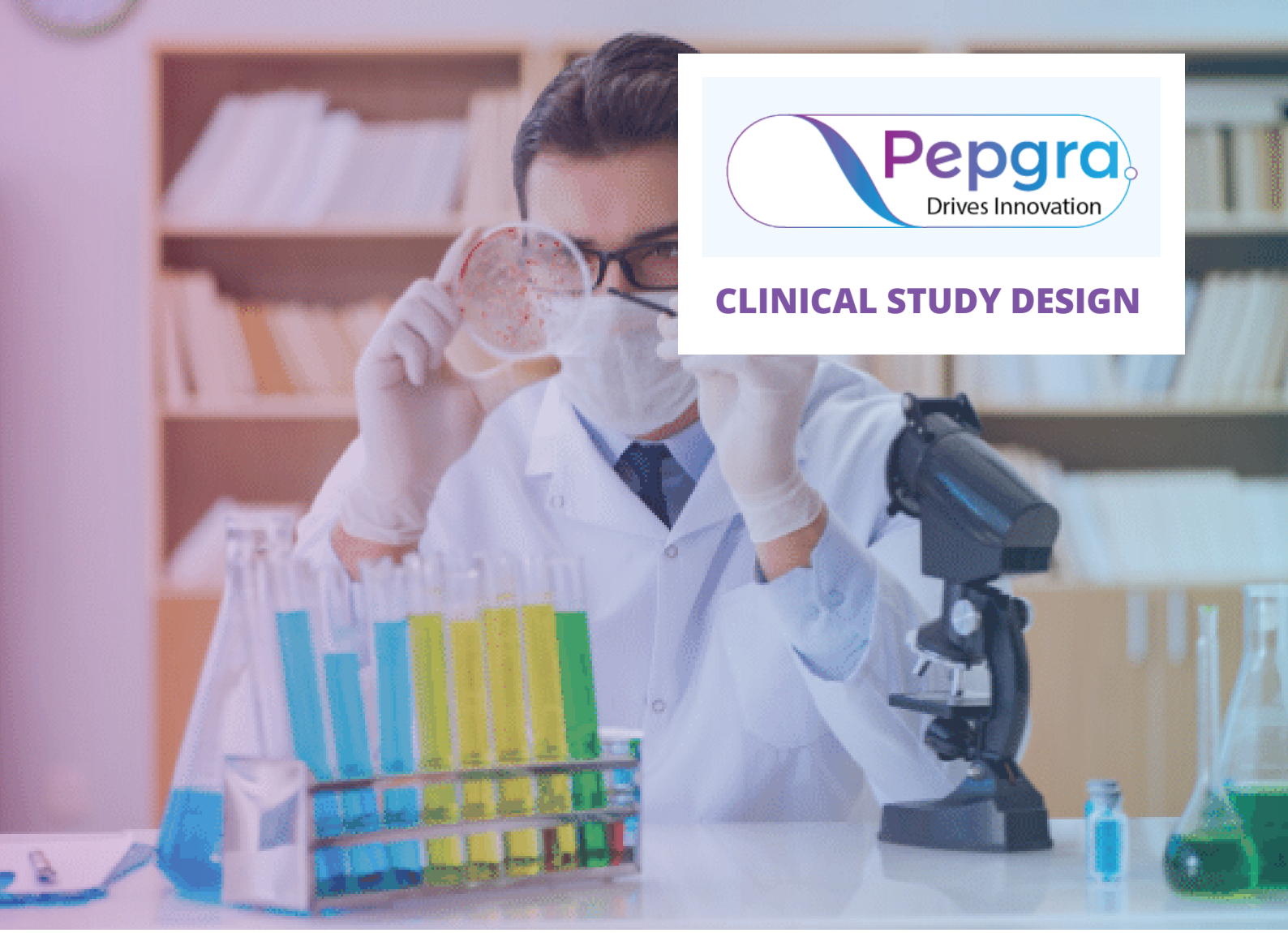

Pepgra
Drives Innovation

CLINICAL STUDY DESIGN

Biomedical research study

Pepgra is your reliable CRO. Our experts in scientific, clinical, regulatory, and statistical study will design your clinical protocols and execute trials.

Clinical study design and protocols that balance the interests of multiple stake-holders

In estimating the magnitude of treatment effect and the difference in the treatment effect, there is a need for a proper trial design approach that allows the treatment effect to be sorted out from person-to-person with variation in the responses. With a better-informed protocol, clinical trials can answer the objectives of the study while reducing the bias in estimating treatment effects, thereby reducing the overall time, costs and also increase value to stakeholders.

At Pepgra, we are sensitive to the need for balancing scientific, regulatory and logistical concerns to design and plan a successful clinical investigation. Our team has experience in developing study design for both new pharmaceutical drugs and medical device despite the risk stratification (or class) of the device. Our experts develop study design based on strong scientific evidence, and our study design experts regularly advise on the necessity, implications, and practicality of clinical study

Clinical Study Design Solutions

- Clinical hypothesis consultation
- Endpoint selection and confirmation
- Statistical sample size calculation
- Adaptive Design Clinical Trial (after initiation without undermining its validity and integrity)
- Protocol writing and Protocol review
- Randomization

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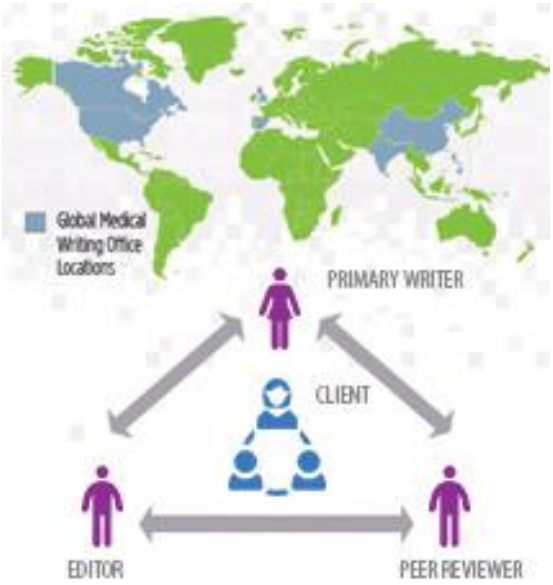
- Interim analysis
- Resource planning
- Cost estimation
- Case report form (CRF) design
- Literature review
- Regulatory counsel
- Sample size calculations and power analysis based on the published data or pre-existing study results
- Literature search and summary
- Randomization scheduling
- Statistical and analysis planning for clinical trial protocols
- Clinical trial Protocol writing and review
- Preparation of draft IDE submission, including protocol summary
- Participation in pre-IDE interactions with FDA
- Submission of IDE to FDA

The breadth and depth of their combined expertise bring efficiency to the process—helping you realize the full potential of your study design protocol.



Pepgra has done plethora of work in the area of clinical study design for top pharmaceutical companies. Our clinical experts will evaluate the efficacy of drugs and procedures while satisfying all stakeholders.

We deliver study designs balanced to meet your business needs and expectations with the current scientific understanding and all regulatory requirements considered.

Allow us to help propel your product forward.

We'll scale up as your needs grow.

No compromising on integrity and quality. Our processes are well defined and flexible to ramp up as per your requirements.

Partnering with you till the project end.

We come with you all the way. From design to market support

Pepgra CRO Offerings

"Changing global regulatory system, globalization of clinical trials, increased consumer expectations, infrastructural and culture issues, and various diagnostic requirements should never hamper your research and development programs. With our support..."

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- 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.