

The EU boosts AI-based healthcare innovation with the launch of the SCAILED project

- *Funded with €14.4 million from the EU4Health programme and a total budget of €18 million, the project brings together 50 partners from 17 EU Member States to drive AI and digital innovation in biotech.*
- *SCAILED will facilitate the development of innovative health solutions through secure and responsible access to high-quality health data and high-performance infrastructure, within the framework of the European Health Data Space (EHDS).*
- *Over the next 36 months, the consortium will work to overcome regulatory and technical barriers, validate AI applications in real-world settings and support their scale-up, helping to strengthen European competitiveness in digital health.*

Luxembourg, 21 October 2026. – The European Union is giving fresh momentum to **AI-based health innovation** with the launch of **SCAILED** (*Scale-up Biotech AI Innovation by Leveraging Responsible Data Use under the European Health Data Space*), a European project that held its kick-off meeting in Luxembourg on 20 and 21 October.

SCAILED is aligned with European priorities in digital health and supports the implementation of [Regulation \(EU\) 2025/327](#) establishing the **European Health Data Space (EHDS)**, which provides a common framework for improving access to and the reuse of health data across the European Union. Funded under the **EU4Health programme** through the call “Health data for biotech innovation leveraging the European Health Data Space”, the project will tackle some of the main challenges facing biotech innovation, such as the complexity of the regulatory environment, the harmonisation of data governance, the access of

high-performance infrastructure services, and the need to strengthen collaboration among the different players in the ecosystem.

SCAILED: from access to health data to the development of AI solutions

During the **kick-off meeting**, the consortium partners addressed the main challenges facing **the development and scale-up of AI-based biotech solutions in Europe**, particularly in relation to access to health data and infrastructure, regulatory complexity and collaboration among the different players in the ecosystem.

To address these challenges, **SCAILED will work to facilitate secure and responsible access to and use of health data, promoting harmonised governance aligned with the European Health Data Space**. It will also help provide greater clarity on the regulatory and ethical requirements affecting innovation, by developing guidance, recommendations and tools to support compliance with European legislation.

The project will also **promote the application of AI solutions through real-world use cases aimed at improving healthcare, diagnosis and patient treatment**, supporting their scale-up through the AI Factories and contributing to a more cohesive and competitive European digital health ecosystem.

*"Europe possesses one of the richest and most comprehensive health data ecosystems in the world. When we combine cutting-edge biotechnology with massive, EU-wide, high-quality datasets and artificial intelligence, we radically transform medicine. The SCAILED initiative embodies this convergence, bridging the gap between cutting-edge AI and clinical validation in biotechnology by harnessing high-quality data within the secure framework of the European Health Data Space. Europe will not need to choose between high patient safety and rapid innovation. We count on SCAILED to make this vision a reality for EU citizens", **Fulvia Raffaelli, Head of the Digital Health Unit at the European Commission's Directorate-General for Health and Food Safety (DG SANTE)**.*

*"SCAILED fits particularly well with Luxembourg's Data Strategy. It relates directly to four of the strategy's six action enablers: infrastructures, the services ecosystem, research, development and innovation, and international collaboration. Together, the Government Commission for data sovereignty and LNDS bring important experience in trusted governance, responsible data reuse, trusted data services and cross-sector collaboration. Through SCAILED, Luxembourg has the opportunity to contribute this experience to European cooperation in health and biotechnology, while learning from partners across Europe", added **Stéphanie***

Obertin, Luxembourg's Minister for Digitalisation and Minister for Research and Higher Education.

From stakeholder collaboration to the validation of AI solutions

SCAILED will develop a working model that **combines the participation of the different players in the health ecosystem, analysis of the sector's needs and validation of AI solutions in real-world settings**. To this end, it will promote spaces for dialogue and collaboration among companies, research infrastructures, health authorities and patient organisations, with the aim of identifying barriers and fostering the joint development of solutions.

This collaboration will be complemented by an analysis of the European innovation ecosystem in AI and health data, which will identify challenges, good practices and opportunities for improvement. The project will also work on integrating existing health data infrastructures within the framework of the European Health Data Space, through pilot projects in areas such as genomics, cancer imaging and brain health, with particular attention to technical interoperability and data governance.

These activities will be accompanied by **use cases in different disease areas**, designed to demonstrate the feasibility and potential of AI solutions in real-world contexts. The results will help facilitate their subsequent development and scale-up, drawing on the capabilities of the AI Factories and helping to move biotech innovation towards concrete applications in healthcare.

A European consortium of 50 partners to drive health innovation

The consortium, coordinated by the **Luxembourg National Data Service (LNDS)**, brings together **47 full partners from 17 Member States, plus one associated partner and two affiliated entities**. It includes health data authorities and agencies, hospitals, research centres, scientific infrastructures, patient organisations, companies and supercomputing centres, which contribute complementary capabilities to address the various challenges of AI-based biotech innovation.

Over **36 months**, the project has a total budget of €18 million, of which €14.4 million comes from European Union funding through the EU4Health programme, representing 80% of the total. The remaining 20 % will be contributed by the consortium partners.

Through this collaboration, **SCAILED aims to deliver progress that will facilitate the adoption of AI solutions in the European health sector**. Expected results include

stronger collaboration among the players in the ecosystem, a better understanding of regulatory requirements and a boost to health data interoperability. As the project advances, these activities are expected to support the inclusion of new infrastructures and the application of the results obtained, helping to accelerate innovation, improve healthcare and strengthen European competitiveness in digital health.

The knowledge, tools and collaboration models developed could also **serve as a reference for future European initiatives in artificial intelligence and biotech innovation.**

*"With SCAILED, we aim to bring together Europe's health data infrastructures, data authorities, AI Factories, AI innovators and broader stakeholder communities to enable responsible data use, support regulatory clarity, and ensure access to secure, high-performance infrastructures for scalable innovation. By connecting these capabilities and supporting their integration with the emerging European Health Data Space, SCAILED seeks to accelerate scalable AI-driven innovation in biotechnology, ultimately contributing to the development of solutions that improve patient care.", concluded **Wei Gu, SCAILED Project Coordinator at the Luxembourg National Data Service (LNDs).***

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About SCAILED

SCAILED (SCale-up Biotech AI Innovation by Leveraging Responsible Data Use under the European Health Data Space) aims to accelerate the development and deployment of Artificial Intelligence (AI) and digital solutions in the European biotech sector by harnessing high-quality health data within the secure, interoperable framework of the European Health Data Space (EHDS).

Project consortium

The SCAILED consortium brings together 47 full partners spanning 17 European Member States and 1 associated partner and 2 affiliated partners from the EU.

Full partners

[Luxembourg National Data Service \(LNDS\)](#) | [PLATEFORME DES DONNEES DE SANTE \(HDH\)](#) | [TERVEYDEN JA HYVINVOINNIN LAITOS \(THL-Findata\)](#) | [INSTITUTO ARAGONES DE CIENCIAS DE LA SALUD \(IACS\)](#) | [REGION MIDTJYLLAND \(CDR\)](#) | [Sciensano](#) | [STICHTING HEALTH-RI \(HRI\)](#) | [BARCELONA SUPERCOMPUTING CENTER CENTRO NACIONAL DE SUPERCOMPUTACION \(BSC\)](#) | [EUROPEAN MOLECULAR BIOLOGY LABORATORY \(ELIXIR\)](#) | [FUNDACION PARA LA INVESTIGACION DEL HOSPITAL UNIVERSITARIO LA FE DE LA COMUNIDAD VALENCIANA \(IISLAFE\)](#) | [EMPIRICA GESELLSCHAFT FUR KOMMUNIKATIONS UND TECHNOLOGIEFORSCHUNG MBH \(EMPIRAX\)](#) | [ASOCIACION ESPANOLA DE BIOEMPRESAS \(ASEBIO\)](#) | [HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO \(CIPH\)](#) | [FUNDACIO CENTRE DE REGULACIO GENOMICA \(CRG\)](#) | [CHARITE – UNIVERSITAETSMEDIZIN BERLIN \(CHARITE\)](#) | [TMF – TECHNOLOGIE UND METHODENPLATTFORM FUR DIE VERNETZTE MEDIZINISCHE FORSCHUNG EV \(TMF\)](#) | [ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS \(CERTH\)](#) | [ASSOCIACAO BIP4DAB \(BIODATA\)](#) | [UNIVERSIDAD DE SANTIAGO DE COMPOSTELA \(USC\)](#) | [FUNDACION PUBLICA GALLEGA CENTRO TECNOLÓGICO DE SUPERCOMPUTACION DE GALICIA \(CESGA\)](#) | [PAGALBOS ONKOLOGINIAMS LIGONIAMS ASOCIACIJA \(POLA\)](#) | [GESUNDHEIT OSTERREICH GMBH \(GÖG\)](#) | [CLINOMIC SOLUTIONS GMBH \(CLIN\)](#) | [Batea Oncology SL \(BATEA\)](#) | [BAHIA SOFTWARE SL \(BAHIA\)](#) | [Alia Sante \(ALIA\)](#) | [DIGITALEUROPE AISBL \(DE\)](#) | [CONSIGLIO NAZIONALE DELLE RICERCHE \(CNR\)](#) | [UNIVERSITE DE LIEGE \(ULIEGE\)](#) | [EBRAINS](#) | [ELLINIKI OMOSPONDIA KARKINOY ELLOK \(ELLOK\)](#) | [Masarykova univerzita \(MU\)](#) | [FUNDACIO PRIVADA INSTITUT D'INVESTIGACIO ONCOLOGICA DE VALL-HEBRON \(VHIO\)](#) | [AGENCE DES DONNEES DE \(SOINS DE\) SANTE \(HDA\)](#) | [UNIVERSITE DU LUXEMBOURG \(UNILU\)](#) | [MINISTERIO DE SANIDAD \(MoH ES\)](#) | [TARTU ULIKOOL \(UTARTU\)](#) | [SPITALUL CLINIC MUNICIPAL CLUJ-NAPOCA \(MCN\)](#) | [INSTITUT NATIONAL DE RECHERCHE EN INFORMATIQUE ET AUTOMATIQUE \(INRIA\)](#) | [MATICAL INNOVATION SL \(MAT\)](#) | [Epidata \(Epidata\)](#) | [UNICANCER](#) | [Curewiki](#) | [INSTITUT NATIONAL DES SCIENCES APPLIQUEES DE LYON \(INSA LYON\)](#) | [CHU HOPITAUX DE BORDEAUX \(CHU Bordeaux\)](#) | [Institut Curie](#) | [SANOFI WINTHROP INDUSTRIE \(SANOFI\)](#)

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