CLINICAL DATA MANAGEMENT

Clinical Data Management

Clinical data management is proving to be a humungous challenge because of continuous and rigorous monitoring by regulatory authorities in addition to the ever-growing intricacies of clinical trial procedures. To overcome the challenge Pepgra CRO experts will assist you in taking responsibility of your clinical data management project.

By considering the complexities and the fundamental nature of a clinical trial, it necessarily warrants the need for a system of clinical management that is state-of-the-art and extensively associated services that go a long way in simplifying the conduct, study design, compliance and management of discrepancies.

The process of gathering, storing and curating copious volumes of clinical data is deemed to be very intrinsic from the perspective of regulatory compliance. Pepgra is a contract research organization engaged in full-fledged and knowledge-based services and offers clinical data management solutions from Phase I through post-marketing trials.

Pepgra offers clinical data management services that are specialized; clinical research organizations can stand to ensure that the quality of data is superior and also assures as to the integrity of the clinical data. Pepgra assures that the data that is being managed totally and complies with international standards to ensure consistency within clinical data. In addition, our team also involves the use of data management best practices while adopting specific technologies that are latest to aid the process of clinical data management.

Comprehensive Regulatory affairs Solutions

Pepgra offers the following services:

- We develop CRF /eCRF papers
- Double-key data entry
- CRF printing and distribution, design and set up of the clinical database
- We develop a clinical database that can be delivered with the help of CDISC SDTM standards
- Ascribes to the specifications as laid down by CDISC CRT-DD
- Effective management of electronic data that (central readers, central labs)
- Data validation
- SAE reconciliation
- Query generation & resolution
- Integration of transferred data into the clinical database
- SAS datasets
- Data management system
- Integration with the clinical database, transferred data being reconciled against CRF data, validation of data and generating query and resolution

Our team of global clinical data management experts are committed to following a process-driven approach, thereby developing a truly customized strategy for your project requirements. We offer technical expertise in running clinical trials on EDC, CTMS, eTMF platforms and importing data from various devices.

Our Expertise and Experience

Here are the advantages of roping in Pepgra experts:

- Well-versed in working with various stake-holders like clinical operations, data man-agement, 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 phar-macokinetics, pharmacodynamics, and pharmacogenomics), over-the-counter medicines, veterinary medicines, cosmetics, biologics and nutraceuticals.
- Complete understanding of drug develop-ment 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), Consolidat-ed Standards of Reporting Trials (CON-SORT), 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: Associ-ation 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.

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