

> Bringing EDC Home:
How to Get the Most from
Technology Transfer

+ *The market is displaying strong indicators that electronic data capture (EDC) is entering the mass adoption phase of its technology lifecycle. Simply look at the accelerated rate at which sponsors and CROs are internalizing the development process in order to build their own studies.*

Technology transfer or in-licensing of software for use across an enterprise is a sure sign that EDC is enjoying a huge surge in adoption.

As an enabling technology, EDC holds the key to far-reaching competitive advantages for drug and medical device companies. It has been tested and proven, and it delivers on its promise.

Companies that are bringing EDC in-house are doing so because they recognize EDC as a strategic weapon in their pursuit of more efficient, cost-effective clinical trials. It's a flexible, scalable technology – giving you control over how much of the system you want to implement and when you implement it based on your corporate strategies.

So, what does a successful technology transfer look like? What are the criteria for evaluation? Certainly, using the software on a per-trial, ASP basis is an important first step. But when it comes to enterprisewide deployment, it requires a very different set of commitments and considerations for sponsors, CROs, and EDC vendors.

Keys to Success

For the sponsor or CRO, there are three critical success factors when undertaking a technology transfer: the full commitment and overarching support of senior management; an anticipated volume of clinical trials to produce the desired ROI; and making EDC an integral part of a company's strategic plan.

As with any corporate technology initiative, there must be corporate sponsors to champion this new eClinical approach. You're making an investment in software ownership and its benefits and impact have to be clearly understood across the organization.

When EDC takes its rightful place within your corporate strategic plan, it means you've set goals and have a roadmap for getting the most out of this powerful technology solution. Your teams will know that success is based on their ability to internalize the technology and demonstrate results over time. A longterm view and enterprise-wide adoption will yield the greatest efficiencies and financial rewards.

EDC vendors, on the other hand, must be able to provide four key program components to make technology transfer a viable, sustainable reality: a proven, repeatable transfer process; tools to ease development and testing; a comprehensive training program for internal and external use; and employees who are experts at adapting technology to the clinical trial process. And as the market matures and consolidates, EDC vendors who provide an end-to-end eClinical platform and are able to integrate multiple data feeds, including traditional EDC, electronic patient diary and IVR systems, will offer the biggest competitive advantage over point solutions or internally developed applications. This will make it possible for sponsors and CROs to successfully standardize on a common data platform.

Your OASIS in the Desert

Many have come to accept technology transfer as a software program packaged on a CD...period.

Implementation issues are addressed by consultants who charge millions of dollars in consulting fees to get sponsors up and running. These methods are neither cost-effective nor do they adequately prepare clinical teams and data management departments for integrating technology with process change.

Technology transfer should be an iterative process that occurs over a series of clinical trials, not a onetime event. If this is the case, then more emphasis must be given to how well an EDC vendor is able to replicate a consistent transfer process so that each client can easily, rapidly and independently get the most out of the technology.

This enterprise-wide, in-licensing model is best achieved when sponsors and EDC vendors view it as a partnership.

The EDC vendor's success is the client's success.

At Merge eClinical, we work side-by-side with our clients to guide them through the process to simplify and accelerate the way they perform clinical trials, as they migrate from paper to an eClinical solution.

Through our OASIS methodology, clients participate in a gradual, staged transfer of technology and knowledge until they have mastered a complete EDC implementation on their own.

OASIS is a five step approach to technology transfer.

The five stages are:

Observe

They first observe the method of setting up and running an electronic clinical trial. They learn the necessary changes in process, job functions and procedures to make the most of the technology. This stage may be repeated several times.

Assist

They assist. We turn over some of the design and deployment functions to them and carefully watch to make certain they are on track to get full advantage of the technology.

Solo

Now they attempt to build and deploy the study on their own, with Merge eClinical in a consultative role.

Integration

When the sponsor company is satisfied that all data feeds are seamlessly integrated and monitoring and reporting are available, Merge eClinical takes a back seat and assumes the role of software vendor.

Success

This is the final stage. The technology transfer has been internalized and adapted to their business system. Ongoing support is always available as the adoption process increases.

By giving our clients a phased handoff approach, we've helped them successfully attain competency at their own pace, transition into software ownership and internalize the process across their enterprise—a process that can be confidently repeated with future trials.

User-Friendly Tools Speed Design and

Testing

Just as important as ease of use is for the front-end data entry component, it is an even more critical differentiator for the back-end design and deployment tools.

Because many EDC tools were designed for their internal programmers to use, they lack the necessary intuitive interface that makes it easy for data managers and clinicians to use. Sponsors and CROs should want tools that not only provide drag-and-drop functionality for designing eCRF pages, but also effortlessly construct the database tables and structures simultaneously.

There is also the issue of validation and testing. Offering tools that proof and validate edits will reduce significant time in the design process and eliminate the need for human intervention. But that is only half of the story. If you are able to simulate data entry and assess system scalability, you will know how your study will perform in real time.

Tools that provide system performance metrics uncover IT-specific issues that can be addressed prior to study launch and keep your software up and running to meet your study schedule.

By providing these forward-thinking solutions, vendors prove that they truly understand all aspects of software in-licensing and demonstrate to sponsors and CROs that the impact of their technology adoption will be minimal and positive.

Technology transfer should be well-planned and designed in such a way that the technology checks itself without involving expensive consultants.

At Merge eClinical, our user-friendly study design tools address these important back-end issues, helping you save time and money.

Training – the Key Enabler

Training has become the linchpin of successful technology transfer. Without the knowledge, tools and resources to effectively use the technology to build your own studies, the promise of repeatability breaks down.

Whether the training program is developed by leveraging internal subject matter experts or in partnership with world-class training companies, the EDC vendor is responsible for a knowledge transfer offering that will accommodate both the sponsor team and investigator sites

on a global basis.

That's why we have developed a multi-tier training program that provides a combination of live instructor-led education, practical, hands-on software training and on-demand, web-based modules and testing.

In addition, we offer a Help Desk and mentoring program to support our users over the course of the implementation and beyond. Based on the client's needs, we are able to build a comprehensive program—from sponsor training to train-the-trainer—to ensure their success. And because our designer tool suite is intuitive and easy-to-use, the knowledge transfer process is that much easier.

The Human Touch

Human capital is a company's most valuable asset. It is the EDC vendor's team of experts who understands the clinical trial process and what it takes for technology adoption. They walk the talk and will be the ones to guide your research and data managers through process changes.

Challenge their credentials. After all, it is their experience and expertise that will ensure a smooth transition and implementation.

With over 900 clinical trials completed, Merge eClinical' clinical staff brings industry-leading experience from Phase I to complex, multinational Phase IV trials. We anticipate client issues and proactively recommend solutions, and we're as easy to work with as our technology is to use.

Franchising Technology

When time to NDA is everything, you want to know that the technology transfer solution you are adopting will provide the most efficient, cost-effective and rapid means to clean, accurate clinical data.

Merge eClinical is committed to giving its customers a "success map" that clearly shows them the steps to take to internalize and optimize the technology—much like a franchised operation where the core of its success is consistency and repeatability.

The franchisee receives all the necessary deliverables to ensure their success—deliverables that have been proven time and time again. By providing centralized resources, a common process and corporate oversight, Merge eClinical' clients are assured of faster deployment, faster time to NDA and reduced risk across their enterprise.

Partnering for Success

Technology transfer is a two-way street. Both the sponsor organization and EDC vendor must carefully assess what it takes to ensure success.

It isn't enough for the EDC vendor to have a repeatable technology transfer process, robust, user-friendly back-end tools, a comprehensive training program and a highly skilled implementation team. If the sponsor or CRO doesn't have senior-level management support and a long-term commitment to EDC, it will fail.

However, when both parties are committed to making technology transfer successful, there is no question that bringing EDC home will reap huge rewards.

About Merge Healthcare

Merge Healthcare is the leading provider of enterprise imaging and interoperability solutions. Merge solutions facilitate the sharing of images to create a more effective and efficient electronic healthcare experience for patients and physicians. Merge provides enterprise imaging solutions for radiology, cardiology and orthopaedics; a suite of products for clinical trials; software for financial and pre-surgical management, and applications that fuel the largest modality vendors in the world. Merge's products have been used by healthcare providers, vendors and researchers worldwide to improve patient care for more than 20 years. Additional information can be found at www.merge.com.

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