Spain as an innovation hub for new developments in the biopharma sector

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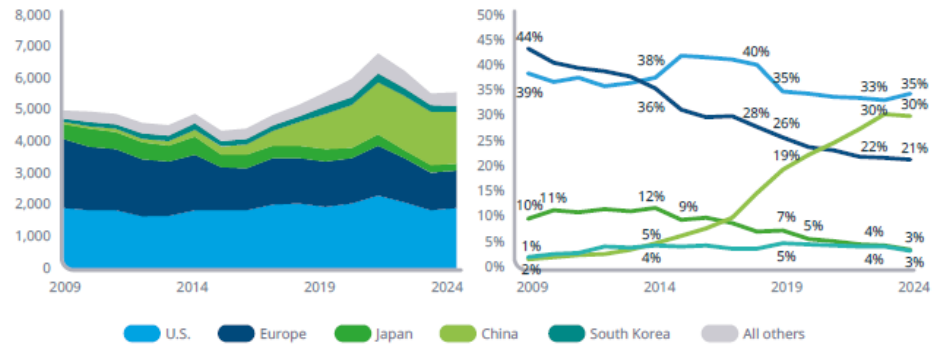
Strategic, innovative and committed industry

Europe has experienced a loss of competitiveness against US and China

Europe's share has declined from 44% to 21% in the last 15 years

Exhibit 13: Number of Phase I to III trial starts based on company headquarters location, 2009–2024



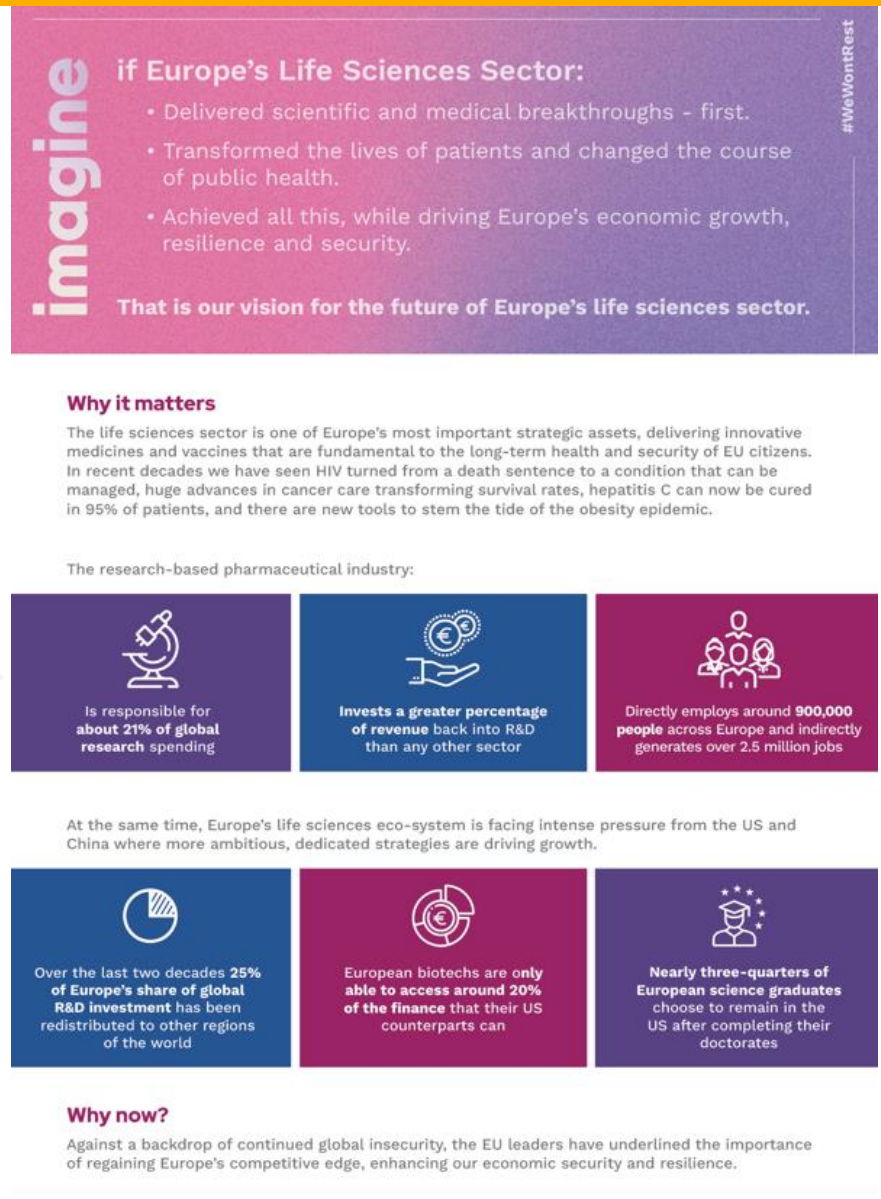
Source: Citeline Trialtrove, Jan 2025; IQVIA Institute, Jan 2025.

Source: IQVIA.Global Trends in R&D 2025

Towards a Strategy for European Life Sciences

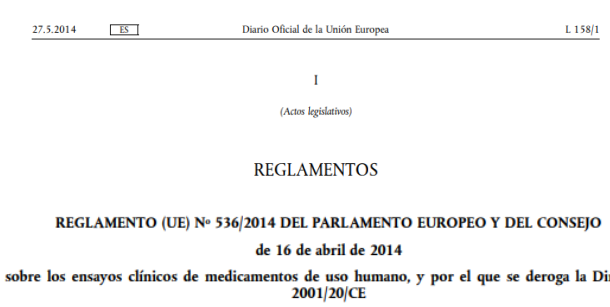
Life sciences can make Europe more competitive and help drive progress in areas such as healthcare, agriculture, energy, food and biotechnology.

For decades, the EU has been a leader in this field thanks to its strong knowledge base and know-how. But we are now losing ground to other global players



Europe: facing an opportunity

Europe has an opportunity to ensure that the region can respond quickly to the needs of European patients and once again become a world leader


27.5.2014 ES Diario Oficial de la Unión Europea L 158/1

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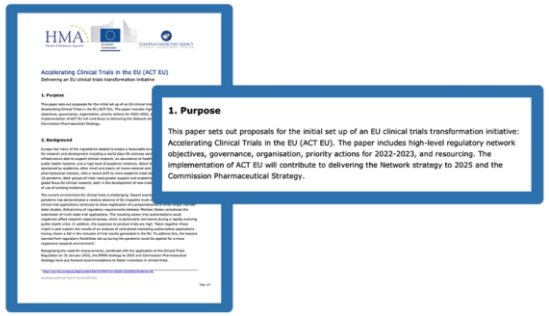
(Actos legislativos)

REGLAMENTOS

REGLAMENTO (UE) Nº 536/2014 DEL PARLAMENTO EUROPEO Y DEL CONSEJO

de 16 de abril de 2014

sobre los ensayos clínicos de medicamentos de uso humano, y por el que se deroga la Directiva 2001/20/CE



We are at a key moment, accelerated pace of innovation:

- Science, technology and talent
- Collaboration and co-creation

Clinical Trial Strategy 2030+ & Action Plan include initiatives such as ACT EU, as well as ongoing actions like:

- **Implementation and improvements of CTR and CTIS** (simplification of functionalities)
- **Biotech Act**
- **Streamlining processes:** enhancing the role of RMS, using common templates, ethical harmonization **…**
- **CTR/IVDR/MDR**: COMBINE program
- **ICH E6(R3) Good Clinical Practice Guidelines**
- Cross-border access to clinical trials (**EU-X-CT**)
- **CTIS MAP**

Europe: facing an opportunity

Currently, the political focus is on **restoring European competitiveness**, which is essential for economic security and strategic autonomy. The European **pharmaceutical industry plays a key** role in this regard, as reflected in various reports:

A new report by IQVIA for EFPIA and Vaccines Europe, shows European clinical trial ecosystem, in which Europe remains a strong global player and has many strengths to build on. The document indicates that **Spain has managed to build an attractive clinical trial ecosystem.**

IQVIA
efpia Vaccines Europe
Assessing the clinical trial ecosystem in Europe

Need to develop a strategy to boost competitiveness

Draghi Report - A great plan for Europe's sustainable prosperity and competitiveness. Proposals aim to address the key root causes driving the EU's emerging competitiveness gap for pharmaceuticals. EFPIA welcomes recognition of the innovative pharmaceutical sector's importance to EU competitiveness and calls for swift adoption of the recommendations.

- Maximise the impact of the EU Health Data Space
- Streamline the set-up and management of multi-country trials in the EU to advance the EU as an attractive place for conducting clinical R&D
- Expedite access to markets through coordinated action
- Provide clear and timely guidance on the use of AI in the lifecycle of medicines
- Rapidly and fully implement the HTA regulation
- Improve business predictability through a continuous evidence-based dialogue with stakeholders
- Increase and focus public R&D investment in the EU
- Mobilise private R&D investment in the EU and bolster the supporting environment
- Develop strategic international partnerships to solidify and bolster the EU's international trade position in pharmaceuticals.

Spain faces a key opportunity in clinical research

We have a unique opportunity to turn Spain into a world leader in biopharmaceutical innovation and to constitute a great pillar for the health, economic and social future of our country.

The Spanish Government approved the 2024-28 Strategy for the Pharmaceutical Industry in Spain. This is the first time that the Government has developed a document of this nature geared towards the pharmaceutical sector.

Context: Ecosystem, EU, health needs and sustainability.

Priorities structured around three pillars: (i) **access and sustainability** (12 actions); (ii) **R&D and innovation (6 actions)**; (iii) **strategic autonomy and resilience** of supply chains (3 actions).

Pharmaceutical industry is committed to Spain

The Government President meets for the second time with representatives of the national, European and global pharmaceutical industry to intensify public-private collaboration

Biomedical Research Ecosystem in Spain

R&D

€ 1.438M
R&D Invested in 2023

€ 1.533M
R&D Invested projected for 2024

€ 646 M
invested in hospitals and research centers

€900 M
invested in clinical trials

83%
of the country's clinical research funding

+170.000
patients have benefited in Spain from participation in clinical trials

Ecosystem

Spain has a vibrant and growing healthcare research ecosystem, supported by a robust infrastructure:

35 accredited Health Research Institutes, which bring together hospitals, universities, and research centers.

Spanish Agency for Medicines and Health Products (AEMPS) plays a key role as the regulatory authority, facilitating clinical trials

Ethics Committees essential for safeguarding participant protection and research integrity

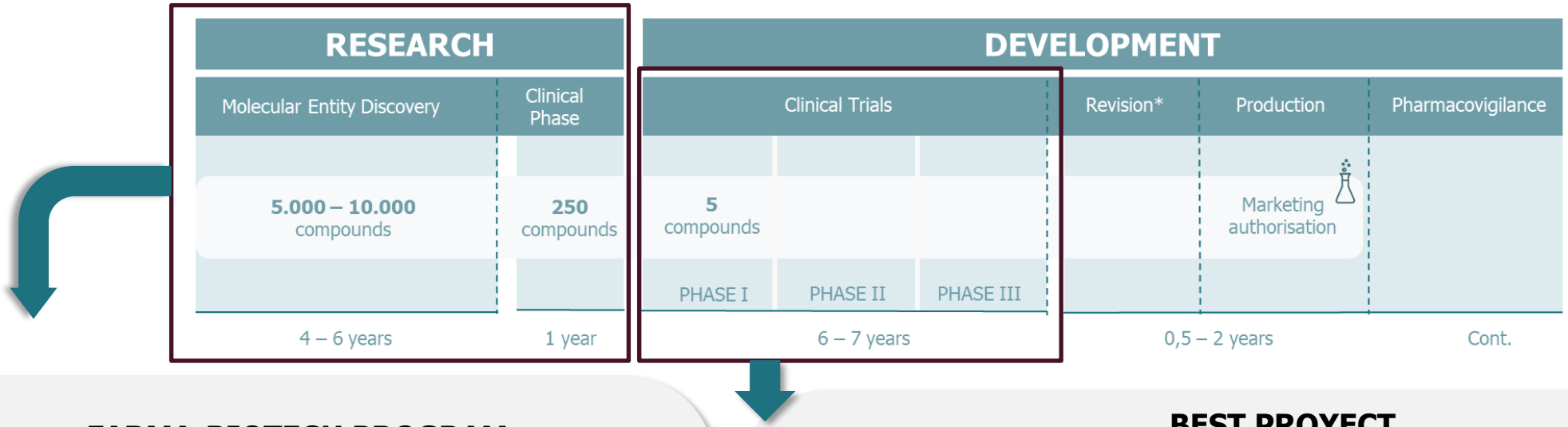
A thriving landscape of start-ups, driving technology transfer and developing disruptive solutions

Pharmaceutical sector is strongly committed: Farmaindustria brings together 130 affiliated laboratories

Several regions stand out for their strong commitment, including **Catalonia, Madrid, Andalucia, Valencia, Galicia and Basque Country**.

However, it is important to highlight that **all Spanish Autonomous Communities** actively support and invest in clinical research, contributing to a nationally coordinated and inclusive research ecosystem.

What we are working on today



FARMA-BIOTECH PROGRAM

- Project started in 2011 aiming to promote collaboration between pharmaceutical industry and biomedical researchers, contributing to the exchange of information and facilitating knowledge transfer
- To date **24 meetings have been held** and up to **154 advanced research projects** have been identified.
- A new meeting is currently being organized in collaboration with Biocat

BEST PROYECT

- It was founded in 2006 and its objective is **to make Spain leader in clinical research**.
- It is constituted as a platform that integrates 59 pharmaceutical companies, 52 hospitals, 17 Autonomous Communities, 6 independent clinical research groups and 1 CRO
- The platform shares and monitors **timelines and recruitment metrics** among all the stakeholders involved, which **allows bottlenecks to be detected and solutions to be proposed**

KEYS TO SPAIN'S LEADING POSITION IN CLINICAL TRIALS

1 PIONEERS IN REGULATION

Our country was the first in Europe to adopt the Clinical Trials Regulation, through Royal Decree 1090/2015, which entailed the simplification, streamlining and harmonization at national level before any other Member State.

2 AEMPS: A COMMITTED REGULATORY AGENCY

Its pioneering and proactive attitude to promote and preserve research activity (thus guaranteeing patient safety) and constant dialogue with the pharmaceutical industry.

3 A STRONG NATIONAL HEALTH SYSTEM

Almost 13,000 health centers and 800 public and private hospitals, plus 35 health research institutes accredited by the Carlos III Health Institute, spread across 13 autonomous communities and employing more than 29,000 researchers in total.

4 TOP-NOTCH HEALTHCARE PROFESSIONALS

Spain has highly qualified healthcare professionals who can face the challenge of clinical research with the highest quality standards thanks to their commitment to continuous training and patient care.

5 PATIENTS INVOLVEMENT AND GENEROSITY

Patients' participation in clinical trials is a great example of altruism, solidarity and generosity, and without the cooperation of patients there is no research.

6 AN ACTIVITY BASED ON ETHICS AND TRANSPARENCY

In Spain, there are currently more than 65 Ethics Committees, and the efficient performance and professionalism of its members have contributed significantly.

7 A STRONG FOOTPRINT IN SPAIN

For many pharmaceutical companies, Spain is already the second-most active country in the world in clinical trials, only behind the United States, and participates in one out of every three trials launched in Europe.

8 PROJECT BEST

A strategic project bringing together all public and private stakeholders to create a platform for excellence in clinical research.

9 A HARMONIZED EUROPEAN SYSTEM

Since 31 January 2022, the new Clinical Trials Information System (CTIS) has been operational. CTIS harmonizes the assessing and monitoring of clinical trials.

10 A MODEL BASED ON PUBLIC-PRIVATE COLLABORATION

Public-private collaboration between health authorities, hospitals, researchers and healthcare professionals, patients and pharmaceutical companies is a key driver in promoting biomedical research in Spain.

Farmaindustria's strategy to strengthen Spain's leadership in clinical research

Spain has a competitive advantage over other countries to underpin its leadership in clinical trials. However, there are challenges and improvement areas in the development of new drugs:

01 **Streamlining and reducing clinical research management processes**

- Prioritizing Fast Track for First in Human
- Promoting harmonized contract clauses
- Addressing Combined Trials - IVDs

02 **Promoting Clinical Research in Primary Care in Spain**

03 **Advancing Decentralized Clinical Trials**

04 **Enhancing Diversity in Clinical Trials**

05 **Guideline for Clinical Trials in Hospital Pharmacy**

06 **Patient Participation in Biomedical R&D**

07 **Fostering RWD, RWE, AI and EHDS**

European Health Data Space (EHDS): new regulation, opportunity to Spain

EHDS is a cornerstone of the European Health Union and **the first common EU data space dedicated to a specific sector** as part of the European strategy for data

Two main aspects

-Primary Use of Data. Access, control and share their electronic health data across borders for the healthcare

-**Secondary Use of Data**. Secure and trustworthy reuse health data for research, innovation.

Key milestone towards full implementation

-March 2025: The EHDS Regulation enters into force, marking the beginning of the transition period

-March 2027: Deadline for CE to adopt several key implementing acts

-March 2029: Rules on secondary use will also start to apply for most data categories

-**March 2031**: Rules on secondary use will also start to apply for other categories (**CT**, genomic data)

Some lessons learned in CTR will be useful for the EHDS

New public-private collaboration initiative

Although Spain holds a strong position in clinical research, we are aiming to promote mechanisms that allow research groups academic institutions and biopharmaceutical sector to be united to **enhance public-private collaboration and technology transfer.**

Working on a project that will bring together all relevant public and private stakeholders **to make Spain a leading player in preclinical research**, building on the success already achieved in clinical research. Currently, 11 pharmaceutical companies are interested in it.