Collaboration via CTMS

Presented by Oscar Cano

Tuesday, July 30

1:00pm-2:00pm

UW Husky Union Building

Room 145

COLLABORATION VIA CTMS

July 30th, 2019

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AGENDA

- What is CTMS?
  - OnCore
  - CTMS Program Office
  - Current and Upcoming OnCore Features
- Activity
- Collaborating on a Clinical Trial - Discussion
- OnCore as a Collaboration Tool
- Debrief
- Q&A

WHAT IS CTMS?

Introduction to CTMS Program Office and OnCore

ONCORE

What is the OnCore CTMS?

- ❑ A Clinical Trials Management System (CTMS) is a data management software that stores clinical trial information.

- ❑ OnCore is the CTMS we use across Fred Hutch, University of Washington and Seattle Cancer Care Alliance.

OnCore

ONCORE

Who has access to OnCore?

- ❑ PI's
- ❑ Research Managers
- ❑ Study/Research Coordinators
- ❑ Data Managers
- ❑ SRC Reviewers
- ❑ Regulatory Coordinators/Managers
- ❑ Directors and VPs
- ❑ Research Scientists
- ❑ Project Managers
- ❑ Research Nurses
- ❑ Administrative Coordinators/Managers

CTMS PROGRAM OFFICE

Cross-Institutional Background

- The Fred Hutchinson/University of Washington Cancer Consortium is a research collaboration comprising Fred Hutch and its strong collaborators: the University of Washington, Seattle Children's, and the Seattle Cancer Care Alliance.
- The Consortium is recognized as an NCI-designated Comprehensive Cancer Center.
- The OnCore CTMS is currently used for all oncology studies in the consortium and for Fred Hutch non-oncology studies.
- The OnCore CTMS will also be used for UW non-oncology studies, which are part of our continuing implementation.

CTMS PROGRAM OFFICE

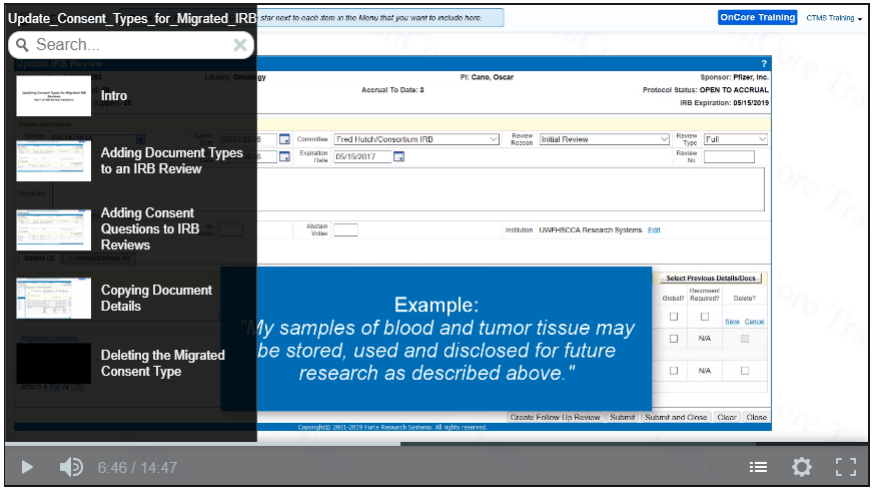
What is the CTMS Program Office?

- The CTMS Program Office is responsible for the implementation and ongoing operation of the CTMS and maintains neutrality across institutions.
- The CTMS Program Office aims to empower study teams to advance clinical research and enable administrators to gain insight on research data through collaboration across our institutions.

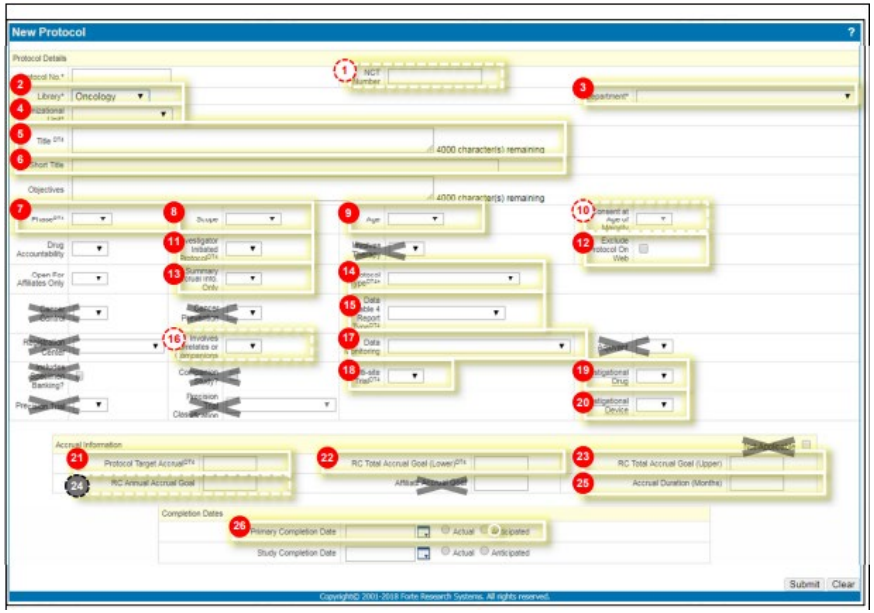
CTMS PROGRAM OFFICE

CTMS Program Office Services

- OnCore Training
  - On-demand, at your desk, video based training
  - In-person group training for ad-hoc topics available on request
- OnCore Support
  - Troubleshooting and live help for OnCore workflows
  - OnCore and access issue resolution



CTMS PROGRAM OFFICE



CTMS Program Office Services

- Quality Control of OnCore data
  - Monitoring of reportable fields for completion
  - Study team notification of missing or incomplete data

ACTIVITY

Build a Structure to Support the Cell

ACTIVITY

Scenario

- ❑ As a team, build the tallest structure possible that will support a 4oz cell toy.
- ❑ Each table is a team.
- ❑ Every person on the team will be assigned a building material.

Materials

- ❑ 10 Marshmallows
- ❑ 10 Pipe Cleaners
- ❑ 10 Building Blocks
- ❑ 10 Building Blocks
- ❑ 10 Poker Cards
- ❑ 10 Strips of Tape
- ❑ 2 Chopsticks
- ❑ 1 Small Tub of Putty

Rules

- ❑ Each person can only use their assigned building material.
- ❑ The building materials can be used and altered as needed, however only the provided materials can be used.
- ❑ Teams do not need to use all materials.
- ❑ A single 4oz cell toy will be floating around if the team would like to test their structure.
- ❑ 10 minute time limit
- ❑ At time, the height of each structure will be measured and the team will place the cell figure on the structure. If the structure doesn't fall, the team stays in. If the structure falls, the team is out. The team with the tallest structure that does not fall, wins.

ACTIVITY

Debrief

- ❑ How did it go?
- ❑ What went wrong?
- ❑ What went well?
- ❑ What would you do differently?

COLLABORATING ON A CLINICAL TRIAL

Discussion

COLLABORATING ON A CLINICAL TRIAL

- What are some common issues you've experienced collaborating within a study team?
  - What about collaborating across teams or with administrative offices?
  - What about across institutions?
- What are some parallels with issues you had collaborating during the activity?
- Recall some of the things that went well during the activity. How can some of those basic concepts be applied to collaboration on a clinical trial?
- What are some resources or tools that you wish you had that would help with collaboration?

ONCORE AS A COLLABORATION TOOL

One Piece of the Toolkit

"It is recognized that well designed trials are the basis for addressing important clinical questions, but science alone will not be sufficient to successfully deliver a trial…Clinical trials all require the same coordinated processes and systems, regardless of the size, scope, costs or duration."

- Farrell B, Kenyon S, Shakur H.
Managing clinical trials

ONCORE AS A COLLABORATION TOOL

The CTMS Program Office aims to empower study teams to advance clinical research and enable administrators to gain insight on research data through collaboration across our institutions.

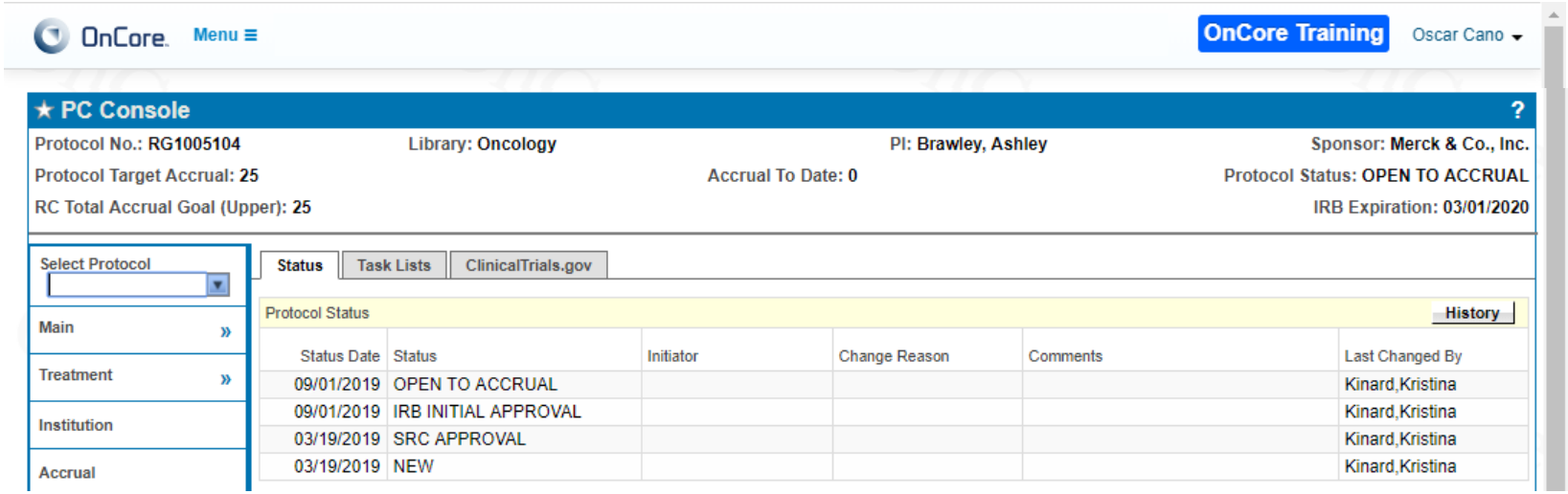
Current Scope:

- ❑ All cancer consortium studies and Fred Hutch non-oncology studies must be entered and managed in OnCore.
  - ❑ Human research studies only
  - ❑ Includes interventional, observational and ancillary/correlative studies

UW non-oncology studies will also use OnCore in the future as part of our continuing implementation.

Protocol Management

- Study details
  - Examples: Title, staff, sponsor, study sites, external protocol numbers
- Study status dates
  - Examples: Open to Accrual date, Closed to Accrual date



Protocol Management

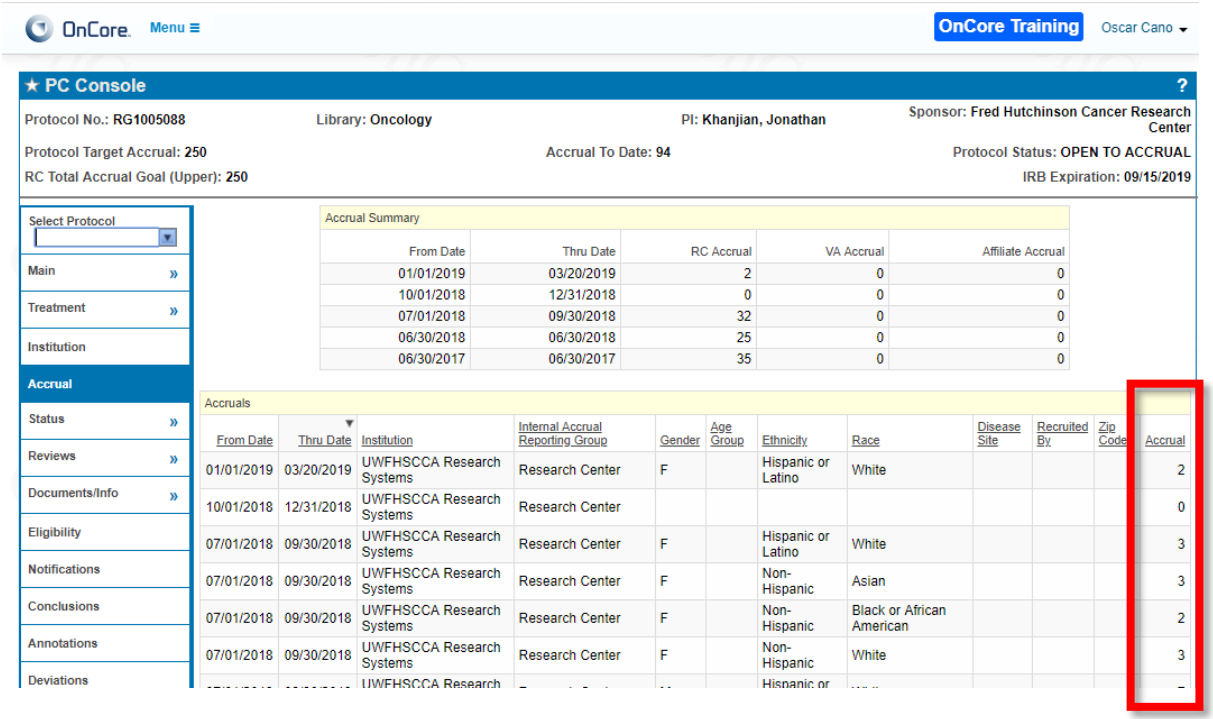
Collaboration Benefits

- Central place to enter, reference and report on high-level study details
  - Example: My team's Regulatory Coordinator enters an IRB Initial Approval in OnCore. This triggers a notification email to staff on that study, which can function as a trigger for additional tasks:
    - The Research manager can then complete the required tasks to Open to Accrual, which will trigger another notification to the team.
    - (Upcoming Feature) The subject coordinator can then go into OnCore and download the approved consent documentation.

DATA MANAGEMENT

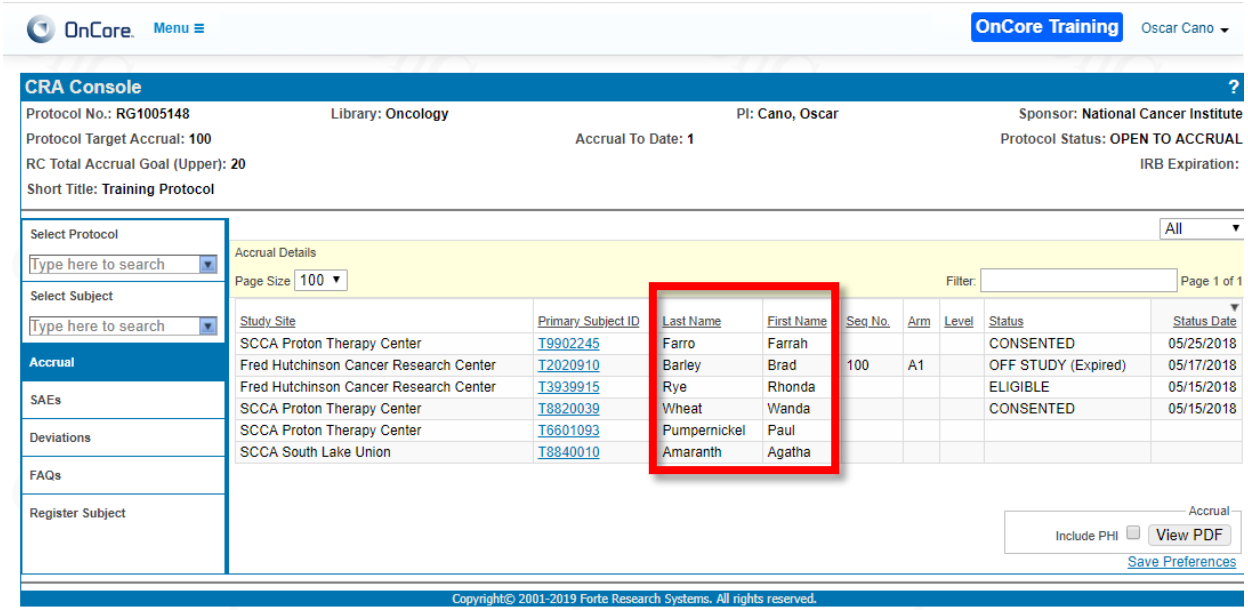
Subject Management

- Ability to record accruals at either:
  - Summary Level
    - Accrual numbers by demographic groups



Subject Management

- Ability to record accruals at either:
  - Summary Level
    - Accrual numbers by demographic groups
  - Granular Level
    - Individual subjects and subject statuses



Subject Management

Collaboration Benefits

- Central place to enter, reference and report on subject details
  - Example: I need to report accrual information for all the studies in my team or for all studies under a certain PI. Since subject milestone dates and statuses were entered as they occurred by various team members:
    - If I need subject level details, I can run a Subject Search out of OnCore and include/exclude which ever data points I need (Demographics, Study Site, Consent Date, On Study Date, Status, etc.). I can also filter by a certain field, such as only including Screen Failures.
    - If I just need an accrual number, I can run a Protocol Search out of OnCore and include Accrual numbers. This will allow me to choose what study details I want to include in addition to Accrual number (Title, IRB #, Study Sites, Protocol Status, etc.).

EPIC INTEGRATION

OnCore is integrated with our Electronic Medical Record (EMR) system, Epic.

- ❑ We receive subject demographic information from Epic
  - ❑ Epic is the source of truth for patient/subject demographics
- ❑ We send study data back to Epic
  - ❑ Protocol #, NCT #, Staff, etc.
- ❑ We also send subject data back to Epic
  - ❑ Protocol # subject is registered to, Subject Status, “Active Start/Stop Dates”, etc.

EPIC INTEGRATION

Collaboration Benefits

- Data entry occurs in the most appropriate system and is automatically updated in the other
  - Example: My study has billing implications that are driven out of Epic but I also need to maintain accruals and study details in OnCore.
    - I can search the EMR to register my subject directly through OnCore. If the subjects demographics are updated in Epic, that information will always flow back to OnCore without me taking any action (name or address change). If the subject expires, that date will automatically flow to OnCore and change the subject status.
    - The protocol details I enter in OnCore will transfer to Epic, including PI and Staff details.
    - This will trigger administrative offices to complete relevant billing tasks in Epic.
    - The Billing Contact I entered in OnCore will be visible in Epic so they can be sent the monthly study invoice.

DATA ACCESSIBILITY AND TRANSPARENCY

OnCore is a centralized tool which is accessible to clinical trial staff and administrative staff across teams and institutions.

- Information entered in OnCore can be viewed by approved staff directly in OnCore or automatically delivered via email report.
  - In general, your data is only viewable by your team and select administrative teams. Your approval is required if an outside study team member needs access to your studies.
- Administrative teams have updated their processes to get data from OnCore instead of via reach out to study teams, where possible.
- The CTMS Program Office proactively reaches out to teams when reportable fields are missing or incomplete.
  - Multiple cross-institutional teams collaborated and agreed on required data points. The CTMS Program Office is continuously working to streamline study team reach out and catch data gaps before they become an issue.

DATA ACCESSIBILITY AND TRANSPARENCY

Collaboration Benefits

- ❑ Where possible, OnCore and the CTMS Program Office act as a link between study teams, administrative offices and data consumers.

UPCOMING ONCORE FEATURES

Upcoming Features

- ❑ Subject calendars
  - ❑ When will a subject be seen, what will be done during each visit, what data will be recorded?
- ❑ Subject visit tracking
  - ❑ Record of what was actually done during a specific visit
- ❑ Financials functionality
  - ❑ Examples: Sponsor invoicing, coverage analysis, study budgeting
- ❑ Store and download most recent IRB reviewed documentation

DEBRIEF

- OnCore is the clinical trial management system (CTMS) we use across Fred Hutch, University of Washington and Seattle Cancer Care Alliance.
- The CTMS Program Office is responsible for the implementation and ongoing operation of the CTMS and maintains neutrality across institutions.
  - Responsible for OnCore training, support and data QC.
- Collaborating on a complex project is difficult
  - See: The tower activity and running a clinical trial
- Where possible, OnCore and the CTMS Program Office act as a link between study teams, administrative offices and data consumers in order to address some of the challenges presented when collaborating on a study.

For more information contact

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