Blueclinical
http://www.blueclinical.com

## Bilateral Meetings

- Wednesday 10:40 h - 13:00 h
- Wednesday 14:00 h - 18:00 h

Description
Blueclinical is a translational medicine company devoted to the development of medicines and medical devices. • Blueclinical Phase I whose mission is to conduct effective studies in healthy subjects and early stage studies in patients, in full compliance with the international regulations. Blueclinical has conducted over 30 phase I trials, both with generics and innovative medicines, in healthy subjects and in selected patient population. Blueclinical has its own phase I unit located at Hospital da Prelada, Porto, where the clinical activities of the phase I trials in healthy subjects are conducted. Our healthy volunteer database currently has over 3 000 registered volunteers. Blueclinical is capable of effectively conducting the clinical part of clinical research protocols in healthy subjects; and is also able to provide its clients with full-service from clinical trial planning up to Study Report writing. • Blueclinical CRP (Clinical Research Partnership) whose mission is to support the activity of clinical research centres, promoting mutual growth, efficiency and excellence in clinical research. So far Blueclinical has established more than a dozen partnerships with Portuguese healthcare institutions belonging to the National Health System. • Blueclinical R&D whose mission is to partner with institutions and companies in the development of successful translational medicine projects.
Organization Type
Company
Areas of Activities

**Medical devices**

**Other**

Offer

## Preclinical and regulatory consultancy and Clinical trials full services

Blueclinical supports sponsors in the definition of the target product profile and the definition of preclinical and regulatory plans.

Blueclinical is prepared to provide qualified “full services”:
- Organization of scientific and regulatory advice by pertinent regulatory authorities (FDA, EMA, etc.), when needed.
- Clinical conduct in according with the best ethical standards and good clinical practice.

- Data management and study reporting according to the latest regulatory requirements
- Standard software used for the analyses (SAS, etc.).
- SAS datasets organized in accordance with CDISC specifications for the FDA.
- Established partnership with worldwide known GLP-accredited bioanalytical providers.

Blueclinical is also available to participate in international consortia candidate to Horizon 2020 calls or to other funding agencies.

Cooperation Offered

1. Research co-operation
2. Other