CLINICAL RESEARCH AREA - IIS La Fe

SERVICE DESCRIPTION

Estabilised in 2010, the Clinical Research Area- IIS La Fe manages, develops and collaborates in clinical studies sponsored by the pharmaceutical industry and by the Institute itself and its researchers.

The Area, in collaboration with other IIS La Fe Areas and Platforms, participates in the startup and monitoring of clinical studies for the clinical validation of innovative health initiatives, promoting the translation of scientific results in improvements to patient's health.

The Clinical Research Area - IIS La Fe provides services needed to carry out clinical studies, including scientific, methodological, ethical-legal, clinical and logistic support as well as project management, coordination and clinical trial monitoring.

It counts with a professional team specialized in clinical trials, including Project Manager, CRAs (Clinical Research Associates), Study Coordinators, Data Managers and CTAs (Clinical Trials Assistants) that provide administrative support on contract management among others. This structure, allows the Area to operate as a CRO (Clinical Research Organization) and offer an integral service in clinical trials in all its phases.

Integrated within its structure, the Area has a Clinical Research and Biological Activity Unit (UICAB), which is a facility strategically located indoor La Fe Hospital, dedicated exclusively to conduct clinical trials in all its phases, including Phase I. This Unit is composed of a multidisciplinary team of doctors, nurses and pharmacists highly trained to treat patients, administer treatments and obtain and process samples in order to achieve high quality clinical trials.

In order to request support from the Clinical Research Area- IIS La Fe, it is necessary to make an appointment by email at investigación_clinica@iislafe.es, specifying the services required by the applicant.

Opening hours are from Monday to Thursday from 9 a.m. to 3 p.m. and from 4 a.m. to 6 p.m. and Fridays from 9 a.m. to 3 p.m.

SECTORS OF BUSINESS APPLICATION

Promoted by IIS La Fe and integrated within its structure, the Clinical Research Area- IIS La Fe offers a comprehensive management service in all aspects related to the design, coordination and development of Clinical Research for Pharmaceutical, Biotechnological and Medical devices companies, in compliance with national and international current standards (ICH/GCP guidelines).

TECHNICAL ADVANTAGES AND BUSINESS BENEFITS

COMPREHENSIVE SERVICE:

Clinical Research Area- IIS La Fe offers collaboration in the following stages of a clinical study:

1. **Initial Stage**

   - Methodological support:
     - Study design (justification, hypothesis, objectives, inclusion and exclusion criteria, sample size calculation, preparation of randomization tables, statistical analysis, interpretation and presentation of results)
   - Drafting and review of all the necessary documentation for the clinical study (protocol, Patient Information Form and Informed Consent Form, CRF, etc.)
   - Budget planning
   - Advice and consultancy in the site and investigators selection. Feasibilities
   - Advice on ethical-legal requirements and study documentation

2. **Startup**

CLINICAL RESEARCH AREA - IIS La Fe

- Submission to Regulatory Authorities (CEIm, AEMPS, …)
- Response to clarifications requested by Regulatory Authorities (CEIm, AEMPS, …)
- Clinicaltrials.gov protocol registration and regular maintenance
- Clinical trial agreements management
- Clinical trial Insurance management
- Monitoring manual drafting
- Preparation of Statistical plans
- Trial master file

3. **Development of the study:**

- Project management (Coordination)
- Clinical trial material, medication and biological samples management
- Design and maintenance of electronic CRF
- Randomization list
- Trial initiation visit and investigators' training
- Trial initiation monitoring report
- Notification of trial initiation to Regulatory Authorities
- Monitoring and preparation of monitoring visits reports
- Remote monitoring visits
- Advice on the compliance of GCPs.
- Nursing procedures: vital signs, ECG, other procedures according to the clinical study, extraction, processing, storage and shipment of biological samples
- Preparation of amendments documentation (protocol, extension of centers ...) and submission to Regulatory Authorities (CEIm, AEMPS)
- Notification of SAEs, SUSARs
- Preparation of annual study reports and submission to Regulatory Authorities (CEIm, AEMPS)

4. **Completion**

- Final trial close-out visits and monitoring reports
- Statistical analysis
- Final clinical trial report
- Custody of clinical trial documentation

PARTNER SEARCHED

We are looking for pharmaceutical, biotechnological and medical devices companies that are willing to carry out clinical research in medicines, nutraceuticals or medical devices.

IMAGES

CONTACT INFORMATION

María Cortell Ballester - **Clinical Research Area- IIS La Fe**
investigacion_clinica@iislafe.es
Instituto de Investigación Sanitaria La Fe
Avinguda de Fernando Abril Martorell, nª 106 - 46026 Valencia