

# Clinical Trial Educators: Game Changers in Patient Enrollment

## Peer-to-Peer Interventions Rescue a Failing Recruitment Plan



*A company developing an injectable urology treatment was in trouble. The company had one drug on the market and another in Phase III trial. But with a goal of recruiting 1,200 patients, the company had in six months enrolled less than 100 patients. And the 60 U.S. trial sites were not all that engaged. inVentiv Clinical Trial Recruitment Solutions came aboard to help out and through its innovative program of Clinical Trial Educators (CTEs) saved the trial by enrolling the remaining 1100 patients in less than 12 months. In fact, iCTRS didn't just save the trial, it may have saved the company. Here's how iCTRS did it.*

### THE SITUATION: High Stakes, Low Numbers

The company profiled in this case study isn't alone. According to Tufts University, 48 percent of sites in a given trial under-enroll or fail to enroll a single patient. Delays caused by a failure in patient enrollment are costly. The respected industry analyst firm Gartner, in a study on clinical trial performance, estimated that a day of drug development costs a sponsor \$37,000 in operational costs, with opportunity costs for delayed drugs ranging from \$600,000 to \$8 million per day.

In this case, the stakes were usually high, and the costs of delay were mounting. Most of the sites had taken on many other studies, so that this trial—for an injectable rather than the more familiar oral medications—was hardly top-of-mind awareness and to some investigators seemed daunting. On the plus side, the remainder of the protocol was not overly challenging, and the inclusion/exclusion criteria did not severely limit the universe of eligible patients.



## THE APPROACH: CTEs Save the Day

iCTRS began by performing a diagnostic analysis to uncover the specific issues within each individual site. One of six full-time Clinical Trial Educators was then tasked with visiting study coordinator, the back-up study coordinator, and the principal investigator (PI). iCTRS assembled its CTE team by drawing on its pool of clinical trial specialists, many of them nurses with disease-specific experience. iCTRS CTEs are on call for full-time, part-time, or per diem assignments.

Based on the site visits, the CTE team lead recommended an overall strategy and a site-specific actions to drive enrollment. In this case, motivation of study personnel, workload, and understanding of available resources, such as media support, were issues. By understanding the specific obstacles, the CTEs were able to make recommendations that turned things around.

Because the study already was underway, the tactics recommended were highly specific and localized. If used at the outset, CTEs can be even more efficient in recommending highly-effective, common approaches to be used across sites.

With the recommendations made, the CTEs rolled up their sleeves and applied their expertise, site-by-site. They:

- Re-educated site staff on the study protocol
- Served as morale boosters, keeping the trial top-of-mind and helping to keep sites motivated
- Provided advice and assistance in recruiting, including supporting community outreach through patient fairs and advocacy groups
- Monitored progress and reviewed metrics with each site, including screen failure rates and recruitment campaign response rates

The CTE visits, which averaged about six to eight hours a month per site in this case, had a different “vibe” from visits by the Study Monitor, whose visits can feel like “enforcers,” said Mary Robinson, senior vice president of operations at inVentiv Therapeutics Institute. CTEs play a helping role, as hand-holders, champions, and advisors. “As peers, they’re able to build a relationship with study personnel that pays dividends.”

*Educating vs. Managing*

CTE’s responsibilities are distinctly different from those of Clinical Research Associates (CRAs), although the two functions certainly work hand in hand.

CTE Responsibilities	CRA Responsibilities
<ul style="list-style-type: none"> <li>● Provide scientific information on product and rationale for clinical development</li> </ul>	<ul style="list-style-type: none"> <li>● Conduct pre-site visits and assessments</li> </ul>
<ul style="list-style-type: none"> <li>● Promote and track enrollment, identifying recruitment strategies and sharing information on sponsor-initiated campaigns</li> </ul>	<ul style="list-style-type: none"> <li>● Provide site with all needed materials</li> </ul>
<ul style="list-style-type: none"> <li>● Serve as conduit for ongoing scientific information on treatment paradigms and guidelines</li> </ul>	<ul style="list-style-type: none"> <li>● Ensure compliance with all trial procedures and guidelines</li> </ul>
<ul style="list-style-type: none"> <li>● Develop relationships with key opinion leaders</li> </ul>	<ul style="list-style-type: none"> <li>● Oversee source verification, eligibility, consent process</li> </ul>
<ul style="list-style-type: none"> <li>● Attend regional and national scientific meetings</li> </ul>	<ul style="list-style-type: none"> <li>● Ensure timeliness of safety reporting</li> </ul>
	<ul style="list-style-type: none"> <li>● Resolve protocol issues with the site</li> </ul>



**THE OUTCOME:** Sharing Best Practices, Meeting Quotas

Over the course of the enrollment period, the CTEs shared best practices, applied them to other sites and in weekly conference calls updated the sponsor.

Within 12 months, they enrolled 1,100 patients to reach the goal of 1,200.

As the project was winding down, the sponsor’s director of clinical operations breathed a sigh of relief: “The CTE team was integral to the success of our study.”

geographic requirements. At a weekly conference call, the sponsor and CTEs reviewed action items and progress at every site and identified activities for follow-up.

Within 12 months, they enrolled 1,100 additional patients to reach the goal of 1,200.

### *An Integrated Approach*

iCTRS is leading the biopharmaceutical sector in redefining patient recruitment, retention, and feasibility for clinical trials – so companies can get to market faster. The CTEs are part of the game-changing support offered by iCTRS that includes:

- Enrollment Modeling & Site Identification
- Behavioral Science Based Interventions
- Communications Planning & Evaluation
- Digital and Social Tools