

PIVOTAL : MEDICAL DIVISION

■ *The Team*

- Oncologists, Haematologist, Cardiologist, Internist, Epidemiologist, Immunologist, Psychiatrist.
- Solid background in Clinical Research: proven track record in drug clinical development in various therapeutic areas.
- Background in Clinical Practice: good understanding of the interphase between Clinical Research and Clinical Practice.

■ *Services offered*

STRATEGIC FOCUS

- Specialisation in different therapeutic areas
- Clinical Trials design from Phase I to Phase IV
- Perform strategic plans for drug development
- Analysis of investigational leads
- Facilitate communication between pharmaceutical companies and cooperative groups
- Consultancy on Scientific/Medical issues

TACTICAL IMPLEMENTATION

- Support to Clinical Operations: Medical Monitoring; Project Management; Handle Clarifications on Protocol's Queries by ECs and AEMPS; Therapeutic Area Training....
- Support to DMBS: Design and Produce CRFs; Query Plans; Statistical Analysis Plans; Final Reports....

MEDICAL WRITING

- Protocols
- Amendments
- Investigator Brochures
- Abstracts/Posters
- Papers
- Product Monographs
- Clinical Dossiers
- Final Clinical Reports (ICH)

PHARMACOVIGILANCE

- SAEs Assessments / Narratives
- Data Bases Reconciliation
- ASRs (Annual Safety Reports)
- Safety Expert reports

MEDICAL MONITORING

- Medical Monitoring of International and Local Clinical Trials
- Solid Experience in First in Human Trials