

**UNIVERSITY OF CALIFORNIA, DAVIS
AUDIT AND MANAGEMENT ADVISORY SERVICES**

**UC Davis Health
Clinical Trials Management System
Audit & Management Advisory Services Project #23-13**

January 2024

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**Clinical Trials Management System
AMAS Project #23-13**

Management Summary

Background

As part of the fiscal year (FY) 2023 audit plan, Audit and Management Advisory Services (AMAS) performed an audit of OnCore, a newly implemented clinical trials management system (CTMS).

UC Davis Health (UCDH) began implementation of OnCore during FY 2021 to provide consistent management of all clinical trial operations and to allow for integration with other UCDH systems, such as the Epic electronic medical record. The benefits of a CTMS include having a single resource for protocol details and reviews, data management and monitoring, comprehensive reporting, research team communication, coverage analysis, budgeting, identification of billable services, and invoicing.

Through a multi-phased approach, OnCore is being deployed to all UCDH areas engaged in industry-sponsored clinical trials. As of November 2023, 1,295 individual trials providing services to 20,732 patients have been added to OnCore, with deployment complete for 19 clinical areas and another seven planned for completion by December 31, 2023.

Purpose and Scope:

The purpose of our review was to assess implementation and internal controls over billing functionalities of the CTMS, which may include patient and sponsor billing.

To accomplish these objectives, we reviewed implementation documentation and procedures, and met with UCDH staff in Information Technology (IT) and CTMS Operations responsible for the OnCore deployment. We also reviewed training materials and received a demonstration of the system functionality and invoicing processes. Finally, we met with end users in CTMS Operations and department-based users in the Department of Neurology, the UCDH Eye Center and the UCDH Cancer Center to discuss training, daily utilization, and local practices.

Conclusion:

We express our gratitude to the CTMS stakeholders for their cooperation and assistance throughout the review process. Overall, the OnCore deployment was viewed favorably by participants, with department feedback that the training was appropriate, the CTMS Operations team was supportive, and that OnCore overall saves them time and improves oversight of clinical trials.

AMAS also found that the processes for billing and collecting from sponsors did not consistently employ appropriate segregation of duties, with staff responsible for generating invoices to sponsors also receiving payments from sponsors.

Additionally, we did not observe a process to ensure that all services provided as part of a clinical trial were billed to the sponsor or that all revenue was recorded in the financial system.

A process to develop an accounts receivable functionality was originally included in the deployment of OnCore but was later removed from scope due to migration to a new financial system in January 2024. During this audit we discussed the risks inherent in the existing billing and collection process with the CTMS Operations team, and they agreed that new processes should be developed. The intent is to implement new processes soon after the migration to the new financial system on January 1, 2024. CTMS Operations is coordinating with the School of Medicine (SOM) Dean's Office, Contracts and Grants Accounting (CGA), and departmental end users to develop a workflow that ensures proper separation of duties.

Observation, Recommendation, and Management Corrective Actions**A. The billing and collection process for clinical trial sponsors does not provide proper separation of duties.**

To ensure the integrity of financial information no one person should have complete control over any transaction, and each person's work should be a complementary check on another's work.

The original OnCore project plan included integration of an accounts receivable (AR) function for the management of clinical trial sponsor payments. However, the AR process was removed from the OnCore project scope due to a delay in the implementation of the Oracle financial system. A review into the existing processes for managing sponsor billing and collections identified the following risks:

- Department personnel responsible for generating sponsor invoices in OnCore also receive sponsor payments.
- Individuals within departments responsible for generating invoices can modify invoice numbers, the invoice amount and/or void the invoice. However, there is no process to review voids or changes made to an invoice. Nor can OnCore generate a report of activity that was changed or voided.
- Milestone and other payments not dependent on direct patient care are sent to the department by the sponsor but those events are not consistently invoiced in OnCore.
- There is not a process to confirm all funds expected from a clinical trial are recorded to the general ledger.

During our review CTMS Operations began taking steps to remediate the above risks and met with personnel from the SOM Dean's Office and CGA. Together these groups are developing a "Clinical Trial Invoicing Process Workflow" to resolve separation of duties issues. This process is currently under review with other UCDH and SOM leaders.

Recommendation

CTMS Operations should finalize and implement an invoice processing workflow that ensures proper separation of duties. Additionally, CTMS Operations should develop a process to validate all funds from sponsors are appropriately billed and collected as a method to confirm compliance with the workflow.

Management Corrective Actions

1. CTMS Operations will coordinate with UCDH and SOM leaders to finalize an invoice processing workflow that ensures proper separation of duties by September 30, 2024.
2. CTMS Operations will also develop a process to confirm compliance with the updated workflow by September 30, 2024.