



Collaboration via CTMS

Presented by Oscar Cano

Tuesday, July 30

1:00pm-2:00pm

UW Husky Union Building

Room 145



Institute of **Translational** Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

COLLABORATION VIA CTMS

July 30th, 2019



Oscar Cano

CTMS Product Manager

ocano@fredhutch.org

CTMS Program Office

CTMS_Office@fredhutch.org

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

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.



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?

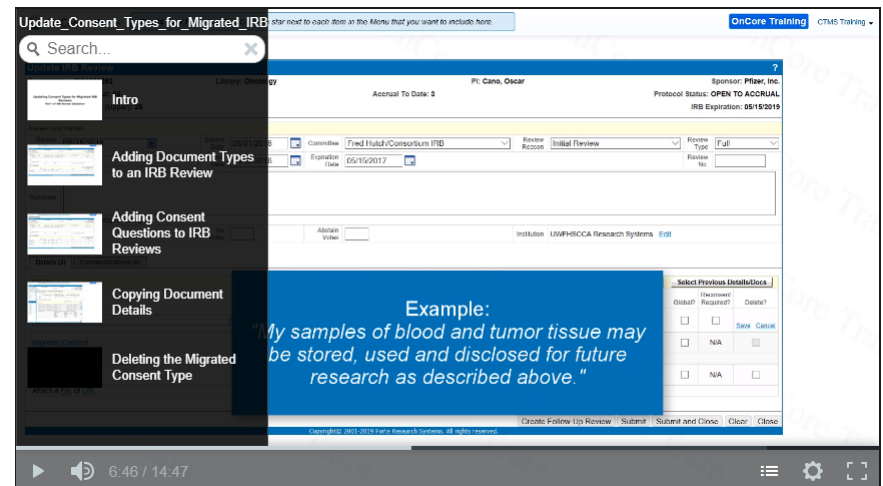
- The CTMS Program Office is responsible for the implementation and ongoing operation of the CTMS and maintains neutrality across institutions.
- The CTMS Program Office aims to empower study teams to advance clinical research and enable administrators to gain insight on research data through collaboration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

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

The screenshot displays the 'New Protocol' form in the CTMS system. It is divided into several sections: 'Protocol Details', 'Objectives', 'Accrual Information', and 'Completion Dates'. Numbered callouts (1-26) point to specific fields and sections across the form, indicating areas of interest for quality control and monitoring. The form includes dropdown menus, text input fields, and checkboxes. Some fields are marked with a red 'X' icon, possibly indicating required or critical data points. The bottom of the form has 'Submit' and 'Clear' buttons.

ACTIVITY

Build a Structure to Support the Cell

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.

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

OnCore Menu

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★ PC Console ?

Protocol No.: RG1005104

Library: Oncology

PI: Brawley, Ashley

Sponsor: Merck & Co., Inc.

Protocol Target Accrual: 25

Accrual To Date: 0

Protocol Status: OPEN TO ACCRUAL

RC Total Accrual Goal (Upper): 25

IRB Expiration: 03/01/2020

Select Protocol

Main »

Treatment »

Institution

Accrual

Status Task Lists ClinicalTrials.gov

Protocol Status History

Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
09/01/2019	OPEN TO ACCRUAL				Kinard,Kristina
09/01/2019	IRB INITIAL APPROVAL				Kinard,Kristina
03/19/2019	SRC APPROVAL				Kinard,Kristina
03/19/2019	NEW				Kinard,Kristina

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.

Subject Management

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

OnCore. Menu

OnCore TrainingOscar Cano

★ PC Console?

Protocol No.: RG1005088Library: OncologyPI: Khanjian, JonathanSponsor: Fred Hutchinson Cancer Research Center

Protocol Target Accrual: 250Accrual To Date: 94Protocol Status: OPEN TO ACCRUAL

RC Total Accrual Goal (Upper): 250IRB Expiration: 09/15/2019

Select Protocol

Main»

Treatment»

Institution»

Accrual

Status»

Reviews»

Documents/Info»

Eligibility

Notifications

Conclusions

Annotations

Deviations

Accrual Summary

From Date	Thru Date	RC Accrual	VA Accrual	Affiliate Accrual
01/01/2019	03/20/2019	2	0	0
10/01/2018	12/31/2018	0	0	0
07/01/2018	09/30/2018	32	0	0
06/30/2018	06/30/2018	25	0	0
06/30/2017	06/30/2017	35	0	0

Accruals

From Date	Thru Date	Institution	Internal Accrual Reporting Group	Gender	Age Group	Ethnicity	Race	Disease Site	Recruited By	Zip Code	Accrual
01/01/2019	03/20/2019	UWFHSCCA Research Systems	Research Center	F		Hispanic or Latino	White				2
10/01/2018	12/31/2018	UWFHSCCA Research Systems	Research Center								0
07/01/2018	09/30/2018	UWFHSCCA Research Systems	Research Center	F		Hispanic or Latino	White				3
07/01/2018	09/30/2018	UWFHSCCA Research Systems	Research Center	F		Non-Hispanic	Asian				3
07/01/2018	09/30/2018	UWFHSCCA Research Systems	Research Center	F		Non-Hispanic	Black or African American				2
07/01/2018	09/30/2018	UWFHSCCA Research Systems	Research Center	F		Non-Hispanic	White				3
		UWFHSCCA Research				Hispanic or					-

Subject Management

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

OnCore Menu

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CRA Console

Protocol No.: RG1005148 Library: Oncology PI: Cano, Oscar Sponsor: National Cancer Institute

Protocol Target Accrual: 100 Accrual To Date: 1 Protocol Status: OPEN TO ACCRUAL

RC Total Accrual Goal (Upper): 20 IRB Expiration:

Short Title: Training Protocol

Select Protocol

Type here to search

Select Subject

Type here to search

Accrual

SAEs

Deviations

FAQs

Register Subject

Accrual Details

Page Size 100

Filter:

Page 1 of 1

Study Site	Primary Subject ID	Last Name	First Name	Seq No.	Arm	Level	Status	Status Date
SCCA Proton Therapy Center	T9902245	Farro	Farrah	100	A1		CONSENTED	05/25/2018
Fred Hutchinson Cancer Research Center	T2020910	Barley	Brad				OFF STUDY (Expired)	05/17/2018
Fred Hutchinson Cancer Research Center	T3939915	Rye	Rhonda				ELIGIBLE	05/15/2018
SCCA Proton Therapy Center	T8820039	Wheat	Wanda				CONSENTED	05/15/2018
SCCA Proton Therapy Center	T6601093	Pumpnickel	Paul					
SCCA South Lake Union	T8840010	Amaranth	Agatha					

Accrual

Include PHI

View PDF

Save Preferences

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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.

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

CTMS Program Office

CTMS_Office@fredhutch.org

<http://iths.org/ctms>