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Informatics: NCI's Cancer Informatics Infrastructure

by John S. Silva, M.D.

Learning from the world of commerce and building on advances in information technology and the explosive growth of the worldwide web, the National Cancer Institute is creating a new Cancer Informatics Infrastructure (CII). By replacing today's paper processes, the CII will speed the translation of exciting basic research discoveries to the practice of medicine at the patient's side. Once in place, this new infrastructure will bring profound changes in the practice and art of cancer care...not unlike the advances brought about by breakthroughs in genetics research. With the development of the polymerase chain reaction (PCR) laboratory process, for example, the practical applications of genetics have been transformed. Similarly, the Cancer Informatics Infrastructure (CII) offers great promise for transforming clinical trials.

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The current national cancer clinical trials program is fraught with redundancies, excessive amounts of paperwork, and fragmentation. With multiple sets of information in many disparate locations, it is nearly impossible to capture an accurate assessment of clinical trials activity in one institution, let alone across the nation. Perhaps more importantly, in the current system there is no way to seamlessly advance the progress made in clinical research to the clinical arena.

This system coexists in a world where consumers can access almost any ATM and make withdrawals that are immediately posted to their bank accounts. When a customer purchases an item at a local department store such as Walmart, for example, a product code informs the company's national headquarters about the kinds of products being sold and the type of customers buying them. It should make sense that clinical trials information, although much more complex, could be shared in much the same manner.

THE PAPER CHASE

Participation in clinical trials can be difficult for physicians and patients alike. Physicians, oncology nurses, and the clinical research team must overcome tremendous paper and administrative "hassle factors" in caring for their patients. To begin, research staff must search for one or more clinical trials that are appropriate for a particular patient. Next, to enter a patient into the trial, they must fill out, submit, correct, and resubmit forms in an elaborate paper chase, involving multiple copies and multiple fax, mail, or express delivery runs between the research office and either a cooperative group or a pharmaceutical company. This iterative process continues throughout the trial, with data shipped back and forth. Further still, the physician must complete forms ordering and authorizing tests and procedures—often arguing with insurance officials over approval, even though those tests are clearly documented by the hospital's "approved" treatment protocol.

Patients have their own version of this paper chase—finding the information they need, getting the forms for the next blood test or X-ray, and ensuring that their insurance company has what it requires to pay the provider. Patients' records remain paper-based, are usually maintained by multiple offices, and are handled manually. Every step involves effort; nothing is automatic.

Simplifying the clinical trials process requires an understanding of the data to be collected in a standardized, simple manner across all involved parties. Whether the user is an administrator, patient, physician, or researcher, he or she can retrieve the information needed in a secure fashion.

The National Cancer Institute's Cancer Informatics Infrastructure (CII) will enable patients and their oncologists to use their computers to identify the best treatments and clinical trials for specific cancer diagnoses and to facilitate entry into the appropriate trial. By speeding the accrual of patients and reducing the time and effort

to complete trials, the CII will accelerate answers to scientific questions.

CANCER TRIALS AND INFORMATICS

Within NCI, work in progress is establishing the foundation for the CII. NCI enterprise systems are being established to provide common models across the institute and to ensure that data and applications are compatible. NCI is working with the cooperative groups and others to simplify the data collected in clinical trials. NCI staff analyzed more than eighty active clinical trials across multiple types of cancer to identify commonalities and to develop a generic "clinical trial model." Six major categories of information were derived:

- eligibility
- efficacy
- schema of the trial
- safety
- informed consent
- the scientific question that the trial proposes to address.

NCI is developing a set of templates for each category that will significantly reduce the time and "hassle factors" for clinical trial authors. NCI is also collaborating with cooperative groups, national experts, and patient advocates to develop a set of common data elements as the standard data collected on case report forms. NCI hopes to establish a "common look and feel" for cancer-related clinical trials data that will substantially reduce the myriad forms and discrepancies in the way data are collected. The public can follow this work in progress. The common data element dictionary is available at http://hiip-wkstn.hpc.org. (Follow links in Projects to Common Data Elements.)

The CII infrastructure will replace cumbersome paper-based data collection by establishing electronic links that connect sites involved in multi-center studies to secure investigator databases. Patient-related data will be collected only once, in a secure fashion, from the physician's local electronic patient record system. Information required specifically by the clinical trial, such as case report forms (CRFs), will be automatically generated from the local systems used to document care delivered to the patient. For the first time, all cancer clinical trials will have common terminology and reporting requirements, greatly increasing the speed and efficiency of conducting a trial and the accuracy of its results.

In such an informatics system, the user makes a web-based request to enroll or file a case report. That request is transmitted to a central repository that contains all the information about what needs to be collected, with edit, consistency, and logic checks built in. A blank record is sent from the repository to the user, who then sends a clean patient report form back to the repository.

In an attempt to address bottlenecks in the paper-based system, efforts are underway to develop concurrent protocol authoring and to use drag-and-drop authoring for electronic protocol generation. Using a mouse to click on elements and insert them into a template, users will be able to spend most of their time on the front end, thinking about scientific questions and how the trial is going to answer them. For instance, we are applying industry-standard workflow tools to the submittal and approval processes for the letter of intent (LOI) activities. Figure 1 shows the simplified approach for an investigator to send his or her LOI to NCI where it will be routed to the appropriate reviewer for a more timely analysis. The investigator can query the LOI

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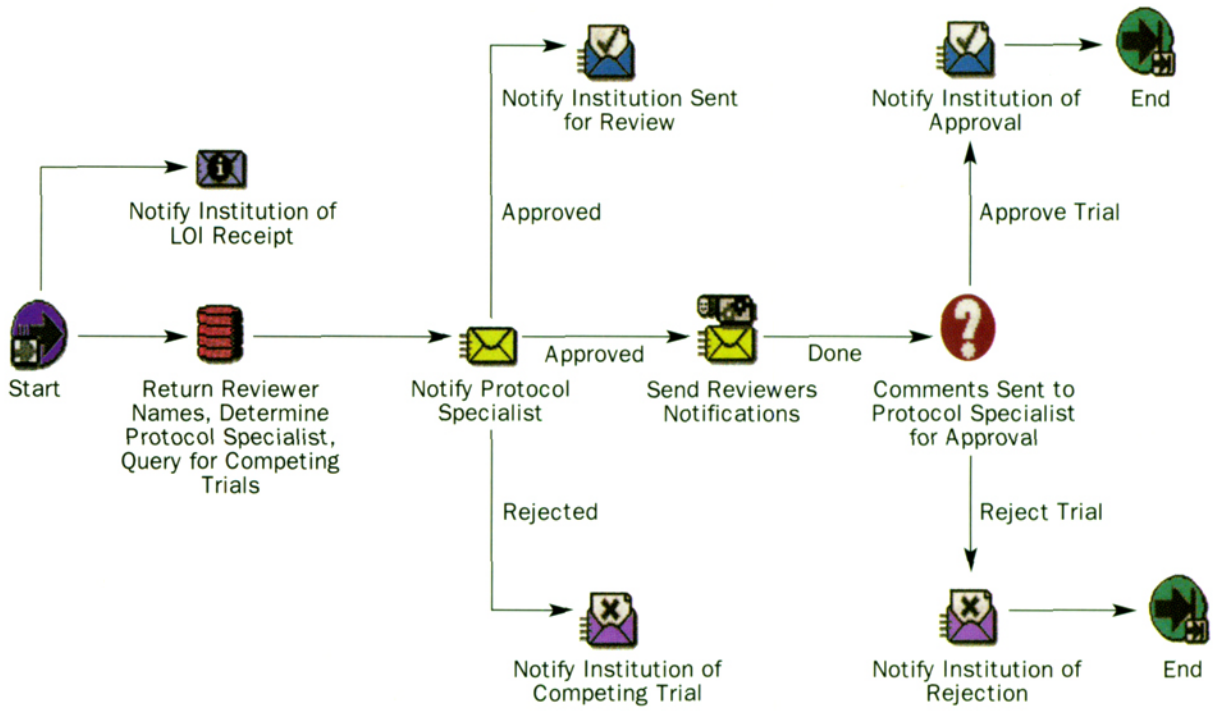
FIGURE 1: SUBMITTAL/APPROVAL PROCESSES FOR LETTER OF INTENT ACTIVITIES



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web site to check the status of his or her submittal, much like a customer can track a package on an express delivery company's web site.

WORKING WITH INDUSTRY PARTNERS

To realize this ambitious vision, NCI is forming public-private partnerships to develop a national-scale blueprint for the CII architecture. NCI will create "Lego blocks," or components that can be re-used many times, not always created anew. These blocks will help accelerate standardized clinical trials and establish informatics specifications and reference architecture for the CII. NCI is conducting pilot projects with ECOG, NSABP, MD Anderson, the University of California at San Francisco, and the Department of Defense to test these standards. The private sector will contribute the majority of the funding and will conduct most of the application development.

In summary, NCI and its partners are striving to eliminate the barriers to clinical trials without reducing the rigor of research. We hope to eliminate the paper chases for clinicians and patients, making clinical trials much more attractive. Perhaps, some day, they will be the preferred method of managing patients with cancer.

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and has developed rules and agreements governing the exchange of encounter data in California. Rules and agreements are posted on the CALINX web site at www.calinx.org.

To collaborate on standards and cooperate on implementation, CALINX has held four summit meetings, gathering decision-makers from all six CALINX partner organizations, plus many others. CALINX summit meetings have resulted in consensus on a number of important issues, including the use of national standards and open, non-proprietary systems. CALINX will hold another summit meeting in June 1999 that will focus on CALINX demonstration projects.

DEMONSTRATION PROJECTS

The health care industry lags behind most other industries in its ability to gather information effectively and use it wisely. Consumers are sometimes denied care or required to pay out-of-pocket for services to which they were entitled because health care information cannot be accessed or verified. For example, health care consumers often encounter long delays while their physician's office seeks to verify benefits or co-payments via telephone. To address this ongoing problem, CALINX intends to launch an eligibility demonstration project that will enable selected California provider organizations with real-time access to timely and accurate eligibility information for all health plans with which they contract.

CALINX will launch five demonstration projects in 1999 that will quantify the benefits of electronic data exchange. These projects will focus on the data exchanged between health care organizations in a managed care setting. Specifically, CALINX will conduct demonstration projects for the administrative and clinical transactions that typically occur within the managed care industry in California. CALINX will pilot the exchange of the following data sets in California:

- enrollment EDI
- eligibility
- laboratory
- pharmacy
- encounter records

Demonstration project participants will commit to the exchange of data according to federal standards (HIPAA) and CALINX agreements. Testing and training will be included in the projects' strategic implementation.

It is hoped that the standardized electronic exchange of health care data will lead to improved customer service, better quality health care, and administrative savings for purchasers, providers, and health plans alike.

INFORMATICS AND STANDARDS WEB SITE

Resources on medical informatics standards for new and veteran users are available at www.mcis.duke.edu. Developed by a grant from the New York-based John A. Hartford Foundation and maintained by professionals at Duke University Medical Center, this site provides information on standards developers, coding systems, informatics organizations, standards organizations, data sets, Internet and middleware standards, government organizations, and specialty specific standards.