IdiPAZ Instituto de Investigación Hospital Universitario La Paz

# CLINICAL TRIALS AND RESEARCH UNIT (UICEC)

# PORTFOLIO OF SERVICES

| CONCEPT | TYPE OF PROFILE |
|---|---|
| **METHODOLOGIC SUPPORT** | |
| Advice on study requirements and documentation | A |
| Protocol development and design, including annexes | A |
| Protocol adaptation | A |
| Patient information sheet and informed consent form writing or adaptation | A |
| **CLINICAL TRIAL PRE-STUDY ACTIVITIES** | |
| Site identification and selection, if applicable | B |
| IMP specific documentation preparation (in case of PEI, importation, distribution or packaging) | A |
| Civil liability insurance policy request (selection, procurement and document processing) | C |
| Local documents preparation and submission to Ethics Committees | C |
| General documents preparation.<br>Clinical trial application to Regulatory Authorities-AEMPS (EudraCT, Annex 1A, A1) | B |
| Protocol submission to AEMPS | C |
| Fee payment (EC fees, AEMPS fees) | C |
| Response to Ethics Committee clarification´s request | A |
| Response to AEMPS clarification´s/ rectification´s request | A |
| Clinical trial registration (www.clinicaltrials.gov) and periodic update | C |
| Spanish Clinical Trials Registry and periodic update | C |
| Site contract´s management | C |
| Specific monitoring plan development | A |
| Sponsor File preparation | C |
| Investigator File preparation (per investigator) | C |

| STUDY DEVELOPMENT | |
|---|---|
| Project management (study coordination) | A |
| AEMPS and EC study initiation notification | C |
| Prepare and perform a Site Initiation Visit and visit report | B |
| Prepare and perform a Pharmacy Initiation Visit and visit report | B |
| Study File mantainance during the study | C |
| «On-line Monitoring» (Web-based) | B |
| Prepare and perform periodic monitoring visits and reports | B |
| Prepare and perform Pharmacy visits, investigational product accountability and visit report | B |
| Periodic Newsletters | A |
| Investigador Meeting organization | A |
| Teleconference´s organization | A |
| Document preparation for protocol ammendments | A |
| Document preparation for new site´s addition | C |
| Ammendment submission to AEMPS | C |
| Ammendment submission to EC | C |
| Finantial management, administrative management and payments | C |
| Management and control of complementary tests (PK, imaging, etc) | B |
| Investigational product shipment management and control | B |
| Study annual report writing | A |
| Annual report processing and notification to AEMPS/EC/Autonomous Regions | C |
| **FINALISATION AND CLOSURE** | |
| Prepare and perform the site close-out visit and visit report | B |
| Pharmacy close-out visit (drug recontiliation and accountability) | B |
| Queries resolution and database lock | A |
| Closure notification to AEMPS | C |
| Closure notification to EC | C |
| Final study report writing (not regulatory) | A |
| Final study report writing (ICH) (Not including safety information) | A |
| Audit preparation | A o B |
| Publication of study results (medical writing) | A |

| PHARMACOVIGILANCE | |
|---|---|
| Implementation plan of Pharmacovigilance activities | A |
| Periodic SAE reconciliación Ander external pharmacovigilance procedures | A |
| Annual safety report writing | A |
| Annual safety report writing (DSUR format) | A |
| Serious adverse events (SAE) and SUSAR management | A |
| Safety reports processing/notification to AEMPS/EC/Autonomous Regions | C |
| Final safety report writing | A |
| **STADISTICS AND DATA MANAGEMENT** | |
| Sample size calculations | A |
| Randomization sequence | A |
| Statistical Analysis Plan | A |
| Database creation and validation | A |
| Electronic CRF design, creation and mantainance | A |
| Data entry | B |
| Statistical analysis | A |
| **MEDICAL AND NURSING TASKS** | |
| Biological simples collection | B |
| Nursing procedures | B |
| Biological simples processing and shipping management | B |
| Recruitiment assistance | A or B |
| Continuous care tasks (working day) | A, B and/or C |
| Continuous care tasks (holiday) | A, B and/or C |

| CONCEPT |
|---|
| **OTROS** |
| Conference room (audiovisual + teleconference) |
| Examination room |
| Filing of 5 boxes (for 25 years) |
| Filing of 10 boxes (for 25 years) |

**TYPE OF PROFILE:**

| PERFIL | Healthcare/not healthcare profile | |
|---|---|---|
| **A** | **High profile** | Project Manager (PM) / Medical Doctor Specialist- Clinical Pharmacologist |
| **B** | **Medium profile** | Clinical Research Associate (CRA) / Nurse |
| **C** | **Low profile** | Clinical Trials Assistant (CTA) / Nurse Assistant |