Introduction to Clinical Research **Boot Camp 2021**

Research Staff

July 19-23

12:00-1:00pm PDT

ITHS | Institute of Translational Health Sciences

ACCELERATING RESEARCH. IMPROVING HEALTH.

Tuesday, July 20, 2021

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Collaboration via CTMS

An overview of the OnCore Clinical Trials Management System

Learning Objectives

- Describe two ways in which OnCore can be utilized as a collaboration tool
- List three components of protocol management
- Name two ways OnCore can enhance communication with the institutions

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

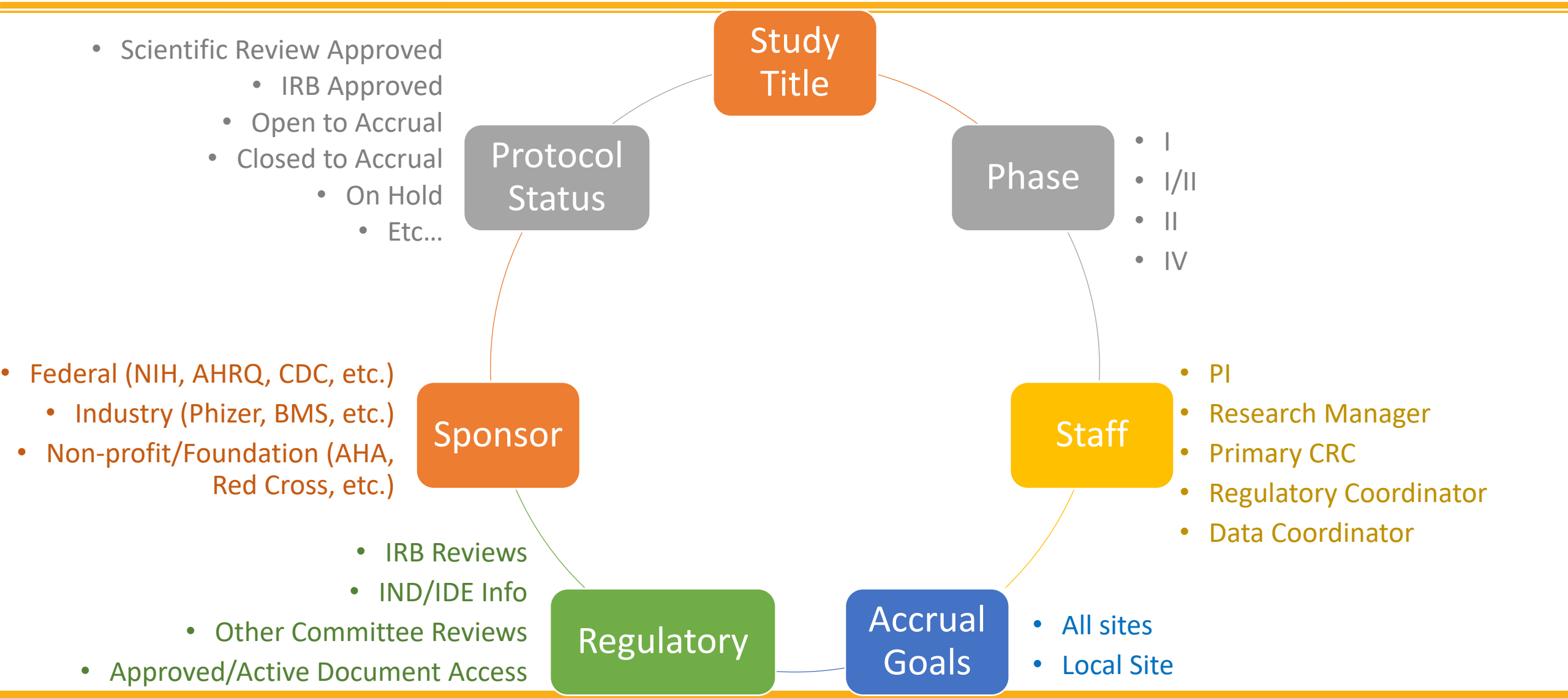
What is a CTMS?

- 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 provide 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 Amendments
  - Operational Data Tracking and Management

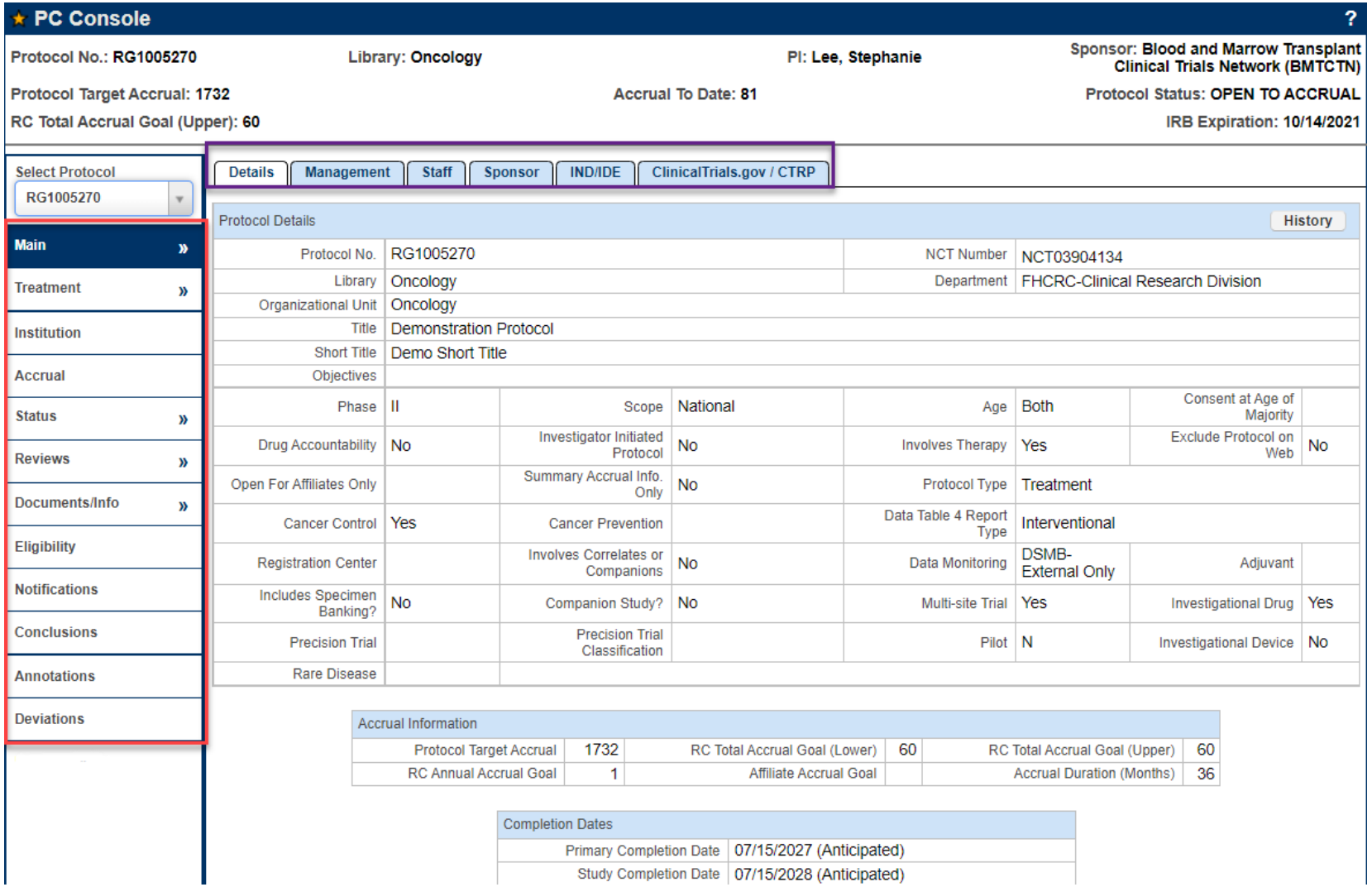
Information Currently Tracked in CTMS

Oncology and FH non-oncology protocols

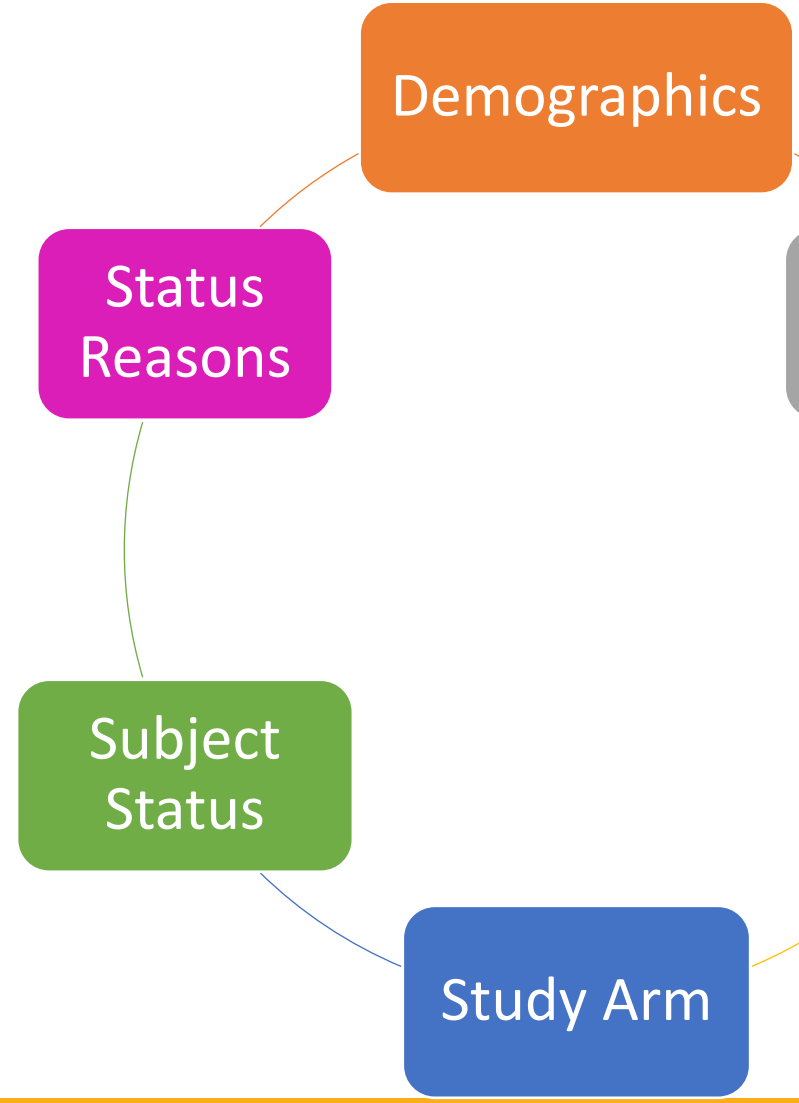
CTMS Protocol Data



OnCore PC Console



CTMS Subject Data



- Interfaced from Epic for applicable studies

- Sequence Number
- Medical Record Number(s)
- Additional Customizable Identifiers

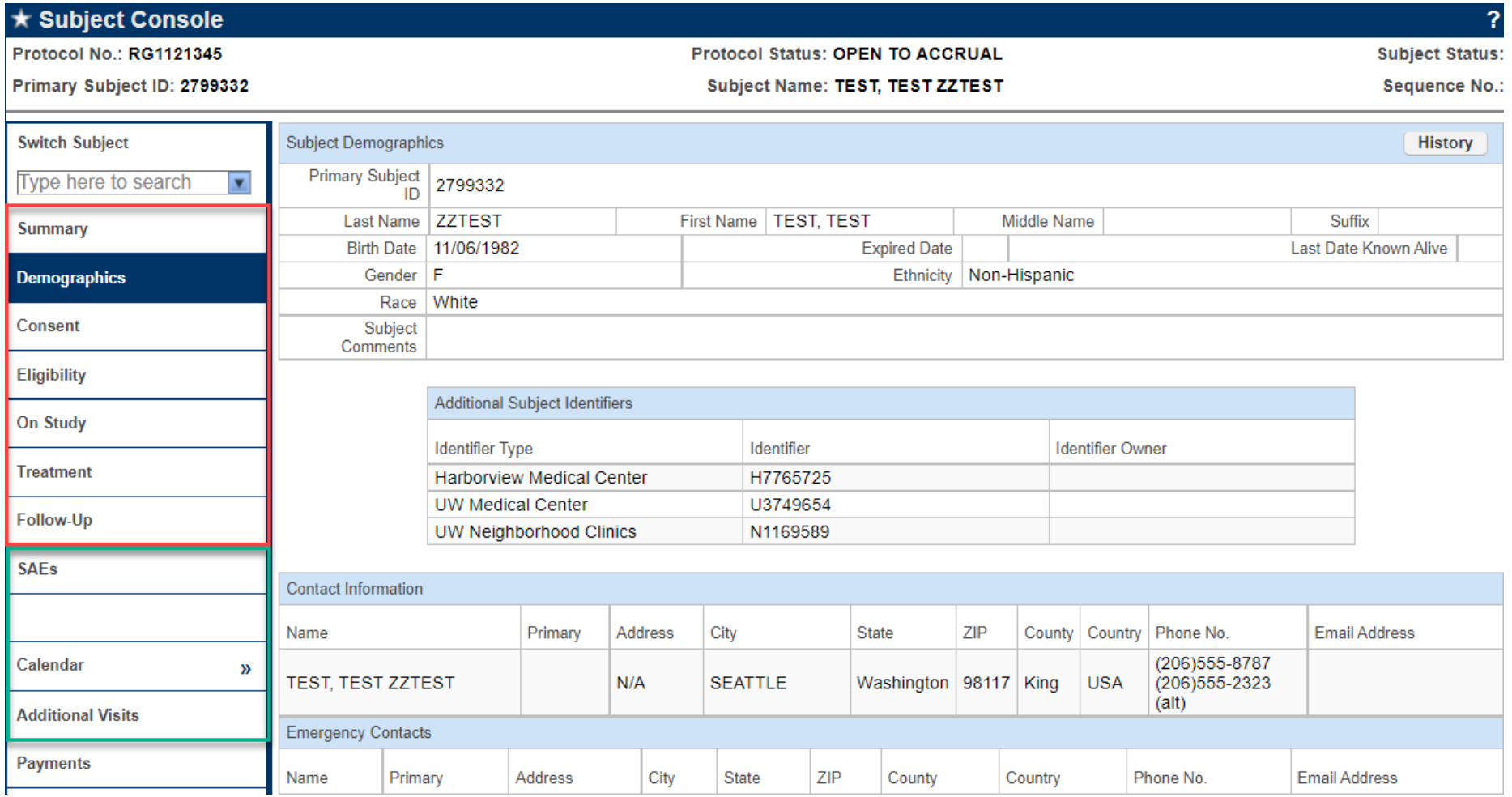
Subject Specific:

- Clinical Research Coordinator
- Treating Physician
- Data Manager
- Accruing Physician

- Consented
- Eligible
- Withdrawn
- On Study
- Off Study
- Etc.…

- Lost to follow up
- Completed protocol
- Side effects
- Etc..

OnCore Subject Console



★ Subject Console ?

Protocol No.: RG1121345 | Protocol Status: OPEN TO ACCRUAL | Subject Status:

Primary Subject ID: 2799332 | Subject Name: TEST, TEST ZZTEST | Sequence No.:

Switch Subject

Type here to search

- Summary
- Demographics
- Consent
- Eligibility
- On Study
- Treatment
- Follow-Up
- SAEs
- Calendar »
- Additional Visits
- Payments

Subject Demographics — History

Primary Subject ID	2799332						
Last Name	ZZTEST	First Name	TEST, TEST	Middle Name		Suffix	
Birth Date	11/06/1982	Expired Date		Last Date Known Alive			
Gender	F	Ethnicity	Non-Hispanic				
Race	White						
Subject Comments							

Additional Subject Identifiers

Identifier Type	Identifier	Identifier Owner
Harborview Medical Center	H7765725	
UW Medical Center	U3749654	
UW Neighborhood Clinics	N1169589	

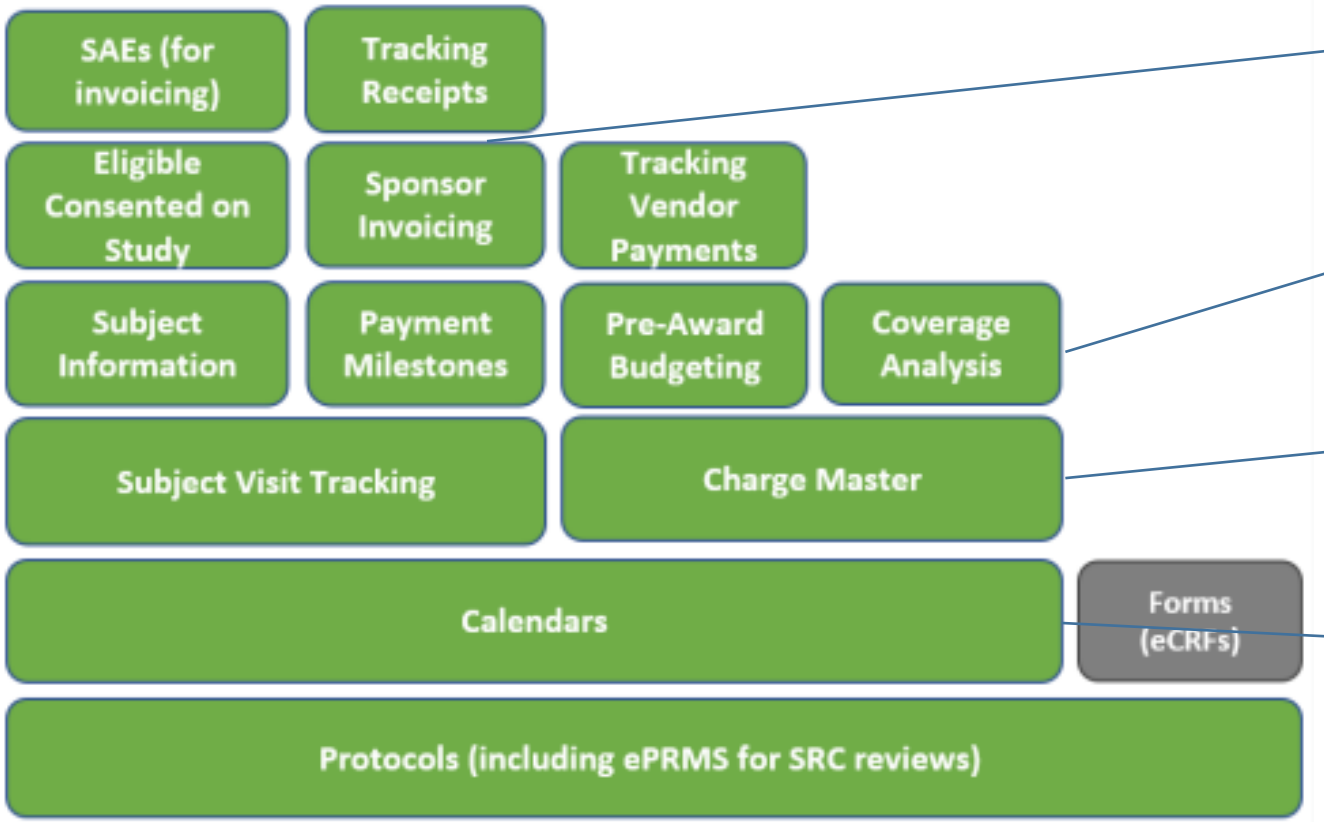
Contact Information

Name	Primary	Address	City	State	ZIP	County	Country	Phone No.	Email Address
TEST, TEST ZZTEST		N/A	SEATTLE	Washington	98117	King	USA	(206)555-8787 (206)555-2323 (alt)	

Emergency Contacts

Name	Primary	Address	City	State	ZIP	County	Country	Phone No.	Email Address

CTMS Financial and Coverage Analysis Data- Coming September 2021!



Sponsor invoicing and receipt tracking to facilitate good fiscal management

Coverage Analysis/Billing Grid: Interfaced to Epic to facilitate compliant research billing

Charge Master: Pricing for each procedure at every hospital/clinic (cost center)

Calendar: Protocol Schedule of events for each subject including projected visit dates

How is OnCore data used?

Examples of how OnCore data is used:

- Protocol and 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 automatic subject association to support research billing review
- Protocol data supports study start-up processes & ongoing monitoring (e.g., SRC Review, low accrual monitoring)
- Dates from processes and tasks are used to visualize study startup metrics

Who has access to OnCore?

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)

Hospital Staff:

- Pharmacists
- Clinic Staff
- Ancillary Staff

Individuals/Study Teams:

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

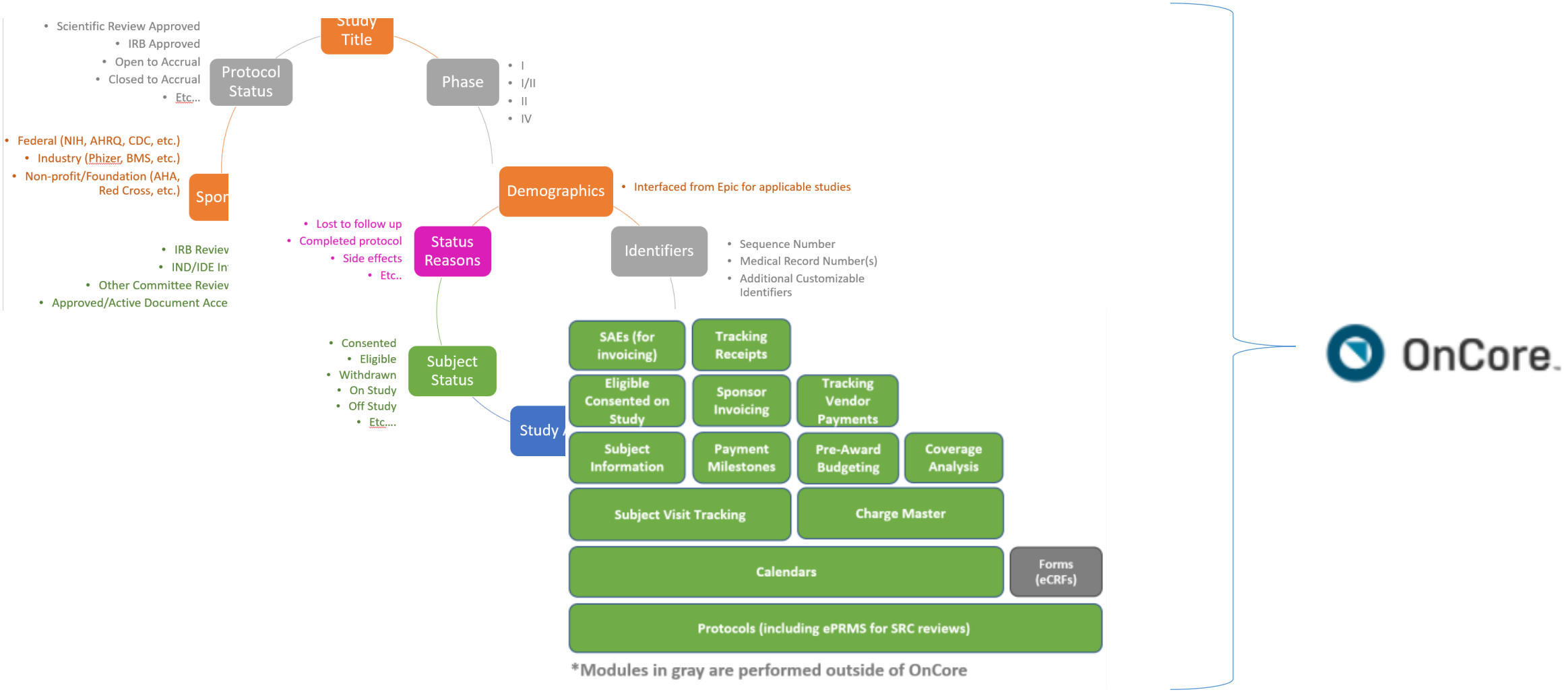
Collaboration within the study team

Poll

How big is your study team?

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

Extensive data in one location paves the way for collaboration



Collaboration within a study team – Scenario 1

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

- Enters IRB Initial Approval in OnCore
- Automatic notification triggered to specific study staff to trigger next steps

- Sends IRB Review invoice to sponsor when item automatically appears in finance console

- Completes required OnCore fields which triggers report for CMTS office to open to accrual

- Receives auto generated report and opens study

- Automatic Notification to specific study staff, clinics, institutional offices and Epic when study is open

Collaboration within a study team – Scenario 2

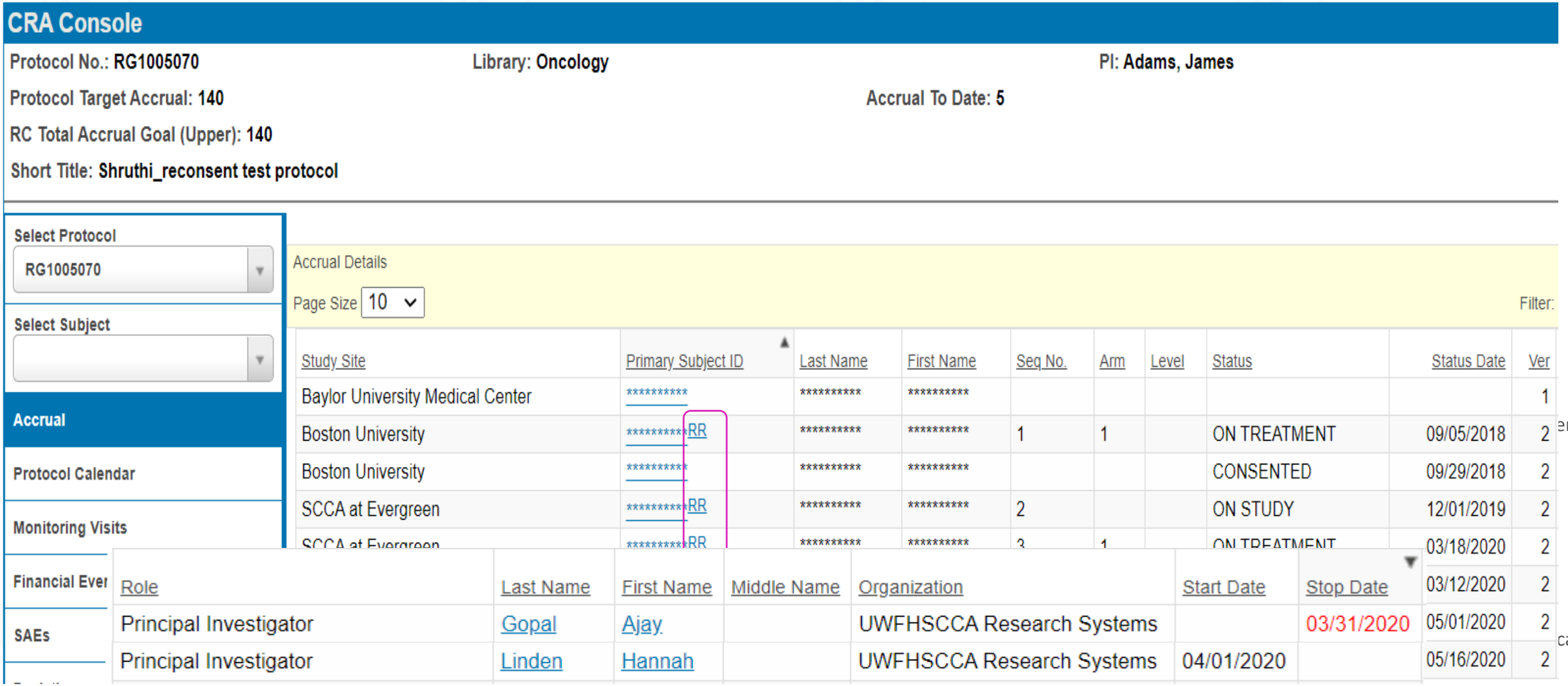
- PI Requests status report of all studies where she is a PI or sub investigator
  - Include subject statuses
  - Number of subjects ‘On Study’
  - Information about the protocols: Protocol Type, Phase, Sponsor, etc.
  - Due: Tomorrow!

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 signing consent form

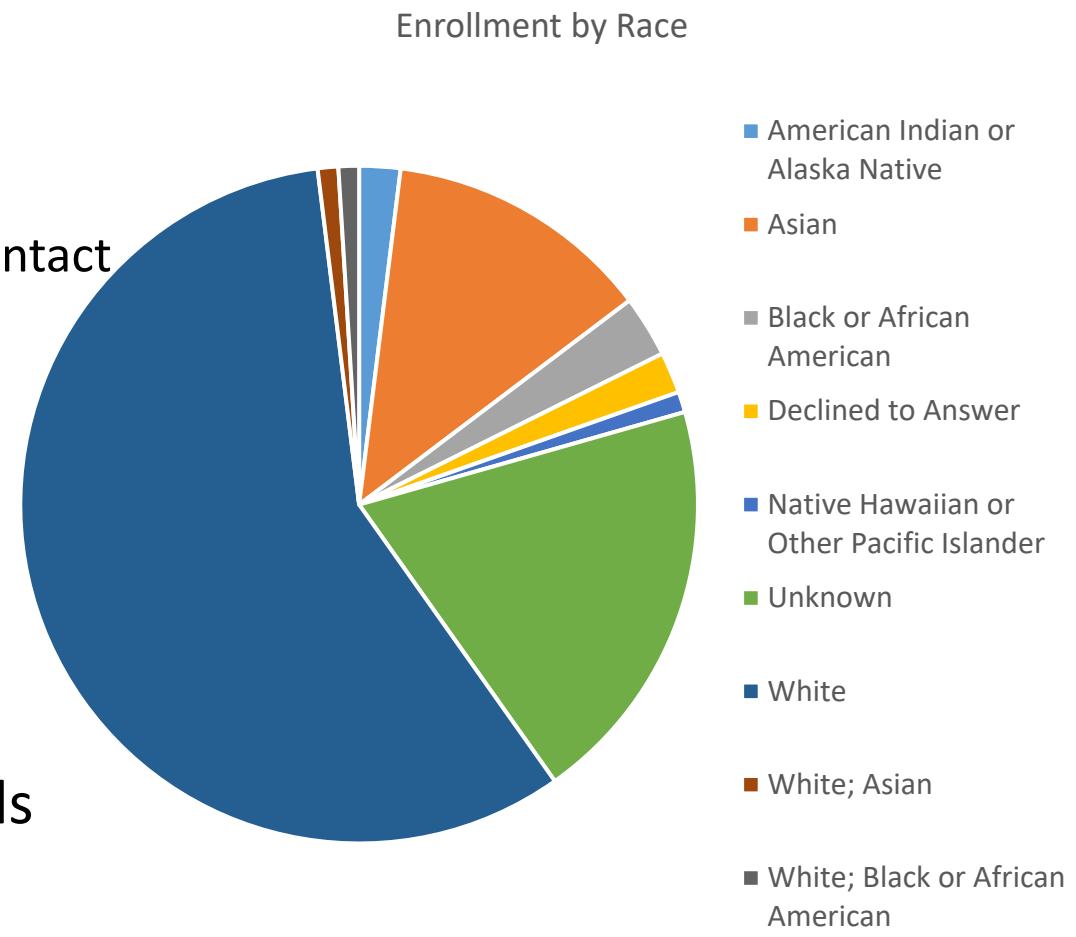
- Enters Consent information
- Automatic notification sent to Biostatistician
- Uploads randomization output to subject console documents

Other collaboration scenarios to consider



Other collaboration scenarios to consider

- **Produce subject demographic reports**
- Track the reconsent of subjects
- Track protocol staff roles, start & end dates
  - Information sent to Epic- eliminate need for clinic contact lists
- Produce IRB Activity reports
- Track IRB expirations
- Document history of protocol status
- Monitor Study Staff subject and protocols volumes to determine appropriate staffing levels



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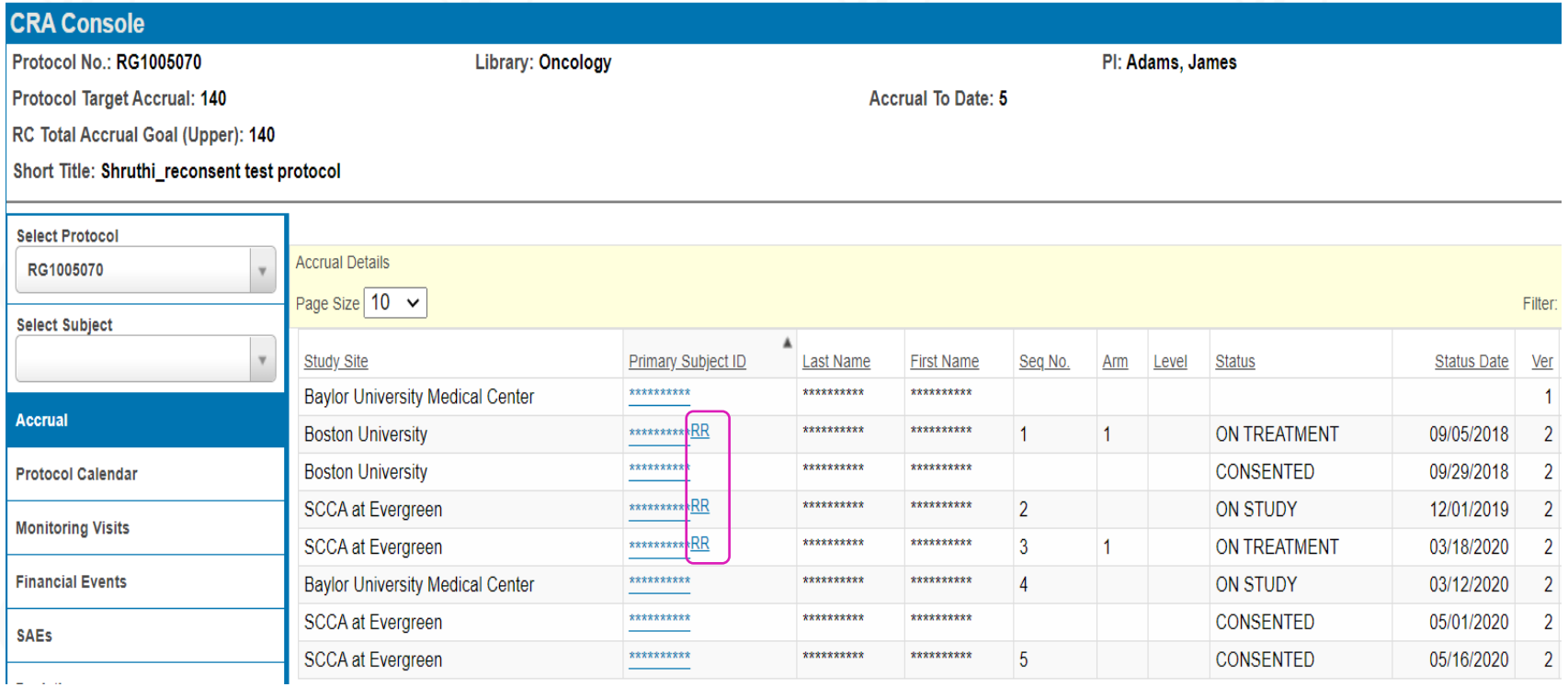

Other collaboration scenarios to consider

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Role	Last Name	First Name	Middle Name	Organization	Start Date	Stop Date
Principal Investigator	Gopal	Ajay		UWFHSCCA Research Systems		03/31/2020
Principal Investigator	Linden	Hannah		UWFHSCCA Research Systems	04/01/2020	

- Monitor S
  volumes
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How can OnCore CTMS enhance communication with hospitals and institutions?

Poll

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

A. Single Institution, One clinic
B. Single Institution, Multiple Clinics
C. 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

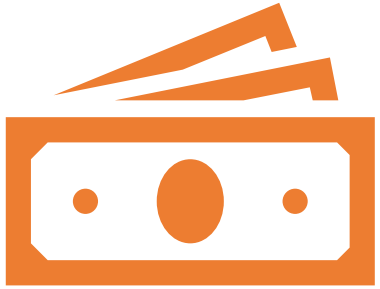
- Automated notification is sent to institution offices to communicate hold status (includes protocol info and status change reason)

- Update processes to reflect hold status

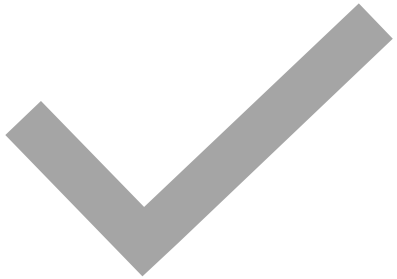
- Off Hold notification sent when startup resumes

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

Communication with Institutions – Scenario 2



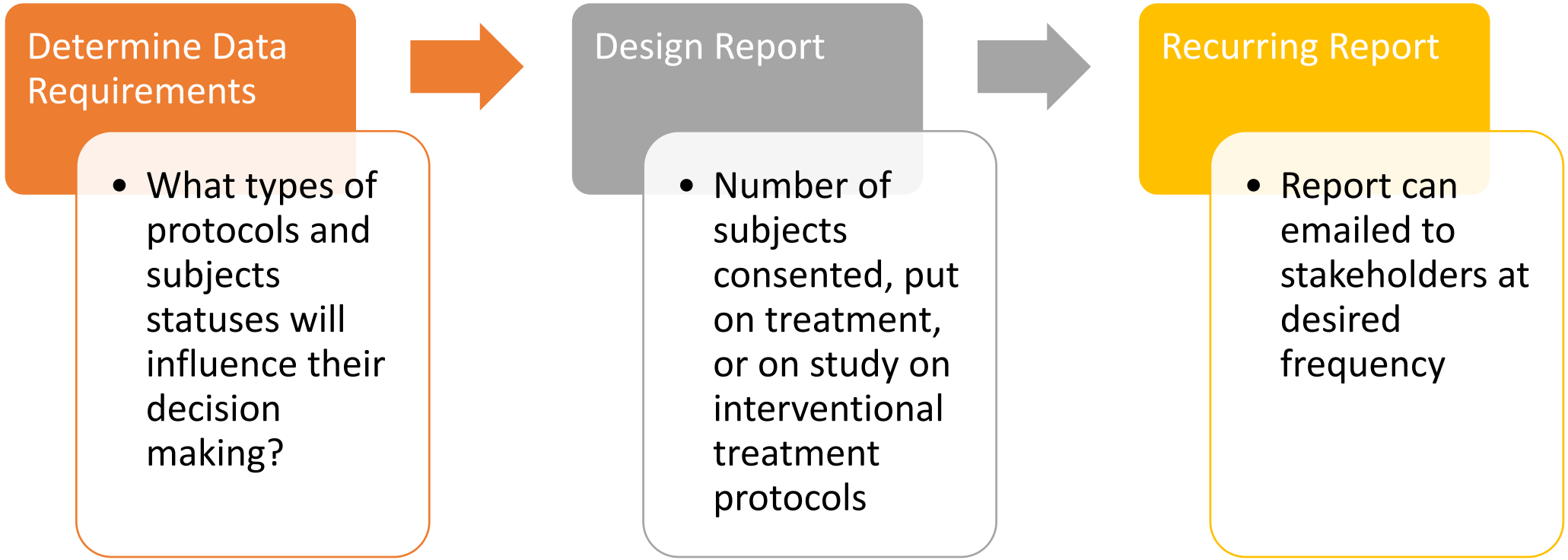
New funding opportunity released for clinical research infrastructure



Required in the funding application is a report of *institution level* data on previous trial success, enrollment breadth, etc. of a similar population

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.



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 (September 2021)

Scope Expansion

- Currently: Cancer consortium research and FH non-oncology protocols and subjects
- September 2021: UW Non Oncology protocols with Epic Billable procedures will start to transition

Calendar and Financial Functions

- 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?

CTMS@fredhutch.org

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THANK YOU!