

WE ARE CONSTANTLY IMPROVING

OUR CLINICAL RESEARCH SKILLS

TO MAKE HEALTH MORE AND MORE

A CERTAINTY THROUGHOUT

HUMAN LIFE

**C**LINICAL

**R**ESEARCH

**O**PTIMIZATION

**C**ERTIFIED UNI EN ISO 9001:2000

PHIDEA Srl



**A**SSOCIATED AICRO (CROs Italian Association)

**PHIDEA**  
THE IDEAL CRO

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## International Contract Research Organisation Offering diversified services in Drug Development

Phidea was founded in Milan in 1982, as a Drug Development Company, and in 1991 the Spanish subsidiary, based in Madrid, started its activities.

Since its foundation Phidea has built a broad know how in global product development, starting its involvement after the definition of the chemical entity of the active pharmaceutical ingredient, and bringing it to registration and supporting its commercialisation.

Phidea can follow all the development thanks to the strong partnerships created with Companies specialised in each step of drug development, and directly working in clinical development.

Phidea's services start with the identification of patent strategy, followed by the coordination of the activities of the Partners involved both in pharmaceutical formulation definition, stability trials, first experimental batch production, and in design and conduct of the pharmacological/toxicological development plan.

Through the years Phidea specialised in Clinical Development, managing directly in all Europe multinational pre registration clinical trials (phase I-Phase III), post marketing clinical trials (Phase IV), as well as epidemiological and observational studies (mega trials). Thanks to this broad range of activities Phidea may now offer its support in all product life cycle.

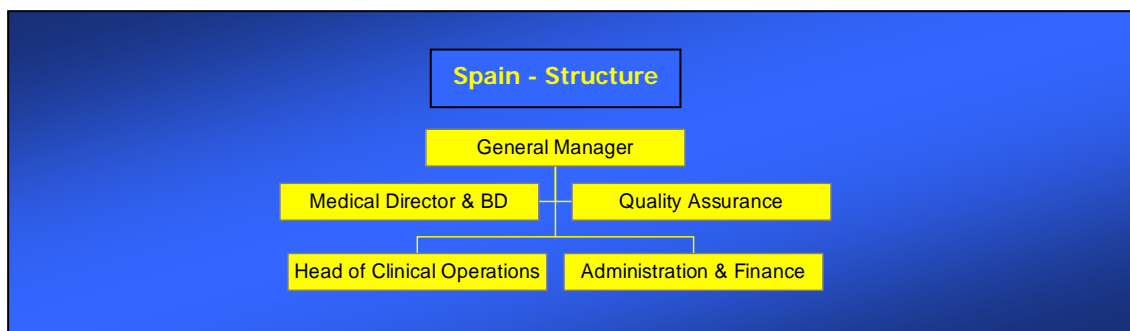
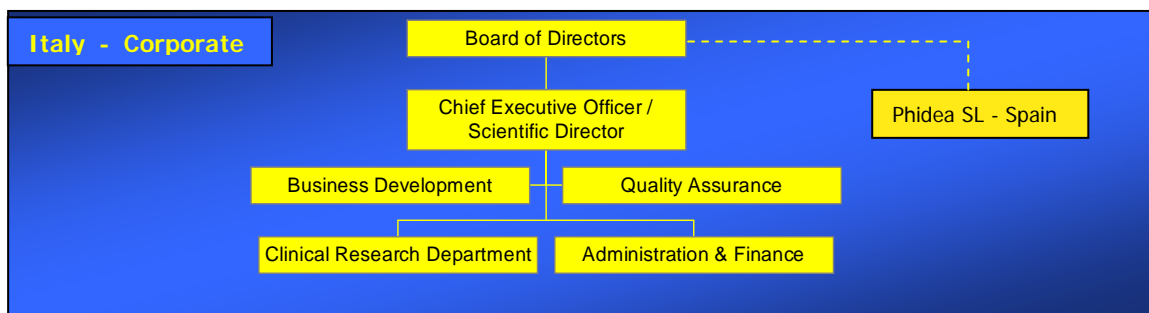
Today Phidea is the ideal partner of those Companies that for any reason need to outsource the development of a specific drug from patent submission to registration in Europe.

# Corporate history milestones

- 📅 1982 Foundation Phidea Italy (Milan)
- 📅 1991 Foundation Phidea Spain (Madrid)
- 📅 2000 New Operational Management in the Italian Office
- 📅 2001 Re-organisation CRA team
- 📅 2002 SOPs re-harmonisation process
- 📅 2003 Start Up Unit foundation
- 📅 2004 Consolidation of Phidea's involvement in European study Management
- 📅 2005 UNI EN ISO 9001:2000 certification  
AICRO Association
- 📅 2006 Kick off of new organisational structure  
Exclusive partnership with Mipharm S.p.A. for  
drug supplies management

Our strengths:  
 experienced and committed team made by professionals,  
 working with  
 qualitative, flexible and innovative processes

Phidea has a central structure, based in Milan (Corsico), working both as Corporate, managing European activities, and local Italian Company, with a dedicated clinical research operations team. To this group in 1991 the Spanish Company was added with its headquarters in Madrid and now with a new office in Barcelona.

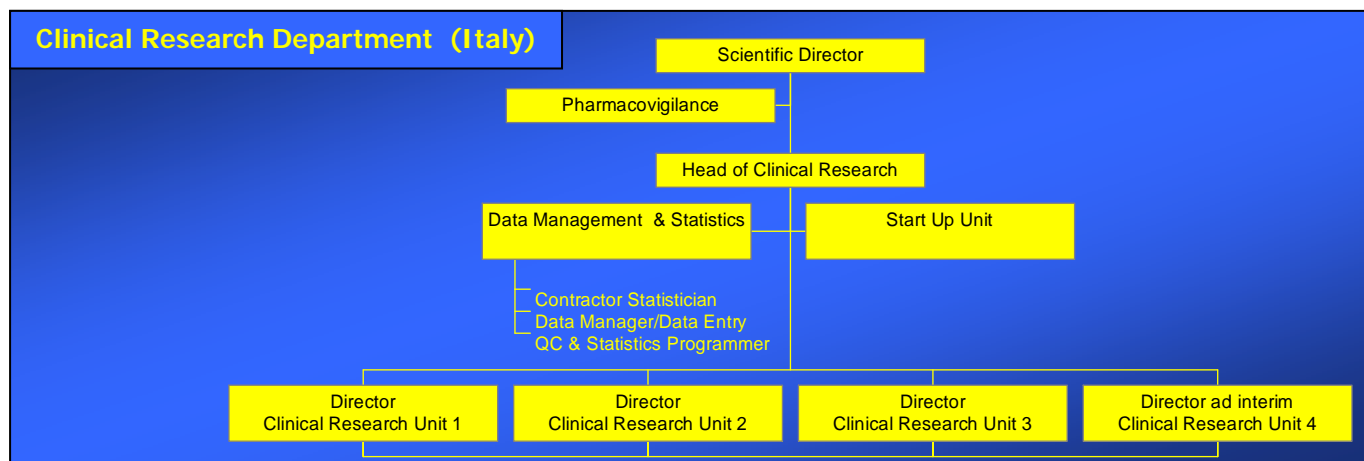




**Our engine:  
a team of people committed to deliver high quality  
products in the scheduled timelines**

Nowadays Phidea in Italy and Spain has almost 100 people on board. The structure of the Italian Clinical Operations group is represented below. Both Italian and Spanish sites have office based as well as home based CRAs.

Phidea has local CRAs in all major European Countries, who may be involved in both country regulatory approvals (Central Authorities and ECs), and monitoring activities.



In Phidea’s structure the real operational engine is the Project Team.

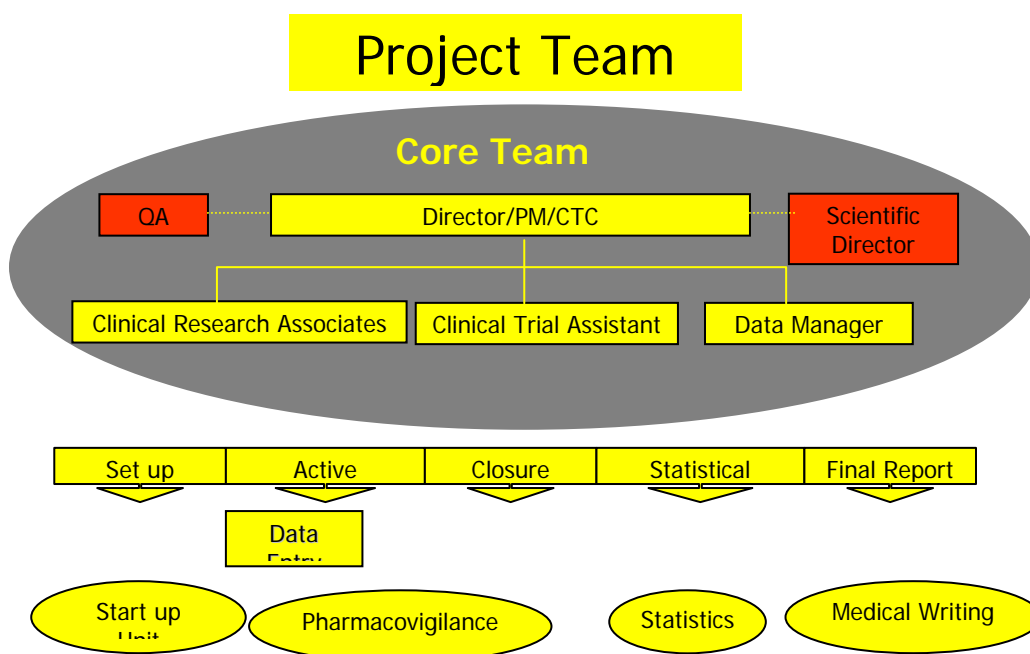
## Project Team

Phidea conducts trial activities through its Project Team organisation: for each new project a dedicated Project Team is created and a Project Manager (i.e.: Director/Project Manager/Clinical Trial Coordinator) is appointed, to manage the full team. Project Manager becomes the key contact for the Sponsor, reporting directly to his/her line Clinical Research Unit Director.

Project Manager is responsible to steer the Project Team, to verify the adherence to the timelines/requirements throughout the study conduct, and is responsible of CRAs and Project Team Members performances.

The "Core Team" is represented by the Project Manager, the CRAs involved, Data Manager, Clinical Trial Assistant and is supported by Quality Assurance and Scientific Director for all relevant issues.

During study conduct, other personnel may join and leave the team (e.g.: Start up unit, etc), depending on the specific moment of study life cycle.





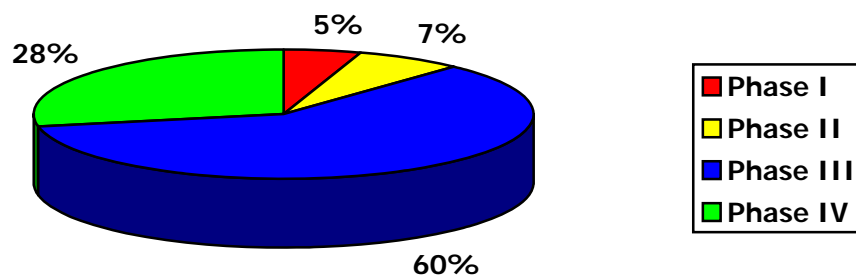
Our experience:  
a constantly increasing store of knowledge  
to be offered to our clients  
in all European Countries

### Experience over the last 2 years

Phidea has a wide experience in both local and international studies (all over Europe).  
European studies are usually conducted by the Italian office.

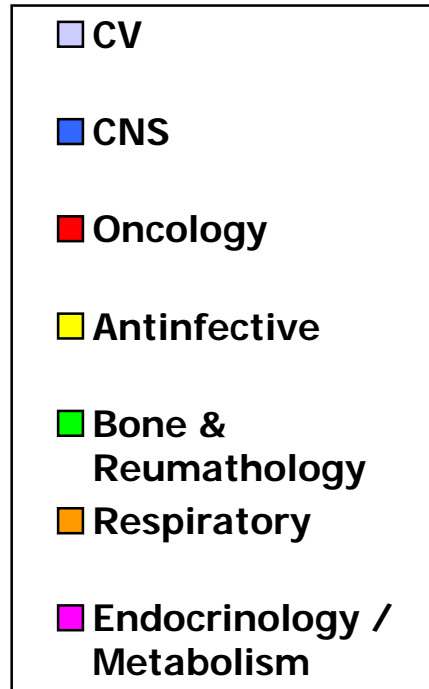
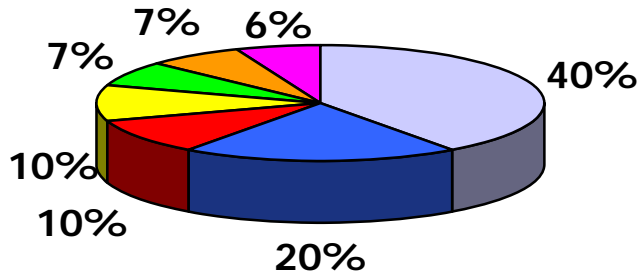
Phidea has a wide expertise in all development phases and in most therapeutic areas. (Data calculated over the last 2 years)

*Phases (Corporate, local Italian and Spanish data):*



Phase I studies are mainly pharmacokinetic and bioequivalence studies conducted in Spain and in other European Countries.

Therapeutic areas (Corporate, local Italian and Spanish data):





## Our goal: give our clients the chance to forget about the project till it's completed

Phidea's 2 major characterisation are:

1. qualitative, flexible and innovative processes;
2. experienced, committed and motivated human resources.

Thanks to these aspects Phidea is able to offer diversified integrated services to support Sponsor in clinical drug development.

The most important areas of business are:

- ✓ international and local clinical trials.

Services in this area are mainly addressed to Medical Departments (phase I-IV) and Medical Marketing teams (phase IV). All clinical research activities may be conducted for trials of phase I (bioequivalence and pharmacokinetic studies), phase II and III (pre-registration studies to get info on drug tolerability, efficacy and dosage), phase IV (post registration studies to confirm pre registration information on tolerability, efficacy and used dosages) and observational studies.

Phidea may follow complete projects from ideation to data publication, taking care of each intermediate step, complete drug supplies management included.

- ✓ Clinical supplies management

Management of clinical supplies from manufacturing to final destruction thanks to the exclusive partnership with Mipharm S.p.A.

Supplies are stocked and managed in the ad hoc Department within Mipharm plant.

- ✓ Pharmacovigilance

PV activities linked to a specific project managed by Phidea

PV activities supporting Sponsors' responsibilities

- ✓ Quality assurance and training

Systematic and independent audits on all CRO activities

QA activities linked to a specific project managed by Phidea

QA independent service

- ✓ Data management and statistics  
Phidea provides internally complete Data Management & Statistics as a whole.  
Specifically trained personnel performs a wide range of tasks from protocol statistical design to statistical report.  
Data and analysis are supported by the highest quality standards.
- ✓ Outsourcing (Spain)



We are committed to exceeding high standards of performance by being responsive and dedicated to the needs of our Customers



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