also has among its functions the support of patients participating in clinical research studies and the acceleration of patient selection using global data and analytics to identify the most suitable patients for each project.

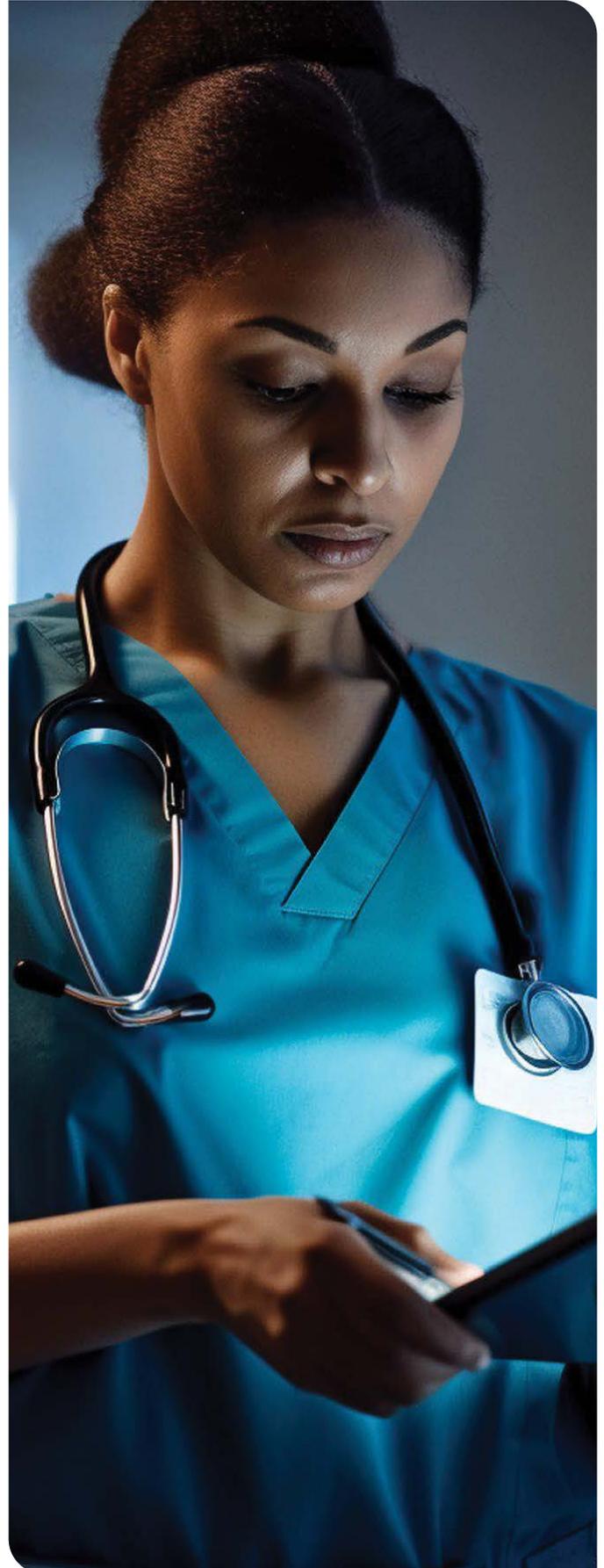
In the wider European context, Innovatrial holds particular relevance as it contributes to the broader landscape of medical research in Europe by offering a scalable solution tailored to the specific needs of the Galician healthcare ecosystem.

The challenges inherent in clinical research are not unique to any particular region and NTT DATA has collaborated with clinical research stakeholders worldwide, gaining insights into the evolving trends and challenges shaping the field.

These challenges include the decentralization and digitization of research, the shift towards patient-centric approaches, and the utilization of real-world data for evidence generation.

As regulatory frameworks evolve and new technologies are integrated into clinical research, the need for innovative solutions becomes increasingly pronounced. With its robust and scalable platform, Innovatrial is poised to address these challenges, paving the way for enhanced efficiency and excellence in medical research in Galicia and beyond.

As the project progresses, it holds the promise of making a substantial impact in the field of clinical research, offering new avenues for collaboration, discovery, and ultimately, improved patient outcomes.



# Why NTT DATA?

NTT DATA has created a **Center for Excellence for Interoperability** that coordinates the research and development of technologies, models and standards for interoperability, and collaborates with healthcare bodies at the regional, national and transnational levels.

Our delivery model for healthcare interoperability is based on the use of an integrated governance model for service outsourcing, which is a methodology that governs the overall delivery of a service ensuring its efficiency, effectiveness, flexibility and quality.

The model is made up of the following components:

## Catalogue of Services

Defines and describes the set of services to be carried out.

## SLAs, KPIs and OKRs

Service Level Agreements (SLAs), Key Performance Indicators (KPIs) and Objectives and Key Results (OKRs) are intended to measure the quality of service and the achievement of set objectives.

## Capacity management and planning

It manages service capacity against demand by prioritizing requests, scheduling them and accumulating the remaining ones (backlog). Capacity and demand management follows an agile methodology that ensures service flexibility.

## Reporting, control and follow-up of objectives

Defines a method to facilitate the monitoring and reporting of the activities carried out and the quality of the service provided.

Adopting this managed services model ensures proper governance by promoting the reuse of APIs and services, creating abstraction, and decoupling systems. It also adds value by orchestrating core and intermediary services that are published on the platform.

