

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

- Sport 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 Production of CRFs; Query Plans; Statistical Analysis Plans; Final Reports

MEDICAL WRITING

- Protocols and papers
- Amendments and Product Monographs
- Investigators Brochures and Clinical Dossiers
- Abstracts/Posters and 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

