CLINICAL TECHNOLOGY & PROCESS

Clinical Technology & Process

Due to an enormous degree of technological innovation in the healthcare system, today's hospitals have become technologically sophisticated centres of healthcare delivery and thus demand technically competent staff

Pepgra CRO offers clinical technologists with the technology side of clinical operations where they play an essential role in assisting the hospitals or physicians by providing the technological support they require.

Pepgra CRO offers you the state of the art services in clinical technology. Our long experience with electronic data capture technology in clinical procedures has enabled us to become one of the frontrunners in the clinical technology services industry. We serve biotechnology, medical device, and pharmaceutical companies with technological support to manage their clinical R&D trials, technology infrastructure, and business operations.

Our global delivery model provides native language support and multilingual support to serve your patients, investigators, site staff, and supervisors. We offer complete assistance in site assessment and internet service provider connectivity. We evaluate the technological infrastructure of the site and ramp-up requirements that would facilitate access to clinical applications and facilities. With our in-house expertise, we ensure that your sites are equipped with custom software images ande provide the necessary hardware support besides solutions for breakage, warranty repairs, and sophisticated remote diagnosis devices to monitor the end-users in the trial.

Our close-out process has been so designed that the data delivered is highly secure and on time. Besides, the process has provided for quality assurance and confirmation from the investigators once they have received and reviewed it. Having understood the varying needs and preferences of our clients, we provide maximum flexibility and scalability to realize their enterprise goals. We leverage our in-house expertise in life sciences support service to provide the most

cost-effective and high-quality service to our clients. Our assistance to pharmaceutical companies in upgrading their IT infrastructure has helped us understand the interaction between the pharmaceutical industry and IT in the global organization and upscale our service offering for life sciences clients.

Our clinical technology training module, which is offered by our experts in-person or through the web, intends to develop your software skills and business process knowledge to help you obtain more accurate and comprehensive clinical trial data. We recognize the challenges before the sponsors and service providers and we are committed to establishing and developing sustainable contracts and working towards achieving a strong partnership with our clients.

Comprehensive Clinical Technology & Process Solutions

Our services include

- Development of Custom software images.
- Hardware support besides solutions for breakage, warranty repairs, and sophisticated remote diagnosis devices to monitor the end-users in the trial.
- Upgrading their IT infrastructure
- Complete assistance in site assessment and internet service provider connectivity

Our Expertise and Experience

Here are the advantages of roping in Pepgra experts:

- Well-versed in working with various stakeholders like clinical operations, data management, biostatistics, medical and safety teams to deliver documents.
- Experience in writing documents for various phases of clinical development including Phase I to Phase IV, PMS and Post-Authorization Safety Studies (PASS).
- Includes medical devices, prescription drugs (with extensive knowledge of pharmacokinetics, pharmacodynamics, and pharmacogenomics), over-the-counter medicines, veterinary medicines, cosmetics, biologics and nutraceuticals.
- Complete understanding of drug development process, including New Chemical Entities (NCEs), generic, biologics and biosimilars.
- Adherence to country-specific guidelines and norms.
- Knowledge of guidelines pertaining to the following: GPP3, International Committee of Medical Journal Editors (ICMJE), Consolidated Standards of Reporting Trials (CONSORT), Strengthening the Reporting of Observational studies in Epidemiology (STROBE), Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) and other applicable regulatory guidelines

Other guidelines include the following: Association of the British Pharmaceutical Industry (ABPI), Standards for Reporting of Diagnostic Accuracy (STRAD), ICH, FDA, and MedDev.

Our Experts (Regulatory Medical Writers):

- Our geographically and professionally broad team of regulatory writers are qualified to the MSC, MD, MBBS, PharmD. or PhD level and possess extensive regulatory knowledge of industry guidelines located in 100+ countries.
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- Our regulatory medical writers have vast experience in writing and editing a wide range of clinical trial documentation involved in the

regulatory process.

- Our writers undergo regular training conducted by the AMWA (American Medical Writers Association) and the EMWA (European Medical Writers Association) and other recognized medical writing organization to keep their skills at the vanguard of the medical writing field.
- Our translation team consists of native speakers with many years of experience in translating all documents necessary for the performance of clinical studies.

Therapeutic Areas that we work

- Vast experience in working across multiple therapeutic areas like Biochemistry, Diabetes, Gastrointestinal, Renal/Nephrology, Respiratory, Psychiatry, Rheumatology, Cardiovascular, Toxicology and Oncology

Editing & Formatting:

- Submission-ready documents in terms of technical information, language, format, and template used to prepare the document

Our Quality Control & Assurance:

- All our clinical development services are done in accordance with our SOPs compliant standards. All our regulatory documents undergo thorough scientific, medical, editorial, quality check and assurance to ensure that the clinical documents we produce are scientifically accurate.
- The documents are prepared using sponsored-provided materials SOPs or Pepgra suite of International Conference on Harmonization ICH-compliant templates and style guides. In either case, Pepgra medical writing team ensures that the document we produce is of the highest quality in terms of scientific content, style and formatting.

Delivery:

- Timely delivery of the highest standard of quality
- Culturally sensitive to the locale and competitive price

Our regulatory medical writers hold vast experience in handling a wide range of therapeutic areas and all phases of development that are sound from both a scientific and regulatory perspective.

Related Services

- Clinical Research Monitoring
- Clinical Study Design
- Global Regulatory Writing
- Statistical Programming
- Patient Recruitment
- Regulatory Affairs
- Data Management
- Post Market Surveillance
- Clinical Technology process
- Healthcare Analytics
- Health Data Collection
- Literature Search Screening

-For Plans and Packages click here-

ABOUT US

At Pepgra we are open to new ideas, different people and various cultures. We'd love to hear as to what you can offer us and we'd like to reciprocate as well. People with ideas, skills and qualifications in the medical and pharmaceutical industry are welcome to contact us for any kind of CRO engagements.

Pepgra has plenty of skills to offer you in various phases of clinical research trials. Be it regulatory writing, biostatistics, regulatory approvals, trial monitoring, drug/device development, and clinical reports.

Our native experts know your market, ethics, protocols and culture. Pepgra is your reliable CRO ally who can pitch in when it is critical. Become our partner today.

Contact us: Greenheys Business Centre, Pencroft Way, Manchester M15 6JJ, United Kingdom.
+919884350006 **pepgrahealthcare@gmail.com** **www.pepgra.com**