

CLINICAL RESEARCH MANAGEMENT, INC

*Research
for the
World*



<http://www.clinicalrm.com/>

About Us

Clinical Research Management, Inc. (CRM)—a woman-owned, small business—is a vibrant and growing company with offices in Frederick, Maryland (Washington, D.C.) and Cleveland, Ohio, and work sites in the U.S., Africa, and Asia. CRM is known for providing high-quality services at a fair price to government and corporate clients.

Services

Management and technical services:

- Clinical research and biotechnology
- Data and administrative services

Personnel provided:

- Scientists
- Technologists
- Technicians
- Clinicians
- Administrative staff

Clinical Research

Project Management and Coordination

CRM has a reputation for effectively managing clinical research projects, from small, critical design and preparation details to full-scale efforts. For example, we successfully manage projects for the U.S. Army that range from initial, small-scale, domestic, Phase I pilot projects to large-scale, overseas, Phase II and III clinical trials. We also recruit and enroll volunteers in clinical trials.

Quality Assurance (QA) Monitoring

CRM provides expert quality assurance monitoring for FDA-approved clinical research projects, including scientific bench work using Good Laboratory Practices (GLP), vaccine production using Good Manufacturing Practices (GMP) and human trials using Good Clinical Practices (GCP).

Our QA staff will:

- Train staff in quality assurance practices.
- Assess sites for regulatory compliance.
- Conduct pre-study visits.
- Prepare quality assurance manuals.
- Review and prepare Standard Operating Procedures.
- Create databases to meet clients needs.
- Prepare and review Investigational New Drugs (IND).
- Audit protocols, final reports, study procedures, buffer preparation records, and regulatory documents.
- Review master and batch production records; testing and chemistry reports; and manufacturing and control documents to ensure GMP compliance.

Protocol Development

We are committed to helping our clients develop efficient, high-quality protocols. Our experience includes:

- Compiling and submitting INDs.
- Creating case report forms.
- Preparing informed consent documents.

Patient Recruitment

CRM recruits and enrolls subjects for inpatient and outpatient FDA-sponsored clinical vaccine and drug trials. Our unique recruitment strategies include skilled recruiters who assess subjects, explain each trial, describe trial expectations, and convey risks and benefits.

We have recruited and enrolled thousands of subjects for clinical trials in the U.S and overseas. All employees involved in recruitment and coordination of subjects are GCP-certified.

Subject Remuneration

CRM has a compensation program that lets our clients contract with us to remunerate research subjects. Payments (checks generally;

We provide innovative,
responsible and effective

research solutions
for our customers



cash if required) have exceeded \$1 million over the past five years. Our staff works closely with each client to schedule subject payments, track subject data, and summarize payments. This program is available to all government and commercial clients.

Medical Support Staff

CRM provides doctors, nurses, phlebotomists, and laboratory personnel to support clinical research projects. Our staff is highly educated, experienced, and thoroughly trained in their technical fields.

Overseas Project Support

CRM provides overseas clinical, scientific research, and administrative support (including short- and long-term staffing and logistic support) around the world. At present, we have personnel in Africa and Asia. Our services also include procuring and shipping computer equipment; laboratory equipment and supplies; and biological material.

CRM is like a wonderful neighborhood Italian restaurant: great quality and a great staff, yet reasonably priced. — A CRM customer

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Biotechnology

Scientific Research

CRM conducts studies and ground-breaking research in biotechnology. Our staff is thoroughly trained and immunized to work in biosafety level (BSL) 2/3/4 laboratories. We provide state-of-the-art research and analysis for a variety of biotechnology research projects in biochemistry, microbiology, virology, immunology, molecular biology, veterinary medicine, bacteriology, and toxinology. We participate in clinical and biomedical research programs at the Walter Reed Army Institute of Research (WRAIR) and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) at Ft. Detrick, MD.

Other current projects include:

- Developing multivalent replicon-based vaccines for anthrax, botulinum neurotoxins, staphylococcal enterotoxins, and other agents.
- Using molecular biological techniques for purifying nucleic acids; gene cloning, expression, sequencing and analysis; DNA restriction mapping and analysis; and nucleic acids amplification and detection.
- Studying the role of dendritic cells, T cells, and B cells in immune responses to Ebola and Marburg viruses.
- Studying the activity of antibiotic compounds against bacterial biological warfare threat agents.
- Performing biochemical procedures, such as spectroscopic assays of protein concentra-



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tion and structure, isoelectric focusing, gel electrophoresis, Western blots, and protein fractionation by liquid chromatography.

- Developing quantitative reverse transcription-polymerase chain reaction (RT-PCR) assay for universal detection of Hepatitis E Virus (HEV) of Asian origins and possible HEV of American origins, such as Mexico and U.S. HEV strains.

Vaccine Production

CRM provides specialized technical and administrative personnel to the WRAIR Pilot Bioproduction Facility, where we research, develop, produce, and test vaccines and other biological products. We produce these pilot-scale (1,000–10,000 doses per finished lot) vaccines under current GMP conditions and all products are tested in compliance with GLP. These products are released for use in Phase I–II clinical studies under IND applications. Vac-

cines produced include those for prophylaxis against shigellosis, meningitis, malaria, dengue fever, HIV virus, and cholera. We are also developing and producing conventional vaccines, as well as recombinant and other genetically engineered vaccines.

We have scientific staff who are experts in the following areas of vaccine production:

- Quality assurance—audit production and testing to ensure compliance with GMP and GLP regulations.
- Quality control—furnish microbiological, serological, and chemical analytical services to support vaccine production.
- Seed preparation and fermentation—culture research-grade seed preparations to prepare master and production (working) seeds; and develop production seeds by fermentation so that we can grow and harvest up to 300-liter batches of seed organism.
- Purification—purify concentrated bacteria or soluble antigens using chromatography, centrifugation, chemical extraction, or other methods.
- Viral products—
inoculate various viral agents into large-scale cell cultures and harvest these agents for further purification and formulation.
- Formulation and filling—formulate and fill bulk lots of vaccine as specified in Batch Production Records.

Auxiliary Services

When clients request data and administrative services that support clinical research and biotechnology projects, we recruit staff, develop plans, and deliver services in these fields.



Data Services

Data Collection and Management

CRM has designed, developed, and created data collection systems and retrieval programs. We have collected and collated data from study subjects using data collection systems and databases, including optical and scannable case report forms that reduce or eliminate the need for manual data entry. CRM also provides other optional data collection systems including optical character readers, bar coding, and double data entry.

CRM provides data validation and data quality and consistency checking for quick, precise data management. We manage and secure pertinent data according to client requirements.

Data Reporting, Analysis, and Presentation

Our statistical reports (for clients and regulatory agencies) include data and trends that we track and present according to client needs. We use state-of-the-art software to:

- Produce data clearly and concisely.
- Tailor reports to meet each client's needs.

Administrative Services

Administrative Personnel

CRM provides its clients with experienced administrative personnel to meet both short-term and long-term needs. We can provide clerk/typists; computer specialists; data specialists; event planners; executive administrators; executive assistants; project coordinators; receptionists; and technical writers and editors.

We regularly add skilled staff to provide a broad range of high-quality services. We also maintain an extensive database of consultants so we can quickly accommodate client needs.

Our company's primary goal is to successfully meet the ever-changing needs of our customers. We offer flexibility, responsibility, value and commitment to our customers and staff. This is what makes us unique. — CRM founder and president, Victoria Tiff



Seminars, Conferences, and Training

We support on-site and off-site seminars and conferences of any size—planning, organizing, executing logistical details, and preparing documentation using a customized menu determined by client needs.

We have developed seminars on topics such as Quality Assurance Monitoring in clinical trials, Good Clinical Practices, and IND and protocol preparation. We use both in-house staff and consultants.

CRM takes a proactive approach to training and educating staff and clients, using meetings, seminars, workshops, courses, and even individualized training.

CRM Profile

Clients

Our major clients include:

- Walter Reed Army Institute of Research (WRAIR)
- U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID; Ft. Detrick, MD)
- U.S. Army Medical Research and Materiel Command (USAMRMC)
- National Institutes of Health

Employees

We have a highly educated and diverse staff that provides a wide range of technical and management expertise.

Core areas of technical competence include the critical scientific specialities of cellular immunology, drug fermentation, flow cytometry, immunology, microbiology, molecular biology, molecular entomology, phlebotomy, and virology.

Support categories include administrative (conference, data acquisition, documentation, and training), biological illustration, laboratory technical practices, process development, protocol nursing, purification, quality assurance, and specimen handling.

Our degreed managers include clinical research coordinators, principal investigators, research data managers, and research scientists.

Achievements

CRM's combination of high-quality personnel and innovative management has delivered tangible benefits to our customers. Among our notable accomplishments, we have increased

productivity at the WRAIR Bioproduction facility by engaging in enlightened personnel practices, such as:

- Managing the HR process with sensitivity.
- Valuing work force continuity.
- Upgrading the staff when positions open.
- Employing effective retention strategies.
- Providing a work environment and opportunities that empowered employees and helped reduce turnover.

We take pride in our employees and are committed to their

professional development

CRM encourages diversity in the workplace

CRM Philosophy: Quality at a Fair Price

Our business philosophy is simple yet powerful: Deliver value to customers, hire good people, and create a work environment in which they can flourish. We're a small, flexible company with the ability to expand because we have the resources and the resolve to grow in a *controlled* fashion.

Our growth rate during the last five years reflects client satisfaction with our high-quality work: Our staff has expanded from 35 in 1998 to 180 today, and business revenue has increased fivefold. We expect growth over the next five years to be double-digit.

This is possible because the CRM management team is committed to meeting the ever-changing demands of the research community with high quality and a fair price—by emphasizing flexibility, efficiency, controls, and partnerships with our clients. This corporate *ethos* guarantees that we meet or exceed expectations and deliver *value*.

Our track record shows that we have:

- Low turnover rates that average 8-9% per year. (A recent survey of U.S. companies by the Society for Human Resource Management reported an average annual turnover rate of 17%.)



CRM employs a culturally diversified, intelligent, and forward-thinking team that...works together to solve problems and get the job done. [That] makes it a pleasure to work here. — Rick, Senior Quality Control Analyst

CRM's Scorecard	
•	Scored "satisfactory" five years running on USAMRIID contract (options are "satisfactory" or "unsatisfactory")
•	Scored 96.5 on initial award-term rating on Bioproduction Facility contract (90+ considered superb for an initial rating)

- High staff conversion at contract transition.
- Employees that express satisfaction at exit interviews, especially with management interaction and the benefits package. (For example, when faced with contract cost restrictions, CRM voluntarily reduced its profit margin rather than eliminate a popular benefit.)
- Quarterly client visits in an industry where annual visits are the norm.

But perhaps the best measures of our success are the long-term relationships we establish with our clients and the outstanding ratings we receive from them (see graphic above).

Today, CRM is poised to become a major force in medical research while diversifying into commercial markets and such non-federal areas as state governments and universities.

CRM History

CRM has established an excellent reputation in the clinical research and development field because we continue to reflect the spirit of its founder, Victoria Tiffit, a third-generation entrepreneur.

Victoria possesses an unusual combination of leadership skills: she is an outstanding research talent with remarkable interpersonal skills. She has worked with the Peace Corps on health issues in developing countries and has been a biologist for the Smithsonian



National Museum of Natural History and coordinator of the Ronald McDonald House in Washington, D.C. Immediately before founding CRM, she assisted in creating the Clinical Trials Center at the Walter Reed Army Institute of Research.

Her dedication to high standards and good communication prompted a client to suggest that she establish her own research support organization, which she did in 1992 under the name Clinical Enterprises.

In 1993, the company—by then known as Clinical Research Management—bid on and won a small contract to conduct clinical trials at the Walter Reed Army Institute of Research. As CRM proved itself, the contract grew and the company expanded from three employees to ten. By 1998, CRM had 35 employees and was managing a major contract at USAMRIID.

Continued outstanding work on both contracts has contributed to steady growth. Importantly, CRM—now nearly 200 employees—is achieving its goal of controlled growth at a pace that ensures high quality at a fair price.

Let Clinical Research Management manage your research and provide the personnel.

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Appendix

CRM's Business Classification Codes

North American Industry Classification System (NAICS) Codes:

- 518210 Data Processing, Hosting, and Related Services
- 541519 Other Computer Related Services
- 541611 Administrative Management and General Management Consulting Services
- 541690 Other Scientific & Technical Consulting Services
- 541710 Research & Development in the Physical, Engineering, and Life Sciences
- 541990 All Other Professional, Scientific, and Technical Services
- 621999 All Other Miscellaneous Ambulatory Health Care Services

Standard Industrial Classification (SIC) Codes:

- 7374 Computer Processing and Data Preparation and Processing Services
- 7379 Computer Related Services, N.E.C.
- 7389 Business Services, N.E.C.
- 8099 Health and Allied Services, N.E.C.
- 8731 Commercial Physical and Biological-Research
- 8733 Noncommercial Research Organizations
- 8742 Management Consulting Services
- 8748 Business Consulting Services, N.E.C.
- 8999 Services, N.E.C.