

# Clinical Research – Clinical Investigations (ISO 14155, GCP-ICH)



- ▶ Clinical Protocol Development,
- ▶ Preparation of Study Documentation:  
Investigator's Brochures, CRFs, Patient Information,  
Patient Informed Consent Letters,
- ▶ Start Formalities Including Ethic Votes Procedures  
and Study Notifications,
- ▶ Organization of Medical Advisory Boards,
- ▶ Preparation and Organization of Investigator Meetings,
- ▶ Study Monitoring,
- ▶ Study Quality Audits,
- ▶ Data Management and Statistic Services,
- ▶ Preparation of Final Clinical Reports.

