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DIRECTOR'S CORNER

Implementing an Enterprise-Wide Clinical Studies Management System

To speed discoveries from bench to bedside, the NIH has made clinical research a primary objective within the “NIH Roadmap.” Clinical research bridges the divide between conducting basic science research and delivering cutting-edge patient care.¹ At the same time, the legal, regulatory and compliance demands on investigators and research staff who conduct clinical research continue to grow. For Washington University and our affiliated hospitals to advance their position as world leaders in biomedical research and patient care, a world-class, highly integrated and multi-disciplinary clinical studies informational infrastructure becomes a necessity and a priority.

An electronically integrated clinical study information system will enhance our work flow and decrease the manual and often redundant processes required to manage clinical research, to meet the increasing compliance demands, and to anticipate growth in clinical research based on NIH’s new Clinical and Translational Science Award (CTSA) model.

It will, among other things:

- Produce tools and templates for budget and protocol development, study management, financial reconciliation, and data capturing and reporting through electronic case report forms;
- Enhance the use of Good Clinical Practices procedures and other best practices in conducting clinical studies;

¹See announcement of the new NIH Roadmap at: nihroadmap.nih.gov/overview.asp

CONTINUES

- Promote compliance with regulatory authorities, sponsor requirements, and institutional policies;
- Address the unique requirements of clinical trial billing compliance;
- Assist the recruitment and retention of clinical study participants and ensure an appropriate distribution of underserved minority participants.

On Feb. 19, 2007, Washington University School of Medicine (WUSM) entered into a Professional Services Agreement with MDLogix (MDL) to begin work on the "Clinical Studies Management System (CSMS) Implementation Project Start-Up Program." The start-up program begins with a period of requirements gathering so that we can better understand the capabilities of the core MDL CRMS product set as developed at Johns Hopkins University, and to enable us to gain a full understanding of the functionality required by our users who will make use of our CSMS.

A unique aspect of this engagement is that this is a joint development effort with The John Hopkins University. JHU also engaged MDL, and together our two institutions

will co-develop the Clinical Studies Management System. The core modules in MDL's Clinical Studies Management System product framework include:

- Participant Registration Module: will track participant activities through the entire span of the protocols
- Protocol Schema Builder Module: will set procedures in a study grid and participant-specific calendar to allow users to schedule time and resources for procedures and to facilitate appropriate billing through the integration with the Financial Module
- Financial Module: for building budgets, capturing cost information, invoicing sponsors and ensuring billing compliance
- Participant Recruitment Module: will have a web-based portal and an internally developed database to facilitate the recruitment of participants
- Data Capture/Forms Builder Module: will have electronic case report forms that are 21 CFR Part 11 compliant.

For questions about this article please contact Jim Moran, Assistant Dean Clinical Trials for WUSM at moranj@wustl.edu or 362-6864.

ADMINISTRATION

Payments from Clinical Trial Sponsors

The Center for Clinical Studies has made some changes in our check depositing procedures. These changes will enable us to expedite services for the University. To maintain accurate records for the departments, the CCS is now providing copies and back-up of checks to the PIs, business managers, and other interested parties in check notification e-mails.

Here is a summary of the check deposit procedures at the CCS. Please use this information as an update to your current billing actions.

- Checks received by noon are deposited that business day.
- Checks are received by CCS via mail or from employees in various departments.
- Checks are stamped with the date and endorsed for deposit by the receptionist at the time of receipt.
- Checks and back-ups are then scanned and copied onto the hard drive.

- Checks are entered into the check log database and deposited.

A quick reminder to all billing personnel for departments: Please include the protocol number as a reference on the return address on all invoices. This allows us to accelerate our check depositing procedures.

We are eager to see these changes in place, and we welcome any feedback about our check depositing procedures at the CCS. If you have any questions we are always willing to help. You may contact Divine Hartwell, the Financial Accounting Assistant, with any questions or concerns at 747-0006.