

DCT Reporting – Introduction to OnCore CTMS

December 11, 2025



AGENDA

Speakers:

Jason Malone
Director, UW HSD

Megan Miller
CTMS Training & Support Program
Manager

UW DCT Policy

Introduction to OnCore & Protocol Workflows

Submitting a New Study to OnCore

DCT Minimum Footprint Data Entry Requirements

OnCore Access, Training, Resources & Support

Implementation Timeline: When to Take Action

Today's Webinar



Intended Audience: UW study teams that do not currently have access to or manage protocols in OnCore CTMS, but will need to use OnCore in the future for DCT Reporting protocols.

**Current OnCore Minimum Footprints cover DCT requirements – no additional data entry, training, access or action needed.*



Purpose of the Webinar: OnCore intro & guidance for protocols in-scope for DCT Reporting, but out of scope for current OnCore Minimum Footprint requirements.



UW DCT Policy

Jason Malone | Director, Human Subjects Division

Applicability

All new clinical trials (NIH definition) submitted to UW HSD on/after January 1, 2026, where UW employees or agents are responsible for or engaged in recruitment and consent activities.

- Would apply regardless where the interventions occur
- Would apply to UW studies relying on an external IRB
- Would be a condition of the UW serving as sIRB for multicenter studies

Policy Exceptions

- Phase 1 or earlier trials
- Pilot and feasibility studies
- Clinical trials involving ‘small populations’
- Clinical trials reviewed by Seattle Children’s or Fred Hutch IRB

Policy Requirements

- Submit a Diversity Plan to HSD that:
 - Establishes Enrollment Goals - age, race, ethnicity, biologic sex, sexual orientation, geographic location, social economic status
 - Provides rationale for current enrollment goals and any exclusions
 - Includes a strategy for meeting enrollment goals (e.g., study design, recruitment, and retentional plan, reducing barriers to participation)
 - Describes efforts/resources utilized for community engagement that informs recruitment strategy
 - Has a plan for tracking enrollment data

Reporting Requirements

- It is UW policy that all clinical trials that require the submission of a Diversity Plan for Clinical Trials Supplement must provide annual updates on their enrollment targets for underrepresented groups using the [OnCore CTMS](#).
- These studies are required to be registered in OnCore CTMS before study approval or authorization to use an external IRB will be granted.
 - Documentation of registration (i.e., email confirmation from CTMS) must be uploaded to Zipline

Reporting Requirements

- **Clinical trials that already must report into OnCore** (e.g., oncology-related, have UW Medicine billable activities, and/or require Epic activation for orders for subject tracking purposes) **do not need to make any additional reporting nor do study staff need to take any additional training. These studies will continue to follow existing requirements.**
- Beginning January 1, 2026, **NEW** clinical trials that are not already required to report in OnCore AND are subject to the [UW DCT policy](#) will follow the new OnCore reporting requirements outlined in today's training.



INTRO TO ONCORE & PROTOCOL WORKFLOWS

Megan Miller | CTMS Training & Support Program Manager

What is CTMS? What is OnCore?

- CTMS = Clinical Trials Management System
 - An enterprise software system used to manage clinical trials & human subjects research.
- OnCore is the CTMS used at University of Washington & Fred Hutch Cancer Center (FHCC).
- Managed by cross institutional teams:
 - UW Medicine Research IT
 - CTMS Program Office



! OnCore CTMS, OnCore and CTMS are often used interchangeably.

A (Not So) Brief History of OnCore

• OnCore Implementation Timeline

2018

- WHO: **Oncology-related & FH Non-oncology Human Subjects Research**
- WHAT: Protocol & Subject Management, SRC Review Process
- WHY: Data collection for National Cancer Institute Reporting (NCI), institutional admin tracking, monitoring, centralized system for study document access

2021

- WHO: New protocols with clinical research billing (**Oncology, FH non-oncology, UW non-oncology**)
- WHAT: Subject Calendars, Coverage Analysis, Study Financials, integration with Epic EHR
- WHY: Centralize cross-institutional research workflows, streamline clinical research billing, standardizes sponsor invoicing activities

2023

- WHO: Backload of protocols w/ clinical research billing that started prior to 2021
- WHAT: Subject Calendars, Coverage Analysis, Study Financials, integration with Epic EHR
- WHY: Centralize cross-institutional research workflows, streamline clinical research billing, standardizes sponsor invoicing activities

OnCore Today

Teams Working in OnCore

- UW & FH Study Teams
- UW Clinical Trials Office (CTO)
- CTMS Program Office
- UW & FH Investigational Drug Service (IDS)
- UW & FH Clinic teams (*Drs, APPs, nurses, assistants, etc.*)
- Other Research Admin, Regulatory, Compliance Offices
- FH Clinical Research Support (CRS)
- FH Scientific Review Committee (SRC)
- FH Clinical Research Business Office (CRBO)
- FH Clinical Readiness Team (CRT)



System Integrations

- UW Workday
- UW/FH Epic Electronic Health Record (EHR)
- UW & FH Vestigo (IDS system)
- UW Florence
- Trial Finder App (Oncology only)

Cross-Institutional Research Workflows

- Scientific Review Committee Approval (Oncology only)
- Coverage Analysis, Coding & Pricing
- Billing Grid production & approval
- Centralized Protocol Document repository
- Sponsor invoicing & payment reconciliation
- Research Billing Compliance
- NCI Reporting

OnCore Today

- 5,554 Protocols have reached an Open to Accrual (OTA) status
 - Currently 2,467 protocols in an “active” status (*post-OTA*)
 - 1,792 Oncology protocols | 434 UW Non-oncology (*Oncology has broader scope*)
 - 431 Protocols in startup (*pre-Open to Accrual; not yet enrolling*)
- 62 Departments from UW & FH that have protocols in OnCore
- > 3,100 active end users across UW & FH
 - 690 Principal Investigators
 - 584 Research Managers
 - 755 Primary Clinical Research Coordinators
- 113,092 Subjects have reached a Consented status
- 72,642 Subjects have reached an Off Study status (*does not include Withdrawn, Not Eligible, Expired terminal statuses*)

Why Use OnCore for DCT Reporting?

1. Centralized, web-based single sign-on (SSO) system w/ the ability to:
 - ✓ Provision access by research areas, departments, groups & teams that meets IT security requirements.
 - ✓ Support data entry requirements for DCT Reporting.
 - ✓ Export data into customized reports.
2. There will be a subset of protocols in-scope DCT Reporting AND meet other requirements of OnCore usage (*e.g., clinical research billing*).
 - ✓ By using OnCore for DCT data collection, these teams would not need to manage data entry in two separate systems.
 - ✓ EXAMPLE: If DCT Reporting was in effect today, there would be ~559 in-scope protocols already in OnCore.

Why Use OnCore for DCT Reporting?

3. CTMS Program Office has the staff, resources & systems needed to support DCT data collection and reporting

QC & Reporting

Perform routine data reviews and study team outreach to ensure accurate data extraction.

- Generate an average of 980 study team outreach tickets per month
- 214 active reports in OnCore
- Respond to an average of 120 data extraction inquiries per month
 - Questions or needs for data/metrics?
Email ctms@fredhutch.org!

Intake Team

Process new studies submitted to REDCap Study Intake Form:

- Weekly average: 15
- Monthly average: 60
- Yearly average: 550
- Average turnaround time: ~2 hours!

Training & Support

In 2025, Training & Support has:

- Solved/resolved 4,790 inquiries
- Helped >300 staff members in Office Hours
- Held 13 Webinars w/ >1,500 attendees
- Published 20 Tips & Tricks newsletters
- Maintained 50 Reference Documents & 8 eLearning Modules
- Trained 190 users for new edit permissions

OnCore Protocol Workflows

Aka: Pre-Open to Accrual (OTA), activation, startup, pre-award



Study Team submits new study to **REDCap Study Intake Form** (at time of Initial IRB Review)



CTMS Intake Team builds OnCore Protocol Record; notifies study team via email



Recommended: **Study Team** reviews protocol record for accuracy; completes data entry of protocol information

Aka: Post-OTA, post-award, active study



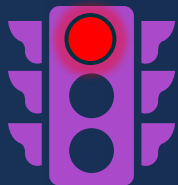
CTMS Intake Team opens the protocol to accrual → Subjects can now enroll



Study Team performs data entry including entering subjects; updating protocol statuses, staff & information; responding to queries



CTMS QC & Reporting will be performing data quality checks and exporting data for policy reporting



When IRB file is closed, **Study Team** performs outstanding subject data entry (all subjects have Off Study statuses) & updates Protocol Status to IRB Study Closure*

**Final QC checks sent out*



Submitting a New Study to OnCore

Megan Miller | CTMS Training & Support Program Manager

Submitting New Studies – Jan. 1 2026

- A [REDCap New Study Intake Form](#) will need to be submitted for studies meeting the following criteria:
 1. New study submitted for UW HSD review **on or after January 1, 2026, AND**
 2. Research that meets the definition of a [clinical trial](#), **AND**
 3. UW employees or agents are responsible for or engaged in recruitment or consent activities.
- Link to REDCap Intake Form is available on the [CTMS Program Office Website \(Study Submissions > New Study Submissions page\)](#).
- Information will be sent out via UW HSD Newsletter, OR
- Reach out to CTMS@fredhutch.org
 - NOTE: If you have access to OnCore, link to the REDCap form is available on the landing page when you first login.



DCT Minimum Footprint Data Entry Requirements

Megan Miller | CTMS Training & Support Program Manager

What is the Minimum Footprint?

- Guidance document on minimum required protocol & subject data that must be entered into OnCore.
- Established in coordination with policy requirements, administrative needs & system functionality.
- Two established Minimum Footprints for current OnCore protocols:
 - Full Minimum Footprint
 - Short Minimum Footprint
- DCT Minimum Footprint being developed for studies out of scope for Full or Short Minimum Footprint protocols.
 - E.g., UW non-oncology clinical research protocols w/ no Epic billing or other activities

Full Minimum Footprint: Current UW Non-Onc Protocol

Details

- Assigned RG Number
- NCT Number
- Library
- Department
- Organizational Unit
- Title: IRB approved title
- Short title*
- Phase
- Scope*
- Age*
- Consent at Age of Majority *
- Investigator Initiated Protocol*
- Summary Accrual info only
- Protocol type
- Involves Correlates or Companions*
- Data monitoring*
- Multi site trial*
- Investigational drug*
- Pilot*

- Investigational device*

- Not applicable checkbox*

- Protocol target accrual*

- RC Total Accrual Goal (lower)

- RC Total Accrual Goal (Upper)

- RC Annual accrual goal*

- Accrual Duration (months)*

- Primary completion date

Management

- IRB number

- Pharmacy number*

- SRC Review required*

- CTSA Participation*

- Comments*

- Coding Scheme*

- Generate

- primary subject ID

- Automated sequence*

- Internal account number*

- Allow duplicate enrollment*

- Management Group

- Management group – primary checkbox

Protocol Staff Roles

- Billing Contact*

- Calendar and Financial Analyst*

- Clinical Research Coordinator*

- Clinical Research nurse*

- Data coordinator*

- Financial post award contact

- Financial Pre Award contact

- Prescribing investigator*

- Primary Clinical Research Coordinator

- Primary Regulatory Coordinator

- Principal Investigator

- Regulatory Coordinator*

- Research Manager

- Study Submission Contact

- Sponsor name

- Sponsor Protocol No.

- Roles

- Principal Sponsor

- Sponsor type override*

- Fund Acct No

- Department that holds funds

- Department that holds funds

- Department that holds funds

- Department that holds funds

- Department that holds funds

Investigational Drug

- ID*

- Holder type*

- Holder Name*

Investigational Device

- ID*

- Holder type*

- Holder Name*

Arms

- Step Code

- Registration or randomization

- Arm code

- Arm description

Diagnosis

- Diagnosis

Institution

- UW/Fred Hutch

- Research Systems Institution and Study Sites

- Institution*

- Coordinating Center*

- Uses Research Center IRB*

- Study participant checkbox*

IRB Reviews

- Review date

- Submit date

- Committee

- Review reason

- Review type

- Action

- Action Date

- Review expires

- Expiration date*

- Institution*

- Type document

- Amendment no*

- Received date

- Version date

- Description

- Reconsent required*

- Document attached*

- Release checkbox*

External Committee Actions

- Committee*

- Submit date*

- Review date*

- Action*

- Action date*

Attachments/Links

- Document type*

- Expiration date*

- Attached file*

- Description*

FAQs

- Question

- Answer

Study Details

- Study pathway

- Ancillary Service*

OTA Task List

- Fred Hutch CRL initial*

- Initial Activation OTA Task List*

- Activation OTA Task List*

- Documents Task List*

- A31 Final Draft Budget and Payment*

- A33: Final draft or approved consent*

- 039: minimum footprint complete*

Protocol Status

- Status date*

- Initiator*

- Reason*

BG & Budget Sign Off

- Approve

Register Subject

- Primary subject ID*

- Last Name*

- Birth date*

Demographics

- Last Name

- First Name

- Birth date

- Expired date*

- Expired date approx.*

- Biological sex

- Ethnicity

- Race

- Address

- Country*

Consent

- Signed date

- Accepted

- Other consent status*

- Other consent status date*

Eligibility

- Version date*

- Eligibility

- status*

- Verified by*

- Status Date*

- Reason Withdrawn*

- Reason not eligible*

On Study

- Sequence no*

- On study date*

- Disease site*

- Research group*

- Zip at registration

- Study site*

- Transferred from site*

- Transferred from date*

- Role: consenting provider*

- Staff name*

Treatment

- Arm*

- On Arm date*

- On Treatment date*

- Off arm date*

Follow Up

- Off treatment date*

- Off treatment reason*

- Off study date

- Off study reason*

- On Follow-up Start Date

- Expired date*

- Expired date approx.*

SAEs

- Event date*

- Reported Date*

- Outcome*

Subject Visit Update

- Visit date*

- Visit status*

- Reset Calendar*

- Procedure Alternative*

- Procedure date*

- SOC*

- Missed*

- NA*

- Missed Count*

- Location*

Additional Visits

- Visit date*

- Visit description*

- Procedures*

- Procedure date*

- Location*

Financial Event

- Financial Events

- Occurred Date

- Count

- Comments

Protocol Event

- Protocol Events

- Occurred Date

- Count

- Comments

Invoices

- Invoice date*

- Bill to*

Full Minimum Footprint vs. DCT Minimum Footprint

Details

- Assigned RG Number
- NCT Number
- Library
- Department
- Organizational Unit
- Title: IRB approved title
- Short title*
- Phase
- Scope*
- Age*
- Consent at Age of Majority*
- Investigator Initiated Protocol*
- Summary Accrual info only
- Protocol type
- Involves Correlates or Companions*
- Data monitoring*
- Multi site trial*
- Investigational drug*
- Pilot*

- Investigational device*
- Not applicable checkbox*
- Protocol target accrual*
- RC Total Accrual Goal (lower)
- RC Total Accrual Goal (Upper)
- RC Annual accrual goal*
- Accrual Duration (months)*
- Primary completion date

Management

- IRB number
- Pharmacy number*
- SRG Review required*
- CTSA Participation*
- Comments*
- Coding Scheme*
- Generate

primary subject ID

- Automated sequence*
- Internal account number*
- Allow duplicate enrollment*
- Management Group
- Management group - primary checkbox

Protocol Staff Roles

- Billing Contact*
- Calendar and Financial Analyst*
- Clinical Research Coordinator*
- Clinical Research nurse*
- Data coordinator*
- Financial post award contact
- Financial Pre Award contact

- Prescribing investigator*
- Primary Clinical Research Coordinator
- Primary Regulatory Coordinator
- Principal Investigator
- Regulatory Coordinator*
- Research Manager
- Study Submission Contact

Sponsor

- Sponsor name
- Sponsor Protocol No.
- Roles
- Principal Sponsor
- Sponsor type override*
- Fund Acct No
- Department that holds funds

Investigational Drug

- ID*
- Holder type*
- Holder Name*

Investigational Device

- ID*
- Holder type*
- Holder Name*

Arms

- Step Code
- Registration or randomization
- Arm code
- Arm description

Diagnosis

- Diagnosis

Institution

- UW/Fred Hutch Research Systems Institution and Study Sites
- Institution*

- Coordinating Center*
- Uses Research Center IRB*
- Study participant checkbox*

IRB Reviews

- Review date
- Submit date
- Committee
- Review reason
- Review type
- Action
- Action Date
- Review expires
- Expiration date*
- Institution*
- Type document
- Amendment no*
- Received date
- Version date
- Description
- Reconsent required*

Document attached*

- Release checkbox*

External Committee Actions

- Committee*
- Submit date*
- Review date*
- Action*
- Action date*

Attachments/Links

- Document type*
- Expiration date*
- Attached file*
- Description*

FAQs

- Question
- Answer

Study Details

- Study pathway
- Ancillary Service*

OTA Task List

- Fred Hutch CRL initial*
- Initial Activation OTA Task List*
- Activation OTA Task List*
- Documents Task List*
- A31 Final Draft Budget and Payment*
- A33: Final draft or approved consent*
- 039: minimum footprint complete*

Protocol Status

- Status date*
- Initiator*
- Reason*

BG & Budget Sign-Off

- Approve

Register Subject

- Primary subject ID*
- Last Name*
- Birth date*

Demographics

- Last Name
- First Name
- Birth date
- Expired date*
- Expired date approx.*
- Biological sex
- Ethnicity
- Race
- Address
- Country*

Consent

- Signed date
- Accepted
- Other consent status*
- Other consent status date*

Eligibility

- Version date*
- Eligibility

- status*
- Verified by*
- Status Date*
- Reason Withdrawn*
- Reason not eligible*

On Study

- Sequence no*
- On study date*
- Disease site*
- Research group*
- Zip at registration
- Study site*
- Transferred from site*
- Transferred from date*
- Role: consenting provider*
- Staff name*

Treatment

- Arm*
- On Arm date*
- On Treatment date*
- Off arm date*

Follow Up

- Off treatment date*
- Off treatment reason*
- Off study date
- Off study reason*
- On Follow-up Start Date
- Expired date*
- Expired date approx.*
- Event date*
- Reported Date*
- Outcome*
- Visit date*
- Visit status*
- Reset Calendar*
- Procedure Alternative*
- Procedure date*
- SOC*
- Missed*

SAEs

- Event date*
- Reported Date*
- Outcome*

Subject Visit Update

- Visit date*
- Visit status*
- Reset Calendar*
- Procedure Alternative*
- Procedure date*
- SOC*
- Missed*

NA*

- Missed Count*
- Location*

Additional Visits

- Visit date*
- Visit description*
- Procedures*
- Procedure date*
- Location*

Financial Event

- Financial Events
- Occurred Date
- Count
- Comments

Protocol Event

- Protocol Events
- Occurred Date
- Count
- Comments

Invoices

- Invoice date*
- Bill to*

DCT Minimum Footprint

Details

- Assigned RG Number
- NCT Number
- Library
- Department
- Organizational Unit
- Title: IRB approved title
- Short title*
- Phase
- Summary Accrual info only
- Protocol type
- Investigational drug*
- Investigational device*
- RC Total Accrual Goal (lower)
- RC Total Accrual Goal (Upper)
- Primary completion date

Management

- IRB number
- Generate

primary subject ID

Protocol Staff Roles

- Primary Clinical Research Coordinator
- Principal Investigator
- Research Manager
- Study Submission Contact

Sponsor

- Sponsor name
- Sponsor Protocol No.
- Roles
- Principal Sponsor
- Sponsor type override*
- Fund Acct No
- Department that holds funds

Diagnosis

- Diagnosis

Institution

- UW/Fred Hutch Research Systems Institution and Study Sites
- Institution*
- Coordinating Center*
- Uses Research Center IRB*
- Study participant checkbox*

IRB

Reviews

- Review date
- Submit date
- Committee
- Review reason
- Review type
- Action
- Action Date
- Review expires
- Institution*
- Type document
- Received date
- Version date

Description

FAQs

- Question
- Answer

Study

Details

- Study pathway

Protocol Status

- Status date*
- Initiator*
- Reason*

Register Subject

- Primary subject ID*
- Last Name*
- Birth date*

Demographics

- Last Name
- First Name
- Birth date
- Expired date*
- Expired date approx.*

Biological sex

Ethnicity

Race

Address

Country*

Consent

- Signed date
- Accepted

On Study

- Zip at registration
- Study site*

Follow Up

- Off study date
- Off study reason*

DCT Minimum Footprint – Data that Study Teams Enter/Maintain in OnCore

Management

- IRB number

Protocol Staff Roles

Roles

- Primary Clinical Research Coordinator
- Principal Investigator
- Research Manager
- Study Submission Contact

Protocol Status

Status

- Status date*
- Initiator*
- Reason*

Register Subject

Subject

- Primary subject ID*
- Last Name*

Demographics

- Birth date*
- Last Name
- First Name
- Birth date
- Expired date*
- Expired date approx.*
- Biological sex
- Ethnicity
- Race
- Address
- Country*

Consent

- Signed date
- Accepted

On Study

- Zip at registration
- Study site*

Follow Up

- Off study

- date
- Off study reason*

Management (IRB No.):

- ✓ Entered prior to or at Open to Accrual (OTA)

Protocol Staff Roles:

- ✓ Initially entered by CTMS prior to OTA
- ✓ Updates maintained by study team, as needed (pre & post-OTA)

Protocol Status:

- ✓ Required pre-OTA (& OTA) statuses updated by CTMS
- ✓ As needed pre-OTA updates entered by study team
- ✓ Required post-OTA updates entered by study team (Closed to Accrual & IRB Study Closure)

Subject Registration & Enrollment Info

- ✓ Study team enters all subject data (post OTA only)
- ✓ Entered annually for IRB Renewal – *recommended to perform more frequent or ongoing data entry for high accruing protocols.*

DCT Minimum Footprint – Data that Study Teams Enter/Maintain in OnCore

Management

- IRB number

Protocol Staff Roles

- Primary Clinical Research Coordinator
- Principal Investigator
- Research Manager
- Study Submission Contact

Protocol Status

- Status date*
- Initiator*
- Reason*

Register Subject

- Primary subject ID*
- Last Name*
- Birth date*

Demographics

- Last Name
- First Name
- Birth date
- Expired date*
- Expired date approx.*
- Biological sex
- Ethnicity

- Race
- Address
- Country*

Consent

- Signed date
- Accepted

On Study

- Zip at registration
- Study site*

Follow Up

- Off study date
- Off study reason*

Management (IRB No.):

- ✓ Entered prior to or at Open to Accrual (OTA)

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Subject Registration & Enrollment Info

- ✓ Study team enters all subject data (post OTA only)

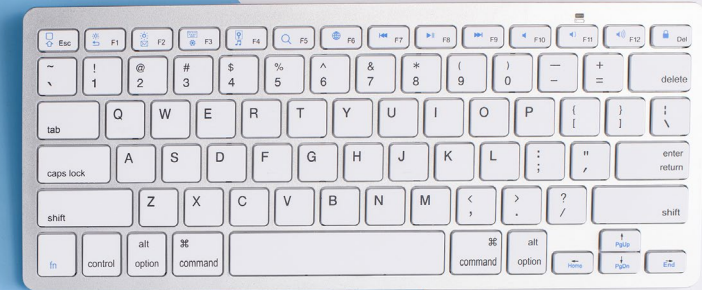
OnCore is a Resource for Study Teams!

OnCore Reports

- Subject status updates
- Subject demographics data (Annual IRB Report Format)

Protocol & Subject Searches

- Configure customized “reports”
- Can share reports with other team members
- Run ad hoc data pulls



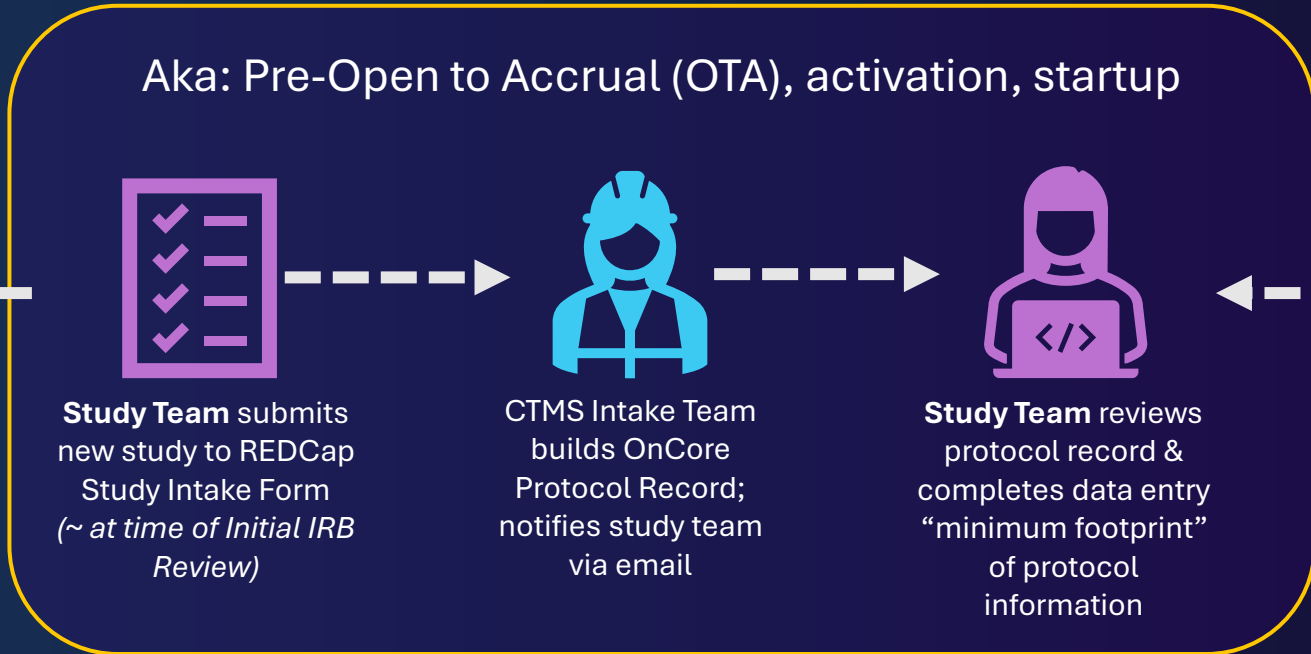
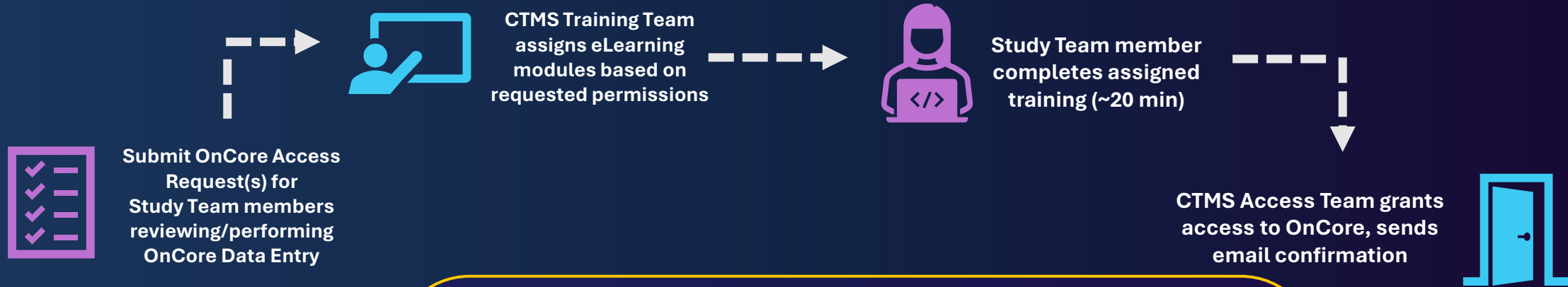
DATA = DATA
IN OUT



Access, Training, Resources & Support

Megan Miller | CTMS Training & Support Program Manager

When do I need access to OnCore?



Q: When do I request access to OnCore?
A: Wait until you submit your first new study (or just prior to submission).

Training for DCT Edit Permissions

- All required OnCore training is located in the [ITHS TREE](#) Learning Management System (LMS)
- Training is assigned “Just in Time” upon submission of OnCore Access Request
- Single eLearning Module must be completed (with 80% passing score) before being granted access to the system
- Approximately 20-30 min long
- OnCore users will retain access to the eLearning module – may review at any time

CTMS Support Resources



Documents*:

- DCT Minimum Footprint
- DCT Data Entry Work Instructions

**Available Jan. 1*



Online Office Hours:

- Drop-in assistance via Zoom
- Breakout rooms for personalized assistance
- Tue. 10am -12pm \ Fri. 12 – 2pm



CTMS Support Desk:

- Mon - Fri 8am – 4:30pm PT
- Email: CTMS@fredhutch.org
- Phone: 206-667-2868



Other Resources:

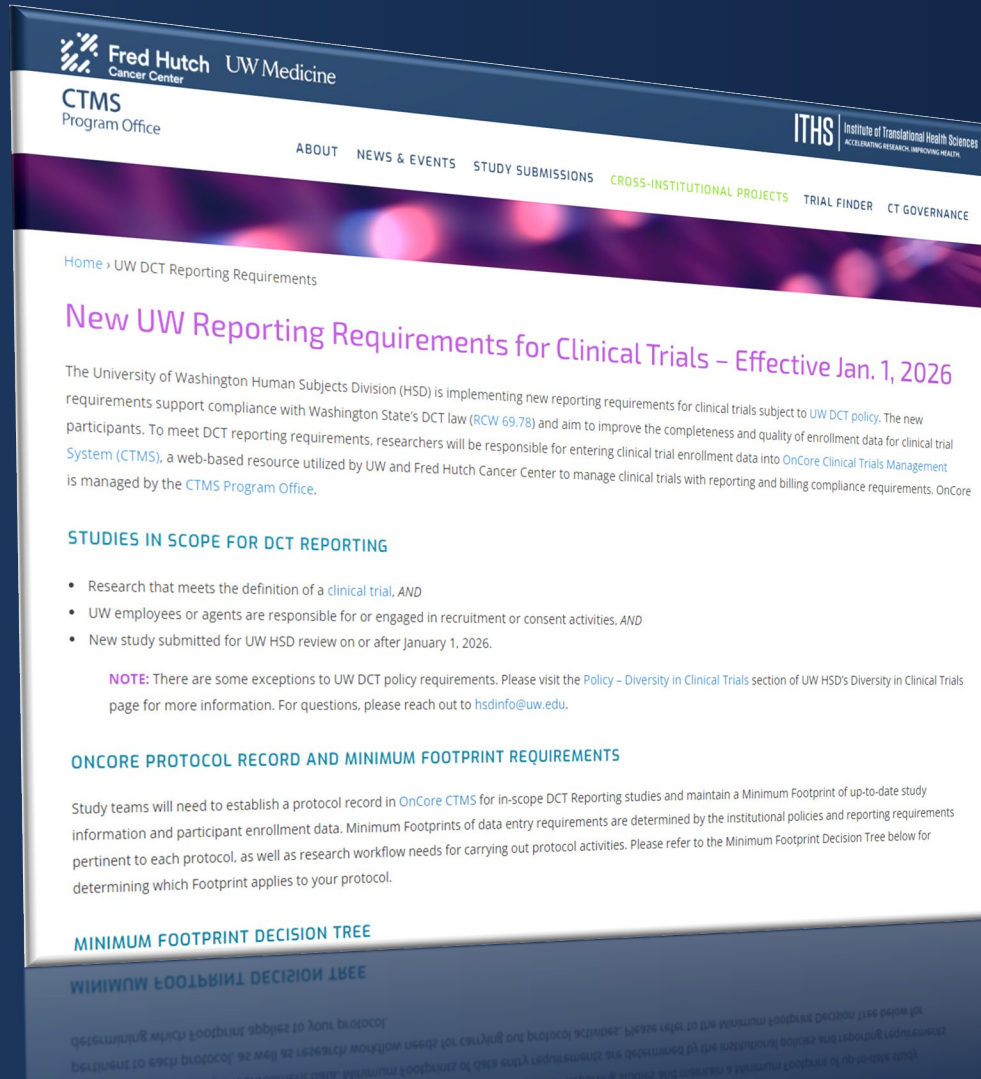
- Individual Team Training on Request
- Monthly Webinars & bimonthly newsletters sent to OnCore users
- CTMS Website



DCT Implementation – When to Take Action

Megan Miller | CTMS Training & Support Program Manager

Where to Go for Updates & Info



- CTMS Program Office Website
 - Webpage dedicated for DCT Reporting; general info on OnCore
 - <https://www.iths.org/ctms/uw-dct-reporting-requirements/>
- Communications via UW HSD Newsletters
- [UW HSD Diversity in Clinical Trials](#)
- [UW Medicine Office of Healthcare Equity](#)



Thank you
for attending.