Clinical Trials Expo 2006
Posters and Demonstrations

Abstracts

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AMIA Clinical Trials Expo 2006

Categories of topics for CTExpo submissions (demonstrations or posters)

- Clinical trial protocol authoring and management tools
- Multi-center trial infrastructure
- Practice-based research networks; Interoperability strategies (messaging, vocabularies, ontologies, etc.)
- Recruitment for clinical research
- Sharing clinical research data (clinical trial registries, etc)
- User tools: collecting and storing data (usability, databases, etc)
- Secondary use of clinical data for research (health services research, outcomes research)

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1. Protocol Tracker – An open source toolkit for building Clinical Trials Management Systems.

Presenter: Robert Dennis, Director, Computing Technologies Research Lab

Organization: David Geffen School of Medicine, UCLA

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Topics: Clinical trial protocol authoring and management tools; Multi-center trial infrastructure; User tools: collecting and storing data

Other authors: Khy Huang, Jeff Wang, Jianming He, Alan G. Robinson, M.D.

ABSTRACT

Protocol Tracker (pTracker) is a toolkit for building clinical trials management systems implemented within the OpenACS (Open Architecture Community System) framework. OpenACS is an open source web application framework. The OpenACS has a dedicated international community of users and contributors, and the software has been used as the basis of some of the busiest web sites.

Our poster and demonstration will present pTracker in context of three specific current clinical trials: the Inter-SPORE Prostate Biomarker Study (IPBS), and two separate clinical trials within the Microbicide Development Program (MDP). IPBS is a prospective study involving all 11 NCI supported Prostate SPORE sites. A total of 700 newly diagnosed patients with prostate cancer will be recruited from across the 11 sites to provide tissue and blood samples prior to primary treatment and 5 years of follow-up information. MDP is a multi-project, multi-center collaborative program with the NIH (U-19) to develop an effective rectal microbicide. The context is HIV-AIDS prevention research. Two of the three projects within the MDP involve clinical trials. In addition, our poster will provide an overview of the same pTracker tools used to develop the patient management system supporting the California state-sponsored Improving Access, Counseling, and Treatment (IMPACT) for Californians with prostate cancer, and the Patient Reported Outcomes of Complimentary, Alternative, and Integrative Medicine (PROCAIM) system. PROCAIM is a self-registered longitudinal study focused on patients and the interactions with physicians in the general field of alternative, integrative and complimentary medicine.

PTracker consists of three main components: a flexible (case report) form builder, a general workflow engine, and a subject management module. Our form builder is a mature question engine that supports complex page flow, logic, and reporting. The pTracker workflow engine is a customization of the basic finite state machine workflow package in the OpenACS. A workflow defines the states and the actions that move subjects through states (transitions). The subject manager is essentially a roster or registry of patients or objects associated to a study within pTracker. Subjects are what are moved through a workflow. Subjects are OpenACS objects. Normally subjects are human patients that move through a well-define workflow (i.e., a protocol). However, in the IPBS one workflow models the handling and inventory of biological specimens at each SPORE site, and so the objects are actually packages of tissues slides and serum vials from many patients that are periodically sent to a central pathology core for later distribution to the biomarker investigators.

Support for the development of pTracker has come in part from Dr Alan G. Robinson's Integrated Advanced Information Management Systems grant from the National Library of Medicine (NLM grant number G08-LM-7851).

2. The Clinical Research Management System

Presenter: Allen Tien, CEO and Research Director

Organization: Medical Decision Logic, Inc.

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Topics: Clinical trial protocol authoring and management tools; Multi-center trial infrastructure; Interoperability strategies; Recruitment for clinical research; Sharing clinical research data; User tools: collecting and storing data; Secondary use of clinical data for research

Other authors: Steven Beales, Geoff Ott, Alexandra Love

ABSTRACT

The Clinical Research Management System (CRMS) is a browser-based Web application with a rich, interactive, user-friendly interface based on Ajax. The CRMS data model builds upon CDISC, HL7 and caBIG models and standards. Developed with an iterative, user-centered design process, the CRMS closely matches research workflow processes and needs. The Subject Registry module handles many research administrative tasks, including eligibility assessment, consent tracking, enrollment, IRB documentation, and reporting. The Protocol Schema module provides a graphical interface and integrated domain specific language (DSL) for building an executable representation of protocol workflow; a dynamic temporal constraint logic engine supports adaptive scheduling. This module also tracks research procedures for billing compliance. The CRMS is easy to configure for a specific protocol. In testing, research staff implemented oncology clinical trial protocols in under eight hours. The CRMS has been deployed at 2 major university research hospitals. Ongoing development will address areas such as tissue banking, adverse events, case report forms, the protocol development process, budgeting, and most generally, knowledge representation, translation, and clinical integration.

3. Towards Semantic Interoperability in a Clinical Trials Management System

Presenter: Ravi Shankar, Research Staff

Organization: Stanford University

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Topics: Clinical trial protocol authoring and management tools; Interoperability strategies

Other authors: Susana Martins, Martin O'Connor, Amar Das, Dave Parrish

ABSTRACT

The lifecycle management of a complex clinical trial typically involves multiple applications facilitating activities such as trial design specification, clinical sites management, laboratory management, and participants tracking. The lack of common nomenclature among the different sources of the tracking information and the unreliable nature of the data generation can lead to significant operational and maintenance challenges. The applications support different but related aspects of a clinical trial, and require clinical trial data flow and knowledge exchange between the applications. Thus, there is a strong impetus to integrate these diverse applications at syntactic, structural and semantic levels so as to improve clarity, consistency and correctness in specifying clinical trials, and in acquiring and analyzing clinical data.

We present Epoch, a knowledge-based approach to support a suite of clinical trial management applications. We are adapting this approach to the Immune Tolerance Network (ITN; www.immunetolerance.org), an international consortium that aims to accelerate the development of immune tolerance therapies through clinical trials and integrated mechanistic (biological) studies. The ITN is involved in planning, developing and conducting clinical trials in autoimmune diseases, islet, kidney and liver transplantation, allergy and asthma, and operates more than a dozen core facilities that conduct bioassay services. At the core of our framework is a suite of ontologies that conceptualizes the clinical trial domain. The ontologies along with semantic inferences and rules provide a common protocol definition for the applications to use to interoperate semantically. We use Protégé, a knowledge-acquisition tool, and emerging semantic technologies such as OWL and SWRL languages to build the Epoch ontologies and to encode ITN clinical trials using these ontologies. In this presentation, we will also illustrate the use of the Epoch framework in supporting the semantic interoperability of a subset of the clinical trial management applications to support specimen tracking.

4. The World Health Organization's International Clinical Trials Registry Platform

Presenter: Ida Sim, Project Coordinator

Organization: World Health Organization

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Topic: Sharing clinical research data

Other authors: An-Wen Chan, Patrick Unterlerchner, Ghassan Karam, A. Metin Gulmezoglu, Tikki Pang

ABSTRACT

Selective reporting of clinical trial results is known to be widespread, and recent high-profile cases have demonstrated the potential impact of suppressing negative findings in healthcare. In order to restore public trust in clinical research, it is clear that transparency and accountability must be strengthened through trial registration and results reporting on public electronic databases.
The World Health Organization (WHO) established the International Clinical Trials Registry Platform in August 2005 with the primary objective of ensuring that all clinical trials worldwide are uniquely identifiable through a system of public registers, and that a minimum set of results is made publicly available. This presentation will highlight the current policies and progress of the WHO Registry Platform, as well as outline the technical and practical challenges of implementing global trial registration.

WHO Registry Platform policies apply to all research studies that prospectively assign humans to one or more interventions, regardless of study design or intervention type. For a trial to be considered fully registered, all 20 items in the WHO Trial Registration Data Set (Version 1.0) must be recorded in a national, regional, or international Primary Register that meets acceptable standards for content, technical capabilities, quality assurance, and administration. A WHO Search Portal to identify trials across Primary Registers will be developed to meet the needs of patients, scientists, and other healthcare workers. The WHO is now also defining a Minimum Trial Report, to be reported for every registered trial.

Informatics challenges for the Registry Platform include the standardization of data fields and clinical vocabulary across international registers, the identification of duplicate registration entries and the assignment of a Universal Trial Reference Number (UTRN) to each globally unique trial, and the definition of a data interchange standard. The WHO is working with CDISC to define this interchange standard, and to test the standard with ClinicalTrials.goV, PDQ, the Trial Bank Project, and several NIH NECTAR and CTSA projects.

Finally, global compliance, oversight, and capacity building must be considered in WHO Registry Platform policies, which will be re-evaluated and refined periodically as the complex field of trial registration continues to evolve.

5. The Trial Bank Project

Presenter: Ida Sim, Associate Professor

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Other authors: Ben Olasov, Simona Carini

Topics: Interoperability strategies; Sharing clinical research data

ABSTRACT

Randomized controlled trials (RCTs) are a key source of evidence for medical practice. However, RCT results are published as text, which computers cannot read. Computers are therefore illiterate of the evidence they could help clinicians apply. The Trial Bank project captures over 160 unique information items about the design, execution, and results of RCTs into a structured knowledge base called RCT Bank.

The Trial Bank Project encompasses work in several related grants that:

1. extend the ontology of RCTs to include cluster-randomized trials, and a standard representation of eligibility rules

2. work with funding agencies (VA, Canadian Institutes of Health Research) and journals (PLoS, BMJ) to capture trials into Trial Bank

3. integrate trial registration and reporting into the Electronic Primary Care Research Network

4. visualize and analyze HIV trials as a Driving Biological Project of the National Center for Biomedical Ontology

By capturing all the information needed for critically applying a trial to clinical care, Trial Bank explores and demonstrates the challenges and opportunities for an open-access, machine-understandable repository of RCT evidence for computer-assisted evidence-based medicine.

The Trial Bank Project is the research foundation for AMIA's Global Trial Bank initiative on open data for clinical trial data reporting. It also incorporates and extends the trial registration and reporting recommendations of the WHO International Clinical Trials Registry Platform.

This exhibit will access the trial-bank server at http://rctbank.ucsf.edu/ to demonstrate: 1) Bank-a-Trial, a website for entering RCT design, execution and summary information into our trial bank with an integrated dynamic UMLS term selector; and 2) RCT Presenter, a website for searching and browsing trials in the trial bank.

Items for discussion include standardization of data models for clinical trial activities, integration of RCT evidence into decision support tools at the point of care, and new models of electronic publication of science.

6. CALAEGS: City of Hope Laboratory Adverse Event Grading System

Presenter: Joyce Niland, Chair and Professor, Information Sciences

Organization: City of Hope National Medical Center

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Topic: Clinical trial protocol authoring and management tools

Other authors: Doug Stahl, David Ko, Jennifer Neat, Jack Lee, Susan Pannoni

ABSTRACT

The monitoring of adverse events (AEs) is a critical component of clinical trial management. The standard tool for AE grading in oncology is the Common Terminology Criteria for AE (CTCAE). A significant portion of the CTCAE grading is based on quantitative laboratory data. Under current practice, Clinical Research Associates (CRAs) transcribe laboratory results for clinical trials patients into a flowsheet, and then use these to interpret the AE grades. At City of Hope a system has been developed to automate the algorithms for grading of laboratory based AEs, greatly improving the efficiency and accuracy of detecting and assessing lab-based toxicities. This system, titled CALAEGS: City of Hope Laboratory Adverse Event Grading System, is now being ported to an open source version for distribution to any institution center requiring such decision support for AE grading.

7. Clinical research workflow in community practice settings and the role of Information Technology

Presenter: Sharib Khan, Project Coordinator

Organization: Columbia University

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Topics: Practice-based research networks

Other authors: Rita Kukafka, Philip RO Payne, Stephen B. Johnson, J Thomas Bigger

ABSTRACT

Introduction: This pilot study was undertaken as part of the InterTrial Project to understand the clinical research workflow, the role of information technology (IT) in clinical research tasks and to identify barriers and attitudes of key stakeholders (research coordinators and principal investigators) towards increased IT adoption by community practices. The findings have informed the development of a web-based application to increase digitization of research data and processes and to improve clinical research information exchange. In addition, follow up studies are being conducted to develop a detailed workflow process models and a behavioral model to predict IT adoption by end users.

Methods: Six community practices were selected for the study. Each was administered two surveys followed by a semi-structured interview and a two-hour long observation visit. Survey data was analyzed to determine the daily activities performed by research coordinators, the tools they use to complete the activities and their satisfaction with the current systems available to perform those tasks. The coordinator's satisfaction with the current processes was also assessed. The interviews were transcribed and coded using the grounded theory methodology to identify important themes related to unmet needs and IT adoption. Observations were used to provide supplementary data.

Results: Systematic analysis reveals that research coordinators are over burdened with mostly paper-based tasks leading to redundancy and inefficiency. There is a lack of appropriate systems, tools and infrastructure to support clinical research. Considerable individual, site and industry-related barriers will have to be overcome to achieve a vision of connected communities engaged in clinical research.

8. OpenClinica 2.0 - Using Open Source in Clinical Research

Presenter: Cal Collins, CEO

Organization: Akaza Research

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Topics: Multi-center trial infrastructure; Interoperability strategies; Sharing clinical research data; User tools: collecting and storing data

ABSTRACT

As clinical research becomes more informatics intensive organizations are beginning to look towards open source to meet the challenges of flexibility, and interoperability, and cost. In the search for low-cost, adaptable technologies to enhance clinical and translational research, open-source software is being embraced by government, academia, and the private sector to drive and accelerate discovery. Open-source solutions are sustained by developer communities and also by commercial vendors who promote agility and choice while easing concerns about data availability, lock-in, interoperability, and regulatory compliance.

OpenClinica is an open source software (OSS) platform for clinical data capture and trial management. The OpenClinica stakeholder community drives innovation, identifies priorities, and sustains rapid development while keeping the platform at low cost. Commercial backing for the platform provides functions for quality management and regulatory compliance within the framework of ICH Good Clinical Practice (GCP) guidelines and FDA 21 CFR Part 11 regulations on electronic records.

Open Source Software provides an innovative way to address many of the complex challenges of data management, compliance, and interoperability in the modern clinical research environment. OSS developed under a collaborative development model can drive the adoption of standards that can cost-effectively enable interoperability in clinical and translational research, particularly in smaller facilities. The paradigm encourages innovation, risk taking, transparency, and collaboration in development.

In this poster, we look at how current OpenClinica 2.0 development activities are leading to reduced costs and driving innovation in areas such as:
- Automated data exchange with other systems in the healthcare and clinical research enterprises
- Efficiencies in electronic data capture (EDC) using common data element libraries, semantically harmonized domain models and vocabularies, and messaging interfaces
- Improving research management and monitoring
- Integration of research data across distributed heterogeneous data sources.
- Collaborative community development teaming commercial, government, and academic informatics professionals developing on a common open platform
- Enabling fully standards-based clinical trial management operations

9. Secondary Use of Health Data to Support Evidence-Based Study Design

Presenter: Charles Barr, Therapeutic Area Director

Organization: Roche Laboratories Inc

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Topic: Secondary use of clinical data for research

Other authors: Deborah Marshall and William Crown

ABSTRACT

Given the high level of investment in clinical trials, both in terms of time and expense, there has been a movement towards establishing data standards for clinical trials that has been estimated to generate considerable savings to the industry. In a similar manner, the secondary use of health data can assist in the planning and implementation of clinical trials and post-launch economic studies to increase the likelihood of successful study results, which critically affect the future of the drug product.

"Real world" health data have the advantages of large sample sizes and represent a broad range of patients. For example, by applying the proposed inclusion and exclusion criteria of clinical trials to large retrospective databases, one can assess whether there are enough patients with the condition of interest to enable the trial to be conducted, the statistical power to detect differences in clinical and economic outcomes, where the patients are located geographically, and their profiles in terms of medical comorbidities, concomitant medications, demographics, and health care expenditures, expected enrollment rate and appropriate length of follow up, as well as the profile of physician specialties treating the patients. Trials that focus on the collection of health economic data present a number of unique challenges – for example, health care expenditure data tend to be highly skewed, which generally requires that health economic trials be substantially larger than efficacy trials.

This session will describe the kinds of secondary health data available and how these data can be applied to expedite and enhance the planning and design of clinical and health economic research trials through simulation models. We will then discuss metrics for evaluating the impact of these data on key business processes and outcomes. Finally, we will build a business case study evaluating the potential ROI for evidence-based design of clinical and health economic research with secondary use of health data.

10. A Contact Registry for Persons with Rare Diseases: A Tool for Recruiting and Retaining

Presenter: Rachel Richesson, Assistant Professor

Organization: University of South Florida

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Topic: Recruitment for clinical research

Other authors: Ken Young, Jamie Malloy, Heather Guillette, Jeffrey Krischer

ABSTRACT

a) Objective: The Rare Disease Clinical Research Network (RDCRN) consists of 10 clinical research consortia and a central Data and Technology Coordinating Center (DTCC). The RDCRN supports many studies in diverse and rare diseases, and tools and methods that enhance recruitment and retention are particularly valuable in this network.

b) Methods: The DTCC maintains a registry of patients who self-identify with a particular diagnosis and express a willingness to be contacted by the RDCRN to enroll in clinical studies. The registry is compliant with the Health Insurance Portability and Accountability Act (HIPAA). To protect the privacy of those in the registry, identifying information is not shared with individual investigators. Rather, RDCRN investigators use the DTCC as a vehicle to push information to potential research subjects on disease treatment updates and upcoming trials.

c) Results: As of October 2006, over 2,700 individuals representing over 40 different rare diseases were enrolled in the RDCRN Contact Registry. This high number of rare disease registrants is impressive considering that the network is new, opened first research protocols to enrollment in March 2006, and has undertaken no formal marketing. Most of the registry enrollees to date joined via the Internet, although in February 2006 the RDCRN Contact Registry began allowing individuals to enroll by mail or by telephone. These individuals overwhelmingly prefer to be contacted about future studies via email (68%) versus mail (15%) or telephone (15%). This poster and demonstration will outline strategies for maintaining valid contact information and for sustaining the interest of those enrolled. Updated data on the number and characteristics of individuals registered will be presented.

d) Conclusions: The Contact Registry offers a means to accumulate potential study participants and has the potential to increase participation in RDCRN studies.

11. An Infrastructure for Conducting Clinical Trials in Primary Care

Presenter: Stuart Speedie, Professor

Organization: University of Minnesota

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Topics: Clinical trial protocol authoring and management tools, Multi-center trial infrastructure, Practice-based research networks, Interoperability strategies, Recruitment for clinical research, User tools: collecting and storing data

Other authors: Theodoros N. Arvanitis, Kevin A. Peterson, Brendan Delaney, Ida Sims

ABSTRACT

The electronic Primary Care Research Network (ePCRN) is an NIH Roadmap funded project designed to explore the feasibility of conducting clinical trials in the community – specifically in primary care settings. It is a collaboration of investigators from the University of Minnesota, University of Birmingham (UK), University of California, San Francisco and 12 primary care research networks across the US. These research networks consist of groups of primary care practices that have administratively organized for the purpose of conducting research studies. The ePCRN electronically links a variety of primary care practices from these research networks and facilitates secure communication with those practices. Therefore, such communication protects the privacy and confidentiality of the patient. In its present physical form, the system consists of a highly secure Citrix computing environment that requires the combined use of an RSA-based token and password for access. The ePCRN consists of three primary components: a trialist's workbench for designing clinical trials, a clinical trials management system for conducting and managing clinical research studies and a translation system of research into practice component. The workbench allows an investigator to formulate and test eligibility criteria for feasibility by anonymously identifying the numbers of eligible patients within the practices that are members of the network. It facilitates simulation of various research designs through a similar mechanism. Once a design is finalized and approved, the same system can be used to notify the practices that specific patients are eligible for the study and should be targeted for recruitment. After a patient has been recruited and met eligibility criteria, they are enrolled in the clinical trials management system (CTMS) and proceed through the planned study under the supervision of that system. One simple trial with 100 participating physicians has been successfully conducted to test the feasibility of the system. The ePCRN project will provide the necessary infrastructure to meet the NIH Roadmap goal of expanding and extending the conduct of clinical trials into community settings, by promoting and facilitating the use of primary care research networks for that purpose.

12. Using Ontology Reasoning to Match Electronic Patient Records to Clinical Trials

Presenter: Chintan Patel, PhD Student, Department of Biomedical Informatics

Organization: Columbia University

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Topics: Recruitment for clinical research, Secondary use of clinical data for research

Other authors: James Cimino (Columbia University), Aaron Kershenbaum (IBM Research), Edith Schonberg (IBM Research), Kavitha Srinivas(IBM Research)

ABSTRACT

Objective: There is a wide gap between the clinical information that gets stored in clinical data repositories and the specification of eligibility criteria in clinical trials. In our research, we are exploring the ways to minimize the gap by using formal ontologies (SNOMED-CT, MED) and semantic reasoning to find relevant patients.

Methods: We started by mapping the local hospital terminology, Medical Entities Dictionary(MED) [1], to SNOMED-CT and representing clinical data (lab, pharmacy and radiology) using the Web Ontology Language (OWL). Next, we developed a semi-automated graphical tool that parsed the eligibility criteria from clinicaltrials.gov and allowed representation of the criteria as formal ontology-based queries (with exclusion criteria modeled as negations). We have developed an OWL ontology reasoner [2] capable of handling large-scale ontologies in secondary storage. The reasoner was used to retrieve semantically matching patients for given clinical trial queries.

Several other intermediate steps were also needed to realize the ontology-based querying infrastructure such as calculating minimal closure of ontologies, modeling inference rules and natural language processing of trial criteria.

Results: We mapped 16,807 (16.7%) of concepts from MED to SNOMED-CT. In our experiment over limited sample size, we were able to query for concepts not explicitly present in the patient data, for example, "pneumococcal pneumonia" inferred from positive lab results for "streptococcus pneumoniae" (SNOMED-CT). We are also able to represent concise queries without exhaustive listing of all possible cases, for example, find patients on "warfarin containing drugs". Several other inferences pertaining to anatomical site, clinical procedures, etc were also performed.

Conclusion: The extensive knowledge encoded in clinical ontologies provides a promising solution to screen patient records in clinical databases matching given protocol criteria. Further work is needed in handling scalability issues and automating query formulation.

References

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2. Fokoue A, Kershenbaum A, Ma L, Schonberg E, Srinivas K. The Summary Graph: Cutting Ontologies Down to Size. International Semantic Web Conference 2006:in press.

13. A Web Database Facilitating Quality Improvement of Inpatient Glycemic Control

Presenter: Prem Thomas, Post-doctoral fellow

Organization: Yale Center for Medical Informatics

Contact: prem.thomas@yale.edu, phone: 203-737-6079

Topics: User tools: collecting and storing data; Secondary use of clinical data for research

ABSTRACT

Recent studies have shown that strict control of hyperglycemia in critically ill inpatients lowers morbidity and mortality. Though these findings stimulated interest in improving management, no standard measure of inpatient glycemic control exists. We developed and proposed candidate metrics, but their calculation involves manipulation and analysis of large glucose datasets. To decrease this barrier to adoption and use by other institutions, we developed a web application that takes de-identified, uploaded glucose data, calculates metrics, and returns a report. To facilitate quality improvement research the application stores the glucoses and metrics in a database for later aggregation and analysis. Through tools for collaboration, discussion, and feedback, it also encourages consensus development on the clinical validity of the metrics. Issues relevant to secondary use of health data included de-identification and formatting of data and the establishment of trust for sharing performance data from multiple institutions. We will demonstrate the application.

14. Automated Sharing of Workflows

Presenter: Amar Chahal, VP

Organization: Velos Inc.

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Topics: Clinical trial protocol authoring and management tools; Multi-center trial infrastructure; Interoperability strategies

ABSTRACT

Protocol specific workflows create great complexity in sites and centers running dozens of protocols for different sponsors. They are often a cause of confusion and non-compliance.

Velos Inc. in its current release of its research and data management system—Velos eResearch, allows the sharing of workflows to other instances of Velos eResearch, allowing local workflows to be co-mingled with sponsor workflows, and ensuring integrity of metadata across instances.

With this kind of approach large networks can interoperate without sacrificing independence, and research workflows specific to protocols can be instantiated at appropriate sites with appropriate controls in place. Local system administrators may further modify and localize such workflows, or may keep them "as is" for specific protocols.

The workflow environment includes messaging and the automation of data handling to central repositories. Teams at Velos Inc. manage the special utilities that broker these specific environments, and ensure configuration and metadata compatibility, synchronicity, and propagation.

This unique perspective allows a blending of multi-site, multi-sponsor, multi-dictionary, and multi-process management at a local level, with a network of equals at some levels, and sponsor or lead-center dictated management at others.

Future efforts include the complete automation of the brokering system without interventions by system administrators.

15. The PEN is Mightier Than the Sword: Applications of Consumer Health Informatics to Patients with Autoimmune Diseases

Presenter: Gale A. McCarty, President

Organization: Rheum.Ed Consulting

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Topics: Sharing clinical research data; User tools: collecting and storing data; Secondary use of clinical data for research

Other authors: Thomas E. Cason (Clinical Data Manager, School of Medicine, Dept of Neurosurgery, VCU)

ABSTRACT

Context: 86% of patients use the internet to search for medical information. Technology to enhance medical information exchange in the patient-doctor-computer triangle remains underutilized. Patients with systemic lupus erythematosus (SLE) and/or antiphospholipid antibody syndrome (APS) seek and require info exchange for empowerment in their care.

Objective: Creation, implementation, and assessment of a platform-independent personal health record (PHR) on a portable USB drive for patients with systemic lupus erythematosus (SLE) and/or antiphospholipid antibody syndrome (APS).

Design, Setting, and Participants: Selected components of a validated point-of-entry web-hosted clinical and research electronic health record (EHR) designed and validated by the Authors in a University-based academic rheumatology clinic setting (Arthritis Rheum 48(9): S459, 1149, '03) were redesigned using Ruby on Rails v1.1.6. for use in a new academic setting. To empower patients as engaged in their own health care and continuing self/family education, the PHRs on USB drives were named LUPEN (LUpus Patient Empowerment Network) and ASPEN (Antiphospholipid Antibody Syndrome Patient Empowerment Network). Patient Demographics, ICD9/10 Diagnosis Codes, Medications, Allergies, Pertinent Past History, Family History, and SF36 comprised textual elements. Graphical elements included basic lab study summaries, autoantibody tests, Sapporo '98 and modified Sapporo '06 criteria-associated and non-criteria associated APS features, representative PACS images of central nervous system MRI, cardiac echo report, and renal biopsy. Patient educational elements on SLE, APS, aspirin/hydroxychloroquine or anticoagulant medications, and a Coumadin Regulation Booklet, were gone over at the first visit, and provided for post-office visit perusal and family/patient advocate education, as well as URLs to major SLE and APS support groups. Patients are also provided a "parallel chart" (narrative medicine, Ann Intern Med 132(1): 63-8, 2000) in a blog-style format to record other facets of the disease not collected in the standardized form. A Sandisk USB drive (256MB) with ergonomic design for easy use by SLE and APS patients was selected. LUPEN and ASPEN are being introduced in new disease-specific University academic rheumatology clinics as a pilot for quality improvement using EHR and PHR.

Main Outcome Measures: Use of the USB key for self- or family-member education, retention of information on basic educational modules by participating patients vs. non-participating patients given text will be randomized 2:1, and ergonomic satisfaction assessed by a survey questionnaire between visits using chi-square. At least 20 patients will have analyzable data at Expo time.

Results: The database built using SQLite3 (www.sqlite.org) was the foundation of building ASPEN/LUPEN. Ruby-on-Rails generated the basic framework and functionality in a matter of minutes. Full design was accomplished in days. All pages are XHTML, CSS, Section 508, and W3C-WAI AA compliant. The Mozilla Firefox browser is provided (v2.0,www.portableapps.com/apps/internet/firefox_portable).The drive is built such that data leaves no trace, or any "registry dust", which ensures complete privacy.

Conclusions: Empowerment of patients with SLE and/or APS in their own healthcare and self/family education is expected to be documented by statistically significant retention of information and use frequency over control patients in this pilot project.