



ISO 9001:2015

CRO

Your reliable CRO partner.

Niche therapeutic CRO solutions provider.

Cardiology, oncology, diabetology, psychiatry, etc.

"When it comes to regulatory affairs, Pepgra professionals know the market like the back of their hand. Considering the fact that it takes 15 years to put your drug on the shelf, you want to bet your stakes on a partner who can guide you through the maze of regulatory changes. Pepgra is that partner."

— **GÜNTER SCHNEIDER,**

Senior Director of a leading drug manufacturer.





CRO

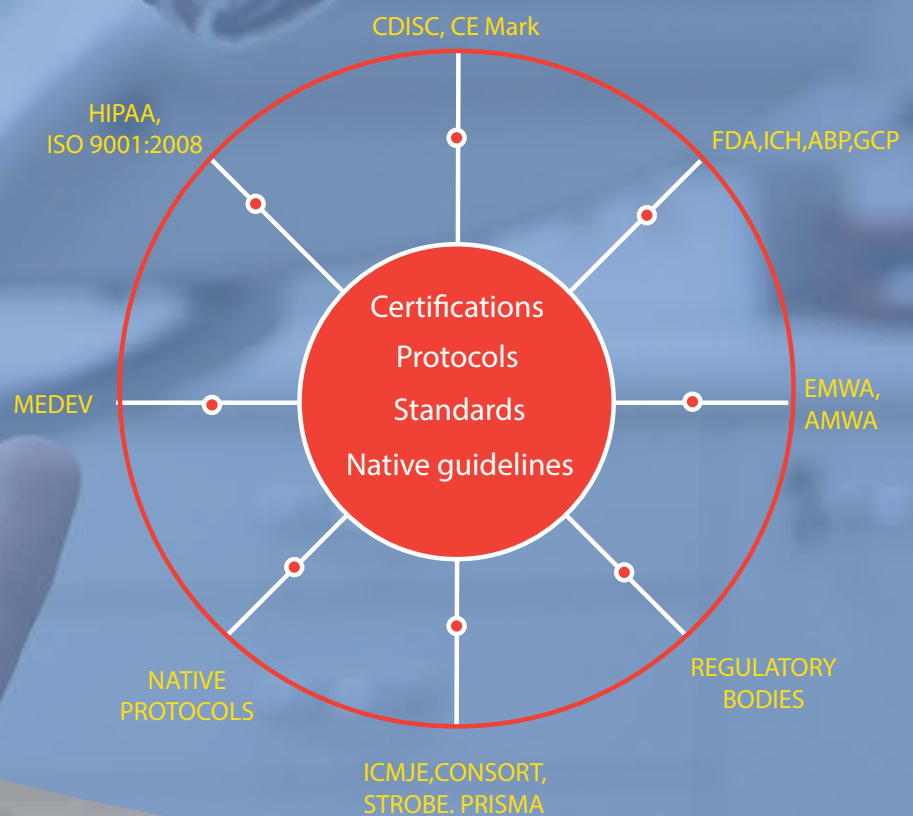
Driving innovation the Pepgra™ way...

Various statistical tools, analytics, and programming languages.

- R programming
- SAS
- SPSS
- Strata
- EViews
- Minitab
- Matlab

and more.

METICULOUSNESS IN COMPLIANCE



CRO—excellence in delivery

Pepgra Clinical research is a division of Pepgra Healthcare Private Limited. It specialized in the planning management, execution, and analysis of Phase IIb-IV Clinical trials, ranging from small studies to complex, multinational projects.

Full-fledged CRO Services

Pepgra offers an array of CRO services right from clinical trial protocol development to post-marketing surveillance. Whatever be your need, rope in Pepgra experts to breeze through regulatory approvals and get your drug or device on the market soon. Complete quality assurance and protocol compliance—guaranteed every step of the way.

Our CRO Offerings

- Clinical research monitoring.
- Clinical study design.
- Global regulatory writing.
- Biostatistical programming.
- Clinical trial patient recruitment.
- Regulatory affairs.
- Clinical data management.
- Clinical technology process.
- Post-market surveillance (PMS).

Quality Assurance and Facilities

• Quality is at the heart of all that we offer you. Our Quality Management System is **ISO 9001:2015** registered. At Pepgra we adhere to a framework and philosophy to maintain a consistent quality culture throughout the organization.

- Partner with us to use our state-of-the-art facilities and CRO resources.





CRO Repertoire

Our CRO team consists of professionals having an academic background from apex institutions of United States and has wide experience in different therapeutic areas. We have vast experience of working with multinational pharmaceutical, biotechnology, medical device industries, hospitals, CROs, and professionals. Our size and niche focus on writing and publishing enable us to be more flexible, affordable and scalable. We combine novelty and the premium technology in the market to meet our customer requirements coupled with best practices in the CRO industry.

Multiple Locations

Our corporate offices are located in Dallas, Texas, UK, India, China, and Malaysia. We have more than 100,000 individuals working across the globe and expertise across over 300 scientific disciplines. We are a team of creative, highly qualified and experienced professionals who are committed to achieving complete client satisfaction through timely quality work. We rank high amongst the few full-service organizations that include clinical research, clinical monitoring, bioavailability/bioequivalence and post-marketing study or surveillance.

Native Experts

We have more than 650 experts across various therapeutic areas to conduct CRO trials. We have experience in scientific publications accordance to the target journal as well as the regulations and norms set in different countries and different continents. Some of which are, Bulgaria, France, India, Germany, Poland, Romania, Spain, Switzerland, Italy, Greece, Netherlands, Austria, Belgium, Russia, Czech Republic, Israel, Sri Lanka, Latvia and Lithuania.





What we do

Our team comprises PHD qualified pros from apex institutions in the US and EU and they have wide experience in different therapeutic areas. We have experience in working with pharma, biotechnology, device manufacturers, hospitals, CROs, and therapeutic professionals.

Clinical trial monitoring solutions

- Customizable training based on the requirements.
- Initiation, interim monitoring, and visits.
- Patient recruitment and management.
- Site personnel communication.
- Local ethics review management.
- Recruitment criteria development.
- Site selection of and feasibility.
- Quality assurance procedures.
- GCP assurance.
- Training and motivational visits.
- Personnel training.

Our size and niche focus enables us to be more flexible, affordable and scalable. Our well-trained Clinical Research Associates (CRAs) are highly trained professionals who ensure integrity and commitment to excellence in line with International Conference on Harmonization (ICH) & Good Clinical Practice (GCP) standards.

Clinical study design

Clinical Trial Protocol (CTP) study designs that balance the interests of multiple stakeholders. Our clinical study design solutions include the following:

- Drafting pre-Investigational Device Exemption (IDE).
- Endpoint selection and confirmation.
- Participation in pre-IDE meetings.
- Clinical hypothesis consultation.
- Clinical trial adaptive design.
- CTP—statistical analysis.
- IDE submission to FDA.
- Resource planning.
- Protocol writing.
- Sampling.
- Randomization.
- Interim analysis.
- Cost estimation.
- Case report form.
- Literature review.
- Regulatory counsel.

The breadth and depth of our combined expertise bring efficiency to the process; thereby helping you realize the full potential of the study design protocol.

Global Regulatory Writing

The team delivers clinical study protocols and findings with precision. Reports are scientifically accurate, culturally sensitive, and meticulously compliant with regulations and statutory bodies. Our comprehensive solutions for pharmaceutical companies include the following:

- Full dossier development.
- Clinical Overview (eCTD Modules 2.5) plus literature review.
- The Common Technical Document (CTD).
- Module 2.3: Quality Overall Summary (QOS).
- Module 2.4/2.6: Non-Clinical Overview (Pharmacology, Pharmacokinetics, Toxicology) and summary.
- Module 2.5/2.7: clinical overview and summary.
- Module 3, 4, & Module 5.
- Regulatory eCTD dossier preparation, publishing and submission.
- Clinical expert statements.
- IND/NDA, MAA, PMA, 510(k) preparation and submission in US FDA, EMA Europe, Canada, Asia Pacific, Gulf countries and semi-regulated countries.
- Briefing documents.
- Labeling and core datasheet.
- Gap analysis for clinical part of the dossier.
- Pharmacovigilance documents: periodic safety update reports.





For medical device manufacturers

We offer pre-market Conformité Européenne (CE) mark report, clinical data, and post-market studies. Pepgra has extensive experience in preparing following reports for Class I (low risk), IIa, IIb, and III (high risk): For medical devices, we are compliant with Medical Device Academy (MedDev) 2.7/1 Revision 4 guidelines to perform the clinical evaluation.

- Comparative Effectiveness Research (CER) is part of the approval process thereby allowing market access (with CE-mark) for a medical device.
- Clinical data: safety and/or performance of information generated from clinical use of a device in question or a similar device for which equivalence has been demonstrated.
- Equivalent device report: similar technical, biological and clinical characteristics.
- In-depth literature search and appraisal of relevant publications.
- Premarket, CE-mark studies, post-market studies and registries.

Here are the advantages:

- 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 classes of device.

- 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.

Global regulatory writers

MD, MBBS, PHARM.D, and PHD—These are the qualifications of our writers; moreover, Pepgra writers are certified by AMWA and EMWA. Familiar with regulatory protocols across EU, US and other countries.





- Our regulatory medical writers have 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 comprises native speakers with years of experience in translating all documents that are necessary for the performance of clinical studies.

Our regulatory medical writers hold experience in handling a wide range of therapeutic areas and all phases of development.

Biostatistical Programming

Extensive research, clinical and regulatory biostatistics services to meet your individual research needs. Pepgra offers regulatory biostatistical analysis as per the principles outlined in the International Conference on Harmonization (ICH) E9 guidelines. We bring a deep understanding of the science of disease and compounds, thereby providing comprehensive planning assistance.

Biostatistical solutions

- Our experts have the capability to comment and describe the objective(s), design, methodology, statistical considerations, and organization of a trial from initial dose titration through post-marketing services.
- Real-time analysis presentation and scientifically sound interpretation and reporting of results.
- Randomization scheduling.
- A design technique for avoiding bias in clinical trials—blinding & randomization.
- Trial design considerations: parallel group design, cross over design, and factorial.
- Sample size estimation based on the study objectives: safety and efficacy.
- Clear definition of null hypothesis.
- We help the organization to collect primary and secondary documents from a wide range of source documents that includes hospital records, clinical and office charts, laboratory notes, memoranda, pharmacy dispensing records, subject diaries or evaluation checklists, copies or transcriptions certified, microfilm, x-ray, and from any other documents.
- Processes for targeted on-site monitoring, Statistical analysis.
- Identify missing data, inconsistent data, outliers, unexpected lack of variability and deviation in the protocol.

Data transformation, estimation, confidence intervals, hypothesis testing, adjustment of significance and confidence interval.

- Examine data trends in terms of consistency, range and data variability within and across sites
 - Intent-to-treat (ITT) analysis, multiple primary variables, multiple treatment comparisons (e.g. Dunnett's, Bonferroni Correction, Closed test procedures, single primary treatment comparison), treatment by centre interaction, dose response analysis, and magnitude effect.
 - Evaluate for significant or systematic errors in data collection and reporting on a site or across site or data integrity problems or potential data manipulation.
 - Analyze characteristics of the sites and performance metrics.
 - Interim analysis to compare treatment arms with respect to efficacy or safety.
- Pepgra experts can help you in the development of statistical analysis plan – a more technical and detailed elaboration for the principle features stated in the protocol. In addition, clinical trial programming using analytical tools such as SAS and R.

Regulatory Affairs

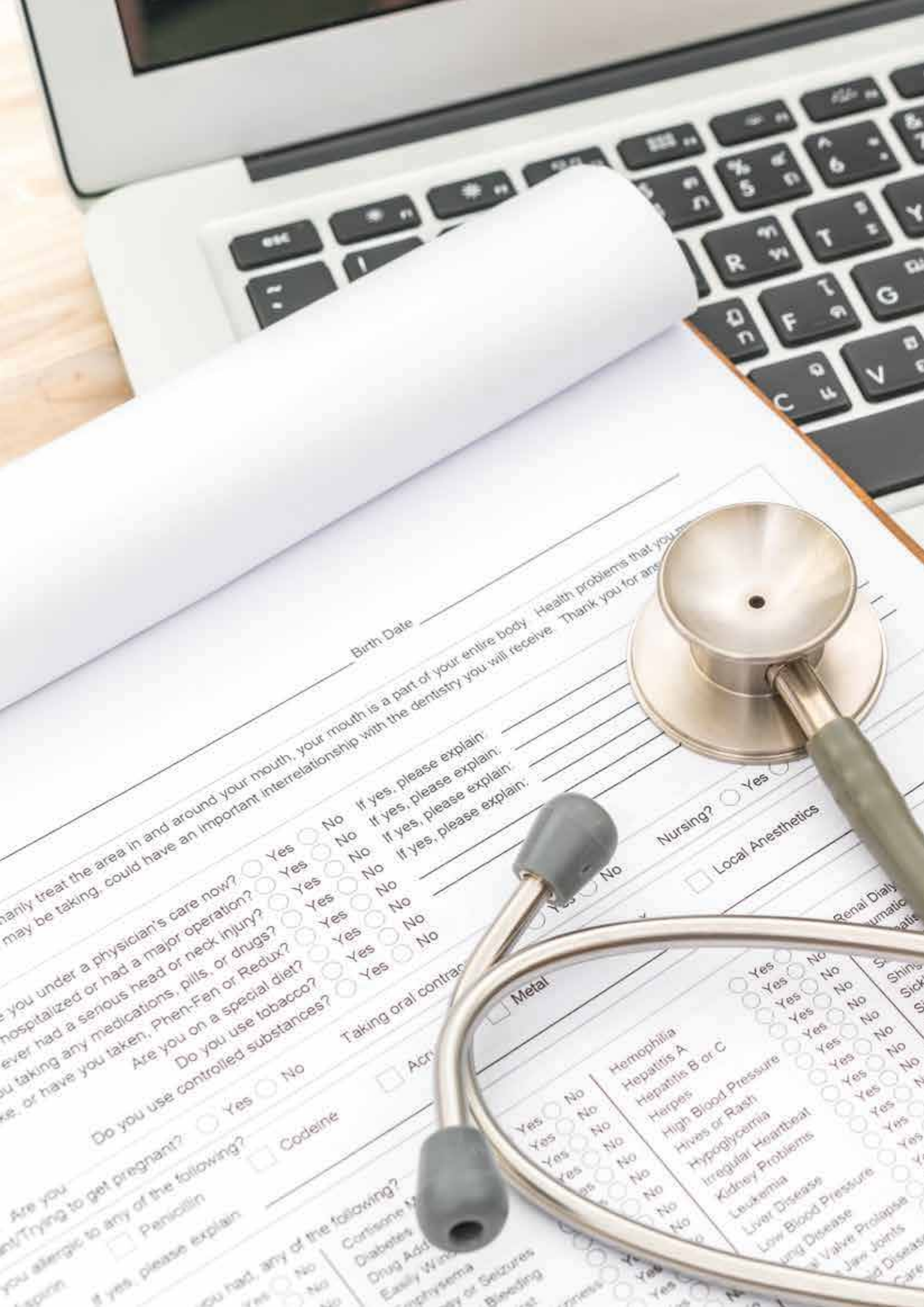
Pepgra experts can help you navigate through the regulatory landscape with ease. We have knowledge of protocols, standards and current trends in the regulatory market. We provide the following comprehensive regulatory affairs solutions:

- Financial analysis and agreement terms for licensing and acquisition.
- Commercial assessment and valuation of biopharmaceutical assets.

- Abbreviated New Drug Application (ANDA).
- Investigational Medicinal Dossier (IMPD).
- Product and portfolio decision making.
- Medical and regulatory writing.
- Health technology assessment.
- Health technology assessment.
- Paediatric investigation plan.
- Statistics and data analytics.
- Pricing and market access.
- Reformatting of dossiers.
- Clinical development.
- CTA submissions.

The fact that our RA professionals work closely with FDA and EMA means you proactively get to know the regulatory climate.





Birth Date _____

Health problems that you may be taking, could have an important interrelationship with the dentistry you will receive. Thank you for answering.

Are you under a physician's care now? ☐ Yes ☐ No If yes, please explain: _____

Ever hospitalized or had a major operation? ☐ Yes ☐ No If yes, please explain: _____

Are you taking any medications, pills, or drugs? ☐ Yes ☐ No If yes, please explain: _____

Are you on a special diet? ☐ Yes ☐ No If yes, please explain: _____

Do you use tobacco? ☐ Yes ☐ No

Do you use controlled substances? ☐ Yes ☐ No

Taking oral contraceptives? ☐ Yes ☐ No

Are you allergic to any of the following? ☐ Penicillin ☐ Codeine ☐ Acetaminophen ☐ Metal

Are you pregnant or trying to get pregnant? ☐ Yes ☐ No

Condition	Yes	No
Hemophilia	<input type="radio"/>	<input type="radio"/>
Hepatitis A	<input type="radio"/>	<input type="radio"/>
Hepatitis B or C	<input type="radio"/>	<input type="radio"/>
Herpes	<input type="radio"/>	<input type="radio"/>
High Blood Pressure	<input type="radio"/>	<input type="radio"/>
Hives or Rash	<input type="radio"/>	<input type="radio"/>
Hypoglycemia	<input type="radio"/>	<input type="radio"/>
Irregular Heartbeat	<input type="radio"/>	<input type="radio"/>
Kidney Problems	<input type="radio"/>	<input type="radio"/>
Leukemia	<input type="radio"/>	<input type="radio"/>
Liver Disease	<input type="radio"/>	<input type="radio"/>
Low Blood Pressure	<input type="radio"/>	<input type="radio"/>
Lung Disease	<input type="radio"/>	<input type="radio"/>
Valve Problems	<input type="radio"/>	<input type="radio"/>
Jaw Joints	<input type="radio"/>	<input type="radio"/>
Shingles	<input type="radio"/>	<input type="radio"/>
Sickle Cell	<input type="radio"/>	<input type="radio"/>
Stomach Problems	<input type="radio"/>	<input type="radio"/>
Diabetes	<input type="radio"/>	<input type="radio"/>
Drug Addict	<input type="radio"/>	<input type="radio"/>
Easily Winded	<input type="radio"/>	<input type="radio"/>
Emphysema	<input type="radio"/>	<input type="radio"/>
Seizures	<input type="radio"/>	<input type="radio"/>
Bleeding	<input type="radio"/>	<input type="radio"/>

Clinical Data Management

In the market environment there is continuous and high degree of monitoring on the part of regulatory authorities. Considering development in the intricacies of clinical trial procedures, effective management of clinical data is daunting. In this light, Pepgra offers the following services:

- Develop Clinical Report Forms (CRF) /eCRF papers.
- Double-key data entry.
- CRF printing and distribution and design.
- Clinical database setup.
- Adherence to Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) standards.

In addition, definitions of data are provided as per requirements laid down by CDISC CRT-DD.

- Electronic data transfer (central readers, central labs).
- Data integration into clinical database (after data transfer).
- Data validation.
- Serious Adverse Event (SAE) reconciliation.
- Query generation & resolution.
- SAS datasets.
- Data management system.

All our experts comply with international regulatory standards and protocols—in all phases of development.

Post-Market Surveillance (PMS)

Pepgra has extensive experience in preparing PMS reports. Our PMS experts adhere to the guidelines such as EMWA, FDA, AMWA and other local guidelines and protocols. Our comprehensive PMS services include:

- Leadership and outreach programs to increase patient pool.
- Training—storing, streaming, and delivering of content.
- Post-marketing literature surveillance.
- Before and after marketing clinical studies.
- Medical monitoring & reporting services..
- Case and/or exposure management.
- Content development and packaging.
- Patient assistance and contact point .
- Key opinion leader management.
- Physician notification and alerts.
- Registration and investigation.
- Adverse event follow-up.
- Complaint management
- Compliant intake
- Product surveillance
- Regulatory assessment
- Trends and analytics
- Diagnostic reporting
- Organizing training
- Complaint analysis
- Product analysis
- Technical services

As PMS regulations become stringent, Pepgra will help you maintain compliance; our PMS experts will help you succeed in regulatory audits.



Who we serve

Pepgra focuses on certain segments of the medical and pharma industry. Here are the key market segments we serve:

Device manufacturers

Pepgra has done extensive work in preparing PMS reports. Our PMS experts adhere to guidelines such as EMA, AMWA, FDA, and other regulatory standards and protocols.

Pharmaceutical industry

Our experts in regulatory affairs—from world's top pharmaceutical firms—provide support for developing new medicinal products as well as integrating regulatory principles.

Diagnostic providers

Our CRAs are highly trained professionals who ensure integrity of the study and they are committed to excellence—on par with ICH & GCP standards.

Therapeutic providers

Therapeutic capabilities play a pivotal role in organization's success as a clinical research service provider. Pepgra has done holistic projects in the area of CRO therapeutics.

Niche focus: our key differentiator

A brief note on our clinical research trials in therapeutics.

Therapeutic capabilities play a pivotal role in organization's success as a clinical research service provider. Pepgra has completed holistic projects in the area of CRO therapeutics for pharmaceutical, and biotechnology firms. Our work in therapeutics spans across multiple specializations.

Top areas of therapeutic focus include but not limited to the following list:

- Cardiovascular
- Psychiatry
- Paediatric
- Rheumatology
- Gastroenterology
- Nutritional & metabolic diseases
- Neurology
- Infectious diseases
- Oncology & hematology
- Gynaecology and obstetrics

Visit our website or have a look at other brochures for details on our niche therapeutic expertise.

A Case in Point

Free up your resources so that you can focus on your core activities while we take charge of your CRO requirements.

Pepgra has worked with a leading healthcare provider in Asia and top medical device manufacturers across the heart of Europe. We have done extensive work in the realm of biostatistics, clinical data management and partner trial site monitoring.

Talk to us today to find out how we can help you in your clinical trial programs

Request a proposal

Quicker drug or device development and time-to-market these play a major role in your success. Take the help of our experts to breeze through regulatory approvals and get you drug on the shelf. Our experts have done extensive work in phase 1 through phase 4 in addition to research work in the market. Therapeutic area focus is an integral part of any CRO. Pepgra offers specialists who can help you in multiple areas of therapeutics.

Call us to find out how our CRAs can help you a specific area or if you want to participate in a clinical trial.

Request us a proposal now.

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Glossary

A glossary of terms for academically inquisitive minds. A list of the important abbreviations pertaining to the medical industry used in this brochure. Please note that this is not an exhaustive list of the medical and pharma industry.

AMWA Founded in 1940, AMWA is the leading professional organization for writers, editors, and other communicators of medical information. The American Medical Writers Association (AMWA) is the resource for professional medical communicators, promoting excellence in medical communication and providing educational resources in support of that goal.

ANDA An abbreviated new drug application (ANDA) contains data which is submitted to FDA for the review and potential approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower cost alternative to the brand-name drug it references.

CDISC The Clinical Data Interchange Standards Consortium (CDISC) is an open, multidisciplinary, neutral, 501(c)(3) non-profit standards developing organization (SDO) that has been working through productive, consensus-based collaborative teams, since its formation in 1997, to develop global standards and innovations to streamline medical research and ensure a link with healthcare. The CDISC mission is "to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare".

CE-mark CE marking is a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA). The CE marking is also found on products sold outside the EEA that are manufactured in, or designed to be sold in, the EEA.

CER Comparative Effectiveness Research (CER) is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition, or to improve the delivery of care.

CRA A clinical research associate (CRA), also called a clinical monitor or trial monitor, is a health-care professional who performs many activities related to medical research, particularly clinical trials. Clinical research associates work in various settings, such as pharmaceutical companies, medical research institutes and government agencies. Depending on the jurisdiction, different education and certification requirements may be necessary to practice as a clinical research associate.

CRO A contract research organization (CRO) is an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. A CRO may provide such services as biopharmaceutical development, biologic assay development, commercialization, preclinical research, clinical research, clinical trials management, and pharmacovigilance. CROs provide a more affordable outlet for companies to pursue new medicines, and a cost-effective solution to develop drugs for even niche markets.

CTP The protocol is a document that describes how a clinical trial will be conducted (the objective(s), design, methodology, statistical considerations and organization of a clinical trial,) and ensures the safety of the trial subjects and integrity of the data collected.

eCTD The electronic common technical document (eCTD) is an interface and international specification for the pharmaceutical industry to agency transfer of regulatory information.

EMWA EMWA is the European Medical Writers Association, a network of professionals that represents, supports and trains medical communicators in Europe. It is a not for profit organization that is run for its members by its members.

FDA The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation

GCP Good clinical practice (GCP) is an international quality standard that is provided by ICH, an international body that defines a set of standards, which governments can then transpose into regulations for clinical trials involving human subjects. A similar guideline for clinical trials of medical devices is the international standard ISO 14155, which is valid in the European Union as a harmonized standard. These standards for clinical trials are sometimes referred to as ICH-GCP or ISO-GCP to differentiate between the two and the lowest grade of recommendation in clinical guidelines.

ICH The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has gradually evolved, to respond to the increasingly global face of drug development. ICH's mission is to achieve greater harmonization worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner.

IDE An investigational device exemption (IDE) allows an investigational device (i.e. a device that is the subject of a clinical study to be used in order to collect safety and effectiveness data required to support a premarket approval (PMA) application or a premarket notification [510(k)] submission to Food and Drug Administration (FDA). Clinical studies are most often conducted to support a PMA. Only a small percentage of 510(k)'s require clinical data to support the application.

ITT One potential solution to this problem is a statistical concept called intention-to-treat (ITT) analysis. ITT analysis includes every subject who is randomized according to randomized treatment assignment. It ignores noncompliance, protocol deviations, withdrawal, and anything that happens after randomization.

PMS Post-marketing surveillance (PMS) (also called post-market surveillance) is the practice of monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market and is an important part of the science of pharmacovigilance.

QOS The Quality Overall Summary (QOS) is a summary document that follows the scope and outline of the Body of Data in Module 3, Quality. The QOS is located in Module 2.3 of the CTD format, and is required for submission of marketing applications.

SAE A serious adverse event (experience) or reaction is any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

SAS (previously "Statistical Analysis System") is a software suite developed by SAS Institute for advanced analytics, multivariate analyses, business intelligence, data management, and predictive analytics. SAS was developed at North Carolina State University from 1966 until 1976, when SAS Institute was incorporated.



Contact Us

CRO projects | Partnership

Do you need strategic reviews or ballpark figures? A Pepgra expert will send you a proposal right away. If you are a biopharmaceutical company, medical device manufacturer or a pharmaceutical firm interested in a partnership or need help in a clinical trial phase, then email us or call us. A consultant is standing by to answer your queries.

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UK

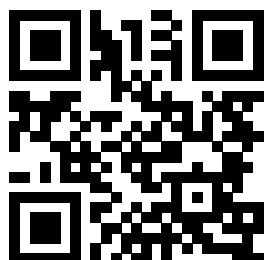
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