

**Clinical Trial Network Infrastructure &
Collaborative Technology
InterTrial**

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Re-engineering clinical research in community practice

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BRIEFING BOOK SUMMARY

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A. PROGRAM SUMMARY

The InterTrial project consists of three major steps: modeling how clinical research is conducted in community practices, developing software to meet perceived needs, and studying the impact of this software.

1. BEHAVIORAL MODELING

This research draws on a theoretical framework by Kukafka et al. that informs the implementation of complex systems through consideration of behavioral factors at multiple levels: individual, group and organization. At this stage, we have gathered two year's worth of data on clinical research workflow using surveys, structured interviews, focus groups and direct field observation. We have published two conference proceedings on this work, and are now working on journal articles that analyze the data in terms of the framework.

2. COLLABORATION SOFTWARE

In parallel, we have been working on software to support collaboration in clinical research networks called WorkWeb. The design of this system is informed by our studies of clinical research workflow and the translation of these observations into user needs that can be met by information systems. The WorkWeb is built on a wiki engine, which allows web pages to be edited directly by the users of the system, facilitating collaborative knowledge sharing. Separate WorkWebs are created for different collaborations (projects, publications, discussions, etc.), allowing access only by designated participants. Some of the most recent developments in the WorkWeb include the following components:

- **Creation of a Stakeholder Database** – WorkWeb maintains a database of users, organizations and collaborations. User information includes contact information, job titles, educational qualifications, organizational relationships, research interests, grants and publications. The WorkWeb makes this information visible to all users and updateable by the individual user (with appropriate access). For example, user information is maintained in online personal profiles, which fosters a sense of ownership and involvement. The database of users profile can be searched online by other users to facilitate both intra and inter organizational collaborations (e.g. to obtain expert assistance, find services or co-author papers).
- **Discussion Forums** – Users can embed a discussion forum in any WorkWeb topic, enabling users to participate in an online discussion that evolves overtime. The discussion is maintained in a hierarchical (threaded) form as users respond to each other. Users may choose to subscribe to a discussion forum, which then provides them emails about the latest postings.
- **Email Integration** – The stakeholder database keeps track of email contact information for users and groups (collaborations). WorkWeb can both send and receive email messages, which can then be integrated into online discussion forums. For example, when a user posts a message in an online

discussion forum, an update is automatically emailed to all participants who are part of that group (such notification is optional). A user receiving this message can respond by email, and the response will appear in the corresponding forum thread as though they had posted the same message online. In addition, this mechanism can be used to send announcements and communications to specific groups of users, or to send surveys to targeted populations.

- **Interoperability** – WorkWeb can serve as a launching point into other related applications. A key feature is to enable a user who has logged into one system to access another without further login. At present, clinical coordinators can access STEPS (Services Tracking and Expedited Payment System).

3. SOFTWARE IMPACT

We are slowly introducing WorkWeb into settings in community practices and in the academic medical center at Columbia University. For both settings, we have designed a new feature intended to facilitate access to study document for all personnel working on a particular protocol – investigators, coordinators and administrators. WorkWeb allows every study to be a separate collaboration that is accessible to only those who are part of the study. Each study in WorkWeb will have a documents page with links to major categories of documents relevant to that study: protocol (original, amendments, consent forms), safety reports and data monitoring board reports. We have created a prototype set of documents for a single clinical trial. This will serve as a model for other studies to imitate.

In the community setting, coordinators can access the financial tracking system (STEPS) through WorkWeb for viewing, and in some cases, data entry. An important function of STEPS is to furnish an event driven calendar for every protocol. STEPS will be augmented with modules to add new protocols and amendments to existing protocols. This functionality, coupled with document management in WorkWeb, will enable a user to have access to all key document components.

In the hospital setting, we have introduced the use of online forums. These appear to be very popular among coordinators. The main interest is in sharing best practices, comparing strategies to solve various problems encounter, e.g. navigating the complexities of the regulatory process. An important finding is the necessity of a moderator to stimulate activity, respond to postings and keep users engaged. While some forums may take off and have a life of their own, we believe careful cultivation is required in the early stages.

B. BUILDING COLLABORATION FOR CLINICAL RESEARCH NETWORKS

The WorkWeb software has been designed to support research collaboration based on direct observation of workflow. The architecture of the WorkWeb allows collaborations to be started ad hoc between any group of people who share a common interest. The WorkWeb contains multiple webs, each web supporting a collaborative group. Each web

has a set of common tools such as group email lists, group documents, group calendar, discussion forums etc. At present we have built prototype webs for individual trials in a particular research offices, a web for our InterTrial research group and for other departments in the academic medical center.

There are several ways in which the WorkWeb is facilitating collaboration within our research group and for other collaborations that have their own WorkWebs. For example, the InterTrial research team uses the WorkWeb to share common documents, collaboratively author minutes of weekly meetings, share thoughts and notes for the quarterly reports and even our briefing book.

We have begun experimenting with our discussions forums and invited 10 research coordinators from community practices and the medical center to use the forums to discuss issues important to them. We started with a limited number of forum topics and they elicited an enthusiastic response from the users. The forums were particularly useful for the community coordinators who till now had limited access to other coordinators for knowledge sharing and support. We intend to expand the WorkWeb and discussion forums to other sites, at which point the critical mass of users will be able to make the resource particularly useful.

WorkWeb supports detailed user profiles. We are building tools that can match researchers based on their common interests or suggest a likely collaborator when a researcher is looking for a partner for grant writing, technical support (e.g., statistical help) or co-authoring papers.

Our technical team has worked out most of the technically challenging aspects of the wiki engine, and has adapted it for our purposes. However, some challenges remain. Each of these can be represented as a construct in our theoretical model of system implementation (predisposing, enabling or reinforcing factors). For example, this technology is unfamiliar to most users, and we will need to provide adequate training as we roll the system out, particularly with regard to integration into daily clinical research and patient care activities. Some kinds of sharing are natural in the research environment, but many are not. Despite the availability of separate webs and security features, there may be perception of risks in sharing. Forums enable users to communicate in new ways, but also open the possibility to make inappropriate statements. Some community sites have opted out of forum activity, which suggests the need for further study. Adequate monitoring and editing is necessary, but must be carried out in a manner that does not stifle participation. Attention must be paid to organizational structure and authority. Supervisors must be aware of and approve of employees using these tools and contributing their time.

Once some of these social engineering problems have been addressed locally, we can begin to test the tool for collaboration with other institutions. One early foray into this area concerns forming a virtual community to discuss implementation details of a commercial clinical trials management system (Velos) with institutions going through similar experiences. Another important goal is to use the platform to support interactions under the Clinical and Translational Science Award (CTSA). These looser, geographically distributed collaborations will present new challenges for adoption and sustainability.

C. ROADMAP PRESENTATIONS AND PUBLICATIONS

ABSTRACTS:

Khan SA, Florenz M, Kukafka R, Bigger, T, Johnson S. Workweb: Enhancing Collaboration and Communication in Community Based Clinical Research through innovative use of wikis. Proceedings of the MEDINFO. 2007. (Accepted)

Bigger JT, Busacca LV, Florenz MK, Salvik WM, Steinman RC, Johnson SB. Re-engineering Clinical Research: A Scalable Model Integrating Financial Management with Workflow in Community Clinical Research Networks. . IECRN National Leadership Forum. 2006

Khan SA et al. Clinical research workflow in community practices and the role of Information Technology. IECRN national Leadership Forum. 2006.

PUBLICATIONS;

Khan SA, Payne PR, Kukafka R, Johnson S, Bigger T. Modeling Clinical Trials Workflow in Community Practice Settings. Proceedings of the AMIA Fall Symposium. 2006;;419-23

Khan SA, Kukafka R, Payne PR, Johnson S, Bigger T. A day in the life of a clinical research coordinator. Proceedings of the MEDINFO. 2007. (Accepted)