Frequently Asked Questions (FAQ)
REV Aug. 2016

Single Enterprise Clinical Trial Management System (CTMS)

1. What is the Clinical and Translational Science Award (CTSA) and how does it relate to the University of Minnesota?

The CTSA program at the National Institutes of Health supports a national consortium of medical research institutions that work together to improve the way clinical and translational research is conducted nationwide to enhance its efficiency and quality. Its goals are to accelerate the process of translating laboratory discoveries into treatments for patients, to engage communities in clinical research efforts, and to train a new generation of clinical and translational researchers. The CTSA award supports the University of Minnesota Clinical and Translational Science Institute (CTSI).

More information is available at The NIH National Center for Advancing Translational Sciences.

2. What is the Clinical and Translational Science Institute (CTSI)?

The Clinical and Translational Science Institute (CTSI) at the University of Minnesota (UMN) is supported through the National Institutes of Health (NIH) Clinical and Translational Science Award (CTSA) program grant 8UL1TR000114-02.

The institute is one of 60 medical research institutions working together to improve the way clinical and translational research is conducted nationwide, enhancing its efficiency and quality.

More information is available at the CTSI website.

3. What is the Single Enterprise Clinical Trial Management System (CTMS)?

Enterprise OnCore, a software product developed by Forte Research Systems, is being deployed as the University of Minnesota single enterprise-level Clinical Trial Management System (CTMS). Enterprise OnCore is a comprehensive Web-based CTMS that offers clinical-trial lifecycle management, study participant and safety management, and electronic data capture and reporting through its core module. Enterprise OnCore also allows for biospecimen management, billing compliance and study budget management, patient registries, and integration with other enterprise-wide systems.

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4. Why are leading academic institutions implementing enterprise-wide clinical trial management systems?

Clinical trial management systems offer a number of benefits for researchers, administrators, staff, and the public. See the [CTMS website](#) for information on the benefits.

5. What are the major accomplishments in implementing the UMN CTMS thus far?

Gain an understanding of the CTMS Objectives and Accomplishments from the [CTMS website](#).

6. Is the Time and Study Collection System (TASCS) going away?

It is a project goal to replace TASCS, and an analysis will be conducted to ensure a transition that is as smooth as possible. Enterprise OnCore is expected to be the tool that replaces most of the TASCS functionality.

Some of the TASCS functionality may move to other existing Enterprise systems to maintain all necessary functionality.

7. Are groups expected to pay a share of the licensing or maintenance cost to use Enterprise OnCore?

No. Enterprise OnCore is viewed as a common-good enterprise system at the University of Minnesota. The Academic Health Center (AHC)/CTSI do not intend to establish a fee structure for use of Enterprise OnCore. Similarly, the AHC/CTSI do not intend to charge specialties for any share of the license fee, nor to bill departments/units for any share of the annual maintenance cost. These Enterprise OnCore costs are built into the budgets for AHC/CTSI.

8. Is "Enterprise OnCore" different from the "OnCore CTMS" system used by some cancer centers in the United States?

Yes. In addition to providing biospecimen and registry management modules, the core Enterprise OnCore component for clinical-trial management was enhanced by the vendor beyond what was developed for cancer centers to allow each specialty to have a uniquely configured "library" and its own workflows. This enhancement allows multiple specialties to utilize the same system across the institution.

9. Once data go into Enterprise OnCore, can they be extracted? If so, how?

Yes. Data needed for analysis can be exported from the Biostat Console in SAS or Excel formats. Researchers can use standard reports that exist within Enterprise OnCore, or can use its search tool for ad-hoc reporting. Searches can be saved and rerun quickly at the click of a button. Custom reports can be developed by a UMN IT team and placed within Enterprise OnCore for use by researchers. Data can be extracted directly from the back-end database by UMN IT staff.

More Information
CTMS website
E-mail oncore@umn.edu with general Enterprise OnCore questions or support needs

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