SERVICES

LeonResearch

A few words about us

LeonResearch

SOME INFORMATION ABOUT US

We are an adaptative and flexible CRO & Pharma Consulting Company that aims to provide solutions during the whole process of your clinical trial

WHY US?

We will consider your study our priority and will take care of it considering it as our own.

We also count on a **wide experience on clinical research** developing all the activities involved in design, medical writing, Phase I to IV clinical trials, medical devices studies, NIS and nutritional studies, registration dossiers and pharmacovigilance, ensuring that your product is introduced on the market fulfilling all the requirements.

OUR PRINCIPLES

- **HONESTY**
- **INTELLIGENCE**
- **CREATIVITY**
- **FLEXIBILITY**

LeonResearch

OUR PRESENCE

DIRECT

SPAIN

- León (Headquarters)
- Madrid

PORTUGAL

- Porto

ITALY

- Torino

WORLDWIDE COVERAGE THROUGH

AICROS

Countries directly managed by León Research

Countries managed through AICROS, Alliance of International CROs www.aicros.com

LeonResearch

OUR EXPERT TEAM

We are a team of 46 members; 36 of them in the following operational departments:

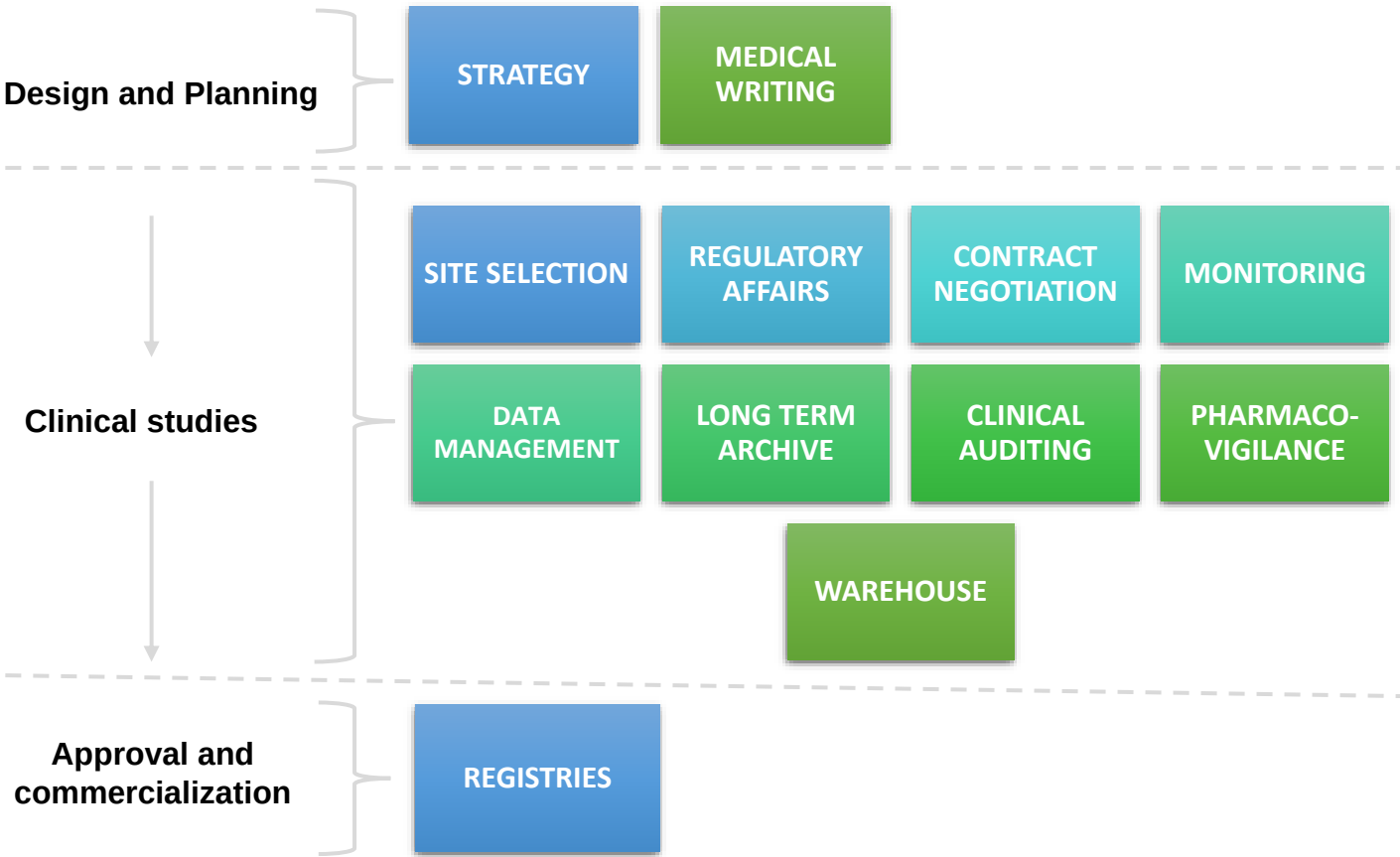
- Pharma Consulting
  - Strategy
  - Medical Writing
  - Products Registration
  - Pharmacovigilance
- Operations
  - Clinical Operations
  - Regulatory Affairs
- Data Management
- Archiving
- Distribution Warehouse

46
employees

SPAIN	ITALY	PORTUGAL
• Since 2007 • 19 people in operations • 4 Project managers	• Since 2014 • 9 people in operations • 2 Project managers	• Since 2009 • 5 people in operations • 1 Project manager

How we do it

OUR SOLUTIONS FOR CLINICAL RESEARCH



OUR SOLUTIONS FOR CLINICAL RESEARCH

DESIGN AND PLANNING

- We support you during the life cycle of your product until its introduction in the market. It includes the definition of the investigation best design, ensuring the best approval strategies.

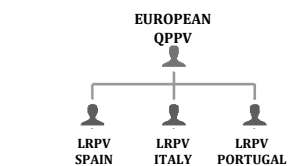
MEDICAL WRITING

- We collaborate with you on the study definition and revision and on the elaboration of the documents needed (Protocol/IB/IMPD/Patient docs) to obtain the approvals of the ECs and the Regulatory Agencies.

REGISTRATION

- Obtain CE Mark for Medical Devices
- Do you want to achieve the Marketing Authorization for your investigational products? We help you on the management of the Marketing Authorization Dossier for the national, centralized, decentralized or mutual recognition procedures.
- For medicines already in the market we support you with registrations in RAEFAR/CESP as well as with fees management and any variations.

PHARMACOVIGILANCE



- European QPPV
- Local QPPV in Spain, Italy and Portugal
- Monitor the safety of Development Medicinal Products (DMP), and Medical Devices (MD)

OUR SOLUTIONS FOR CLINICAL RESEARCH

FULL SERVICE CRO

- Design, setting up and monitoring of clinical trials and research studies
- Management of data and Statistical analysis
- Monitoring the safety of the product during all phases
- Ensuring that regulatory requirements are met with the Competent Authorities and Ethic Committees.
- Pre-market and post-market stages for both Medical Devices and Medicinal Products

LEGAL REPRESENTATION IN EU

- We can act as Legal Representatives for your clinical studies in the European Union.
- Valid liability Insurance Policy

CLINICAL AUDITING

While finishing your study in Spain, if you need to perform an audit of the site or the study performance, we are the best option to audit the study and all documentation ensuring that are in perfect conditions and inspection ready.

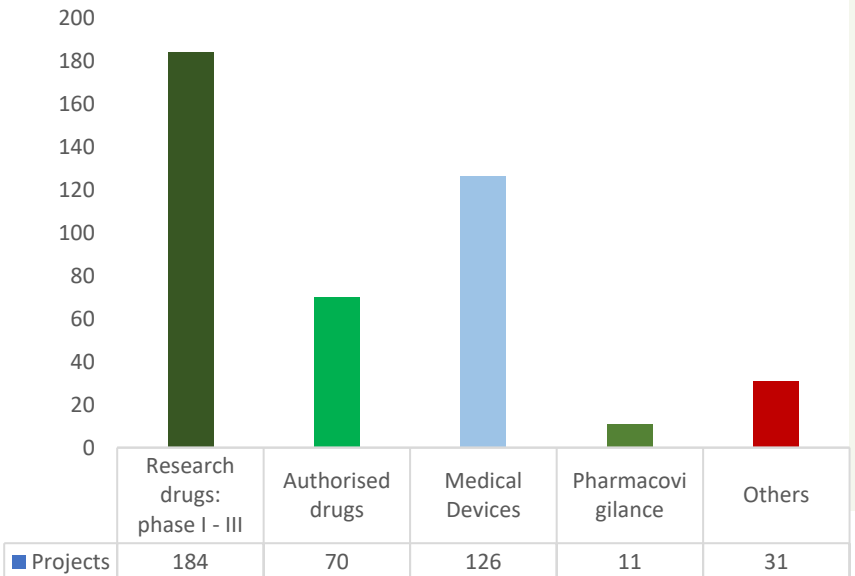
WAREHOUSE

- We have a In-house storage facility located in León (HQ) to import and store Medical Devices throughout Europe
- Our facilities are equipped with advanced technology for inventory processing, management, transportation and distribution, and fully compliance with all applicable regulations.

Experience

OUR EXPERIENCE

16 years of experience and our work in more than **400 projects** endorse us the expertise we have today.



MAIN THERAPEUTIC AREAS:

- **ONCOLOGY**
- **OPHTHALMOLOGY**
- **CARDIOLOGY**
- **ENDOCRINOLOGY**
- **TRAUMATOLOGY**
- **RARE DISEASE**
- **NEUROLOGY**
- **PNEUMOLOGY**
- **HEMATOLOGY**

LeonResearch

Imagine

MAGINE WORKING WITH US

- **Your unique solution** with a finished end product
- **A valuable family of** 46 members in Spain, Italy and Portugal
- **Up-to-date** in changes and innovations in the sector
- **The most adaptative and flexible partner** in the performance of studies
- A qualified solution certified by the **ISO 9001: 2015**

QUALITY CERTIFICATIONS

- **Quality Management System** certified by the ISO 9001: 2015.
- We work according to our **Standard Operating Procedures**.
- We are officially certified on complying with Data Protection according to the General Data Protection Regulation (EU) 2016/679 (EU **GDPR**).
- Trained on **Good Clinical Practices** (GCP).
- Trained on **ISO 14155:2020**- Clinical investigation of medical devices for human subjects.
- Qualified as **Regulatory Consultancy SME** enterprise by the **European Medicines Agency** since 2017.
- Qualified as **Innovative SME** by the Spanish Ministry of Science and Innovation

LeonResearch

LeonResearch

An expert on your path

Ask us for more information:

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