CLINICAL TRIAL AUDIT & SITE MONITORING SERVICES

Clinical Trial Audit & Site Monitoring Services

Regulatory affairs are another core area for clinical trials. Pharmaceutical firms need a constant update on in-and-out on country-specific regulatory and ethics requirements to keep compliant with ever-changing legislation.
A team regulatory affair at Pepgra CRO advice on legal and scientific restraints from a global perspective thereby help you achieve your goals

Pepgra CRO offers its clients high quality Clinical and Regulatory Expert Services. Our expertise in the regulatory services draws extensively on the latest research for helping you design and implement clinical, regulatory framework depending on their requirement. Our services in regulatory services have been widely appreciated by our clients from pharmaceutical and biotechnology industries.

Our experts in regulatory affairs from world's top pharmaceutical firms pay the closest attention to providing support in developing new medicinal products, integrating regulatory principles, and drafting and submitting relevant reports to health authorities. Our project management team will gather all documents including informed consent forms, writing the information for volunteers, competing the online IRAS form and also obtain necessary documentation and specialist opinion for ethics submission. We guide our clients in planning and implementing post-marketing activities. We provide enhanced guidance to the start-ups in discovering, testing, manufacturing, and marketing of medicinal products and thus ensure that the products supplied to make a useful contribution to public health.

We offer our clients customized service assistance in decision making, planning and management, and availing and executing strategic training and projects. Our experts keep a close track of the periodic and interim changes in the legislation in various regions and guide our clients in incorporat-

ing necessary changes in the products and advise them on legal and scientific restrictions

Comprehensive Regulatory affairs Solutions

- abbreviated new drug application (ANDA)
- investigational medicinal dossier (IMPD)
- CTA submissions
- paediatric investigation plan
- reformatting of dossiers
- financial analysis and agreement terms for licensing and acquisition
- health technology assessment
- medical and regulatory writing
- clinical development
- commercial assessment and valuation of biopharmaceutical assets
- health technology assessment
- pricing and market access
- product and portfolio decision making
- statistics and data analytics

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 Medi-

cal 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