POST MARKET SURVEILLANCE

Monitoring drug safety

Pepgra has extensive experience in preparing post-market surveillance (PMS) reports. Our PMS experts adhere to guidelines such as the European Medicines Agency (EMA), Food & Drug Administration (FDA), and other local country guidelines.

Extensive Post-Market Surveillance

In recent years, emphasis on legislation in post-market clinical data is becoming increasingly more prevalent. Thus, regulatory agencies have compelled the need for a feedback system specifically to provide early warning of quality problems and require input into corrective and preventive action processes for the manufacturers.

Pepgra CRO helps in advancing public health by detecting and assessing safety indications from available data sources using evidence-based techniques and recommends appropriate regulatory actions such as changes in labelling, Risk Evaluation and Mitigation Strategies (REMS) and communication of relevant safety information.

Pepgra CRO, with its vast knowledge of pharma industry and impressive in-house capabilities, offers their clients a high quality and cost-effective services in post-marketing surveillance. Our post-marketing surveillance experts with strong educational background and experience in clinical training offer you effective solutions to mitigate the adverse effects of drugs and medical devices. We leverage our state-of-the-art technological infrastructure to transfer the benefits of the latest advancements in PMS to our clients.

We collaborate with expert PMS analysts and systems around the world to provide the best of PMS services to our clients. Our scrupulous adherence to global guidelines and best practices in documentation has enabled us to win distinct appreciation from our clients for consistency and professionalism. Our team has a well-versed understanding of various guidelines, including MEDDEV, and EN ISO. We understand the repercussions of administering drugs or medical devices that are likely to cause serious adverse effects in the patients.

Pepgra CRO organizational philosophy shows zero

tolerance to even marginal fluctuations when it comes to maintenance of safety standards and effectiveness of the drug or medical device. Our service in the way of an end-to-end complaint management system is beneficial to our clients in addressing issues related to patient outcomes in a cost-effective way. We ensure that all our PMS services conform to GPSP and GVP standards.

At Pepgra CRO, PMS experts undergo continuous scientific training to gain insights into the latest processes, procedures and technological advancements that impact the quality and delivery of PMS services. In addition, Pepgra CRO's customized learning and development programs prepare our expert team to meet the challenges of technically complex PMS processes. Our team of consultants possess excellent knowledge of engineering, quality assurance, product engineering besides considerable regulatory compliance experience. We make the optimal use of global PMS template in offering PMS services to our clients. Our global network helps us to provide services of international standards at reasonable prices. Our blend of highly qualified and trained PMS specialists and sophisticated technological prowess is enabling us to provide effective PMS suggestions and recommendations to our clients.

Comprehensive post-market surveillance

Full dossier development

- Case and exposure management
- The adverse event follow up
- Medical monitoring & reporting services
- Post-marketing literature surveillance
- Marketing clinical studies—before and after cases
- Compliant intake
- Registration and investigation
- Product surveillance
- Complaint management
- Technical services
- Regulatory assessment
- Diagnostic reporting
- Organizing training
- Complaint analysis
- Content development and packaging
- Product analysis
- Contact centre for patient assistance
- Physician notification and management
- Trends and analytics, leadership management, and outreach programs to increase patient pool
- We are imparting training (store, stream, deliver content) as a service
- Key opinion leader management as a service
- Content development and packaging
- Unique outreach platforms to increase patient pool

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**