

Overview: Clinical Trial Management Today

The EDC pilot phase is over. Electronic Data Capture for clinical trials is here to stay. More than two decades old, EDC is now being embraced by the drug development industry as an integral part of the eClinical portfolio of solutions for clinical data management. In 2007, Health Industry Insights predicts fifty-percent (50%) of all new clinical trials will use electronic data capture to help improve operational effectiveness and accuracy of safety information for new drugs.

U.S. Health Industry 2007 Top 10 Predictions, Health Industry Insights

Most pharmaceutical, biotech and even medical device companies have now come to accept the fact that electronic data capture is going to save them time and money. Leaders in life sciences have seen the benefits of earlier and more comprehensive visibility to trial data. Successes in managing costs, changes in business processes and minimizing risk have made EDC a viable tool for Sponsors. As a result of this dynamic shift in the methodology of data capture, Sponsors are embracing the promise of EDC.

"Big pharma makes good on promise of more than 90% EDC by the end of 2010."

- Laura Ramos, Forrester Research Market Overview, The Promise of Next-Gen eClinical Trial Software, March 15, 2006

Everywhere you look Sponsors are rolling out EDC company-wide. Many of these companies even have mandates that they will be 100% electronic at some point in the near future. To achieve this goal, however, Sponsors have had to outsource their EDC needs, either to an EDC vendor or to a Contract Research Organization (CRO) that can support EDC.

CROs: True Value Add Services for Drug Development

For years drug development companies have trusted CROs to provide the value-added services necessary to manage more than half of the clinical trials in drug development. According to a study conducted by the Tufts Center for the Study of Drug Development, CROs provide substantial global capacity to drug developers and have become a critical contributor to clinical trial activity.

*January/February Tufts CSDD Impact Report 2007,
The Tufts Center for the Study of Drug Development*

"The results of our study challenge the conventional notion that CROs are simply vendors providing capacity for a specific project," says Ken Getz, Senior Research Fellow at Tufts CSDD. "Clinical outsourcing offers a development speed advantage at comparable quality. And as the volume and scope of clinical research activity worldwide continues to grow, CROs are increasingly providing a workforce that is essential to the long-term viability of the enterprise."

Just as Sponsors look to CROs for their expertise in streamlining the process of managing clinical trials, forward thinking CROs realize the value of partnering with EDC companies that offer the greatest potential for improving the data capture process and ultimately bring products to market faster. In order to stay competitive, smart CROs will partner with top tier EDC companies rather than compete with them. They will expand their service offering to include progressive companies that will deliver the next generation eCT (eClinical trial suites) for trial management built on industry standards and commercial middleware.

For those CROs that have adopted EDC technology early on, the advantages have been substantial. However, the vast majority of CROs, particularly the mid-size

to smaller ones, have been caught trying to play catch up to the increase in demand. The reasons for this can differ from CRO to CRO, but several of the commonly cited reasons are:

- A general feeling that EDC will erode CRO services and profit margins.
- Lack of infrastructure to support EDC.
- Lack of training of CRO personnel to support EDC during and after the bid process.
- High up-front costs of EDC and pricing models that don't coincide with CRO revenue streams.
- Inability to accurately predict and convey EDC pricing to the Sponsor during the bid process.
- Timelines that can't accommodate the new technology.

One thing is clear, though. For CROs to compete and win business with those Sponsors that have mandated EDC, they will have to find ways around the obstacles preventing them from implementing EDC. The answer may not be as far away as you might think...introducing the OmniComm CRO Preferred Program.



Working with OmniComm

TrialMaster, First in Functionality™

OmniComm Systems, Inc. is an eClinical software and services company dedicated to helping the world's life sciences companies to maximize the value of their clinical research investments through the use of innovative and progressive technologies.

Partnering with OmniComm includes access to the industry's first in functionality eClinical management solution, TrialMaster. This web-based software goes far beyond traditional EDC and allows you to easily and securely collect, validate, transmit, and analyze clinical study data including patient histories, patient dosing, adverse events and other clinical trial related information. The 21 CFR Part 11 compliant solution offers unrivaled freedom to conduct clinical trials with unparalleled flexibility, ease-of-use and complete control over data. Developed using forward-looking technology based on Microsoft® .NET architecture, TrialMaster provides a simple "drag and drop" design tool and a straightforward, logical build process that allows easy, rapid trial development. There's no programming involved.

"Since Catalyst is a rapidly growing full service CRO, we rely on technology driven products like TrialMaster™ to enable us to perform more studies, faster; with greater data quality compared to traditional methods, all at a lower cost to our Sponsors. And the fact that we can do this for a fixed price has allowed Catalyst to offer predictable and consistent pricing for EDC to our valued customers."

– **Rick Anthony**, Chairman & CEO, Catalyst Pharmaceutical Research, LLC

INTRODUCING THE
OMNICOMM
SYSTEMS

CRO Preferred PROGRAM

A Distinct Advantage

The CRO Preferred Program is designed specifically for the unique needs of you, the CRO. The partnership allows you to expand your service offering to deliver an industry leading EDC solution, TrialMaster®, to your customers and increase your revenue stream and ratio of business won. The following exclusive features are available to you when you partner with OmniComm.

Fixed Pricing for Phase I-III Trials

- OmniComm provides consistent and predictable pricing based on the services you need.
- A fixed, preset price for all Phase I, Phase II, and Phase III studies.
For Terms and Conditions for Fixed Pricing, please request the CRO Preferred Program Pricing Sheet.
- No mid-study change fees or hidden costs.
- No upfront fees, you pay as you go.

Sales and Marketing Support

- OmniComm will conduct technical and demonstration support for all sales presentations.
- Full proposal support for Sponsor RFPs is available to you.
- OmniComm will supply targeted sales support materials.
- OmniComm will allow for private branding of TrialMaster.
- OmniComm will deliver market coverage in the form of joint press releases and provide partner visibility on the OmniComm website for you.
- OmniComm will solicit joint speaking opportunities and create customized case studies.

Dedicated, Hosted Environment

- OmniComm will supply a 21 CFR Part 11 compliant environment in our world-class IBM Hosting facility.
- Full web-based access for all CRO and Sponsor participants.
- Study set-up, validation, system administration, full back-ups and disaster recovery contingency services included in the price.

Training & Support

- Site-based and internal training is included in the fixed price.
- Ease of use and solid training = A better user experience.
- Our trainers are available to attend Investigator meetings, provide hands on training with site personnel, and/or conduct online training.
- Training is supported with comprehensive printed training manuals and documentation.
- If you need help, real-time support for your trial is never more than a phone call away. 24x7x365.

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EDC/CLINICAL TRIAL MANAGEMENT

For more information on the CRO Preferred Program and its fixed pricing, contact:

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