Fighting Today’s Emerging Infectious Diseases to Prevent Tomorrow’s

- Medical Expertise & Thought Leadership
- Global Infrastructure Development & Training
- Basic, Applied & Phase I-IV Clinical Research
- Bio-intelligence & Therapeutic Development
- Rapid Response to Infectious Disease Outbreaks
- International Collaborations Across All Major Markets

Serving the U.S. Government for Over 20 Years
ClinicalRM
We Serve Where Few Others Do

A FULL-SERVICE CRO

Founded in 1994, ClinicalRM is a full-service Contract Research Organization (CRO) specializing in support of clinical research and clinical trial services for biologics, drugs, and devices. With our commitment to global health, multi-therapeutic expertise, and international partnerships, we are able to assist in improving the quality of life in communities throughout the world. Our thought leadership and collaborations with some of the world’s most prestigious research institutions creates a one-of-a-kind synergy that allows us to be at the forefront of efforts to combat global health crises. With a global team and highly efficient Medical Expert Office, we manage all aspects of research and clinical development programs from preclinical through Phase IV studies.

Our expertise spans multiple marketplaces

Commercial  Government  Academic

ClinicalRM supports its customers with a wide array of research, regulatory, and sponsor services tailored to accommodate global clinical trials.

Medical Expert Office
Where Access to Expertise is Granted

A CENTRAL ALLIANCE OF THERAPEUTIC EXPERTISE

ClinicalRM’s Medical Expert Office (MEO), composed of world-renowned physicians and scientists, provides a single point of access for customers seeking rapid medical expertise and guidance for drug development. With field-established thought leaders in multi-therapeutic areas, knowledge is shared with our customers to support the entire lifecycle of product development and launch. Access to our central alliance of medical expertise and program oversight is the keystone of success for your clinical project.

CORE SERVICES

• Development Planning (Pipeline through Development Launch)
• Advisory Boards (CEC/DSMB)
• Study Design & Protocol Development (Highly Efficient Adaptive Design Implementation)
• Regulatory Authority Guidance & Support (FDA/MOH)
• Feasibility & Patient Recruitment & Retention

Visit www.clinicalrm.com/meo-team to meet our medical experts.
ClinicalRM’s Global Infrastructure Development (GID) group works independently, as well as collaboratively with other ClinicalRM departments and our international partners to oversee the development of infrastructure solutions and collaborate on clinical studies. Our solutions focus on overall logistics and operational feasibility to bring our customers’ clinical trials to developing countries.

**RECENT PROJECTS**
- Mobilization of plasmapheresis blood mobiles in West Africa
- Identifying and training of clinicians and technicians in Guinea, Liberia, Nigeria, and Sierra Leone
- Managing Ebola study sample shipments from West Africa to USAMRIID
- Renovations of the ELWA Hospital Clinical Lab
- Renovations of the Sierra Leone National Blood Bank
- Site assessments and feasibility studies at Aspen Medical and Phebe Hospital for clinical trials
- Standup and training for an ELISA lab in Liberia

**EXPERTISE**
The GID group at ClinicalRM is a unique, autonomous team with expertise in public health, epidemiology, scientific research, grant management, and data analysis. GID subject-matter experts have diverse backgrounds in the public health sector, adding to the strength of the group, the breadth of services, and the ease in which they collaborate in multiple, international marketplaces. They are both educators and developers alike, forming the backbone support of our global capacity-building projects.

Visit [www.clinicalrm.com/gid](http://www.clinicalrm.com/gid) to meet the team.

**MISSION**
- Improve the overall infrastructure and ‘leave something behind’ in the places where our services are performed
- Provide effortless transitions to study start-up, conduct, and close-out

**CORE SERVICES**
- Laboratory Assessments, Standup, & Training
- Strategy Consulting to Effectively Navigate the Logistical & Governance Challenges in Country
- IT & Communications
- Supply Chain Management
- Site Assessments, Training, & Recruitment
- Feasibility Studies & Baseline Analysis (Public Health, Laboratory Networks, & Healthcare Systems)
- Project Evaluation, Monitoring, & Auditing
- Ethnographic Insight & Cultural Socialization

**CLINICALRM’S BOOTS-ON-THE-GROUND FIRST RESPONDERS**
### Program/Project Management
- Comprehensive Program/Project Planning & Implementation
- Site, Communication, Schedule, & Financial Management
- Contract Management
- Protocol Execution & Compliance
- Risk Assessment & Contingency Planning
- Site Consortium Recruitment & Retention
- Trial Master File Maintenance
- Clinical Study Reporting

### Clinical Monitoring
- Experienced Monitoring Staff in US & Abroad (Africa, Eastern Europe, & India)
- Risk-Based Monitoring: Central and Remote Approaches
- Monitoring Plan Development
- Investigator Evaluation & Selection
- Regulatory Document Review & Collection
- Site Qualification, Initiation, & Close-Out Visits
- Interim Site Monitoring
- Source Document Verification
- Investigational Product Accountability

### Clinical Operations, Regulatory/Medical Affairs, and Quality Management & Training

### Compliance
- Research Readiness Assessment
- Metrics
- Event Reporting & Safety Reporting to FDA
  - IND Safety Report

### Data Management
- Project Management & Technical Guidance
- CDISC Compliance
- Case Report Form (CRF/eCRF) Development
- Database Development & Maintenance
- Data Processing & Integration, Including External Data
- Discrepancy Management
- Reconciliation of SAEs
- Medical Coding
- Customized Study Tracking & Reporting

### Safety Oversight and Pharmacovigilance
- IND Safety Report Preparation
- Safety Reporting to FDA & Sponsor
- Writing of SAE Narratives
- Reviewing/Evaluating Adverse Event Reporting & Data

### Statistical Analysis and Reporting/Medical Writing
- Adaptive Design Model
- Development of Statistical Sections of the Protocol
- Design of Randomization Schemes
- Statistical Analysis Plan
- Statistical Programming
- Support of DSMB/SMC Clinical Summary Reports, Manuscripts, ISS/ISE, & Consent Forms
  - Clinical Study Report (CSR)

### Regulatory Support
- IND/IDE Regulatory Submission Support
- IRB Submission Support
- FDA Meeting Preparation
- Review of Clinical Site Essential Documents

### Quality Management and Compliance
- Quality Management Plans
- Metrics for Performance & Compliance
- GLP, GMP, & GCP Consultation/Audits
- Investigative Site & Vendor Audits
- Clinical Site & Core Laboratory Research Readiness Assessment (Specialty, PK, Imaging, ECG)

### GCP Training
- GCP Basic & Advanced
- 1-2 day GCP Conferences
- Customized Training Programs

### Education
- Webinars & Workshops
- 1:1 Mentoring Program
- Safety Reporting, Project Management, Data Management, & Data Safety Monitoring

### Contact Us
For general inquiries, email us at info@clinicalrm.com.

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**Full CRO Services**  
**Clinical Operations, Regulatory/Medical Affairs, Quality Management & Training**

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**Stay Connected with Us**
Visit [www.clinicalrm.com](http://www.clinicalrm.com) for news and announcements and read more about our global efforts.

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**#MakeADifference**

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