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The Automatic Clinical Trial: Leveraging the Electronic Medical Record in Multi-site Cancer Clinical Trials

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Abstract

Submission of data into clinical trial electronic data capture (EDC) systems currently requires redundant entry of data that already exist in the electronic medical record (EMR). Being able to automatically transfer data from the EMR to the EDC would save many hours of arduous effort, especially for multi-site data-intensive oncology trials. Standardization of the way in which data is stored and retrieved in the medical record and techniques for mining data from the unstructured narrative will provide opportunities for transferring data from EMR to EDC. As different EMRs proliferate, other technology in the form of data mining or middle tier applications are certain to provide assistance in this effort.

Keywords

Electronic Medical Record; Electronic Health Record; Electronic Data Capture; Clinical Trial; Oncology; Multi-site

Introduction

Building a link between the electronic medical record (EMR) and clinical trial research has long been considered to be the next improvement in data collection and processing, following the electronic data capture (EDC) systems that were developed to replace paper. Integration between the EMR and EDC would enable more accurate and efficient collection of clinical trial data, particularly in multi-site trials. In this article we describe current efforts to move in this direction, and some barriers to further progress. We conclude with a look to the future. Our focus throughout is on cancer clinical trials, though the concepts generalize easily.

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The Way We Are: From Paper to Electronic Data Capture

In moving from paper to EDC, cost savings and quality improvements have been significant. With the paper systems in use in the cancer cooperative groups beginning in the 1950s, clinical research associates (CRAs) at the trial sites had to locate the patient chart and then transcribe the data into paper case report forms for mailing to the central statistical center. At the statistical center data were entered into a trial database, often with double entry verification (which of course ensured accuracy only for this last step in the process). Any queries and answers went back and forth by mail.

EDC systems are now used in more than 40 percent of all trials [1]. EMR use will increase as hospitals and clinics adopt EMR technology to meet the requirements of the American Recovery and Reinvestment Act (ARRA), which includes a mandate that healthcare facilities implement electronic health records by 2015. Diminishing incentives began being offered beginning in 2011 and penalties in the form of reduced Medicare and Medicaid payments begin in 2015. Despite expansion in the implementation of EMR technology, CRAs continue to be faced with having to find data in electronic records and then manually enter them into electronic case report forms (eCRFs), typically collected in a Web-based EDC application. To enter data into the EDC, CRAs must either view two separate application windows on their computer workstation and copy the information from the EMR to the EDC, or they print the data from the EMR and enter it into the EDC from a paper copy [2]. The EDC generally features extensive edit checks for item integrity and inter-item consistency, and also a system for posting and answering queries electronically.

SWOG, a National Cancer Institute (NCI)-supported cancer clinical trials cooperative group, realized the advantages of conducting studies using electronic forms in 2003 when the group launched its first trial within its EDC system. Prior to moving to EDC, SWOG undertook the scanning of 80,000 paper charts. The effort began in 1999 and wrapped up in 2005. The paper charts were converted to a collection of 2.2 million images that make up electronic charts viewed and maintained using an in-house application called Chart Manager, a web-based application that interfaces with an Oracle® database where the charts are now stored.

EDC systems clearly are an improvement over paper in the timeliness of data capture for analysis, but there remains an inefficient and error-prone step at the site, as data are re-entered from one electronic system into another. The pharmaceutical industry feels that this is enough of a problem that it has subjected data for trials meant for registration of new agents with the Food and Drug Administration to 100% verification against the data in the EMR by on-site clinical monitors. This comes at great expense and with the additional cost of considerable disruption at the clinical sites. Thus there is substantial motivation in having the relevant data from the EMR automatically populate the EDC, or otherwise having the data in the EMR automatically transferred to the trial database at the central statistical center.

The Ways Forward: Getting From Here to There

The efficiency of electronic forms hasn't resolved the greatest challenge of collecting clinical research data, redundant data entry [3]. Integration of the EMR into the EDC offers a much greater potential for savings and increased efficiency by reducing data entry errors along with the number of queries, monitoring costs, and data need only be entered once [3]. Getting the data out of the EMR is a challenge, however, as current EMR systems are designed to record individual transactions and lack the standardization necessary to support quality initiatives or even clinical trials [4].

There are many reasons for clinicians and researchers to be motivated to solve the puzzle of true EMR to EDC integration with significant time and cost savings as potential rewards. The use of EMR data in oncology trials can be particularly valuable in the collection of data on detailed diagnoses, medical histories, complex treatment regimens, and treatment outcomes [5]. Oncology outcomes research, for example, requires comprehensive data related to all aspects of patient treatment.

In 2009, the National Cancer Institute (NCI) Center for Biomedical Informatics and Information Technology (CBIT), the American Society of Clinical Oncology (ASCO), and the National Community Cancer Centers Program (NCCCP) developed guidelines for the selection of an electronic health record (EHR) system. The Clinical Oncology Requirements for the EHR (CORE) document recommends functional requirements for an EHR system to meet patient care needs, including a cancer treatment plan, treatment summary, and oncology-specific documentation and functionality [6]. These requirements include tracking of staging information, chemotherapy dose and route of administration, toxicity and safety assessments, and drug inventory [6, 5]. The CORE document also requires that the EHR support oncologists in matching patients to clinical trials by including tools to assess eligibility and to link to trial summaries to be shared with the patient, and suggests that an oncology-supportive EHR provide tracking and procurement of investigational drugs, include storage and administration data, support decision-making related to protocol-mandated dose modifications, capture more complete protocol-specific data elements, comply with regulatory documentation, and streamline the audit process [6]. ASCO has pushed this project further with its Blueprint for Transforming Clinical and Translational Cancer Research, and is pursuing the vision with the Cancer Learning Intelligence Network, CancerLinq.

The CORE document also calls for integration with clinical trial and research support systems. The value of this integration cannot be overstated. It has been estimated that anywhere from 5 to 35 percent of patient data from medical history to demographics, along with medication information and some baseline measures could be integrated directly from the EMR [7]. The ability to use technology to transfer even a small percentage of existing EMR data to a clinical trial without having to manually reenter the data offers significant benefits and barriers to multi-site oncology trials (Table 1). Although the barriers may seem to be insurmountable, they are similar to those faced when clinical trial research moved from paper to electronic data entry.

Finding potential subjects is one of the most challenging aspects of clinical trial recruitment. This is particularly true of research trials with narrow eligibility criteria, and when investigating rare disease types [14]. Mass screenings, through patient examinations at screening events or by leveraging the data in patient records, can improve recruitment efforts. The Medical University of South Carolina (MUSC) effectively uses the EMR to identify potential subjects through analysis of test results for nearly 70,000 patients [14].

Research questions themselves might also be answered by examining patient data that already exists in the EMR [13]. The EMR has been utilized in this way through the study of patient data at multiple sites within organizations. The Mayo Clinic, for example, has used data from health records to enhance patient care and provide researchers and administrators with insight into treatment. Mayo's enterprise-wide data warehouse called the Enterprise Data Trust serves as a resource to support high-level decisions related to care, research and education. With the Enterprise Data Trust and other initiatives to standardize and share data across systems, Mayo can analyze patterns of clinical trial accrual, patient volumes, patient filtering, and eventually hopes to be able to provide patients with best options for participation in clinical trials [15].

Interorganizational efforts have also had some success at developing combined warehouses of data. The Veterans Affairs Healthcare System (VA) uses a centralized system for management of patient records called the Computerized Patient Record System (CPRS) which can support multi-site clinical trials. The VA's records system has been used for what has been called a point-of-care clinical trial with a focus on comparative effectiveness research [8]. With 152 medical centers and more than 275 outpatient clinics, the VA system is in a good position to leverage its EMR data in multi-site clinical trials [16]. The VA's CPRS provides a platform that follows patients through inpatient and outpatient treatment and while in long term care settings. The health record system is a part of the Veterans Health Information Systems and Technology Architecture (VistA), established in 1996, which connects all sites [17]. In addition to being implemented across all VA patient sites, including long term care facilities, CPRS incorporates a programmable reporting system which can search for or alert on data relevant to studies [8].

Since 2007, eMERGE, a consortium of five institutions, has been working to create a genomics-focused data warehouse that combines data from the EMR and DNA biorepositories to assist in genetic research. Under funding from the National Human Genome Research Institute (NHGRI), Group Health Cooperative of Puget Sound with the University of Washington, Marshfield Clinic, Mayo Clinic, Northwestern University, and Vanderbilt University combined efforts in Phase I of the project to collaborate on development of a system to support large scale genetic research. The focus of initial eMERGE studies was to use genome-wide association analysis to discover relationships that exist between genetic variation and two or more human traits found to be common among the network participants. In 2011, under Phase II of the project, Geisinger Health System and Mount Sinai School of Medicine were added to the eMERGE network and a coordinating center was opened at Vanderbilt. The goal now is to find ways to incorporate genetic variants into the EMR to improve "genetic risk assessment, prevention, diagnosis, treatment, and/or accessibility of genomic medicine" [18, 19].

Despite the success in sharing genomics information, regulatory requirements that protect patient privacy and data integrity are potential barriers to integration of the EMR and clinical trials [1]. The Health Insurance Portability and Accountability Act (HIPAA) restricts the sharing of patient information to protect their privacy and the security of the data. For research trials that will be submitted to the FDA for approval of a drug or therapy, Title 21 of the Code of Federal Regulations (CFR) Part 11 adds additional levels related to the security, integrity, and validity of the data, requiring that electronic signatures be valid and reliable. In addition, there are ethical and privacy concerns regarding the impact of clinical trial data on patients if trial data were included in the EMR [12].

Electronic transfer of data from the EMR to send to the clinical trial EDC has had technological barriers, primarily related to the format of the data. Data standards bodies, such as Health Level Seven (HL7) and the Clinical Data Interchange Standards Consortium (CDISC) have respectively set standards for healthcare data exchange and medical research [11, 20]. Those efforts led to development of data standards through the Integrating the Healthcare Enterprise (IHE) initiative, an effort that was begun in 1998 by the Radiological Society of North America and the Healthcare Information and Management Systems Society (HiMSS) to solve issues of interoperability between healthcare systems [9, 21].

IHE provides profiles to manufacturers and healthcare organizations that describe the technical workflows, communication, and security standards which can be used across clinical and operational business units. These standards are then used to improve the interoperability between systems. An EMR is made up of systems that track patient demographics and observations, laboratory measurements, pharmacy distributions, and so

on as a legal patient record [10]. A standard for entering information into this record, Cross-Enterprise Document Sharing (XDS), was created by IHE for sharing documents across disparate work areas, while XDS-1 was created to facilitate the sharing of images and associated records [9].

The Automatic Clinical Trial: The Holy Grail?

Researchers and clinicians have the same goal when it comes to the integration of medical records with a clinical trial research database, decreasing time and cost by reducing extraneous effort while obtaining accurate data. Achieving the ultimate in efficient clinical trial research may be similar to the search for the Holy Grail, linking the EMR directly to the EDC to pass existing electronic information directly to the research database. This would produce the automatic clinical trial with full integration between the EMR and the EDC.

Technology has brought hope to those searching for the automatic clinical trial, but new technologies have yet to be fully utilized and integrated. While ARRA requirements have prompted many organizations to implement electronic medical records, not all organizations are ready to adapt to standards which will facilitate data sharing. For example, HL7 and CDISC standards are being synchronized into HL7 Version 3 but implementation is slow as organizations are finding it difficult to change from HL7 Version 2 [10]. Implementation of these standards will be crucial to the integration of clinical trial systems with patient records.

Another hopeful technology is found in natural language processing (NLP). Unstructured narrative data which is prevalent in the EMR can be defined and extracted using NLP and intelligent character recognition (ICR) to provide valuable insight into pathology and treatment. A form of data mining, NLP has been used successfully by the Enterprise Data Trust and eMERGE Network as participating institutions applied the approaches to structured and unstructured data to genomics research [15, 19].

Data mining may yield important research data and reveal new ways to learn from the narrative information in the EMR.

Yet another approach calls for the use of data repositories and applications that act as a conduit between the EMR and EDC. Three methods have been discussed for using technology to facilitate data integration for multi-site clinical trials: 1) creation of an EMR data warehouse which acts as a multi-site repository for all patient data and interfaces directly with the clinical trial EDC; 2) development of a research data warehouse where data for all patients on trials is entered, with the data then being copied to EMR databases; 3) use of an application that interfaces with data from the EMR or an associated research database to reuse data from the EMR in the EDC.

The first method, creation of a data warehouse, calls for centralization of patient medical records across multiple organizations within the research EDC. While the ability to integrate systems to share data for the benefit of patients and research is a goal of ARRA legislation, a centralized, one-source clinical trial database is unlikely to be an effective approach as disparate databases would need to be mapped and translated to interact and healthcare facilities would need to agree to share their records [22].

The second method calls for creation of a research data warehouse for tracking clinical trial data across multiple studies and multiple sites. Benefits to this approach include accessibility to the data by researchers and validation of the data as it is entered, eliminating dual data entry and reducing monitoring costs as the database would contain primary source data [22]. The greatest barriers would be ethical considerations related to entering trial data directly

into the patient medical record, which might directly impact the patient, and dealing with the complexity of transmitting data from research EDC systems to the EMRs [1].

The third method may be the most effective bridge between clinical and research systems. It involves a use of middle tier applications, separate from EDC and EMR, which would either accept submissions from the EMR or CRAs and then pass the data to the EDC (e.g. a management system such as Velos' eResearch) or accept requests from the EDC and extract the data from the EMR (e.g. a reporting system such as Deep Domain™, Inc.). The Retrieve Form for Data Capture Profile (RFD), endorsed by IHE and CDISC, defines the method that an outside application can use to interface with an EMR system and display a form with data gathered from the medical record. RFD supports the concept of single source whereby data are entered only once and can then be used for multiple purposes. RFD allows for clarification of the data on the displayed form such that it might be modified to match the needs of the outside application. In a clinical trial setting, the EDC would interact with the EMR to populate eCFRs with data from the medical record and then allow clinical research associates to complete and validate the data for submission to the EDC. Besides a reduction in redundant data entry, other potential benefits to this approach include time savings, greater accuracy, and lower monitoring costs [1].

Researchers at Kyoto University in Japan tested methods that are similar to the concept of using a middle tier application to interface with the EMR [23]. Instead of using a third-party application, researchers designed case report forms within the EMR application using template technology that was already available. Protocol specific requirements were embedded in these clinical pathway templates, and required structured data were entered via the templates directly into the EMR. A simple retrieval system then extracted data in a format accessible by the central statistical center. In Japan, standardized medical record requirements will facilitate the extension of these templates to other healthcare organizations [23; 24]. Statistics from 2009 indicate that 825 major hospitals, with 400 or more beds, have implemented EMR technology in Japan and more than 60 percent of their medical records are electronic [24]. As EMR technology is adopted widely across Japan, researchers suggest that the eCRFs within the EMR could replace EDC systems and would improve data quality, avoid redundant data entry and reduce costs associated with source data verification [23]. Under this scenario, a mostly automatic clinical oncology trial could be conducted at multiple sites with regular upload of data to a central database at a coordinating center.

A similar approach was taken some years ago by Don Simborg with iKnowMed™, now owned by US Oncology, a division of the McKesson Corporation. The iKnowMed system provides for data capture into the EMR via a common flow sheet paradigm, which can in principle be easily adapted to the requirements of a particular clinical trial. SWOG implemented several of its trials in iKnowMed in a proof of principle project in the early 2000s [25].

SWOG has proposed a similar test to that conducted by Dr. Yamamoto and his team. The SWOG Statistical Center is working with the UC Davis Comprehensive Cancer Center to design a proof of concept for the automatic clinical trial to be facilitated through a middle-tier application. This study will interface the SWOG clinical trial EDC with Velos eResearch, the clinical trial management system (CTMS) in place at the UC Davis. The cancer center uses eResearch to manage the clinical trials in which it participates. While eResearch can integrate directly with the EMR, the center's work flow is currently designed around using eResearch to collect clinical trial data in the CTMS database.

At UC Davis, the eResearch CTMS saves cancer center staff time and effort by making study data readily available. While there is some redundant data entry between the CTMS

and EMR systems, entry of patient data into the clinical trial EDC is yet another example of redundant data entry. The proof of concept study will be designed to test the effectiveness of integration of the CTMS with the SWOG EDC which is housed at Cancer Research And Biostatistics (CRAB), which partners with Fred Hutchinson Cancer Research Center as the Statistical Center for SWOG. The SWOG EDC system provides an excellent platform for testing an automatic clinical trial workflow. SWOG application development staff will set up the proof of concept study in a test environment that mirrors the production environment. While the NCI has moved all cooperative groups to the Medidata Rave® EDC and clinical data management system, more efficient data entry into the SWOG EDC system continues to be relevant, as the SWOG system, developed starting in 2000 and enhanced over the years, continues to host more than 100 active oncology trials.

The proof of concept study is designed to effectively utilize existing technology and to be compliant with standards and regulations. Using the EDC functionality of eResearch, UC Davis staff will create one or two key trial eCRFs which can be populated with active patient trial data (Figure 1). Upon submission of the form, the eResearch system will send the form data to the SWOG EDC via a Web service, a communication applications that transmits data securely from one site to another in a standard format such as XML. The SWOG EDC will then store the data in staging tables, which are used as eCRF data storage prior to successful submission. The CRA at UC Davis will next login to the SWOG EDC where eCRFs will be prefilled the pre-filled eCRF will be accessible via a staging table. The CRA need only review and submit the form, rather than re-entering the data. Upon submission, field edit checks will run and notify the CRA of any potential issues with the data. Once issues are resolved, the eCRF data will be stored in the clinical trial database. The Web services will also be used to transmit queries from the EDC to the CTMS so CRAs can answer them within the CTMS system. Early evidence is that approximately 30 percent of the data items for the chosen SWOG trial can be captured automatically in this way, without changing the implementation of that trial in the eResearch system. Prior planning could increase that fraction to near 100 percent.

This trial model ensures that data are verified within the clinical trial EDC system, generates queries that are tracked in the EDC as a part of the audit trail, and eliminates redundant entry by CRAs. This design does not provide EDC to EMR communication, so any corrections made in the trial database must be manually made in the EMR if the EMR is to also contain a record of the clinical research. Another limitation is that the CRA must use two independent systems, so the solution is not a true single source implementation.

If successful under further testing, this technology can be extended to other institutions with similar middle-tier technology. For other facilities that use eResearch, pre-built templates that are setup once in one location can be provided to similar sites with setup instructions. Many sites with a similar CTMS application can then participate in multi-site trials using the template. Companies like Velos provide tools that automate creation of case report forms and other content from XML and comma-delimited files for use within their products and thereby with the EMRs with which they integrate. Their systems also monitor and facilitate audits of EMRs and other source system interfaces for research purposes. This enhances study compliance, increases data accuracy, and reduces study monitoring efforts associated with source data verification.

Yet another now proven approach is for study sponsors to simply use the EDC systems of vendors like Velos that are already in use at research sites and integrated with EMRs. This approach can eliminate the EDC-to-EMR update limitation mentioned above and also is a true single source implementation with built-in EMR integration where such interfaces are implemented. The arguable limitation of this approach is that the sponsor must either use

that particularly EDC tool or be willing to accept electronic trial results from such a system. The ability to conduct an FDA 21 CFR Part 11 audit and ensure study compliance is essentially the same as with the conventional EDC approach.

While CTMS systems might be best suited to pushing data to the EDC, another middle-tier application, such as analytics and reporting systems like the application developed by Deep Domain, can work from the source and push data to the EDC or from the receiving end act as an agent to pull data into the EDC. The Deep Domain system directly accesses structured data from any source, including the EMR, based on rules developed to acquire the required information. The advantage of this system is that operates on permission-based requests; the owner of the data need only create a list of approved resources and any user with the appropriate authentication can access them with no further input from the owner. Deep Domain also uniquely possesses the capability to run complex rule logic on the data it extracts and return the results to the requestor. Using this system, the clinical trial EDC can request information directly from the EMR based on pre-defined rules and secure permissions, or the CRA can make the request and send the data to the EDC.

Conclusion

CTMS and adaptive analytics reporting systems are regularly being enhanced to better use existing data in medical records so we can more efficiently enter patient data into clinical trials. Two systems of which we have knowledge were mentioned here. Other applications offer similarly innovative ways with which to manage patient data. As we look to the future, the standardization and harmonization of data reporting and the interoperability of systems may someday provide a link between the EMR and the EDC such that multi-site clinical trials can be conducted without dual data entry. A key element will be the motivation of EMR vendors, healthcare providers and researchers to define workflows across multiple organizations [10]. Open system development that adheres to industry standards offers the most practical solution for integration of the EMR and EDC [14]. Middle tier applications that can seamlessly pass data between the health record and data capture system, whether they be clinical trial management systems or transactional systems, can vastly improve the efficiency and effectiveness of multi-site oncology trials.

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Fig. 1.
CTMS to EDC data submission, showing data flow from the UC Davis CTMS to the SWOG
EDC with verification

Table 1**Multi-site EMR integration with clinical trial EDC**

Benefits	
1	Time savings [7]
2	Costs savings [7]
3	Objective data [8]
4	Fewer patient visits or other communications (Fiore et al., 2012)
5	Increased options for patients
6	More efficient and effective research
Barriers	
1	EMR systems disparate [9, 10].
2	Implementations of EMR differ across organizations [11]
3	Data privacy issues [12, 1]
4	Validated process requirements [2]