RTI (h)(s)
Health Solutions

Clinical and Medical Services:
Driving Drug Development at Every Step

Integrated clinical development services customized for biotechnology and emerging pharmaceutical companies.

Comprehensive Clinical Capabilities

Whether you need support for a specific aspect of a study or a complete integrated solution, we are a full-service clinical research partner tailored to meet the needs of small and emerging pharmaceutical companies. Our operational structure has been refined to allow us to meet your requirements proficiently and cost-effectively.

Our team will help you at every stage of the clinical development process, including optimizing the study design, defining the study population, selecting endpoints that comply with regulatory guidance and that best fit your drug, and planning and conducting the most appropriate data analysis.

Consulting to Support Strategic Objectives

We help you formulate clinical development strategies for use with internal and external stakeholders, including venture capitalists and development and commercial partners. We outline clinical development programs and estimate the resources required for implementation.

Clinical Development Integrated with Commercial Objectives

As part of our integrated services, our recognized experts in health economics and patient-reported outcomes can help design health economics and outcomes endpoints into your clinical study that will provide necessary evidence to demonstrate value and achieve market access for your product.

Our Clinical and Medical Services:

Strategic Planning
- Clinical Development Plans

Design
- Protocol Development
- Case Report Form Development
- SAP Development
- Regulatory Guidance Through a Strategic Partner
- FDA Meeting Presentations and Representation

Implement
- Project Management
- IRB Approval
- Site Selection and Management
- Investigator Meetings
- Subject Recruitment
- Medical Monitoring
- Safety Surveillance Oversight
- Data Management Oversight
- Central Laboratory Oversight
- Regulatory Submissions Through a Strategic Partner
- Quality Assurance

Analysis
- Biostatistics

Medical Writing
- Clinical Study Report
- Manuscript Development

Contact Us:
info@rtihs.org
www.rtihs.org

RTI Health Solutions®

Key Technical Staff

Allen Mangel, PhD, MD
Executive Vice President
amangel@rti.org

Lynne Hamm, BSN Senior Director, Clinical and Medical Services
lhamm@rti.org

Phase 1–3 Clinical Services

When you select us as your partner for clinical development services, you gain access to a team with experience across all phases of drug development.

Clinical Development Planning

Successful drug development requires you to have an objective and, more importantly, to have a roadmap to achieve that objective. We'll assist you by laying the foundation for your success in the form of a clinical development plan. We'll work with you to determine what development work has been completed on your drug and assess the validity and regulatory acceptability of that work. We'll survey the regulatory landscape and determine the requirements for obtaining marketing approval for your drug. And, finally, we'll provide a list of the studies required to meet your objectives supplemented with a protocol synopsis and associated budget for each.

As studies are conducted and results analyzed, we'll work with you to hone the clinical development plan based on completed study results and shifting regulatory guidance with the intent of maximizing formulary uptake post-launch and minimizing both development time and cost.

Study Design

At the individual study level, forethought, planning, and a comprehensive understanding of the therapeutic area are crucial to ensure reliable, actionable results. Our experts will collaborate with you to design your clinical study based on your needs, the literature, the regulatory environment, and any other factors critical for study success.

Study Implementation

Without competent execution, a well-planned study will yield poor data. Therefore, we proactively oversee all aspects of study implementation, including IRB approval, site selection and management, investigator meetings, subject recruitment, medical monitoring, safety surveillance, data management, central laboratory performance, and quality assurance. Our structure allows us the flexibility to customize implementation so we can provide technical and human resources as needed.

Analysis

We provide comprehensive support for data analysis and preparation of clinical study reports. Our biostatisticians understand that a missed efficacy or safety signal can result in the loss of millions of invested dollars. Why take that chance? We provide comprehensive analysis plans and, when necessary, design and conduct ad hoc analyses to ensure that any signal of efficacy is accounted for and to ensure that any safety signal is identified as early as possible. This allows you to make critical decisions to obtain the widest possible indication and/or determine the viability of continued development of the drug.

After the analysis has been completed, our biostatisticans work closely with our medical writers to ensure results are reported accurately and completely to you and to the relevant regulatory authorities.

FS.CMS.0617