MEDSOURCE
Taking Relationships as Seriously as Science

Early clinical development strategy? IND applications? Protocol writing?

FIND OUT WHY MEDSOURCE SHOULD BE YOUR FIRST CONSULT

SCIENTIFIC DEVELOPMENT DEPARTMENT

For more than 20 years, MedSource has been delivering high-quality clinical trial services to help biotech and pharmaceutical companies move new therapies and treatments from first-in-human studies to market. But, unlike traditional clinical research organizations (CRO), MedSource has the expertise to deliver standalone consulting services for early clinical development or as part of our full service, end-to-end clinical trial solutions.

MedSource's Scientific Development Department's mission is to help drug developers take assets from the post-discovery stage into the clinic and strategize pathways to accelerate the development to market. Our team is nimble, flexible and composed of seasoned clinical scientists and subject matter experts with exposure across science, medicine, regulatory affairs, clinical development and clinical operations.

The broader MedSource clinical trial service teams can then execute the clinical trials designed by the Scientific Development Department. As a full-service CRO, we understand what is needed to advance a therapy through each stage of the clinical development process. Whether designing clinical development plans, identifying which indication(s) to prioritize, or delivering strategies that efficiently advance new drug candidates into the clinic, MedSource has the experience to deliver results.

We pride ourselves on being a true strategic partner for our clients, and we work to deliver services that suit individual customer needs and goals. By leveraging our expertise at the early development phase of your project, MedSource can help move assets smoothly, strategically and efficiently through Investigational New Drug (IND) enabling or clinical trial application submission processes.

ABOUT MEDSOURCE

MedSource is an award-winning, full-service CRO focusing on complex study designs and diseases with particular expertise in oncology and central nervous system disorders. The company's Scientific Development Department is based in the Cambridge Innovation Center (CIC) in Cambridge, Massachusetts, and is available to support clients anywhere in the world.

HOW CAN WE HELP?

To find out more about how MedSource can assist your company with early clinical development services, contact Doris Sanchez, Senior Director of the Scientific Development Department, at **DSanchez@medsource.com** or **(877) 269-2987**.

SERVICE OFFERING

Clinical Development Planning

Most start-up, small- or mid-sized biotech or pharmaceutical companies lack the resources and the time to conduct the detailed research, strategy and planning to build an extensive publication/literature library that organizations need to complete a solid clinical development plan, indication prioritization and pipeline overview.

MedSource has the expertise to assist with all of the following services:

- Indication prioritization – We conduct a comprehensive publication/literature investigation, data mining and data collection exercise that will help confirm clinical scientific evidence as well as identify which lead candidates to take into the clinic. This exercise helps identify possible accelerated regulatory pathways and once lead candidates are identified, our team can advise on how to move forward with each application.
- Clinical development plan (CDP) – The CDP is a comprehensive plan that maps out the overarching strategy and vision for the drug or therapy. It includes indication prioritization, mapping out a tiered plan for the asset in development, outlining program timelines, decision gates and costs, outlining possibilities for program movement based on results of early trials, list of differentiating factors, preliminary gap analysis, and much more.
- Competitive intelligence – We provide a detailed analysis of the competitive trial and treatment landscape including what differentiates your molecule and other approved drugs on the market or in clinical development.
- Scientific rationale support – We assist in the development of clinical resources, documents, and/or presentations for various target audiences (e.g. investors, key opinion leaders or physicians).
- Early drug development literature – We conduct research on a range of topics from biology, compounds, specific indications and patient populations.

Regulatory Authority Submissions and Preparation

MedSource has the experience and know-how to develop materials and prepare companies throughout the IND application or Clinical Trial Application (CTA) process.

MedSource will be your valued partner and can assist to:

- Develop and prepare gap analysis to determine IND or CTA strategy and plan
- Assist with the preparation for pre-IND or other regulatory agency meetings, which can even include mock meetings with our expert regulatory team members
- Compile/draft modules for the IND/CTA application
- Organize and submit the final IND/CTA application

Medical Writing

MedSource has a team of experienced medical writers who can draft and produce high-quality documentation to support regulatory authority requirements and broader medical writing, such as protocols, investigator brochures and clinical study reports.

Experience. Focus. Trust. Respect.

If these aren't words you typically associate with a CRO, perhaps it's time to consider MedSource.