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Analysis And Modeling of the New Italian HIS model "Fascicolo Sanitario Elettronico 2.0 and EDS" towards further actionable solutions to enabling improved healthdata access and secondary data use for research purposes

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ABSTRACT

This doctoral thesis investigates how Italy, within the European Union framework, can overcome the fragmentation and inefficiencies that have constrained the digital transformation of its National Health Service and limited health data management and access and its secondary use for research. The analysis focuses on the *Fascicolo Sanitario Elettronico* (FSE), the Italian Electronic Health Record, and its evolution into FSE 2.0, which, in alignment with the European Health Data Space (EHDS), is intended to secure more reliable and equitable access to clinical data.

The research systematically analyses and models the current Italian FSE architecture, highlighting the regulatory, organisational, and technological barriers that have prevented effective interoperability. It combines workflow modelling with the analysis of the more recent legislative reforms and incorporates insights from interviews with key stakeholders, including ministries, regional authorities and healthcare professionals.

The findings identify four fundamental requirements for the effective development of FSE 2.0: the delivery of a homogeneous national supply of digital health services; the standardisation of data content to guarantee semantic interoperability; the development of a robust infrastructural model linking national and regional systems; reinforcing governance ensuring compliance with standards, validation of interoperable software, definition of performance indicators, and equitable service levels.

The thesis presents actionable proposals, which are fully aligned with the developed national guidelines and relevant legislation, with appliable solutions for improved data access, including health-data access for secondary use and research purposes. Conducted within an industrial doctoral programme, the research moves beyond theory by providing implementable technical solutions that address policy objectives while enabling improved health data access and usability.

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TABLE OF CONTENTS

ABSTRACT 2

ACKNOWLEDGEMENTS 3

TABLE OF CONTENTS 5

1. INTRODUCTION AND CHALLENGES TO HEALTH DATA ACCESS 7

1.1 Research outline and objectives 7

1.2 Challenges for health data access in Italy 10

1.3 The Italian digital healthcare context 12

1.4 The paramount role of interoperability for health data primary and secondary usage 13

2. THE CURRENT ITALIAN HEALTH DATA MANAGEMENT CONTEXT ... 19

2.1 The Italian Electronic Health Record: FSE 1.0 19

2.2 FSE 1.0 Structural and Functional Limits 22

2.3 The revision of FSE 1.0 towards FSE 2.0.: the need for a new architecture 23

3. THE PATHWAY TOWARDS A NATIONAL GOVERNANCE MODEL FOR THE NEW ITALIAN EHR: FSE 2.0 25

3.1 The National Regulatory Framework 25

3.2 The Italian NRRP and Component 2 of Mission 6 (Investment 1.3.1) to implement a new Electronic Health Record (FSE 2.0) 28

3.3 Institutions involved and their role in the national FSE 2.0 implementation project 30

3.4 The new FSE 2.0 Structure and Architecture 34

3.5 Differences between FSE 1.0 and the new FSE 2.0 43

3.9 Expected benefits of FSE 2.0 implementation 45

3.6 The central role of the Health Data Ecosystem (EDS) and the design of 'data-driven' services 50

3.7 Data culture, interoperability and wider societal impact 53

3.8 State of the new Italian HIS (FSE 2.0/EDS) implementation project 54

4. THE EVOLVING EUROPEAN CONTEXT: THE EUROPEAN HEALTH DATA SPACE 56

4.1 Adoption of the European Health Data Space (EHDS): Objectives and institutions involved 56

4.2 The European legal framework of reference 57

4.3 EHDS enabling technology architecture 58

4.4 EHDS interconnection with the Italian FSE 2.0 59

5. IN-DEPTH INTERVIEWS WITH ITALIAN STAKEHOLDERS 61

5.1 Methodology 61

5.2 Main findings 62

5.3. Other points emerged by category of stakeholder 70

6. PROPOSALS FOR EFFECTIVE NATION-WIDE IMPLEMENTATION OF THE NEW ITALIAN HIS (FSE 2.0 + EDS) 72

6.1 EDS-enabled 'data-based' services 72

6.2 The potential of Machine Learning and Artificial Intelligence to deliver 'augmented' EDS services 78

6.3 EDS-FSE 2.0 data access for secondary use 79

6.3 User Experience, Accessibility and Awareness 89

7. CONCLUSIONS 92

GLOSSARY 96

INDEX OF FIGURES 98

INDEX OF TABLES 99

REFERENCE LEGISLATION 100

BIBLIOGRAPHY 102

1. INTRODUCTION AND CHALLENGES TO HEALTH DATA ACCESS

1.1 Research outline and objectives

The management and interoperability of health data represent a fundamental pillar for contemporary healthcare systems [33, 40, 43, 51]. The potential of digital transformation of healthcare and emerging needs shown by the COVID-19 pandemic [39] have highlighted the critical need for a national infrastructure capable of collecting, organizing, sharing, and enhancing clinical information in a secure and efficient manner. While health data is crucial for both advancing medical research and improving healthcare outcomes [4, 34], the reliable access to these data for research purposes still presents significant challenges across Europe and worldwide [12, 15, 30], with Italy facing unique hurdles [14].

In this context the **Electronic Health Record (EHR),** in Italy called **Fascicolo Sanitario Elettronico - FSE**, is an essential tool for the digitisation of the Italian National Health System (SSN) [11, 37], with the aim of ensuring continuity of care and improving the use of clinical information by doctors, health professionals and citizens. In spite of its considerable potential, the fragmentation of regional solutions and regulatory complexity [13, 26, 37, 39] combined with technological and organisational challenges, have hindered its full realisation [47, 48]. This research work systematically analyses the current Italian EHR architecture, the interoperability standards in use, the governance models at regional and national level and the regulatory framework of reference, providing a modelling of the current state of the art. Building on this analysis, the research moves on to propose a new design and implementation of an improved architectural model, FSE 2.0, that could be developed within the framework of the **National Recovery and Resilience Plan**[1], in alignment with the European Health Data Space[2] (EHDS) regulation and the more recent Italian legislation[3] on the subject.

Following recent legislation, the Italian Electronic Health Record, FSE, must evolve into a new FSE 2.0. by 30 June 2026 to represent a key digitalisation tool of the **Italian National Health Service** (hereafter also referred as **Servizio Sanitario Nazionale - SSN**), with the aim of responding, through an advanced and structured management of health data (both at national and local level) to the following crucial requirements:

1. ensure a nationally **homogeneous and uniform** supply of **digital health services**;

1https://www.italiadomani.gov.it/en/strumenti/documenti/archivio-documenti/national-recovery-and-reslieince-plan.html

2 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en
3 Decreto 30 dicembre 2024, G.U. n. 33 del 10/02/2025: https://www.gazzettaufficiale.it/eli/id/2025/02/10/25A00808/SG

2. **standardise the content of the FSE**, in terms of the data and coding adopted, to ensure semantic consistency of the FSE feeding data, their usage for medical prevention and treatment and **interoperability between different health organisations and units**;

3. **strengthen at national and local level the architecture of the FSE**, in order to create a composite infrastructure of data and clinical documents, capable of interoperating with the information systems in use at the various healthcare facilities in the territory;

4. **strengthen national and local FSE governance** to ensure the definition and management of the new FSE 2.0 implementation rules on 3 key dimensions (services, content, architecture), through:

    a. the standardization of the implementation specifications;

    b. validation and qualification of interoperable software solutions with the FSE to ensure their supply;

    c. the definition of Key Performance Indexes (KPIs) and service levels offered by the FSE in a homogeneous manner throughout the country;

    d. control and monitoring of the complete and timely supply of the FSE at every level of the National Health Service (NHS), by all healthcare facilities, both public and private.

This evolution is reinforced by the recently established, last December 2024, Italian Health Data Ecosystem[4] (EDS), which should work in synergy with the new FSE 2.0. to ensure efficient data exchange, increased data privacy and access for secondary usage.

This research, as part of an industrial doctoral programme, has aimed to bridge the gap between theoretical research and applied innovation by combining advanced computer sciences doctoral training with elements of health management and public policy to reach results and solutions that can effectively be implemented to address real national healthcare system challenges. The scope of my thesis has extended beyond computer sciences and IT by using multidisciplinary elements of public policy, health management and administrative law in the attempt of providing results which could be transferred into real solutions and generate tangible societal impact.

[4] https://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2025-03-05&atto.codiceRedazionale=25A01321&elenco30giorni=false

My research work has attempted to employ a multi-faceted approach to investigate the transition from the existing FSE 1.0 to the new FSE 2.0. The research begins with an in-depth analysis and modelling of the structural attributes of FSE 1.0. Subsequently, it identifies and critically evaluates its inherent limitations that have led to new legislative frameworks and guidelines for the design and deployment of an enhanced model: FSE 2.0.

Moreover, the study broadens its perspective to consider the national framework, multilevel governance and European strategies that regulate digital health. Attention is posed to the Italian EDS and the EU EHDS. Regarding the EDS, this dissertation will explore how to use it in combination with the new FSE 2.0 to make available web services for healthcare users and patients, as well as clinical data for secondary use such as life-sciences research and will propose an effectively viable architectural solution model to ensure interoperability, security and privacy standards.

The thesis is structured into seven chapters. Chapter 1 introduces the problem and the research outline; chapter 2 analyses how the Italian Health System digitalisation has evolved and the current Italian FSE, with an original modelling of its existing architecture and workflows. Chapter 3 analyses how the new Italian legislation which establishes the creation of a new FSE 2.0 intends to improve data in association with EDS and provides original modelling of what is set to be implemented. Chapter 4 describes and discusses the European Union EHDS regulation context. Chapter 5 presents a field analysis with in-depth interviews with main stakeholders (Ministry, Regions, healthcare professionals) conducted spring-summer 2025 to outline the **"key" aspects of what kind of data access should be implemented and adopted**, in terms of (i) FSE 2.0 objectives and ability to overcome the limitations of the FSE 1.0 version; (ii) enabling technological architecture; (iii) expected benefits from the dissemination of FSE 2.0 for each category of Users (Citizens, Health Professionals, Health Governing Authorities, Research Institutions); (iv) problems to overcome to enable an advanced management of health data throughout the national territory.

Drawing from the previous chapters modelling and results of field interviews, Chapter 6 presents specific proposals for a new technical model to improve the concrete deployment of the new legislation with **actionable architectural solutions,** at a national and regional level able to **ensure an effective implementation and full access to health data, including secondary usage and research purposes.**

Lastly, chapter 7 concludes the thesis, providing a summarised analysis of the research results and indicating what could be future implementations and research related to this subject of study.

1.2 Challenges for health data access in Italy

Italy's healthcare landscape is characterized by a proliferation of HIS, deployed heterogeneously across regions and at varying temporal scales, with disparate objectives, territorial coverage, and governance structures [16]. This decentralized approach has resulted in a fragmented data ecosystem, encompassing numerous independent data centers and a lack of interoperability due to inconsistent data formats [14], a problem shared with most other countries [19], thereby hindering comprehensive health data analysis and exchange. Although both the legislation and the regulatory efforts have made significant progresses over the last ten years for improving the standardisation of national HISs, the different levels in the spending capacity and innovation capability of the various regions responsible for the deployment on the field make the situation still very fragmented.

Some Italian regions have also invested in other local data-producing digital systems or applications. For example Region Lombardia has built a data-as-a-service (DAAS)[5], an hub for sharing health data with accredited research institutions, while Region Abruzzo has invested in setting up monitoring dashboards for coping with the COVID pandemic [20]. Additionally, by enforcing a very strict interpretation of the GDPR, Italian authorities have required researchers to obtain informed consent from the individuals whose data is being used [26] to access health data for secondary use. This proves almost impossible on a large scale or when genomic data are involved. Furthermore, data anonymization and encryption methods are required to protect the privacy and confidentiality of the data and full anonymised data can be of scarce value for some medical studies, i.e. epidemiology.

Following the FAIR framework, which the main 4 principles are [57]:

1. **Findability**: the precondition to use data is to find them, thus rich and clearly indexed metadata is crucial for machine readability and easy automatic discovery.
2. **Accessibility**: must be ensured using free and open communication protocols and standard authentication and authorisation processes.
3. **Interoperability**: this is essential because in research data need to be integrated with other data and should come in formats that allow its usage with applications to process analysis.
4. **Reuse**: to guarantee reuse of data, metadata and data should be richly and accurately described and must meet domain relevant standards.

5https://osservatorioepidemiologico.regione.lombardia.it/wps/portal/site/osservatorio-epidemiologico/DettaglioRedazionale/collaborazioni-con-gli-enti/daas+2-0/red-daas-2-0

the main problems that can be identified in the current Italian National HIS architecture to provide reliable health data access for both primary and secondary usage are summarised in the following table (Tab.1).

Table 1 Main challenges for health data access of Italian HIS

Main challenges	Description
Lack of interoperability and no real-time access	The Italian SSN uses different HISs with varying software and ontologies, resulting in limited interoperability and reliance on external systems for data access. Regional differences in data collection and legal interpretations hinder national health data use. Interoperability issues stem not only from technology gaps but also from low digital skills among healthcare professionals [9]. Due to regional infrastructure, current Italian EHR data isn't stored in a centralized cloud, preventing real-time sharing. Federated networks may offer a solution to overcome regional data silos [28].
Non standardised formats and data ontology	Standardization is crucial for reliable research and effective data use, but data formats are often fragmented, causing issues during processing and analysis [2]. Although there are many standard formats available (HL7 CDA, HL7 FHIR, NEMA DICOM, JSON), and efforts have been made by AGID to improve standardization, the lack of an applied shared national ontology and the fragmented regional HIS hinder nationwide interoperability and standardization.
Data inaccuracy and unreliability	Current Italian EHR data are often inaccurate and inconsistent, partly due to a lack of standardization and fragmented workflows, as well as limited awareness among healthcare professionals about accurate data collection [9]. Including contextual information (e.g., source, metadata, data author) and improving shared ontologies are essential to ensure data fairness and enhance EHR data quality.
Cybersecurity and data protection regulatory issues	Cyber-attacks frequently target public administrations, including healthcare systems, making data integrity a major concern due to profit-driven attacks and ransomware. In 2022, Italy's National Cybersecurity Agency introduced a national strategy[6] with a taxonomy for cyber incidents to aid response efforts. Ensuring constant data availability requires secure, certified, and monitored hosting. Cloud storage enhances both access and security of medical records. Despite existing technologies like blockchain and encryption, the

[6] https://www.acn.gov.it/portale/documents/20119/531899/ACN_EN_Strategy.pdf/4ccff3e7-b88f-e5e2-d429-01c982994e73?t=1719931787736

Main challenges	Description
	healthcare sector still lacks widely usable, systematic applied solutions.

1.3 The Italian digital healthcare context

Over the last two decades, technological evolution has had a profound impact on all sectors of public and private life, changing the paradigms of access to information, the relationship between citizens and institutions, and the ways in which public services are provided and used. In this scenario, healthcare represents a particularly strategic area for the digitalisation of the Public Administration, both for the high social and economic value of healthcare services and for the quantity, quality and sensitivity of the data processed.

Since the early 2000s, and particularly after 2010, Italy has also seen the launch of important projects for the transformation and digital innovation of healthcare processes, initially focused on single functions or areas (e.g. dematerialisation of prescriptions, introduction of the Health Insurance Card), up to the establishment of the **Electronic Health Record** (hereinafter also referred to as **'Fascicolo Sanitario Elettronico'** or 'FSE 1.0') - formally introduced with Italian Decree Law no. 179 of 18 October 2012 (converted with amendments by Law no. 221 of 17 December 2012) - as a **tool for the collection of digital health documents** of NHS patients.

However, the implementation of the Italian Electronic Health Record in its first version (hereinafter also referred to as **FSE 1.0'**) was entrusted to the Regions and Autonomous Provinces, following the national health System governance model, each of which developed its own 'regional FSE' solution based on specific local needs and resources. This approach has generated significant heterogeneity throughout the country in technological architectures, in the content available on the FSE, and in the methods for accessing, updating and disseminating the FSE, limiting its effectiveness as a unified national tool.

The need to have an FSE that is homogeneous in content, fed in real time and standardised and spread throughout the national territory, has become even more pressing in the wake of the COVID-19 pandemic [39], which has highlighted the 'structural' areas of concern of the Italian healthcare system, including the lack of a unified and interoperable national digital infrastructure capable of providing reliable health data in a timely manner for emergency management, continuity of care and healthcare governance at national and local levels. The pandemic crisis has clearly shown how crucial the availability and quality of health data are not only for ensuring the best healthcare for each NHS patient, but also for planning and implementing advanced public health policies and for the overall resilience of the system.

In response to these challenges, the Italian National Recovery and Resilience Plan (NRRP)[7], framed within the European Union's Next Generation EU (NGEU)[8] initiative, envisaged, under Mission 6 (Health)[9], an ambitious and comprehensive revision of the national health information system, including the design and implementation of a new national Electronic Health Record (*Fascicolo Sanitario Elettronico*: FSE 2.0). At the same time, a process of profound renewal of digital health policies has also started at **European Union** level, culminating in the **European Health Data Space (EHDS**) regulation[10]. The EHDS represents the first sectoral common data space to be developed under the 'European Data Strategy' and aims to promote shared governance, cross-border portability of health data and full 1, between health systems of EU Member States.

Thus, the current context is characterised by a dual digital transition, nationally through the deployment of FSE 2.0 and the Italian EDS and at the European level via the European Health Data Space (EHDS), converging on the development of a digital health ecosystem based on reliable, accessible, interoperable, and secure data access. In this perspective, national measures for implementing FSE 2.0 not only address the challenges highlighted by the COVID-19 pandemic (in particular the lack of a homogeneous, nationwide FSE populated with structured data and documents) but also present a strategic opportunity to align with the European framework and to enhance the value of health data as a key asset for the future of public health and life-sciences research.

1.4 The paramount role of interoperability for health data primary and secondary usage

Health data interoperability is a fundamental pillar for securing the effectiveness, sustainability, and fairness of a digitalised health system [1, 29, 35, 51]. It entails secure and semantically coherent exchange, interpretation, and reuse of health information across heterogeneous systems and stakeholders, from public and private actors to local and national authorities, clinical care providers, and research organisations. Effective interoperability is therefore a prerequisite for a genuinely integrated digital health system committed to the continuous improvement of patient care [1, 35]. Thus, in the context of the evolution of the Italian National Health Service, achieving interoperability at both national and regional levels is essential to obtain improved digital health services.

The concept of interoperability, as outlined in the **Guidelines on Technical Interoperability of Public Administrations**[11] adopted by the Italian National Agency for Digitalisation (AGID), is composed of three elements:

7 https://www.italiadomani.gov.it/content/sogei-ng/it/it/home.html
8 https://next-generation-eu.europa.eu/index_en
9 https://www.italiadomani.gov.it/content/sogei-ng/it/it/il-piano/missioni-pnrr/salute.html
10 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en
11 https://www.agid.gov.it/index.php/it/infrastrutture/sistema-pubblico-connettivita/il-nuovo-modello-interoperabilita

1. **Technical interoperability**, enabling secure data transmission through standard infrastructures and protocols;

2. **Semantic interoperability**, which ensures that exchanged information retains the same meaning from one system to another, through the use of codified terminologies and controlled vocabularies (e.g. HL7 FHIR, SNOMED CT, LOINC);

3. **Organisational interoperability**, which concerns the consistency of processes, access rules and governance models between the different organisations handling data.

Interoperability is not only about technical capability but it needs to be assessed with a multidimensional approach that encompasses: (a) technical/syntactic interoperability (the reliable transmission of data between systems); (b) semantic interoperability (the shared and computable meaning of exchanged information); (c) organisational/process interoperability (alignment of workflows, responsibilities, and governance across institutions); and (d) legal interoperability (consistent rules for consent, privacy, and liability). Achieving interoperability requires coordinated advances across all these dimensions so that data can be exchanged securely, interpreted unambiguously, and reused appropriately by diverse stakeholders profiles (clinicians, public health authorities, researchers, and patients).

The current Italian Electronic Health Record (FSE 1.0) lack of effective interoperability has represented a structural and very significant limitation [14]. The first generation of the Italian EHR was, in fact, characterised by heterogeneous regional implementations, based on architectures built and managed locally[12] and on poorly standardised data models. The prevailing presence of clinical documents in PDF or CDA2 format, often lacking shared metadata, is also noted as a limiting factor in the Guidelines for the Implementation of the Electronic Health Record 2.0[13] (in Italian: *'Linee Guida Fascicolo Sanitario Elettronico 2.0'*) issued by the Ministry of Health in May 2022. Moreover, the regional implementation of the previous Italian EHR laid on different Health Information System (HIS) and data silos and resulted in the substantial lack of a harmonised semantic layer that significantly hindered the capacity to perform aggregated and comparative analyses across the various regional health information systems.

12 The exceptions are the regions of Abruzzo, Calabria, Campania and Sicily which, in accordance with the principle of subsidiarity, have chosen to use the National Infrastructure for Interoperability-INI to implement their respective regional EHRs, instead of developing local autonomous solutions.
13 https://www.gazzettaufficiale.it/eli/id/2022/07/11/22A03961/SG

The new framework outlined in the cited FSE 2.0 Guidelines, elaborated by a joint working group of the Ministry of Health and the Department for Digital Transformation (DTD), has been adopted in May 2022 addressing some of the most critical issues. Specifically, the adopted Guidelines establish the need to:

a) **extend and homogenise on a national basis the minimum set of compulsory FSE documents** (e.g. emergency room reports, reports of outpatient specialist services, hospital discharge letters) and to **improve their standardisation**;

b) **evolve the FSE interoperability infrastructure** through the creation of a national index, a national register of patients and a component for acquiring data and documents from the different sources;

c) **standardise at national level the services provided to citizens and health professionals** through the existing regional FSE portals;

d) **adopt a system for controlling and monitoring the quality of clinical information** feeding the FSE;

e) Introduce and govern **national standardisation processes** of the FSE various dimensions.

To complete the strategic design of the new FSE 2.0, more recently in 2024 the Health Data Ecosystem (EDS - Ecosistema Dati Sanitari) has also been introduced, aimed at increasing data feed into the FSE and making it available for secondary usage, such as prevention, health planning, epidemiological surveillance and scientific research.

In fact, following the favourable opinion of the Italian Data Protection Authority, EDS has been established by Decree of the Ministry of Health on December 31, 2024[14]. EDS is a large-scale technological infrastructure, designed to include data transmitted to the EHR (FSE 2.0) by the National Health Service facilities (managed and governed by Regions and Ministry of Health) as well as data made available through the Tessera Sanitaria[15] (Health Card) system (managed and governed centrally by the Ministry of Economic and Finance), which includes medical prescriptions and other tax and fiscal patient data [14]. Through the collection and processing of this information, the EDS aims to provide, in a uniform manner throughout the country, support services not only for treatment, but also for healthcare governance and scientific research in the medical, biomedical, and epidemiological fields.

EDS is intended to be a central component of the new FSE 2.0, capable of enabling 'data-driven' services for citizens and healthcare professionals for the diagnosis and treatment of their patients, as well as support tools for healthcare facilities and institutions that will be able to use clinical information from the FSE, in compliance with data privacy laws and the General

14 https://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2025-03-05&atto.codiceRedazionale=25A01321&elenco30giorni=false
15 https://sistemats1.sanita.finanze.it/portale/home

Data Protection Regulation (GDPR), to perform clinical data analysis (anonymised and/or pseudo-anonymised) and improve healthcare service delivery.

It is precisely this concept of secondary access to health data what constitutes a strategic innovation that characterises both recent national legislation and the emerging European framework [30], according to which EHR data should be used not only for diagnosis and treatment purposes, but also for:

a) **prevention** activities planned and implemented at national and local level;
b) the management of structured and effective **international prophylaxis** processes;
c) **study and scientific research** in the medical, biomedical and epidemiological fields;
d) **health care planning**, quality of care verification and evaluation at national, regional and individual health authority level.

In the subsequent table (Tab.1) there is a summary of non-exhaustive examples of **secondary use of health data** that could be obtained with the new FSE 2.0 and associated EDS.

Table 2 Examples of secondary use of health data that can be activated by FSE 2.0 with EDS

Secondary use of health data	Description	Potentially issues
Development of predictive models through Artificial Intelligence (AI)	Health data collected through the FSE 2.0 (integrated with other national and local digital health platforms - e.g. National Telemedicine Platform) can be used to train AI algorithms in order to build predictive models and virtual personal assistants. This approach improves patient care and the efficiency of healthcare services.	Possible algorithmic biases, caused by the fact that the training data may not cover all patient categories, consequently producing discriminatory results. In addition, AI requires large volumes of accurate and standardized data, and any errors would reduce performance.
Health care planning and quality of care assessment	The analysis of health care data enables health governing authorities (e.g. Ministry of Health, Regions) to plan interventions, allocate resources efficiently and improve the quality of services offered. For example, by assessing the effectiveness of specific health treatments or interventions, corrective measures can be implemented where necessary.	One of the risks that may arise for this secondary use is related to differences in regional systems and data collection methods, which may therefore be difficult to compare. In addition, if collected data contain outdated or incomplete information, health prevention plans may not result accurate.
Monitoring, active epidemiological surveillance and	During the COVID-19 pandemic, the analysis of health data enabled the development of dashboards to monitor infection trends at the local level, supporting the	During a health emergency such as COVID-19, delays in data collection slowly can compromise the timely enforcement of containment measures. In

Secondary use of health data	Description	Potentially issues
management of pandemic events	decisions of health authorities. For example, the 'COVID-Pro in Italy'[16] [24] provided tools to analyse the epidemic by considering daily data at provincial level.	addition, the rapid and sudden increase in volume of data to manage can cause systems overload.
Cancer Registries: The **Italian Association of Cancer Registries (AIRTUM[17])**	Coordinates the collection of data on cancer cases in Italy. These registers provide essential information for research into the causes of cancer, evaluation of preventive interventions and analysis of the effectiveness of cancer treatments.	The registries handle extremely sensitive information that requires strict protection mechanisms to avoid re-identification risks. In addition, since the data come from different healthcare facilities, they may not share the same semantics.
Pharmacovigilance: The **National Pharmacovigilance Network (RNF)**	Collects and analyses reports of suspected adverse drug reactions, using data from various healthcare sources. This system makes it possible to monitor the safety of drugs post-marketing and to intervene promptly if necessary.	In addition to the already mentioned risks of data privacy and interoperability, there is the potential issue related to adverse reactions that are not reported or are only partially described, thereby reducing the reliability of the analyses.
Epidemiological analyses and disease prevention	The secondary use of health data makes it possible to monitor the spread of diseases and assess the effectiveness of preventive measures. For example, analysis of seasonal influenza data can help predict epidemic peaks and organise targeted vaccination campaigns.	Potential issues of data bias, since if data collection is partial or focused on specific population groups, analyses may not be fair or fully representative. In addition, epidemiological models may be influenced by external factors that are difficult to predict.
Contact tracing	During public health emergencies, such as the COVID-19 pandemic, contact tracing was crucial to quickly identify and isolate potentially infected individuals, limiting the spread of the virus. Analysis of the data collected supported these activities.	Contact tracing is successful only if there is mass participation. If user adoption of tracing tools is limited, effectiveness decreases significantly.

In terms of interoperability standards, the new FSE 2.0 and the establishment of the EDS highlights the advantages of adopting the FHIR standard [6] within the Italian national

16 https://ceeds.unimi.it/covid-19-in-italy/

17 https://www.registri-tumori.it/cms/

healthcare architecture and marks a decisive step towards more interoperable and semantically uniform management of healthcare data. In both FSE 2.0 and EDS the adoption of FHIR is designed in a structured manner, with the aim of overcoming the limitations of previous standards and enabling new scenarios for the use of clinical data for both treatment and secondary purposes. FHIR (Fast Healthcare Interoperability Resources) is a standard developed by Health Level Seven International (HL7) to enable interoperable exchange, sharing and automated processing of healthcare information [2], which allows the exchange of medical data in the JSON format in different forms and elements called resources. FHIR defines a modular, resource-oriented data model (Resources) that represents clinical and administrative concepts (e.g., Patient, Observation, Medication) and standardises how these resources are represented (JSON, XML, Turtle), exchanged (RESTful APIs, messaging, bulk data), and constrained (profiles, value sets, implementation guides).

Considering all of the above, the next chapter will examine in detail the current Italian HIS by providing an analysis and modelling of the FSE 1.0 architecture and functions in order to outline the structural limitations that have led to the recent regulatory revisions.

2. THE CURRENT ITALIAN HEALTH DATA MANAGEMENT CONTEXT

2.1 The Italian Electronic Health Record: FSE 1.0

The Electronic Health Record in its original configuration, defined within this dissertation as **Fascicolo Sanitario Elettronico - FSE 1.0**, has represented one of the main innovations introduced over the last 15 years by the Italian legislator in the context of the digitalisation of healthcare. Formally instituted by Article 12 of Decree-Law No. 179 of 18 October 2012[18] (converted with amendments by Law No. 221 of 17 December 2012), the FSE 1.0 was initially conceived as a tool aimed at collecting patients' health and social-health digital data and documents, generated by present and past clinical events.

From the earliest regulatory formulations, the FSE 1.0 has been vested with a variety of purposes, as outlined in Article 12(2) of the decree, such as:

1. diagnosis, treatment and rehabilitation (point a);
2. prevention (a-bis);
3. international prophylaxis (a-ter);
4. study and scientific research (point b);
5. health care planning and evaluation (point c).

These aims qualify its hybrid nature: not only a clinical tool to support the activities of healthcare professionals, but also an information infrastructure serving the Italian and local healthcare system as a whole.

The operational implementation of the FSE was entrusted to the 21 Italian **Regions and Autonomous Provinces**, which were assigned by the legislator the task of setting up and managing the regional EHR, in accordance with national provisions and respecting local organisational and technological specificities. This approach led to the creation of 21 regional EHRs, formally distinct but connected through the **National Infrastructure for Interoperability (INI)**, managed by the Ministry of Economy and Finance through the Health Card System.

The minimum dataset content of the FSE 1.0, as set out by the Prime Minister Decree No. 178 of 29 September 2015[19], included:

1. laboratory reports;
2. first aid reports;
3. discharge letters;
4. pharmaceutical and specialist prescriptions;

18 https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legge:2012-10-18;179!vig=
19 https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.del.presidente.del.consiglio.dei.ministri:2015-09-29;178!vig=

5. Vaccinations;
6. summary health profile (Patient Summary);
7. personal notebook of the assisted person;
8. exemption data and administrative information.

However, the actual availability of such data in the FSE of each patient varies considerably from region to region, due to different implementation timeframes, local strategic priorities and technical capabilities of given local contexts. In some regions, over the years, the FSE 1.0 has become a central access point for citizens to digital health services; whereas in others, its outreach has remained scarce, with only a limited set of data and documents fed in the system and/or low dissemination and access by users (both citizens and healthcare professionals).

The 21 regional EHRs had a common architecture, which is described in the following diagram (Fig.1).

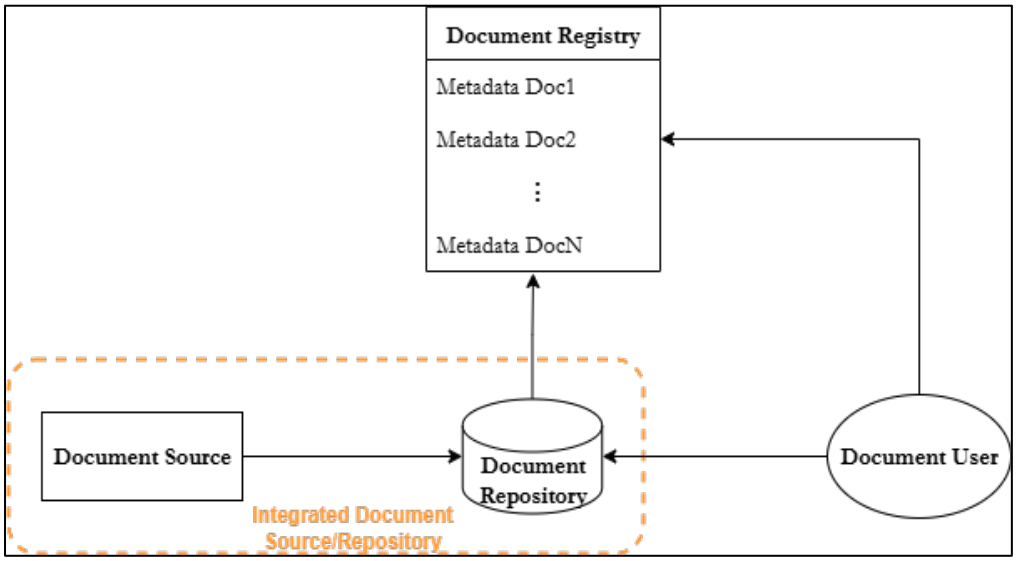

Figure 1 Architecture of a regional FSE 1.0

The architecture of the system is based on four main elements:

1. Document Source,
2. Document Repository,
3. Document Registry,
4. Document User

The **Document Source** represents the system responsible for generating clinical documents, which may originate from laboratories, hospitals, general practitioners, or any other authorized healthcare providers. Once created, the document is transmitted to the Document Repository, through a process that includes both the delivery of the document itself and the request to

register its associated metadata. The **Document Repository**, acting as the storage node, receives and physically archives the file, making it available for future consultation. Simultaneously, the same Repository forwards the **document's metadata** to the Document Registry. These metadata serve to identify and uniquely locate the document within the system, without transmitting the actual content. The **Document Registry** functions as an **internal index** within the document-sharing infrastructure, acting as a reference point for retrieving documents by authorized systems. When a **Document User** (i.e., a healthcare professional or a patient) wishes to access one or more clinical documentation, it queries the Document Registry, which returns the relevant metadata associated with the documents available for the patient. Based on these metadata, the User can then submit a request to the Document Repository to retrieve the document's actual content. The architectural model also accounts for scenarios in which the Document Source and Repository are integrated within the same system (as represented by the dashed box labeled "Integrated Document Source/Repository," representing co-located production and storage).

This framework is supported by a key enabler: the **National Infrastructure of Interoperability (INI)**[20].

The figure below (Fig.2) shows how each regional FSE interacts via INI, which acts as a central proxy and orchestration layer between regional FSE nodes. It receives consultation requests from users and, based on the patient's reference region, it redirects those requests to the appropriate regional system using the standardised interfaces defined in the FSE base services framework. It thus serves as a service infrastructure that ensures the continuity of information flow and the consistency of access to healthcare documents on a national scale, while repositories and registries are autonomously maintained by each Region.

[20] https://www.fascicolosanitario.gov.it/en/interoperability-services.html

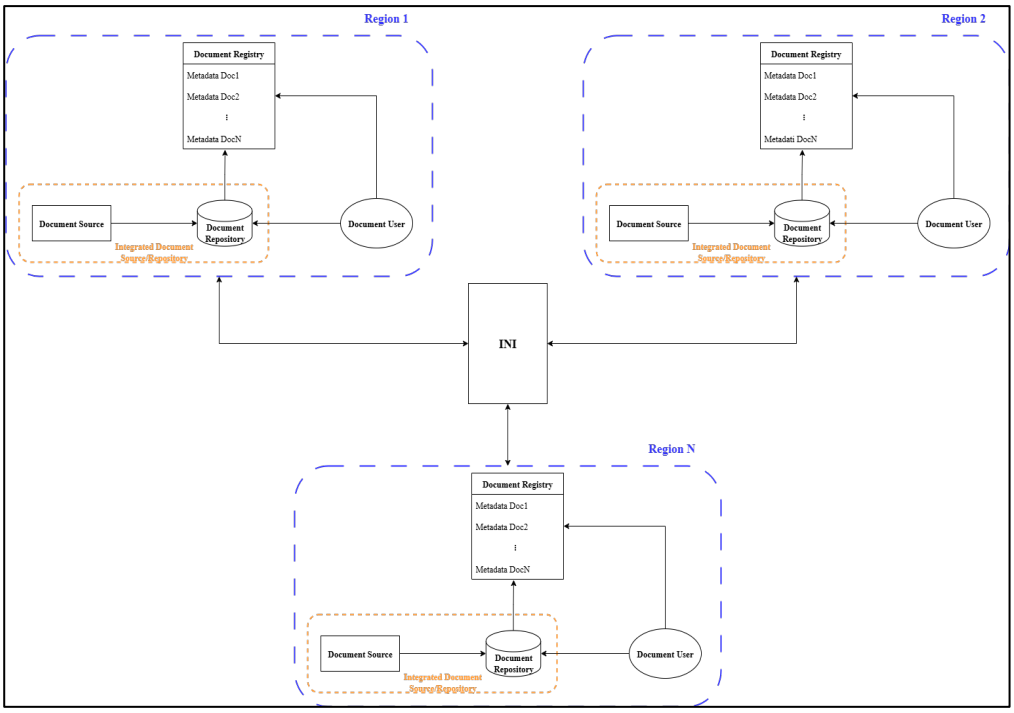

Figure 2 INI architecture in FSE 1.0

2.2 FSE 1.0 Structural and Functional Limits

Despite its regulatory importance at the time of its first conception in 2012[21], the first Italian FSE (1.0) has shown several structural limitations.[11, 14, 18, 37, 48] that have compromised its effectiveness from the very beginning of its adoption. More specifically:

1. **Territorial inhomogeneity and fragmented governance**: the regional implementation has produced twenty-one models with significant differences in terms of architecture, content, standards and access modalities.

   This has led to:

   a. **Insufficient technical and semantic interoperability** between the different regional systems and at national level;
   b. **unstructured data: FSE 1.0 was conceived as a collection of clinical documents (e.g. in PDF format), with insufficient data structuring,** resulting in**:**
      i. Data cannot be effectively used for computational analysis, artificial intelligence or automated decision-making tools;
      ii. difficult semantic alignment between different information systems;

21 The Electronic Health Record in Italy was firstly established by Decree-Law No. 179 of October 18, 2012, and it took more than 2 years to start its implementation at the regional level in 2015. Its implementation improved with the 2017 Budget Law, which made the FSE mandatory for all regions.

iii. some dataset cannot be effectively queried or indexed.

c. **lack of a uniform user experience and access interfaces (for both patients and health professionals)** which is significantly different from region to region.

2. **Lack of a unified data governance model**: no mandatory standards for **data quality, validation, updating and control**. Therefore, the 21 regional FSE 1.0 data are often:
    a. Incomplete or outdated;
    b. non interoperable;
    c. not subject to a national quality monitoring system and standards.
3. **Limited adoption by healthcare professionals**: not all and not often General Practitioners (GPs), Paediatricians (Paediatricians) and medical specialists use the FSE 1.0[22] as part of their ordinary workflows, due to:
    a. Lack of integration with wide-spread management software used on hospitals, territorial and primary care practices (e.g. medical record software adopted by GPs/PLS);
    b. delays in automatic document feeding;
    c. perceived as an useless tool in everyday healthcare practice.
4. **Limited adoption by patients**: despite the availability of regional web-services in all regions, patients' access to their files remains very limited to date[23]. Main reasons include:
    a. Fragmentation: different portals for each region, heterogeneous authentication systems and unfriendly interfaces;
    b. lack of communication and advertising;
    lack of digital skills in some demographic groups.
5. **Regulatory and privacy issues**: data protection rules (consent) have also represented an obstacle for adoption and implementation.

2.3 The revision of FSE 1.0 towards FSE 2.0.: the need for a new architecture

Considering the above, the need for a structural and systemic redesign of the FSE 1.0 has become evident for a while, from both a technological and organisational point of view. The limitations highlighted in version 1.0 are not exclusively due to technical issues, but reflect an original design elaborated at a time when an architecture with a national orchestration was not on the agenda.

22 https://monitopen.fse.salute.gov.it/usage#medics and https://monitopen.fse.salute.gov.it/usage#companies
23 https://monitopen.fse.salute.gov.it/usage#citizens

More recently, and especially after the experience of the COVID-19 pandemic, the availability of structured health data in real time for both medical care and secondary purposes (e.g. research, health planning,, international prophylaxis) have become a key policy objective for both clinical practice and the National Health System governance [39]. In this perspective, the FSE transition from version 1.0 to a redesigned FSE 2.0, promoted within the framework of Mission 6 of the National Recovery and Resilience Plan of EU Next Generation programme, hereafter also referred as NRRP, is not merely an incremental evolution, but rather a radical transformation of the NHS Information System.

The transition from FSE 1.0 to the new architecture of FSE 2.0 introduces a change of paradigm, which intends to overcome data regional fragmentation to move towards an interoperable, standardised system within a national framework. This is a necessary evolution to respond to current health policy and medical research challenges and to ensure consistency with ongoing European initiatives on Digital Health, first and foremost the European Health Data Space (EHDS), but needs to be aligned with the organisation and functioning of the Italian National Health Service and the autonomy exercised by the regions[24], combining standardisation with a possible "federated" model [28].

24 Although the SSN was established by Law No. 833/1978 as a universal, tax-funded system guaranteeing nationwide access to a defined package of essential health services, the 2001 constitutional reform (Constitutional Law No. 3/2001) reconfigured its governance by substantially enhancing regional autonomy in the organisation and management of healthcare. Consequently, the central State's role is principally limited to defining the fundamental principles and the minimum essential levels of care (i.e., *Livelli Essenziali di Assistenza*, LEA), while Regions assume primary responsibility for the delivery, administration, and local implementation of health services (including e-health).

3. THE PATHWAY TOWARDS A NATIONAL GOVERNANCE MODEL FOR THE NEW ITALIAN EHR: FSE 2.0

3.1 The National Regulatory Framework

The implementation of the Electronic Health Record in Italy, and more recently its evolution towards the FSE 2.0 model, is based on an articulated body of legislation, built up progressively since 2012 and boosted by the measures undertaken by the Italian Government after the COVID pandemic in the framework of the NextGenerationEU[25] programme. This regulatory framework regulates the design, management, interoperability, security and purposes of the Italian Electronic Health Record system within the National Health Service and has incorporated over the years both the continuous technical advancements and the changes occurred in the European Union data protection measures and regulations, among which, most importantly, the General Data Protection Regulation (GDPR; Regulation (EU) 2016/679)[26] [5].

The table below (Tab.3) summarises the main legal and regulatory instruments that comprise the multi-layered Italian framework for the implementation and management of the electronic health record (EHR)[27]:

Table 3 Main legal instruments of the Italian normative framework regarding the electronic health record (FSE)

Subject	Law/Regulation	Description
Establishment of Italian EHR (Fascicolo Sanitario Elettronico) and its	Decree-Law No. 179 of 18 October 2012	Converted with amendments by Law No. 221 of 17 December 2012, it introduces the concept of FSE into Italian law, specifying its institutional purposes and scope.

25https://commission.europa.eu/strategy-and-policy/eu-budget/eu-borrower-investor-relations/nextgenerationeu_en#documents

26 The General Data Protection Regulation (GDPR; Regulation (EU) 2016/679) is a binding EU regulation that harmonises personal data protection across Member States and has significantly expanded the previous legal framework established by Directive 95/46/EC. Applicable since 25 May 2018, the GDPR establishes uniform substantive rules on the processing of personal data and replaces divergent national transpositions with a directly applicable instrument.

Substantively, the GDPR sets out core principles for lawful processing (lawfulness, fairness, transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality) and requires controllers to demonstrate accountability for compliance. It defines a range of legal bases for processing (e.g., consent, performance of a contract, legal obligation, vital interests, public interest, and legitimate interests) and mandates specific safeguards for special-category data, of which "health" is one of the most relevant.

The Regulation codifies extensive data-subject rights, including rights of access, rectification, erasure ("right to be forgotten"), restriction of processing, data portability, and objection, as well as heightened transparency and information obligations. It also requires implementation of technical and organisational measures (including data protection by design and by default), appointment of Data Protection Officers in designated circumstances, and conduct of Data Protection Impact Assessments (DPIAs) for high-risk processing.

27 A more detailed and comprehensive list of national regulatory framework is available at https://www.fascicolosanitario.gov.it/normativa-di-riferimento.html

Subject	Law/Regulation	Description
national interoperability	Decree-Law No. 69 of 21 June 2013	Converted with amendments by Law No. 98 of 9 August 2013, it provides urgent measures to stimulate economic growth, including specific measures to develop the digitisation of healthcare services.
	Law No. 232 of 11 December 2016 (Budget Law 2017), art. 1, paragraphs 382 and 383	It provides the establishment of a national infrastructure for the interoperability of Fascicolo Sanitario Elettronico, to be designed by the Agency for Digital Italy (AGID) in coordination with the Ministry of Health and the Ministry of Economy and Finance, together with the regions and autonomous provinces, and to be managed by the Ministry of Economy and Finance through the use of the Sistema Tessera Sanitaria. It also establishes that Regions are obliged to adopt the FSE and and the Sistema Tessera Sanitaria must, via the national interoperability infrastructure, make available to regional FSEs and to regional pharmaceutical dossiers the data it holds relating to beneficiaries' exemption statuses, prescriptions, and pharmaceutical and specialist services provided and charged to the National Health Service (Servizio Sanitario Nazionale, SSN).
General regulation for the FSE structure and functioning	Prime Minister's Decree No 178 of 29 September 2015	Represents the pivotal regulation for the implementation of the FSE, defining its minimum contents, feeding methods and interoperability functions.
	Decree of 4 August 2017 of the Ministry of Economy and Finance	Establishes the technical modalities and web services available for FSE interoperability.
	Decree of 25 October 2018 of the Ministry of Economy and Finance	Amends the previous decree of 4 August 2017, updating the technical modalities for interoperability.
FSE provisions to respond to emergency contexts	Decree-Law No. 183 of 30 December 2020	Converted by Law No. 21 of 26 February 2021, it strengthens the digital infrastructure in healthcare, with reference to the management of the FSE.
	Decree-Law No. 50 of 17 May 2022 (Art. 27)	Introduces new measures in support of the digitisation of healthcare.

Subject	Law/Regulation	Description
Regulatory update towards FSE 2.0	Decree 20 May 2022 of Ministry of Health, Ministry of Technological Innovation and Digital Transition and Ministry of Economy and Finance	Adopts the Guidelines for the implementation of the evolution of the FSE, implementing sub-investment "Fascicolo Sanitario Elettronico" under Mission 6 "Health" of the Italian NRRP
	Decree 18 May 2022 of Ministry of Health, Ministry of Technological Innovation and Digital Transition and Ministry of Economy and Finance	Defines the integration of the essential data-set to be included in the FSE documents.
	Decree of 7 September 2022 of Ministry of Health, Undersecretary of the Prime Minister for Technological Innovation and Ministry of Economy and Finance	Updates the regulatory framework of the Electronic Health Record to design a new Fascicolo Sanitario 2.0, defining new set of data to be available, interoperability and institutional interdependencies for its implementation
	Decree of the Ministry of Economy and Finance of 17 October 2024	Regulates interoperability standards to access FSE through INI and defines its functioning with the Health Card System and the Territorial Information System (SIT).
	Decree of the Ministry of Economy and Finance of 22 October 2024	Modifies Article 5-bis of the Decree of 4 August 2017, re-introducing objection or erasing rights against the automatic data feeding of the FSE (for data prior 18 May 2020).

3.2 The Italian NRRP and Component 2 of Mission 6 (Investment 1.3.1) to implement a new Electronic Health Record (FSE 2.0)

The Italian National Recovery and Resilience Plan[28] functions as the operational vehicle through which Italy deploys the resources and policy priorities of the EU's NextGenerationEU[29] instrument to stimulate economic recovery after the COVID-19 pandemic [39], together with infrastructural transformations. By articulating a coordinated package of investments and accompanying reforms, the Italian NRRP has attempted to align national objectives with European priorities, including the transformation and strengthening of the National Health System (SSN). In particular, the plan is built around three main pillars, shared at European level:

1. **digitalisation and innovation**: one of the main objectives of the NRRP is the creation of a renewed National Health System (NHS), capable of ensuring social and economic development and prepared to meet the health needs of future generations as well;
2. **ecological transition**: investments and reforms included in the NRRP must comply with the "Do No Significant Harm" principle, meaning they must not produce harmful effects on the environment;
3. **social inclusion**: the NRRP includes reforms and investments aimed at reducing territorial, generational, and gender disparities.

The Plan is divided into **six Missions** and **sixteen Components**. These, in turn, are structured into: **Reforms**, i.e., structural changes that produce lasting and significant improvements in a market, a policy, an administration, or in the achievement of important goals; and **Investments**, i.e., expenditures that generate structural changes and long-term benefits for the economy, society, and employment. The total funds allocated for the NRRP amount to €222.1 billion, of which €191.5 billion are financed through the Recovery and Resilience Facility (RRF) and €30.6 billion through the Complementary Fund, established by Decree-Law 59/2021.

The resources allocated to Healthcare amount to approximately €22 billion, of which €20.22 billion are for Mission 6, while the remaining share concerns cross-cutting interventions involving several missions that fall within the broad scope of healthcare (Mission 1 and Mission 5).

28 https://www.governo.it/sites/governo.it/files/PNRR.pdf
29https://commission.europa.eu/strategy-and-policy/eu-budget/eu-borrower-investor-relations/nextgenerationeu_en#documents

Figure 3 Missions and related goals of the NRRP retrieved 1 July 2025 at https://www.italiadomani.gov.it/content/sogei-ng/it/en/home.html

The Component 2 of Mission 6 (Investment 1.3.1) of the Italian NRRP (code M6C2-00) has earmarked EUR 1.38 billion for the development of FSE 2.0, with the aim of ensuring its homogeneity and accessibility throughout the country. This measure is developed along four complementary strategic lines:

1. **Access**: create a homogeneous FSE throughout the country, representing the main access point for all patients to SSN services;
2. **Integration**: making the FSE an effective tool for diagnosis and treatment, sharing relevant clinical data between professionals and healthcare facilities nationwide, guaranteeing continuity of care throughout the national territory;
3. **Personalisation**: increase the availability and quality of clinical data in the FSE to increase the SSN capacity of delivering personalised diagnosis and treatment;
4. **Policy**: improve available data to create a knowledge base on the population health status to support SSN and health-related institutions in the design and implementation of prevention planning and policies, and to support medical and biomedical research.

The **Department for Digital Transformation (DTD)** coordinates the measure activities with the 21 Autonomous Regions and Provinces (Owners of regional FSE), with a project deadline set at 30 June 2026.

The FSE 2.0 Implementation Project is divided into 3 integrated and complementary macro-interventions:

1. **Work-package 1: Implementation of a new national architecture for the FSE system** which ensures the indexing and standardization at regional and national level of clinical data and documents produced by SSN facilities and the creation of a

national **Health Data Ecosystem (EDS)** and associated "data-driven" services. The objective is to fulfil different targets' needs, including the following set of available services:

a. Patients: search and consultation of personal clinical data, booking and payment of healthcare services
b. Healthcare professionals: search and consultation of patients clinical data for supporting clinical decisions, preventive evaluation of prescriptions appropriateness
c. Ministry of Health and Regional Health Directorates: prevention policy and planning, international prophylaxis, support medical and biomedical research;

2. **Work-package 2: Technological adaptation at a regional level** to produce the minimum set of clinical data and documents required to feed, in a structured manner and according to nationally defined interoperability standards, the new FSE 2.0 (e.g. Electronic Medical Records of Wards and Emergency Departments, laboratory and/or outpatient specialist reporting systems) including the systems used by General Practitioners (GPs) and Pediatricians of Free Choice (PFCs), in compliance with the new FSE system architecture defined at a national level (e.g. production of clinical documents with structured and codified data pursuant HL7-CDA2 standards, adoption of the PaDES digital signature);
3. **Work-package 3: Training and engagement of the 21 Regions and Autonomous Provinces of the Healthcare Professionals.** All SSN professionals who will be required to use (both feed and consult) the new FSE 2.0 will have to access multi-disciplinary training programmes implemented at a regional level and functional to improve digital skills of healthcare professionals across all areas (e.g. primary care, hospital care, territorial services, social-healthcare sectors, etc.). Additionally, the workpackage is intended to maximise dissemination and knowledge to engage all operators in the strategic importance of the development of FSE 2.0 in every sphere of healthcare.

3.3 Institutions involved and their role in the national FSE 2.0 implementation project

The implementation of the Electronic Health Record 2.0 represents one of the most complex digital projects of the NRRP for the health sector and requires multiple institutional actors at both national and regional level. The multi-level governance, defined under sub-investment 1.3.1 of Mission 6, Component 2[30], is based on the collaboration between different institutional

30 https://www.italiadomani.gov.it/content/sogei-ng/it/it/Interventi/investimenti/rafforzamento-dell-infrastruttura-tecnologica-e-degli-strumenti-per-la-raccolta-l-elaborazione.html

actors with specific competences in the fields of health, digital transformation, registry management, cybersecurity and research.

The Department for Digital Transformation (DTD), at the Presidency of the Council of Ministers, is the implementing body of the national project and responsible for strategic supervision and coordination. It coordinates the action of the Regions and Autonomous Provinces, ensures alignment with the NRRP timetable and promotes the definition of common architectural and functional standards, in liaison with the Ministry of Health and the MEF.

The Ministry of Health is responsible for the technical-health policy of the project and the owner of the data processing within the Health Data Ecosystem (EDS). It contributes to the definition of the implementing decrees and ensures the coherence of the intervention with national health policies, prevention, governance and research purposes, as well as with the principles of clinical governance and digital public health.

The Ministry of Economy and Finance (MEF), through the Sistema Tessera Sanitaria (STS), plays a central role in the management of the pre-existing infrastructure components. It is responsible for the **INI** and collaborates with Sogei for the provision of central components and for the integration of health information flows.

Sogei - Società Generale d'Informatica S.p.A., an in-house company of The Ministry of Economy and Finance he MEF, is the operational technology partner for the development and maintenance of the FSE central platforms. It supports the management of the INI, the National FSE Document Index, the National Register of Consents and Revocations, and the **National FSE Portal.** Sogei also acts as a technical hub for the collection, synchronisation and transfer of data between regional systems and national infrastructures, in accordance with the standards set by ministerial guidelines.

AGENAS - (National Agency for Regional Health Services), pursuant to the Ministerial Decree of 31 December 2024, is responsible for the operational management of the EDS. It ensures the development of services for the secondary re-use of health data for prevention, planning, epidemiological surveillance and research purposes. It also provides technical support to the regions, monitors data quality and evaluates access projects submitted by institutional and research bodies.

All Regions and Autonomous Provinces are the owners of the FSE at a territorial level and responsible for its operational implementation. They are responsible for the evolution of regional information systems, the publication of clinical documents, the activation of the FSE

regional portals, as well as the training and involvement of healthcare professionals, in accordance with the Operational Plans approved under the NRRP framework.

Other institutional actors with relevant tasks are:

1. AgID, for the definition of technical interoperability and security rules, including guidelines on Application Programming Interfaces (APIs), computer documents and encryption;
2. Garante per la protezione dei dati personali (Independent Authority for the protection of personal data), whose opinion is mandatory in the definition of data processing and consent;
3. Scientific and regulatory institutions (e.g. ISS, AIFA, IRCCS), as potential users of EDS services for study, monitoring and evaluation activities.

To better understand the relationships between the different institutions involved, hereafter is reported an overall organisational network map showing governance and operational inter-dependencies. The Garante is an independent authority but with a transversal role of surveillance of all other actors' implementation actions about data treatment. DTD, MEF and the Ministry of Health hold the same institutional level and cooperate together. AgID depends on the DTD, while AGENAS and Sogei are respectively under the coordination and management of the Ministry of Health and the MEF. With a specific contract under the NRRP framework, Sogei also works for the Ministry of Health and the DTD. Regions and Autonomous Provinces preserve their constitutional autonomy and independence in how they implement national guidelines.

When the design and first implementation phase of the NRRP project M6C2-00 "Fascicolo Sanitario Elettronico 2.0" will be concluded[31], set for 30 June 2026, both FSE 2.0 and EDS will enter their full-scale management phase, which will require a stable, sustainable and fully integrated organisational set-up in the national health system. The post-2026 phase will mark the transition from the design and start-up to permanent national digital infrastructures, the success of which will depend on the capacity of the institutions involved to ensure operational continuity, data quality and sustainable innovation, while preserving interoperability of technical and organisational standards for fair and reliable health-data management. Institutions involved will have to ensure not only the maintenance of the standards achieved, but also their continuous evolution, in line with national and European digital health strategies.

The design plan envisages the following roles:

[31] https://www.pnrr.salute.gov.it/it/pnrr-contenuti-di-sezione/target-milestone/

The Ministry of Health, as the EDS data owner (Art. 3, Ministerial Decree of 31/12/2024), will hold responsibility for governing the system, defining the priorities for data secondary usage (prevention, planning, monitoring and research purposes). As of 1 July 2026, the Ministry will be called upon to coordinate the updating of technical and clinical standards, integration with NHS information flows and consistency with European initiatives, in particular the European Health Data Space (EHDS).

AGENAS, designated as the agency responsible for the EDS operation will have to ensure:

A. continuous management and operation of the EDS platform;
B. evaluation of data access for research, policy and prevention purposes;
C. analysis of data quality and impacts produced;
D. technical and scientific support to the regions and authorised bodies.

SOGEI, will manage the system **core components**, including:

1. the National Infrastructure for Interoperability;
2. the National Document Index;
3. the National Register of Assisted Persons (ANA);
4. the National Register of Consent and Revocation;
5. the National FSE Portal.

Sogei will be required not only to perform technical maintenance of the above technical infrastructures, but also to evolve platforms according to scalability, economic sustainability and regulatory compliance.

Regions and Autonomous Provinces, as owners of their respective FSE 2.0 will maintain the obligation of systematic data feeding and quality, as well as the management of the **Regional Archiving Units (UA-R)** provided for by the Ministerial Decree of 31/12/2024. They will also be responsible for the **continuous training of healthcare professionals**, local governance of consent and the management of regional FSE portals (integrated with the national portal).

AgID will continue to oversee the technical standards for interoperability and Application Programming Interface (API) security, while **the Agency for National Cybersecurity (ACN)** will ensure compliance with regulations on critical infrastructure, qualified clouds, and cryptography, which are crucial in managing a system that is as sensitive as it is distributed.

Garante for the protection of personal data will exercise continuous control over the system compliance to privacy regulations, consent management and data pseudonymisation. Garante

will also participate in access policy revisions and contribute to the definition of how to implement data treatment compliant profiling for research and epidemiological studies.

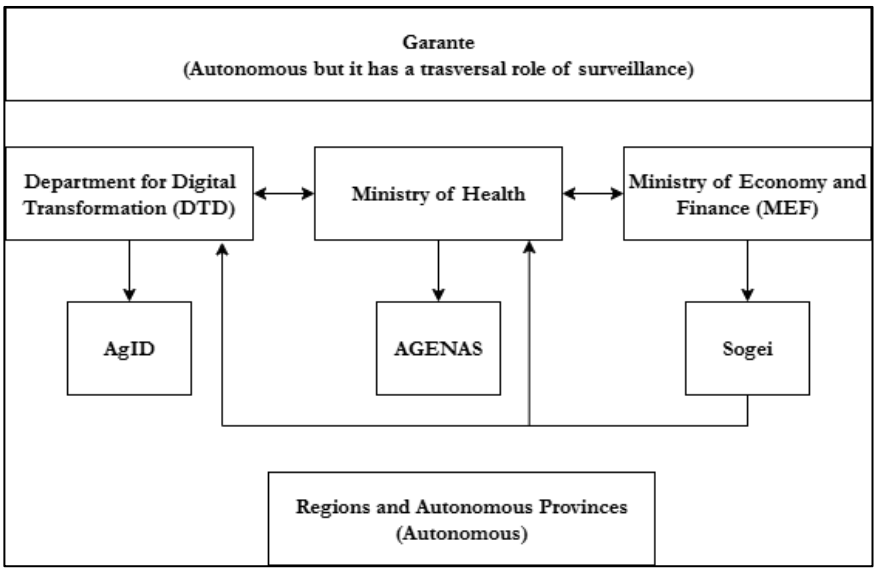

Figure 4 Inter-organizational dependency diagram

3.4 The new FSE 2.0 Structure and Architecture

The implementation of the Electronic Health Record 2.0 aims at overcoming the difficulties that emerged in the FSE 1.0 implementation phase and at achieving the strategic objectives defined by the NRRP, through a system that guarantees advanced digital services, data quality and availability, national and European interoperability. The expected benefits for citizens, health professionals, public authorities and the research world can only be achieved if supported by an adequate, secure, federated and fully interoperable technological architecture. Accordingly, the technical architecture of FSE 2.0 should be understood not merely as an infrastructural upgrade but as a strategic enabling platform designed to support the homogeneous, secure and regulatory-compliant collection, access and processing of health data, and to serve as a foundational element for integration with the European Health Data Space (EHDS).

The main components of the system are schematised below (fig.4), in accordance with the implementing decrees and technical guidelines adopted by the Ministry of Health and other competent authorities.

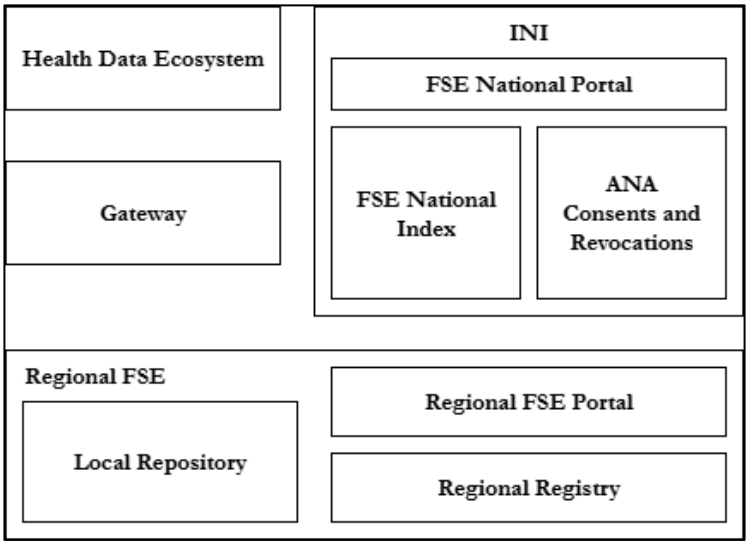

Figure 5 New FSE 2.0 System components

All these components work in synergy and cooperate in the new architecture of the FSE 2.0, which must implement mechanisms that, by promoting peripheral integration, allow for the complete feeding of the EHR through data and documents required by law and according to standard formats. This represents a necessary condition to also effectively enhance interoperability mechanisms. Another goal to be achieved is to ensure uniform access to online healthcare services throughout the national territory and to make information accessible both through natively digital documents and through the atomic data that compose them, ensuring the conditions for the development of increasingly advanced patient care services.

From an operational point of view, this translates into the implementation of components capable of:

a) Acquiring data and documents from different software platforms feeding the FSE 2.0 and verifying their compliance with national standards.
b) Enabling more effective interoperability mechanisms to make FSE 2.0 accessible and homogeneous at the national level.
c) Building the infrastructure necessary for the storage and native management of both data and documents.
d) Enabling the application infrastructure that allows the new FSE 2.0 to be the single point of access to online healthcare services for citizens
e) Enabling interoperability with platforms designed for the secondary use of health data.

The new architecture includes:

1. a **federated structure for document management**, distributed across all Regions. These documents must be in standard HL7 CDA2 format and include a "human readable" representation in PDF format. For this reason, **the CDA2 containing the structured data of the clinical event to which the document refers must be injected into the corresponding PDF**, which must then be digitally signed in PaDES.
2. **adoption of FHIR standard and a Central Data Repository to store clinical data acquired from producing healthcare providers** (and, where applicable, also in regional data repositories by reusing what has been implemented for the Central Data Repository), which will be accessible via EDS (Article 21 of Law Decree 4/2022) APIs for the development of the following types of services:
    a. Prevention, diagnosis, care, and rehabilitation (target users: a) healthcare professionals and authorized healthcare facilities, according to data processing consent granted by patients, b) patients to consult their clinical information
    b. Prevention, epidemiological surveillance, health policies, international prevention and prophylaxis (target users: Regional and Autonomous Provinces Health Directorates, and Ministry of Health)

Clinical data are acquired and validated by gateways when they are produced by the systems used in healthcare facilities and before the clinical documents are indexed in the regional EHRs.

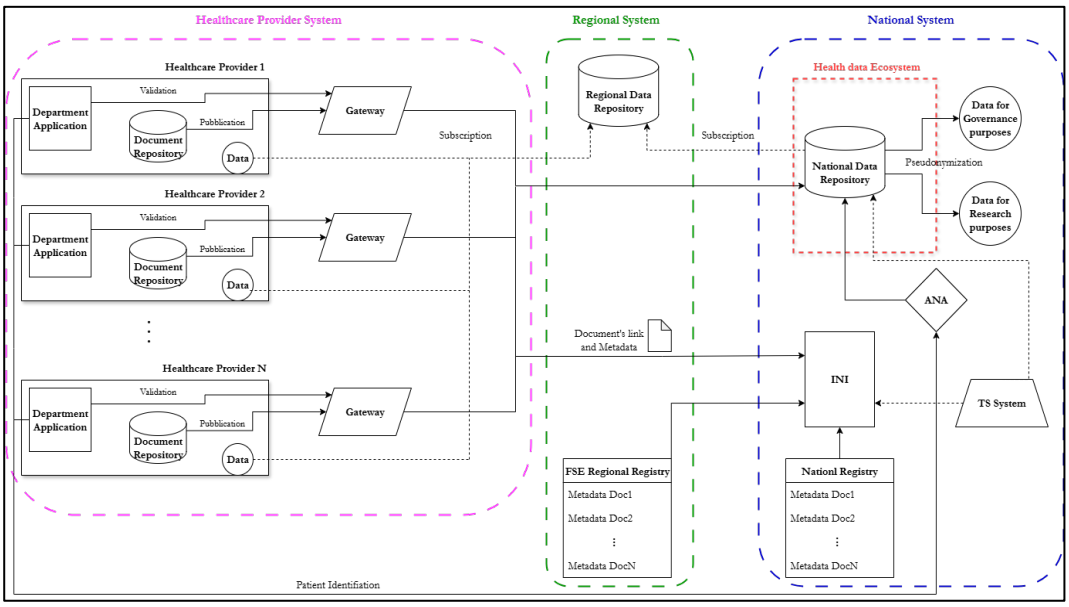

Figure 6 Architecture of new FSE 2.0

The new components of this EHR architecture for new FSE 2.0 are:

a) **Gateway**: verifies that clinical data produced by the platform/systems used by medical professionals and healthcare facilities comply with the syntactic and semantic composition rules prescribed by law and, once validated, translates them into HL7 FHIR format (if not natively in that format), to be sent to the National Data Repository. After validation, if data is extracted from a structured document, the gateway also indexes the document in the Regional and National Registry via INI, to ensure correlation between the document and the FHIR data derived from the document. It also collects log data of completed transactions and sends them to the Monitoring and Control System implemented in the EDS.

b) **Health Data Ecosystem**, described in paragraph 4.5, as per Art. 21 of Law Decree 4/2022, includes:

    1) **National Data Repository**: stores clinical data acquired from systems used by medical professionals and healthcare facilities, patient-generated health data, and data from telemedicine systems, and makes them available according to the data processing consent granted by patients, to:

        i. Healthcare professionals and providers and to the patient themselves, for purposes of prevention, diagnosis, care, and rehabilitation
        ii. Regional Health and Autonomous Provinces Directorates for prevention, epidemiological surveillance, and governance
        iii. Ministry of Health, for international prevention and prophylaxis
        iv. Research institutes, for biomedical and medical research purposes

    The National Data Repository also enables data interoperability among the different regions

c) **The Monitoring and Control System**: evaluates the effectiveness of data and document feeding into the FSE, doctors' and patients' usage and volume of access, and service continuity.

d) **The National Registry**: stores FSE 2.0 indexes to improve national-level interoperability.

Clinical data acquired and validated by the Gateway, in addition to feeding the National Data Repository, may also be notified and archived in designated repositories, as follows:

1. **At regional level**, within the FSE of every Region, for purposes of prevention and governance
2. **At healthcare facility level (ASL/AO)**, for purposes of prevention and care.

If a Region and/or Healthcare facility chooses to establish its own repository of clinical data, it must be implemented by reusing the software and technological architecture used for the National Data Repository and configured as an instance of the latter. Any customizations of the local data repositories can only be made at the level of data integration, analysis, and processing services, with no divergence from national data standardization rules.
Databases based on a single data model at all levels are intended to simplify the reuse of technological services developed by the ecosystem's various actors.
Repositories to host structured clinical data at a regional/healthcare facility level is still a possibility but entirely optional, while the primary responsibility remains assigned to the National Data Repository.
The alignment of regional and healthcare facilities repositories with the National Data Repository is meant to be ensured through subscription to updated services provided by the National Repository, after validation and conversion of the acquired data.

Additional integration services already designed in the new legislation include:

a) **National Register of Patients (ANA)**, for patient demographic data associated with GPs/PLSs; the ANA positions are directly used by the Gateway (to verify the existence of the demographic data linked to the acquired data), by the Central Data Repository and the National Registry, and indirectly by producing systems and Regional EHRs that adopt them in their regional/company systems.
b) **Health Card System (TS System)**, for acquiring administrative data related to prescriptions and certifications, as well as data of doctors and health professionals registered with professional bodies.
c) **INI–National Consent Register**, to verify patient consent for consulting the EHR at the time of access requests by healthcare personnel.
d) **INI–National Register of Delegations**, for verifying third-party subjects delegated by the patient to access EHR-related services.
e) **Healthcare facility Document Repositories**, which, fed by producer systems with clinical documents they generate after validation by the Gateway, provide the Gateway with references to the documents published therein and their metadata.

The gateway is the tool for transforming, validating, and sending structured data according to the HL7 FHIR standard to the National Data Repository, as well as publishing the associated documents. Gateways are used by public healthcare facilities (SSN), private healthcare facilities, as logical components within the architecture of producing systems or as functional modules of enterprise integration platforms (Enterprise Service Bus), where present.

These are elements developed, maintained, provided, and centrally managed, in compliance with the standardization rules set at the national level.

The gateway is evidently the "key" component of the new FSE 2.0. It consists of the following functional blocks, as represented in Fig.7:

1. Acquisition of data and documents from healthcare facilities applications; the accepted input formats are HL7-FHIR, HL7-CDA2, HL7 2.x
2. Syntactic and semantic validation of the acquired data and documents
3. Mapping of incoming data into FHIR format
4. Creation and transmission to the EDS Monitoring and Control System of data quality and usage metrics
5. Creation of the document index for registering its metadata on all FSE/EHR (Regional and National Registries) through integration with INI
6. Data Transmission to the Central Data Repository

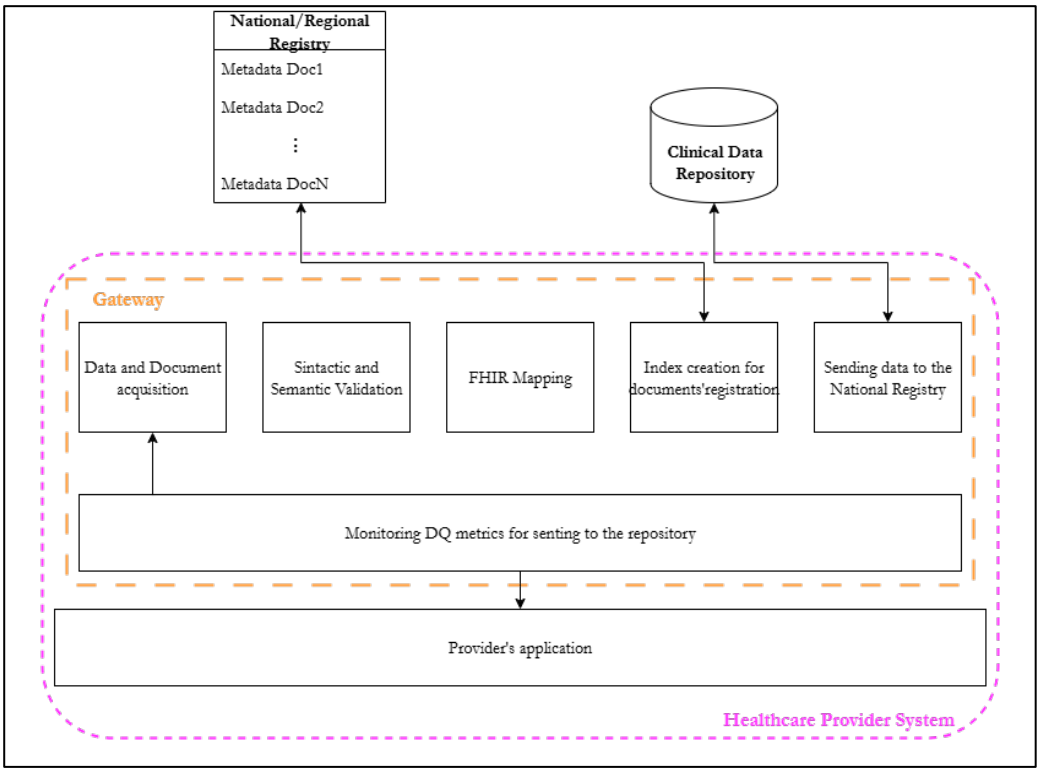

Figure 7 FSE 2.0 Gateway structure and functions

The clinical data acquired and validated by the Gateway, as previously mentioned, may also be optionally notified and stored in repositories established in compliance with the HL7 FHIR standard at the regional/healthcare facility level through subscription mechanisms to the National Data Repository.

Considering that the Gateway is part of the process of delivering a healthcare service by validating clinical data before generating and signing the corresponding document, the application of SLAs (Service Level Agreements) is foreseen, in terms of response times of the functions performed by the Gateway. These SLAs will have to ensure operational performance by the medical staff responsible for producing the act, equal to or better than current practice. The definition of these SLAs and related policies for handling exceptions will be subject to future documents and technical rules.

The **expected benefits** for the introduction of the Gateway will allow:

1. Optimization of the EHR feeding process by enterprise systems
2. Validation and compliance check with data and indexed document standards
3. Automation of the mapping process of data and documents into HL7 FHIR
4. Automatic collection of metrics feeding the EHR usage and quality monitoring dashboard

Another functional component of the FSE 2.0 structure is the National Registry (shown in Fig.8), which collects all the indexes of the regional health records and enables the implementation of more effective interoperability mechanisms. The data of the National Registry are accessible through INI services, which will be updated to allow the association between data and document (e.g., data that allow graphing a parameter can be associated with the documents containing them).

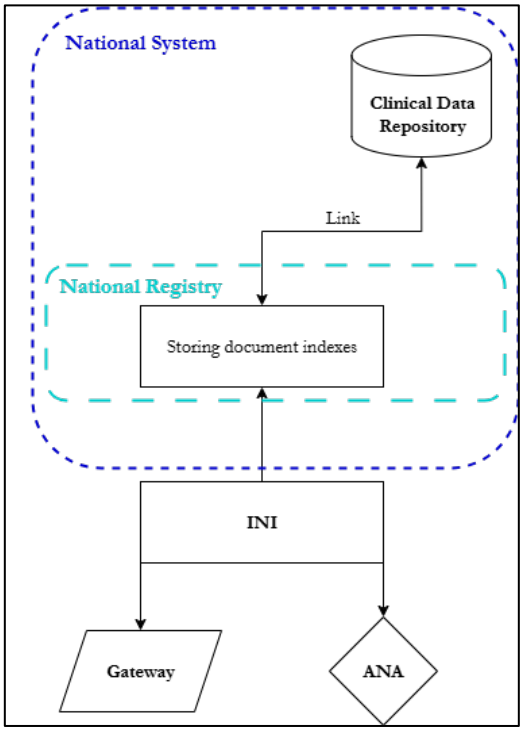

Figure 8 Structure and functions of National Registry of the new FSE 2.0

The services implemented by the National Registry are to be published on the **National FSE/EHR Portal**, which is the component that provides the following services:

a) Search and consultation of clinical documents indexed in the National Registry.
b) Access to clinical data stored in the Central Data Repository.
c) Access to regional EHR portals, created by the individual Regions, towards which the National EHR Portal acts as a proxy, redirecting the user (citizen or healthcare provider), once authenticated, to the EHR portal of their Region of competence.

The **expected benefits** for the introduction of the National Registry will be:

a) Improving the efficiency of the interoperability process understood as access to data and documents produced outside the user's region of care.
b) Improving and automating the process of transferring the FSE of a patient in case of a change of region of care.

Below a summary scheme (Fig.8) that outlines the services that the new FSE 2.0 should eventually provide.

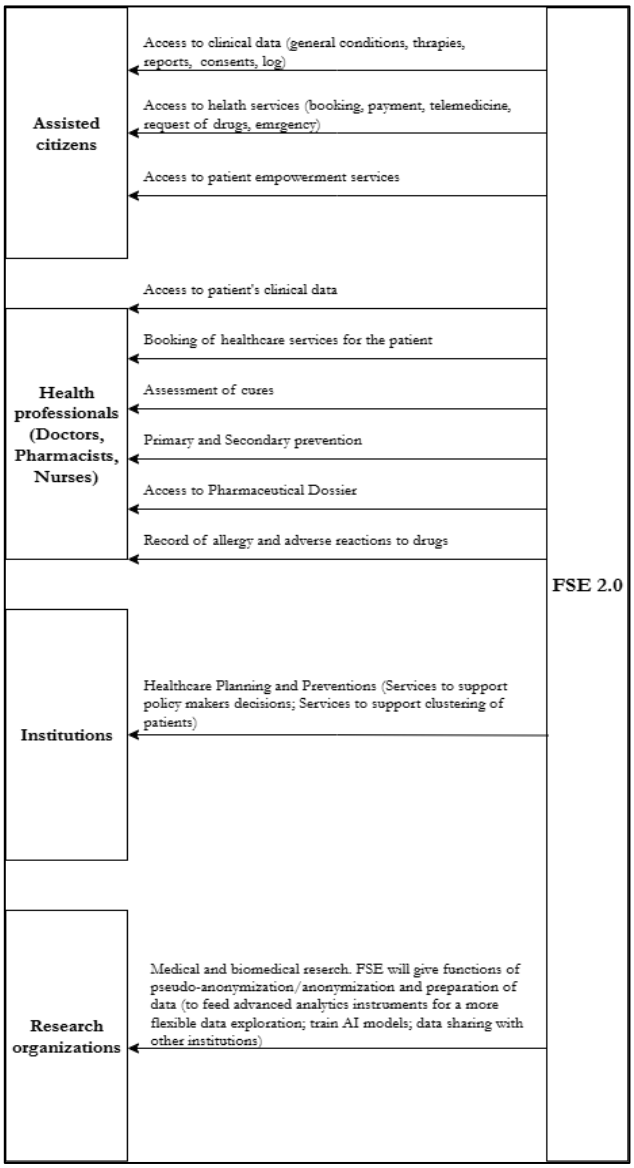

Figure 9 Outline of the new FSE 2.0 Services

To provide a clearer understanding of the interactions between FSE 2.0 and its users, below some illustrative diagrams. Figure 9 shows the interaction between the patient, the medical doctor and the new FSE 2.0 in the context of a clinical decision, when a clinical report is updated. Figure 10 illustrates the interaction between the patient and the FSE 2.0 for accessing his/her personal clinical information and managing consent preferences.

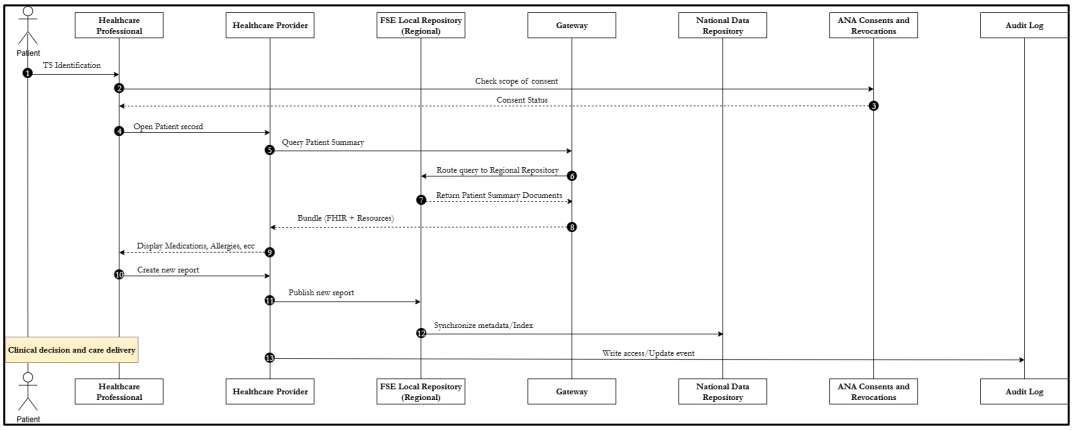

Figure 10 FSE 2.0 medical doctors/patients interactions for clinical purposes

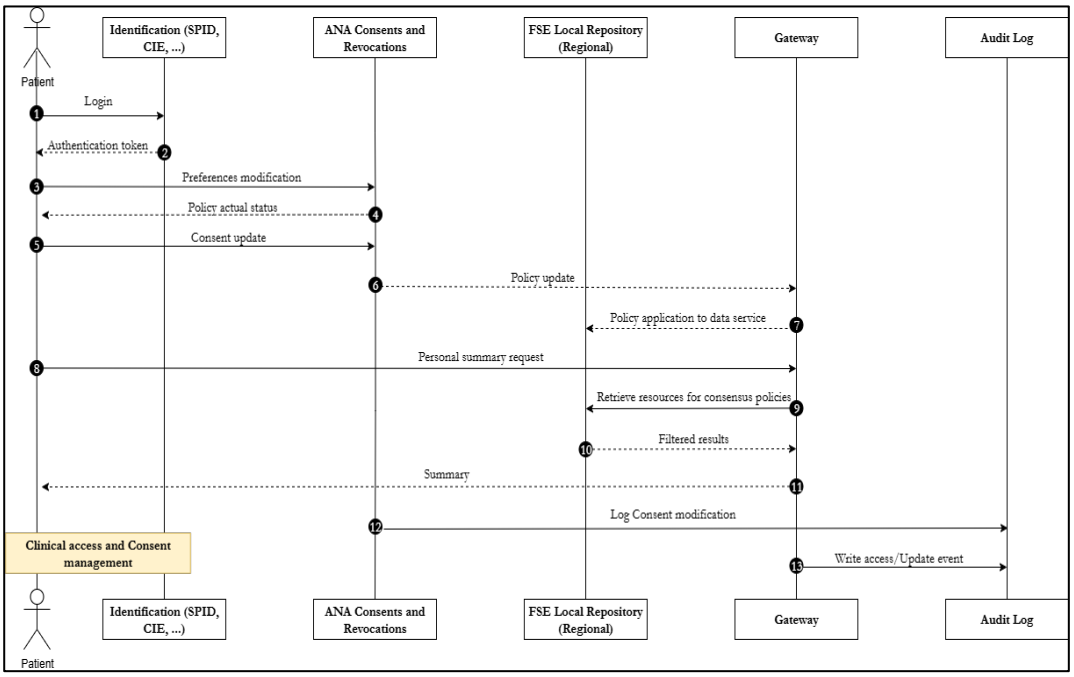

Figure 11 FSE 2.0 Patient – System interaction for data access and consent management

3.5 Differences between FSE 1.0 and the new FSE 2.0

The main limitations of current FSE (1.0) that the new FSE 2.0 is intended to overcome can be summarised as follows:

a) **Technological fragmentation across Regions**: in the FSE 1.0 each Region had very different implementations and standards, instead the FSE 2.0 is based on the obligation to use **standardised and interoperable formats**, both for clinical content (e.g. HL7 FHIR for structured data and HL7 CDA2 for clinical documents), and for

metadata and communication systems between services (secure APIs according to AGID Guidelines No. 547/2021[32]).

b) **Incomplete data access**: in FSE 1.0 patients could only access data from their own regional web portal and cross-regional access for healthcare professionals was unreliable or unavailable, instead in FSE 2.0, thanks to INI which orchestrates and harmonizes all queries, data should be accessible nationwide via a central portal.

c) **Limited secondary use of data**: in the FSE 1.0 secondary use was not clearly regulated and mostly inaccessible; in the new FSE 2.0 data can be reused in pseudonymized form for research and policy planning through the Ecosystem of Health Data.

d) **Inconsistent security and traceability**: in FSE 1.0 logging and auditing were handled locally, often with heterogeneous implementation, instead in FSE 2.0 the architectural components of will have to guarantee:

    a. **strong authentication and delegation** management via SPID/CIE and the Delegation Management System (Art. 64-ter CAD);
    b. **encryption of sensitive data**, access traceability, mandatory audit logs (Art. 22, EDS Decree);
    c. **pseudonymisation and anonymisation** in accordance with the requirements of the GDPR and the Privacy Code, using certified techniques;
    d. **compliance with ACN Regulation 2024** on cloud and critical PA infrastructure.

The **standard technological solutions** issued by AGENAS (Art. 1, lett. r, Ministerial Decree 7/9/2023[33]) will have to ensure:

    a. formal and semantic control of all documents that will feed the new FSE 2.0
    b. automatic conversion to the defined FSE 2.0 standard interoperability formats for health data
    c. secure transmission to the FSE 2.0 and the associated EDS.

32 https://trasparenza.agid.gov.it/page/9/details/2372/determinazione-n-547-del-1-ottobre-2021-adozione-delle-linee-guida-tecnologie-e-standard-per-la-sicurezza-dellinteroperabilita-tramite-api-dei-sistemi-informatici-e-delle-linee-guida-sullinteroperabilita-tecnica-delle-pubbliche-amministrazioni.html

33 https://www.gazzettaufficiale.it/eli/id/2023/10/24/23A05829/sg

Table 4 Comparison FSE 2.0. Vs. FSE 1.0

Aspect	FSE 1.0	FSE 2.0
Technology and standard	High technological fragmentation across Regions, with different implementations and standards.	Mandatory use of standardized and interoperable formats: HL7 FHIR for structured data, HL7 CDA2 for clinical documents, secure APIs according to AGID Guidelines No. 547/2021.
Data Access	Patients could only access regional data; cross-regional access for professionals was unreliable or unavailable.	Nationwide data access via a central portal, enabled by INI orchestration and harmonization.
Secondary Use of Data	Unclear and fragmented use of data for secondary purposes.	Pseudonymized data can be reused for research, planning, and governance via the Health Data Ecosystem.
Security and Traceability	Logging and auditing handled locally, often inconsistently.	Architectural components must ensure: 1. strong authentication and delegation management; 2. encryption of sensitive data, access traceability, mandatory audit logs, 3. pseudonymization and anonymization in line with GDPR and Privacy Code; 4. compliance with the 2024 ACN Regulation on cloud and critical infrastructure for public administrations.

3.9 Expected benefits of FSE 2.0 implementation

The FSE 2.0 is no longer a simple document repository, but a true digital platform of health services for Citizens, Health Professionals, Health Authorities (national and local) and the scientific research sector.

This evolution, made possible by the combination of standardised architectures, uniform regulatory rules and new technological components, can allow the achievement of concrete and differentiated benefits for each of the impacted categories of users, in full compliance with the national regulatory framework and European rules on data protection and portability.

The expected benefits, which will be detailed in the following subsections, relate to four macro-areas of users:

a) **Citizens/Carers**, who will be able to consult and manage their health data and documents easily and securely;
b) **Healthcare professionals**, who will have an up-to-date and complete clinical picture for the purpose of caring for their patients;
c) **Health authorities (national and regional)**, which will have structured data at their disposal for monitoring, evaluating and planning health care provision;
d) **Institutions and research organisations**, which will be able to access anonymised and aggregated data, in full compliance with ethical and regulatory standards in the field, for scientific, research and innovation purposes.

Specifically:

a) Benefits for Assisted Citizens

The FSE 2.0, as governed by the **Ministerial Decree of 7 September 2023**, allows citizens assisted by the National Health Service to access, via regional portals and the FSE national portal, their health records in electronic format, by authenticating with SPID, CIE or CNS.

Pursuant **to Article 11 of the Ministerial Decree of 7 September 2023**, the Assisted Party is entitled to:

A. consult the clinical documents in one's FSE that represent one's medical history
B. download documents in interoperable format;
C. receive notifications of new available documents;
D. access graphical representations and periodic reports generated from FSE data;
E. use Personal Notebook management tools (provided for in Article 3 of the Ministerial Decree of 7 September 2023), to enter subjective information;
F. access, through the FSE Portals dedicated to the Citizen, information services and devices ("citizen services") to access, book, pay for and benefit from healthcare services provided by the Regional Health System of reference

The Respondent may at any time express or revoke consent for secondary access to his or her data by healthcare institutions or research bodies, through the **National Register of Consents and Revocations** provided for in **Article 8 of the Ministerial Decree of 7 September 2023**.

b) Benefits for Health Professionals

In the FSE 2.0 model, the healthcare professional becomes not only a 'key' user, but also a central actor in the supply and enhancement of the clinical data and documents available within the tool. In the long run, the FSE 2.0 is conceived as a daily operational tool, perfectly

integrated in the workflows of the clinical-assistance processes and interoperable with the management systems already in use (e.g. software of the GPs/PLS, hospital systems, regional platforms). Its consultation and updating will take place directly through the regional FSE portals made available to healthcare Professionals or, progressively, through the national portal, according to the methods defined by Article 11 of the Ministerial Decree of 7 September 2023.

The main benefits for healthcare professionals fall into three areas: support for care, reduction of clinical risks, and process optimisation. Below, main expected benefits for each category.

1. **Access to comprehensive and up-to-date clinical overview**

   FSE 2.0 will enable General Practitioners (GPs), Paediatricians of Free Choice (PLS), Specialists, Nursing Staff, Pharmacists and other social and health workers to access the patient's medical history at any time, even when produced in different care settings and in different Regions. This is made possible by the national synchronisation guaranteed by the National Infrastructure for Interoperability (INI) and by the regulatory obligation of systematic and timely supply of documents (art. 12, paragraph 15-bis, Decree Law no. 179/2012; art. 5, Ministerial Decree 7/9/2023).

   This accessibility helps, among other things, to ensure:

   1. **continuity** in the care of the patient (e.g. chronic patients) between hospital and territory;
   2. the **coordinated** management **of chronic** and frail **patients;**
   3. the improvement of the diagnostic process, through **structured and semantically validated documents**;
   4. efficient and needs-centred management of all doctor-patient interactions, thanks to the real-time availability of up-to-date data and documents.

2. **Patient Summary as a priority clinical tool**

   A central element of the FSE 2.0 is the Summary Health Profile **(Patient Summary)**, a standardised clinical document **summarising essential information on the patient's health status**: chronic conditions, current therapies, allergies, vaccinations, transplants, functional status and other relevant data (Art. 3, Ministerial Decree 7/9/2023). Drafted and updated by the attending physician, the Patient Summary is:

   1. **accessible by any qualified professional**, even in an emergency or emergency room (Art. 20, Ministerial Decree 7/9/2023);

2. **exportable in interoperable format according to HL7 CDA2 and FHIR standards**, for cross-border use (consistent with the European Health Data Space - EHDS).

3. **Clinical risk reduction**

Timely access to validated information reduces the possibility of:

1. diagnostic duplications;
2. therapeutic errors;
3. dangerous drug interactions.

In addition, FSE 2.0 integrated with the **Pharmaceutical Dossier**, allows the practitioner to learn therapies prescribed and dispensed by other practitioners, thus improving **therapeutic adherence** and **patient safety**.

4. **Process efficiency and interoperability**

The integration of the FSE with territorial and/or private healthcare facilities (e.g. electronic medical records of wards/ambulatory/emergency departments, laboratory systems) allows:

1. automatic feeding of the FSE with documents processed through vertical production systems (e.g. reports, emergency room reports, discharge letters);
2. elimination of hard copies or manual mailings;
3. direct transmission of digitally signed documents to the patient's file;
4. immediate visibility of data generated in other regions or care settings.

Reduction of administrative burden and time-consuming bureaucratic tasks will allow more time for core healthcare activities and improve organisational well-being.

c) Benefits for Health Governance Authorities at both national and regional level

The implementation of FSE 2.0 can bring numerous benefits to health governing authorities, both at national and local level, enabling more effective management of health resources, improved health planning and timely response in the event of health emergencies.

These benefits are closely linked to the centralisation and interoperability of data, which enable competent authorities to monitor, among other things, disease trends, quality of care and the effectiveness of health policies. These aspects are crucial for health governance and the planning of health activities, as outlined in the Ministerial Decree of 7 September 2023 and the Guidelines for the implementation of the FSE.

1. **Improving resource management**

   One of the main benefits of FSE 2.0 for health governing authorities would be the ability to improve the management of health resources. Centralised access to data allows these authorities (e.g. Ministry of Health, Agenas, Regions) to monitor, in real time, the distribution and use of resources in the health system.
   According to the provisions of the Ministerial Decree of 7 September 2023, digitisation and centralisation of information enable a more targeted and efficient management of resources, reducing waste and inefficiency. In addition, the analysis of FSE data allows health authorities to quickly identify areas of criticality, enabling timely and targeted interventions to resolve any distribution problems or resource shortages

2. **Support for programming and operational planning public health policies**

   FSE 2.0 is intended to represent a key tool for health planning, as highlighted in the Guidelines for the Implementation of the FSE. With access to aggregated health data information, authorities can monitor disease trends at regional and national level, enabling more informed and precise planning of health policies. The availability of real-time updated data, structured and interoperable across regions, facilitates the planning of targeted prevention campaigns and interventions and the optimisation of the provision of health services. Moreover, the analysis of the data collected through the FSE helps the authorities to assess the effectiveness and quality of the services provided and to optimize the allocation of resources at hospital and territorial level.

3. **Timely response to emergencies**

   The FSE 2.0 is designed to ensure that health authorities can rely on a system to quickly and effectively respond to health emergencies (e.g. COVID-19 pandemic). Improved data interoperability as designed in recent legislation with information centralised in the FSE 2.0 should allow effective monitoring of health emergencies in real time. In the event of health emergencies, such as the spread of infectious diseases, the authorities will be able to use FSE 2.0 data to plan and implement containment measures, such as targeted lockdowns or vaccination campaigns. In addition, FSE 2.0 should facilitate epidemiological surveillance, enabling authorities to quickly collect and analyse the data needed to manage health crisis situations.

d) Benefits for Research Institutions

The implementation of FSE 2.0 should also bring significant benefits for **health research.** As stipulated in Decree-Law No. 179 of 18 October 2012, converted with amendments by Law No. 221 of 17 December 2012, health data collected in the FSE can be used not only for healthcare purposes, but also for **scientific research in the medical and biomedical field.** However health data access for research has been very limited and scarce with FSE 1.0.

FSE 2.0 can represent a crucial resource for life-sciences research, as it provides **access to a large amount of structured and coded health data**, which can be used for epidemiological, biomedical and treatment evaluation studies. This type of data access would allow research institutions to develop more accurate predictive models and analyses, thus contributing to innovation in therapies and disease management. Researchers should finally be enabled to access an ecosystem of structured data to develop new therapeutic solutions and to conduct research in life sciences. The regulatory provisions, in particular the Ministerial Decree of 7 September 2023 and the Guidelines for the implementation of the FSE, regulate access to FSE 2.0 data for research, prevention and health planning purposes, allowing health data to be exploited in a secure and privacy-compliant manner.

3.6 The central role of the Health Data Ecosystem (EDS) and the design of 'data-driven' services

The new FSE 2.0 is conceived not only as a uniform and interoperable collection of digital clinical documents, but as a data-enabled intelligent platform. This transformation can be possible by the activation of a complementary and integrated infrastructure, the so-called EDS (Health Data Ecosystem). EDS is a digital infrastructure designed under the coordination of the Ministry of Health and the Department of Digital Transformation of the Presidency of the Council of Ministers to **collect, integrate and analyse in a secure manner and in full compliance with privacy regulations (GDPR) health data and information from different sources** (e.g. FSE 2.0, Telemedicine platforms, health cards), with the aim of improving the quality and efficiency of health services provided throughout the country.
In synergy with the data collected through the new FSE 2.0, the EDS has been designed to reach the following strategic aims:

a) **care and prevention**: to provide health professionals with 'data-driven' services with up-to-date information for accurate diagnosis and timely treatment of individual patients;
b) **scientific research**: supporting medical research through access to aggregated and anonymised data.

c) **Healthcare policy planning**: facilitating the planning and evaluation of health services to improve the efficiency of the Italian NHS;

d) **international prophylaxis**: managing and monitoring preventive measures against the global spread of diseases.

With EDS the Italian HIS attempts to progress from a **document-centred** approach **to a data-driven** approach. The new FSE 2.0 is therefore intended to be not only a mere repository of data, but a dynamic and enabling system, designed to generate continuous information value from the data it collects and those fed in other relevant public systems.

The EDS is designed with a 3 modules architecture:

1. Data module
2. Broker EDs
3. Service module

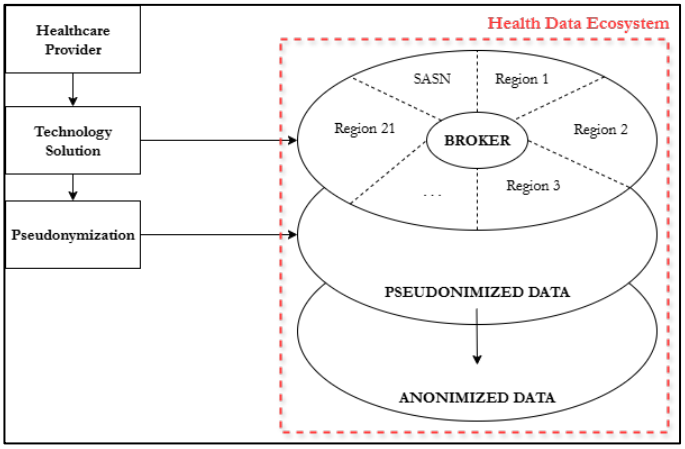

Figure 12 Structure and functions of EDS

The **Data module** is structured on three levels:

1. **Clear data**, composed of 22 independent Archiving Units (UA): 21 are specifically dedicated to each Regions and Autonomous Provinces (UA-R), while one is reserved for the Health Assistance Services for the Maritime Personnel (UA-SASN). This distribution ensures that data from each Region remains distinct and separate, avoiding unauthorized access. The system requires that data shared by the Health Card System is directed to and stored exclusively within the archiving unit of the Region that originally produced it, further strengthening the principle of territorial segregation of information.

2. **Pseudonymized data**, consisting of a single unit (Pseudonymized Data Unit – UD-P), with logical partitions by Region, Autonomous Province, and SASN. The pseudonymization process is based on the rigorous separation between demographic and clinical data, with the introduction of a unique identifier code randomly generated and not derived in any way from the patient's demographic data. This code is further protected using advanced encryption procedures before being associated with clinical data.
3. **Anonymized data**, consisting of a single platform (Anonymized Data Unit – UD-A), optimized for the generation, from UD-P, of "views" of anonymized data. The techniques used are divided into three main methodological categories. Randomization alters the truthfulness of the data using strategies such as the introduction of statistical noise, permutation of values within the dataset, and the implementation of differential privacy techniques. Generalization, on the other hand, acts on the granularity of the information, diluting personal attributes through grouping into broader categories and reducing the precision of individual data. Finally, advanced methods such as k-Anonymity, l-Diversity, and t-Closeness ensure formal properties of indistinguishability among subjects represented in the data.

Regions and autonomous provinces may create and manage their own UA-R or use the one provided by the Ministry of Health.

The **EDS Broker** is the component that implements the regional cooperation model, as well as cooperation with the SASN storage unit. The Broker will implement functionalities for data retrieval for care, prevention, and international prophylaxis purposes, constantly verifying data treatment consents and authorisations.

The **Service module** will include all EDS functionalities, among which the following are already envisaged in the legislation:

a) **Consultation services**, FSE 2.0 data access according to the defined authorization roles and profiles
b) **Terminology management services**, including codifications, dictionaries, and mappings to align technological solutions and ensure proper functioning
c) **Data quality verification services**, to ensure no duplication and proper harmonization of the data
d) **Demographic query services**, which ensure the correct identification of patients and the verification of data access profiling (delegations and consents)
e) **Data pseudonymization services**, which carry out the pseudonymization process of the received FHIR data

f) **Data anonymization services**, which extract data from previously pseudonymized patient data, ensuring the non-traceability of the individual
g) **Interoperability services**, enabling the management of data flows between the platforms included in the EDS data module, ensuring full alignment between regional FSEs documents and the data contained in the EDS data module.

In view of the above, in the current evolution, EDS should not be deemed as an additional technical component, but an 'enabling condition' to improve FSE 2.0 and the whole revised Italian HIS for all users' categories, as follows:

a) Patients: by more easily accessing their FSEs can benefit from personalised digital health services (e.g. consultation of the progress of their clinical data) and proactive notifications;
b) Healthcare professionals, will be supported by digital tools and services in their daily practice;
c) Authorities that can count on real data for healthcare planning at national and regional level;
d) Researchers, who will be able to access reliable and up-to-date datasets for life-sciences scientific research and continuous testing of innovative solutions in healthcare.

3.7 Data culture, interoperability and wider societal impact

The introduction of EDS also entails a cultural and methodological change. Health data, in the logic of EDS, is a public asset to be 'protected', valorised and returned to the public in the form of knowledge, tools and services.

This implies:

a) strong awareness of all actors involved (health professionals, regions, health authorities, central bodies) for a secure management of health data for the purposes of treatment, prevention, research and health governance;
b) the adoption of a common language, through the mandatory use of shared semantic standards (FHIR, CDA2, LOINC, SNOMED-CT);
c) opening up to cross-border interoperability to connect with the European Health Data Space (EHDS).

The new logic behind the system gives EDS almost an "epistemological" role, as the system provides the basis for building a national healthcare system that is no longer performance-centred, but can count on the knowledge it produces and shares. Should the EDS be correctly and fully implemented, the Italian national health system will also be able to evolve from

reactive governance, based on historical and partial data, to adaptive and predictive governance, based on up-to-date, reliable and accessible data in real time.

This step is particularly crucial in a societal context characterised by:

a) increase in chronicity and care complexity;
b) need to manage limited resources dynamically;
c) emerging public health risks (epidemics, climatic events, territorial inequalities);
d) pressure on sustainability and accountability of health policies.

The correct implementation of EDS can enable institutions to forecast needs, assess impacts, monitor outcomes and test innovative models, reducing uncertainty and shortening the time between knowledge and decision.

For the potential of EDS to be fully expressed, it needs to be recognised not only as a technical platform, but as a systemic project that involves:

a) technical elements (information systems, standards, security);
b) organisational elements (flow integration, consent management);
c) ethical, legal and communication elements (transparency, trust, right to knowledge).

Therefore, the useful implementation of EDS will need to involve:

a) citizens and health professionals full awareness;
b) FSE 2.0 adoption in day-to-day clinical and management healthcare practice;
c) Transparent, reliable and accountable governance.

3.8 State of the new Italian HIS (FSE 2.0/EDS) implementation project

The project started in 2022, in line with the milestones and targets defined by Mission 6 of the NRRP (Component 2 - Investment 1.3.1). Based on the public information made available by the relevant institutions, it is noted that to date:

1. The Department for the Digital Transformation, in collaboration with the other national stakeholders (e.g. Ministry of Health, Ministry of Economy and Finance, Agenas, Sogei), is designing and implementing the national components of the new FSE 2.0 (e.g. Gateway, EDS architecture, FSE 2.0 Services enabled by the EDS), in compliance with the FSE 2.0 Guidelines and the regulations issued;
2. The 21 Italian Regions and Autonomous Provinces are proceeding, in accordance with the provisions of the Ministerial Decree of 8 August 2022, albeit with different degrees of progress for each regional context, with:

a. The adaptation of regional technological architectures, in line with the nationally defined architectural model and with the provisions of the relevant implementing decrees and technical specifications defined at national level (e.g. DTD, AGID);
b. The adaptation of the clinical document production systems feeding the new FSE 2.0 to ensure compliance with the interoperability specifications defined at national level;
c. The design and delivery of training and communication programmes aimed at health professionals to ensure the increase of digital skills necessary to guarantee a full and widespread supply of FSE 2.0 throughout the country.

By 30 June 2026 (NRRP deadline), the project should be completed with a new FSE 2.0 system implemented nationwide. In the coming months, therefore, the national stakeholders and the Regions and Autonomous Provinces, will face the "crucial" phase of the project, with the objective of ensuring the achievement of all the NRRP milestones and targets defined at the national level and agreed with the European Community (e.g. supply of the new FSE 2.0 by at least 85% of all the GPs/PLS on the national territory; full activation of the infrastructure for the FSE 2.0 interoperability by 30 June 2026; adoption of the new FSE 2.0 by all the Regions by 30 June 2026).

NRRP monitoring data[34] show that the measure progress in terms of investments is at 37% completion as of 30 June 2025 and this may suggest that the final completion of all NRRP deadlines will not be fully met in time by June 2026.

34 https://openpnrr.it/tema/ammodernamento-tecnologico/

4. THE EVOLVING EUROPEAN CONTEXT: THE EUROPEAN HEALTH DATA SPACE

4.1 Adoption of the European Health Data Space (EHDS): Objectives and institutions involved

The European Health Data Space (EHDS) represents a crucial element of the European data strategy, aimed at creating a shared regulatory, technical and organisational environment for the secure, accessible and interoperable processing of electronic health information across the European Union and at establishing the required infrastructure and governance model to promote the interoperability of health data across Europe [43]. EHDS aims at providing improved exchange and access to health data across Europe to support healthcare services - primary use of data - and facilitate access to health data for research and policy-making purposes - secondary use of data. It is not just a regulatory framework, but an operational and technological infrastructure that redefines the governance of health data, both at the primary level (for treatment) and at the secondary level (for research, innovation, public health and regulation) [30,31].

The EHDS, provided for in **COM(2022)197 final** and officially adopted in January 2024, is part of the wider vision laid out by the 2020 European Data Strategy (COM(2020)66 final), which identified nine strategic sectors for common data spaces, including the health sector. The overarching objective is to overcome legal and technical barriers to data sharing by combining tools, infrastructure and governance mechanisms to ensure trust and usability [47].

The EHDS is based on three fundamental pillars:

a) **Citizens' digital rights**: guarantee every natural person residing or transiting in the EU the right to access, transfer, share and correct their electronic health data in an interoperable format, even across borders. More specifically, Citizens have the right to: (i) to access (and to authorize another person to access) the electronic health data concerning them, (ii) to rectify them, (iii) to obtain their portability, (iv) to insert additional information into their own electronic health record, which must, however, remain separate from the information entered by healthcare professionals, (v) to restrict access to their data to those providing healthcare, (vi) to be informed about access made to their electronic health data.

b) **Secondary use of data**: enabling controlled access to health data for purposes of public interest (research, innovation, statistics, regulation, health crisis response), through a federated infrastructure and access bodies designated by the Member States. The Regulation also defines both allowed (e.g. public health, policymaking, education, AI training, medical innovation) and forbidden purposes (e.g. discriminatory decisions, marketing, developing harmful products).

c) **Single market for digital health solutions**: promote standardisation and certification of health information systems, with common requirements for security, interoperability and algorithmic transparency, including for clinical support software and digital health applications.

There are many actors involved in the implementation of the EHDS:

1. **European Commission** (DG SANTE and DG CNECT), responsible for regulatory and technical coordination;
2. **MyHealth@EU**[35], the infrastructure for cross-border exchange of primary data (already active for prescriptions and Patient Summary between some countries);
3. **HealthData@EU**[36], the federated network for secondary data access, which will be operational once the regulation is adopted;
4. **HaDEA**[37], which supports with services and funding all EU Member States in the domains of health, food safety, digital technologies and networks;
5. National **Health Data Access** Bodies, designated to authorise secondary access to data, according to common criteria.

The relevance of EHDS lies not only in facilitating continuity of care across national borders, but also in being a strategic lever for the development of European health research based on real-world data, with high ethical and scientific standards. Its implementation can represent one of the main enablers for the predictive, personalised and cooperative healthcare of the next decade [30, 31, 47].

4.2 The European legal framework of reference

The implementation of the **European Health Data Space (EHDS**) is based on an articulated European legal framework, progressively developed to regulate the management, interoperability, security and purpose of health data within the European Union. This regulatory framework incorporates fundamental principles of digital health and personal data protection, as follows:

a) **Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016**: known as the **General Data Protection Regulation (GDPR)**, sets out the rules on the protection of natural persons with regard to the processing of personal data, including health data, ensuring the free movement of such data within the EU.

b) **Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022**: known as the **Data Governance Act (DGA**), it establishes conditions

[35] https://www.interregeurope.eu/sites/default/files/2022-04/EW0220140ENN.en_.pdf
36 https://acceptance.data.health.europa.eu/?locale=en
37 https://hadea.ec.europa.eu/programmes/eu4health_en

for secure data sharing in the EU, promoting the availability of data while respecting fundamental rights, including those relating to health.

c) **Regulation (EU) 2023/2854 of the European Parliament and of the Council of 11 January 2024**: referred to as the **Data Act**, it introduces harmonised rules on fair access to and use of data, also applicable to health data, and will be fully applicable from 12 September 2025

d) **Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025**: establishes **the European Health Data Space (EHDS)**, creating a uniform legal framework to facilitate the management and sharing of health data in the EU

e) **Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022**: known as the **NIS 2 Directive**, updates the measures for a high common level of security of networks and information systems in the Union, including specific provisions for the health sector

The above legislation provides the legal basis for the implementation of EHDS, ensuring harmonised and secure approach to electronic health data management in the European Union.

4.3 EHDS enabling technology architecture

The technological architecture envisaged by Regulation (EU) 2025/327 of the European Parliament and of the Council is based on mandatory harmonised software components to ensure the interoperability and security of electronic health record systems. Article 2(2)(n) and (o) define two key components:

1. **European software component for interoperability of electronic health record systems**: designed to facilitate the cross-border exchange of electronic health data between Member States.
2. **European electronic health record systems software component**: aimed at ensuring traceability of access and operations performed on electronic health records.

These components are designed to integrate with existing cross-border infrastructures, such as **MyHealth@EU**, which supports the primary use of electronic health data, and **HealthData@EU**, which facilitates the secondary use of such data.

The regulation also stipulates that electronic health record systems and other healthcare applications that declare interoperability with such systems must comply with technical and security requirements defined at European Union level. This includes the adoption of common standards for semantic and syntactic interoperability, as well as measures to ensure the protection of personal data and the security of the information processed.

In order to facilitate the implementation and adaptation to these requirements, the European Commission envisages co-financing pilot projects, such as **HealthData@EU** and the joint action **Xt-EHR**[38], which provides direct funding to Member States for the development of the necessary infrastructure.

In summary, the framework architecture outlined in Regulation (EU) 2025/327[39] aims at establishing a secure, interoperable and citizen-centric European Digital Health ecosystem, promoting innovation and improving the efficiency of health services in the European Union, as outlined in the following graph:

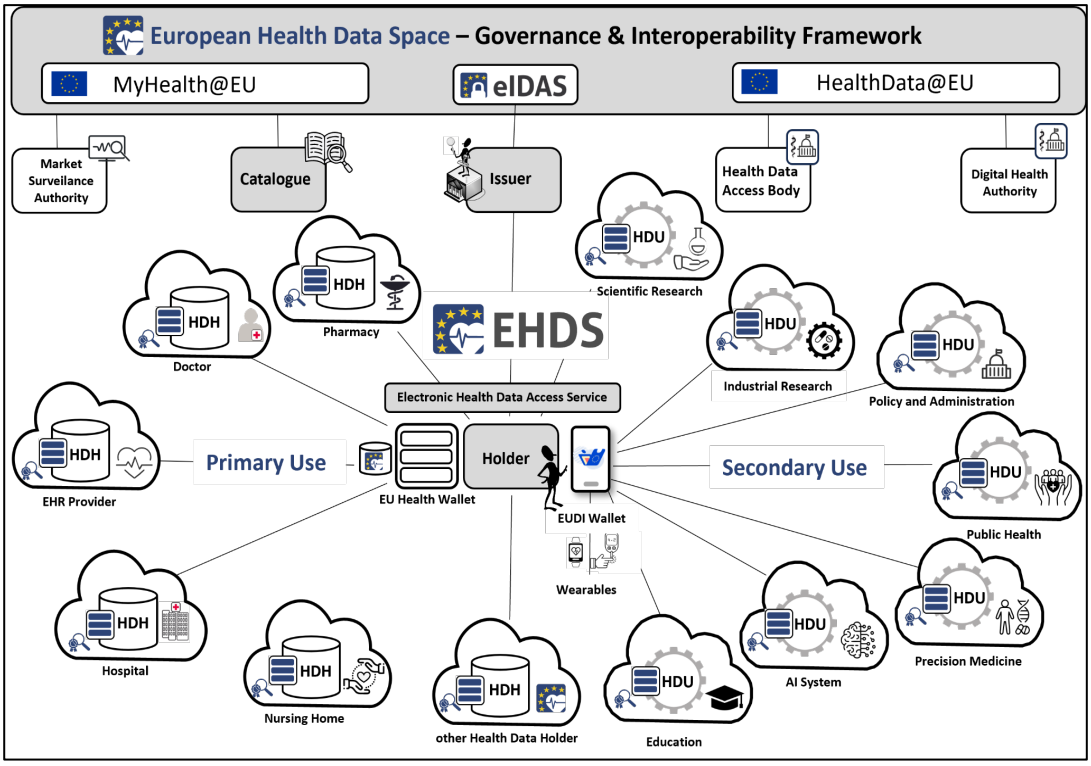

Figure 13 EHDS Governance and interoperability framework as retrieved at https://www.ehds.io/index.html (1 June 2025)

4.4 EHDS interconnection with the Italian FSE 2.0

With the initiatives launched in the framework of EU NextGeneration programme, Italy has started a path of progressive technical and organisational alignment with EHDS. In particular, the Ministry of Health Decree of 31 December 2024[40] establishing the Italian Health Data Ecosystem is designed to be fully compatible with the EHDS infrastructure, thus fostering full

38 https://www.xt-ehr.eu/
39 https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng
40 https://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2025-03-05&atto.codiceRedazionale=25A01321&elenco30giorni=false

cross-border portability of data and Italy's participation in the European health research and governance networks. In Italy, the role of national access body will be played by AGENAS.

The adoption of the EHDS implies a number of converging actions for Italy:

a) full adherence to European standards for data and metadata (e.g. HL7 FHIR, SNOMED CT, eIDAS);
b) harmonisation of consent and transparency policies;
c) provision of secure mechanisms for access by authorised third parties, ensuring the untraceability of the assisted person's identity (GDPR-compliant pseudonymisation/anonymisation);
d) participation in the European HealthData@EU nodes for controlled data sharing.

Moreover, Italy will have to align its national governance with European structures, adopt adequate indexing and labelling practices for data access, and implement awareness and digital literacy campaigns to foster public trust and understanding. The EHDS regulation also includes rules for data access from third countries, requiring reciprocity and equivalent safety, and establishes enforcement mechanisms at both national and EU level, including sanctions and compensation provisions in case of breaches.

The European Health Data Space also marks a change in direction for secondary data usage, compared to the previously more limited approach based on a restrictive application of the GDPR. Health data contained in EHR can be shared for primary and secondary use unless the data subject opts out and preliminary consent (opt-in) is no longer required. This new approach, which will make secondary usage for research significantly more effective, needs significant and adequate investments in infrastructures and technologies that make data sharing feasible and secure, as well as wide public awareness and communication initiatives to ensure citizens' trust [50].

5. IN-DEPTH INTERVIEWS WITH ITALIAN STAKEHOLDERS

To investigate stakeholders' attitude and perception regarding the current evolution of Italian health data management and EHR recent transformation, and more in general about how digitisation can improve healthcare, I have conducted a number of in-depth individual interviews with key players in the healthcare Italian system.

5.1 Methodology

Methodology used is qualitative in-depth interviews [46] employing semi-structured, one-to-one oral interactions to elicit rich, detailed accounts of respondents' experiences, beliefs and opinions. I have used semi open-ended questions, together with active listening and flexible probes to explore respondents' perspective, considering this methodological approach to be particularly suited to exploring complex institutional practices and policy-relevant processes that require contextualised, interpretive insight [44].

Interviews were conducted between April and July 2025.

Respondents included prominent figures of the following Italian healthcare related institutions:

1. **National Government**
    - **Roberto Soj**, Head of EDS (Health Data Ecosystem) of the Department of Digital Transformation at the Italian Presidency of the Council of Ministries
2. **Regional and Autonomous Provinces**
    - **Alessandro Bazziga**, Director of Technology at ASTT (Azienda provinciale per i servizi sanitari Provincia autonoma di Trento) of Trento Autonomous Province
    - **Enrico Zanella**, Director General of IN.VA S.p.a., ICT inhouse provider of Valle d'Aosta Region
    - **Salvatore Lopresti**, Medical Doctor and Coordinating Manager of ICT for the Health Sector of Calabria Region
3. **Local Health Authorities and Hospitals**
    - **Mauro Luciani,** Biomedical Engineer, Director of ICT and Clinical Engineering at AST (Azienda Sanitaria Territoriale) of Pesaro-Urbino, Marche.
4. **Medical doctors and researchers**
    - **Maria Stumpo**, Medical Doctor, Surgeon and researcher
    - **Claudio Zanon**, Medical Doctor, epidemiologist and Director of Association Motore Sanità

Italian Health Information Systems (HIS) and Health Data Management models & Electronic Health Records (EHR) evolution – Stakeholders perception

In-depth interviews designed to investigate main stakeholders' insights, attitudes and evaluation of the evolving health data management scenario in Italy within the National Health System (NHS). Outputs used to fine-tune research proposal and presented extrapolating cross-interviews emerged point.

Interview protocol

Name, Profession and title + Type of stakeholder

1. General attitude towards HIS
   / strongly agree / agree / neutral / disagree / strongly disagree

   a. Technological developments help the NHS to accomplish tasks more quickly
   b. Digitalisation increases NHS efficiency and productivity
   c. Existing EHR helps NHS workflow
   d. New EHR guidelines will improve data access and management

2. Main problems/issues with existing Italian EHR and HIS:

   a. Interoperability with other health structures
   b. Nationwide interoperability and access
   c. Costs and sustainability
   d. Technical reliability of HISs
   e. Training and awareness of medical staff
   f. Effective interaction with patients
   g. Other ...

3. Main problems/issues to solve with the implementation of new Italian EHR and HIS:

   a. Interoperability with other health structures
   b. Nationwide interoperability and access
   c. Costs and sustainability
   d. Technical reliability of HISs
   e. Training and awareness of medical staff
   f. Effective interaction with patients
   g. Other ...

4. Greatest obstacles for the digitalisation and full data management of SSN / Italian NHS?

5. Main recommendations for the positive evolution of EHR and data access in Italy:

Figure 14 Research Interviews Protocol

5.2 Main findings

a) General Attitude Towards Italian NHS Health Information Systems (HIS)

Respondent name and role	Feedback
Mauro Luciani, Biomedical Engineer, Director of ICT and Clinical Engineering at AST (Azienda Sanitaria Territoriale) of Pesaro-Urbino, Marche.	- Technological developments help the NHS to accomplish tasks more quickly - Digitalisation increases NHS efficiency and productivity - New EHR guidelines will improve data access and management
Alessandro Bazziga, Director of Technology at ASTT (Azienda provinciale per i servizi sanitari Provincia autonoma di Trento) of Trento Autonomous Province	- Technological developments help the NHS to accomplish tasks more quickly - Digitalisation increases NHS efficiency and productivity - New EHR guidelines will improve data access and management
Enrico Zanella, Director General of IN.VA S.p.a., ICT inhouse provider of Valle d'Aosta Region	- Technological developments help the NHS to accomplish tasks more quickly - Digitalisation increases NHS efficiency and productivity - Existing FSE/EHR already helps NHS workflow - New EHR guidelines will improve data access and management
Maria Stumpo, Surgeon and researcher	- Technological developments help the NHS to accomplish tasks more quickly - Digitalisation increases NHS efficiency and productivity - New EHR guidelines will improve data access and management
Salvatore Lopresti, Medical Doctor and Coordinating Manager of ICT for the Health Sector of Calabria Region	- Technological developments help the NHS to accomplish tasks more quickly - Digitalisation increases NHS efficiency and productivity: agree - New EHR guidelines will improve data access and management: agree
Claudio Zanon, *Medical Doctor, epidemiologist and Director of Association Motore Sanità*	- Technological developments help the NHS to accomplish tasks more quickly - Digitalisation increases NHS efficiency and productivity - New EHR guidelines will improve data access and management

Roberto Soj, Head of EDS (Health Data Ecosystem) of the Department of Digital Transformation at the Italian Presidency of the Council of Ministries	- Technological developments help the NHS to accomplish tasks more quickly - Digitalisation increases NHS efficiency and productivity - Existing EHR (FSE 1.0) is primarily document-based and lacks structured data for optimal support - New EHR guidelines (FSE 2.0) will improve data access and management:the new framework is designed to move from document archiving to structured, interoperable data

b) Main Problems/Issues with Existing Italian EHR (FSE 1.0) and HIS

Respondent name and role	Feedback
Mauro Luciani, Biomedical Engineer, Director of ICT and Clinical Engineering at AST (Azienda Sanitaria Territoriale) of Pesaro-Urbino, Marche.	- Lack of interoperability within regions: fragmented cross-provider data sharing due to heterogeneous platforms and standards - Nationwide interoperability and access: a pressing problem; the lack of a unified national architecture limits continuity of care - Costs and sustainability: fragmented procurement and overlapping solutions increase costs - Technical reliability: generally acceptable but not uniform; legacy systems hinder performance and innovation - Training and awareness of medical staff: a significant issue with widely varying digital maturity - Effective interaction with patients: currently limited, with patient access often passive
Alessandro Bazziga, Director of Technology at ASTT (Azienda provinciale per i servizi sanitari Provincia autonoma di Trento) of Trento Autonomous Province	- Interoperability among different regions is a strong problem and Italian HISs are not adequately reliable - Training and awareness of medical staff is also a significant obstacle
Enrico Zanella, Director General of IN.VA S.p.a., ICT inhouse provider of Valle d'Aosta Region	- Believes that Interoperability within regions is a strong problem and there is need for improved nationwide interoperability and access: strongly agree - The reliability of Italian HIS does not represent a problem, but both training of medical staff and effective interaction with patients do

Maria Stumpo, Surgeon and researcher	- Interoperability among regions is the main problem, together with the need to improve nationwide interoperability and access - Training and awareness of medical staff represent a system weakness
Salvatore Lopresti, Medical Doctor and Coordinating Manager of ICT for the Health Sector of Calabria Region	- Interoperability within the regions is the main problem, together with the need to improve nationwide interoperability and access: main problem - Also training and awareness of medical staff represent a system weakness
Claudio Zanon, *Medical Doctor, epidemiologist and Director of Association Motore Sanità*	- Interoperability within the regions is the main problem, together with the need to improve nationwide interoperability and access: main problem - Also training and awareness of medical staff represent a system weakness
Roberto Soj, Head of EDS (Health Data Ecosystem) of the Department of Digital Transformation at the Italian Presidency of the Council of Ministries	- Interoperability within the regions is the main problem, together with the need to improve nationwide interoperability and access: highlights lack of complete semantic and technical alignment between regions - Costs and system sustainability are also a problem: legacy systems require significant investment - Technical reliability: legacy platforms are stable but not adaptable to new requirements - Training and awareness of medical staff: insufficient training on data-centric use of EHRs - Effective interaction with patients: systems are not adequately user-friendly

c) Main Problems/Issues to Solve with the implementation of the new Italian EHR (FSE 2.0)

Respondent name and role	Feedback

Mauro Luciani, Biomedical Engineer, Director of ICT and Clinical Engineering at AST (Azienda Sanitaria Territoriale) of Pesaro-Urbino, Marche.	- Interoperability (regional and national): must become the core priority - Costs and sustainability: can be managed and optimized with proper governance and guidelines - Technical reliability: can be improved with structured testing and cloud-native architectures - Training and awareness of staff: a critical barrier that requires a national program for digital skills - Patient engagement: should evolve from access-only to interactive tools
Alessandro Bazziga, Director of Technology at ASTT (Azienda provinciale per i servizi sanitari Provincia autonoma di Trento) of Trento Autonomous Province	- Interoperability among different regions and training of medical staff for improved usage of FSE 2.0 are the main priorities
Enrico Zanella, Director General of IN.VA S.p.a., ICT inhouse provider of Valle d'Aosta Region	- Interoperability among different regions - Nationwide interoperability and access - Training and awareness of medical staff - Improved interaction with patients
Maria Stumpo, Surgeon and researcher	- Interoperability among different regions, nationwide interoperability and improved access and training of medical staff for improved usage of FSE 2.0 are the main priorities - Technical reliability of HISs, costs and interaction with patients are not significant problem
Salvatore Lopresti, Medical Doctor and Coordinating Manager of ICT for the Health Sector of Calabria Region	- Interoperability among different regions, nationwide interoperability and improved access and training of medical staff for improved usage of FSE 2.0 are the main priorities - Technical reliability of HISs, costs and interaction with patients are not significant problem

Claudio Zanon, *Medical Doctor, epidemiologist and Director of Association Motore Sanità*	- Interoperability among different regions, nationwide interoperability and improved access and training of medical staff for improved usage of FSE 2.0 are the main priorities - Technical reliability of HISs, costs and interaction with patients are not significant problem
Roberto Soj, Head of EDS (Health Data Ecosystem) of the Department of Digital Transformation at the Italian Presidency of the Council of Ministries	- Interoperability among regions is important with harmonization of technical and semantic standards - Nationwide interoperability and access is main problem: to address with the implementation of EDS as a federated architecture - Costs and sustainability should be resolved with central government standards to reduce duplication - Effective interaction with patients can be solved with the simplification of user interfaces

d) Greatest Obstacles for the Digitalisation and Full Data Management of the NHS

Respondent name and role	Feedback
Mauro Luciani, Biomedical Engineer, Director of ICT and Clinical Engineering at AST (Azienda Sanitaria Territoriale) of Pesaro-Urbino, Marche.	Main obstacles include: - Cultural resistance to change among healthcare management and clinical staff - Regional autonomy and fragmentation with insufficient coordination - Low investment in change management and continuous education - Misalignment between political priorities and technical roadmaps
Alessandro Bazziga, Director of Technology at ASTT (Azienda provinciale per i servizi sanitari Provincia autonoma di Trento) of Trento Autonomous Province	Main obstacles include: - stability of the integration IT backbone - relationships between regions and central administration - regional legacy systems
Enrico Zanella, Director General of IN.VA S.p.a., ICT inhouse provider of Valle d'Aosta Region	Main obstacles include: - Lack of commitment from medical professionals in using IT tools - Cybersecurity

Maria Stumpo, Surgeon and researcher	- Cultural resistance in the healthcare sector
Salvatore Lopresti, Medical Doctor and Coordinating Manager of ICT for the Health Sector of Calabria Region	- Cultural resistance in the healthcare sector
Claudio Zanon, *Medical Doctor, epidemiologist and Director of Association Motore Sanità*	- Cultural resistance in the healthcare sector
Roberto Soj, Head of EDS (Health Data Ecosystem) of the Department of Digital Transformation at the Italian Presidency of the Council of Ministries	- The cultural approach is still largely document-centric. There is an insufficient focus on extracting actionable clinical data from documents, which limits the potential for predictive and personalized medicine.

e) Recommendations for the positive evolution of Italian EHR (FSE 2.0) and health data access

Respondent name and role	Feedback
Mauro Luciani, Biomedical Engineer, Director of ICT and Clinical Engineering at AST (Azienda Sanitaria Territoriale) of Pesaro-Urbino, Marche.	- Establish a centralised national governance body with operational authority - Promote interoperability by design through mandatory compliance with standards like FHIR and IHE - Create a national training and certification program for digital health - Enable citizen-centric services by integrating Personal Health Records (PHRs) - Fund shared platforms and middleware to avoid local duplication.
Alessandro Bazziga, Director of Technology at ASTT (Azienda provinciale per i servizi sanitari Provincia autonoma di Trento) of Trento Autonomous Province	- Implement the new EHR system with a definitive integration with the national patient registry (ANA) - Ensure effective local master data management - Involve GPs (NHS general practitioners) - Define a consistent and accurate regulatory framework for data processing and dissemination.

Enrico Zanella, Director General of IN.VA S.p.a., ICT inhouse provider of Valle d'Aosta Region	- The new EHR adoption must be supported by adequate training for doctors and healthcare staff - Provide specific support for low digital skills patients - Interoperability between hospital systems across different regions is essential to develop national-level tools
Maria Stumpo, Surgeon and researcher	- There should be only one national institution centrally to drive the implementation of the new FSE 2.0
Salvatore Lopresti, Medical Doctor and Coordinating Manager of ICT for the Health Sector of Calabria Region	- There should be only one national institution centrally to drive the implementation of the new FSE 2.0
Claudio Zanon, *Medical Doctor, epidemiologist and Director of Association Motore Sanità*	- There should be only one national institution centrally to drive the implementation of the new FSE 2.0
Roberto Soj, Head of EDS (Health Data Ecosystem) of the Department of Digital Transformation at the Italian Presidency of the Council of Ministries	- Harmonization of technical and semantic standards and implementation of a federated architecture - Central service policies to reduce duplication - Large-scale training programs for medical staff - Simplification of user interfaces for patients - Launch a change management framework to guide the transition from legacy systems

f) Additional Comments

Respondent name and role	Additional meaningful insights
Mauro Luciani, Biomedical Engineer, Director of ICT and Clinical Engineering at AST (Azienda Sanitaria Territoriale) of Pesaro-Urbino, Marche.	- Other problems/issues with existing HIS: governance fragmentation, legal and organizational inertia, inconsistent use of standards (e.g., FHIR), and lack of integration of imaging systems (RIS/PACS) into the EHR ecosystem - Other problems/issues to solve: transparent and accountable national governance, better integration with public health and research data, and the inclusion of private healthcare providers in the EHR ecosystem
Alessandro Bazziga, Director of Technology at ASTT (Azienda provinciale per i servizi sanitari Provincia autonoma di	- Lack of innovation mindset in the national healthcare system represent a significant cultural problem

Trento) of Trento Autonomous Province	
Enrico Zanella, Director General of IN.VA S.p.a., ICT inhouse provider of Valle d'Aosta Region	The cultural attitude in the Italian NHS and lack of incentives for general practitioners represent obstacles
Maria Stumpo, Surgeon and researcher	- Lack of innovation mindset in the national healthcare system represent a significant cultural problem
Salvatore Lopresti, Medical Doctor and Coordinating Manager of ICT for the Health Sector of Calabria Region	· Other problems/issues with existing HIS: the cultural approach is still largely document-centric · Other problems/issues to solve: roll-out of service policies to ensure homogeneous behavior between central and regional systems. Creation of a change management framework to guide the transition from legacy EHR to FSE 2.0/EDS Progressive integration of structured, interoperable data models to move from "counting documents" to generating clinical and operational value for clinicians, patients, and policy-makers

5.3. Other points emerged by category of stakeholder

a. **Central government representative** emphasised that the Next generation EU resources represent a unique opportunity to bridge the digital divide between Italian regions and to push regional FSE platforms towards greater interoperability with a view to a single national FSE 2,0 (e.g. adoption of HL7 FHIR) and expressed the need for a 'permanent technical table' in which central state and regions would agree on roadmaps and mandatory minimum standards;

b. **Regional representatives** appeared to be in favour of strengthening the role of central governance institutions for the development of an improved FSE, provided that local expertise and projects already under way are preserved, but highlight the problem of financial sustainability

c. **Health Authorities and Hospitals** have highlighted the need to simplify access to health data by medical doctors and the need for improved interoperability with software 'already used on the ward' to avoid duplication of activities

d. **Medical doctors and researchers** express concern about the burdensome and time-consuming nature of data-entry tasks and the need for advanced functionalities (e.g., extraction of longitudinal data to analyse clinical trends), which are not consistently available in regional FSE platforms. Also report lack of streamlined procedures for obtaining large-scale pseudonymised datasets, resulting in protracted authorisation processes that constrain the competitiveness of Italian researchers in the international arena.

6. PROPOSALS FOR EFFECTIVE NATION-WIDE IMPLEMENTATION OF THE NEW ITALIAN HIS (FSE 2.0 + EDS)

Considering the structural weaknesses of the FSE 1.0 implementation and the fragmentation of the different regional contexts, the new HIS envisaged in the measures designed within the Italian NRRP will need careful and detailed deployment actions. For the new FSE 2.0 to actually become the public infrastructure for national digital health, a set of targeted measures for effective management and use of collected health data will need to be put in place.

To this end, this research proposes **a set of measures to be implemented**, aimed at the actual deployment of the joint FSE 2.0/EDS system through:

a) the introduction of AI enriched services, enabled by EDS for the systematic use of data by all categories of FSE 2.0 users;
b) the improved integration of regional and healthcare facilities local platforms with the national system;
c) the optimisation of the user experience with FSE improved interfaces;
d) the enhancement of training, communication and awareness-raising measures for all categories of users, with the aim of maximising the degree of dissemination and use

These proposals are designed in compliance with the targets, milestones and guidelines defined by the NRRP measure and with the aim of defining a roadmap beyond the end of the European Union funding programme (30 June 2026).

6.1 EDS-enabled 'data-based' services

a) "EDS Services" for Patients

In compliance with the provisions of the Ministry of Health Decree of 31 December 2024, which regulates the functioning of the Health Data Ecosystem (EDS), it is proposed to **design and implement "data-based" services aimed at Citizens/Patients**, accessible through the FSE 2.0 interfaces made available at the national and regional level, including:

1. **Consulting information on personal clinical status and history** (e.g. chronic pathologies, ongoing pathologies, missing organs, transplants performed, current/previous pharmacological therapies, recent prescriptions, vaccinations performed, risk factors, allergies and/or adverse reactions certified by the doctor), having evidence of the relevant data sources (e.g.: Summary Health Profile, laboratory report);

2. **Visualising personal health trends** based on chronological clinical and vital parameters and values, with evidence of threshold values and their exceedance over time;
3. **Consulting information about personal care therapy** contained in the Individual Care Plan (PAI) defined for the Citizen-Assisted Person;
4. **Consulting and filtering** data about own personal **pharmaceutical dossier** (information on prescriptions, administration and dispensing of therapies contained in their pharmaceutical dossier);

The proposal is to activate a nationally orchestrated system **for the design and implementation** of the above services that would ensure:

a) the targeted **involvement of all the 'key' categories of end-users** (e.g. from Gen Z and digital natives who constantly interact with Public Services through digital touchpoints, to chronic over-65 patients with lower digital skills) in the phase of **functional co-design of the use cases** related to the above-mentioned micro-services;
b) the development of EDS services, centred on the health care and information needs of all categories of assisted Citizens, which **"simplify" and speed up** their **interaction** with all components of the regional health care system (e.g. Family Doctor, Specialists), saving time and avoiding unnecessary visits/interactions;
c) the development of EDS services to ensure **greater awareness and involvement of patients**, through data and information that facilitate personal monitoring of own medical conditions and enable 'active prevention' paths;
d) the activation of **nationwide homogeneous EDS services** for Citizens, with a view to guaranteeing the implementation of an FSE 2.0 'equal' for all NHS Patients, regardless of their Region of residence.

b) "EDS Services" for Healthcare Professionals

In compliance with the provisions of the Ministry of Health Decree of 31 December 2024, which regulates the functioning of the Health Data Ecosystem (EDS), it is proposed to **design and implement "data-based" services aimed at Healthcare Professionals** , accessible through the FSE 2.0 interfaces made available at the national and regional level, including:

a) **Consulting information concerning the clinical history** of their patients (e.g. summary health profile, chronic pathologies, current pathologies, missing organs, transplants performed, current/previous pharmacological therapies, recent

prescriptions, vaccinations performed, risk factors, allergies and/or certified adverse reactions), having evidence of the relevant data sources;

b) **Searching and consulting data of a clinical event of hospitalisation or access to the emergency department** of a specific patient, searchable by period, type of event, name and type of facility where the event occurred, level of urgency associated with the event, diagnosis and diagnostic suspicion

c) **Visualising patients' health trends** based on chronological clinical and vital parameters and values, with evidence of threshold values and their exceedance over time;

d) **Consulting and filtering data** about the **pharmaceutical dossier** of any specific patient (information on prescriptions, administration and dispensing of therapies contained in their pharmaceutical dossier);

e) **Consulting information about healthcare services undertaken by any specific patient** (type of service, date, diagnostic issue, healthcare facility, assigned specialist doctor);

f) **Filling the Patient Summary of** an individual patient (Following the search and selection of a specific patient, the medical professional should be able to request the data necessary for the creation of the Patient Summary Health Profile).

The proposal is to activate a **nationally orchestrated system for the design and implementation** of the above services that would ensure:

a) the targeted **involvement of all the "key" categories of end-users** of the above-mentioned services (e.g. primary care professionals, GPs, emergency room staff, medical specialists, nursing staff) in the **co-design** phase of **the use cases** related to the above-mentioned micro-services;

b) the development of EDS services centred on the information needs of the various categories of health professionals, aiming at **simplifying and speeding up interaction** with their patients;

c) the development of EDS services that help ensure **rapid and secure sharing of health data between different healthcare providers**, ensuring more coordinated and timely treatment;

d) the development of EDS services that help to **significantly reduce the time spent on reconstructing** the patient's **clinical and documentary history**:

   i. The medical doctor should immediately access a complete, updated and integrated picture of the patient's medical history;

ii. The medical doctor can access all information from FSE 2.0 amd HIS sources with no need to ask the patient or his family further information;
iii. No need to wait for documentation to be sent by other healthcare facilities;

e) the development of EDS services to ensure **the reduction of unnecessary visits and lab exams**, avoiding duplication of examinations and enabling better management of doctor-patient interaction;
f) the activation of **nationwide homogeneous EDS services for Healthcare Professionals**, with a view to guaranteeing the implementation of an FSE 2.0 'equal' for all NHS professionals and facilities, regardless their Region of location.

c) "EDS Services" for Healthcare Government Authorities

In compliance with the provisions of the Ministry of Health Decree of 31 December 2024, which regulates the functioning of the Health Data Ecosystem (EDS), it is proposed to **design and implement "data-based" services aimed at Healthcare governing Authorities (Ministry of Health, Regions and Autonomous Provinces)**, accessible through the FSE 2.0 interfaces made available at the national and regional level, including:

a) **Consulting pseudonymised data for prevention** purposes, to analyse health phenomena of public relevance, plan prevention campaigns and assess population adherence to screening or vaccination programmes;
b) **Consulting pseudonymised data of atypical health events**, sentinel signs and abnormal environmental factors, related to possible health emergencies (e.g. epidemiological events);
c) **Consulting pseudonymised data to support the development of health plans**, public policy impact assessment, monitoring the effectiveness of interventions and resource allocation

The proposal is to activate a nationally orchestrated system **for the design and implementation** of the above services that would ensure:

a) the targeted **involvement of all the "key" categories of End-Users of the above-mentioned services (e.g. Ministry of Health, Agenas, Regions and Autonomous Provinces)** in the **functional co-design** phase of **the use cases** related to the above-mentioned micro-services;
b) the development of EDS services, centred on the **'key' information needs** at national and regional level for the management of **prevention, international prophylaxis, healthcare planning and active epidemiological surveillance**;

c) The activation of **nationwide homogeneous EDS services for Regional Health Authorities (Regions and Autonomous Provinces) and local healthcare facilities**, with a view to guaranteeing the implementation of an FSE 2.0 'equal' for all.

Among healthcare professionals, within the Italian SSN framework, **General Practitioners (GPs**) and **Paediatricians of Free Choice (PFCs)** will have to play a crucial role in the daily feeding and consultation of the FSE 2.0, as they are the main actors of the patient's ongoing care.

However, the use of electronic health records by GPs/PLSs is still uneven and often not integrated with the patient's FSE 1.0, due to lack of integration between local software and regional FSE.

In order to address this critical issue, it is deemed crucial to implement a targeted pathway **of structural integration between the software adopted by GPs and PLSs and the new FSE 2.0**. This integration is not only a technical issue but represents a fundamental enabling factor for transforming the FSE from a documental archive to a **clinical tool for daily use in primary care**, capable of supporting clinical decisions, improving the quality of care, and facilitating the multidisciplinary care of the patient.

A fundamental aspect of integration must address the feeding of the **Patient Summary (Synthetic Health Profile)**, a central component of the FSE 2.0, which collects the most relevant clinical information of the Patient. The GPs/PFCs are primarily responsible for updating the Patient Summary. To facilitate this activity, the management software used by MMGs and PLSs needs to be integrated with the FSE 2.0, allowing the automatic sending and pre-compilation of the Patient Summary with relevant data available in the MMG/PLS records, such as:

a) Significant health problems of the resident (e.g. active chronic diseases, significant past diagnoses influencing current health status)
b) Contacting the Assisted Person in an emergency
c) Currently prescribed drugs, including dosage
d) Recently taken drugs with any important indications
e) Allergies to drugs, food, environmental substances and significant past adverse reactions (drugs, vaccines, etc.)
f) Recent values of blood pressure, blood sugar, cholesterol, weight and height (BMI), oxygen saturation, etc.

The health record software of the GP/PLS must make this information automatically available to the FSE 2.0, reducing the risk of errors and guaranteeing the completeness of the summary health profile of the patient.

A comprehensive compilation of the Patient Summary (also enabled by integration with GP/PLS records) would offer the achievement of numerous concrete benefits:

a) **Improved quality of care:** an up-to-date Patient Summary allows professionals to have a complete view of a patient's medical history, supporting more informed decisions.
b) **Reduced administrative burden:** automating the feeding of the Patient Summary reduces the time spent on manual operations, allowing professionals to focus more on patient care.
c) **Optimal continuity of care:** thanks to the centralisation of data, healthcare professionals can easily access critical information, even when patients move between different healthcare facilities or regions.
d) **Prevention and personalised medicine:** a properly fed Patient Summary enables the development of personalised treatment approaches, improving the management of chronic diseases and supporting prevention.

d) "EDS Services" for Research Institutions

In compliance with the provisions of the Ministry of Health Decree of 31 December 2024, which regulates the functioning of the Health Data Ecosystem (EDS), it is proposed to **design and implement "data-based" services aimed at Researchers** to consult anonymised data for scientific purposes:

a) **analysing epidemiological trends and developing new therapeutic approaches**;
b) **detect new diseases early, monitor their spread,** evaluate the effectiveness of preventive measures taken and define possible new measures;
c) **analysing large volumes of data (Big Data) to carry out and accelerate the development of epidemiological studies**, identification of patterns and risk factors, and in-depth studies on rare diseases.

The proposal is to activate a nationally orchestrated system **for the design and implementation** of the above services that would ensure:

a) the targeted **involvement of all the "key" categories of end-users** of the above-mentioned services (e.g. university researchers, research institutes

representatives) in the **functional co-designing** of **the use cases** related to the above-mentioned micro-services;

b) The **development** of EDS services, centred on the **'key' information needs** that already exist at national and local level in the field of life sciences and medical research (e.g. scientific research in the field of precision medicine, prevention of chronic diseases, management of rare diseases, study of side effects and pharmacovigilance, monitoring of pandemics and emerging infectious diseases);

c) The activation of **nationwide homogeneous EDS services for Research**, with a view to guaranteeing the implementation of scientific research access 'equal' for all scientific and academic institutions in Italy

6.2 The potential of Machine Learning and Artificial Intelligence to deliver 'augmented' EDS services

My research also led to identify the need of a national level programme for the adoption of consistent and safe Machine Learning (ML) and Artificial Intelligence (AI) models and applications [7, 31, 37, 41, 42] to **enhance the 'information capacity' of EDS Services**.

Specifically, the implementation of targeted interventions powered by Artificial Intelligence applications and models, could enable, by way of example, but not limited to:

1. **predictive analysis and prevention models and processes**: ML/AI will be able to analyse large volumes of health data made available through EDS to identify patterns and predict disease occurrence, enabling timely preventive interventions (e.g., predictive algorithms can identify patients at risk of developing chronic conditions, facilitating customised prevention programmes);
2. **assisted' diagnosis and clinical decision-making**: AI-based solutions can support medical personnel in the immediate interpretation of clinical data (and related trends), increasing accuracy and reducing diagnosis time and developing Clinical Decision Support System (CDSS) [36];
3. **personalisation of treatments**: By analysing patients' clinical data, AI will be able to help develop tailored treatment plans, improving the effectiveness of therapies and reducing side effects;
4. **research and development**: AI will facilitate and accelerate the analysis of vast data sets to discover new correlations and insights, accelerating scientific research and the development of new drugs and treatments.

6.3 EDS-FSE 2.0 data access for secondary use

As mentioned in previous chapters, the prospects for data-driven innovation in life sciences research are unprecedented in both scale and significance, offering transformative potential for advancing healthcare and global well-being [4, 12, 14, 15, 23, 31, 57]. Yet, the realisation of this potential remains constrained by persistent structural barriers in standardised and readily accessible health data access [25]. This proposed architecture aims to enable the secondary use of clinical data which will be collected in the FSE 2.0, in accordance with the provisions of the Ministry of Health Decree of 31 December 2024 (EDS), using HL7 FHIR as the reference standard. This solution is designed for asynchronous data usage only and therefore would still not support synchronous operations or real-time data processing, but could represent a first step to improve health data access in Italy for research purposes.
It is based on a logical and technological chain articulated into seven consecutive phases (summarized in Fig 12 below), ranging from the extraction of primary data to the delivery of aggregated and anonymised results to an authorised subject.

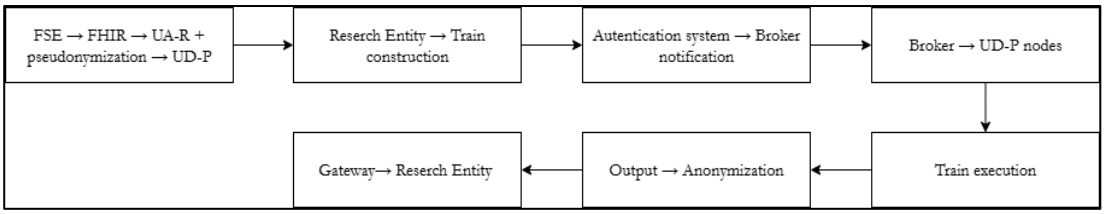

Figure 15 Diagram chain of FSE 2.0 secondary use data access

In more detail:

1. The process begins with the extraction of clear-text clinical data from the regional FSE systems. These data, originally represented as structured clinical documents (typically in CDA R2 format), are converted into granular and computable FHIR resources, such as *Condition*, *Observation*, and *Procedure*. This conversion takes place within the UA-R, which constitutes the boundary for clear-text data processing within the EDS. In this phase, the data are also pseudonymized through the removal of direct identifiers and the assignment of a non-reversible pseudonym code linked to a specific subject. The transformed and pseudonymized data are then transferred to the UD-P, which serves as the central infrastructure for storing datasets intended for analytical use. Although the UD-P is structurally unified at the national level, it is logically partitioned by Region or Autonomous Province, thereby ensuring data ownership and territorial segregation.

2. Once the data are available in the UD-P, the proposing entity becomes involved: an authorized organization, such as an IRCCS, a ministerial agency, or a university, intending to conduct a clinical, epidemiological, or operational analysis. This entity prepares what is referred to as a **Train** [37], an autonomous and portable computational unit composed of three key elements:
    a. a clinical query expressed in Clinical Quality Language (CQL), an HL7 standard designed to formally and computably query FHIR resources;
    b. an analysis script, typically written in Python or R, responsible for performing statistical operations on the extracted data (e.g., computing averages, running regression models, or performing clustering);
    c. a metadata file that describes the identity of the proponent, the purpose of the request, the resources involved, and the applicable regulatory constraints.

    The Train is then structured within an **isolated computational module**, ensuring its executability across heterogeneous environments and consistent behaviour during execution, in line with the principles of federated computation.
3. The constructed Train is transmitted through a secure channel to the **EDS user authentication and authorization system**, which plays a crucial role in access control. This module, already provided for within the EDS infrastructure, is responsible for verifying the identity of the requesting party and its authorization to process data. It examines the Train's metadata to assess its legitimacy (e.g., compliance with authorized roles), the declared purpose (e.g., research, governance, planning), and its alignment with the access rules defined by the normative framework. If the request is approved, it is logged for audit purposes and a notification is sent to the **EDS Broker**, which acts as the orchestrator for the next phase.
4. The Broker is responsible for analysing the metadata contained in the Train and determining which regional partitions of the UD-P hold the clinical data relevant to the analysis. This process is performed by comparing the criteria defined in the Train with the metadata stored in the pseudonymized repositories. Only the relevant UD-P nodes receive the Train, which is executed exclusively where necessary, thus minimizing the risk of unjustified access. Transmission occurs through secure and traceable internal EDS channels. Each receiving UD-P node prepares the local execution environment required to process the Train.
5. Within each receiving UD-P node, the isolated computational module is executed. The CQL query directly interrogates the local pseudonymized FHIR database, extracting the subset of data consistent with the specified criteria. The resulting dataset is then processed by the analysis script, which performs the required computational

operations. The output of this phase, still potentially linkable to specific individuals, is immediately subjected to a **pre-anonymization processing phase**.

6. In accordance with the provisions of Annex B of the EDS Decree, anonymization is performed using established techniques such as **k-anonymity**, **l-diversity**, and **t-closeness**, which ensure protection against both direct and indirect re-identification attacks. If the analysis involves multiple UD-P nodes, the anonymized results are securely and consistently aggregated to produce a unified, non-identifiable dataset.
7. The final phase involves the delivery of the anonymized and aggregated result to the requesting entity via the **national EDS Gateway**. This component acts as the system's output interface, ensuring that data leave the Ecosystem perimeter only in a form that fully complies with requirements for security, anonymity, and traceability. The entire process is monitored through access logs and auditing tools, to ensure compliance with governance policies and informed consent requirements.

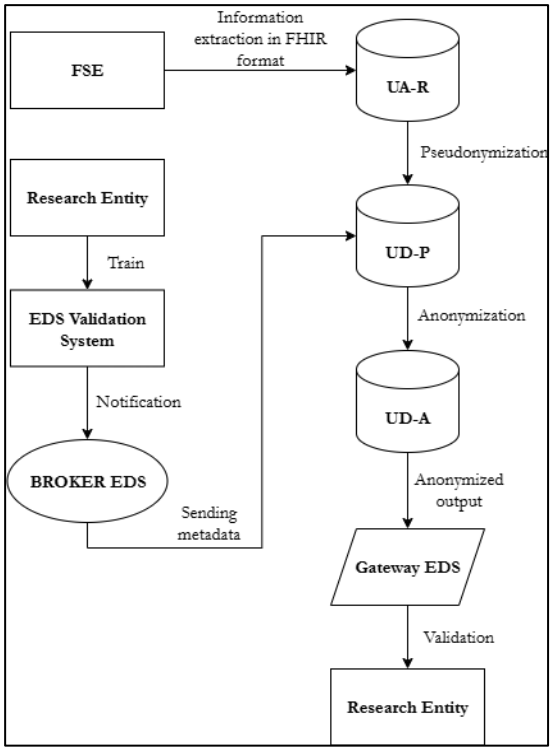

Figure 16 Architectural proposal for FSE 2.0 data access for secondary usage

A prototype using Figma[41] collaborative platform has been developed and is accessible at the following URL https://www.figma.com/proto/BIzyd4VAHd4BMmp0KKlkJ9/Portale-Sanit%C3%A0?page-id=1%3A32&node-id=4-13220&p=f&viewport=-

41 https://www.figma.com/

48%2C283%2C0.19&t=ePops8edgcdrpa4A-1&scaling=scale-down&content-scaling=fixed&starting-point-node-id=4%3A13220&show-proto-sidebar=1

Below screenshots of the developed prototype:

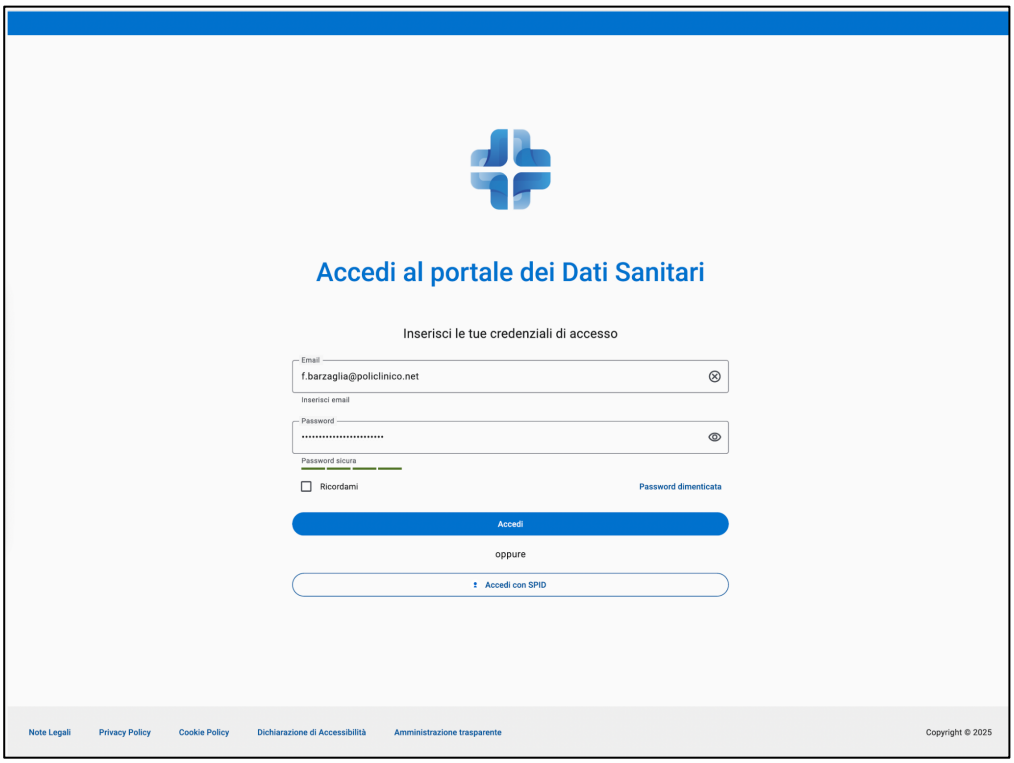

Figure 17 Screenshot 1 User Interface prototype - data access for secondary usage

Access login-in page – strong authentication process – including Italian eIDAS [42] and SPID[43] - to enable data protection, security and user profiling

42 https://www.eid.gov.it/it
43 https://spid.governo.it/?relayState=8x1000

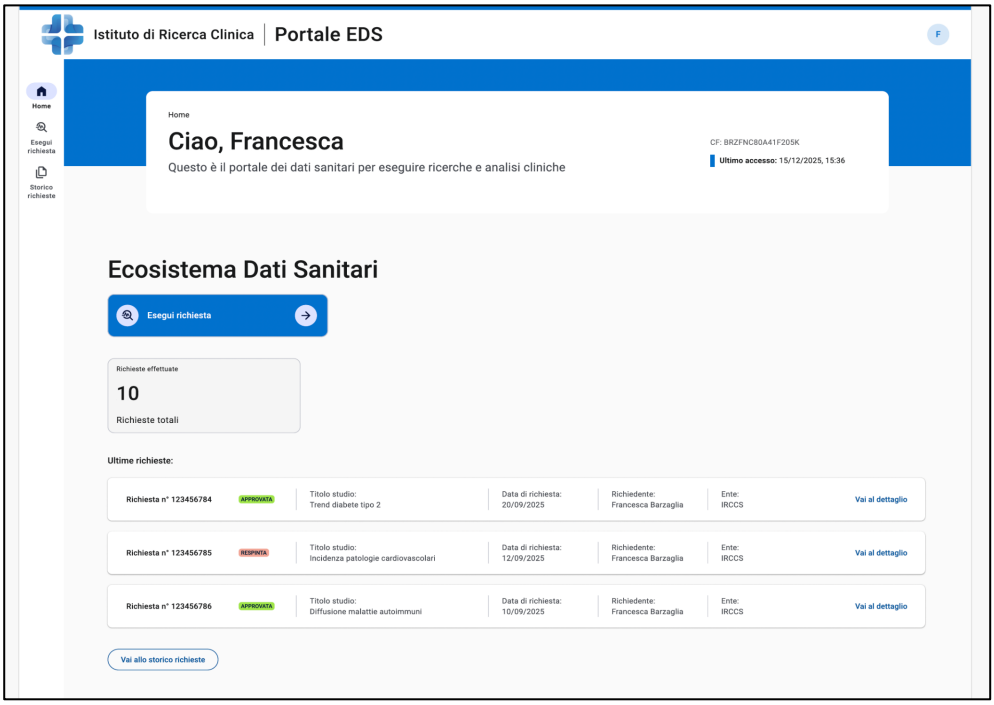

Figure 18 Screenshot 2 User Interface prototype - data access for secondary usage

Personal researcher profile area: contains list and access to previous requested and accessed dataset

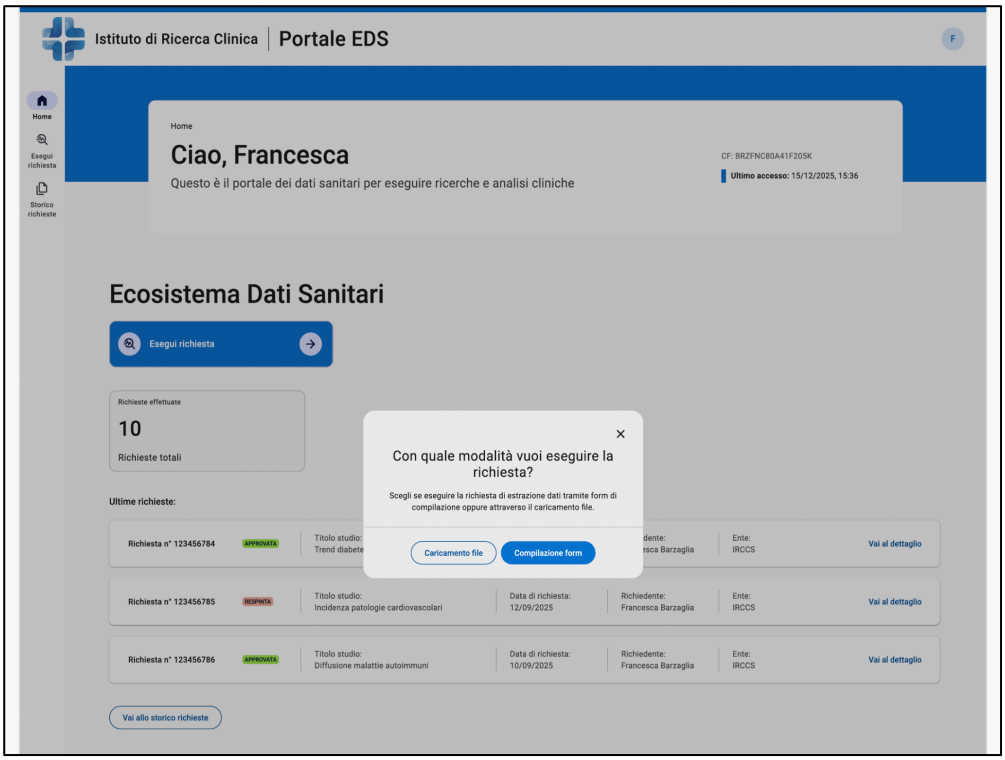

Figure 19 Screenshot 3 User Interface prototype - data access for secondary usage

Access request and choice of type of query

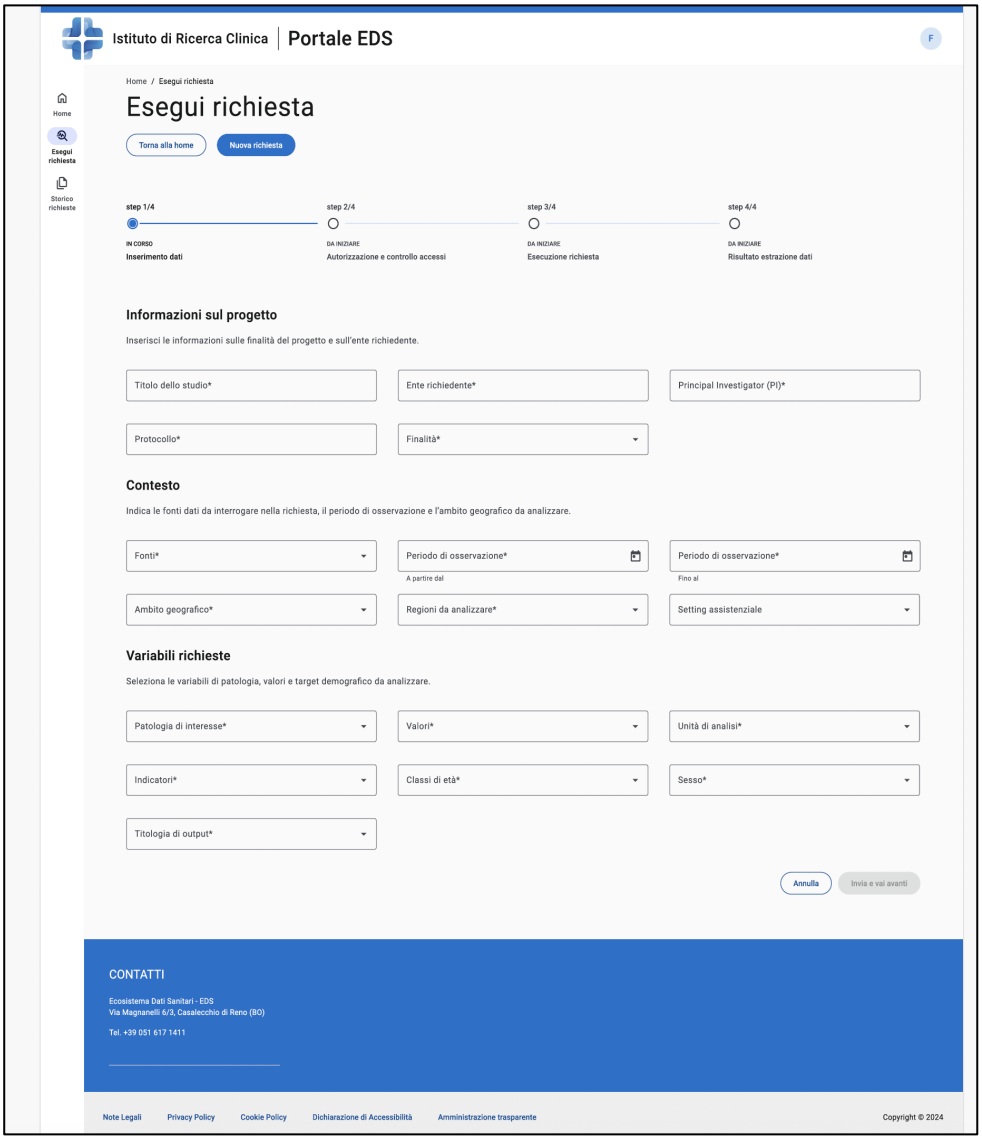

Figure 20 Screenshot 4 User Interface prototype - data access for secondary usage

Request form: includes project detains and fields to enable audit and authorisation

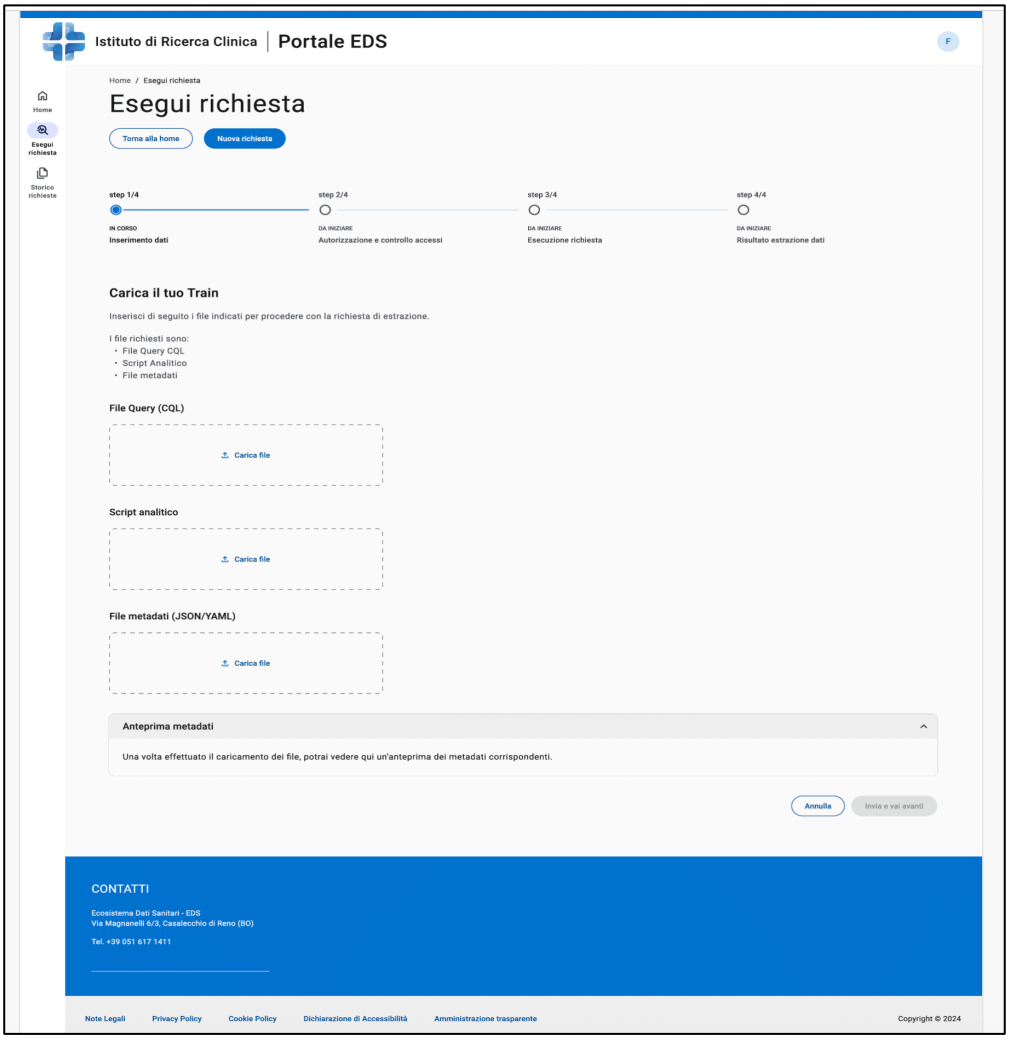

Figure 21 Screenshot 5 User Interface prototype - data access for secondary usage

Query form to upload train (pertinent UD-P) and choose output formats

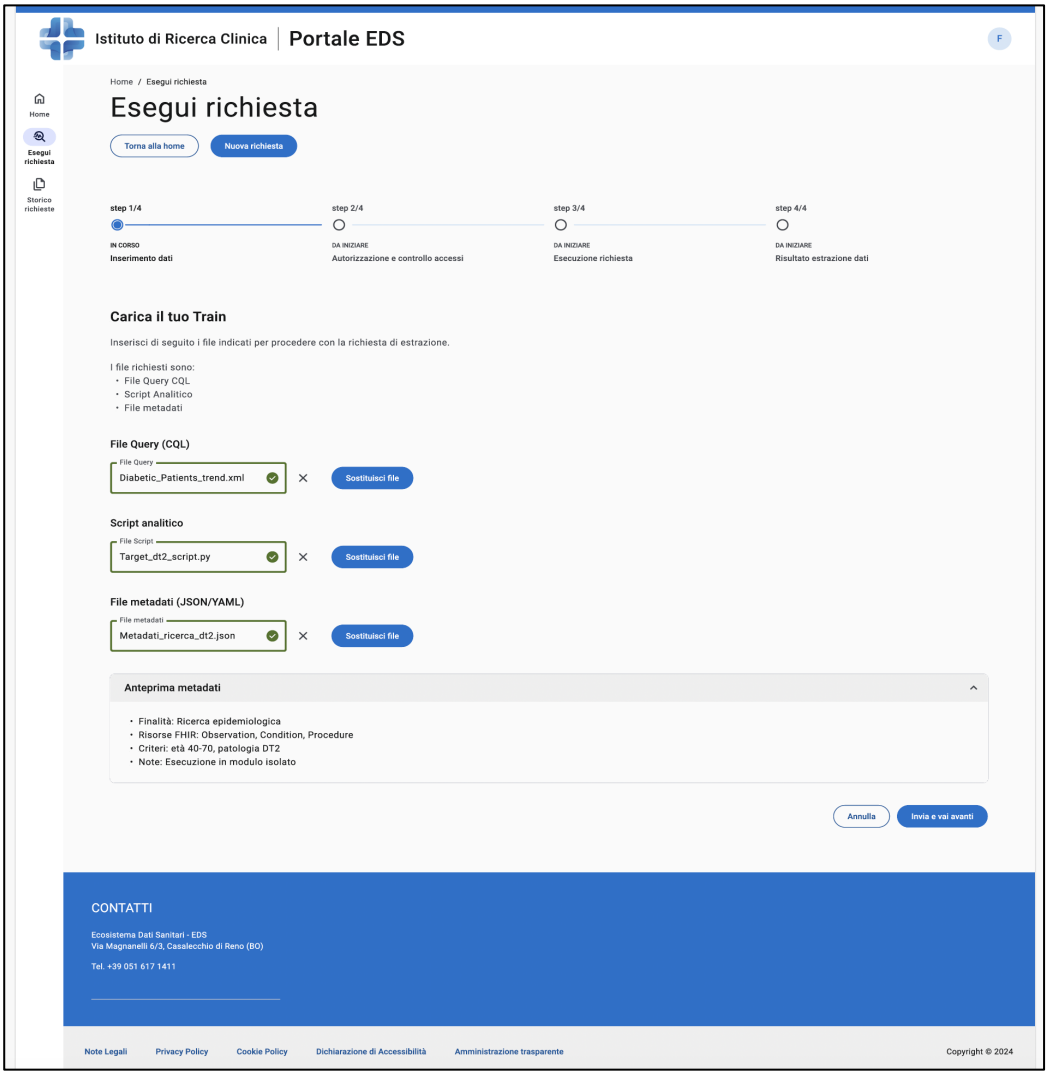

Figure 22 Screenshot 6 User Interface prototype - data access for secondary usage

Query form completed

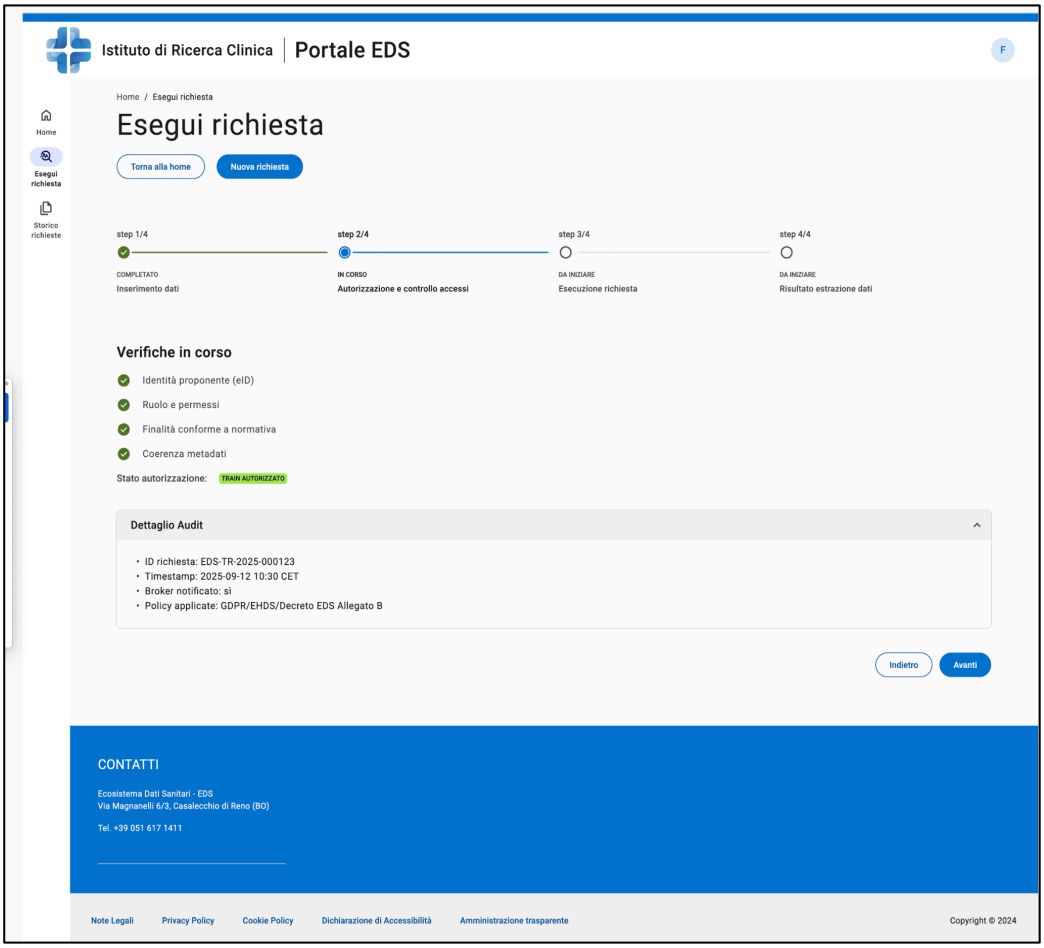

Figure 23 Screenshot 7 User Interface prototype - data access for secondary usage

Check and authorisation page

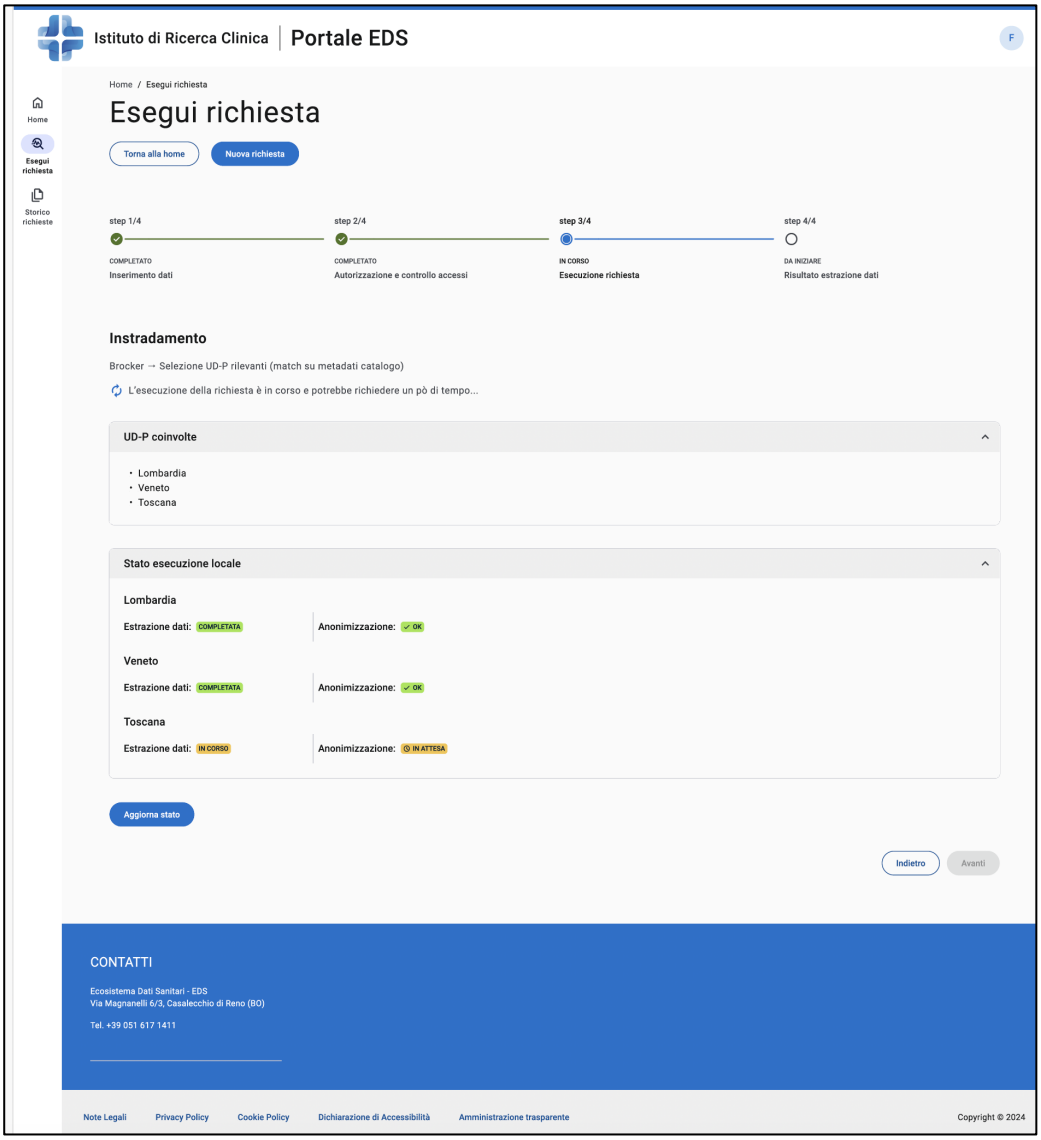

Figure 24 Screenshot 8 User Interface prototype - data access for secondary usage

Output page – data processing by Broker

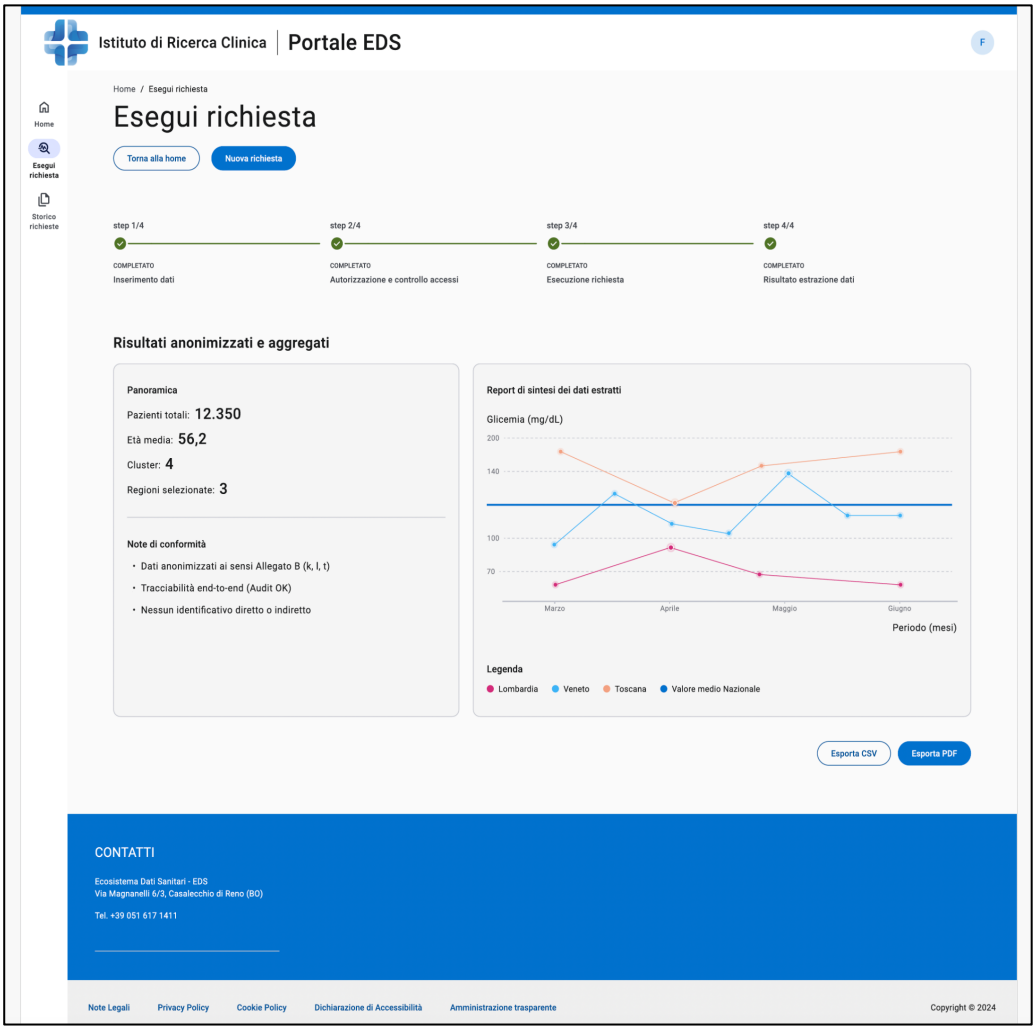

Figure 25 Screenshot 9 User Interface prototype - data access for secondary usage

Output page with anonymised and aggregated results: dashboard and results

6.3 User Experience, Accessibility and Awareness

One of the main problems that have hindered adoption and correct implementation of the initial FSE 1.0 has been the scarce awareness and support of healthcare professionals and the low citizens' usage, also due to poor user experience and friendliness of usage [9, 18, 27, 33, 52]. In order to ensure optimal adoption of the news HIS (FSE 2.0 + EDS) the research proves that is will be crucial to invest in the improvement of the FSE 2.0 user experience for both healthcare professionals and patients, with the aim of ensuring:

a) the provision of a **single digital touchpoint** to which they can refer for all their information and interaction needs with their local health system of reference/affiliation;
b) **intuitive navigation of the FSE 2.0 and EDS web services** for all users;
c) **immediate and easy search for data, information and documents**;

d) **interaction that is fluid**, **reactive** (providing immediate answers to information requests expressed by Users) and **proactive** (through the sending of timely and useful notifications to users with respect to updated data, information and services of interest).

In order to achieve the above-mentioned objectives, a transformative pathway coordinated at a central should be activated in order to ensure that each Region adopts the following:

a) **Responsive Design**: Implementation of a design that ensures optimal visualisation of the FSE 2.0 web services on different sizes devices, such as smartphones, tablets and desktops, improving user experience on all platforms;
b) **Intuitive Navigation**: Designing a clear and consistent information architecture and navigation structure, with well-organised menus and logical paths, facilitating quick access to the desired information;
c) **Systematically check FSE web portals compliance with accessibility guidelines**, ensuring that the all FSE 2.0 web services comply with the Web Content Accessibility Guidelines (WCAG) 2.0[44] that define international standards for web content accessibility.
d) **Compatibility with Assistive Technologies**: Systematic check that FSE web services are compatible with tools such as screen readers, screen magnifiers and voice commands, to support users with visual or motor disabilities;
e) **Usability and Accessibility**: Regularly conducting tests with real users, including those with disabilities, to identify and correct any barriers in interacting with FSE 2.0 web services;
f) **User Feedback**: Implementation of mechanisms to receive users' feedback, promoting a continuous improvement process based on users' needs.

The successful deployment of FSE 2.0 depends not only on the technological infrastructure put in place, but also on the ability of FSE users - citizens and health professionals - to understand, use and exploit the digital tools made available to them [27, 52].

To this end, the NRRP national project has provided for a digital skills, training and communication campaign aimed at health professionals in the NHS to ensure adequate awareness-raising and digital upskilling of health personnel for a targeted and widespread use of the new FSE 2.0.

Following findings of this research it is deemed crucial the activation of short and long term campaigns of communication, training and engagement of healthcare professionals and

44 https://www.w3.org/TR/WCAG20/

citizens, to ensure a correct, targeted, systematic and homogeneous supply and consultation of the new FSE 2.0/EDS throughout the country.

With specific reference to healthcare professionals, it is proposed to design and implement medium- to long-term digital upskilling paths as follows:

a) activate **- in each Region - 'permanent' training models for the healthcare personnel** to promote correct and widespread use of the technologies made available to support clinical and healthcare processes;
b) design **customised training plans and contents** for each category of professional users (e.g. GPs/PLSs, First Aid Medical Staff, Oncologists, Territorial Care Nurses, etc.) with self-assessment sessions;
c) use **innovative, "engaging" and micro-learning didactic tools** that allow the individual health professional to benefit from the training contents (e.g. training video-pills, tutorials, podcasts usable in synchronous mode, also through mobile devices);
d) design **operational models of communication and engagement** involving all stakeholders (e.g. training structures, communication and human resources of the health care companies, associations and professional representations of GPs/PFCs, etc.) with the aim of maximising the level of interest and degree of participation in the training programmes;

With specific reference to Citizens, it is proposed to design and implement **medium- to long-term digital engagement & upskilling paths** in order to:

a) **increase the level of awareness** with respect to the digital health services provided by FSE 2.0;
b) promote **innovative, "engaging" and micro-learning teaching tools** that allow citizens to benefit from training contents (e.g. training video-pills, tutorials, podcasts usable in synchronous mode, also through mobile devices);
c) spread of **periodic multi-channel information campaigns**, with the aim of maximising the level of interest of citizens in the digital upskilling programmes made available to them;
d) establish **digital centres** for assisted activation, use and consultation of the FSE 2.0 and EDS services among low digital-skills users (eg. Elderly users).

7. CONCLUSIONS

The transition from Electronic Health Record 1.0 to EHR 2.0 represents a strategic milestone in the digitalisation of Italy's National Health Service (SSN). This dissertation has attempted to demonstrate that the new model is not to be considered a mere technical upgrade, but rather a systemic reform that addresses long-standing challenges and must pave the way for more interoperable and value-oriented data governance in healthcare.

The research conducted has sought to analyse, model and propose actionable solutions for the evolution of the Italian Electronic Health Record (FSE) into its second generation, FSE 2.0, in synergy with the more recently established Health Data Ecosystem (Ecosistema Dati Sanitari – EDS) and in alignment with the European Health Data Space (EHDS). What has emerged clearly is that the transition from FSE 1.0 to FSE 2.0 cannot be deployed as a mere technical adjustment, but rather as a structural and systemic reform of the Italian National Health Service (Servizio Sanitario Nazionale – SSN), with profound implications for its governance, clinical practice, patients' empowerment, and health-data access to advance medical research.

By tracing the limits of FSE 1.0, characterised by regional fragmentation, heterogeneous standards and low levels of adoption, this study has shown how digital health infrastructures are deeply intertwined with organisational, policy, and cultural dimensions. The modelling of workflows and architectures has clarified how technical obstacles such as poor interoperability and non-standardised ontologies were amplified by governance fragmentation and asymmetries and uneven capacities across regions. These insights have reinforced the notion, already stressed in cited international literature, that digital health is as much a matter of institutional design and stakeholder engagement as it is of technology.

The research has also attempted to demonstrate that the Italian case is emblematic of broader European challenges. As noted in the European Commission's 2022 proposal for the EHDS, the capacity to ensure reliable access to health data for both primary and secondary use is a precondition for achieving equitable, sustainable and innovative healthcare systems. The Italian NRRP has provided an unprecedented opportunity, in terms of available financial resources, to bridge structural gaps and consolidate a national infrastructure for health data, but its success will depend on the ability to enforce standardisation, sustain investments over the time, and maintain stakeholders trust.

In this thesis I have tried to integrate perspectives from computer science, health management and public policy. From a methodological point of view, the combination of technical modelling, policy and legal analysis, with stakeholder interviews had the intent to produce a

multidisciplinary approach capable of generating insights that are both theoretically robust and practically implementable. On the academic level, the thesis wants to provide a contribution by presenting a structured analysis of the interoperability barriers and architectural requirements for a national Italian EHR and HIS aligned with European strategies. On the applied level, the proposals resulted from this research, which are fully aligned with the developed national guidelines and relevant legislation, intend to provide a set of actionable solutions on four important strategic and complementary axes, to make the deployment of the new Italian HIS possibly successful:

a) the **design and implementation of innovative "data-driven" digital health services** - and enabled by the EDS, a key component of the FSE 2.0 digital ecosystem - that are conceived (and co-designed) according to the needs of each "key" category of FSE users (e.g. Citizens, Health Professionals, National and Local Health Authorities)

b) a concrete improvement of **the usability and accessibility of the FSE web services**, with the aim of ensuring a user experience of digital health services that truly simplifies both citizens' lives and healthcare professionals' work;

c) the adoption, throughout the country, of targeted **integration** measures **between the software (electronic medical records) adopted by GPs and PLSs and the new FSE 2.0**, with the aim of fostering **an agile, structured, automated and systematic compilation of the FSE 2.0 Patient Summary**, making the latter a useful tool that is really used by the entire 'network of professionals' who take charge of the individual patient;

d) **a concrete and continuous increase of digital skills**, which represent *a conditio sine qua non* for an efficient use of digital health tools and platforms centred on FSE 2.0 and EDS.

Additionally, this dissertation presents an operational model for the secondary use of FHIR-based health data. Based on federated computation and robust pseudonymization workflows, the proposed seven-phase chain ensures GDPR compliance while enabling large-scale clinical, epidemiological, and policy-relevant analysis.

The interviews conducted with institutional actors, healthcare professionals, and regional authorities have highlighted that the future of FSE 2.0 will be decided not only by the robustness of its technical infrastructure, but also by the degree to which stakeholders are engaged and trained. Healthcare professionals emphasised the importance of integration into

daily workflows, while policymakers stressed governance clarity. Patients need to remain at the centre of the system: their consent, awareness, and trust are fundamental for the actual functioning of FSE 2.0 and EDS. Without this trust, even the most advanced infrastructures risk remaining underutilised.

Another contribution this research has attempted to provide is in showing how FSE 2.0 and the EDS should be understood (and deployed) as a socio-technical ecosystem. The value of these infrastructures lies in their ability to generate services: new services for patients and medical doctors, predictive models powered by artificial intelligence, epidemiological monitoring dashboards, planning tools for national and regional health authorities, and new data access platforms for biomedical research. This ecosystemic perspective resonates with the FAIR principles for data management, which emphasise findability, accessibility, interoperability, and reusability as prerequisites for a sustainable data economy in science and healthcare.

Looking forward, hopefully the results of this research will be able to have some impact to the current implementation phase. At the national level, Italy faces the challenge of ensuring that the results achieved by the 2026 NRRP deadline will not only be "on paper", but will end in a functioning and trusted new FSE 2.0. This will require continuous investment in infrastructure, mandatory compliance with interoperability standards (HL7 FHIR, CDA2) and robust governance mechanisms involving the Ministry of Health, MEF, AGENAS and regional authorities. At the European level, the interconnection with the EHDS will be decisive, both for ensuring cross-border health data portability and for positioning Italy as an active contributor to the European digital health ecosystem. The challenge, in the post-NRRP phase, will be to transform this new Italian HIS into a transparent, accessible, widespread digital infrastructure, fully fed by the whole healthcare chain and centred on the real needs of patients and healthcare professionals. Ultimately, the success of the new Italian HIS and the new FSE 2.0 joint with EDS will lie in its ability to recognise that health data is a collective good, fuelling an equitable, innovative, and resilient digital health system centred on real user needs.

At the same time, new avenues of research and innovation emerge. Artificial intelligence and machine learning promise to generate augmented services from the FSE 2.0 data streams, but they also raise ethical and technical challenges, including algorithmic bias, explainability, and the need for representative datasets. The capacity of the system to enable personalised medicine and advanced epidemiology will depend on the quality, completeness, and semantic standardisation of the data it collects. Moreover, the governance of secondary data use requires continuous dialogue between data protection authorities, researchers, and citizens, to balance innovation with personal data protection.

Finally, the research results have also highlighted the crucial role of training and public awareness in the actual adoption of digital transformation in public services. A successful deployment of FSE 2.0 requires healthcare professionals to embrace new digital tools in their daily practice, patients to recognise the benefits of accessing and controlling their own health information, and institutions to foster a culture of transparency and accountability. This perspective makes it clear that FSE 2.0 is not just a technological project but it is a national system that could help reshaping the relationship between the state, healthcare providers, and patients around the shared public asset of health data.

GLOSSARY

Abbreviation	Definition
ACN	Agency for National Cybersecurity
AGENAS	National Agency for Regional Health Services
AgID	National Agency of Digitalization
AI	Artificial Intelligence
ANA	National Register of Assisted Person
API	Application Programming Interface
CDA	Clinical Document Architecture
CDA2	Clinical Document Architecture Release 2
CDSS	Clinical Decision Support System
CQL	Clinical Quality Language
DAAS	Data-as-a-service
DGA	Data Governance Act
DPIAs	Data Protection Impact Assessments
DTD	Department of Digital Transformation
EDS	Health data Ecosystem
EHDS	European Health Data Space
EHR	Electronic Health record
EU	European Union
FHIR	Fast Healthcare InNteroperability Resource
FSE	Fascicolo Sanitario Elettronico
GDPR	General Data Protection Regulation
GPs	General Practitioners
HIS	Health Informations System
HL7	Health Level Seven
INI	National Infrastructure for Interoperability
IRCCS	Istituti di Ricovero e Cura a Carattere Scientifico
JSON	JavaScript Object Notation

Abbreviation	Definition
KPIs	Key Performance Indexes
LOINC	Logical Observation Identifiers Names and Codes
M6C2	Mission 6 Component 2
MEF	Ministry of Economy and Finance
ML	Machine Learning
NGEU	Next Generation EU
NHS	National Health Service
NRRP	National Recovery and Resilience Plan
PFCs	Pediatricians of Free Choice
PS	Patient Summary
RESTful	Representational State Transfer
RNF	National Pharmacovigilance Network
SIT	Territorial Information System
SLAs	Service Level Agreements
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
Sogei	Società generale d'informatica
SSN	Servizio Sanitario Nazionale
TS	Tessera Sanitaria
UA-R	Regional Archiving Unit
UD-A	Anonymized Data Unit
UD-P	Pseudonymized Data Unit
WCAG	Web Content Accessibility Guidelines
XML	Extensible Markup Language

INDEX OF FIGURES

FIGURE 1 ARCHITECTURE OF A REGIONAL FSE 1.0 20

FIGURE 2 INI ARCHITECTURE IN FSE 1.0 22

FIGURE 3 MISSIONS AND RELATED GOALS OF THE NRRP RETRIEVED 1 JULY 2025 AT HTTPS://WWW.ITALIADOMANI.GOV.IT/CONTENT/SOGEI-NG/IT/EN/HOME.HTML 29

FIGURE 4 INTER-ORGANIZATIONAL DEPENDENCY DIAGRAM 34

FIGURE 5 NEW FSE 2.0 SYSTEM COMPONENTS 35

FIGURE 6 ARCHITECTURE OF NEW FSE 2.0 36

FIGURE 7 FSE 2.0 GATEWAY STRUCTURE AND FUNCTIONS 39

FIGURE 8 STRUCTURE AND FUNCTIONS OF NATIONAL REGISTRY OF THE NEW FSE 2.0 41

FIGURE 9 OUTLINE OF THE NEW FSE 2.0 SERVICES 42

FIGURE 10 FSE 2.0 MEDICAL DOCTORS/PATIENTS INTERACTIONS FOR CLINICAL PURPOSES 43

FIGURE 11 FSE 2.0 PATIENT – SYSTEM INTERACTION FOR DATA ACCESS AND CONSENT MANAGEMENT 43

FIGURE 12 STRUCTURE AND FUNCTIONS OF EDS 51

FIGURE 13 EHDS GOVERNANCE AND INTEROPERABILITY FRAMEWORK AS RETRIEVED AT HTTPS://WWW.EHDS.IO/INDEX.HTML (1 JUNE 2025) 59

FIGURE 14 RESEARCH INTERVIEWS PROTOCOL 62

FIGURE 15 DIAGRAM CHAIN OF FSE 2.0 SECONDARY USE DATA ACCESS 79

FIGURE 16 ARCHITECTURAL PROPOSAL FOR FSE 2.0 DATA ACCESS FOR SECONDARY USAGE 81

FIGURE 17 SCREENSHOT 1 USER INTERFACE PROTOTYPE - DATA ACCESS FOR SECONDARY USAGE 82

FIGURE 18 SCREENSHOT 2 USER INTERFACE PROTOTYPE - DATA ACCESS FOR SECONDARY USAGE 83

FIGURE 19 SCREENSHOT 3 USER INTERFACE PROTOTYPE - DATA ACCESS FOR SECONDARY USAGE 83

FIGURE 20 SCREENSHOT 4 USER INTERFACE PROTOTYPE - DATA ACCESS FOR SECONDARY USAGE 84

FIGURE 21 SCREENSHOT 5 USER INTERFACE PROTOTYPE - DATA ACCESS FOR SECONDARY USAGE 85

FIGURE 22 SCREENSHOT 6 USER INTERFACE PROTOTYPE - DATA ACCESS FOR SECONDARY USAGE 86

FIGURE 23 SCREENSHOT 7 USER INTERFACE PROTOTYPE - DATA ACCESS FOR SECONDARY USAGE 87

FIGURE 24 SCREENSHOT 8 USER INTERFACE PROTOTYPE - DATA ACCESS FOR SECONDARY USAGE 88

FIGURE 25 SCREENSHOT 9 USER INTERFACE PROTOTYPE - DATA ACCESS FOR SECONDARY USAGE 89

INDEX OF TABLES

TABLE 1 MAIN CHALLENGES FOR HEALTH DATA ACCESS OF ITALIAN HIS 11

TABLE 2 EXAMPLES OF SECONDARY USE OF HEALTH DATA THAT CAN BE ACTIVATED BY FSE 2.0 WITH EDS 16

TABLE 3 MAIN LEGAL INSTRUMENTS OF THE ITALIAN NORMATIVE FRAMEWORK REGARDING THE ELECTRONIC HEALTH RECORD (FSE) 25

TABLE 4 COMPARISON FSE 2.0. VS. FSE 1.0 45

REFERENCE LEGISLATION

- Decree-Law No. 179 of 18 October 2012, converted with amendments by Law No. 221 of 17 December 2012 - Introduction of the Electronic Health Record (Fascicolo Sanitario Elettronico - FSE) in the Italian legal system.
- Decree-Law No. 69 of 21 June 2013, converted with amendments by Law No. 98 of 9 August 2013 - Urgent provisions for the relaunch of the economy, including the digitisation of healthcare services.
- Law No 232 of 11 December 2016 (Budget Law 2017), Articles 382 and 383 - Availability of data from the Health Tessera System in the FSE.
- Prime Ministerial Decree No 178 of 29 September 2015 - Pivotal regulation for the implementation of the FSE, minimum contents and interoperability modes.
- Decree of 4 August 2017 of the Ministry of Economy and Finance - Technical modalities for the interoperability of the FSE.
- Decree of 25 October 2018 - Amendments to the Decree of 4 August 2017 to update the technical modalities.
- Decree of 3 November 2020 - Methods for implementing the provisions of the 'Ristori Decree' (Decree-Law 137/2020).
- Decree-Law No 18 of 17 March 2020, converted with amendments by Law No 27 of 24 April 2020 - Measures to strengthen the NHS during the COVID-19 pandemic.
- Decree-Law No. 183 of 30 December 2020, converted by Law No. 21 of 26 February 2021 - Strengthening the digital health infrastructure.
- Decree 20 May 2022 - Adoption of the Guidelines for the implementation of FSE 2.0 within the NRRP.
- Decree 18 May 2022 - Integration of FSE core data.
- Ministry of Health Decree of 7 September 2023 - Organic update of the FSE 2.0 regulatory framework.
- Decree of the Ministry of Economy and Finance 17 October 2024 - Arrangements for making FSE available through the INI.
- Decree of the Ministry of Economy and Finance of 22 October 2024 - Amendments to Article 5-bis of the Decree of 4 August 2017.
- Regulation (EU) 2016/679 (GDPR) - Protection of Personal Data in the European Union.
- Regulation (EU) 2022/868 (Data Governance Act) - Secure data sharing in the EU.
- Regulation (EU) 2025/327 - Establishment of the European Health Data Space (EHDS).
- Directive (EU) 2022/2555 (NIS 2) - Network and Information System Security.

- AGID Guidelines No. 547/2021 - Standards for APIs, IT documents and cryptography.
- WCAG 2.0 Guidelines - International Standards for Web Content Accessibility

BIBLIOGRAPHY

[1] Ademola, Adetunji & George, Carlisle & Mapp, Glenford. (2024). Addressing the Interoperability of Electronic Health Records: The Technical and Semantic Interoperability, Preserving Privacy and Security Framework. Applied System Innovation. 7. 116. 10.3390/asi7060116

[2] Ait Abdelouahid, R., Debauche, O., Mahmoudi, S., & Marzak, A. (2023). Literature Review: Clinical Data Interoperability Models. *Information*, *14*(7), 364. https://doi.org/10.3390/info14070364

[3] Ali, W., Shafique, M. U., Majeed, M. A., Faizan, M., & Raza, A. (2020). A Review of Data Science and Big Data Computing. Asian Journal of Research in Computer Science, 6(3), 1- 11, https://doi.org/10.9734/ajrcos/2020/v6i330158

[4] Anam, and Haque, "Big Data Analytics in Health Sector: Need, Opportunities, Challenges, and Future Prospects", in Tanwar, P., Jain, V., Liu, C.-M. and Goyal, V. (Ed.) Big Data Analytics and Intelligence: A Perspective for Health Care, Emerald Publishing Limited, (2020) https://doi.org/10.1108/978-1-83909-099-820201006

[5] Arias, J. J., Taylor, J., & O'Sullivan, S. (2022). "Privacy and Security in Health Data: Challenges and Opportunities in the Era of Digital Health." Journal of Medical Internet Research, 24(1), e34467.

[6] Ayaz M. et al., (2023) «Transforming Healthcare Analytics with FHIR: A Framework for Standardizing and Analyzing Clinical Data,» Healthcare, vol. 11, n. 12, p. 1729, 2023.

[7] Bianchi, A., Di Marco, A., Marzi, F., Stilo, G., Pellegrini, C., Masi, S., Simeoni, M. (2023). Trustworthy Learning Predictions to Support Clinical Research and Decisions.

[8] Candiello A., Albarelli A., Cortesi A. (2012), Quality and impact monitoring for local eGovernment services. Transforming Government: People, Process and Policy, 6(1), pp. 112–125

[9] Casà, C., Marotta, C., Di Pumpo, M., Cozzolino, A., D'Aviero, A., Frisicale, E. M., Silenzi, A., Gabbrielli, F., Bertinato, L., & Brusaferro, S. (2021). COVID-19 and digital competencies among young physicians: are we (really) ready for the new era? A national survey of the Italian Young Doctors Association. Annali dell'Istituto Superiore Di Sanità, 57(1), 1–6. Retrieved from https://annali.iss.it/index.php/anna/article/view/

[10] Christensen D.V et al (2022), Neuromorph. Comput. Eng. 2 022501, doi.org/10.1088/2634- 4386/ac4a83

[11] Ciampi, M., Sicuranza, M., Esposito, A., Guarasci, R., De Pietro, G. (2017). A Technological Framework for EHR Interoperability: Experiences from Italy. In: Röcker, C., O'Donoghue, J., Ziefle, M., Helfert, M., Molloy, W. (eds) Information and Communication Technologies for Ageing Well and e-Health. ICT4AWE 2016. Communications in Computer and Information Science, vol 736. Springer, Cham. https://doi.org/10.1007/978-3-319-62704-5_6

[12] Conesa A., Beck S., Making multi-omics data accessible to researchers (2019) Sci Data 6, 251, 2019. https://doi.org/10.1038/s41597-019-0258-4

[13] Cordella A., Paletti A., (2019), Government as a platform, orchestration, and public value creation: The Italian case, Government Information Quarterly, Volume 36, Issue 4, 2019, 101409, ISSN 0740-624X, https://doi.org/10.1016/j.giq.2019.101409.

[14] Cortesi, A., Poggiani A. (2024). "Challenges in Health Information Systems: health data management and access for life sciences research". CISIM

[15] Dash, S., Shakyawar, S.K., Sharma, M. et al. (2019) Big data in healthcare: management, analysis and future prospects. J Big Data 6, 54, 2019. https://doi.org/10.1186/s40537-019- 0217-0

[16] Datta, P. (2020). Digital Transformation of the Italian Public Administration: A Case Study. Communications of the Association for Information Systems, 46, pp-pp. https://doi.org/10.17705/1CAIS.04611

[17] Datta, P.M. (2022). Digital Transformation in a Globalized World. In: Global Technology Management 4.0. Palgrave Macmillan, Cham. https://doi.org/10.1007/978-3-030-96929- 5_14

[18] De Benedictis A, Lettieri E, Gastaldi L, Masella C, Urgu A, et al. (2020) Electronic Medical Records implementation in hospital: An empirical investigation of individual and organizational determinants. PLOS ONE 15(6): e0234108. https://doi.org/10.1371/journal.pone.0234108

[19] de Mello, B. H., Rigo, S. J., da Costa, C. A., da Rosa Righi, R., Donida, B., Bez, M. R., & Schunke, L. C. (2022). Semantic interoperability in health records standards: a systematic literature review. Health and technology, 12(2), 255–272. https://doi.org/10.1007/s12553-022-00639-w

[20] Di Lorenzo A et al, (2023) One health system supporting surveillance during COVID-19 epidemic in Abruzzo region, southern Italy, One Health, Volume 16, 2023, 100471, ISSN 2352-7714, https://doi.org/10.1016/j.onehlt.2022.100471

[21] Dragoni, N., Giallorenzo, S., Lafuente, A. L., Mazzara, M., Montesi, F., Mustafin, R., & Safina, L. (2021). "Microservices: Yesterday, Today, and Tomorrow." Present and Ulterior Software Engineering: Special Issue on Healthcare Systems, 108, 75-103.

[22] El-Gazzar, R., & Ostërle, H. (2021). "Architectural Models for Cross-Organizational eHealth Systems: A Systematic Review and Research Agenda." Health and Technology, 11(4), 795-814.

[23] Fanelli S., Pratici L., Salvatore F., Donelli C, Zangrandi A, (2022) Big data analysis for decision making processes: challenges and opportunities for the management of health-care organizations, Management Research Review, May 2022, ISSN: 2040-8269

[24] Ferrari L., Gerardi G., Manzi G., Micheletti A., Nicolussi F., Salini S., (2020) COVID-Pro in Italy: A dashboard for a province-based analysis, University of Milan, Italy, https://doi.org/10.48550/arXiv.2004.12779

[25] Fillinger S., de la Garza L., Peltzer A., Kohlbacher O., Nahnsen S., (2019) Challenges of Big Data Integration in the Life Sciences in Analytical and Bioanalytical Chemistry 6791–6800. doi:10.1007/s00216-019-02074-9

[26] Foglia, M, (2020) Patients and Privacy: GDPR Compliance for Healthcare Organizations, Eur. J. Privacy L. & Tech. 43

[27] Fornes-Romero G., et al. (2020) Digital and innovation skills in health care professionals in Europe, European Journal of Public Health, Volume 30, Issue Supplement_5, September 2020

[28] Hallock H., et al. (2021) fhir

[29] Federated Networks for Distributed Analysis of Health Data. Frontiers in Public Health. 9. 10.3389/fpubh.2021.712569

[30] Hughes, N., Kalra, D. (2023). Data Standards and Platform Interoperability. In: He, W., Fang, Y., Wang, H. (eds) Real-World Evidence in Medical Product Development . Springer, Cham. https://doi.org/10.1007/978-3-031-26328-6_6

[31] Hussein R, Gyrard A, Abedian S, Gribbon P, Martínez S. (2025) Interoperability Framework of the European Health Data Space for the Secondary Use of Data: Interactive European Interoperability Framework–Based Standards Compliance Toolkit for AI-Driven Projects, J Med Internet Res 2025;27:e69813, DOI: 10.2196/69813

[32] Hussein R., Scherdel L., Nicolet F., Martin-Sanchez F., (2023), Towards the European Health Data Space (EHDS) ecosystem: A survey research on future health data scenarios, International Journal of Medical Informatics, Volume 170, 2023, ISSN 1386-5056, doi.org/10.1016/j.ijmedinf.2022.104949

[33] Karim M. R., et al. (2018), A distributed analytics platform to execute mchine-based phenotyping algorithms, in Semantic Web Applications and Tool for Healthcare and Life Sciences, vol. 1.

[34] Kawu AA, Hederman L, O'Sullivan D, Doyle J, (2023) Patient generated health data and electronic health record integration, governance and socio-technical issues: A narrative review, Informatics in Medicine Unlocked (2023), doi.org/10.1016/j.imu.2022.101153

[35] Lee, S., Xu, Y., D'Souza, A., Martin, E., Doktorchik, C., Zhang, Z. & Quan, H. (2020). Unlocking the potential of electronic health records for health research. International Journal for Population Data Science, 5(1). https://doi.org/10.23889/ijpds.v5i1.1123

[36] Lehne M, Sass J, Essenwanger A, Schepers J, Thun S. (2019) Why digital medicine depends on interoperability. NPJ Digit Med. 2019 Aug 20; 2:79. doi: 10.1038/s41746-019-0158-1. PMID: 31453374; PMCID: PMC6702215

[37] Lin, T.-H., Chung, H.-Y., Jian, M.-J., Chang, C.-K., Perng, C.-L., Liao, G.-S., Shang, H.-S. (2024). An Advanced Machine Learning Model for a Web-Based Artificial Intelligence–Based Clinical Decision Support System Application: Model Development and Validation Study. Journal of Medical Internet Research, 26(3), e56022.

[38] Marino, Alfonso & Pariso, Paolo & Landriani, Loris. (2020). E Health and Electronic Health Record: The Italian experience in the European Context. 10.21203/rs.3.rs-31655/v1.

[39] Migliorini, M., Hagen, J.S., Mihaljević, J., Mysiak, J., Rossi, J.-L., Siegmund, A., Meresercahliksetian, K. and Guha Sapir, D. (2019), "Data interoperability for disaster risk reduction in Europe", Disaster Prevention and Management, Vol. 28 No. 6, pp. 804-816

[40] Natali, David & Pavolini, Emmanuele & Terlizzi, Andrea. (2023). Multi-Level Governance Feedback and Health Care in Italy in the Aftermath of Covid-19. Politics and Governance. 11. 365–377. 10.17645/pag.v11i4.7356

[41] Obermeyer Z, Emanuel EJ. (2016) Predicting the future – Big data, machine learning, and clinical medicine. N Engl Journal Med. 2016; 375(13):1216-9

[42] Park, S. H., & Cha, W. C. (2022). Application Strategies for Artificial Intelligence– based Clinical Decision Support System: From the Simulation to the Real-World. Healthcare Informatics Research, 28(3), 185–187.

[43] Queralt-Rosinach, N., Kaliyaperumal, R., Bernabé, C.H. et al. (2022) Applying the FAIR principles to data in a hospital: challenges and opportunities in a pandemic. J Biomed Semant 13, 12. https://doi.org/10.1186/s13326-022-00263-7

[44] Reina, J., & Llorente, S. (2022). "Towards Interoperability in eHealth Systems: A Practical Approach Based on Standards and Best Practices." Journal of Biomedical Informatics, 127, 103988

[45] Rubin, H. J., & Rubin, I. S. (2012). Qualitative Interviewing: The Art of Hearing Data (3rd ed.). Sage.

[46] Rumbold, J. M. M., & Pierscionek, B. K. (2021). "The Effect of the General Data Protection Regulation on Medical Research." Journal of Medical Internet Research, 23(2), e23868.

[47] Rutledge, P.B. and Hogg, J.L.C. (2020). In-Depth Interviews. In The International Encyclopedia of Media Psychology, J. Bulck (Ed.)

[48] Schmitt, Tugce & Cosgrove, Shona & Pajić, Vanja & Papadopoulos, Kimon & Gille, Felix. (2023). What does it take to create a European Health Data Space? International commitments and national realities. Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen. 179. 10.1016/j.zefq.2023.03.011

[49] Slawomirski L. et al., (2023) "Progress on implementing and using electronic health record systems," OECD Publications https://doi.org/10.1787/4f4ce846-en

[50] TEHDAS, Second Joint Action Towards the European Health Data Space (2024) Available from: https://tehdas.eu/

[51] Thobani, S. (2024). "Verso il regolamento UE sullo spazio europeo dei dati sanitari (European Health Data Space)". Persona e Mercato, 1393-1399.

[52] Torab-Miandoab, A., Samad-Soltani, T., Jodati, A. et al. (2023) Interoperability of heterogeneous health information systems: a systematic literature review. BMC Med Inform Decis Mak 23, 18. https://doi.org/10.1186/s12911-023-02115-5

[53] Tsai, C. H., Eghdam, A., Davoody, N., Wright, G., Flowerday, S., & Koch, S. (2020). Effects of Electronic Health Record Implementation and Barriers to Adoption and Use: A Scoping Review and Qualitative Analysis of the Content. Life, 10(12), 327. https://doi.org/10.3390/life10120327

[54] Van de Wetering, R., Versendaal, J., & Zwetsloot, I. (2023). "An Integrated Health Information Architecture: Understanding Implementation Challenges and Critical Success Factors." International Journal of Medical Informatics, 171, 104999.

[55] Van Panhuis W.G., Paul P., Emerson C., Grefenstette J., Wilder R., Herbst A.J., Heymann D., Burke D.S. (2014), A systematic review of barriers to data sharing in public health. BMC Public Health, 14 (1), art. no. 1144 (2014). DOI: 10.1186/1471-2458-14-1144

[56] Wang Y, Kung L., Byrd T., (2018) Big data analytics: Understanding its capabilities and potential benefits for healthcare organizations, Technological Forecasting and Social Change, Vol- ume 126, 2018, Pages 3-13, ISSN 0040-1625,

[57] Wang, Y., Kung, L. A., Gupta, S., & Ozdemir, S. (2020). "Leveraging Big Data Analytics to Improve Quality of Care in Healthcare Organizations: A Configurational Approach." British Journal of Healthcare Management, 26(8), 221-232.

[58] Wilkinson, M., Dumontier, M., Aalbersberg, I. et al. (2016) The FAIR Guiding Principles for sci- entific data management and stewardship. Sci Data 3, 160018, doi.org/10.1038/sdata.2016.18

[59] Zarour, M., et al. (2021) Ensuring data integrity of healthcare information in the era of digital health. Healthc. Technol. Lett. 8, 66–77 https://doi.org/10.1049/htl2.12008