

CRO Gains Competitive Advantage with etrials Software Solutions and Technology Transfer Program

Most Contract Research Organizations can grasp the potential benefits of designing and managing clinical trials in-house, but few can actually acquire the technology, training and competence to do it. That is, unless they have the right partner. Such was the challenge facing Omnicare Clinical Research, a Phase I to IV contract research organization providing drug development services to pharmaceutical, biotechnology and medical device companies in 30 countries.

An early adopter of eClinical and electronic patient diary technology, Omnicare is a forward-thinking company with a proven 3-year track record of success partnering with etrials for electronic clinical trials — often at the insistence of their sponsor clients. etrials planned studies for Omnicare that used etrials' fully-integrated platform of technologies including electronic data capture (EDC), electronic patient diaries (eDiaries) and interactive voice response (IVR).

Out of that success and trusted partnership grew Omnicare's desire to own the trial development process and technology themselves by licensing it from etrials. This licensing approach represented a tremendous undertaking and commitment for Omnicare that they hoped would pay off by enabling direct communication with their clients to work out a study's specifications and develop the CRFs, instead of being a middle man between their client and etrials. In addition to having a closer dialogue with their client, they hoped an in-house approach would allow them to offer clients faster time to start for their trials and allow Omnicare to keep a greater share of the trial revenue. Omnicare also liked the idea of being able to use in-house the same Design and EDC applications that etrials had so successfully used for their trials in the past.

Omnicare signed up for the etrials Technology Transfer program, a software in-licensing option for etrials subscription clients who want to build their own studies. Unlike some EDC vendors that approach a technology transfer as a mere software handover complete with limited training, the etrials process for technology transfer provides all of the elements needed to make a technology transfer successful, including a standardized transfer process, tools to ease development and testing, a comprehensive training program for internal and external use, and an expert team to adapt the technology to Omnicare's clinical trial process.

With etrials, Omnicare could select what capabilities they wanted to transfer in-house to meet its goals. Omnicare wanted to bring design, quality control, project management and administration tasks in-house immediately. Other tasks it wanted to have the option to add later, and still other tasks it never planned to take on in-house. Omnicare decided its technology transfer should include etrials Designer and etrials EDC. Designer would let Omnicare develop the electronic Case Report Form (CRF) pages and build a complete study according to their client's specifications. The tools that go along with etrials EDC would let Omnicare monitor the clinical data and oversee the project itself. Omnicare knew that down the road, after they mastered the EDC and Design tasks, if they wanted they could work with etrials to take the eDiary or IVR functions in-house as well.

The two companies worked in true partnership to achieve a seamless technology transfer. They started by developing a training plan crafted specifically for Omnicare based on the tasks that Omnicare want to take in-house and the pace at which they wanted to learn the etrials applications that support those tasks. The training plan defined the training format, structure and duration to best meet Omnicare's needs, including how many hours Omnicare could dedicate at a time to training, homework and practice. With a training plan in place, the etrials Technology Implementation department joined with etrials subject matter experts and developers to conduct the training sessions. Sessions were held at Omnicare and online per the training plan. The training program provided a structured format for teaching

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Omnicare developers every aspect of how to use the etrials Designer and EDC software. It included required homework where the developers had to create studies. After successful completion of the program the Omnicare developers were certified on the use of the etrials Designer and EDC applications. Omnicare and etrials were able to complete training and attain certification in the four months allotted in their training plan.

After the Omnicare developers learned the software and documented processes around the use of the software, etrials and Omnicare jointly evaluated their progress. They knew that future study sponsors would audit Omnicare on the technology like they would audit etrials. After verifying that nothing about the people, processes and technology involved in the transfer was overlooked, the two companies agreed that Omnicare was ready to take on the tasks in-house. Omnicare began realizing the benefits of its in-house design strategy right away. The company won two studies over other CRO's within a couple of months of completing the technology transfer. Winning this business was possible in large part because they were able to design the trial themselves and handle its quality control, administration, and project management in-house, without the need to coordinate with third-party vendors. Being able to offer clients this level of control also meant they could design studies faster than other CRO's who were still outsourcing.

etrials Worldwide, Inc., a leading provider of eClinical software and services to pharmaceutical, biotechnology, medical device, and contract research organizations offers insight into all aspects of clinical trials, maximizing return on investment and accelerating time to market. With global operations, etrials is the only top tier solutions provider to offer electronic data capture (EDC), interactive voice response (IVR), and electronic patient diaries (eDiary) as part of an integrated software as a service (SaaS) platform or as individual solutions to optimize clinical trials. As an experienced leader, etrials has facilitated over 900 trials involving more than 400,000 patients in 60 countries; and has participated in 33 studies used for new drug applications. Having partnered with over 100 clients, including 16 of the top 20 global pharmaceutical companies and top CROs, etrials is leading the way towards Adaptive Trials and integration between eClinical and electronic health records. To learn more visit us at www.etrials.com.

As Omnicare began developing the first two studies that would use the in-house systems, they weren't left to figure things out on their own. To ensure the efficient use of etrials technology within Omnicare's structure, the same etrials developers that assisted with the training and practice study homework provided continuing support to Omnicare developers for another 8 months after certification was complete. Today, Omnicare still receives 24x7 help desk support provided by etrials employees.

In addition to ongoing support, Omnicare also enjoys all of the benefits of their etrials solutions without any of the headaches that would come along with building and maintaining such a sophisticated system. For example, etrials maintains the documentation for system development and validation, and keeps up with technology advancements and system updates as needed. As updates are released, etrials trains Omnicare developers on the updates. This leaves Omnicare free to take advantage of the new versions and functionality in-house with minimal distraction or downtime.

Today 70% of clinical trials still use paper, but it is expected that demand for electronic trials will continue to increase, especially for certain clinical trials such as Phase 3 trials with 1000+ patients, which can gain huge benefits by collecting and managing trial data electronically. Through its technology transfer strategy, Omnicare is positioned to standardize the use of electronic data capture across multiple projects, realizing greater data transfer, reporting and training efficiencies. With these added efficiencies, Omnicare expects to continue winning business over other CRO's.

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