

Insider Insights:

## Clinical Research Management (ClinicalRM)

CWWeekly's semi-monthly company profile feature, *Insider Insights*, interviews executives of companies and organizations in the clinical trials space. Writer Ronald Rosenberg sat down with Victoria Tift, founder and Chief Executive Officer of Clinical Research Management.

**Q** How did your background, from volunteering in the Peace Corps in Togo, West Africa, to working as a biologist at the Smithsonian, a manager and coordinator at Ronald McDonald House and a contractor at the Walter Reed Army Institute of Research lead you to start a CRO nearly 20 years ago?

**A** In the Peace Corps I was exposed to the devastation of disease and the personal toll it takes. I returned to the U.S. committed to be a part of the solution. My work at WRAIR [Walter Reed] was my first step toward that goal, and starting Clinical Research Management was a way of expanding that. Making a difference is a big part of who I am, and it's an underpinning of our company values. I'm very pleased to say that our work does make a difference—not just for war fighters, but for the global community at large.

**Q** A major portion of your company's business is with the U.S. military. What are the significant differences and distinctions in conducting clinical trials for the U.S. Armed Forces

versus civilian pre-clinical and phase I-III clinical research? How is informed consent different?

**A** The U.S. military works under the same FDA and ICH guidelines [International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use] that commercial industry does. I think there is the perception that because the military is a "captive audience" that informed consent might be less stringent. Quite the opposite is true.

In the commercial industry, informed consent needs to go through only one IRB review. In the military, there are additional review layers for added safeguards. Our clinical trials professionals who work with the military fall under all the same FDA guidelines as our commercial clients, with an additional two layers of approval. The process takes longer, and often our military clinical trials staff serve in an advisory role to new military primary investigators (PIs) to help them navigate the additional layers of regulation.

**Q** Your company has worked with Walter Reed Army Institute of Research and stated that it has been instrumental in developing FDA-approved diagnostic assays. Are there other tools and tests developed for the military that have crossed over to the civilian side?

### Clinical Research Management (ClinicalRM)

**Headquarters:** Hinckley, Ohio

**Year Founded:** 1992

**Description:** ClinicalRM is a full-service CRO with an array of global research, regulatory and sponsor services for the government, academic and commercial marketplaces. Experience includes over 18 years of military research, clinical trials and FDA-approval of vaccines and biologics, including over 500,000 man-hours with the military (the WRAIR, USAMARIID, USAMMDA).

**Officers:** Victoria Tift, Chief Executive Officer  
Sue Chase, RN, CCRP, Chief Operating Officer  
Wayne Mosley, CPA, Chief Financial Officer  
Lori Gipp, Director of Business Development

**Offices:** Hinckley, Ohio and Frederick, Md.

**Employees:** 330

**Expertise:** Government and military clinical research

**Foreign operations experience:** Armenia, Thailand, France, Tunis, Mali, Peru, Kenya, South Africa, Ukraine and Egypt

**A** We have developed a number of tests and screening assays for infectious agents of interest to the military at Walter Reed Army Institute of Research. One example initially used data from studies of L. major-infected BALB/c, a mouse screening model for anti-leishmanial agents [L=Leishmania, a protozoan parasite used, in this case, to infect a mouse, the BALB/c strain of mice]. This assay was designed to assist in the diagnosis of cutaneous leishmaniasis in humans and is based on a PCR (polymerase chain reaction) kit than has now received FDA approval. The kit is being modified for use with other pathogens of military and civilian interest.

We are also developing a screening library for potential drug compounds. This library has been used to assist in the development of several new drugs as well as variations of older drugs, including one that is a formulation with puromycin and gentamicin, as a topical agent for cutaneous leishmaniasis. A second compound is a primaquine analog, for the treatment of visceral leishmaniasis.

[Note: Leishmaniasis is a parasitic disease spread by the bite of infected sand flies. There are several different forms, the most common

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of which are cutaneous and visceral. The cutaneous type causes skin sores, while the visceral type affects internal organs such as the spleen, liver and bone marrow. Leishmaniasis is found in parts of about 88 countries, mostly in tropics and subtropics.]

We provided clinical and laboratory data for FDA submission for a well-known pediatric study conducted in Kenya. In another study, we assisted

Navy researchers to complete an efficacy and safety human clinical trial of a new malaria vaccine that protects the liver from infection. Such a vaccine can prevent both liver and blood infections, as well

as prevent relapses from certain forms of malaria. Our experience also led us to assist on one of the newest malaria vaccines for the Army with product sponsor GlaxoSmithKline that included the completion of a clinical trial.

We also developed several processes for particle-based vaccines using recombinant virus techniques with such agents as adenoviruses and poxviruses, as well as other vaccines based on recombinant bacteria such as *E. coli*, salmonella or lactobacillus for malaria, along with several other pathogens of military interest. These vaccines are currently in various stages of FDA review.

Some years ago, the company assisted the military in the development of a pilot-scale production facility at WRAIR, which has been used to produce a number of biological products such as agents for phase I and II clinical studies for a variety of vaccines. Among the products produced at this facility were vaccines against infectious diseases such as HIV, hepatitis A, malaria, dengue fever, *E. coli*, meningitis, shigellosis and leishmaniasis. The company still provides personnel to assist the military in the work at this facility.



**Q** According to a press release announcing your award of a five-year, \$97 million research support contract by the U.S. Army, you will conduct work to “improve national/international efforts to develop drugs and vaccines,” as well as products to “enhance warfighter resilience and reduce and mitigate the impact of brain injury and combat stress.” Exactly what will your company be doing?

**“Every war has its legacy medical breakthroughs. It seems that the improvement of traumatic brain injury, concussive effect, resilience and post-traumatic stress disorders may be this war’s legacy.”**

*Victoria Tiff, founder and CEO, Clinical Research Management*

**A** We are meeting this week to understand the specific nature of the research that will be supported under the recent award. That said, the solicitation was designed to bolster two programs with growing needs: global trials and evaluations, and projects within the neurological and psychological arena. With our war fighters in geographies with different diseases than we face in the U.S., it is not surprising that the emphasis on trials in Africa, Asia and Eastern Europe would dominate the landscape. Drugs developed to combat diseases such as malaria and dengue fever will also benefit the global community at large, as those diseases are prevalent in underdeveloped countries.

Every war has its legacy medical breakthroughs. It seems that the improvement of traumatic brain injury, concussive effect, resilience and post-traumatic stress disorders may be this war’s legacy. We will understand better, over the next few months, exactly where the primary emphasis will be.

**Q** While CROs have become more strategic in the clinical design process as trials increase in size and complexity, how will U.S. employment of CRAs and support

staff change in the coming years? What advice would you give people considering careers as CRAs?

**A** With the increased challenge that both pharmaceutical and medical device companies have toward decreasing the costs of product development, there is a trend to maintain agility in their respective work forces. This movement results in increased outsourcing. CROs need to maintain the same level of agility to accommodate this trend. Many CRAs are currently operating as independent contractors to adapt to the changes initiated by this economic need.

The role of technology in trials is growing rapidly. Often the nuances can be buried in technology. This transition adds a burden on the CRA to not only maintain a high level of clinical and regulatory expertise but also now have an understanding of the applied technologies needed to evaluate compliance with the ongoing changing requirements.

Technology is also opening a new door to clinical monitoring using risk-based assessments to determine visit structure and trigger an on-site visit as an exception. Source data verification may be defined per patient or per data field.

Finally, the clinical trials field is experiencing a global push more than most other careers. Knowledge of a foreign language, along with both global cultural and regulatory awareness, will be commonplace for the next generation of CRAs.

Our advice to those considering careers as CRAs would be to think of themselves as small businesses and develop a “customer base” among CROs. In addition to scientific training, a strong technology and language underpinning will be valuable career assets to those considering a CRA career. 