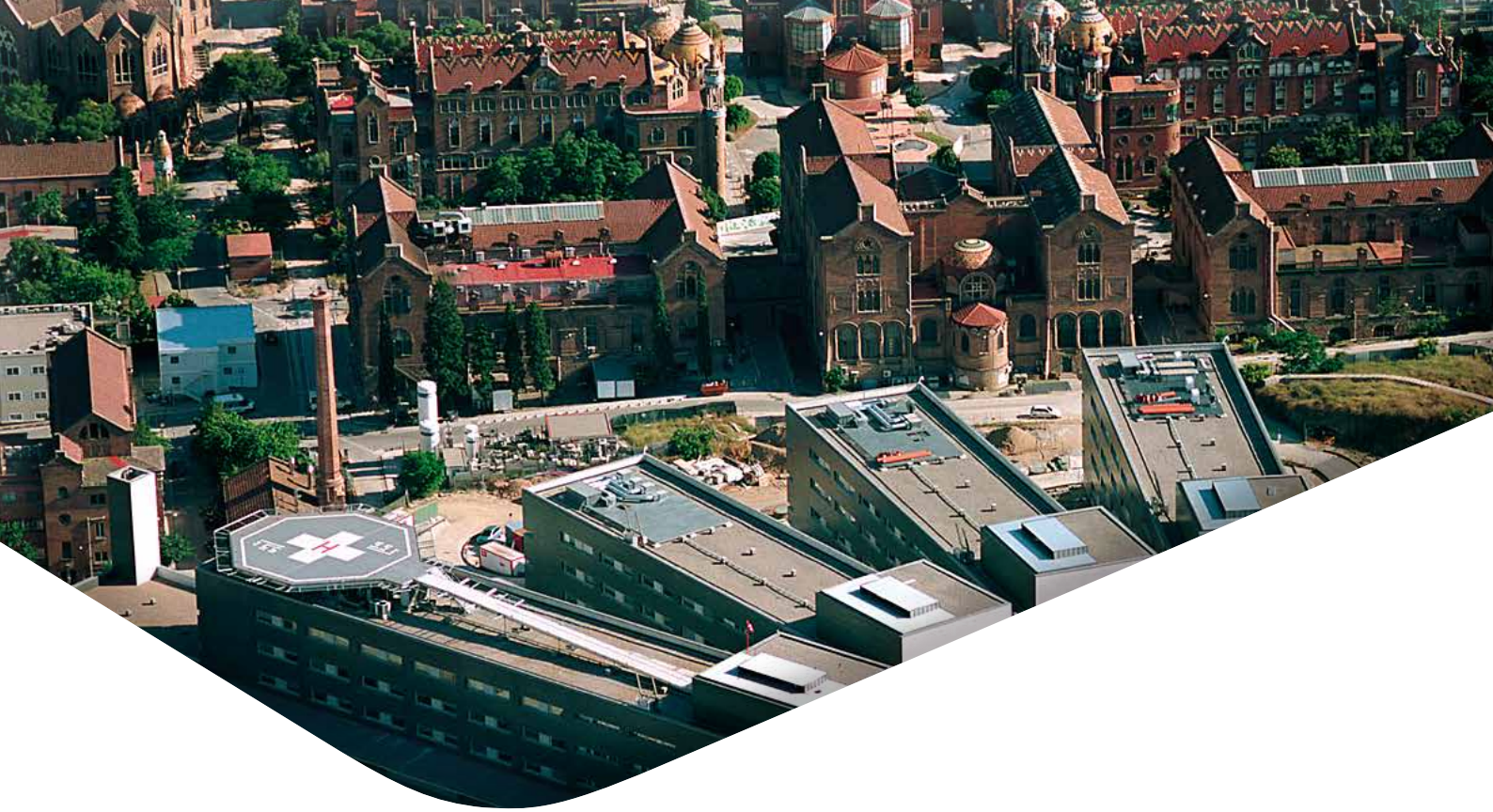


Drug Research Center CIM Sant Pau



CIM Sant Pau began its activities in 1983, in partnership with the clinical pharmacology department of the Hospital de la Santa Creu i Sant Pau and the pharmacology and therapeutics department of the Autonomous University of Barcelona. CIM Sant Pau is functionally and organizationally part of the Biomedical Research Platform of Sant Pau Biomedical Research Institute (IIB Sant Pau).



CIM Sant Pau operates in two main areas:

Clinical research as a business unit:

- Phase I clinical trials: first-in-human administration (bioequivalence, tolerability, pharmacokinetics/ pharmacodynamics in healthy volunteers and special populations).
- Cooperation with Hospital de la Santa Creu i Sant Pau researchers in phase II, phase III and phase IV clinical trials.

Research in Neuropsychopharmacology:

- Psychoactive drug effect evaluation on the central nervous system of the sleep-wake cycle:
 - Wakefulness effects study (daily security).
 - Sleep-quality and sleep-architecture effects study.

ACTIVITIES

Integration of different scientific knowledge areas:

- Ties with the Hospital de la Santa Creu i Sant Pau and the Autonomous University of Barcelona.
- Collaboration with national and international research support organizations (SCReN, ECRIN, CIBERSAM, EIN).
- Multidisciplinary professional team.

Experience, quality and productivity:

- More than 400 studies for national and international pharmaceutical companies.
- Experience with spin-offs and small biotech companies: provision of particular services or joint participation in competitive research funding calls.
- Experience in conducting studies for the food industry.
- High recruitment capacity: database with over 500 active volunteers.
- High levels of activity and productivity.
- Adherence to Good Clinical Practices.

Customer orientation:

- Proximity and flexibility.
- Direct client/expert contact.
- Excellent value for money.
- Adaptation to customer needs.

CIM STRENGTHS



The CIM Sant Pau premises of 650 m² is divided into 2 main areas:

Medical care area, with 4 sections:

- Admissions area, with 24 beds in 4 modules, 100% visible at all times from the nurses' station, and 2 single-bed rooms for polysomnography studies.
- Outpatient area, with 4 individual units equipped for medical, neuro-physio-psychology and psychomotor performance.
- Service and rest area: with bathrooms, kitchen, dining and leisure area.
- Restricted-access area for drug storage and biological sample processing and storage.

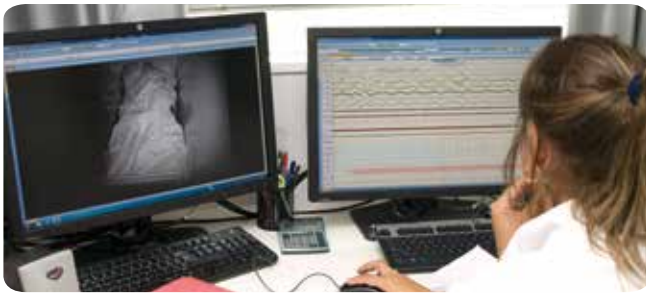
Management, administration and data processing area

- 5 office rooms and a large temporary filing area for clinical trial documentation.

FACILITIES

CIM Sant Pau has the following equipment:

- Clinical facilities for medical tests and intensive vital signs monitoring.
- Equipment for neuro-physio-psychological and psychomotor performance testing.
- Equipment for polysomnographic recordings.
- Equipment and facilities for processing and storing biological samples.
- Continuous recording and temperature control system.



EQUIPMENT

The team consists of 21 professionals from a variety of disciplines, with a solid scientific background and extensive experience in conducting clinical research:

- Specialist research staff (doctors, pharmacists, neurophysiologists, psychologists and nurses).
- Specialist support staff (statistician, laboratory technician, administrators, economists).
- Qualified quality assurance and control personnel.

STAFF

CIM Sant Pau offers the following comprehensive clinical research services:

- Expert advice regarding the clinical development of drugs and food products.
- Project planning and management.
- Protocol and informed consent preparation.
- Preparation, presentation and follow-up of applications to clinical research ethics committees and the Spanish Medicines Agency (AEMPS).
- Clinical trial monitoring.
- Selection and recruitment of volunteers for clinical trials (healthy subjects and patients).
- Pharmacokinetic and/or pharmacodynamic clinical trials (phase I and phases II/III/IV).
- Behavioural safety assessments (psychomotor performance tests).
- Neuro-physio-psychological evaluations.
- Polysomnographic recordings.
- Database design.
- Data management plan development.
- Statistical analysis plan development.
- Data management (input and processing).
- Statistical analysis.
- Final clinical trial report preparation.
- Scientific article preparation.

***SERVICES TO
THE PHARMA-
CEUTICAL AND
BIOTECHNOLOGY
INDUSTRIES***



CIM Sant Pau provides its services to a large number of pharmaceutical companies, innovative and generic, multinational and local and has, in recent years, begun to work increasingly with biotechnology companies.





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