GLOBAL AND LOCAL LITERATURE SEARCH SCREENING

Global and Local Literature Search Screening

Screening published medical and scientific literature regarding medical devices, and medicinal products is a mandatory requirement for Marketing Authorization Holder (MAH) or license holders. MAHs need to regularly monitor the literature for suspected Adverse Drug Reactions (ADRs) and other information, including potential drug interaction, misuse, off-label use, and class effects.

Pepgra offers pharmacovigilance literature review search services as part of the drug safety and efficacy services. Our medical regulatory staff have extensive experience in searching for articles from multiple databases published. They can comprehensively and cost-effectively manage your literature screening requirement in conjunction with writing periodic safety reports. Our literature specialist team of Pepgra has 15+ years of experience in global pharma, with a focus on literature. We work closely with customers on the one-on-engagement model and develop the search strategy methodology to ensure that criteria are robust and an unbiased approach. We perform the literature search be for aggregate reports, or benefit-risk analyses or for signal evaluation or ongoing screening as required by local and regional requirement. Our weekly search is not only limited to the identification of individual case safety reports but also detection of safety issues. We can conduct literature screening as per your requirement in local territories.

Our pharmacovigilance researchers are aware of the standard pharmacovigilance guidelines and regulations, including 21 CFR part 314.80 and 600.80 and basics of clinical development of a drug. Besides, our reports will be prepared based on ICH E2C (R2) PBRER and other reports (PFSB/SD 0917/2; PFSB/SD 0216/2; PFSB/SD 033 /9). Our writers also aware of data protection /privacy regulations, and work under stringent timelines in tandem with multiple stakeholders who might have different opinions, to arrive at a suitable consensus promptly.

Our local representatives perform the review of specific local-non-indexed scientific and medical journals for the identification and processing of ICSRs.

Our Comprehensive Literature Review Screening Solutions

Identification of Studies: Our experts conduct searches through validated databases including Embase, Medline or other local country-specific publications (e.g. JDream Databases for Japan) and screen abstracts for identification of potential ICSRs. We notify immediately of new safety information from screening.

Regular Reviewing of local (non-indexed) Journals and documentation of all serious, unexpected adverse reactions (AR) and non-serious adverse reactions reported in the scientific literature. Even if there are no ARs, an ASR will be prepared and shared. In case reports present evidence of any serious, suspected adverse reactions, it would be forwarded receipt immediately.

Literature Review Protocol identifying the elements, including the background, objectives, and methods for identification, selection and collection of the relevant publication to address literature review questions. Full published articles will be shared as per the order in which they have been used. Full quality checked report.

Abstracts screening for identification of potential new and significant safety findings for inclusion in PSURs. The following information will be collected, as appropriate.

- Pregnancy outcome with no adverse events.
- Compassionate supply named patient use
- Asymptomatic overdose, abuse or misuse
- Off-label use, class effects
- Drug/food interaction, the suspected transmission of an infection's agent
- Use in pediatric, elderly or organ impaired population
- Any other important non-clinical safety results. Ordering selected full publications for evaluation of ICSRs or safety issues

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.

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