CLINICAL DEVELOPMENT SERVICES

FOR CLINICAL DEVELOPMENT SERVICES OPTIMIZED FOR MEDTECH, VERANEX IS YOUR DIFFERENCE

Veranex
Transforming Your MedTech Innovation

DESIGNING AND CONDUCTING YOUR MEDICAL DEVICE STUDY REQUIRES EXPERTISE — FROM SMART STUDY DESIGN TO EFFICIENT EXECUTION — TO DEMONSTRATE THE VALUE OF INNOVATION

Clinicians, payers, regulators, and patients are demanding clinical evidence to demonstrate safety, effectiveness, and overall value of innovation. Designing and conducting your medical device study requires expertise, from thoughtful study design to efficient execution, in order to demonstrate clinical value. With a comprehensive clinical development solution encompassing clinical strategy, protocol development/study design, site selection, end-to-end clinical operations, and best-in-class supportive services, we ensure your clinical trials are efficient and successful.

Veranex not only helps you design and manage clinical trials, but also develop innovative business models that help you win in the following clinical areas:

- Orthopedics
- Cardiovascular
- Diabetes
- CNS/Neurology
- Wound Care
- OB-GYN
- Pulmonology
- Oncology
- Imaging/Visualization (all modalities)
- Ophthalmology
- Women's Health
- Surgical Devices
- Drug Delivery/ Combination Products
- Cellular Therapeutics
- Dental
- Inpatient Monitoring
- Remote Monitoring/ Home Health

FOR EFFICIENT CLINICAL DEVELOPMENT SOLUTIONS TO DEMONSTRATE THE VALUE OF YOUR INNOVATION, VERANEX IS YOUR DIFFERENCE

For a truly comprehensive solution from concept to commercialization, experience the Veranex difference

▶ Get in touch to learn more about our integrated MedTech solutions.

VeranexSolutions.com

Clinical Development: Where Concept and Commercialization Meet

At the center of Veranex's integrated, concept-to-commercialization approach lies clinical development. After working with you through concept development and preclinical testing, our experts know you, your vision, and your product. The knowledge we gain and relationships we build allow us to develop sound protocols, efficiently oversee your clinical trials, and support you through regulatory approval.

Our Clinical Services:

Clinical Study Design

- First-in-human
- Early feasibility
- Pivotal
- Postapproval study (PAS)
- Postmarket surveillance
- Patient registries

Clinical Documentation

- Case report forms (CRFs)
- Informed consent
- Investigator brochure
- Clinical management and safety plans

Protocol Development

- Clinical strategy evidence planning
- Comprehensive literature searches
- Risk and complexity assessment
- Trial design consulting
- Biostatistical strategy and analysis plan
- Protocol writing
- Peer review

Site and Management Support

- Identification/selection/activation/initiation
- Institutional Review Board (IRB)/Ethics Committee (EC) submission
- Interim monitoring/oversight
- Investigator agreements qualification
- Regulatory files
- Study budgets
- Training
- Closeout

Patient Recruitment

- Patient identification
- Study marketing and patient advertising

Project Management and Clinical Trial Management

- ClinicalTrials.gov reporting and updates
- Establishment and management of data and safety monitoring boards (DSMBs) and clinical event committees (CECs)
- Maintenance of essential documents/central study files
- Investigator meetings
- Development of manual of operations
- Data monitoring plan and oversight
- Data management and query resolution
- Reading center/core lab interface
- Review and classify adverse events (AEs)
- Generate AE narratives and reporting
- Bioresearch monitoring (BIMO) inspection preparation and support

Monitoring and Engagement

- Site monitoring plans and oversight
- Data integrity audits
- Data query resolution
- Independent reading centers interface
- Core lab interface
- Review and compile AE material

Clinical Reports

- IDE annual progress reports
- Statistical analysis reports (SARs)
- Interim and financial clinical study reports

ABOUT VERANEX

Veranex is the only truly comprehensive, global, tech-enabled service provider dedicated to the medical technology industry. Offering expert guidance from concept through to commercialization and across the development continuum, Veranex enables accelerated speed to market, controlled development costs, development risk mitigation, and accelerated market viability assessment.

At every stage, Veranex customers realize efficiencies in cost and time, while our integrated and comprehensive solutions unify the entire development process. With Veranex as your end-to-end partner, you're well-positioned to deliver the safest, most effective devices to improve outcomes to patients everywhere.

Veranex

Transforming Your MedTech Innovation

info@veranexsolutions.com
919-297-8881