Phaze S.A. is a contract research organization established in April 2010, in Athens, Greece, offering a wide range of services in the clinical research field.

With our team of dedicated & experienced clinical research professionals, we offer high quality tailor made solutions to pharmaceutical & biotechnology companies, as well as CROs and other research institutions.

phaze
clinical research & pharma consulting

face to phaze

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phaze
the future
together

OUR VISION

We are a committed and fully reliable partner for pharmaceutical, biotechnology, CRO industry and medical researchers in Greece and overseas market, offering always the maximum of our capabilities in quality, flexibility, initiative, creation and effectiveness.

OUR MISSION

The proper use of our knowledge, experience, confidence and relationships for timely & accurately surveying the results of clinical studies (phase I-IV) in order to become meaningful partners in the rapid development and promotion of pharmaceutical products.

OUR VALUES

People: Our first and highest priority are the people; colleague, collaborator, client, physician but above all the patient.

Trust: We strive at developing relationships of mutual trust with the entire network of people, organizations and authorities relating to our work.

Moral integrity: Is for us a core foundation of leadership & we lead by being transparent, honest and ethical in all our interactions with employees, clients, investigators, partners & vendors.

Communication: We believe in a culture of open communication at all levels as a key to success.

Team spirit: We are our team, managing successfully clinical development programs via continuous effort, continuous improvement, and continuous innovation.

Quality: We focus strongly on quality processes to access, anticipate & fulfil clinical research needs.

OUR SERVICES

Project Management

- study design generation & core study document creation
- study planning set up & management (project management, risk management, change management, recruitment, & communication plans)
- site contract negotiations & set up
- team management (train, support & manage project dedicated teams)
- study completion according to the agreed deliverables, budget & timelines

Clinical Monitoring

- recruitment and selection of study sites
- study files set up and maintenance
- in-house and on-site management and monitoring
- investigator & monitors meeting organization, conduct and participation
- SAE and SUSAR reporting
- investigators' payment & clinical grants management
- remote monitoring

Safety & Pharmacovigilance

- safety review of CRFs in house by qualified personnel
- full reporting of SAEs according to Sponsor's safety reporting SOPs and systems
- timely follow-up of all SAEs in close collaboration with all related parties
- AE/SAE (s) Reconciliation

Complete pharmacovigilance services offered via established partner which include:

- provision of responsible person for pharmacovigilance
- Eudravigilance registration & Safety reporting
- assessment and medical review of serious adverse events
- Safety Update Reports to Authorities
- 24hr Safety Contact Person

Data Management

- protocol and (e) CRF development
- database set-up & programming
- creation of annotated CRF
- query management
- medical data Coding
- single/double data entry
- creation of DMP (Data Management Plan) data validation checks, creation of validation programs and DCFs generation
- SAE reconciliation
- database QC

Biostatistics

- statistical input in study protocols including sample size calculation
- randomization schedule creation
- creation of SAP (Statistical Analysis Plan)
- statistical programming
- development of statistical tables, figures and listings
- interim analysis
- statistical or integrated report preparation
- creation of CDISC compliant databases

Market Research

- questionnaires' development
- coordination of questionnaires' distribution/collection
- organization & conduct of focus groups and advisory boards
- data entry and statistical analysis
- interpretation of results (report)
- presentation custom made to clients' requirements

Medical Writing

- scientific & clinical documents (protocol synopses/full protocols, patients' informed consent & case report forms) preparation & writing
- abstract, poster presentation and manuscript preparation & writing
- clinical study report
- literature search & review conduct, as appropriate for publication/document development
- training material and clinical manuals preparation

Medical/Scientific Translations

- translation of medical and scientific texts, including protocols, patients' informed consent forms journals, articles, abstracts/posters, scientific/clinical manuals, contracts & training materials
- proofreading and certificate of translation or/and backtranslation by a certified translator are available upon request

ADDITIONAL SERVICES

Regulatory Affairs: support in strategy set up, IRB/IEC & RA submissions, site contract management.
Quality Assurance: study/site/TMF/vendor audits, SOP development.
Training: detailed & comprehensive clinical research training programme, ICH-GCP training, investigator clinical research & study specific training programs.

eqa quality for leaders ISO 9001:2015

HACRO Hellenic Association of CROs
Founding Member of Hellenic Association of CROs