

The Emergence and Adoption of Electronic Data Capture (EDC) in Clinical Trials Data Collection

Premier Issue

Welcome to our premier issue! *EDC Today* is an independent publication on current information and issues on Electronic Data Capture (EDC) strategies and technologies for the Biotechnology and Pharmaceutical (biopharma) industry. Each month we will examine topic areas related to EDC theory, technology, practice or implementation.

Our premier issue serves to set the background. We will examine where EDC has been, where it is now, and where it might be going. We hope that a broad introduction will set the stage for more in-depth discussions in future issues. Our hope is that you will want to hold onto this issue for future reference!

The biopharma industry is undergoing a fundamental change in business paradigm. As the era of "blockbuster" drugs draws to a close, products must be developed with the expectation of lower revenues. At the same time, the number of drugs and biologics in development and review is expected to increase. These converging trends are urging the clinical development process to become more efficient.

Biopharma companies are required by the FDA to perform controlled clinical trials of potential drug compounds. The FDA reviews the data from these trials to determine if the compounds are safe for human consumption as well as effective for treating human diseases.

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*In the next issues
of **EDC Today:***

**"Job Evolution or
Revolution?"**
EDC's Impact on the
Clinical Trial Team"

**"Regulations and EDC:
Assuring Compliance"**

About EDC Management:

EDC Management was founded to assist biopharma companies plan, prepare for and implement Electronic Data Capture (EDC) strategies according to their data management goals and objectives. We do not sell or endorse any specific EDC software application or vendor.

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Available **EDC In Depth** Research Reports related to this issue:

"A Historical Review of Electronic Data Capture"

Earlier attempts for streamlining clinical data capture include fax, optical character recognition, intelligent character recognition, interactive voice response, speech recognition, and Remote Data Entry (RDE). This report details those attempts, their successes and failures.

"Current State of Clinical Trials Data Collection"

Companies are adopting new data collection technologies at varying paces. In our report we review what others in the industry say about the state of clinical trials data collection and their current and future plans for EDC adoption. Plus we examine and analyze the meaning of conflicting industry statistics.

"Transition from RDE to Web-based EDC"

Despite promises of increased efficiency, all forms of electronic data capture have been slow to catch on. This is due in part to the well-known problems of Remote Data Entry (RDE). This report discusses the advantages and weaknesses of RDE and the emergence of web-based EDC as the next significant advancement.

"Web-based EDC, is it the answer?"

Today, the challenge of making EDC successful through the use of web based data collection depends on both overcoming the issues that hindered earlier EDC technologies as well as avoiding new pitfalls. This report discusses the technological weaknesses of current web-based EDC applications and offers suggestions for improving them.

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The collection of data that will quantitatively demonstrate safety and effectiveness is a critical part of executing clinical trials.

Evolution of Clinical Trials Data Collection Systems

Traditionally, clinical trials data are collected on paper forms called Case Report Forms (CRFs). Investigator site personnel complete a paper CRF for each trial subject during the course of the trial. Data entry personnel at the biopharma company running the trial (also called the sponsor) transcribe that written data into electronic form using an in-house data entry application to record the data in a clinical trials database.

Figure 1 describes the details of the minimum steps involved in the paper-based data collection process.

The traditional paper-based data collection process is known for its inefficiencies. The largest time lags occur at two points in the process: during the transfer of CRF data to the sponsor, and during the transfer of Data Clarification Form (DCF) responses (corrections to the data) to the sponsor.

As a key to improved efficiency, EDC transforms the process of clinical trials data collection from a paper-based CRF process to an electronic one. In the clinical research setting, EDC helps to produce cleaner data faster, allows personnel to monitor study progress more efficiently, and permits more effective use of resources for important and timely decision-making.

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Steps 6-9 are repeated until all checks are passed to sponsor or QA authority's satisfaction

Figure 1

STEP 1: DELIVERY

Delivery of study materials — CRFs, Investigator Brochure, and "Study Compound" — to site.

STEP 2: ENROLLMENT

The investigator will enroll a patient into the trial and get necessary enrollment or randomization information from the sponsor.

STEP 3: FORM COMPLETION

The investigator will have a member of the site staff fill out the CRFs from the patient charts, lab records, and other pertinent medical records. The patient likewise fills in patient diaries at this point in time.

STEP 4: SOURCE DATA VERIFICATION

The CRA goes to the site to review the CRF, adds notes to the CRFs, and then brings them back to the sponsor or sends them to the sponsor.

STEP 5: DATA ENTRY

Once the sponsor receives the completed parts of the CRFs, the data is entered into a clinical data entry system.

STEP 6: DATA VALIDATION

Once the data is in electronic form, a number of checks are run on the data to verify its correctness.

STEP 7: DATA CLARIFICATION/QUERIES

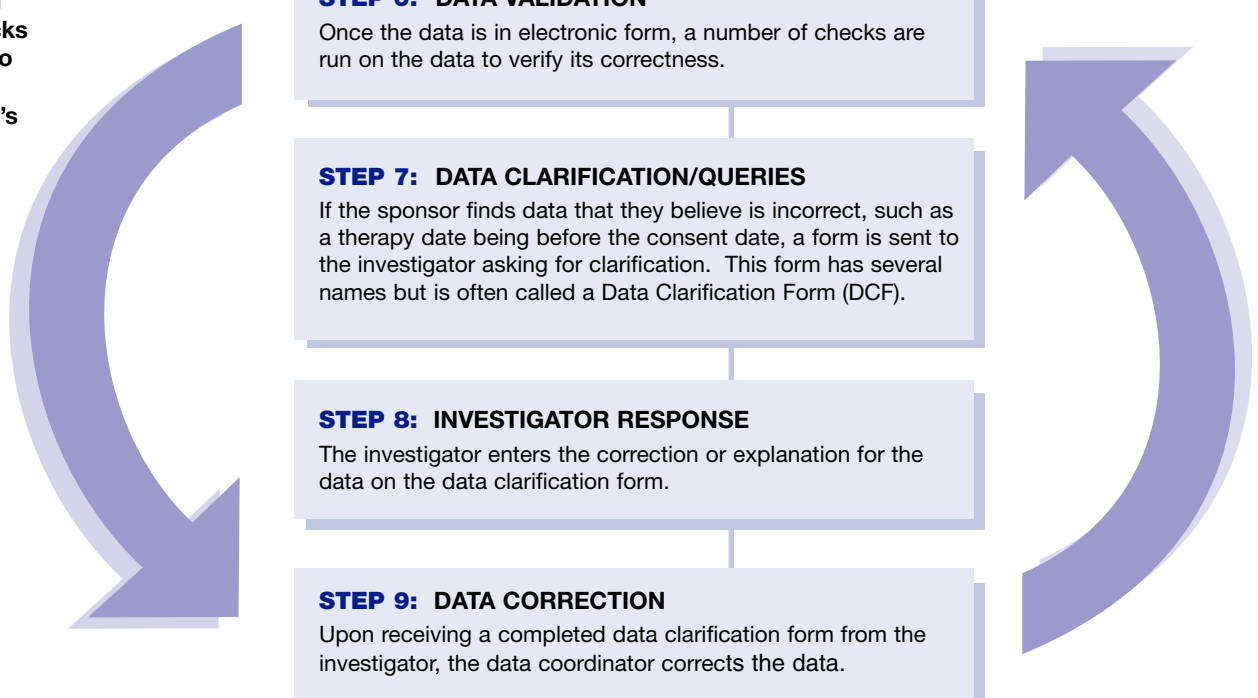
If the sponsor finds data that they believe is incorrect, such as a therapy date being before the consent date, a form is sent to the investigator asking for clarification. This form has several names but is often called a Data Clarification Form (DCF).

STEP 8: INVESTIGATOR RESPONSE

The investigator enters the correction or explanation for the data on the data clarification form.

STEP 9: DATA CORRECTION

Upon receiving a completed data clarification form from the investigator, the data coordinator corrects the data.





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EDC addresses the inefficiencies in the paper-based process by moving both data entry and data validation to the source of the data, the investigator site. Specifically, EDC greatly modifies steps 3 through 5 of the paper-based process (Figure 1). Data entry is now performed at the investigator site into a Web-based form, replacing paper-based step 3. Looping through steps 6 to 9 is also greatly reduced. Source Data Verification, step 4, now compares source documents to the contents of the database instead of the paper CRF. Finally, EDC completely eliminates paper-based step 5.

Early EDC Incarnations— Fax, OCR/ICR, IVR, and RDE

Early approaches to EDC include fax, optical character recognition (OCR), intelligent character recognition (ICR), interactive voice response (IVR), speech recognition, and Remote Data Entry (RDE). These attempts to accelerate the collection and cleaning of clinical data varied in their successfulness.

RDE, the first full attempt to enter data at the investigator site, strived to overcome the shortcomings of paper-based CRFs and early EDC strategies. Specifically, RDE focused on getting data entered into the database more quickly, improving the quality of entered data, and improving data monitoring by allowing monitors to examine the data before making site visits.

Though RDE systems have achieved documented improvements in the clinical trials process, they have been beset by a variety of logistical issues that have limited the success of their original potential.

EDC Today

Current EDC systems owe much of their strength to the past; they are built on the shoulders of the technological predecessors discussed above. The newest generation of EDC approaches — specifically Web-based — promises to overcome many of the technical, logistic and human-factor barriers of prior data collection methods.

By building on the strengths of earlier approaches and addressing their weaknesses, Web-based EDC moves even closer to the coveted prize of all highly technological data management systems: more accurate and timely data collection resulting in a shorter trial and faster time to market.

Although EDC systems have been used in only a small number of clinical trials to date — approximately 4% of current clinical trials employ some form of EDC¹ — more and more industry leaders are embracing this data capture tool. In fact, a growing number of biopharma companies indicate plans to either adopt EDC in the near future or start performing pilot studies using EDC. One survey finds that over half (54%) of the clinical trials conducted by the top ten pharmaceutical companies will incorporate EDC by 2004².

EDC in the Future

The history of RDE and EDC — full of both unyielding limitations and steady improvements — provides a rich guide for moving forward. By learning from the past, we can achieve smarter and more efficient evolution.

The challenge of making EDC successful depends on overcoming those issues that stymied the greater acceptance of RDE while avoiding new issues stemming from new, cutting-edge technology. When integrating future EDC technologies with existing applications, systems developers should strive to reduce complexity, increase functionality and improve the overall user experience.

While the evolution and adoption of EDC has been slow, the convergence of increased industry pressure and increased technical standards creates a profound opportunity for EDC success. As the industry embraces more technologically advanced solutions such as Web-based EDC, more efficiently run clinical trials may become reality.

1. Andrus, J., K. Carlson, et al. (2001). "Analysis of Current and Future Use of Technology." *Data Basics: A Newsletter of the Society of Clinical Data Management* 7(3): 7-13.
2. Waife R. (2001). *The Waife & Associates EDC Report*.

Who's behind the research?

Our lead researcher, **Kirk Mousley** received BS and MS degrees in Electrical Engineering from MIT and a PhD in Computer Science from Lehigh University. He has been the President of Mousley Consulting, Inc. since its founding in 1993 and has directed the company's efforts in the areas of clinical database design, data editing/cleaning, document management, and submissions.

Karl Mousley received his BS in Mechanical Engineering from Rose-Hulman Institute of Technology and a MS in Computer Science from Villanova University. He has been a senior member of the technical staff at Mousley Consulting, Inc. since 1993. Among his significant accomplishments are the investigation, evaluation, and implementation of new computer technologies for clinical data management systems and developing strategic plans for integrating these technologies into current systems. He has extensive experience preparing Standard Operating Procedures (SOPs).

Robert Pearsall received his BS in Electrical Engineering from MIT and his MS in Nuclear Engineering / Biomedical Instrumentation from The Ohio State University. He is Senior Consultant and Vice President for Business Development at Mousley Consulting, Inc. He has been involved with a variety of clinical data system projects for biopharma, including data management systems, electronic data capture (EDC), electronic submissions, validation compliance, and Knowledge Management. He was team leader and design architect for pilot projects in FDA/CBER electronic submissions.

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EDC Today and EDC In Depth

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