Clinical Trial Management System (CTMS)
Enterprise OnCore®

WHAT IS IT?
OnCore is a comprehensive web-based Clinical Trial Management System (CTMS) that offers clinical-trial lifecycle management, study participant and safety management, sponsor billing compliance, study budget management, and electronic data capture and reporting through its core module.

OnCore also allows for biospecimen management, patient registries, and integration with other enterprise-wide systems.

WHAT ARE THE BENEFITS OF A CTMS?
• Consistently capture and track protocol, study, administrative, and financial data needed for management of trials
• Added transparency between study and finance teams to track study activities and payment
• Reduce multiple isolated, informal environments for managing and tracking study data
• Eliminate redundant/multiple software infrastructures
• Reduce costs to manage clinical research within individual units
• Increase the capability to provide meaningful reports and data regarding the financial status of a study to Principal Investigators
• Improve regulatory compliance
• Central repository for study-related information (budgeting, patient tracking, care reports) and a catalogue for materials stored in biorepositories

WHO BENEFITS FROM A CTMS?
Researchers
• A Principal Investigator Console displays information pertinent to PIs, including accrual and protocol status
• Access to reports on accrual, financial status, subject safety and more
• Review and capture subject safety information consistently across studies
• Secures research data and allows audit logging of data modifications
• Supports study participant recruitment through a public Web
• Provides integrated biospecimen management for studies with sample collection*
• Stores and provides access to patient registry data*

Research Staff
• Web accessibility to protocol and subject information, including consent forms, visit schedule and electronic case report forms
• Integrations with other enterprise-wide systems lead to reduced duplicate data entry and increased data quality
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- Automated email notifications to support communication and efficient workflows, such as, including IRB expiration alerts, IRB notifications, protocol and subject status
- Provides a calendar view of when your research participants are scheduled for visits
- Access can be limited to approved consent forms
- Additional recruitment capabilities through public display of study information

**Administrative Directors**
- Access to key reports on financials, cycle times, staff workload and other key metrics
- Better understand your clinical trial research portfolio
- Ensure standard procedures are being followed consistently
- Provide the use of a single tool to adhere to a well-defined set of common processes
- Allows trends and opportunities for improvement to be identified through metrics tracking and reporting

**Regulatory Administrators**
- Tracks submissions, communications and actions for various regulatory bodies including scientific review committees, FDA, IRB and data safety monitoring committees
- Generates automated notification alerts prior to IRB expiration
- Generates automated notifications to inform the research team of key status changes as you enter regulatory tracking information

**Finance Staff**
- Links study procedures to a single rate list provided by our primary clinical providers and labs
- Provides financial projections for sponsor billing based on the linked study calendar and negotiated study budget
- Offers an accurate and timely view of what items are ready to be invoiced to a sponsor
- Tracks invoices and receivables

**Public**
- Added support for obtaining research results faster
- Provides a searchable view of accurate and up-to-date open study information by you or your care provider via the Web

*modules not part of initial roll out

**WHAT IS THE CURRENT STATUS OF THE CTMS AT USC?**
The enterprise-wide OnCore implementation is a large and complex project that incorporates clinical research trials conducted at USC and CHLA. The implementation began at the end of 2014 with anticipated roll out beginning Summer 2015. The initial roll out is planned to include industry and non-industry clinical research studies that include a billable services at CHLA, USC, and/or LAC. OnCore is planned to be integrated with iSTAR (IRB system) and Cerner (PowerTrials) electronic health record systems. Additional integrations are being reviewed, such as, KF and KFS. Studies utilizing OnCore will be exempt from tracking in True II, True, and Iris.
As we write, we are building the bridges between our enterprise registration systems and OnCore so that study coordinators will have an easier time selecting patients who are already patients of Keck Medicine of USC and CHLA. Once this phase is complete, we will be setting the more definitive dates for our two pilot studies (in the July -August timeframe). The purpose of our pilots is to maximize our understanding of optimal workflows using the new system and to ensure readiness for system wide deployment.

For additional information on implementation, requests to participate in working groups, investigators wishing to pilot and/or general questions, please contact Amanda Schmitz Schmitza@usc.edu (323) 442-4047.

Project Liaisons
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