



# 10 REASONS WHY SPAIN IS A WORLD LEADER IN CLINICAL TRIALS

Spain is a world **leader** and the **top European country** in the conduction of clinical trials.

Clinical trials are one of the best examples of how very diverse sectors and stakeholders can create **a virtuous dynamic that benefits society** as a whole by joining forces with the same objective - which is none other than discovering new drugs to improve the patients' health.

But **what are the reasons** that have led Spain to becoming one of the world leaders in clinical trials? These are the keys to success:

## 1. EUROPEAN REGULATORY IMPLEMENTATION

Spain was the first Member State in Europe to adopt the [Clinical Trials Regulation](#), through [Royal Decree 1090/2015](#), which entailed the **simplification, streamlining and harmonization** at national level of the procedures for conducting these studies, a greater role for patients, an increase in early-phase trials (which require a higher level of complexity), and a greater commitment to research into **rare diseases and diseases affecting the paediatric population**.

## 2. AEMPS: A COMMITTED REGULATORY AGENCY

The [Spanish Medicines Agency](#) (AEMPS), part of the Ministry of Health, is the competent authority for authorizing clinical trials. Among other things, its **pioneering and proactive attitude** to promote and preserve research activity (thus guaranteeing patient safety) and **constant dialogue** with the pharmaceutical industry that sponsors the studies have facilitated the initiation of clinical trials in Spain in recent years.



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### 3. A STRONG NATIONAL HEALTH SYSTEM

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Spain has one of the most robust and highest-quality healthcare systems in the world, with almost 13,000 health centres and nearly 800 public and private hospitals (although not all of them conduct clinical trials), in addition to the Carlos III Health Institute's [35 accredited health research institutes](#) spread across **13 autonomous communities** and employing over **29,000 researchers** in total. The Spanish model has another great strength: quality pharmaceutical provision, one of the most comprehensive at international level.

### 4. TOP-NOTCH HEALTHCARE PROFESSIONALS

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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. Moreover, clinical trials allow **doctors, nurses, pharmacists**, et al. to be at the cutting edge of knowledge and improve pharmaceutical provision and healthcare services within the NHS.

Healthcare professionals are an **essential part** of clinical research. Participating in a trial is an important decision, as is understanding the decision to take part in a trial. Healthcare professionals are the ones who bring research to patients and open the first window of hope.

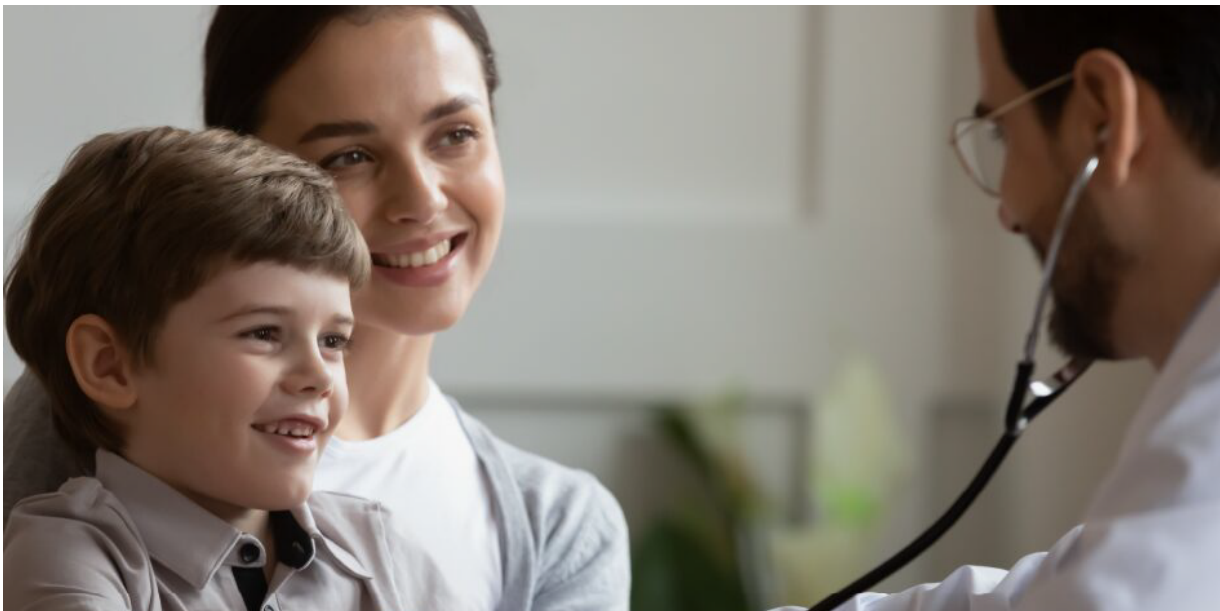


## 5. INVOLVEMENT AND GENEROSITY OF PATIENTS

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According to estimates by the pharmaceutical industry, around **170,000 people in Spain** are currently taking part in an active clinical trial. Patients' participation in clinical trials is a great example of altruism, solidarity and generosity, because even if the trial does not directly benefit them, it will directly benefit future patients.

More and more people in Spain are getting involved in clinical trials and they are another important cornerstone of research: **without the cooperation of patients there is no research.**



## 6. AN ACTIVITY BASED ON ETHICS AND TRANSPARENCY

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The Drug Research Ethics Committees (CEIm) are independent accredited bodies that guarantee the ethical and scientific quality of clinical studies on medicines. There are currently more than 65 Ethics Committees, and the efficient performance **and professionalism of its members** have contributed significantly to the fact that clinical trials in Spain are conducted under the strictest ethical criteria.

Likewise, the Spanish Data Protection Agency (AEPD) approved the *Code of Conduct regulating the processing of personal data in the field of clinical trials and other clinical investigations and pharmacovigilance*, promoted by Farmaindustria, in 2022. It is **the first sectoral code of conduct in Europe** of its kind and serves as another example of the pharmaceutical industry operating in Spain's commitment to transparency and of the sector's respect for citizen's fundamental rights in terms of how their data are processed.



## 7. A STRONG FOOTPRINT IN SPAIN

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The pharmaceutical industry is one of the industries with the highest investment in research in Spain. Patients are the main beneficiaries of this investment, as 60% (of the almost 1.4 billion euros in 2022) is earmarked for clinical trials, which means that thousands of people in Spain will have **early access to the treatments of the future**.

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. THE “BEST” PROJECT

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Farmaindustria launched **the “BEST” Project** in 2006, after detecting a loss of competitiveness based on regulations prior to 2015. It is a strategic project bringing together all public and private stakeholders to create a **platform for excellence** in clinical research.

Its objective has from the start been to promote investment in R&D by monitoring the situation of clinical trials in Spain, to identify the different practices, and taking measures to improve their efficiency and competitiveness. Before this initiative, up to sixteen countries in Europe began a clinical trial before Spain did. Now, in many cases, Spain is the first country in Europe to recruit the **first patient for a trial**.

## 9. A HARMONIZED EUROPEAN SYSTEM

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The way clinical trials are conducted in the European Union is undergoing important changes for the benefit of patients. Since 31 January 2022, the **new Clinical Trials Information System (CTIS) has been operational**. **CTIS harmonizes the assessing and monitoring** of clinical trials, with the aim of streamlining these studies and, consequently, so new medicines reach the people who need them sooner.

With CTIS, clinical trial sponsors can request authorization for a clinical trial simultaneously in all EU countries with **a single application**. Spain has also been one of the first to carry out the necessary training for the use of this new platform and the AEMPS is one of the best-positioned regulatory agencies in this area.

## 10. A MODEL BASED ON PUBLIC-PRIVATE COLLABORATION

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**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.

The pharmaceutical industry spent **633 million euros**, almost half of its investment in R&D in 2022, on research contracts with hospitals, universities and public and private centres.

Continuing to promote public-private alliances is key in achieving a true **transfer of knowledge** and for companies to be able to fully harness their potential so that new medicines reach the patients who need them as soon as possible.

Although it faces a number of **challenges ahead that need to be overcome** so as not to lose leadership, the Spanish clinical-research model, guided by these 10 keys to success, works. On the one hand, there is the [promotion of clinical trials in primary care](#), as well as implementing the **decentralized elements of clinical trials** so that these can be carried out online and so more patients across all autonomous communities of Spain can benefit from medical advances. Furthermore, we must continue simplifying procedures to be competitive in terms of speed of initiating trials.

On the other hand, there is the **general public's knowledge** of the value that clinical trials have, since they attract resources and savings for the National Health System, allow healthcare professionals to increase knowledge and provide patients with early access to new medications, which could be the last opportunity for many patients to cure their illness or make their illness chronic.



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