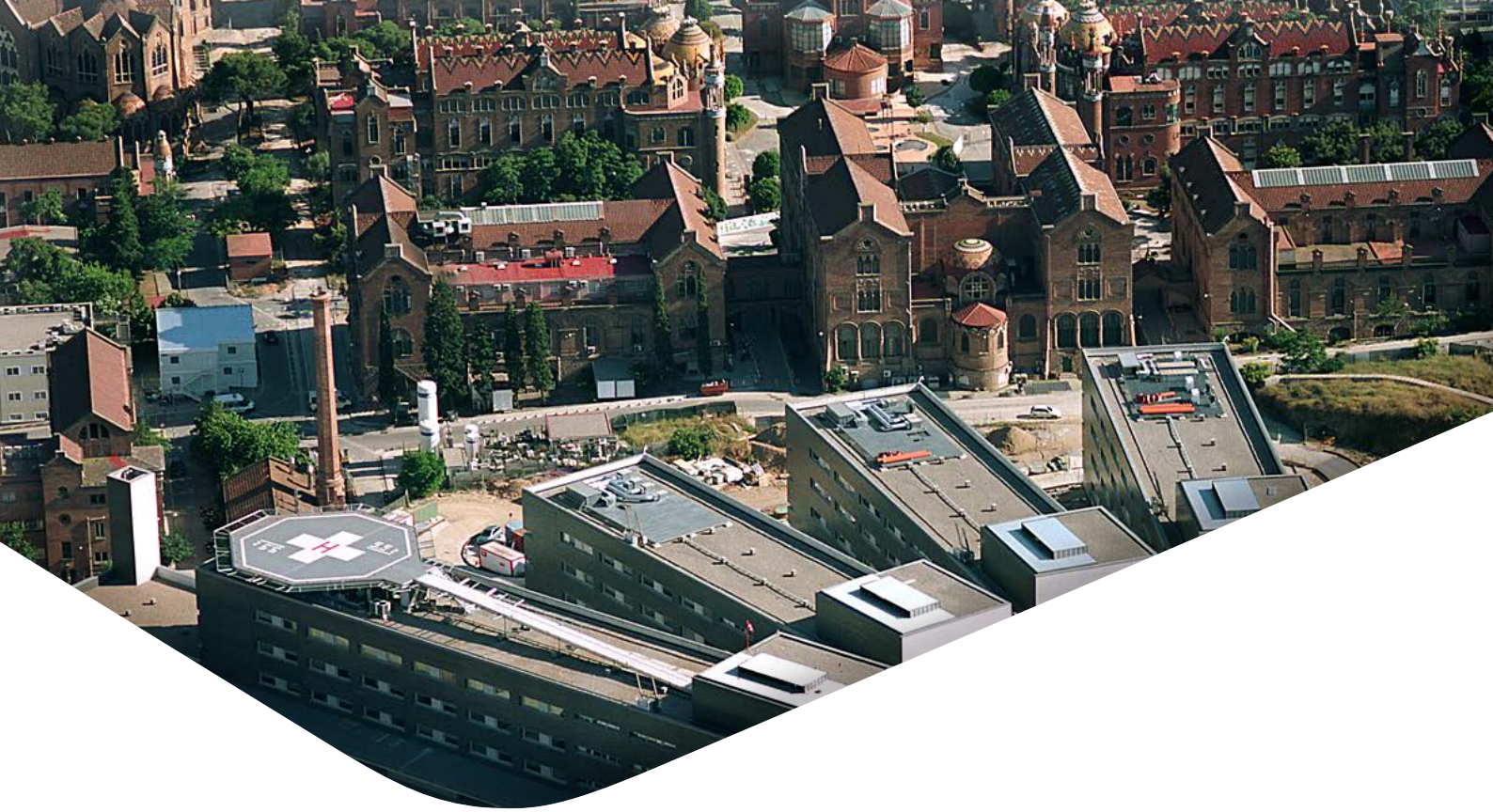


Centre for Drug Research CIM Sant Pau



CIM Sant Pau began its activities in 1983, in partnership with the clinical pharmacology department of the HSCSP and the pharmacology and therapeutics department of the Autonomous University of Barcelona. CIM Sant Pau is functionally and organizationally part of the 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, pharmacokinetics/ pharmacodynamics in healthy volunteers and special populations).
- Cooperation with HSCSP researchers in phase II, phase III and phase IV clinical trials.

Own research lines:

- Evaluation of the effect of drugs on the central nervous system (physiological, pharmacological and pathological aspects of the sleep-wake cycle and neuropsychopharmacology of the higher mental functions).
- Research into the use of predictive mathematical models in pharmacology. Evaluation of the dose-concentration-response relationship using the population approach in order to resolve pharmacological and therapeutic issues.

ACTIVITIES

Integration of different scientific knowledge areas:

- Ties with the HSCSP and the Autonomous University of Barcelona.
- Multidisciplinary professional team.

Experience, quality and productivity:

- More than 300 studies for national and international pharmaceutical companies.
- Experience with spin-offs and newly created biotechs: provision of particular services or joint participation in calls for competitive research funding.
- 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



FACILITIES

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 and neurological, physiological and psychological tests.
- Service and rest area, with bathrooms, kitchen, dining area and leisure area (with activities).
- Restricted-access area for drug storage and biological sample processing and storage.

Management, administration and data processing area

- 5 generously sized offices and a large temporary filing area for clinical trial documentation.

CIM Sant Pau has the following equipment:

- Clinical facilities for medical tests and intensive vital signs monitoring.
- Equipment for neurological, physiological and psychological 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, pharmacists, psychologists, neuropsychologists and nurses).
- Specialist logistical support staff (statisticians, laboratory technicians, 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).
- Neurological, physiological and 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.





Contact

Dr. Rosa M^a Antonijoan
CIM Coordinator
rantonijoana@santpau.cat
Tel. +34 93 553 71 99

Dr. Ildefonso Hervás
Transfer and Innovation Unit Coordinator
IIB Sant Pau
ihervas@santpau.cat
Tel. +34 93 553 78 69

 Follow us on Twitter: @iibsantpau



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