

MARTY ANDERSON - senior director, project management, i3 Research

## Rescue leader in study start-up

With 70% of all clinical trials bogged down by delays somewhere along the timeline, improving study start-up efficiencies has become increasingly critical. Struggles in this area usually result in a disruptive domino effect on the timing for future project milestones.

In hopes of reversing sagging study start-up prospects, drug developers are turning to contract research organizations, particularly those with leaders who possess site-selection savvy and expertise. Judging by her track record, industry veteran Marty Anderson, senior director of project management at **i3 Research**, the CRO division of i3 (i3global.com), fits such a mold. Ms. Anderson began her career working in the laboratories at University of North Carolina Hospitals, but soon transitioned to the CRO industry, where after just one year, she began training junior clinical research associates. Ms. Anderson has taken on numerous positions within the industry since, including three years in her current post at i3, where she leads a team of 90 people.

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months, and 808 in five months. The achievement did not come without several challenges along the way, Ms. Anderson says. A major hurdle occurred during patient enrollment, when the American Diabetes Association changed its treatment guidelines for type 2 diabetics, advocating for dual therapy when i3 needed to recruit patients for a monotherapy product.

In dealing with the potential setback, Ms. Anderson, whose husband is a military reservist, says she approached the project with the mindset of a “military commander who must still accomplish the mission, even when resources are thin.”

“Everyone on my projects brings a unique talent to the team,” Ms. Anderson says. “Soldiers will march into battle for a cause they believe in, but only because they will move with those they trust, with discipline and flexibility. I take what I have learned from my husband and translate it to what I know – that we can get victory after victory with persuasion, discipline, creativity, and flexibility.”

Under Ms. Anderson’s guidance, a team at i3 identified and screened more than 1,200 sites in less than three months for the diabetes rescue study. The team helped develop i3’s platform, Rapid Study Start-Up, a process that has been demonstrated to compact the normal sponsor/site approval process from two weeks to two days. By developing an electronic site evaluation form and reaching agreement with the sponsor on key site qualifications, i3 clinical research associates are able to evaluate



sites quickly, enabling sponsors to turn their approvals around within a day.

More recently, Ms. Anderson and her team played a role in H1N1 immunization efforts, when i3 was selected to conduct some of the pivotal trials on a candidate swine flu vaccine. According to Ms. Anderson, public fear of the pandemic and the necessity to enroll many patients very quickly were exacerbated by the need to condense a significant amount of work into a short period of time. Her team, Ms. Anderson says, was up to the challenge.

With the sponsor committed to presenting ongoing data to FDA on the vaccine, i3 used its Rapid Study Start-Up engine to launch eight projects. A team worked on the ground in Latin America for one of the studies and was the first to deliver data to FDA. Ms. Anderson led her project team to three pivotal benchmarks, including obtaining European study approvals within four weeks after the program was awarded versus a typical three-month period; completing enrollment of the first adult trial of 800 patients in three days compared with the typical two weeks; finishing the U.S. pediatric trial enrollment two weeks ahead of schedule; and completing the last trial’s first subject/first visit 16 days after receipt of the final protocol.

### FAST FACTS

- Her team enrolled more than 8,000 patients worldwide in pivotal trials on a candidate H1N1 vaccine, driving at least eight database deliverables in less than three months.

- Contributed to the development of i3’s Project Excellence, an internal program that provides therapeutic oversight to project teams.

- Joined i3’s respiratory and infectious diseases therapeutic specialization in 2007.