



outside the CRO box

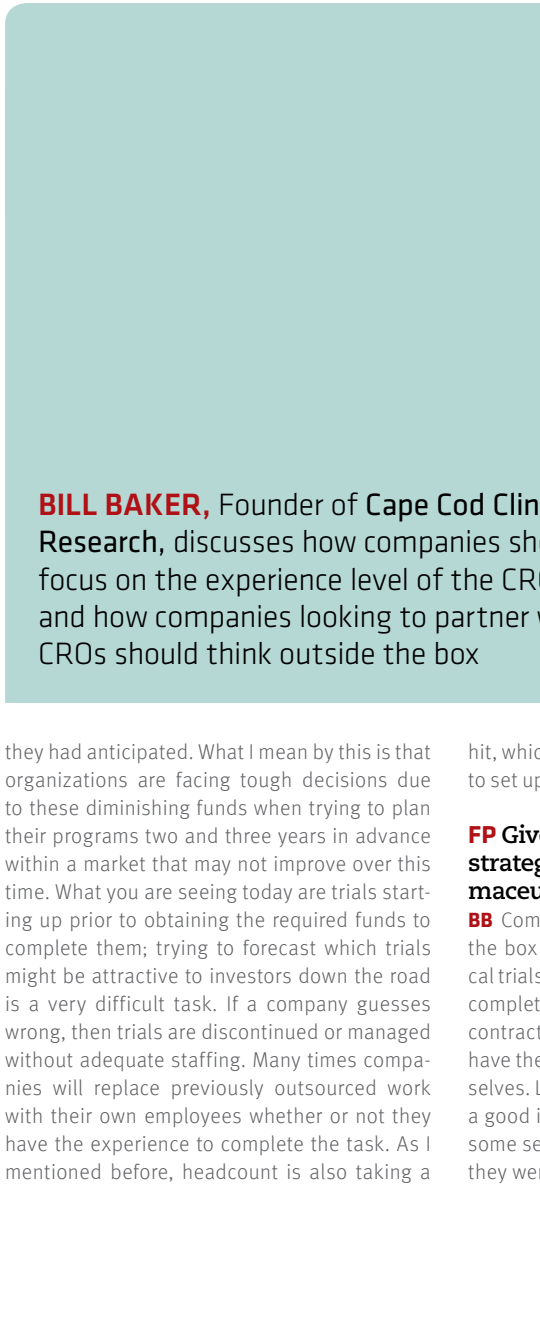


Future Pharmaceuticals From what you've seen, how is the current economic situation impacting the field of clinical research?

BILL BAKER I believe that the current economic environment has had a severe impact on the field of clinical research. This impact has caused a decrease in the number of trials being conducted in three areas. First are investments: biotech companies are now scrambling for fewer investor dollars. In the past, investment money was readily available, even on what could be considered more risky trials, but with these funds drying up, we now have more of an investor's market. This means that venture capitalists can be far more selective in where they invest their funds. Additionally, to remain competitive, companies are spending more on preclinical work to boost their research portfolios, which is a great idea, but again it adds more strain to the research budget. Second: companies are now spending far more time evaluating which research trials will actually be conducted, in an effort to minimize cost. With fewer available funds, many trials that would produce strong supportive data, but aren't considered primary efficacy or safety data, are not being conducted or are being combined into one larger trial. Lastly: companies are forced to reduce staffing as there are fewer trials and even less funds available, there is just no need to maintain the current head counts; this often leaves companies understaffed to do the work that needs to be completed.

FP Do you see the reduction in available funds impacting the amount of current and future trials?

BB I do, the reduction in funds is absolutely having an effect on current and future trials. Companies currently running trials without full funding are now realizing that they may need to complete these trials with fewer funds than what



BILL BAKER, Founder of Cape Cod Clinical Research, discusses how companies should focus on the experience level of the CRO staff and how companies looking to partner with CROs should think outside the box

they had anticipated. What I mean by this is that organizations are facing tough decisions due to these diminishing funds when trying to plan their programs two and three years in advance within a market that may not improve over this time. What you are seeing today are trials starting up prior to obtaining the required funds to complete them; trying to forecast which trials might be attractive to investors down the road is a very difficult task. If a company guesses wrong, then trials are discontinued or managed without adequate staffing. Many times companies will replace previously outsourced work with their own employees whether or not they have the experience to complete the task. As I mentioned before, headcount is also taking a

hit, which means fewer individuals are available to set up and execute research programs.

FP Given these conditions, what new strategies should biotech and pharmaceutical companies consider?

BB Companies need to start thinking outside the box in how they will be running their clinical trials in the future. Previously, work has been completed by in-house individuals or by larger contract organizations if a company did not have the headcount to complete the work themselves. Larger contract organizations have been a good investment in the past as they provided some security for smaller companies being that they were big and many had employees all over



the world with cost not really being an issue. In today's market, however, larger contract organizations' costs are becoming prohibited for mid to smaller companies with modest budgets as well as quality now being put into question. More of the upfront planning for these trials needs to include who will be completing the work a company must outsource; these decisions cannot be limited by a name or a size of an organization. Factors such as experience, location, as well as cost must all be considered in determining who gets to work on any given project.

FP How can companies get better value for their research dollar?

BB I think that there are many ways that

companies can get better value for the research dollar. One way is to look at companies that either specialize in one discipline of research — for example data management organizations, clinical operation organizations, or auditing. Another way is for companies to team up with other organizations under one umbrella to provide what is formally being considered as a full-service organization. Keep in mind that “full service” now only means that an organization can complete all the tasks, but companies that can specialize in individual disciplines not only can perform the task, but by using consultants in their workforce, provide an experience level and flexibility that larger CROs simply cannot provide. The benefit to the biotech and

pharmaceutical industry: trials that can be conducted where cost effectiveness in combination with appropriate experience and performance become a priority — not an afterthought.

FP Does this mean companies will have to compromise the quality of service?

BB Absolutely not, in fact the opposite is true for companies that are seriously looking at ways to maximize the research dollar. Simply stated, the level of experience that a consultant can bring cannot be matched by a larger contract organization, whose staffing may be in the first two to three years of their careers. Additionally, consultants that work with organizations, like Cape

OUTSIDE THE CRO BOX

Cod Clinical Research, are all incorporated — meaning that they are business owners who are just as invested into each project as a sponsor company is. Furthermore, the more experienced the individual, the more they can bring to the project, not just the usual input that you might receive from a contract organization, but more focus on: the design of the trial, areas that may be difficult for sites to complete, better strategies on screening and enrollment, as well as the ability to troubleshoot issues as they arise as well as knowing which issues need to be escalated and how to appropriately do so. Remember that a consultant that's been around for 10-plus years has worn many different hats — from monitoring to project management, they have a much broader background to bring to the table. The level of experience, the maturity level, that a consultant workforce can bring to the project, is truly unmatched when comparing it to some of the other solutions that are available today.

FP Can you give me an example of how Cape Cod Clinical Research is providing this level of service?

BB We've established over the last 10 years, a network of individual consultants that can perform activities anywhere from basic monitoring to lead CRAs, project management, auditing, medical monitoring, as well as compliance auditing. Teams are established after the sponsor company has reviewed and approved all CVs — no one works on any projects until they see who we're going to put on the project and they approve them. As stated previously, turnover is extremely rare as each consultant does take ownership of the project. CCCRI is not an organization that looks for young talent and trains them as to the way that we think research should be conducted. We look for individuals who started out as study coordinators, CRAs or other positions within the industry and have been in the industry for seven to 10 years. These are the individuals who have the broad experience that can contribute to the development of a program, many times bringing new ideas from other trials that they've worked on in the past. Being able to know what your sponsor

company needs and having the knowledge to obtain it from them, as well as the sites, is a trait that cannot be taught — it's really something that is developed over time. Lastly, we are developing technology now to help companies manage their regulatory documentation as well as their screening, enrollment and other project management activities.

FP How does this technology provide value?

BB Technology can be a great advantage as long as the technology doesn't surpass the knowledge of each team member who needs to use or even access it. I'm sure we've all worked on different project management software that requires hours of data entry to produce only a few useful reports (if you can find them on a list of a 150 that were provided with the software). This is why we developed our program, called TrialDox, which is a powerful tool in the organization of regulatory documents. This system is very simple to use and is as easy to use as Windows Explorer and requires minimal effort entering the information into the system. Team members can easily navigate through protocol regulatory documentation from anywhere that Internet access is available allowing them to see documents that otherwise weren't available unless of course you were standing in the file room holding the piece of paper. One problem that outsourcing has brought to the table is that as companies outsource, people get further away from the actual source of information; TrialDox solves that problem by bringing the source of information back to everyone regardless of their location.

Additionally, we are developing a proprietary system called EnrollmentDox, which is our monitoring tracking enrollment database. This program, which again is accessed through our secure Web site, provides real-time access to screening and enrollment information from each site. It also provides monitor information as well as other basic project management information that sponsors need to access. The benefit is that the site enters the data from the Web site at each visit so that there is no more screening or faxing of logs into the sponsor and then the sponsor

needs to figure out how to put all the information together and produce their own reports.

FP What are three tips that Cape Cod Clinical Research could provide to companies looking to adapt their clinical trials to the times?

BB First, you can obtain experienced individuals for your trials at a very cost-effective rate if you know where to look for them. Cape Cod Clinical Research's business model is designed to provide higher quality individuals while remaining cost effective to the sponsor company. When deciding on who will be awarded contracts, companies should review and approve all individuals working on their trials, not just what CROs or larger contract organizations are willing to give them — interview all your outsourced team members and make sure that you would hire them as if you were going to hire them to work for your own company. Review CVs from different organizations first, then decide who should be awarded a contract.

Secondly, I would look for and use appropriate technology for your trial. Every trial does not need to utilize electronic data capture or project management software that will present budget strains just for entering basic information. Smaller trials, for example, may not be appropriate when considering the amount of time and effort you need to enter data into these systems and may be summarized in several reports that you simply don't need. Our systems at Cape Cod Clinical Research are appropriate for smaller as well as larger trials and the difference is that our systems can be used by anybody that can point and click with a mouse.

The third and most important is: piece of mind. Cape Cod Clinical Research is a smaller firm, but we provide a level of maturity and experience that simply cannot be touched by larger organizations. Companies need to take the initial step and look at firms, like ours, versus other organizations. Taking the time to do this may result in significant savings for them without ever compromising quality, but it does require that organizations open up and start thinking outside their current box on how they conduct their clinical trials. **FP**



BILL BAKER, MBA, President of Cape Cod Clinical Research, Inc., founded CCCRI in 2000. CCCRI is a leader in building clinical teams using employees, sub-contractors as well as consultants to work together in a seamless fashion. By utilizing this cost efficient approach, CCCRI is able to bring the highest level of quality to its clients. Mr. Baker has over 20 years experience in the areas of domestic and international clinical research and regulatory affairs for companies such as Bayer, Astra Pharmaceuticals and Boehringer Ingelheim Pharmaceuticals. Mr. Baker experienced firsthand, the need to reduce costs and increase the efficiency of clinical trial execution.