Finanziato dall'Unione europea NextGenerationEU
Ministero dell'Università e della Ricerca
Italiadomani PIANO NAZIONALE DI RIPRESA E RESILIENZA
Consiglio Nazionale delle Ricerche

FROM CONTROL TO SHARING: THE EVOLUTION OF EUROPEAN REGULATION ON BIOLOGICAL DATA AND THE ELIXIR EXPERIENCE¶

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NextGenIT
Consolidation of the Italian Infrastructure for Omics Data and Bioinformatics

ELIXIR-IT

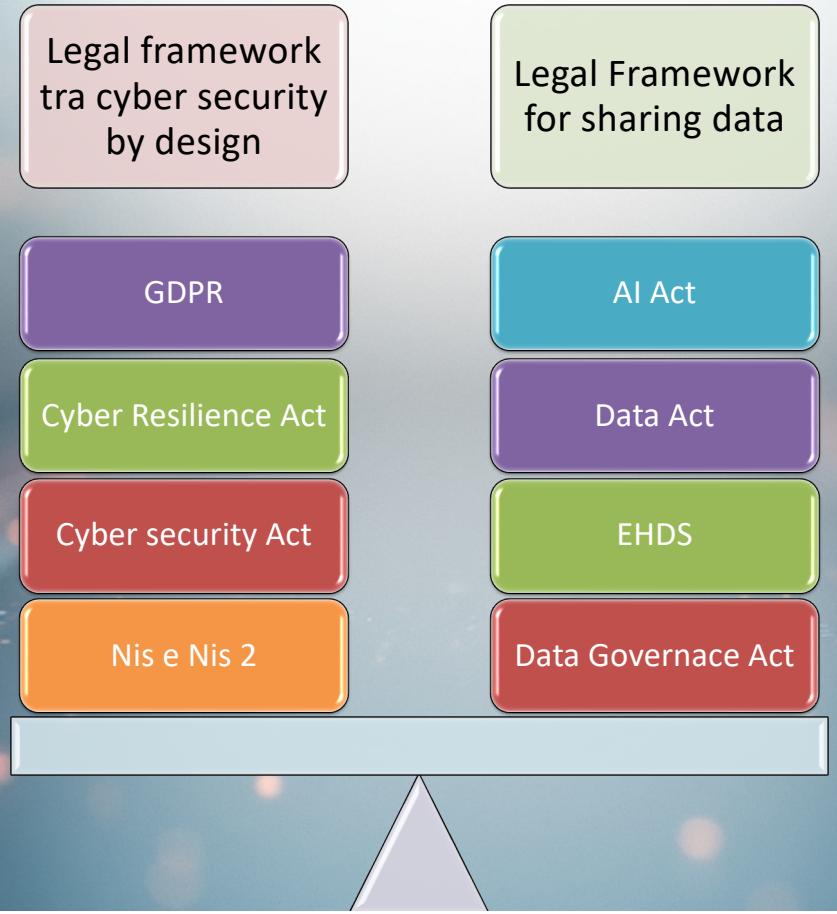
31 Members

The **Italian Node of ELIXIR (ELIXIR-IT)** is formally established as as a **Joint Research Unit (JRU)** through a specific agreement among the coordinating organization (National Research Council, CNR) and the other 30 members. Apart from the CNR, the largest public research institution in Italy, the other members are composed of Universities, and scientific and technological institutes that, in most cases are leaders in the country in their respective fields of expertise (e.g. CINECA and INFN in supercomputing, ISS in public health, GARR in IT infrastructure for research, TIGEM for rare diseases).

The **leading Institution** (**CNR**) has been designed by the Ministry of University and Research.

The **organisational layout** of the node has three layers: 1) policy and oversight; 2) coordination; and 3) operational. The General Assembly (GA), advised by an international SAB, is the main body of the Node, leaded by the HoN (designated by the President of CNR) and including delegates designated by the legal representatives of participating institutions. The coordination and operational layer, including the staff involved in all ELIXIR-IT activities includes both in-kind and full-time staff (about 20 FTE in 2023).

EU LEGAL FRAMEWORK



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HUMAN RIGHT AND OPEN SCIENCE

Open Access

Art. 15 International Covenant on Economic, Social and Cultural Rights

A new way of conducting research

- Budapest Declaration 2002,
- Bethesda 2003
- Berlino 2003

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PRINCIPLE OF DATA ALTRUISM (DGA)

1. What it is
   - Voluntary sharing of data — without receiving any reward — by individuals or organizations for general interest purposes (research, health, environment, public services, etc.).
   - The DGA formalizes this practice, providing a legal and secure pathway for the reuse of personal or non-personal data.

How it works
- Data altruism organizations: nonprofit entities, transparent, secure, respecting donors' rights.
- Consent / permission: data donors authorize reuse according to standardized European procedures.
- Purpose: data used for general interest objectives, e.g., scientific research, healthcare, public policies.

Importance for ELIXIR / data infrastructures
- Provides a stable and transparent legal framework for sharing sensitive data while protecting privacy and rights.
- Enables creation of large-scale data pools for genomic, epidemiological, and AI-driven analyses.
- Supports a federated, responsible, and collaborative governance model, aligned with FAIR principles and ethical data reuse.

DATA SHARING FOR RESEARCH & DATA ALTRUISM: KEY CHALLENGES (EDPB)

European Data Protection Board

1. “Anonymisation”

According to the EDPB, data can be considered truly anonymised only when re-identification of individuals becomes technically impossible in practice, even when combining multiple methods or datasets. This sets a very high threshold.

2. “Research purposes”

The EDPB often interprets “research purposes” as referring to a specific research project, meaning that the usual legal basis (typically consent) can only authorise the processing of personal data for that one clearly defined study, not for broad or future research uses.

NOT JUST LIGHTS: THE SHADOWS (AND RISKS) FOR PERSONAL DATA PROTECTION

- “Data controller” vs. “controller” under the GDPR;
- The DGA adopts a “proprietary” conception of data, which is, however, foreign to the GDPR’s understanding of personal data;
- Lack of coordination with the GDPR;
- Uncertain equivalence between pseudonymized and anonymized data (only the latter are excluded from the GDPR regime: Deloitte Judgment C-413/23 P (EDPS v. SRB));
- The concept of “data sharing” and its compatibility with the principles of privacy by design and by default;
- The regulation of “data altruism”: need for greater clarity in consent collection and in defining purposes.

SANDBOXES FOR RESPONSIBLE ARTIFICIAL INTELLIGENCE

1. “Regulatory sandboxes ”

Article 54 states that AI Act regulatory sandboxes: ‘***shall provide a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time***’

2. “What are the benefits and shortcomings of regulatory sandboxes? ”

Regulatory sandboxes make it possible to test new technologies transparently and contribute to evidence-based lawmaking. From a market actor perspective, one of the main benefits is the additional flexibility in terms of regulatory burden. In addition, the controlled environment of regulatory sandboxes is particularly accommodating to products and services that do not easily fit the traditional regulatory framework.

POSSIBLE POINTS OF CONFLICT

1. “Artice 54 of AI Act ”

Article 54 on the further processing of personal data provisions for developing certain AI systems in the public interest in the AI regulatory sandbox. Are these provisions intended to apply as lex specialis (and thus override the General Data Protection Regulation (GDPR)) or merely to complement the existing provisions in the data protection legislation?

2. “Digital Omnibus on AI - Proposal 19/11/2025”

the package includes a digital omnibus that streamlines rules on artificial intelligence (AI), cybersecurity and data, complemented by a Data Union Strategy to unlock high-quality data for AI and European Business Wallets that will offer companies a single digital identity to simplify paperwork and make it much easier to do business across EU Member States

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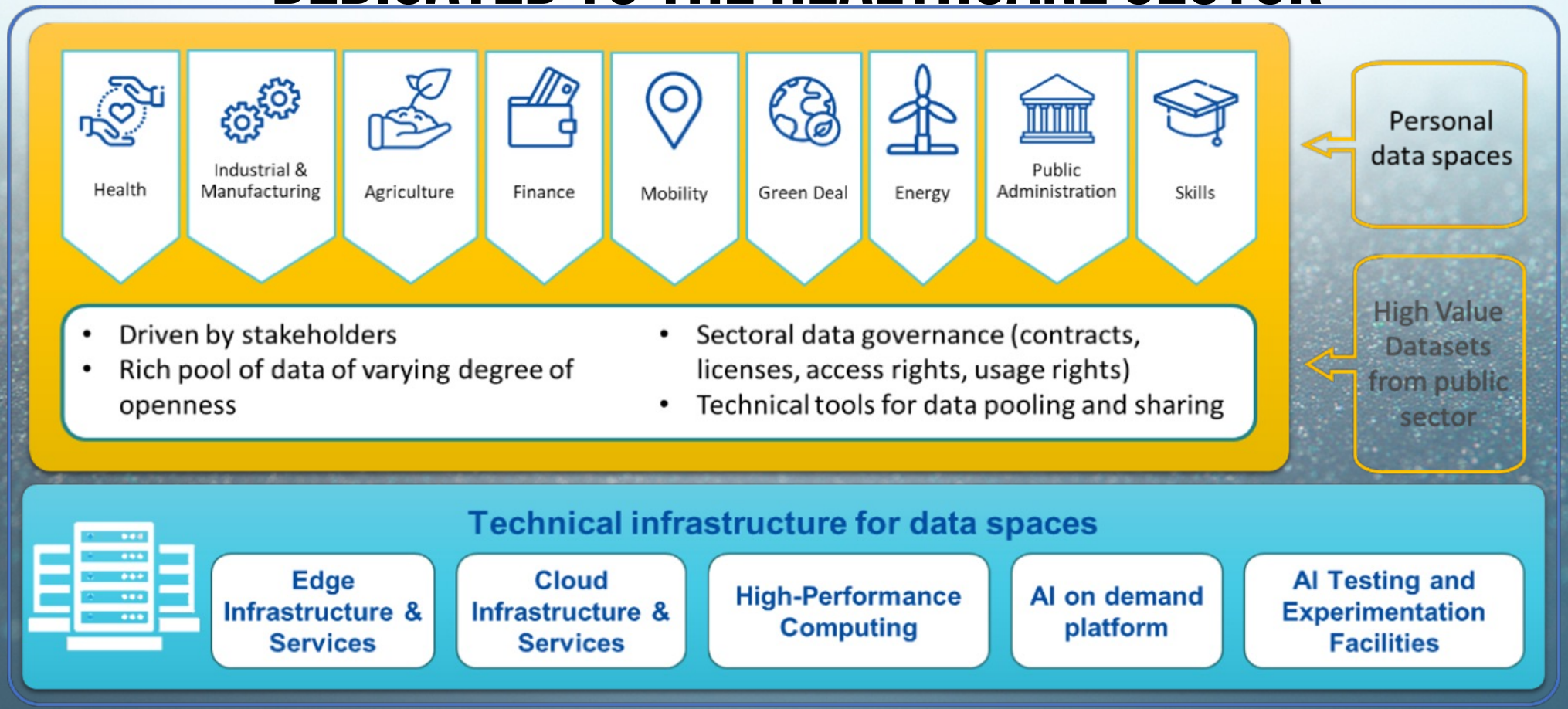
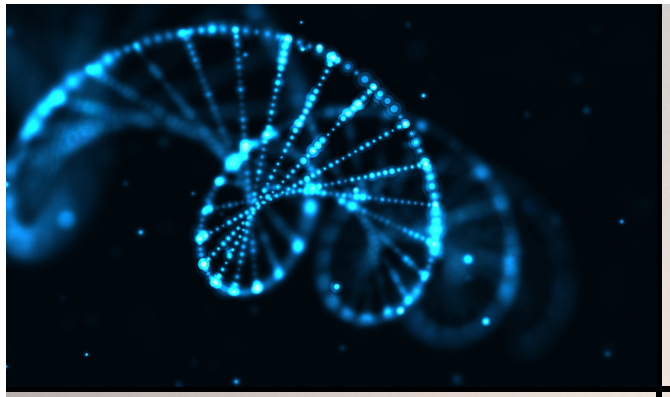
EHDS –THE FIRST EUROPEAN DATA SPACE SPECIFICALLY DEDICATED TO THE HEALTHCARE SECTOR





EHDS

Objective #1	to enable individuals to access, control, and share their electronic health data across borders in order to facilitate the provision of healthcare (primary use of data)
Objective #2	to enable the safe and trustworthy reuse of health data in areas such as research, innovation, policymaking, and regulatory activities (secondary use of data)
Objective #3	To promote a single market for electronic health record systems, supporting both primary and secondary use.

Project in which ELIXIR-IT is involved

European Genomic Data Infrastructure

Pillar I:

Governance: Decentralized with short-term and long-term models

Definition of Access Models

Definition of Access Policies

Connection with EHDS

EUROPEAN GENOME-PHE ARCHIVE

Objective

Privacy and Trust

FAIRness

Diversity

Definition of workflow for Access

B1MGplus **Input**

WP2: Stakeholder Engagement:

stablishing legal and policy frameworks:

Building long-term sustainability

Developing data standards:

GOE GENOME OF EUROPE **Objective**

- WP5 (ELSI Expert Group)
- Partecipazione WP4 Task 4.2 - ELSI checks subtask
- Metadata standards & Quality checks
- Clarify terminology
- Standard Operating Procedures (SOPs)
- Node task plans

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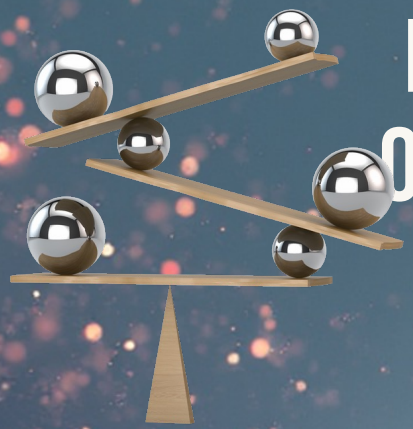

BALANCING LEGAL COMPLIANCE AND OPEN SCIENCE IN ACCESS TO ELIXIR-IT SERVICES

Compliance by Design
#1

Structured and Tiered Access
#2

Governace trasparente
#3

Modularity of Documentation
#4

Principle of “Open as Possible, Protected as Necessary”
#5

Technical Tools for Balancing
#6

Training and ELSI Support
#8

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Best Practices developed in the ElixirXNextGenIT project

WORKFLOW

Work Flow

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ELSI Web Cafè

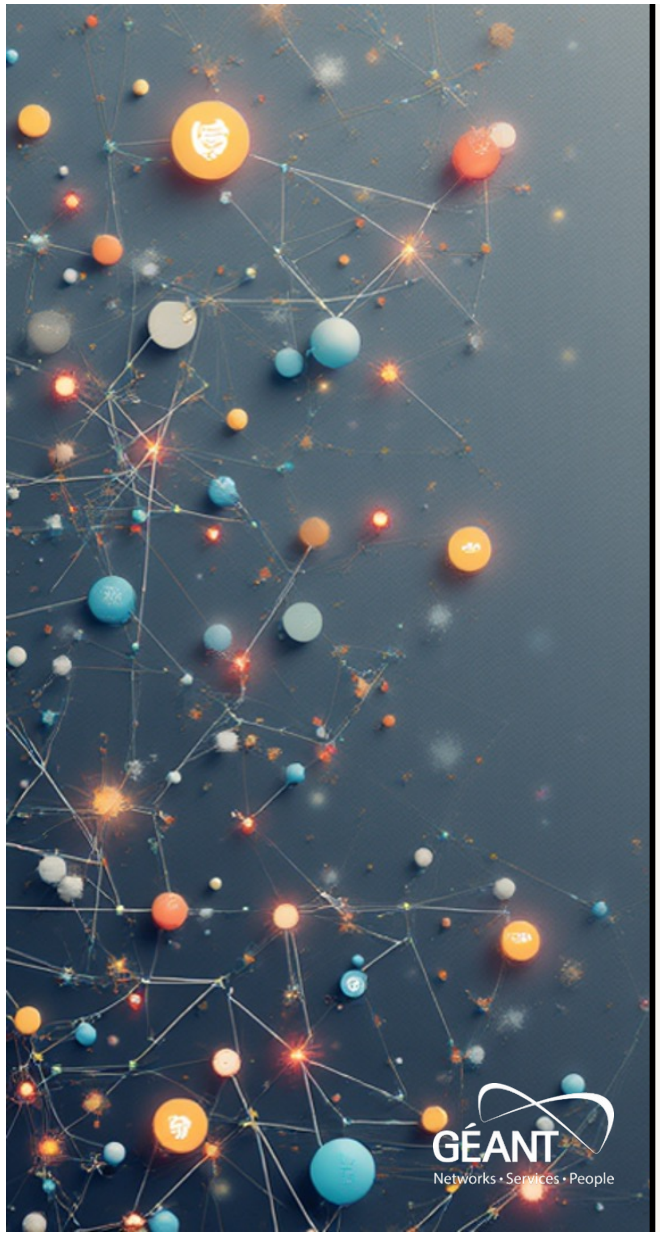
ELSI Web Cafè: Nuovo Appuntamento su *e Proprietà Intellettuale nell'Open Science.*

16 Giugno 2025 ore 10:30 | Online

Come bilanciare apertura e tutela dei diritti nella condivisione dei dati scientifici? Quali modelli di licenza adottare per garantire un uso trasparente e responsabile delle risorse digitali?

A queste domande risponderà il nuovo appuntamento del ciclo **ELSI Web Café**, intitolato *"Licenze e Proprietà Intellettuale nell'Open Science – Aspetti legali e modelli di licenza per l'accesso ai servizi di ELIXIR-IT"*, in programma il **16 giugno 2025 alle ore 10:30** su Zoom.

Il seminario, promosso da **ELIXIR-IT**, si rivolge a ricercatori, sviluppatori di servizi e data steward interessati a comprendere meglio i principali strumenti giuridici applicabili all'ambito dell'Open Science. L'incontro offrirà una panoramica



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