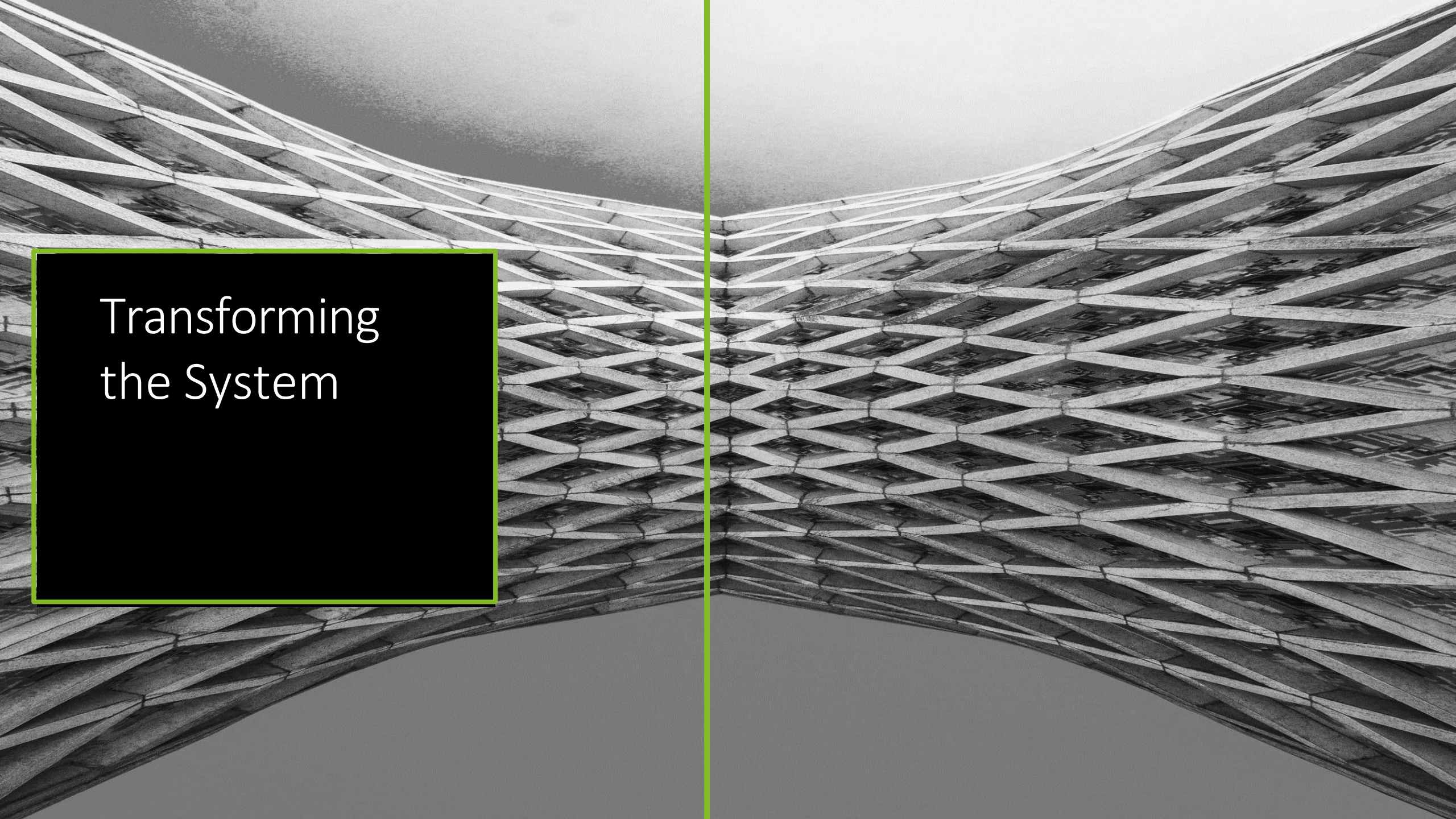

Transforming
the System

Enable Data Ecosystem

European Health Data Space provides a great opportunity for the country to make the leap-frog and drive value creation through extensive secondary data use

Current State

The upcoming establishment of the **EHDS provides a significant opportunity for Greece to modernize its health data governance** and capitalize on its emerging digital capabilities. As digitalization steadily advances, **investments in infrastructure and electronic registries are beginning to improve data availability, granularity and timeliness**.

To fully unlock this potential, Greece must now focus on building an integrated data ecosystem—one that includes **central governance mechanisms, clear access frameworks and a common technical architecture** across all healthcare stakeholders. This would not only ensure **alignment with European standards** but also create the **basis for a structured and secure secondary use of data.** Importantly, doing so **could establish a new revenue stream for the system**, as structured health data becomes a valuable asset for research, innovation, and strategic planning.

A major contributor to the **current underutilization** of health data remains the **fragmentation of information systems**, coupled with limited interoperability and non-standardized input protocols. These issues **reduce both data quantity and quality**, inherently lowering its value. Additionally, multiple public entities, such as EOPYY, EKAPY and IDIKA, hold data across different segments of care, without a unified access or governance model, further complicating structured and timely data use.

Why it is important

Leveraging the opportunity that EHDS presents and building a **centralized data access** hub is essential for building **a modern, transparent, and investment-ready healthcare system.**

A streamlined, accessible health data ecosystem is a **critical enabler of innovation**. For pharmaceutical and life sciences companies, access to robust real-world data (RWD) is a key factor in investment decisions Greece risks missing out on opportunities to position itself as a **hub for research and digital health development**, as well as leveraging **potential revenue streams** from providing value to the ecosystem.

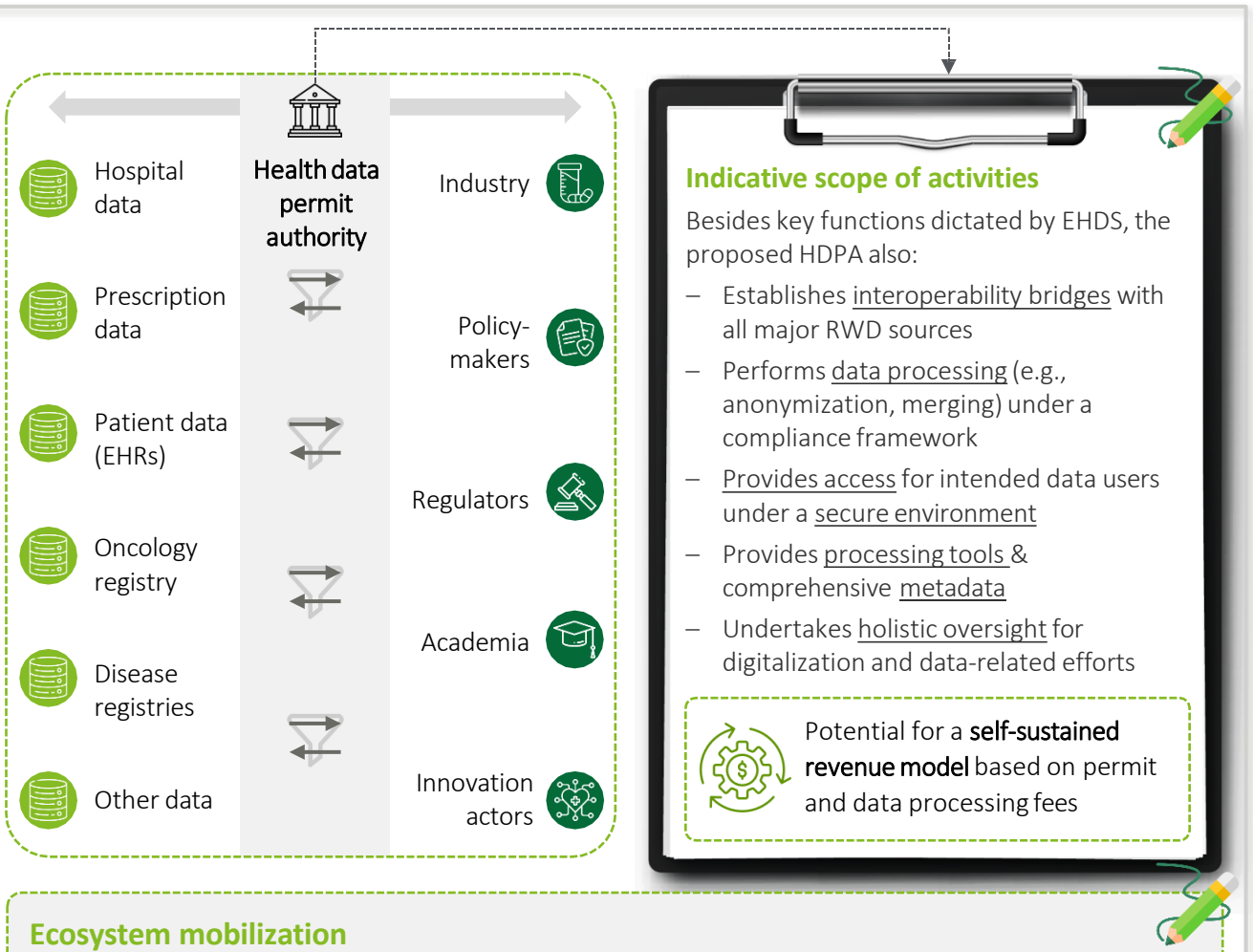
Proposal's Rationale

The proposal aims to define characteristics of a **HDPA body** that will maximize the value of Greek health data by ensuring as many stakeholders as possible can gain access to RWD for legitimate purposes. To accomplish this, the HDPA should have **a one-stop-shop role,** providing the **necessary tools and regulatory support** to assist SMEs, innovative companies and small research teams in **creating value to the health ecosystem through data.**

Enable Data Ecosystem

Setting a robust data framework by introducing a Health Data Permit Authority with extended scope and role is expected to unlock significant value for the entire ecosystem

Proposal conceptualization



Ecosystem mobilization

- Define **vision and priorities** to drive fund allocation and stakeholders' efforts
- Establish **dedicated financing tools** for research, technology commercialization and investments
- Draft a dedicated **national strategy for AI in health data**, establishing priorities and funding options

Case Study Highlights

Health Data Permit Authorities

Findata provides access to a broad array of data and advanced research and processing tools, including pre-processed data, under a fee-for-service revenue scheme

The French HDPA provides a holistic access framework while also providing research grants provisions & release of specific data challenges with monetary prizes

Spain was part of the EHDS2Pilot, aiming to define and build a common IT infrastructure and common standards, metadata catalogs, data quality and interoperability, while has also legislated the respective framework and documented acceptable use cases

Enable Data Ecosystem

A national permit authority must standardize secure, structured access and processing in line with EHDS, enabling evidence-based decision-making

Key Implementation Considerations

Technical Onboarding

Deployment of a data access platform that links hospital, EHR and registry systems via EHDS-compliant APIs, using data standards to enable secure, structured integration of data systems which are often provided by different vendors.

Permit Workflow

Definition of structured permit workflows and anonymization requirements, including screening for applications, thoughtful usage rules and audit mechanisms to streamline access while safeguarding data privacy.

System & Human Capabilities

Development of digital tools and upskilling programs for data users and permit authority staff to ensure secure and consistent data access, processing and remaining up to date with industry and research modus operandi.

Monitoring System

Establishment of audit mechanisms and real-time monitoring tools to ensure compliant data use, detect misuse, and maintain transparency within the permit authority.

Anticipated Impact

Data-driven Policy-making

The structured secondary use of real-world data enables smarter planning, targeted interventions, and evidence-based resource allocation across all levels of the health system.

Enhanced HTA Capabilities

Use of structured data supports dynamic HTA processes, horizon scanning, post-launch monitoring, and value-based pricing models tailored to real-world performance. Aligning with EU HTA will raise the bar even further in terms of data usage requirements.

Research & Innovation

Direct access to real-world data reduces duplication, shortens timelines, and enables studies that reflect actual patient populations, treatment pathways, and system needs.

Sustainable Funding Pathway

Fee-based services for permits and data handling can support the long-term operation of the system, ensuring sustainability without exclusive dependence on public budgets.

Initial implementation timeline

12 months (design) / 12-36 months (Implementation)

Israel Case Study – Data Ecosystem Fundamentals

Israel is a global leader in digital health, known for its advanced data collection and long-standing use of digitized medical records that drive innovation and improve patient care

National Digital Health plan

Ministry of Health

- Regulates data access, privacy, and interoperability standards
- Oversees HIE infrastructure and approves secondary use frameworks

Initial investment of ~$260m for digital infrastructure & regulatory reforms

HMOs	Hospitals	Research Institutions / Academia	Advanced Research Databases
EHRs and prescription data	*Clinical and inpatient data*	*Proprietary & statistical data*	*Big data (Tamma system)*

Health Information Exchange platform

EITAN is Israel's national health data exchange platform, run by the Ministry of Health, using a decentralized architecture to securely share clinical data in real time across providers

Key characteristics

- *Ownership Model*: each healthcare organization retains full ownership and control over the clinical data it generates
- *Decentralized Control*: EITAN does not store patient data centrally. Instead, it enables data exchange through a federated model, where data remains within local systems and is shared only upon request and authorization
- *Selective Sharing*: Participation in the exchange requires mutual agreement. Organizations decide what data to expose and under what conditions. No data is automatically centralized

Implementation Design

No use of a central database	Ensured security standards	Provision of data at time of care only	Private sector know-how utilization
Decentralized approach in storing medical data for enhanced security and greater stakeholder acceptance (incl. patients' resistance)	All data transfers and inter- organizational connections must comply with Israeli security and privacy regulations, as well as international standards like HIPAA, GDPR, and ISO	Israel enhances medical data security by allowing access only to authorized healthcare professionals at the time of care, ensuring that data is shared for specific purposes, with limited scope and duration	Indirect access through government-approved research collaborations and secure sandbox environments managed RWD providers and dedicated platforms such as TIMNA and Lynx MD

Source: Government of Israel, ICLG - Digital Health Laws and Regulations – Israel, The Implementation of a National Health Information Exchange Platform in Israel

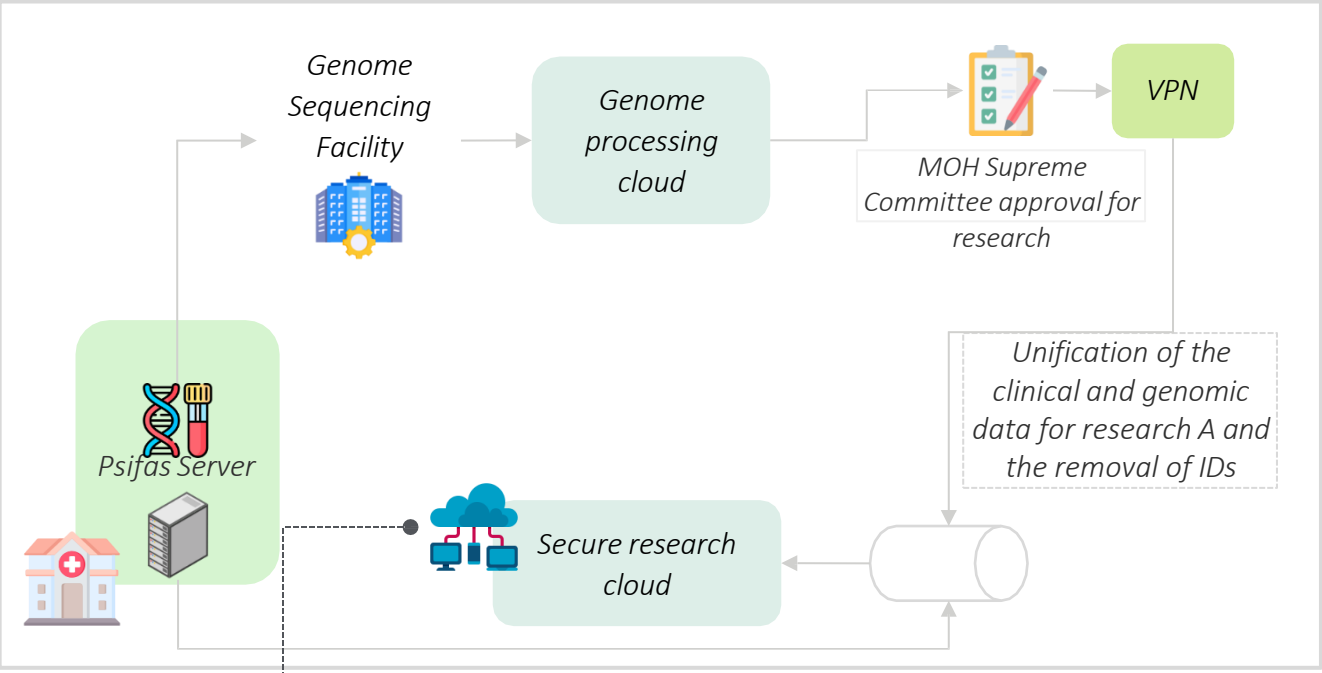
Israel Case Study – Sharing Data With Academia

Academia plays a leading role in health innovation, with the Mosaic initiative showcasing collaboration with the state to integrate genomic and clinical data for research

The Mosaic Initiative

A national program, launched in 2023, aimed at building a national infrastructure for personalized medicine by integrating genomic sequencing with long-term clinical data from health organizations

Led jointly by government and top academic institutions like Weizmann and Bar-Ilan, forming a strategic alliance with hospitals and HMOs



Universities use the genomic-clinical data to develop AI tools, support drug trials, and advance disease-specific research

Financing Evidence-based Research

Magnet

- Supports generic infrastructure tech development in areas where Israeli industry has or can build a global competitive advantage
- Enables cooperation between academia and industry, facilitating knowledge sharing and joint R&D
- Offers up to 100% funding for academics, 66% for companies, depending on consortium type

Magneton

- Promotes technology transfer from academic institutions to industry via mutual cooperation between an industrial company and an academic research group
- Provides up to 66% of the approved budget, with the research institute owning the knowledge and acting as a full partner—not a subcontractor

NOFAR

Supports applied academic research in biotechnology and nanotechnology that is not yet mature enough for industry investment or the MAGNETON program

Source: ICPerMed, Bar-Ilan University, Israel Innovation Authority

SFEE Studies

Name	Year of Publication
The Pharmaceutical Market in Greece: Facts & Figures (IOBE)	2012-Yearly
Public Perception of the Pharmaceutical Industry & Effects of the Economic Crisis on Healthcare in Greece (Medimark)	2018-2019
Market Research Results on Clinical Studies (Medimark)	2019
Towards a Sustainable Healthcare Policy in Greece: Unlocking Value Through Pharma (Deloitte Study)	2020
Truths and Myths about Pharmaceutical Consumption in Greece (i-hecon)	2020
Attract clinical trials in Greece (PwC)	2021
The Pharmaceutical Investment Handbook for Greece (PiHG) (Deloitte)	2021
A comparative analysis of Hospital Pharmaceutical Expenditure trends in the EU: how does Greece compare? (i-hecon)	2022
Innovative drugs availability in Greece	2024-Yearly
Making the economic case for biomarkers reimbursement in Greece Availability, accessibility, affordability and efficiency considerations (i-hecon)	2024
The Burden of Diabetes and Options for Reform: Insights for the Greek Health System (LSE)	2025
The Way Forward: A Roadmap for Greece's Pharmaceutical Policy (Deloitte Study)	2025
Comparative study of volume of pharmaceutical consumption in Greece & EU (i-hecon)	2025
Barriers to Access to Healthcare Services for Cancer Patients in Greece (HPI)	2026
UWWTD study	2026

EFPIA Studies & Position Papers

Name	Year of Publication
EFPIA Patients W.A.I.T. Indicator Survey	2017–Yearly
The root causes of unavailability and delay to innovative medicines	2021–Yearly
EFPIA Pipeline	2022–Yearly
The Pharmaceutical Industry in Figures	2014–Yearly
Novel Pricing and Payment Models: New solutions to improve patient access	2020
Revision of the General Pharmaceutical Legislation: Impact Assessment of European Commission and EFPIA proposals	2023
Unmet Medical Need: Case studies from those directly affected	2023
A Competitiveness Strategy for European Life Sciences	2024
Assessing the clinical trial ecosystem in Europe	2024
Access to Oncology Combination Therapies in Europe: Moving Forward	2024
Economic footprint of the pharmaceutical industry in Europe	2024
Comparator Report on Cancer in Europe 2025 -Disease Burden, Costs and Access to Medicines and Molecular Diagnostics	2025
A forward-looking assessment of the impact of introducing transferable exclusivity vouchers (TEV) in Europe	2025
Clinical trials: to strengthen the research ecosystem, Europe needs to function as a unified region	2025
EU Cardiovascular Health Plan EFPIA & Vaccines Europe position paper	2025
Strengthening incentives for novel antimicrobials in the EU General Pharmaceutical Legislation	2025
Europe's Beating Cancer Plan in Action: National Implementation for the Future	2025
10 Actions for Competitiveness Growth and Security	2026
A comparative analysis of biopharmaceutical strategies in 10 countries	2026
Investing in a Healthier, More Resilient Europe Tackling the NCD Challenge from Prevention to Cure	2026
EFPIA position on Cardiovascular Health Checks	2026
Unlocking the Value of Cardiovascular Health Check	2026
The economic impact of industry clinical trials across Europe	2026