Introduction to Clinical Research Boot Camp 2020

RESEARCH STAFF TRACK
Day 2

Tuesday, July 21, 2020

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Introduction to Clinical Research Boot Camp 2020

Collaboration via CTMS

An overview of the OnCore Clinical Trials Management System

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Agenda

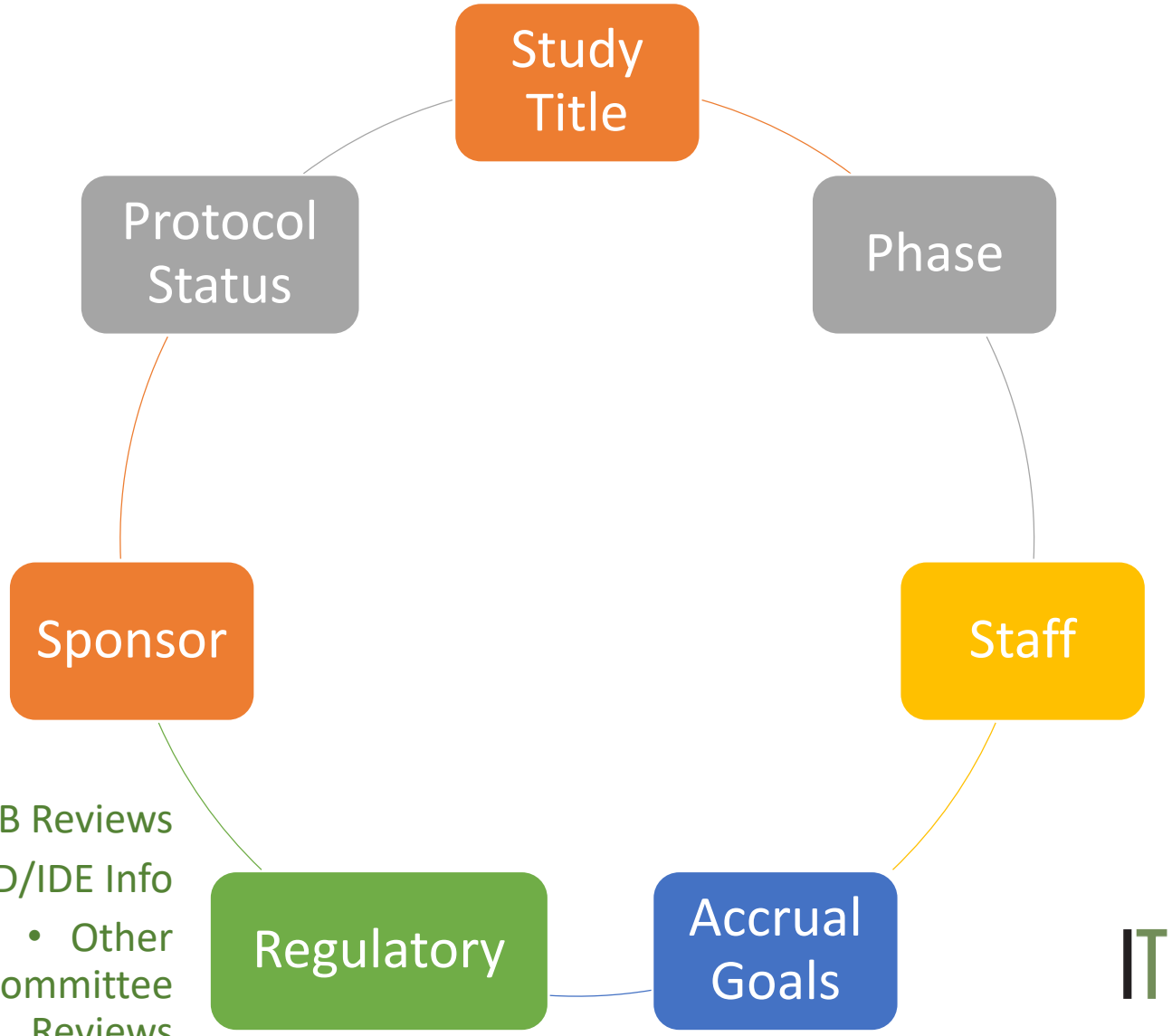
- What is a CTMS?
- What data is currently tracked in the CTMS?
- Opportunities for Collaboration within study teams
- Opportunities for enhanced communication with institutions
- Future CTMS expansion
- Questions

What is a CTMS?

- CTMS = Clinical Trial Management System = OnCore at UW/FH/SCCA
- CTMS is a standardized workflow and operational data management system designed to centralize, manage, and gain insight into all research-related activities at an institution including:
  - Reporting:
    - Cancer Center Support Grant (CCSG)
    - Clinical Trials Reporting Program (CTRP)
    - ITHS Metrics
    - Leadership: Department, Division, Study Group, etc.
  - Electronic Health Record (Epic) Integration
  - Committee Management – Cancer Consortium Scientific Review Committee
  - Clinical Research Workflow – Protocol Startup and Amendment
  - Operational Data Tracking and Management

Information Currently Tracked in CTMS

CTMS Protocol Data



- Scientific Review Approved
- IRB Approved
- Open to Accrual
- Closed to Accrual
- Etc…

- I
- I/II
- II
- Pilot
- Etc….

- NIH
- Seattle Genetics
- Pfizer
- NSF
- Etc….

- PI
- Manager
- Primary CRC
- Regulatory

- IRB Reviews
- IND/IDE Info
- Other Committee Reviews

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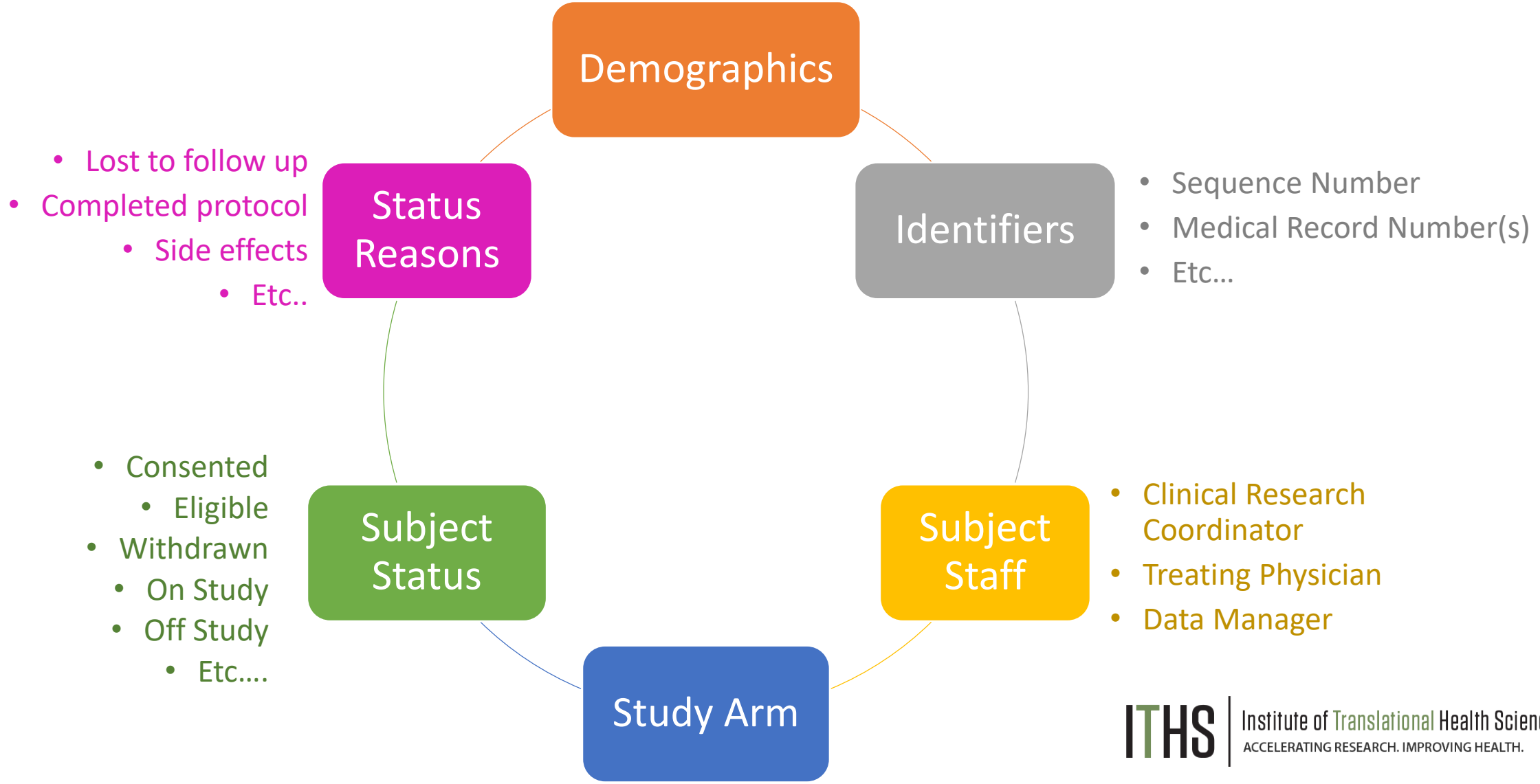
CTMS Subject Data



How is OnCore data used?

Examples of how OnCore data is used:

- Accrual data is used for reporting requirements for the National Cancer Institute (NCI) Cancer Center Support Grant (CCSG)
- Subject study registration and status is sent to Epic for research billing review
- Protocol data supports study start-up processes & ongoing monitoring (e.g., SRC Review, low accrual monitoring)

Who has access to OnCore?

Individuals/Study Teams:

- PI's
- Research Managers
- Study/Research Coordinators
- Data Managers
- Biostatisticians
- SRC Reviewers
- Regulatory Coordinators/Managers
- Directors and VP's
- Research Scientists
- Project Managers
- Research Nurses

Institutional Offices:

- UW Clinical Trials Office/Clinical Research Budget & Billing (CRBB)
- Epic Research Billing Teams (UW and SCCA)
- FH Clinical Research Support (CRS)
- Cancer Consortium Scientific Review Committee (SRC)
- SCCA Clinical Research Business Office (CRBO)

Collaboration within the study team

Poll

How big is your study team?

- I’m a team of one (PI fills all roles)
- We are a team of 2-3 members (PI plus 1-2 study staff)
- We a larger team of a 4+ members (PI plus 3 or more study staff)
- I use the ITHS coordinators to help my study team

Collaboration within a study team – Scenario 1

- Study receives IRB Initial Approval and is ready to open to accrual
  - Other study members need to perform next steps
  - CTMS Office performs Open to Accrual with study team go-ahead

Regulatory Coordinator	Research Manager	Budget Manager	CTMS Office	Open to accrual
• Enters IRB Initial Approval in OnCore • Automatic notification triggered to specific study staff to trigger next steps	• Completes required OnCore fields required for open to accrual	• Sends IRB Review invoice to sponsor	• Receives auto generated report of studies ready to be opened • Opens study to accrual	• Automatic Notification to specific study staff and institutional offices

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Collaboration within a study team – Scenario 2

- PI Requests status report of all studies where she is a PI or sub investigator
  - Include subject statuses
  - Number of subjects ‘On Study’
  - Information about the protocols: Protocol Type, Phase, Sponsor, etc.
  - Due: Tomorrow!

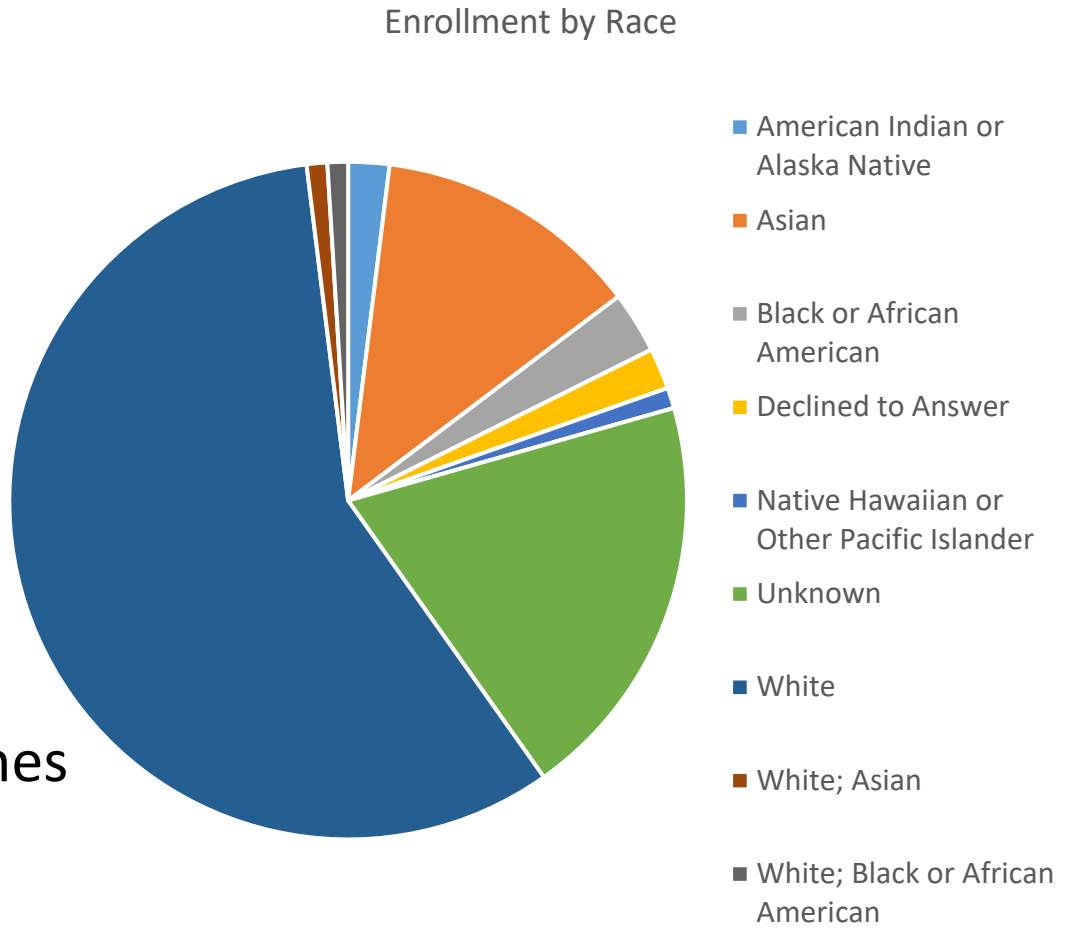
Collaboration within a study team – Scenario 3

- Each time a subject is consented the study team emails the biostatistician for randomization and arm assignment
- Information to be included: Subject Name, consent date, PI name, Study Title
- Timing: Within 1 business day of enrollment

- Enters Consent information
- Automatic notification sent to Biostatistician
- Uploads randomization output to subject console documents

Other collaboration scenarios to consider

- Produce subject demographic reports
- Track the reconsent of subjects
- Produce IRB Activity reports
- Track IRB expirations
- Document history of protocol status
- Track protocol staff roles, start & end dates
- Monitor Study Staff subject and protocols volumes to determine appropriate staffing levels



How can OnCore enhance communication with institutions?

Poll

How many institutions and clinics does a typical protocol involve within your study team?

- Single Institution, One clinic
- Single Institution, Multiple Clinics
- Multiple Institutions, Multiple Clinics

Communication with Institutions – Scenario 1

- During study startup a worldwide pandemic disrupts financing for a new protocol. Sponsor tells study teams to pause all startup activity pending resolution.
- Study Team must notify institutions that study startup is on hold

- Updates Study Status in OnCore to 'ON HOLD'
- Status includes a change reason and comments

- Automated notification is sent to institution offices to communicate hold status (includes protocol info and status change reason)

- Update processes to reflect hold status

- Off Hold notification sent when startup resumes

- Following open to accrual the billing contact changes. Staff changes in OnCore are sent to the billing offices automatically.

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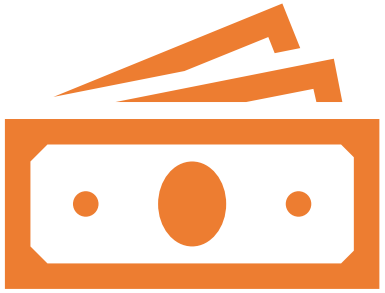
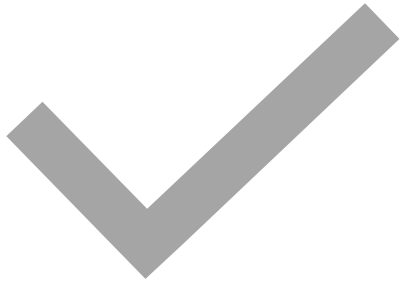
Communication with Institutions – Scenario 2



New funding opportunity released for clinical research infrastructure



Criteria to apply for funding include significant reporting requirements of institution level data on previous trial success, enrollment breadth, etc.

Communication with Institutions – Scenario 3

- A worldwide pandemic causes hospitals to divert resources to caring for the pandemic patients. Clinics must reevaluate staffing and supply resources frequently to determine capacity.

Determine Data Requirements

- What types of protocols and subjects statuses will influence their decision making?

Design Report

- Number of subjects consented, put on treatment, or on study on interventional treatment protocols

Recurring Report

- Report can emailed to stakeholders at desired frequency

Takeaway

- 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 directly in OnCore** or automatically delivered via **email report**.
- Administrative teams have updated their processes to get data from OnCore instead of via reach out to study teams, where possible.
- Where possible, OnCore and the CTMS Program Office act as a link between study teams, administrative offices, and data consumers to enhance collaboration and communication across the clinical research enterprise.

Future CTMS Expansion

T3 – Target 3 implementation (currently underway)

Scope Expansion

- Currently: Cancer consortium research and FH non-oncology protocols and subjects
- Early 2021: UW Non Oncology protocols and subjects go live

Calendar and Financial Functions (Mid 2021)

- Protocols calendars will be built based on schedule of events
- Financial information linked to calendar, budgeting and invoicing functions
- Medicare coverage analysis built in CTMS and sent to Epic
- Epic and UW Research Office will route charges based on coverage analysis


Questions?
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