NRG ONCOLOGY

Advancing Research. Improving Lives.™

The NCI National Clinical Trials Network (NCTN)

Changes in Rosters, Roles, OPEN and Rave after NCTN

Ravi Rajaram, Cancer Trials Support Unit (CTSU)
Darlene Kiniry, NRG Oncology

NRG Oncology Semi Annual Meeting
Chicago, IL
11 Jul 2014

Agenda

- Overview
- Network Group Organization Structure
- Participation Categories
- Crediting Rules
- OPEN
- Rave
- Person Roles
- NCTN Studies
- CTSU Website
- CIRB
- Per Case Management Funding

NRG ONCOLOGY™

NCTN Overview

The overall goal of the NCI's National Clinical Trials Network (NCTN) Program is to conduct definitive, randomized, late phase clinical treatment trials and advanced imaging trials across a broad range of diseases and diverse patient populations.

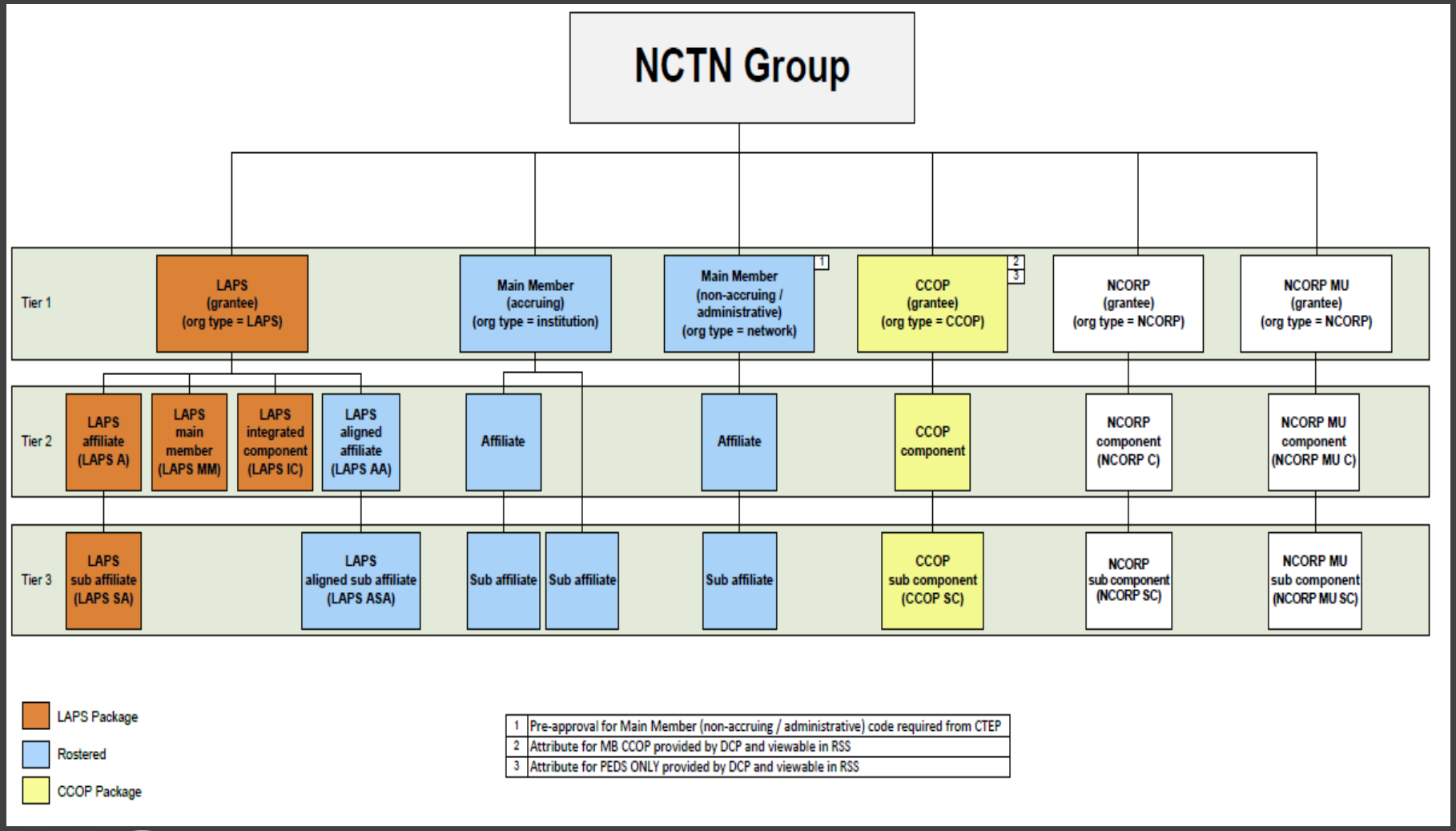
NRG ONCOLOGY™

NCTN Overview (2)

- The NCTN was launched on March 3, 2014.
- The Network now consists of:
  - 4 Adult U.S. Network Groups
  - 1 Pediatric U.S. Network Group
  - 1 Canadian Network Group
- LAPS – Lead Academic Participating Site
  - Separate grants.
  - Academic institutions that provide scientific leadership in the development and conduct of clinical trials as well as substantial accrual to clinical trials conducted across the entire Network.

NRG ONCOLOGY™

Network Group Structure



NRG ONCOLOGY™

Participation Categories

Sites are able to participate in one of 3 mutually exclusive ways with the exception of some pediatric sites. Sites may be members of multiple Network Groups with varying types of membership but the NCTN component must remain the same across all Groups.

NCTN Component	Component Tiers/Membership
Lead Academic Participating Sites (LAPS)	• LAPS Main Member • LAPS Integral Component • LAPS Affiliates/Sub-Affiliates • LAPS Aligned Affiliates/Sub Affiliates (funded by Network Group)
CCOPs/MB-CCOPs (NCORPs/NCORP MUs)	• CCOP/NCORP Component • CCOP/NCORP Sub-Component
Adult Network Group OR Pediatric Network Group	• Main Member • Affiliate • Sub-Affiliate • Main Member

NRG ONCOLOGY™

Crediting Rules

- US sites may credit any participating Network Group to which the site and credited investigator are affiliated and participating on the protocol.
- Canadian sites must credit the NCTN Group that holds the CTA.
- International sites must credit the Lead Protocol Organization (LPO) if they are a member of the LPO.
- International sites that are not members of the LPO must receive approval from their credited Group and consistently credit the same Group for the protocol.

NRG ONCOLOGY™

Oncology Patient Enrollment Network (OPEN)

- All NCTN trials, including active legacy trials (defined as trials open prior to the start of the NCTN), use OPEN for enrollment.
- Pre-NCTN OPEN roles were retained if the institution is an active participant in the NCTN.
- OPEN will be used to document requirements for additional reimbursements for correlative, QOL and supplemental funds, when required.

NRG ONCOLOGY™

OPEN Access

Site users must have <u>all</u> the following to access OPEN:

- ✓ Active CTEP-IAM account
- ✓ Active treatment roster status on a Network Group roster
- ✓ Active Registrar role on a Network Group roster
- ⊗ CTSU Roster no longer controls access

OPEN Oncology Patient Enrollment Network

NRG ONCOLOGY™

Rave

- All new trials in the NCTN will be using Rave for data collection.
- Active legacy trials continue to use the data collection mechanism used prior to the NCTN.
- Pre-NCTN Rave roles were retained if the institution is an active participant in the NCTN.

NRG ONCOLOGY™

Rave Access

Site users must have all of the following to access Rave:

- ✓ Active CTEP-IAM account
- ✓ Active or follow-up treatment roster status on a Network Group roster
- ✓ Active Rave role on a Network Group roster
- ⊗ CTSU Roster no longer controls access

NRG ONCOLOGY™

Rave Access

- A number of users may have received additional Rave Invitations for studies as access rights now look across organizations.

- Invitations may be managed by taking one of the following actions:
  - Accept the invitation in iMedidata.
  - Decline the invitation in iMedidata (*this action is not recommended if access may be needed in the future as manual intervention will be needed to regain access*).
  - Ignore the invitation until access need is determined.
  - Adjust Rave roles in the roster by withdrawing the institutional Rave roles from persons at the site and reassigning the Rave roles to each person at the protocol level.

NRG ONCOLOGY™

Access Paradigm

- OLD (Pre NCTN)
  - For **OPEN and Rave,** access was controlled by the LPO roster for sites that were members of the LPO and by the CTSU roster for cross-group participants
  - **CTSU Website:** All persons that were members of the CTSU could view protocol documents for the Cooperative Group studies.
- NEW (NCTN)
  - For **OPEN and Rave,** the LPO and Participating Organization (PO) rosters control access.
  - **CTSU Website:** All Persons must be members of a LPO or PO roster to view the protocol documents.

NRG ONCOLOGY™

Person Roster Rules

- All persons must have a CTEP ID assigned through the Investigator Registration Process for MDs and DOs or CTEP-IAM for associates.
- All Persons must re-register with CTEP annually to maintain their roster status.
- Persons must be linked to a clinical site or administrative organization.
- Access to protocols, OPEN, and Rave is controlled by the LPO and Participating Organization (PO) rosters.

NRG ONCOLOGY™

Adding Persons and Roles

Event	Type of Site	System
Add Person	CCOP/NCORP	CCOPSYS
Withdraw Person	CCOP/NCORP	CCOPSYS
Add Person	LAPS	Contact Group**
Withdraw Person	LAPS	Contact Group**
Add Person	Rostered Site (MM/Affiliates)	Contact Group**
Withdraw Person	Rostered Site	Contact Group**
Add Primary Role*	All	Contact Group**
Add Non-Primary Role	All	Site Roles (CTSU website)

** Primary roles are defined as those that cannot be added through Site Roles*
*** By Fall 2014, this can be done via CTSU Website using the Roster Update Management System (RUMS)*

NRG ONCOLOGY™

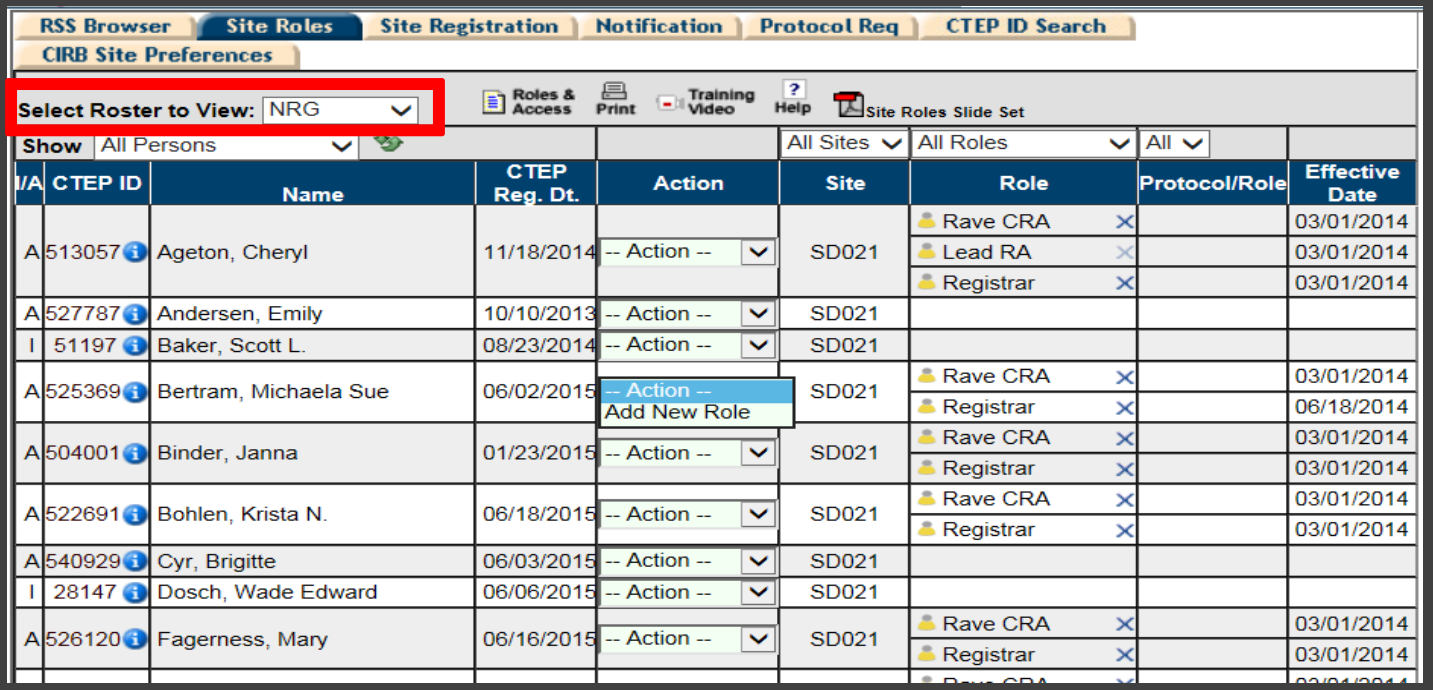
Standard Roles

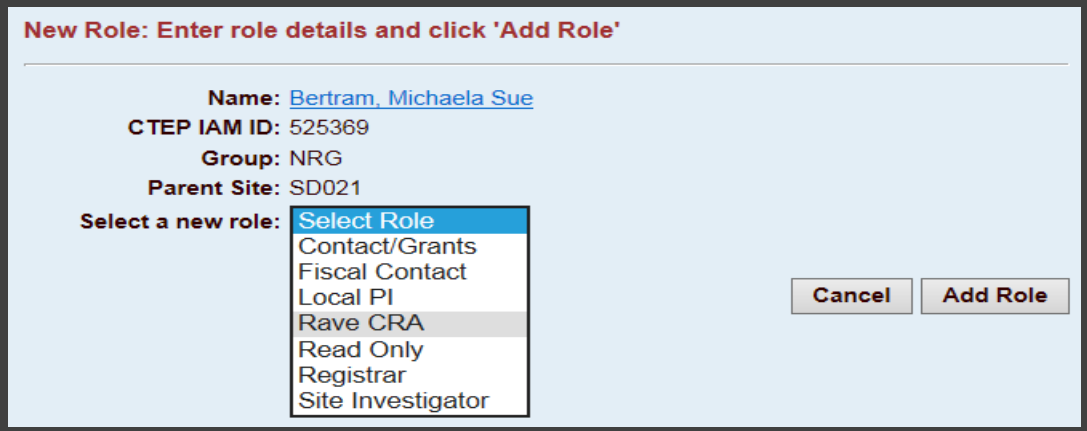
System	Role for all Rosters
Rave	Rave CRA, Read Only, Site Investigator, CRA (LabAdmin), SLA
OPEN	Registrar
TRIAD	Site User (maintained on the CTSU roster)

- Select roles can be maintained from the Site Roles tab for all NCTN groups.
- Rules for roles maintenance vary by NCTN Group.
- For NRG, the Lead RA, Co-Lead RA, and Local Lead RA can add roles.
- Resources on the Site Roles tab include a Roles & Access table and updated Help document.

NRG ONCOLOGY™

Managing Site Roles





NRG ONCOLOGY™

NRG Roster Rules (1)

Sites	Roles	Access
LAPS and CCOP (Tier 1)	Lead RA Co-Lead RA LAPS PI Check Addressee Fiscal Contact Grants Contact PI Contact PI	Site Roles Application Site Roles Application
LAPS and CCOP (Ties 2 and Tier 3)	Local Lead RA Local PI Rave CRA Read Only Registrar Site Investigator	Site Roles Application RAVE RAVE OPEN RAVE

NRG ONCOLOGY™

NRG Roster Rules (2)

Sites	Roles	Access
Main Members	Lead RA	Site Roles Application
	Co-Lead RA	Site Roles Application
	Check Addressee	
	Fiscal Contact, Grants Contact	
	PI, Contact PI	
	Rave CRA	RAVE
	Read Only	RAVE
	Registrar	OPEN
	Site Investigator	RAVE
Affiliates and Sub-affiliates	Local Lead RA	Site Roles Application
	Local PI	
	RAVE CRA	RAVE
	Read Only	RAVE
	Registrar	OPEN
	Site Investigator	RAVE
Main Member Follow Up Only	Lead RA	Site Roles Application
	PI, Contact PI	
	Fiscal Contact	
	RAVE CRA	RAVE
	READ Only	RAVE
	Site Investigator	RAVE

NRG ONCOLOGY™

Studies Available in the Network

- All phase 3 studies.
- All phase 2/3 studies.
- All phase 2 for which CTEP holds the IND.
- Selected other phase 2 studies with CTEP approval.
- Selected AYA studies with CTEP approval.
- Other Networks' studies may be available with CTEP approval.

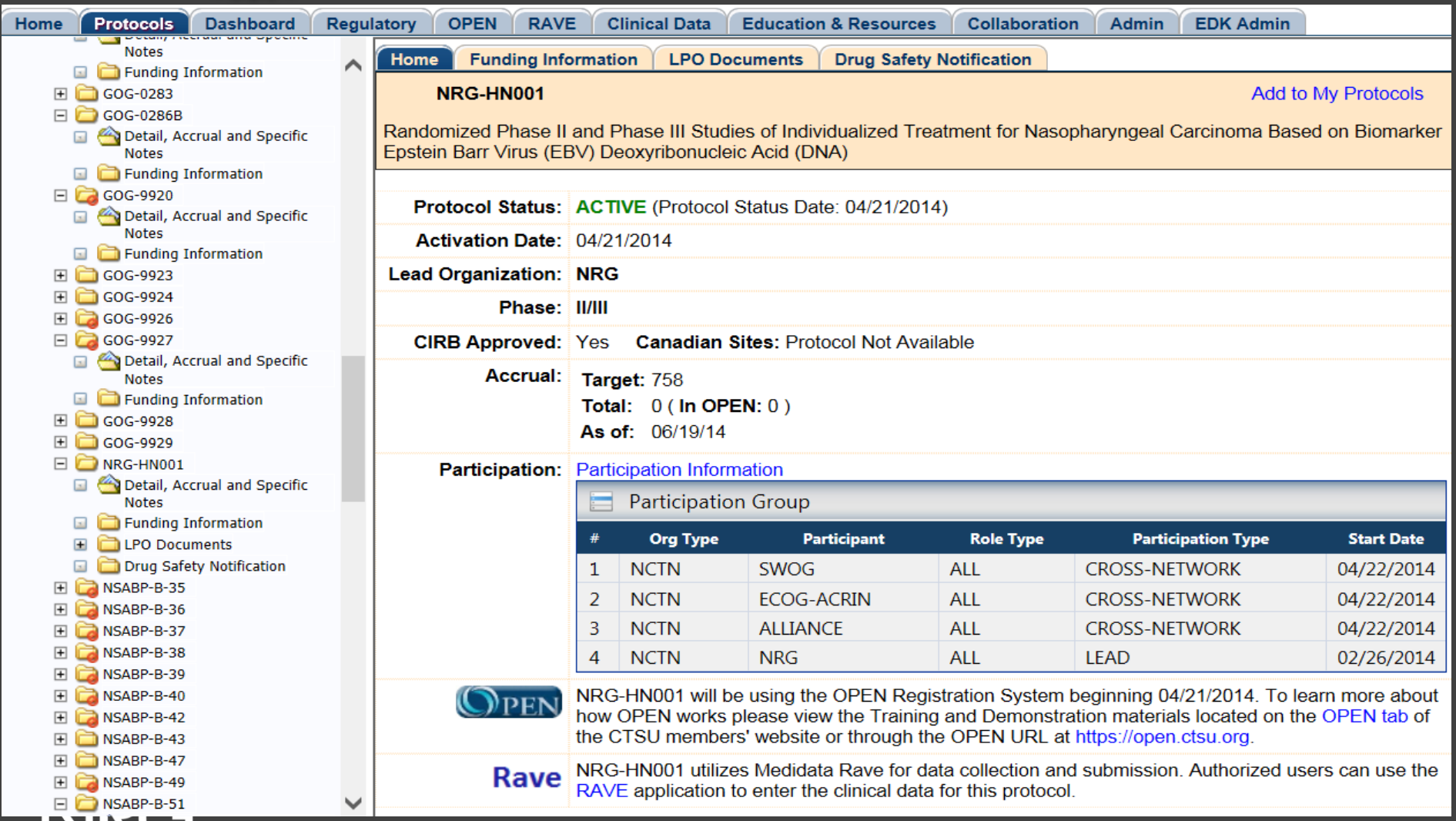
NRG ONCOLOGY™

CTSU Website New Protocol Screens

- Home Tab - a quick glance of protocol basics, including protocol status, accrual information, participation information and more.
- Funding Information Tab - contains all funding associated with a protocol (for all NCTN protocols).
- LPO Documents Tab - contains the protocol and all associated documentation, (formerly named “documents”).
- Drug Safety Notifications Tab - contains all DSNs for drugs associated with the protocol.

NRG ONCOLOGY™

NEW Protocol Screens (2)



NRG ONCOLOGY™

NCI Central Institutional Review Board (CIRB)

- All U.S. Institutions/Sites participating in NCTN trials as a member of one or more Network Groups will be required to use the NCI CIRB as the IRB of record in the future.
  - More information on timelines for joining the CIRB and the waiver process will be released later this year.

- A waiver will only be granted if it can be demonstrated that an institution's local IRB is able to review studies in a similar time-frame.

  - The waiver process for a site to be exempt from using the CIRB will be established in late 2014.

NRG ONCOLOGY™

NCI CIRB Independent Model Sites

- In June CTSU has started receiving the CIRB approvals electronically from CIRB.
- Starting soon institutions utilizing the CIRB will no longer be required to send documentation of initial, continuing and amendment reviews to the CTSU.
- The CTSU is able to process an institution's CIRB approvals by:
  - Verifying the institution is on the CIRB's roster in RSS.
  - Using a new CTSU Site Preference feature on the CTSU website to record which CIRB Institutions are participating in a CIRB approved trial (Phase 2 of the implementation).
- Information on the transition was released in the CTSU BI-monthly broadcasts in June and July.
- Educational material is now available on the CTSU webpage

NRG ONCOLOGY™

Per Case Management Funding

- The NCTN trials will follow NCI's CTEP per case management funding principles for cancer treatment and advanced imaging trials.

- NCI's DCP grant provides funding for quality of life endpoints, cancer control and cancer prevention studies.

- Funding for trial activities fall under one of the following categories:
  - Screening for Intervention
  - Basic Intervention
  - Advanced Imaging
  - Biospecimen Collection
  - Special (complex or rare disease trials)
  - Quality of Life (NCI DCP's grant covers this funding)
  - Non-NCI/DCTD Funding (e.g., Industry)

NRG ONCOLOGY™

How Sites Receive Funding

- NCI Funds
  - NCI per case management funds are provided to all NCTN sites enrolling patients onto NCTN trials via one of 3 NCI funding mechanisms:
    1. NCTN Group rostered sites including the Non aligned affiliates
    2. NCTN LAPS (Lead Academic Participating Sites)
    3. CCOPs/MB-CCOPs (future NCORPs)

- Non NCI Funds
  - Non-NCI funding obtained by the Network Groups to supplement trial support is dispersed to all of the 3 categories of sites by the Lead Group.

  - All non-NCI funding is available to any site that meets the specific requirement for the study and is tracked by the Lead Group; therefore, no OPEN steps are needed to trigger these funds.

NRG ONCOLOGY™

How Sites Receive Funding (2)

- NCI per case management funding will be made by the Network Group credited with the accrual or the equivalent will be provided via NCTN LAPS grant or CCOP grant directly.

- To receive per case funding for specific tests and/or biospecimen submissions, completion dates must be entered in the OPEN 'funding module' post enrollment.

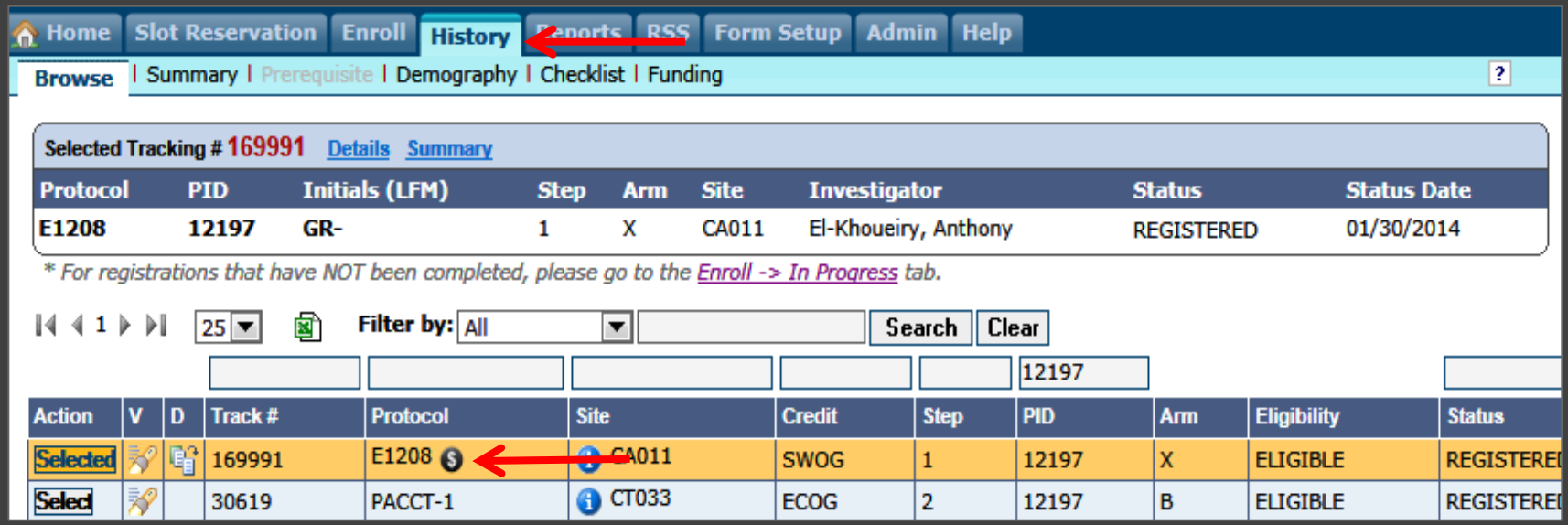
- Completion dates for biospecimens should be the date the specimen was sent out. Entry of the completion date for QOLs is only required one time.

- DCP's CCOP/NCORP funding is provided by credits and is inclusive of all trials components, unless otherwise noted.
  - More details are available at the protocol funding tab on the CTSU website for study specific information.

NRG ONCOLOGY™

OPEN Funding Screen

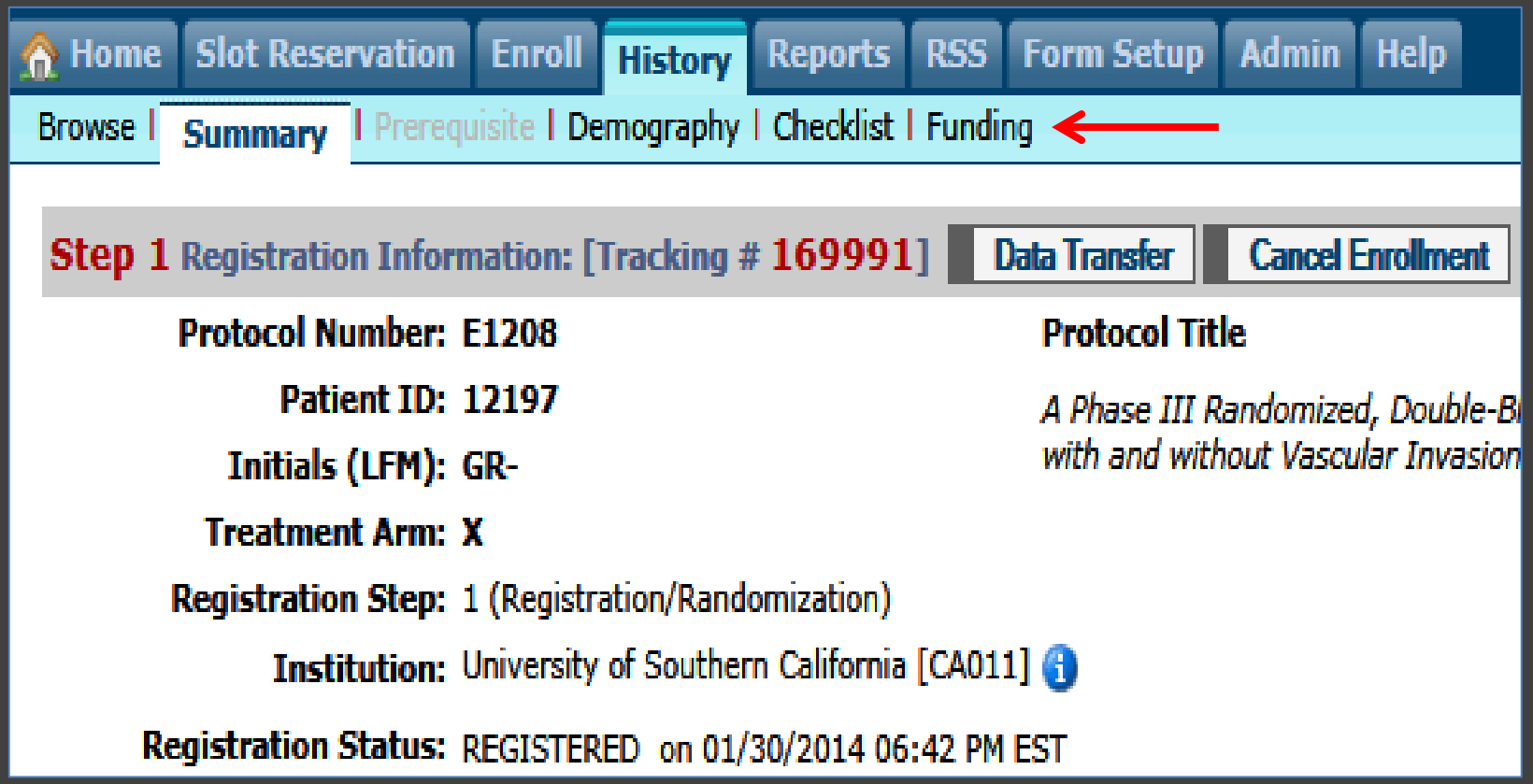
- To enter the data needed to trigger funding in a trial, click the history tab & search for the Patient ID (PID) associated with the enrollment. Enrollments with additional funding will have a '$' icon next to the protocol number. Click on 'select' next to the patient enrollment with the required PID. The summary screen will be displayed.



NRG ONCOLOGY™

OPEN Funding Screen (2)

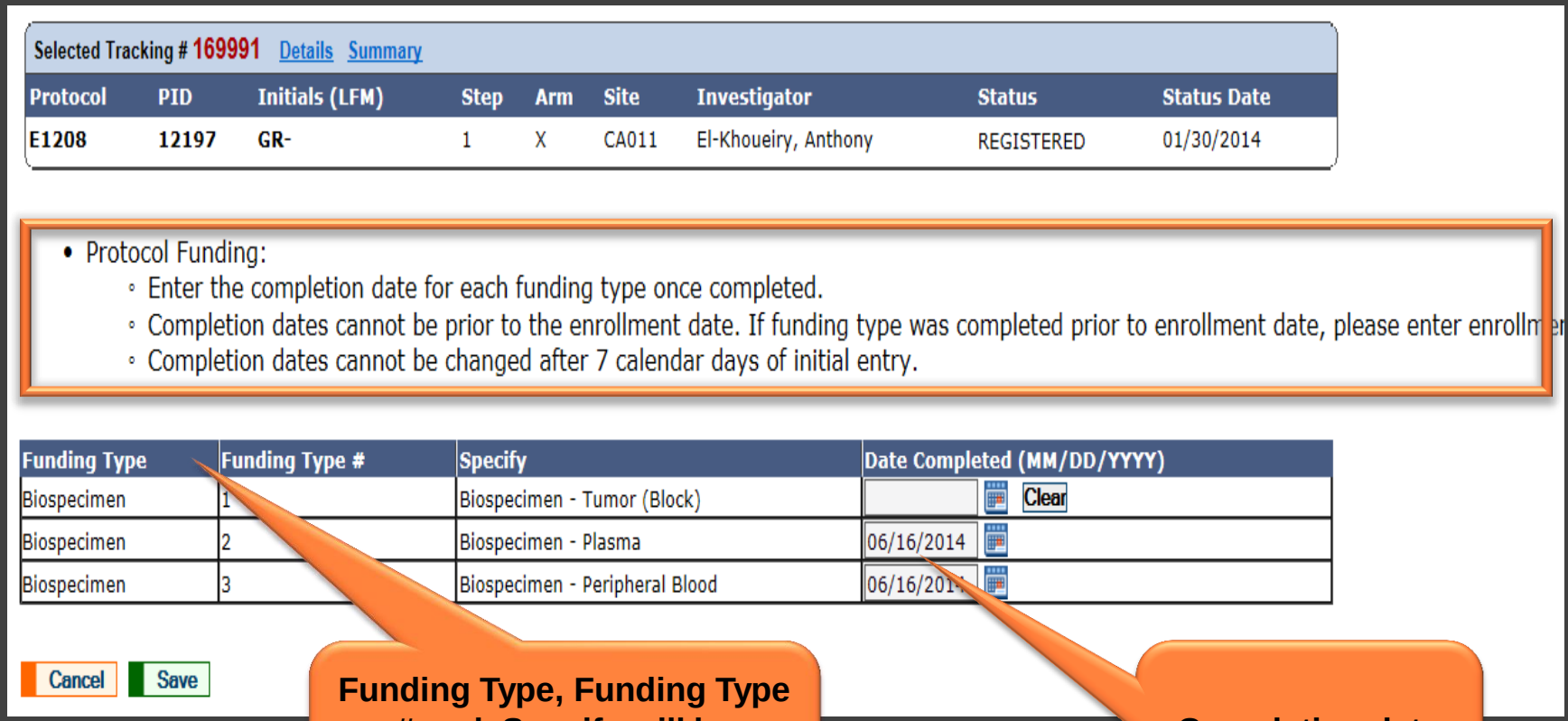
- Click on the Funding sub tab at the top of the screen.



NRG ONCOLOGY™

OPEN Funding Screen (3)

- The enrollment data will be displayed at the top and a funding table will be populated with each of the funding types available.



Selected Tracking # 169991 Details Summary

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
E1208	12197	GR-	1	X	CA011	El-Khoueiry, Anthony	REGISTERED	01/30/2014

- Protocol Funding:
  - Enter the completion date for each funding type once completed.
  - Completion dates cannot be prior to the enrollment date. If funding type was completed prior to enrollment date, please enter enrollm
  - Completion dates cannot be changed after 7 calendar days of initial entry.

Funding Type	Funding Type #	Specify	Date Completed (MM/DD/YYYY)
Biospecimen	1	Biospecimen - Tumor (Block)	Clear
Biospecimen	2	Biospecimen - Plasma	06/16/2014
Biospecimen	3	Biospecimen - Peripheral Blood	06/16/201

Cancel Save

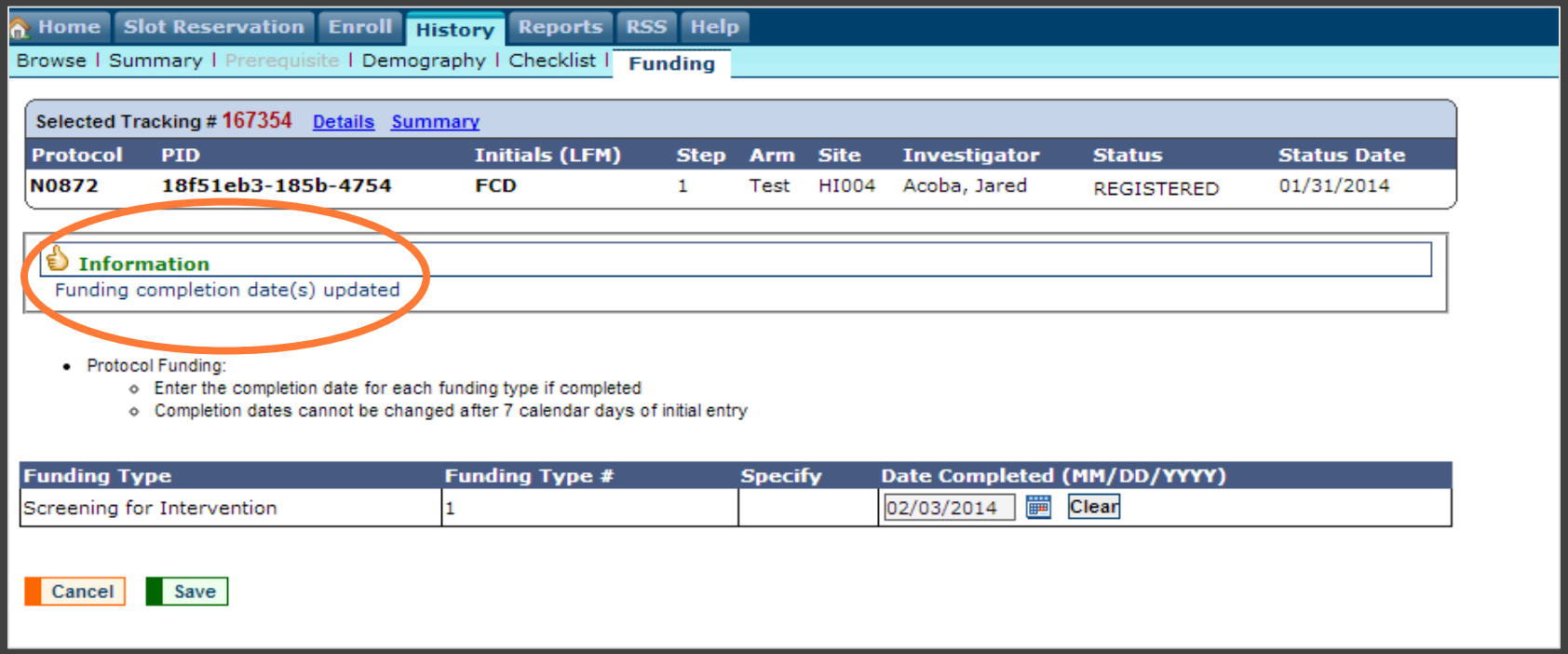
Funding Type, Funding Type # and Specify will be prefilled based on study requirements

Completion date is required

NRG ONCOLOGY™

OPEN Funding Screen Confirmation

- Multiple dates may be entered at one time or users may return to the funding screen later to enter additional dates.
- A confirmation screen will be displayed. Completion dates cannot be changed after 7 days of initial entry.



Where to Find NCTN Trial Funding Information Funding Subfolder – CTSU Website

- All NCTN protocols will have a funding subfolder on the CTSU website with a funding table and link to a funding sheet.
- Timely entry of dates in OPEN is recommended as this will record completion for per case funding.
- Funding sheets will contain additional information about non NCI funding sources if available.

NRG ONCOLOGY™

Funding Subfolder – CTSU Website

Home | Funding Information | LPO Documents | Drug Safety Notification

S1007

Add to My Protocols

A Phase III Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less.

NCI Funding Information (other sources of funding may be available, please review the Funding Documents)

5 records

#	Funding Source	Funding Type	Funding Type #	Specify	Collect Type	$ Value	CCOP Credit	Funding Status
1	DCTD	Base Intervention			Mandatory	$2,250.00	1	ACTIVE
2	DCTD	High Performance Intervention		LAPS Intervention	Mandatory	$4,000.00		ACTIVE
3	DCTD	Biospecimen	1	Bio-specimen – Tumor (Block)	Conditional	$150.00		ACTIVE
4	DCTD	Biospecimen	2	Bio-specimen – Whole Blood	Conditional	$100.00		ACTIVE
5	DCTD	Biospecimen	3	Oncotype Dx Submission	Conditional	$250.00		ACTIVE

Funding Documents

1 records

#	Document Title	Document Date	Format	Post Date
Funding				
1	S1007 Funding Sheet		PDF	03/13/14

NRG ONCOLOGY™

Site Resources

- The CTSU Bi-Monthly Broadcast, distributed on the 8th and 22nd of each month, will continue to be the main vehicle of communication.
  - Broadcasts are delivered directly via email and posted to the CTSU website.
- The CTSU Newsletter is distributed 3-4 times a year and contains detailed updates and news on CTSU initiatives.
- Link to NCTN informational documents under the Education and Resources Tab on the CTSU Members' website.
- CTSU Help Desk - ctsucontact@westat.com
- NRG Membership - membership@nrgoncology.org
- NRG Oncology Support email- support@nrgoncology.org

NRG ONCOLOGY™

Questions?

NRG ONCOLOGY™

Legacy Studies

- Trials approved to transition to the NCTN have been updated with the new lead Network Group.
  - Protocol names and numbers did not change.

- The cover page for all legacy trials have been updated to include all of the participants approved to enroll to the trial.

- The navigation tree on the Protocols Tab of the CTSU website has been updated to include nodes for the NCTN and folders for the new Network Groups. Legacy trials (status=Not Complete)will be located under the new Network Group folder.

- All studies now have an updated financial page with information on per case reimbursement. Additional data may be collected in OPEN where required.

NRG ONCOLOGY™

Tips for Sites Entering Funding Data

- To receive site per case funding for specific tests and/or biospecimen submissions, completion dates must be entered in the OPEN 'funding screen' on, or post, enrollment.
- Completion dates for biospecimens should be the date the specimen was sent out.
- Completion dates for QOLs or any testing that is required at multiple time points are only required to be entered one time and can be the initial completion date.
- Completion dates may be entered in the OPEN funding screen for any trial component that was completed after March 1st, regardless of when the patient was enrolled to the trial.
- The instructions are also available in the funding page of the CTSU website along with PPT file for more detailed information.

NRG ONCOLOGY™