KlinAR

Contract Research Organization

Optimize your expectations!

To whom it may concern;

Klinar CRO is happy to share its 9 years of history of information and experience with its clients.

With full-service area, Klinar CRO is an independent research organization specialized with Phase II, Phase III and Phase IV clinical researchs and post-marketing trials.

Since it was established, our company that operates on clinical research area and has an expert staff; provides the other services specified in attachment in addition to the services which are provided in research.

Since it was established, it has been involved in successful trials on clinical research area in a short time with emphasis on quality.

Unchangeable principle of our company is always quality, service and reasonable prices. Klinar CRO that works with principle of "the guarantee of success and sustainability in the sector is honesty and quality service" thanks for your interest and support and will continue to provide service today and in the future.

KLİNAR CRO

MAIN SERVICE COMPONENTS

The most important responsibility towards our clients is providing updated regulatory consultancy, and accommodating to the changed guidelines and requirements and applicable laws. To perform this responsibility we are following the activities of Regulatory Authorities and updating other documents and process about our standart operating procedures (SOP) . The most important services that we provided within this scope are;

Design and Regulatory Services

Developing Standart Operating Procedure and giving necessary counseling in this regard,

Providing central audit and system audit counseling and staff hiring for preparation,

Preparation of Ethics Committee – Ministry of Health Submission Files, Submission Follow Up and Approval,

Designing and conducting of drug studies, observational studies, medical device studies, pattern studies, pharmacoeconomy studies, compassionate use program,

Preparation of study support material and process management
(Guideline, patient cards, physician information cards, brochures, newsletter, e-newsletter etc.)

Increase of quality control systems with performing the monitoring of all studies.

Organization Services

Performing feasibility activities and preparation of feasibility reports

Organization and process management of institution or private examination centers, providing sample transfers domestic and foreign in clinical research,

Organizations and purchasing of all third party payments and delivery, accounting records

Import licence and customs procedure follow up

Organization of patient support and patient transfer procedures

Employment Services

Site coordinator support service (employment, management, payment organization)

Employment of data entry support employee

Hiring clinical research associate

Employment of clinical trial assistant

Employement of study nurse

Training Services

ICH-GCP training

Basic CRA and clinical research associate trainings (with workshop)

Biostatistics training

Budgeting research and process management training

Pharmacoeconomy trainings

Pharmacovigilance trainings

Time management, management skills, leadership trainings

Research Management Services

Project management

Site management

Investigator Meeting Planning and Coordination

Site Specific File Management

Clinical research documentation (storage of completed study materials)

Storage and destruction procedures of clinical research returned materials

Data Management and Analysis Services

Sample calculation

Data base prepations

Preparations of statistical analysis plan

Data entry and data clearing systems (double data entry)

Preparation of query systems and clean data

Statistical analysis

Interim analysis

Preparation of clinical study report

Electronical study design

Finalization of validation processes and electronic data capture desing according to the international guidelines

Translation and Publication Services

Performing clinical study translations

Performing all kinds of article, literature, abstract translations

Preparation of synopsis and articles to journals

Journal Synopsis and Articles Redaction

Graphic and Visuals Preparation

Poster preparation

Article and poster submissions to Medical journals and congresses and follow up

Pharmacovigilance Services

Assessment of drug/medical device adverse events

Adverse event follow-up

Adverse event classification

Updating literature

Literature follow-up

Reporting to the authorities

Building electronical tracking systems integrate with TÜFAM (Turkish MoH) and periodically reporting

Reporting to the company

Adverse event notification

Pharmacovigilance training (clinical drug studies)

Pharmacovigilance training (accredited drugs)

Serious Adverse Event Reporting

Safety Notifications (SUSAR Notification / IN Preparation and follow-up)

Other Services

Large Scale Site Studies, Design of sample size according to the regions

Pollster training and pilot survey scheme

Collecting necessary samples and pilot survey scheme

Patients calls (call center)

Social studies

Medical association and public health department studies

Preparation and conducting of university support and donation project submission file (TUBİTAK, ARDEB etc.)

Regulatory Authority Submissions (All submissions of related clinical trial department are performed by us on a monthly basis price)

Setting up electronical order portals, tracking product storage stock information and preparation and submission of necessary reporting


RESEARCH MANAGEMENT SERVICES
PHARMACOVIGILANCE SERVICES
ORGANIZATION SERVICES
TRAINING SERVICES
DATA MANAGEMENT AND ANALYSIS SERVICES
REGULATORY SERVICES DESIGN AND
EMPLOYMENT SERVICES
PUBLICATION SERVICES TRANSLATION AND