OnCore

CLINICAL TRIAL MANAGEMENT SYSTEM (CTMS)

Frequently Asked Questions

1. **What is OnCore?**
   OnCore is a software product developed by Forte Research Systems and is being deployed as the UAB enterprise-wide Clinical Trial Management System (CTMS). 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. OnCore also allows for billing compliance and study budget management as well as integration with other enterprise-wide systems such as IRAP or Greenphire.

2. **Why is UAB implementing OnCore?**
   For the past 12 years, UAB has used SiteMinder to manage its studies with clinical billables. While this system has served us well, it is no longer supported by its developer (Oracle). The implementation of OnCore across the institution will enable us not only manage our clinical billables within studies, but also to manage other important components of clinical trials including participant visits and study financials.

3. **Is OnCore currently being used at UAB?**
   Yes. OnCore was first introduced at UAB in 2010 when it was implemented at the Comprehensive Cancer Center (CCC). The system has been in use within the Center for Clinical & Translational Science (CCTS) in 2014 to help manage the clinical services they provide.

4. **What does Enterprise OnCore mean?**
   Enterprise OnCore refers to the expanded installation of OnCore across all disease groupings. OnCore was originally developed for cancer centers in 2000, and as people recognized the value in using the system for other kinds of trials, additional functions were added to better fit the needs of non-cancer trials. OnCore is now used in 31 academic medical centers and 13 health care systems in addition to 49 cancer centers across the US.

5. **Can data be extracted from OnCore?**
   Yes. Research administrative data needed for analysis can be exported in SAS or Excel formats. Researchers can use standard reports that exist within OnCore, and they can use its search tool for ad-hoc reporting. Searches can be saved and rerun quickly. Custom reports can be developed by the OnCore Report Writer, Nicky Welch (nwelch@uab.edu), and saved within the system for use. Data can be extracted directly from the back-end database by the OnCore Technical Administrator.

6. What studies are required to go into OnCore?
   Currently, all studies that were previously managed in SiteMinder are expected to be entered into OnCore. Unlike SiteMinder, however, activities in addition to the clinical billables, will also be built into the protocol calendar so that staff will be able to see all activities associated with participant visits and not simply billables related to CTBN creation.

7. Can trials be entered that do not have billables?
   Trials without clinical billables may not be entered into OnCore at this time as that is outside the scope of the initial implementation. These trials will be addressed in the future.

8. Will studies still be available in SiteMinder after implementation?
   Yes. Studies with an expected end date within 6 months of a Department's go-live will not be migrated into OnCore and will continue to be managed in SiteMinder until the study's completion.

9. What fields are required to be entered into OnCore?
   There are several fields that are required due to either system or institutional requirements. Contact OnCore Support at OnCore@uabmc.edu for a list.

10. What is the timeline for OnCore implementation?
    OnCore will be implemented across the School of Medicine in 3 Waves. The 11 Divisions within the Department of Medicine will go live in December 2017 and January 2018. The other 26 Departments will be implemented in April and September 2018. The additional Schools and Colleges with applicable clinical trials activities at UAB will be implemented after 2018.

11. Are there any core functions of OnCore that are currently not available for expanded use?
    Yes. Currently we are not planning to enable the use of Registries or Biospecimen Management by the institution at large.

12. Can I access OnCore from clinic?
    Yes. OnCore is available from anywhere with an internet connection. An RSA token is required for off-campus access.

13. What is the maximum upload size of a document into OnCore?
    25 MB

14. How long does one have before the system automatically logs off due to inactivity?
    15 minutes

15. How many failed log-in attempts is one allowed before the system locks a person out?
    3 times. If you are locked out of the system, please contact HSIS Help Desk: 205.934.8888

16. What is the difference between a 'Department' and a 'Management Group'?
    A 'Department' defines the financial reporting area. We have aligned OnCore 'Departments' with our institutional Departments within the School of Medicine such as Neurology, Medicine, Psychiatry, Surgery, etc. A 'Management Group' represents the team responsible for the study. Examples of 'Management Groups' include Endocrinology, Cardiology, and Nephrology Transplant. Every protocol in OnCore is associated with one 'Department' and one or more 'Management Group'.

17. Can there be more than one Principal Investigator associated with a study in OnCore?
    No. There cannot be more than one PI listed for a protocol. There may, however, be more than one sub-investigator listed.

18. Given the presence of the Coverage Analysis console in OnCore, how does this change the submission process with Clinical Billing Review (CBR)?
    The billing plan tab will no longer be completed in the CBR Submission Workbook. Sites will be required to have the protocol calendar (including the billing designations) built within OnCore prior to submission to CBR for review.

19. Will UAB discontinue the use of REDCap because of the implementation of OnCore?
    No. REDCap, which is a browser-based, metadata-driven Electronic Data Capture (EDC) software solution for designing clinical and translational research databases, has many applications in research and will continue to be available.

20. Who do I contact for customer support?
    HSIS Help Desk: 205-934-8888. You may also reach out to the SuperUser in your area.

21. Will there be a cost associated with using OnCore?
    Yes. A line item direct cost is the emerging standard to be incorporated into study budgets. This is part of a larger effort to better manage the financial performance of clinical trials.

PowerTrials

CLINICAL RESEARCH MODULE

Frequently Asked Questions

22. What is PowerTrials?

PowerTrials integrates research processes into the workflow of Cerner's electronic health record (IMPACT), ensuring that clinical research and clinical care share relevant data. Its primary goals are as follows:

i. Enhance patient safety - PowerTrials is embedded in the EHR, thus all clinicians have awareness of their patients' research participation via an "on study" flag.
ii. Streamline research processes - PowerTrials integrates with core EHR features so you can ensure accurate and efficient research visits.

23. What are PowerPlans?

PowerPlans are a group of specific orders. With PowerPlans, researchers have the ability to group orders into a multi-tiered plan of care. By having study-specific PowerPlans, researchers can use IMPACT to drive the procedures and assessments for each study visit. Researchers also can link the PowerPlan to study enrollment status to limit the use of the plan to those enrolled on the study. Finally, using the PowerPlan research account feature, your research site can delineate research charges from standard of care.

24. How do OnCore and PowerTrials relate?

Study creation begins in OnCore, our clinical trials management system. Once the information is in OnCore, the clinical trial data is sent to the PowerTrials PowerPlan team. Once the trial is built as a PowerPlan, participants can be registered; trial information can be made available; and research PowerPlans can be developed. As patients are registered to trials in OnCore, the registration will flow into PowerTrials and their charts will be updated to reflect their participation as well as provide clinicians the research summary.

25. How is PowerTrials currently being utilized?

The Comprehensive Cancer Center (CCC) is beginning to utilize PowerPlans for studies that are open to accrual. Expansion to other departments will begin in 2018, subsequent to the implementation of OnCore in that unit.

26. How can I access study information in IMPACT?

To access the Research Summary in the patient's electronic health record, click 'PowerTrials' on the Menu tab or 'On Study' in the banner bar.