PEER REVIEWED | Brenda Reese, RN, CCRA, BSN

The Seven Key Traits of the Great CRO CRA

A great CRO CRA is someone who demonstrates strong leadership skills, has a thorough understanding of the rules and regulations, and has the ability to apply them in all situations.

With the current trend of big pharmaceutical companies outsourcing to contract research organizations (CROs), it's an interesting time to be a clinical research associate (CRA).

A September 20, 2010 Dow Jones Newswire story reported that CROs have expanded dramatically in the past 10 years, as sponsors increasingly turn to outsourcing as a way to decrease clinical research costs. Additionally, according to research firm Business Insight, recruiters report that CRA positions (also known as monitors) are available primarily at CROs, which are on track for 14% growth over the next three years, to $35 billion by 2013.

Based on my own experiences working as and managing CRO CRAs, I'd like to offer advice on what I consider the seven key traits that make a CRO CRA not just good, but great. First, let's look at why CRAs should consider working for CROs.

The Benefits of Working for a CRO

Years ago, working for a CRO did not always offer the same rewards as working for a pharmaceutical company. CROs in general had a reputation for high turnover because they tended to hire unqualified, underpaid, over-traveled monitors who rapidly burned out. However, that image is disappearing as more CROs understand the long-term financial benefits of finding and keeping qualified CRAs.

Today, being a CRO CRA is an exciting challenge and an incredible opportunity for professional and personal growth. Most CRO CRAs receive in-depth and continual training because they work on studies for different sponsors. This continued education and level of experience makes CRAs highly valuable employees.

In my experience, both as a pharmaceutical company and CRO CRA, I have found greater opportunity for growth and advancement at CROs because they tended to promote CRAs into study management and other aspects of the clinical trial process. As an added incentive, many CROs offer regional positions, so their CRAs do not have to move to advance their careers.

For CRAs looking to move into the CRO world, I suggest seeking a company that demonstrates an appreciation for its CRAs' contributions and fosters an environment in which they can do their best work and continue to learn and develop their skills.

The Great CRO CRA

What makes a great CRO CRA, and why are they among the most valuable clinical research professionals? A great CRO CRA is someone who dem-

onstrates strong leadership skills, has a thorough understanding of the rules and regulations, and has the ability to apply them in all situations.

Of course, CRAs need to have a good knowledge of clinical practice and local regulations. In the U.S., the rules are codified in Title 21 of the *Code of Federal Regulations*. In the European Union, these guidelines are part of the EudraLex.

Ultimately, the best CRO CRAs know that, at the end of a study, all the sponsor has are the research data. Thus, CRAs must make a personal commitment to deliver high-quality, audit-ready data to the sponsors so that they can bring new drugs and therapies to the market.

CRO CRAs have the confidence to work in environments where they might not know anyone at first, but their expertise, dedication to ensuring the highest quality data, and diplomatic skills enable them to develop excellent relationships with research sites. Having worked with many CRAs over my career—and having been one myself—I have identified seven key traits of the great CRO CRA:

1. Personal commitment to high-quality data
2. Positive, "can do" attitude
3. Excellent organizational skills
4. Ability to embrace inevitable change
5. Desire to stay engaged
6. Know-how to prevent personal burnout
7. Flexible travel strategies

In the following sections, we will take a closer look at these important traits.

Personal Commitment to High-Quality Data

Successful CRO CRAs make a deep personal and professional commitment to the data. They adhere strictly to the study protocol, not only to collect high-quality data, but also to make absolutely certain that study patients are enrolled accurately and kept safe throughout their participation in the research.

I recommend that CRAs train sites to document study information for accuracy and efficiency, and discourage them from documenting the same information in numerous locations. It is important to integrate every possible communication vehicle—telephone, e-mail, fax, regular mail communications—into a solid monitoring strategy. If CRAs use an electronic data capture system, they should monitor their assigned sites' data entry periodically. The great CRA always wants to know his or her query rate, follows through on all action items, and closely monitors serious adverse events.

Organization is the single most important trait all great CRO CRAs share.

CRAs should use follow-up letters and reports to address action items, and enter resolution with a date/initial next to all action items. Many CROs ask the principal investigator to sign the letter. It is important to write the report as soon as possible, if not immediately, while the information is still fresh. I always suggest starting the report while the CRA is still at the site.

Positive, "Can Do" Attitude

A positive, "can do" attitude can go a long way toward helping when problems crop up. We are all human, but the site is looking to the CRA to maintain a positive attitude no matter what happens. A strong CRA always handles problems with tact. Before addressing a difficult situation, the CRA should do whatever it takes—count to 10, breathe deeply, or put on a "poker face"—before calmly and professionally addressing the situation.

Enthusiasm is contagious! Committed CRO CRAs are always enthusiastic about their research and assigned projects. They are the first to volunteer for special projects. A positive outlook will go a long way with sites and the CRA's own management team.

Excellent Organizational Skills

The third trait is equally as important as enthusiasm, because it allows the CRA to translate an outstanding attitude into concrete results. Organization is the single most important trait all great CRO CRAs share. It is crucial to develop organizational tools to keep track of study updates across all studies, site updates, and study documents. Some CROs have sections on their intranets to give their CRAs all study information while they are traveling and/or onsite. The CRAs create and maintain their own decision log for each study assigned, and all changes and updates are immediately recorded on the log.

I suggest keeping an electronic "Hot List" for each site/study to record any action items the CRA needs to address that were not recorded on the follow-up letter. One idea is to turn the protocol into a "pocket protocol" the CRA can keep and carry, or to copy the essential pages of the protocol for each study assigned. Scanners can be very useful, and CRAs also can sign up for an eFax solution, such as www.myfax.com.

The CRA should have a general plan for what will be monitored at each site visit and how much attention should be given to each activity. It helps to be aware of where problems are most likely to arise during the conduct of a study. A good indication of potential problems is the list of activities that received the most deficiencies during U.S. Food and Drug Administration audits. This list is published annually by the Center of Drug Evaluation and Research, and has remained essentially unchanged for more than a decade. The top five categories for site inspections as reported in the 2001 Report to the Nation are:

- Failure to follow the protocol
- Failure to keep adequate and accurate records
- Problems with the informed consent form

- Failure to report adverse events
- Failure to account for the disposition of study drugs

Ability to Embrace Inevitable Change

Change is the one thing CRAs can be sure will happen during every study. A successful CRA embraces the change, and trusts the study management team when they say that the change is warranted.

Moving beyond the difficulties of the change allows CRAs to see them as challenges and opportunities. From the site perspective, addressing challenges gives CRAs the chance to showcase their ability to create ideas, action plans, and tools to address any situation. From the CRO perspective, handling changes gives CRAs a valuable learning experience as they work with their employers to effect the change or solve the problem.

Desire to Stay Engaged

In my opinion, great CRO CRAs are 100% focused and fully engaged with their studies, their sites, and their study teams. They take pride in their individual contributions and work closely with their colleagues to deliver high-quality data. They know and understand everything about their protocols. They are proactive in developing tools to keep all sponsor/study information organized. They keep a list of questions for each study, and are prepared, active, and engaged on all conference calls. The CRA is the CRO's eyes and ears on the study. CROs depend on the CRA's regular feedback, especially when changes or issues occur.

more the sites will go the extra mile for and with them.

Sites are taking a more active role in the quality of monitoring they are receiving, and have no problems reporting problems to the sponsor, so it is vital for CRAs to be professional in their dress, punctuality, and behavior. CRAs represent their CROs; their demeanor reflects not just on them, but on their employers.

Know-How to Prevent Personal Burnout

Great CRO CRAs know how to prevent their own burnout by fostering open, honest communication with their management. Being truthful up front about personal objectives, work-life balance, and the acceptable amount of travel they can handle enables both sides to set the proper expectations.

Managers play a key role in preventing burn out. They can help with strategies that include making sure that CRAs understand all aspects of their studies, problem-solving, alternating assignments so they get a mix of small and large studies, giving CRAs time for training and education, and making sure CRAs take their vacation. Then, if the CRA decides to move to a new job, it will be for positive reasons.

Flexible Travel Strategies

The CRO CRA can spend a good deal of time on the road; here's some advice based on my experiences and those of our CRAs:

Keep a bag packed. The CRA's life will be easier if he or she always has bags packed for that last-minute assignment. It is also wise to have two sets of travel/site clothes to rotate between trips. Savvy CRAs schedule their next visit prior to leaving the site, and they loop visits so they can see several sites in one trip instead of making several short trips. If CRAs schedule their own travel, I recommend they use Google calendar/Google Sync with their personal digital assistants and laptops to manage their itineraries. Several hotels and airlines have links to add reservations to Google calendars. My favorite travel websites are www.hopstop.com, www.kayak.com, www.homeandabroad.com, www.chowhound.com, www.seatguru.com, www.menupages.com, and www.lastminutetravel.com.

Have fun! When it is possible, even the most dedicated CRA should take time after the day's work is complete to see the local sights or have dinner out. It can be fun to collect items from each location—maybe a magnet, mug, or spoon. Some CRAs I've known carry maps of the U.S. and mark all the places they have visited.

Be careful. Downtime is always a good opportunity to work while on planes and trains, but please, not in automobiles!

The more open and available CRAs can be, the more the sites will go the extra mile for and with them.

CROs are Grateful

Great CRO CRAs are worth their weight in gold, and great senior managers know it even if they do not always show it. CRO CRAs work in a demanding, yet satisfying, profession. Those who demonstrate the traits of a great CRO CRA and who go above and beyond to ensure a job well done, protect patients, and deliver high-quality data for sponsors are among the most valuable members of the team. The great CRO CRAs are not only appreciated for their efforts, they earn the right to realize the many benefits of working for a CRO, including career success and ongoing opportunities for advancement. **ACRP**

Brenda Reese, RN, CCRA, BSN, vice president of business operations for DSP Clinical Research, has been in the pharmaceutical industry for more than 14 years and gained extensive experience in clinical research as well as corporate management and development practices related to solving the challenges faced by sponsors and CROs. In addition to *The Monitor,* she has contributed articles to *Applied Clinical Trials* and other publications devoted to the clinical research enterprise, and she speaks frequently on topics of vital interest to the profession. She can be reached at brenda@dspclinical.com.

FXM RESEARCH

IT'S NOT JUST CLINICAL RESEARCH!

IT'S CLINICAL RESEARCH EXCELLENCE... SUSTAINED!

Founded in the year 2000, **FXM Research** is a privately owned and operated Clinical Research Site that conducts phase II, III, and IV clinical research trials specializing in Dermatology. Throughout the years, our ability to deliver aggressive, time bound enrollment goals, while providing trustworthy data to Pharmaceutical companies and CROs, has earned **FXM Research** a great deal of notoriety and fame within the Dermatology research industry.

Today, FXM Research's success is widely regarded throughout our four operating branches: **FXM Research Corp.**, based in Miami, Florida and home of our headquarters, **FXM Research Miramar**, located in the city of Miramar, Florida and **FXM Research International**, including two branches in Belize City, Central America.

OUR MISSION

At the core of our business and operating systems, **FXM Research** mission is to support pharmaceutical companies and CROs with introducing new and approved FDA medications successfully into the marketplace. We perform this efficiently and effectively by providing the highest quality service in a timely fashion and at the lowest possible cost.

- We specialize in conducting phase II, III, and IV Dermatology Clinical Trials.
- Our primary concerns are subject safety and adherence to the protocol.
- Turnover time for Regulatory Documents, budgets, and contracts is usually 24 to 48 hours.

OUR SUCCESS

- We offer experienced, trained, and bilingual personnel (English and Spanish), who interact with our subjects, sponsors, and CROs as a cohesive team.
- Our Principal Investigators are Board Certified Dermatologists and Certified Clinical Research Investigators with many years of extensive experience. They are located onsite and are available full-time.
- Most subjects are recruited from the office of our PI's private practice, and/or FXM Research's extensive clinical database. We draw heavily from a Spanish speaking population, a group often under-represented in clinical trials. We also have continuing extensive experience with a pediatric population.
- We do whatever is necessary to accommodate our subjects' school and/or work schedule, which maximizes compliance and retention.
- We are confident that we can surpass sponsors expectations relating to cost, subject enrollment/retention, and the quality of our work.

TO CONTACT US

Francisco Moncada, R.N., B.S.N., C.C.R.C., President & Director of Clinical Research
Email: info@fxmresearch.com • www.fxmresearch.com

FXM Research Corp.
Hector Wiltz, M.D., CPI
(305) 220-5222 Office
(305) 675-3152 Fax

FXM Research Miramar
Francisco Flores, M.D.
(954) 430-1097 Office
(305) 675-3152 Fax

FXM Research international - Belize, Central America
Julitta Bradley, M.D. & Ines Mendez-Moguel, M.D.
(305) 220-5222 Office
(305) 675-3152 Fax