Alliance Clinical Research Professional Information Session – CTSU Website and open updates

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Agenda

1. CTSU Website Updates
    1. Protocol Tab
        - New Look
        - Funding Information
        - CIRB Documents
    2. Dashboard
    3. Regulatory Tab
        - Site Roles
        - CIRB Preferences

2. OPEN Updates
    1. Entering Funding Information
    2. Transfer and Update Module (T&UM)

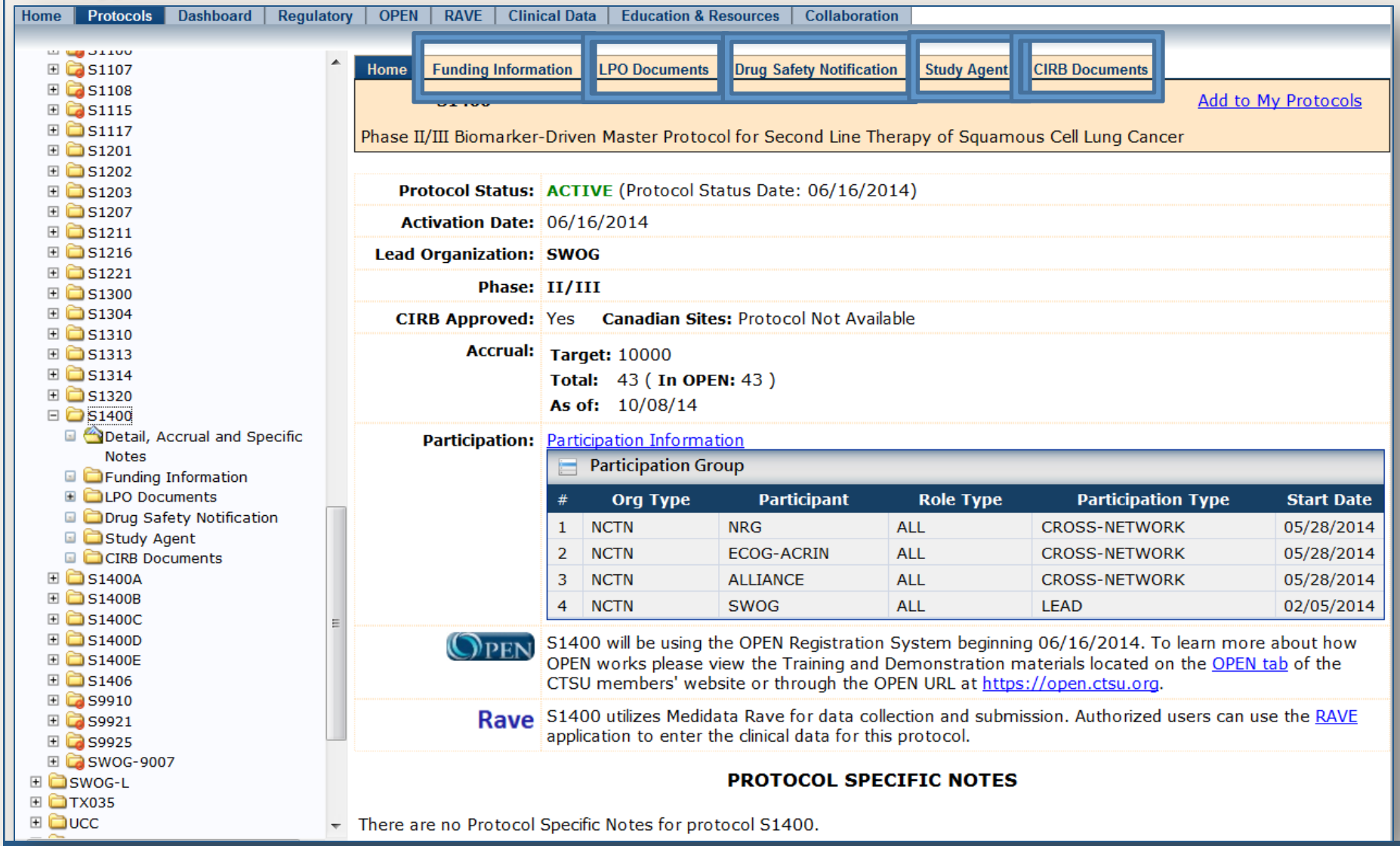

https://www.ctsu.org/public/Default.aspx?mode=ph
Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE
Contact the CTSU
Version: 6.1.3.0
IMPORTANT NOTICE
Thursday October 16, 2014 - CTSU Monthly Maintenance:
CTSU Systems staff will be performing scheduled monthly maintenance on its servers this Saturday, October 18th, between 8:00 and 11:00 AM. This Website will be unavailable intermittently during the maintenance. We apologize for any inconvenience this may cause you.
CTSU Members
Log In
Need help?
Go to the login page.
CTSU Registration Procedures
The CTSU Registration Page contains detailed information and links for Investigators and Associates to obtain access to the CTSU Members' website.
Today's Clinical Trials for Tomorrow's Cancer Treatments
WE HAVE A NEW LOOK
clinical trials for qualified clinical sites and to support the management and conduct of those clinical trials. CTSU Membership provides access to a wide range of information and support services for qualified investigators and research staff. The CTSU Registration Page provides additional details regarding member access. For those who are not CTSU Members this website provides a listing of active protocols that the CTSU supports along with links to resources for additional information on NCI-funded clinical trials.
information, and provides links to study abstracts and clinical sites that have the trial open.
Exceptional Responders Study
Now Active: The Exceptional Responders Study is a new initiative which studies the molecular characteristics of tumors of patients who had an exceptional response to a systemic cancer therapy. For more information click here.
ALCHEMIST
Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials, a set of 3 integrated, precision medicine trials testing targeted therapy in early stage lung cancer are now active. Please refer to the NCI ALCHEMIST Press Release, the
More about the Cancer Trials Support Unit
The NCI launched the CTSU in 1999 to streamline and harmonize support services for phase three Cooperative Group cancer clinical trials funded by the NCI. Since that time the scope of the CTSU has expanded to include support of multiple NCI-funded networks and clinical trials of all phases and types including cancer treatment, prevention and control, advanced imaging and correlative science studies. The CTSU collaborates with the NCI and its funded organizations to develop and support operational processes and informatics solutions leading to cost-effective solutions that reduce administrative burden on the clinical sites.
Under guidance of the NCI, the CTSU provides centralized services to support the following goals and objectives:
Facilitate investigator and research staff participation in selected NCI multi-center programs and their clinical trials.
Increase investigator and patient awareness and enrollment to cancer clinical trials.
Provide standardized, integrated, and comprehensive support services to selected NCI multi-center programs.
Identify best practices and streamline or eliminate redundant processes and procedures.
Improve operational efficiency, enhance productivity and deliver products offering measurable business value to selected NCI multi-center programs.
NCI cancer research networks supported by the CTSU include:
NCI National Clinical Trials Network (NCTN) - is a new clinical trials research network that provides an infrastructure for NCI

General Website Updates

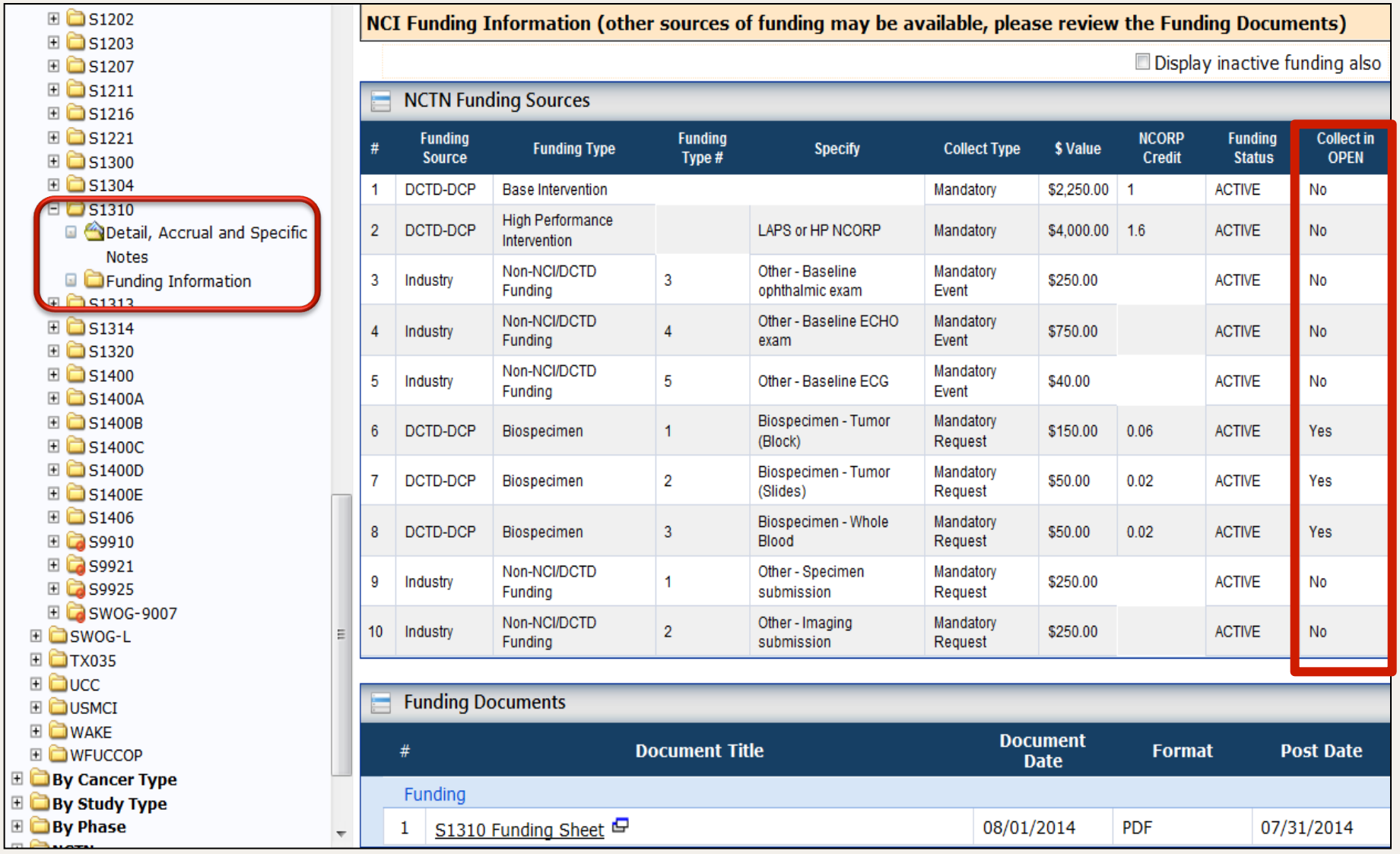
- Revised public page
- Updates to page layout and graphics (style and color) to improve visual continuity
- Updates to web page and report formats
- Updates to the underlying database structure to improve functionality

CTSU PROTOCOL SCREENS

New Protocol Screens



Funding Subfolder



CIRB Documents Tab

Home | Funding Information | LPO Documents | Drug Safety Notification | Study Agent | CIRB Documents

S1400 Add to My Protocols

Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer

CIRB Details

#	Documents used for CIRB approval
1	CIRB's Consent Form for Protocol Version Date 05/20/14: Screening
2	Protocol Version Date 05/20/14
3	CIRB's Consent Form for Protocol Version Date 05/20/14: Sub-Study A
4	CIRB's Consent Form for Protocol Version Date 05/20/14: Sub-Study B
5	CIRB's Consent Form for Protocol Version Date 05/20/14: Sub-Study C
6	CIRB's Consent Form for Protocol Version Date 05/20/14: Sub-Study D
7	CIRB's Consent Form for Protocol Version Date 05/20/14: Sub-Study E

Initial Reviews | **Amendment Reviews** | Continuing Reviews

Amendment Review Documents

CIRB Approval- Recruitment/Patient Education Materials- Lung-MAP Website

CIRB Applications	
1	CIRB Amendment Application (Protocol Version Date 05/20/14)
Correspondence	
1	07/25/14: CIRB Approval Letter for Recruitment/Patient Education Materials: Lung-MAP Website
2	07/23/14: Study Chair Response Memo: Lung-MAP Website
3	07/18/14: CIRB Approval Pending Modification for Recruitment/Patient Education Materials: Lung-MAP Website
Minutes	
1	Minutes - Recruitment Material Review: Lung-MAP Website (Protocol Version Date 05/20/14)

DASHBOARD

CTSU Website Dashboard

- The CTSU website is growing larger day by day due to:
  - Increasing number of protocols
  - New integrations such as the CIRB Integration
  - New funding folders for all protocols
- There was a need for site users to have a single place to view user-centric data & access systems under the CTEP Federation (applications using single sign-on)

Paradigm Shift From

Protocols tab

Regulatory tab

Clinical Data tab

OPEN tab

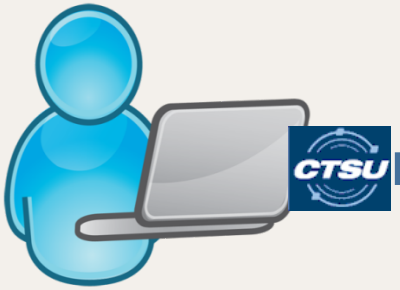
RAVE tab

medidata Rave

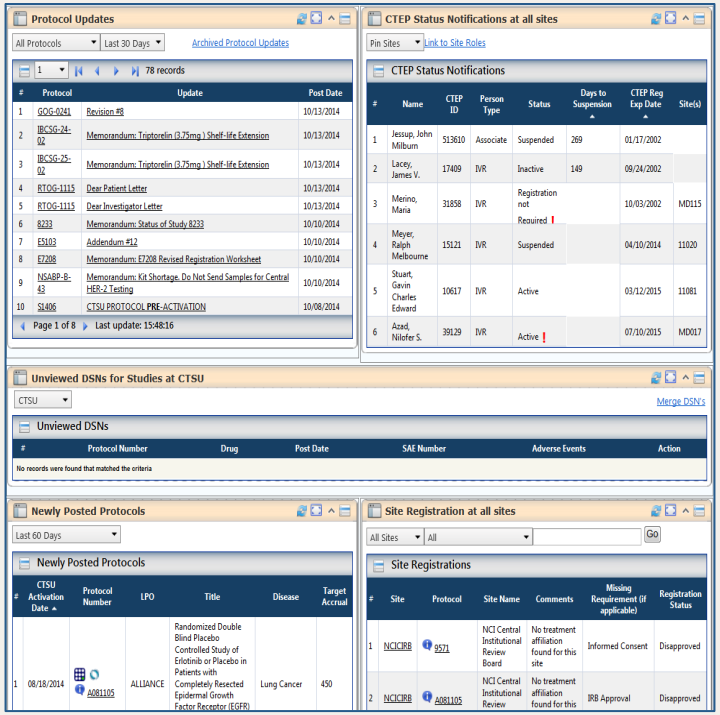
OPEN

Paradigm Shift To

With CTSU Dashboard



User-centric



Protocols tab

Regulatory tab

Clinical Data tab

OPEN tab

RAVE tab

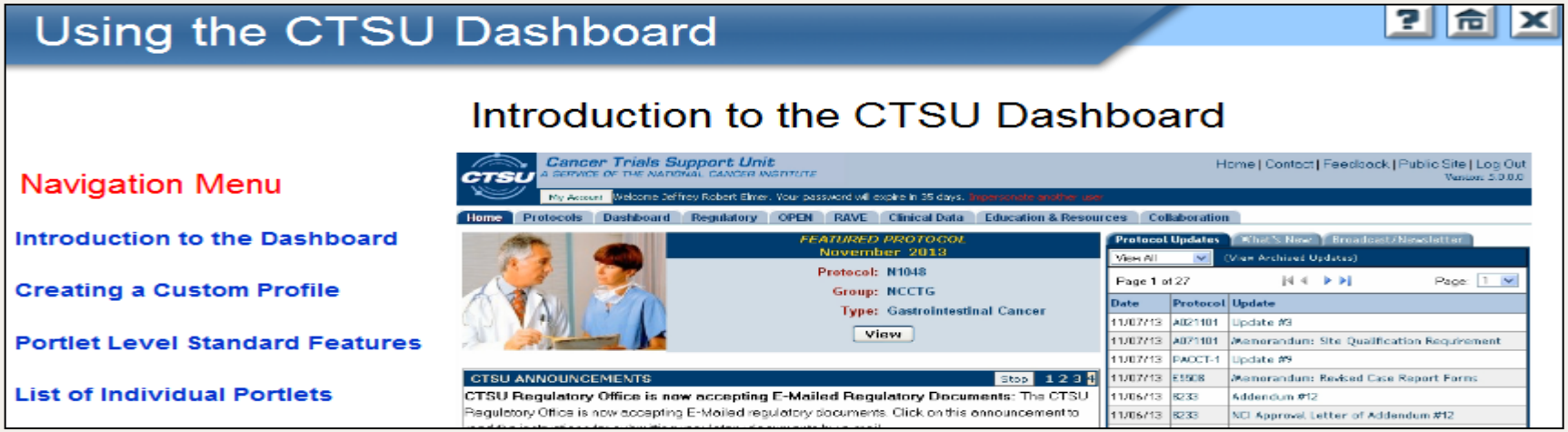
OPEN

medidata Rave

How do I set up my Dashboard?

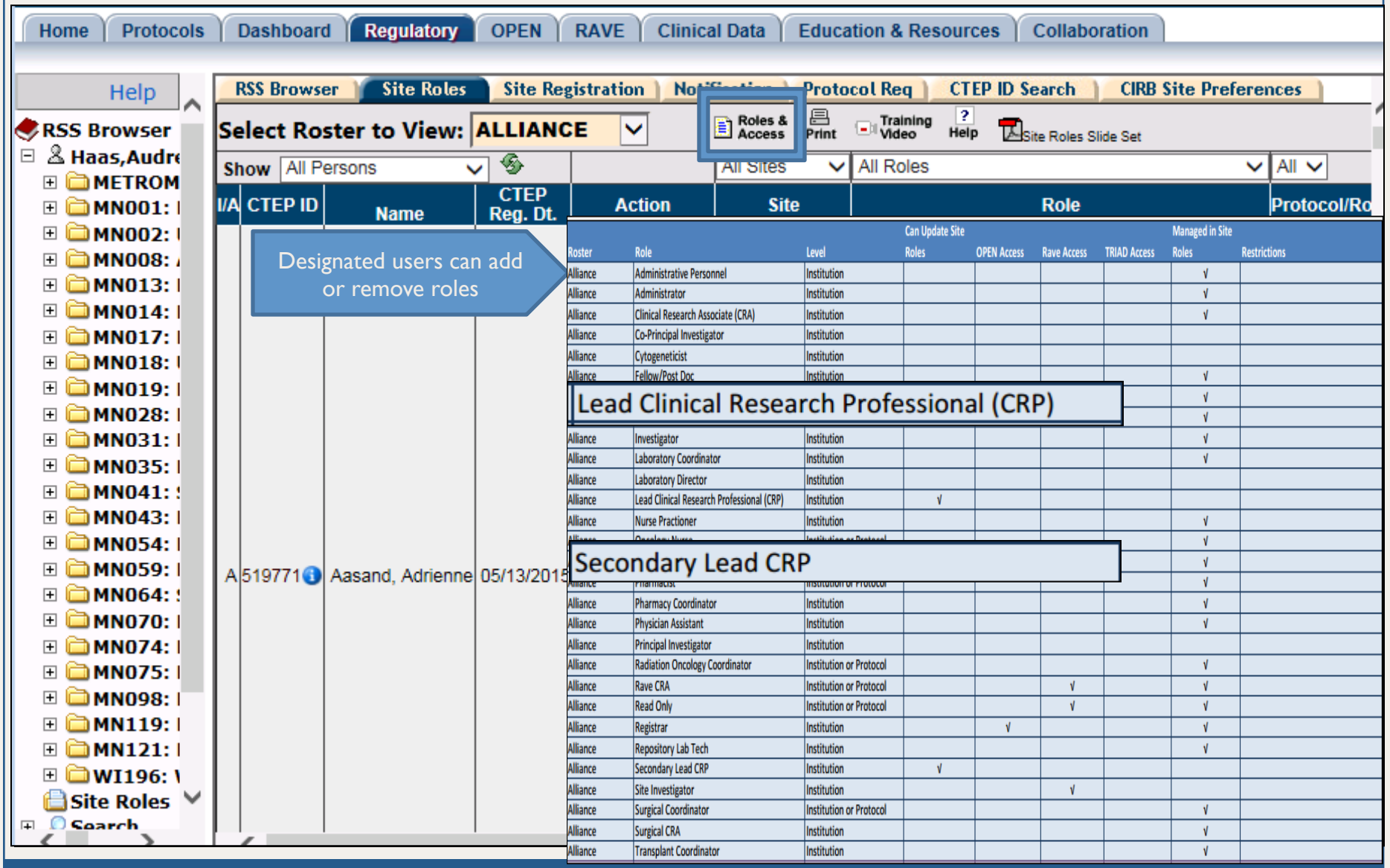
- Video Tutorial is available on the website

Click to open CTSU website tutorial in a separate window



REGULATORY TAB – SITE ROLES AND CIRB INTEGRATION

Site Roles Sub Tab



CIRB Integration

- Sites will be required to use CIRB unless a waiver is granted; information on use of the CIRB and the waiver process will be released at a later date
- Sites currently participating with the CIRB and accepting CIRB oversight for protocols no longer need to send acknowledgement of CIRB approval to the CTSU Regulatory Office
- Sites should contact the CTSU Regulatory Office at CTSURegPref@ctsu.coccg.org to set Site Preferences
- Site Preferences can be set at the network level (adult/ pediatric) and by CIRB site type (all, Signatory, per site, or per protocol)

CIRB Site Preference Screen

RSS Browser | Site Roles | Site Registration | Notification | Protocol Requirements | CTEP ID Search | CIRB Site Preferences

Instructions

The CTSU loads and maintains site preference settings for CIRB Signatory Institutions. You are viewing the site preference settings provided by your Signatory Institution to the CTSU.

If you are aligned to more than one Signatory Institution, use the drop-down to select a Signatory Institution. To view the specifics loaded for a particular site preference setting, click the setting name.

If you wish to change any of these settings, call or email the CTSU Regulatory Office at 1-866-651-CTSU (2878) or CTSURegPref@ctsu.coccg.org

See Help for additional information on the Site Preference application.

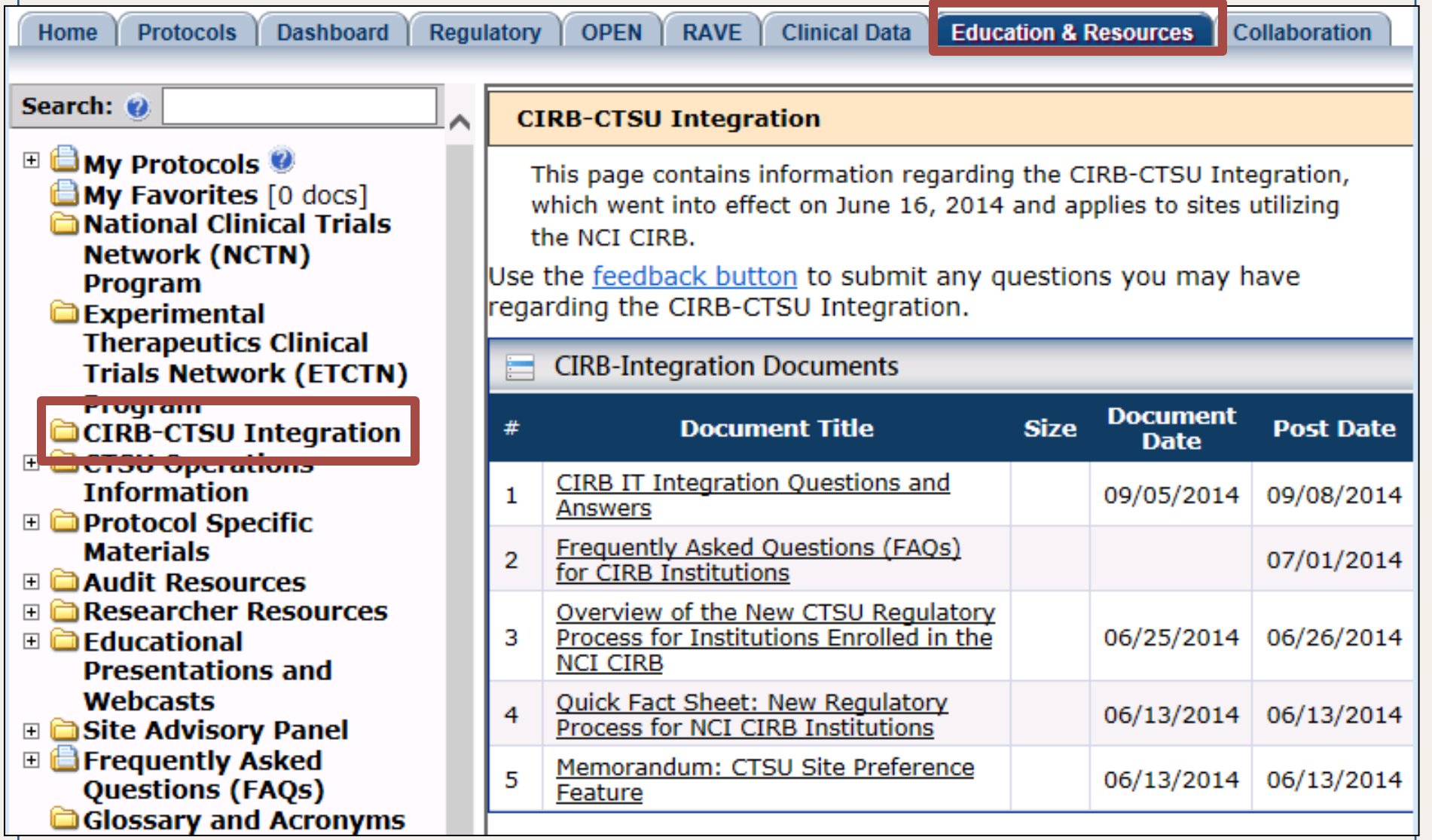
To view the CIRB Affiliate and Component Institutions on the CIRB roster in RSS that are affiliated with your Signatory Institution click the "i" button.

Signatory Institution: WA008 Help

Fred Hutchinson Cancer Research Center

#	Network Level	Preference Settings
1	ETCTN LAO	ALL SIGNATORY ONLY SITE SPECIFIC PROTOCOL NONE
2	ETCTN P2C	ALL SIGNATORY ONLY SITE SPECIFIC PROTOCOL NONE
3	NCTN Adult	ALL SIGNATORY ONLY SITE SPECIFIC PROTOCOL NONE
4	NCTN Pediatric	ALL SIGNATORY ONLY SITE SPECIFIC PROTOCOL NONE

NCI CIRB Educational Material



OPEN – PER CASE MANAGEMENT

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 Funding (e.g., Industry)

How Sites Receive Funding

- 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 or NCORP grants
- DCP's NCORP funding is provided by credits and is inclusive of all trials components, unless otherwise noted; please refer to the protocol funding tab on the CTSU website for study specific information
- OPEN is being used to capture the funding triggers for the Adult NCTN Trials

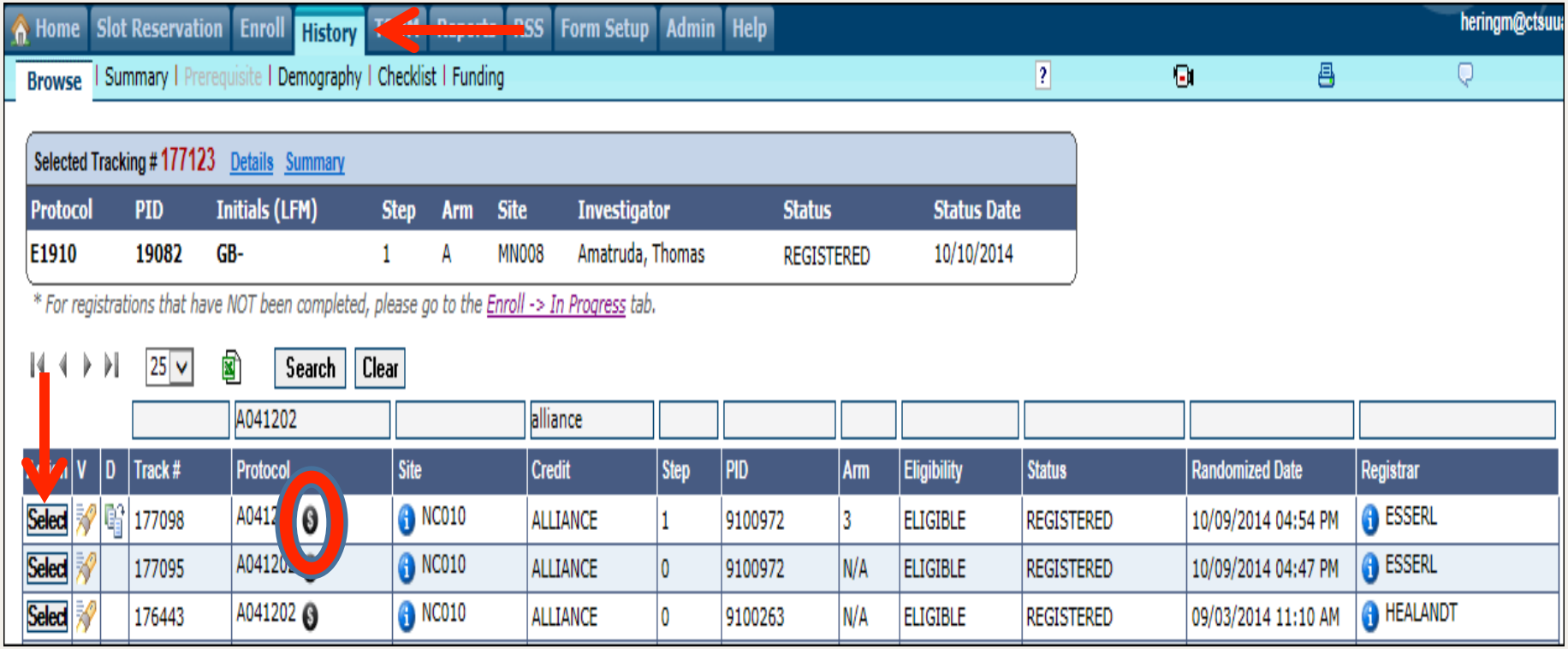
How Sites Receive Funding

Non-NCI Funds

- Non-NCI funding obtained by the Network Groups to supplement trial support is dispersed to sites by the Lead Group *(directly or through credited 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

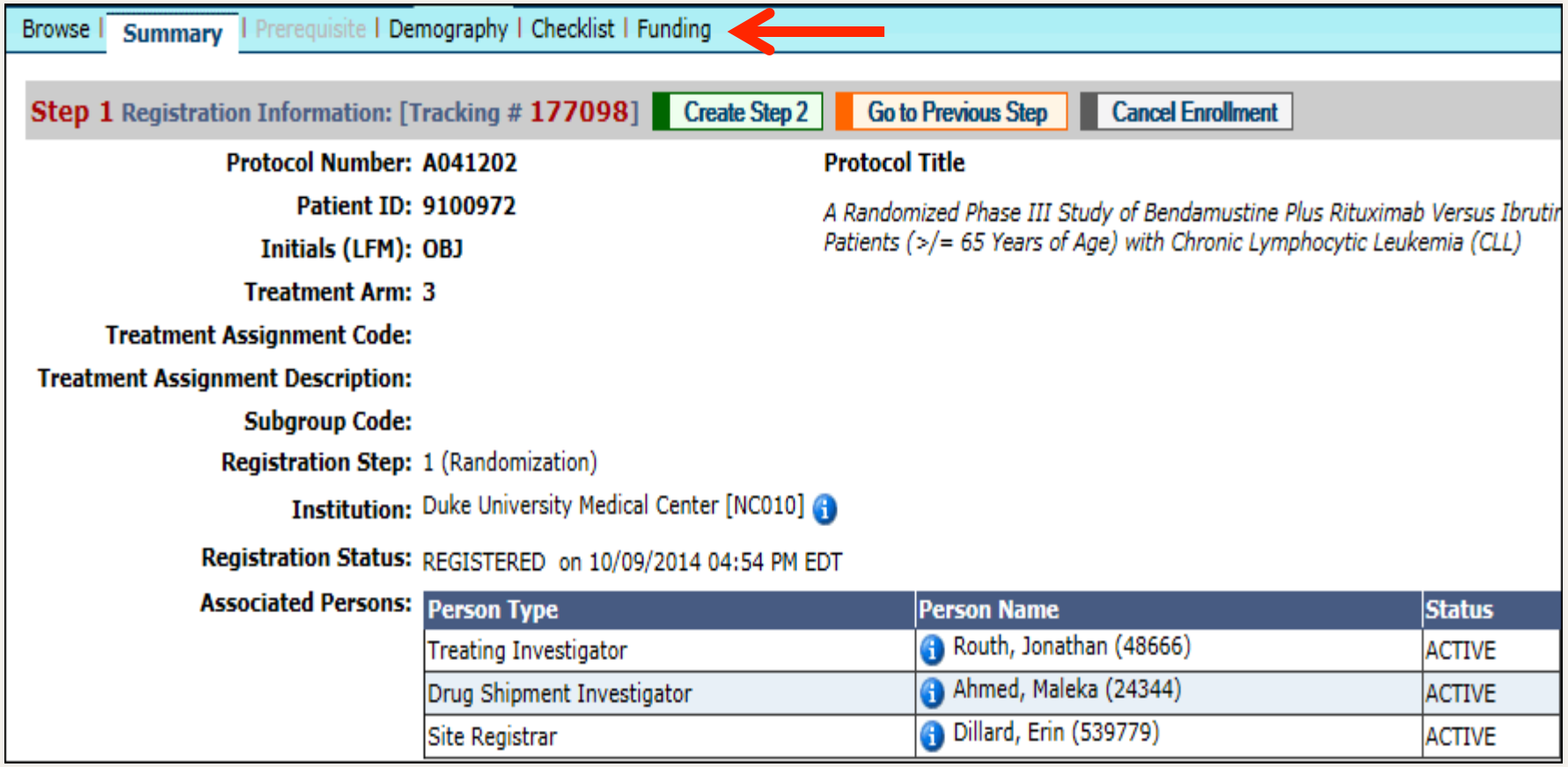
OPEN Funding Screen

To enter funding data, 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.



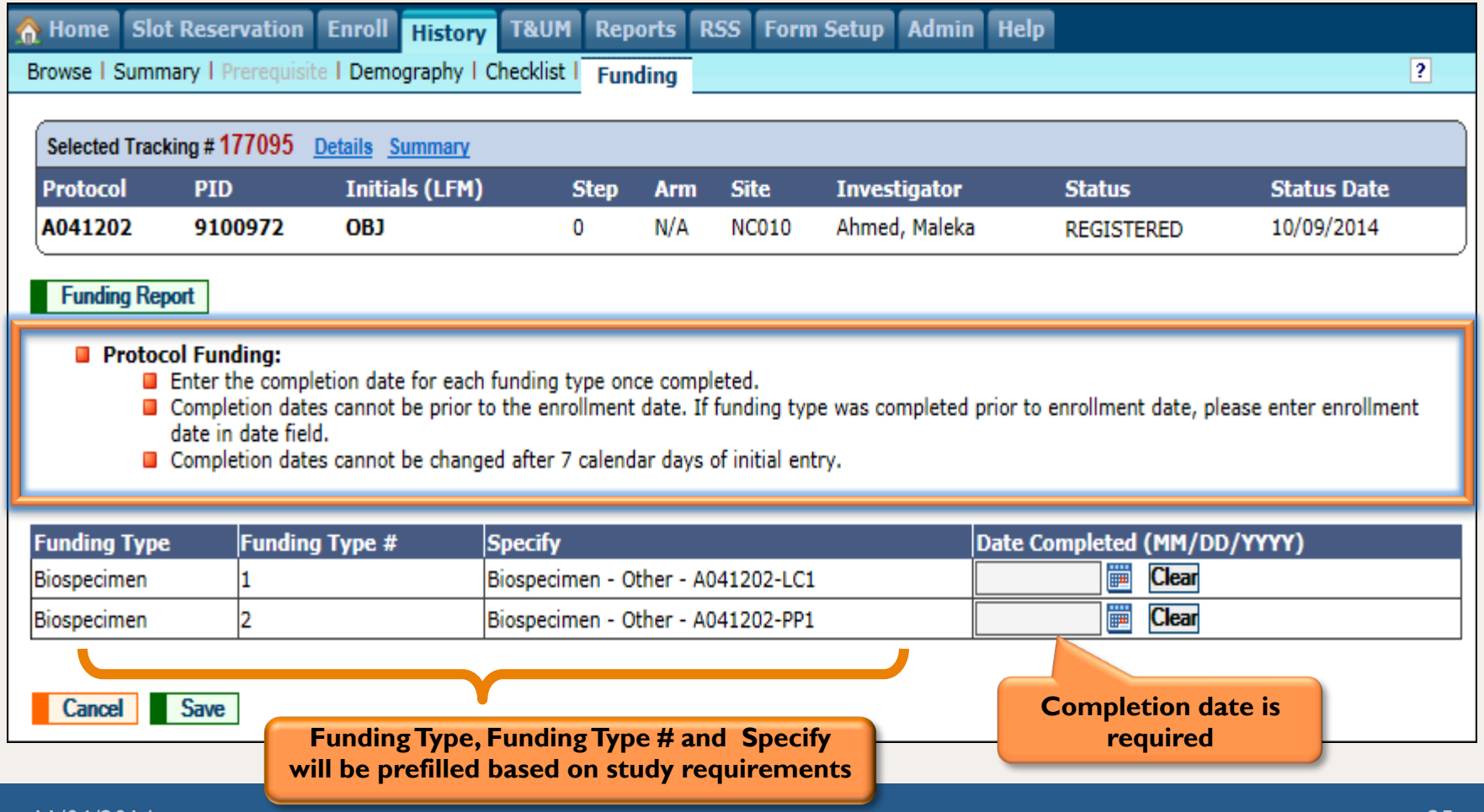
OPEN Funding Screen

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



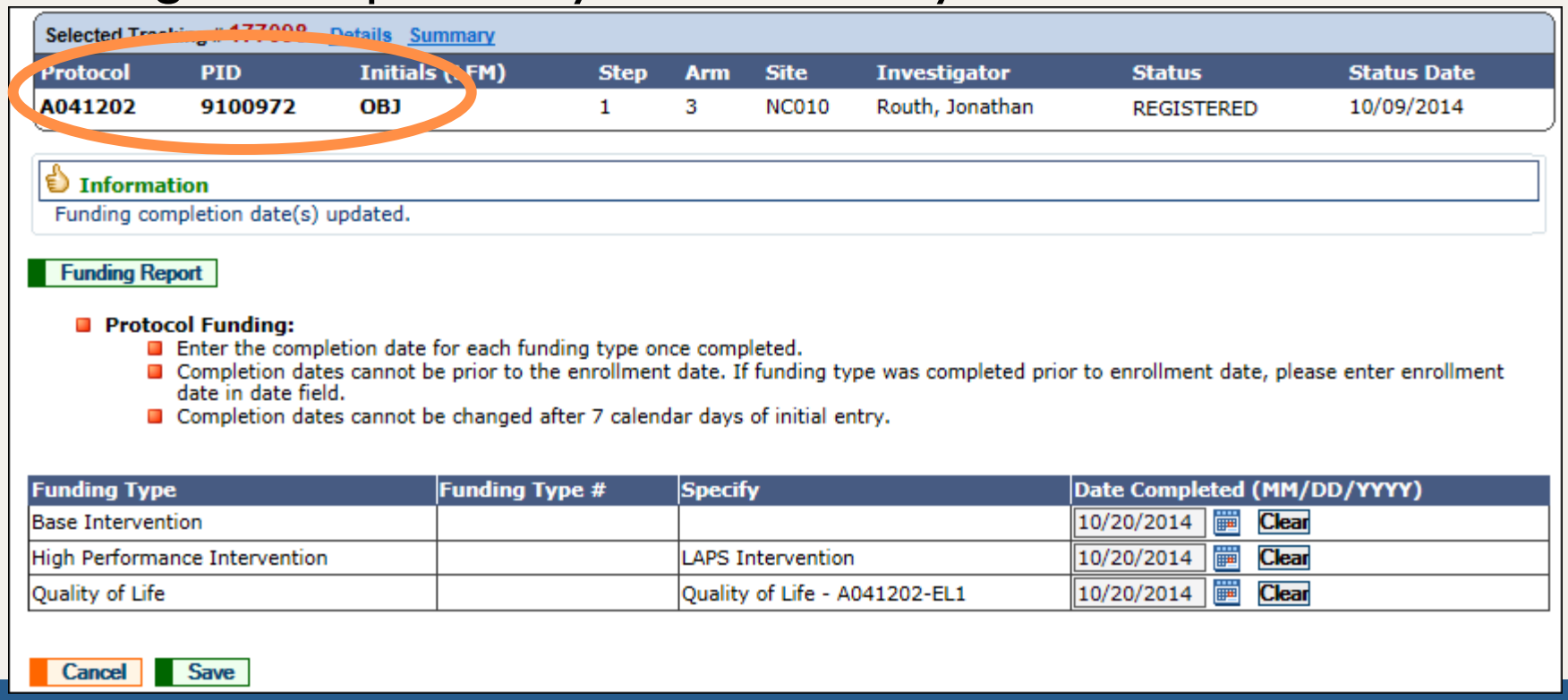
OPEN Funding Screen

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



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 can be changed for up to 7 days of initial entry



Tips for Sites Entering Funding Data

- 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

- To receive site per case funding for specific tests and specimen submissions, completion dates must be entered in the OPEN 'funding screen' on, or post enrollment

Tips (cont.)

- Completion dates for any testing required at multiple time points should be entered one time and can be the initial completion date
- NCORP sites are required to enter completion dates for any trial component completed after August 1st, regardless of when the patient was enrolled to the trial
- Timely entry of dates in OPEN is recommended as this will record completion for per case funding

OPEN TRANSFER & UPDATE MODULE

COMING SOON!

Overview of OPEN v7.0 Release

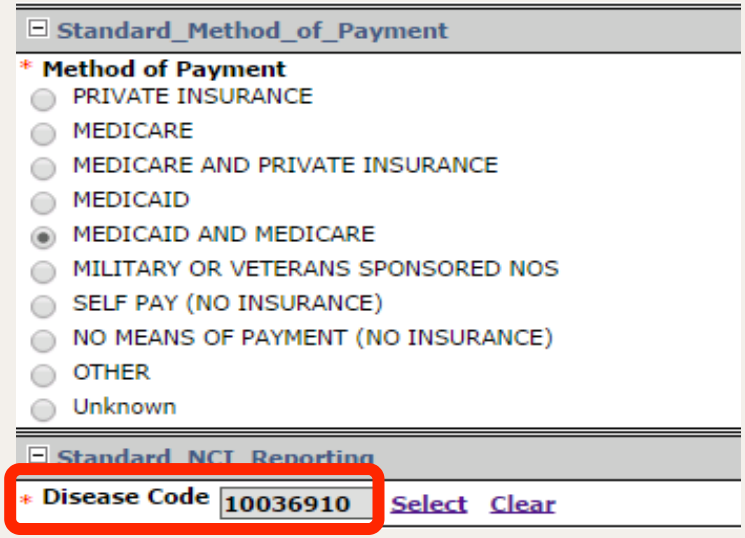
- New NCI Reporting Requirements to collect additional data points to support SAE and other reporting
  - Treatment Assignment Code (TAC)
  - Treatment Assignment Description (TAD)
  - Disease Code and Disease Name
  - Subgroup
- Transfer & Update Module (T&UM)
  - Allows sites to update enrollment data post entry in OPEN and sends updated data to the LPO RandoNode and Rave
  - Data Updates Allowed
    - Transfer of patient from one site to another
    - Updates to credentialing data
    - Updates to demographic data

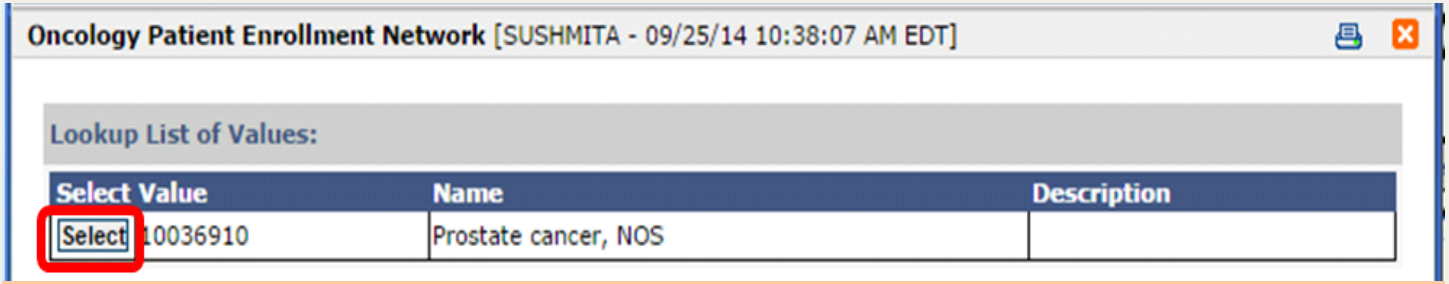
Disease Code

- Disease Codes will be collected on the Demography Screen in OPEN
- Current process for collection of disease code varies with each Lead Protocol Organization (LPO)
  - Part of the eligibility checklist
  - Added on the backend by LPO
- New Process:
  - This field will be a drop down box with the valid responses on the demography screen
  - Users will select the response from the provided values *(In some cases only one response may be available)*
  - If question is part of EC the field will be auto filled with response from demography screen

OPEN Screen Changes

- Demography Form
  - Added Disease Code





TAC, TAD and Subgroup Code

Selected Tracking # 176979 Details

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status
S1400E	700147	III	1	1	MA125	Zimbler, Harvey	REGISTERED

Information

- Network Group response for tracking #176979
- This registration can now be found in the HISTORY section

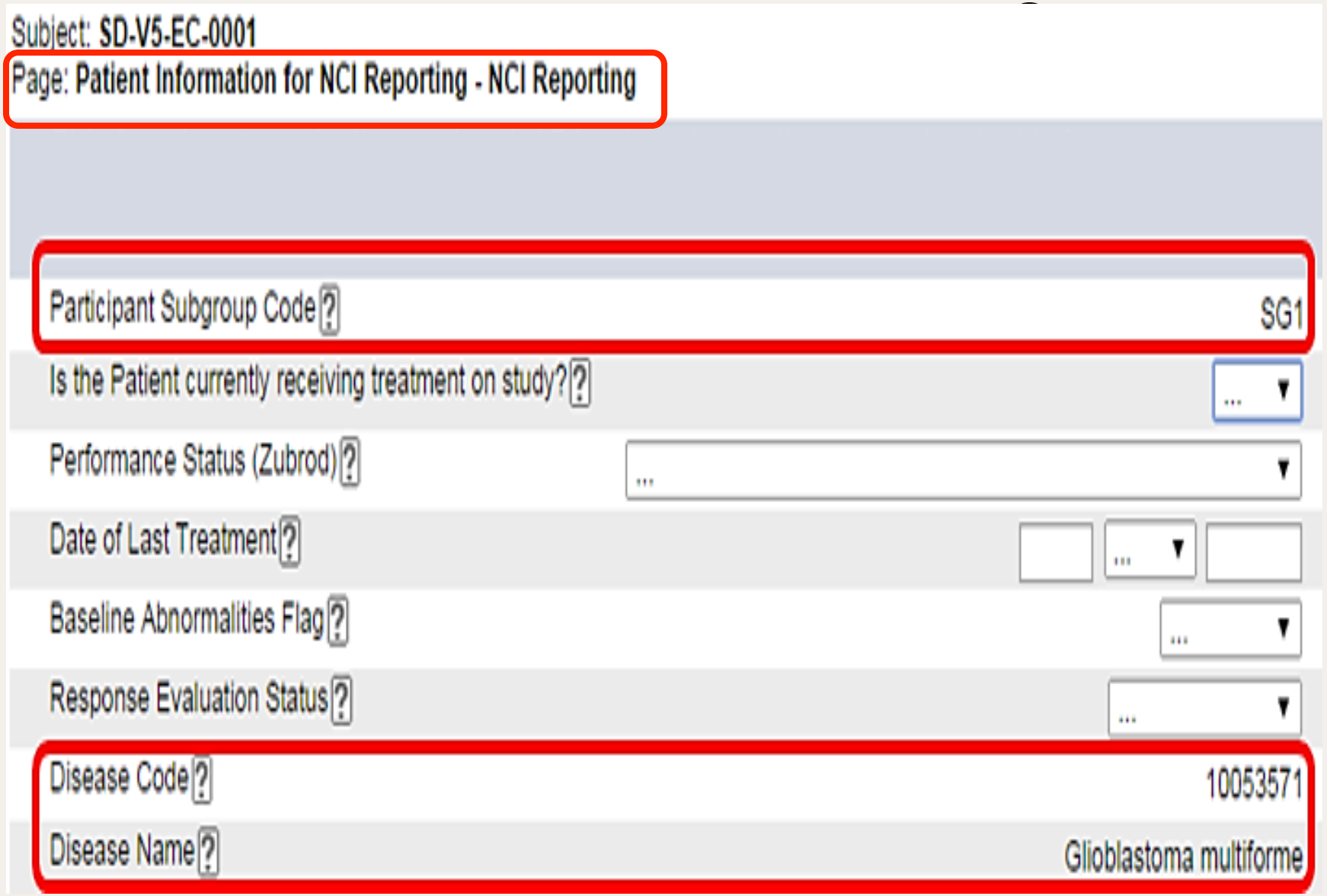
Network Group Response(s)	
Eligibility:	ELIGIBLE
Ineligibility Reason:	None.
Patient ID:	700147
Treatment Arm:	1
Treatment Assignment Code:	
Treatment Assignment Description:	
Subgroup Code:	

Rave Standard Forms

- TAC and TAD will be added to the Step Information and Treatment Assignment Forms in Rave
- TAC and TAD will be prepopulated from the confirmation page in OPEN to the Treatment Assignment Form in Rave.

Subject: **SD-V5-EC-0001**
Page: **Treatment Assignment - Enrollment Forms**

#	Arm Name	Step No	Event description	Date of Intervention/Treatment Assignment	Event Time	Treatment Assignment Code (TAC):	Treatment Assignment Description (TAD):
1	1	1	Registration	4 Sep 2014	04:15:25:PM EST	other	TAD
2	A	1	Randomization	11 Jul 2014	03:59:00:AM EDT	A2 LEVEL 6	


Subject: SD-V5-EC-0001
Page: Patient Information for NCI Reporting - NCI Reporting
Participant Subgroup Code
SG1
Is the Patient currently receiving treatment on study?
Performance Status (Zubrod)
Date of Last Treatment
Baseline Abnormalities Flag
Response Evaluation Status
Disease Code
10053571
Disease Name
Glioblastoma multiforme

Patient Transfers

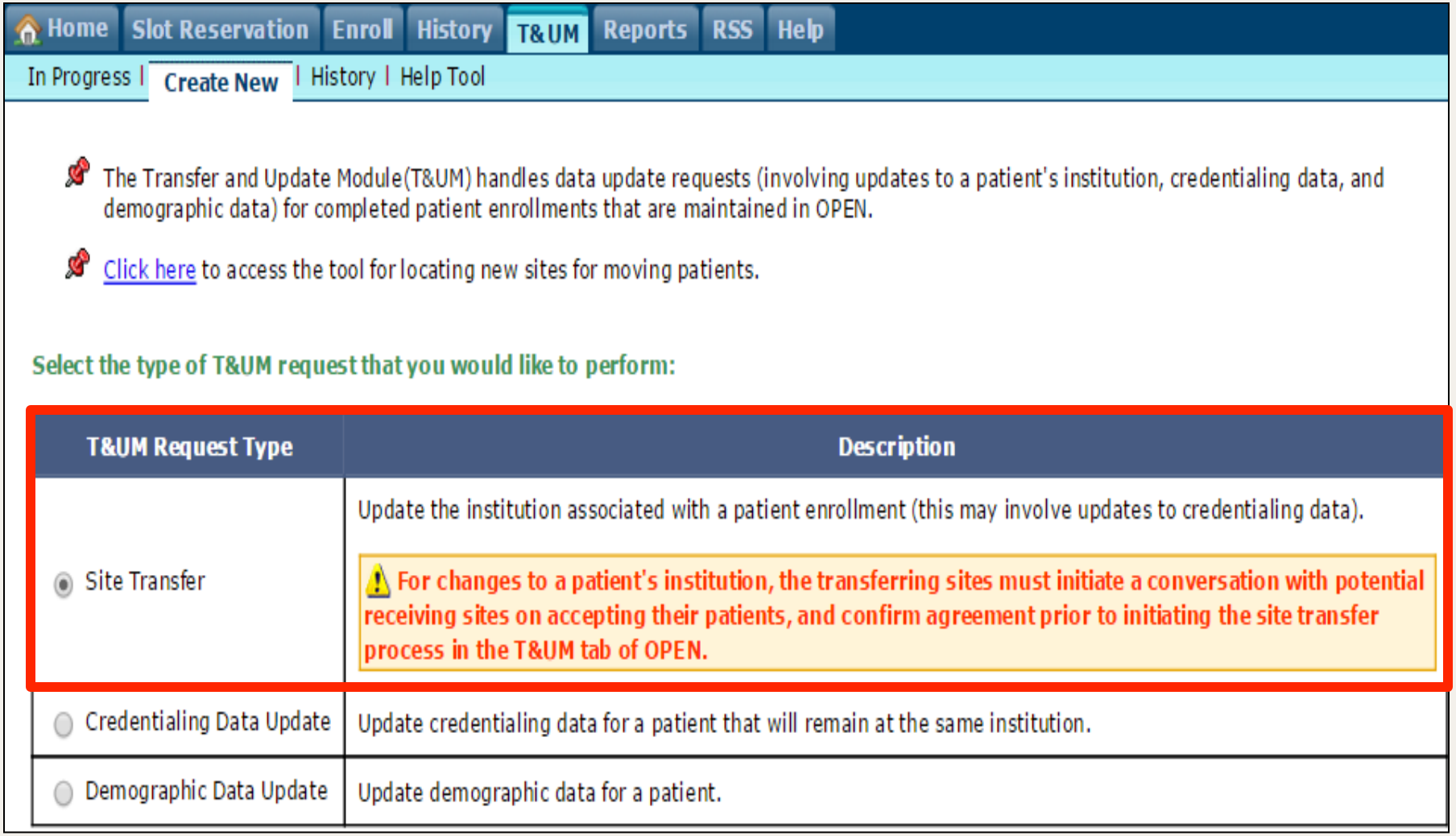
- Patient transfers are currently handled through multiple processes:
  - Submitting a transfer request form to the CTSU
  - Entering transfers in LPO systems
  - Backend updates

- A new tab will be added to OPEN (the T&UM tab) which will provide a central location for OPEN users to request and manage these updates

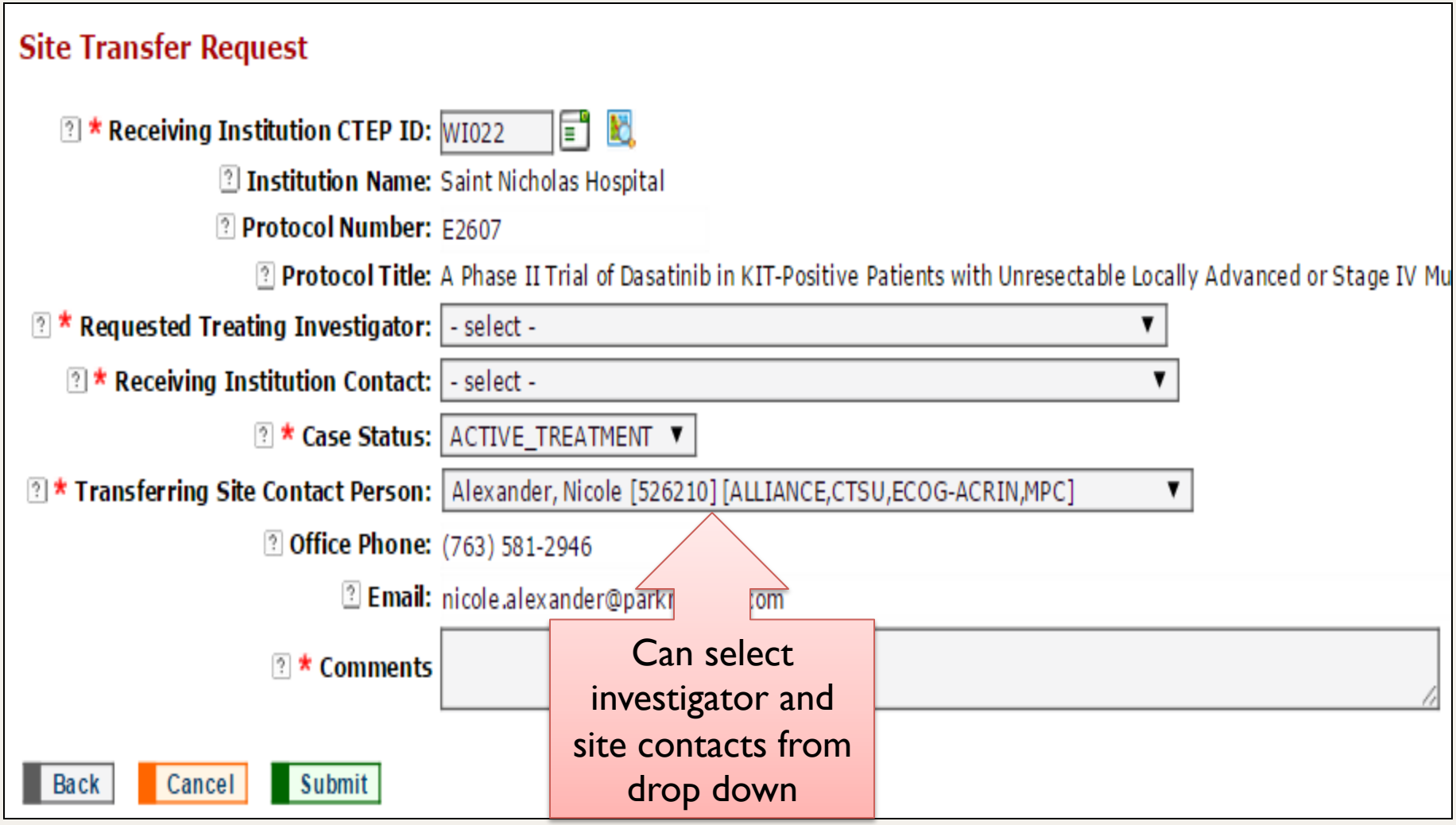
Patient Transfers (cont.)

- Automate and standardize the manual process currently being used for patient transfers and data updates across all LPOs
  - Ability for sites to view the eligible investigators and credit groups during patient transfers
  - All patient transfers will be tracked centrally in OPEN
  - The audit trail (previous value, new value) of data changes and patient transfers will be available in OPEN

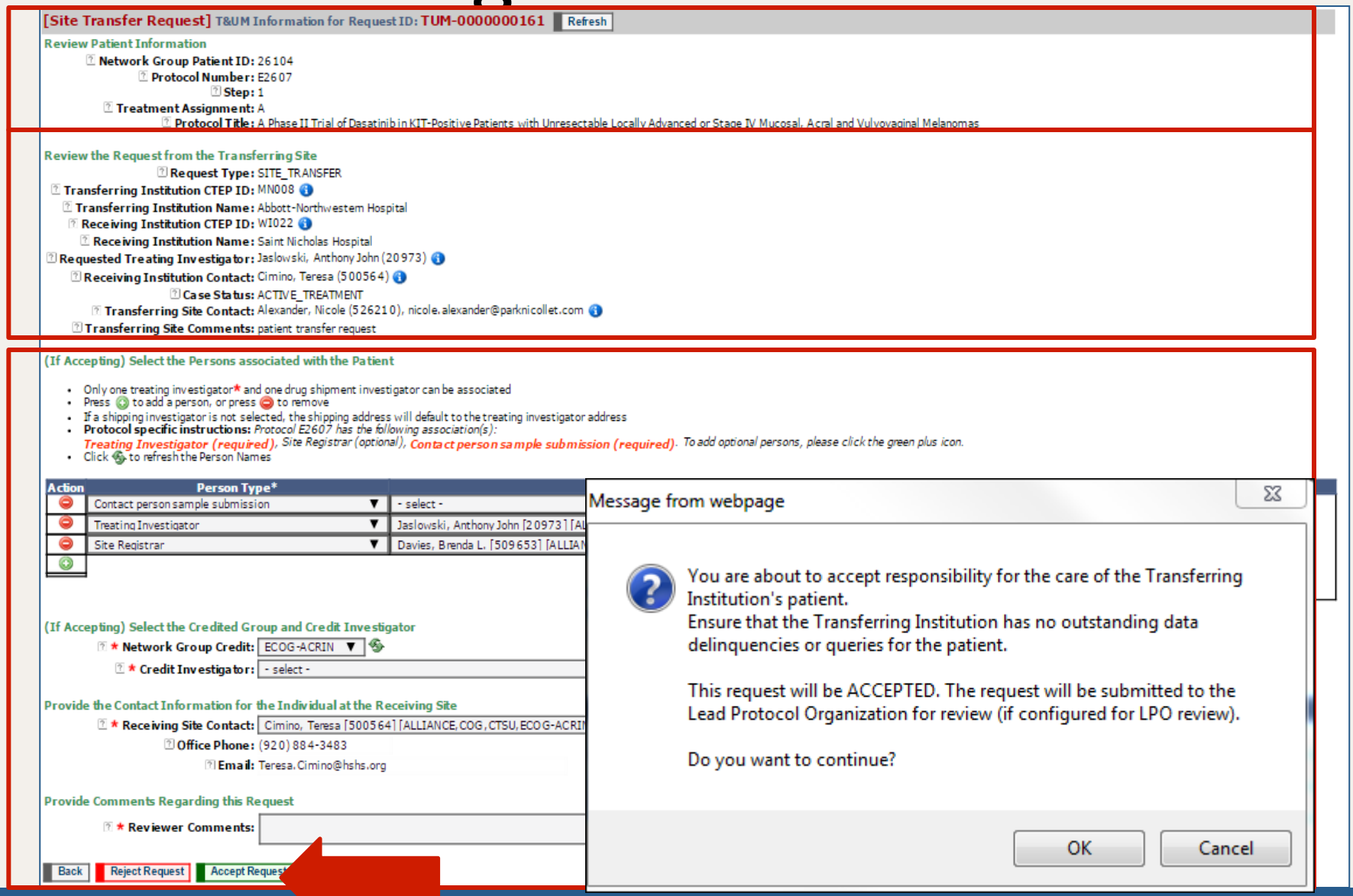
T&UM – Create New Screen



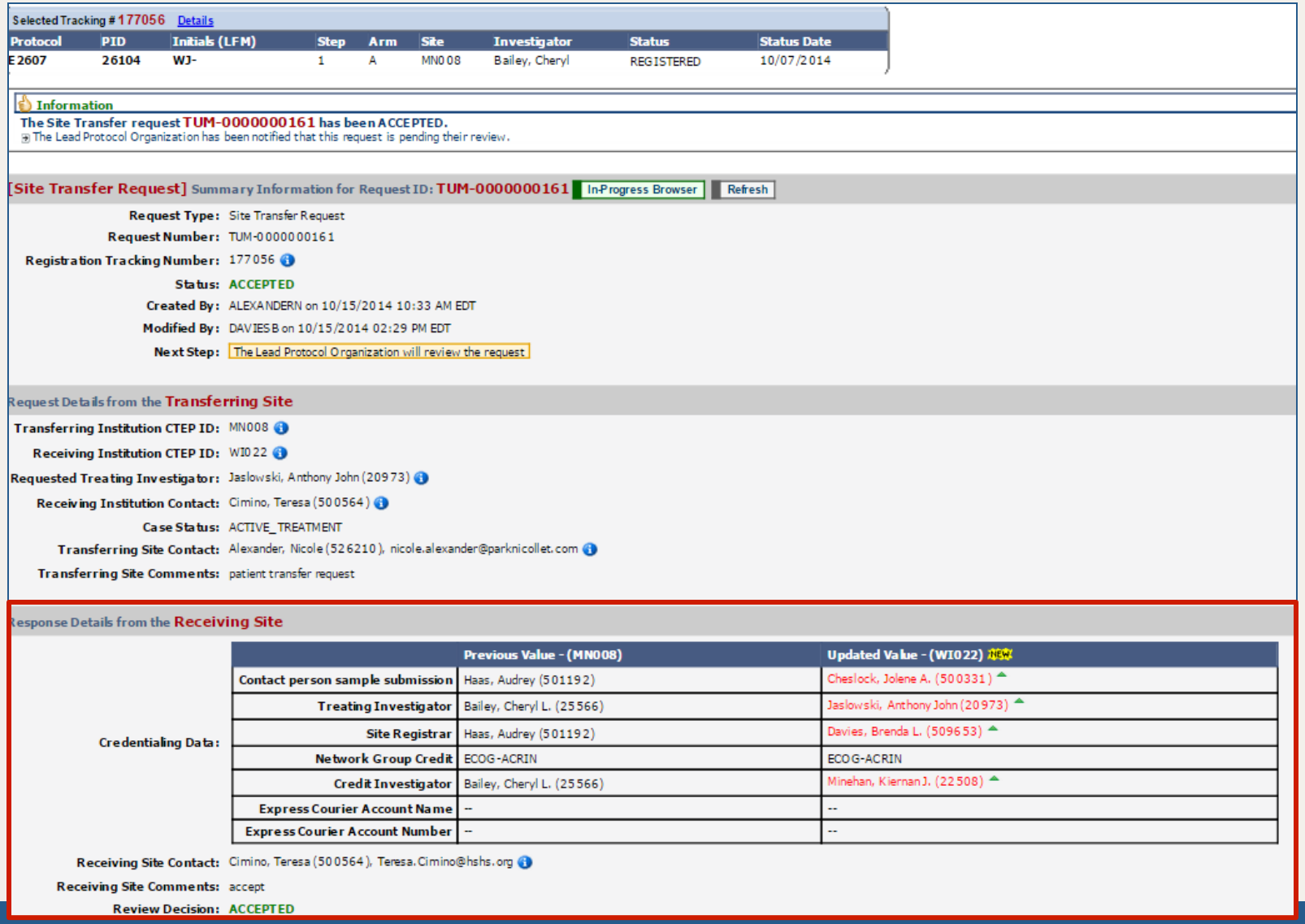
Data for Transfer Request



Receiving Institution Screen



Transfer Accepted



Selected Tracking # 177056 Details

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
E2607	26104	WJ-	1	A	MN008	Bailey, Cheryl	REGISTERED	10/07/2014

Information

The Site Transfer request TUM-0000000161 has been ACCEPTED.

The Lead Protocol Organization has been notified that this request is pending their review.

[Site Transfer Request] Summary Information for Request ID: TUM-0000000161 In-Progress Browser Refresh

Request Type: Site Transfer Request
Request Number: TUM-0000000161
Registration Tracking Number: 177056
Status: ACCEPTED
Created By: ALEXANDERN on 10/15/2014 10:33 AM EDT
Modified By: DAVIESB on 10/15/2014 02:29 PM EDT
Next Step: The Lead Protocol Organization will review the request

Request Details from the Transferring Site

Transferring Institution CTEP ID: MN008
Receiving Institution CTEP ID: WI022
Requested Treating Investigator: Jaslowski, Anthony John (20973)
Receiving Institution Contact: Cimino, Teresa (500564)
Case Status: ACTIVE_TREATMENT
Transferring Site Contact: Alexander, Nicole (526210), nicole.alexander@parknicollet.com
Transferring Site Comments: patient transfer request

Response Details from the Receiving Site

Credentialing Data:

	Previous Value - (MN008)	Updated Value - (WI022) NEW
Contact person sample submission	Haas, Audrey (501192)	Cheslock, Jolene A. (500331)
Treating Investigator	Bailey, Cheryl L. (25566)	Jaslowski, Anthony John (20973)
Site Registrar	Haas, Audrey (501192)	Davies, Brenda L. (509653)
Network Group Credit	ECOG-ACRIN	ECOG-ACRIN
Credit Investigator	Bailey, Cheryl L. (25566)	Minehan, Kiernan J. (22508)
Express Courier Account Name	--	--
Express Courier Account Number	--	--

Receiving Site Contact: Cimino, Teresa (500564), Teresa.Cimino@hshs.org
Receiving Site Comments: accept
Review Decision: ACCEPTED

Demography Updates

- The following demography data points can be updated:
  - Patient initials
  - DOB
  - Ethnicity
  - Gender
  - County of Residence
  - Zip Code
  - Race
- Disease code cannot be updated

Approvals for Transfers

- Transfers may be configured for auto approval or LPO approval
- Auto approval – once the transfer passes all of the validation checks the transfer is complete and emails will be sent to the sites and LPO
- LPO Approval – LPO will receive notification of pending transfer requests for Group approval. Once approved, emails will be sent to the sites

Notifications

- Automated e-mail notifications:
  - Between transferring sites
  - To LPOs for transfers, person updates, and demographic updates
  - To requestor after rejection or acceptance of request for transfer or demographic update

T&UM Access

- Persons with an OPEN registrar role will have write access to T&UM module
- Audit trails will be maintained on all request and data changes

T&UM Validation Checks

- Patient Transfer Checks
  - The receiving site must be approved for the protocol the patient is enrolled on
  - For closed protocols, the receiving site must have an IRB approval on file with the CTSU Regulatory Office
  - The receiving site must be a member of the participating organization that is receiving credit
  - The receiving investigator must be on the roster at the receiving site

T&UM Validation Checks

- Credentialing Checks
  - Investigators must be active with CTEP
  - Credited investigators must be active on the roster of the credited group at the enrolling site
  - Treating and shipping investigators must be active on the site's roster participating on the protocol
  - Associates must be active and on a participating roster at the site

When Can You Start Using the T&UM?

- OPEN Release is scheduled for November 6th
- Each LPO will determine when they will begin to use the T&UM for their trials
- Each LPO will decide if LPO approval is required for patient transfers or updates
- Information will be available on the OPEN Home Page, the OPEN tab of the CTSU website, and in the Bi-Monthly Broadcast

Training

- The OPEN Site User Guide will be updated to include the T&UMs
- A quick reference guide will be available on the OPEN Home Page and the OPEN tab of the CTSU website
- A T&UM section will be added to OPEN Site Training Video 

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
- Links to NCTN informational documents under the Education and Resources Tab on the CTSU Members' website

CTSU Help Desk - ctsucontact@westat.com

Questions?