

# Pharmacological Research in Humans



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## Main Lines of Research

### Clinical Trials with no Therapeutic Benefits to Volunteer Participants

- ▶ Phase I clinical trials (healthy volunteers) whose main objectives include: first-time-in- humans, safety and tolerability (local, systemic/dermatological, ophthalmological, vaginal), pharmacokinetics, bioavailability and bioequivalence (generic drugs), pharmacodynamics, interactions (drug-drug/drug-food), evaluation and characterization of biomarkers, proofs of concept, acceptability and preference studies.
- ▶ Follow-up studies in populations with the same or different characteristics (elderly, obese, postmenopausal, with liver or kidney failure).
- ▶ Collaboration with clinical services to conduct phase II/III studies.

### Neuro-Physio-Pharmacology of Sleep/Wake States

- ▶ Investigate human brain activity in sleep and wakefulness, mechanisms involved in these states, problems derived from sleep disturbances and possible interventions.
- ▶ Approach the phenomenon as a continuum: appropriate interpretation of the impact of a certain intervention, whether pharmacological or not, should take into account the complementarity of evaluations performed during sleep and during wakefulness.
- ▶ Develop studies that consider the 24-hour day/night cycle as the phenomenon under study cannot be evaluated without taking this interactivity into account.
- ▶ Develop psychomotor performance tests, subjective evaluation scales, neurophysiologic recordings (quantitative EEG, evoked-sensorial potentials and polysomnography), psychophysiological tests and pupillometric tests.

## Challenges

- ▶ Consolidate and strengthen leadership in this field in Spain, conserve relationships with the pharmaceutical industry on a national level and strengthen and extend relations abroad with multinational enterprises and industries from other sectors.
- ▶ Broaden the range of questions to address in research projects along the lines of the neuro-physio-pharmacology of sleep/wake states, focusing on pharmacotherapeutic objectives and also on physiopathologic objectives in related fields, such as dreams.
- ▶ Develop neurophysiologic recording performance in ambulatory conditions, simplifying participation of volunteers but not lowering the quality of data obtained (non-negotiable element of their application as a research variable).
- ▶ Promote dissemination of our activity with a dual objective: to return knowledge generated to society and demystify research in humans, bringing it closer to the community so as to foster participation in clinical trials (particularly in specific sectors of the populations, such as the elderly).
- ▶ Set up educational activities related to our two main research lines: the application of good clinical practices in clinical research into sleep medicine and its medical (pathology, and treatment) and social (quality of life, prevention of accident risk) consequences.

## Collaborations

### External Collaborations

- ▶ Phase I-II clinical trials for national and international pharmaceutical companies.

## Active Grants

- ▶ Rosa Maria Antonijoan Arbós. Desarrollo de una combinación de sensibilizantes de la acción de la insulina y antiandrógenos para el tratamiento del síndrome de ovario poliquístico en adolescentes y mujeres jóvenes RTC-2016-5671-1. Ministeri d'Economia i Competitivitat. Duration: 2016-2019. 100,796.00 €.

Note: Total amount granted to PI. It does not include indirect costs.

\*TIF: 22.251 \*\*MIF: 2.7813

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