

CANCER TRIALS SUPPORT UNIT (CTSU

CTSU WEBSITE AND OPEN UPDATES

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Alliance Meeting May 14, 2015

Agenda

- I. CTSU Website Dashboard
- OPEN Transfer and Update Module (T&UM)
- 3. OPEN Funding
- 4. Regulatory Site Roles
- Lead Protocol Organization (LPO) Documents
- 6. Additional CTSU Updates





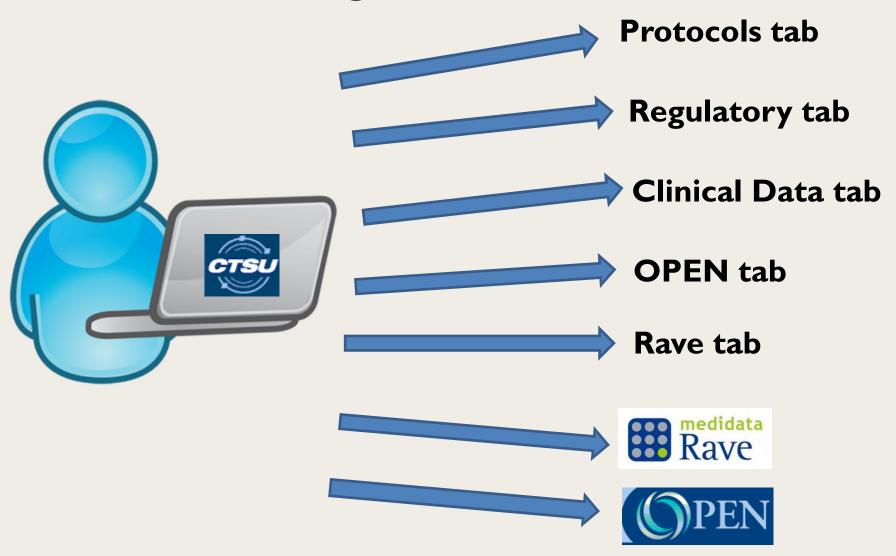
CTSU WEBSITE DASHBOARD

Motivation Behind Dashboard

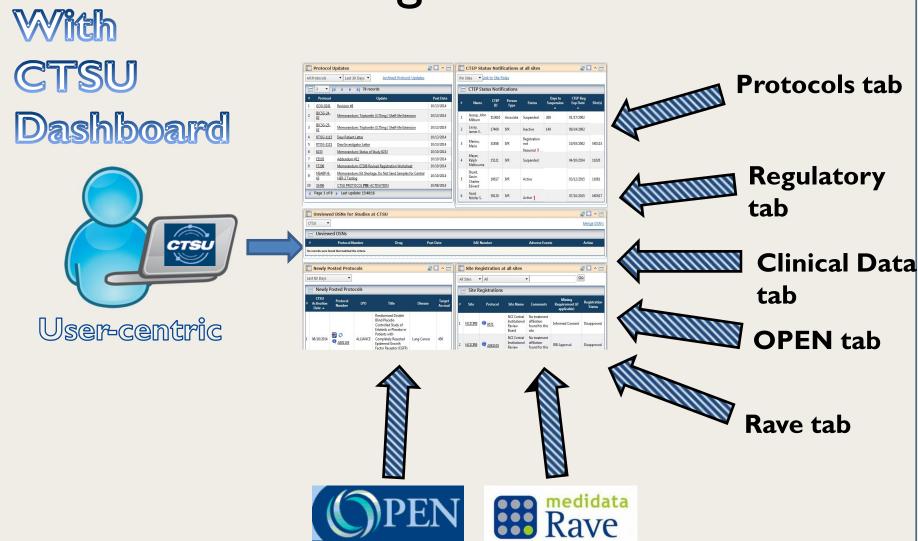
- CTSU website is growing larger due to:
 - Additional document postings (i.e., CIRB, Funding Information).
 - Integrations with other systems (i.e., Rave, IRB Manager).
- Site users would benefit having one webpage to view user-centric information that **they** think is important.

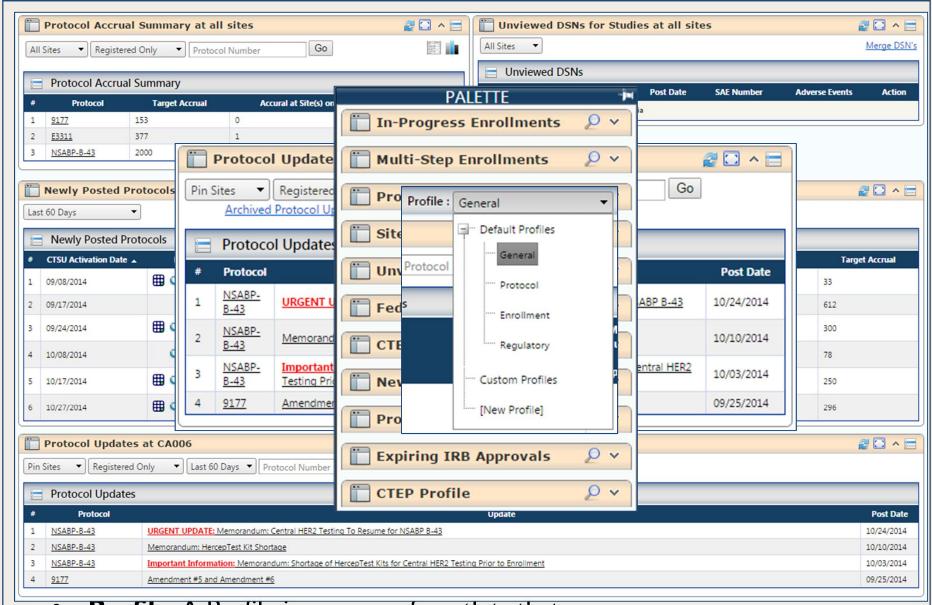
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Paradigm Shift To



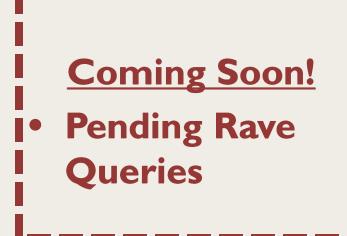


 Profile: A Profile is a group of portlets that are arranged in a particular configuration on dashboard.

Dashboard Portlets

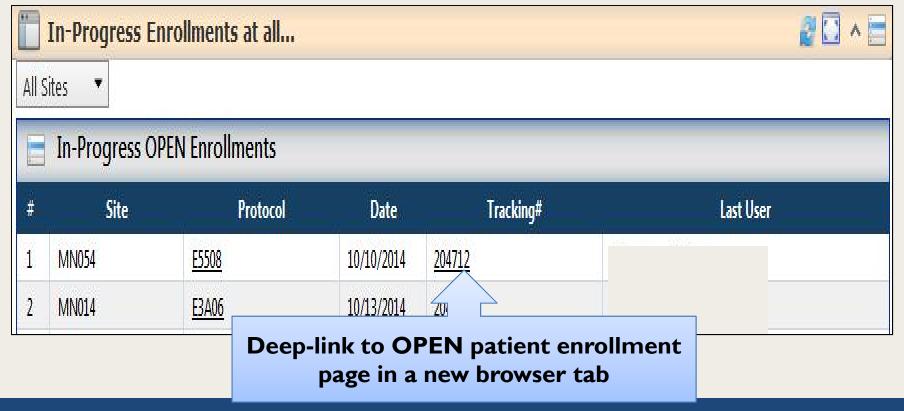
Currently Available

- In Progress Enrollments
- Multi Step Enrollments
- Protocol Updates
- Site Registration
- Unviewed DSNs
- Federation Access
- CTEP Status Notification
- Newly Posted Protocols
- Protocol Accrual Summary
- Expiring IRB Approvals
- CTEP Profile
- Site Accrual Reports
- Rave Study Access



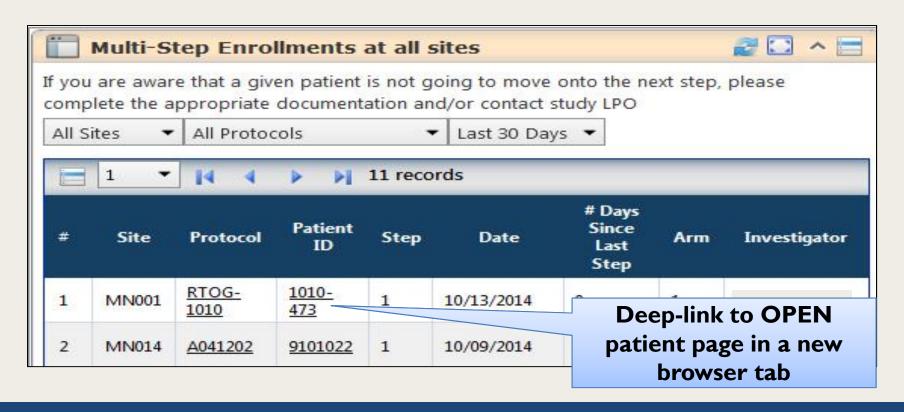
In-Progress Enrollments

Displays a list of in-progress OPEN Enrollments for protocols open at your site(s).



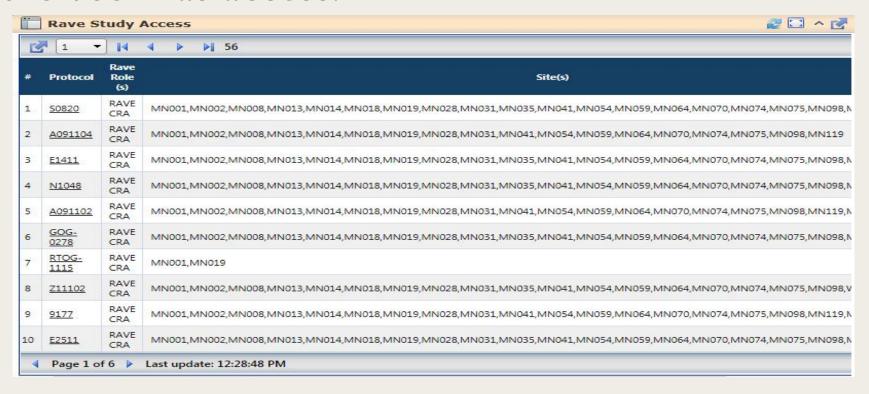
Multi-Step Enrollments

Displays enrollment information for multi-step enrollment protocols open at your site(s).



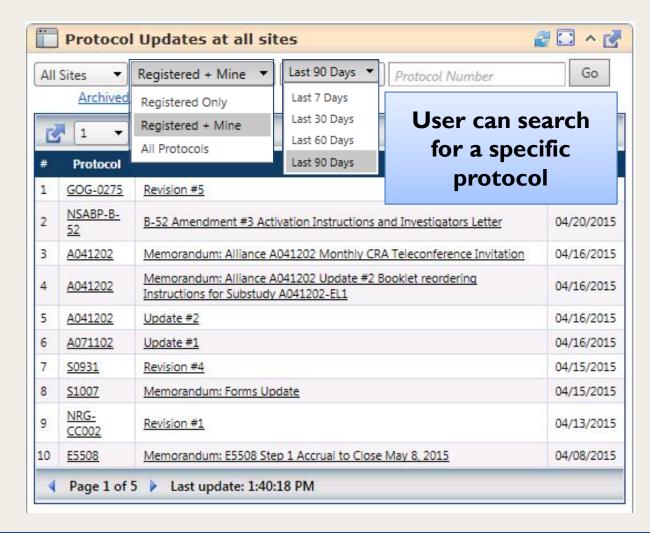
Rave Study Access

Ability to view a table of Rave Studies for which the user has access.



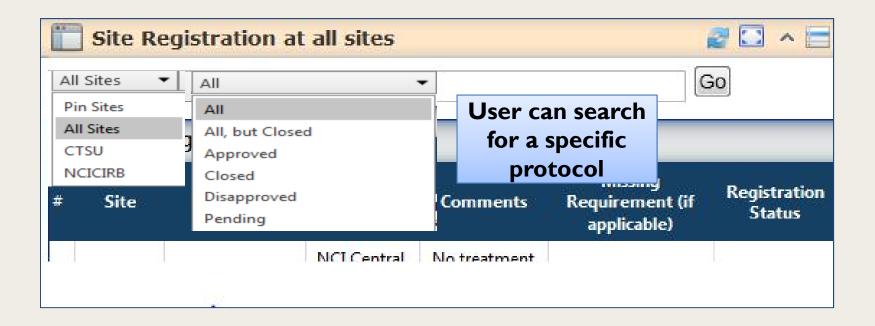
Protocol Updates

Displays
protocol
updates for
protocols
open at your
site(s).



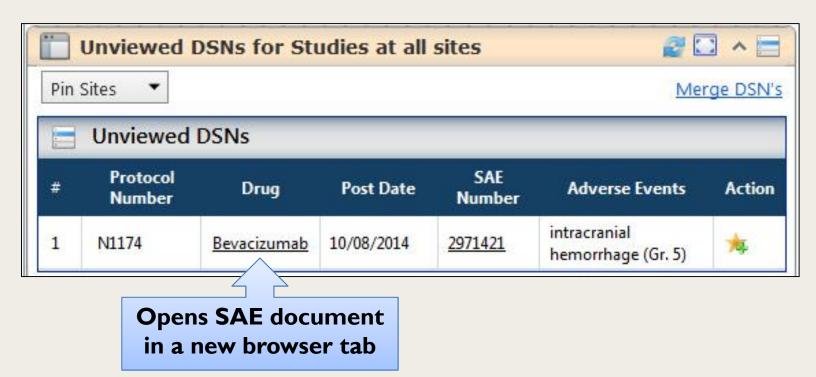
Site Registration

Displays the protocol registration statuses for all protocols open at your site(s).



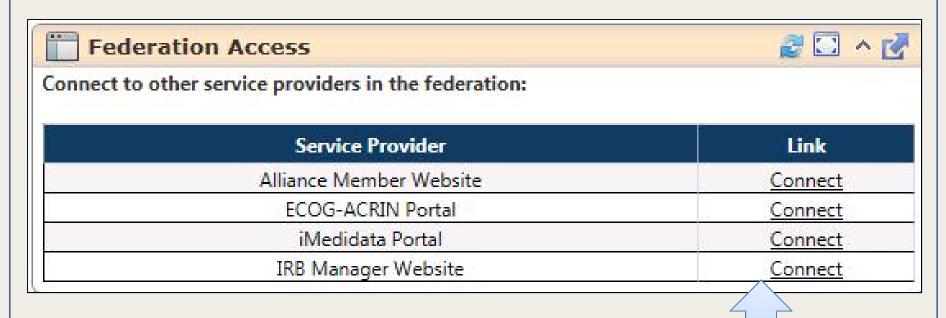
Unviewed DSNs

Displays a list of all unviewed Drug Safety Notifications specific to all protocols open at your site(s).



Federation Access

Displays quick links to other applications in the Federation.



Opens application in a new browser tab without the need to login again

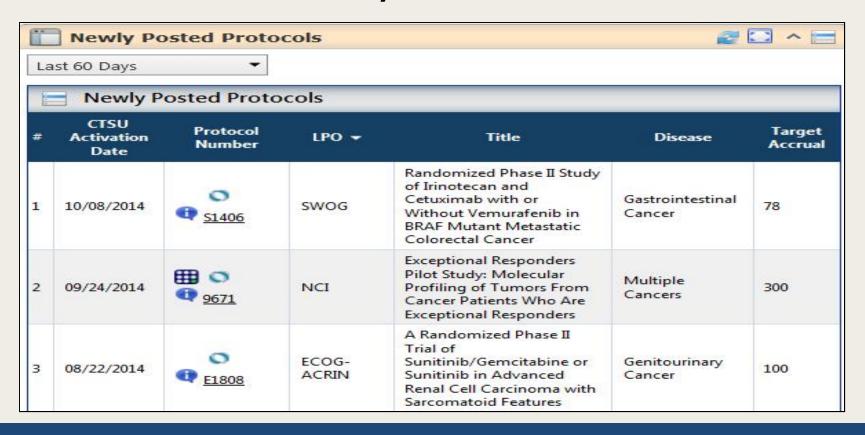
CTEP Account Status Notifications

Will display registration statuses for all users claimed at my site(s). This will include the number of days until suspension for each account. This portlet is particularly useful for Site Administrators.



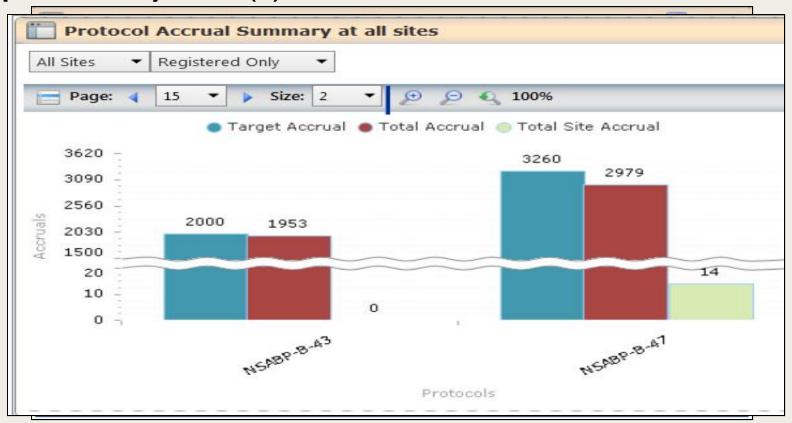
Newly Posted Protocols

Displays a listing of all CTSU trials that have been activated recently.



Protocol Accrual Summary

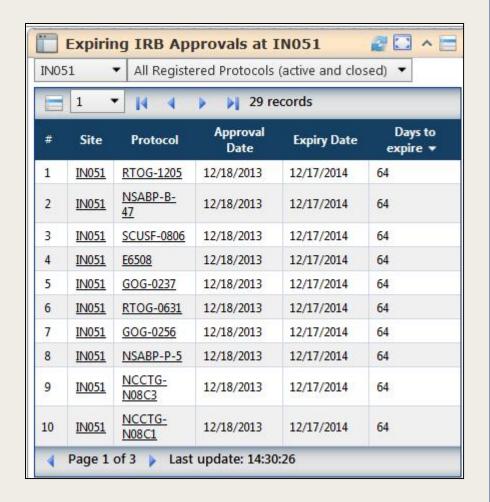
Tracks accrual information for all protocols open at my site(s).



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Expiring IRB Approval Status

Will display the IRB Approval statuses for all protocols open at your site(s).



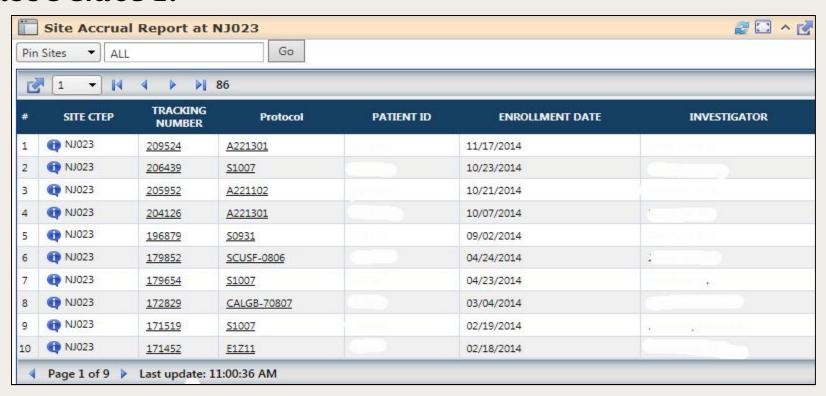
CTEP Profile

Will display all relevant information related to your account. Will also allow renewal of your CTEP registration and password.



Site Accrual Report

Displays the accruals for the site that the user is associated.

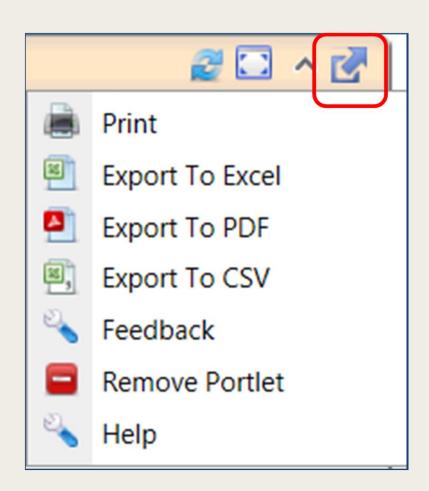




STANDARD DASHBOARD FEATURES

Standard Features

- Refresh
- Maximize/Minimize
- Print
- Collapse/Expand
- Export
 - Excel, CSV, PDF
- Feedback
- Portlet Help PDF





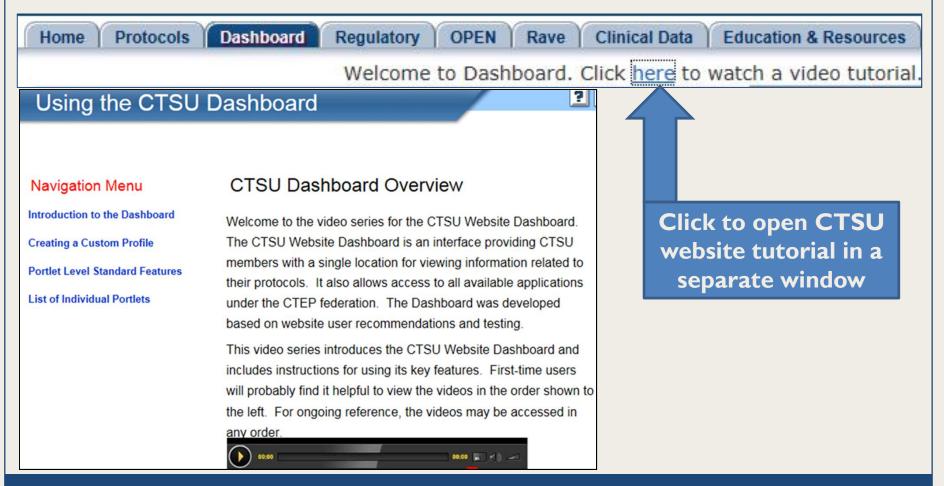
GETTING STARTED...

How do I set up my Dashboard?

- Dashboard is already set for you. You can use any of 4 system profiles:
 - General
 - Protocol
 - Enrollment
 - Regulatory
- Users can customize the default profiles and save them under different names.
- Users can also create custom profiles according to their preferences.

How do I set up my Dashboard?

A video tutorial is available on the website





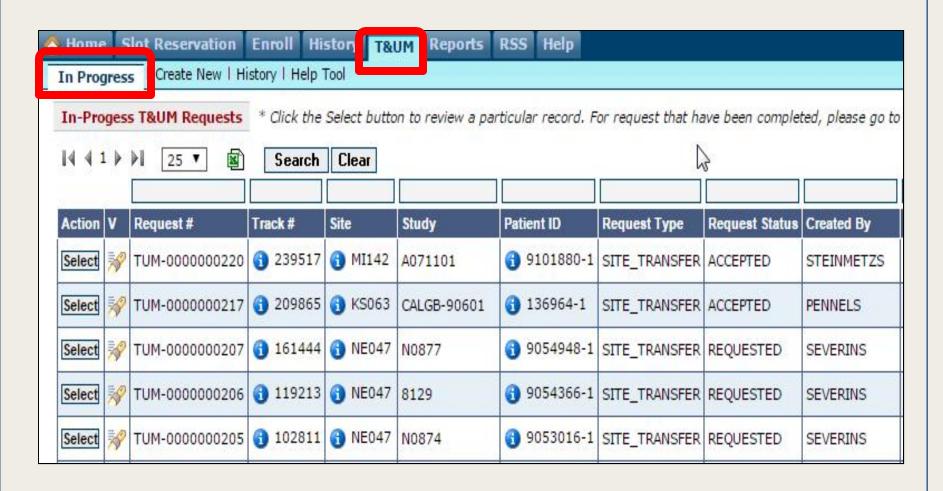
OPEN TRANSFER & UPDATE MODULE

NOW AVAILABLE!

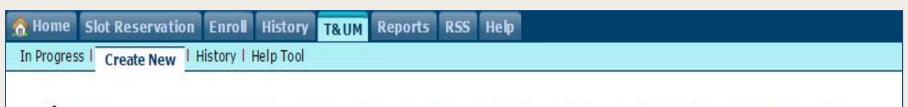
Types of Updates/Transfers

Action	Scenarios
Patient Transfers	 Patient needs to change to a different institution. Credentialing data (i.e., Investigator, Credited Organization) may need to be changed due to the institution change.
Credentialing Data Updates	 Patient credentialing data (Investigator, Credited Organization) needs to be changed at the current institution. Changes to the credited organization can only be performed within seven days of the patient enrolling in OPEN.
Demographic Data Updates	Patient demographic data needs to be changed.

Transfer & Update Module



T&UM – Create New Screen



- The Transfer and Update Module (T&UM) handles data update requests (involving updates to a patient's institution, credentialing data, and demographic data) for completed patient enrollments that are maintained in OPEN.
- Click here to access the tool for locating new sites for moving patients.

Select the type of T&UM request that you would like to perform:

T&UM Request Type	Description
Site Transfer	Update the institution associated with a patient enrollment (this may involve updates to credentialing data).
	For changes to a patient's institution, the transferring sites must initiate a conversation with potential receiving sites on accepting their patients, and confirm agreement prior to initiating the site transfer process in the T&UM tab of OPEN.
Credentialing Data Update	Update credentialing data for a patient that will remain at the same institution.
O Demographic Data Update	Update demographic data for a patient.

Notifications

- Automated e-mail notifications:
 - Between transferring sites.
 - To LPO for transfers, person updates, and demographic updates.
 - To requestor after rejection or acceptance of request for transfer or demographic update.
 - To the Pharmaceutical Management Branch for transfers and investigator updates.

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.

- 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.

Who Is Currently Using the T&UM?

- T&UM is now available in OPEN.
- T&UM is currently being used for ALLIANCE and SWOG protocols in OPEN.
- As of 11/4/2014 there have been:
 - 51 Site Transfers
 - 40 Credentialing Data Updates
 - 18 Demographic Data Updates



Training

- The OPEN Site User Guide has been updated to include the T&UM.
- A quick reference guide is available on the Help tab in OPEN.
- T&UM section will be added to OPEN Site Training Video.

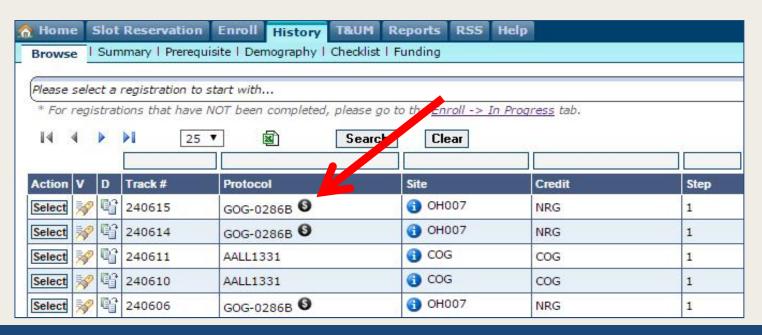




OPEN FUNDING

OPEN Funding Report

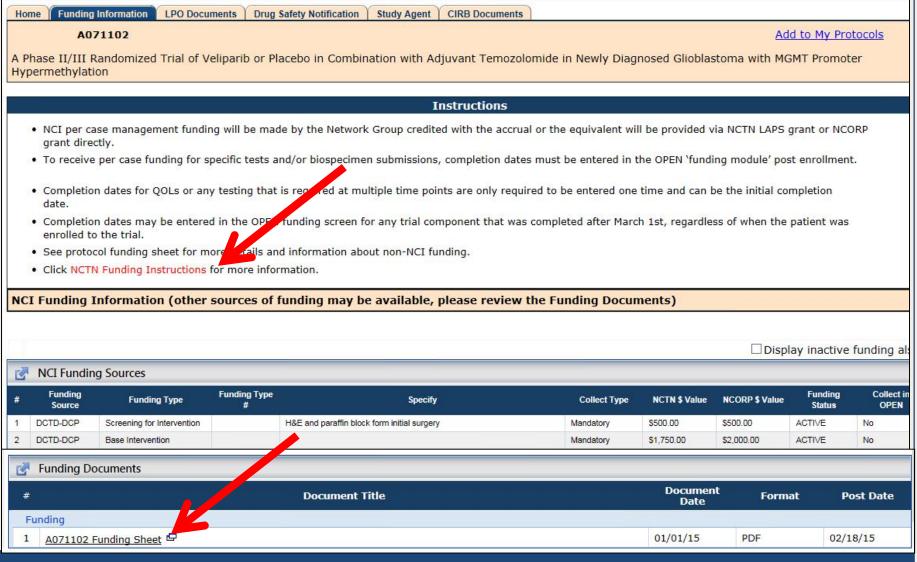
- The OPEN funding report was added to OPEN to display all funding information for a site's enrollments.
- A comments field will be added to the Funding page in the next OPEN release in August 2015.



OPEN Funding Report



Funding Information Page



Home Protocols Dashboard Regulatory OPEN Rave Clinical Data Education & Resources Collabor



OPEN is the web-based registration system for patient enrollments onto NCI-sponsored Network Group (
Network Groups' registration/randomization systems for patient registration/randomization. OPEN provious through role assignments in the CTSU Regulatory Support System. To access OPEN:

- · Site staff will need to be registered with CTEP and have a valid and active CTEP-IAM account.
 - · This is the same account (user id and password) used for the CTSU members' web site.
- . To perform registrations, the site user must have the 'Registrar' role on Network Group.
- · Role assignments are handled through the Groups in which you are a member

If you have questions about this please contact the CTSU Help Desk

Learn More About OPEN

Training and Demonstration Materials

OPEN 7.0 Site User Guide

The User Guide contains a linkable Table of Contents that will bring you to any topic you choose, or you can scroll through and/or print the entire guide.

OPEN Demo Video

The OPEN training video has been reformatted. It is now easier to access the information you need. Just click on one of the tabs at the top of the screen for a drop down list of instructional topics, then click on the specific topic you want to view.

Guidelines for OPEN Access and Crediting

This document outlines the set of guidelines for OPEN access and crediting.

OPEN FAQs

OPEN Frequently Asked Questions

For NCTN sites: Slot Reservation Quick Reference Site Use Guide

This user guide is a quick reference intended to assist sites with the process of reserving a slot for a patient on protocols that use the slot reservation system.

• For ETCTN sites: Slot Reservations and Cohort Management User Guides

For user guides on the use of IWRS for request prand managing slot reservations and cohorts, please go to the Downloads page on Theradex's website.

· OPEN Funding Screen Site User Guide



REGULATORY - SITE ROLES

Basic Role Information

- All persons associated with the site on a Network roster can view roster information in the Site Roles application on the CTSU website.
- Persons allowed to modify roles for their institution vary by Network roster. A table of authorized users by Network roster is available under the toolbar on the Site Roles tab.
- Authorized individuals on the CTSU roster (Site Administrator and Data Administrator) can add and remove persons from the CTSU Roster.
- Role changes are automatically available in the Regulatory Support System (RSS)

How Roles are Managed

	CCOP Sites	Non-CCOP Sites			
Action	Performed In	Performed In			
Add Person	NCORPPSYS database	Network Group(s) system			
Remove Person	NCORPSYS database	Network Group(s) system			
Add Role	Site Roles on CTSU website	Site Roles on CTSU website			
Remove Role	Site Roles on CTSU website	Site Roles on CTSU website			
Add Restricted Role*	Network Group(s) system	Network Group(s) system			
Remove Restricted Role*	Network Group(s) system	Network Group(s) system			

^{*}Restricted roles are roles that cannot be updated through the Site Roles application

Site Roles Table

			Can Update S	lte			Managed in Site
Roster	Role	Level	Roles	OPEN Access	Rave Access	TRIAD Access	Roles
Alliance	Administrative Personnel	Institution					V
Alliance	Administrator	Institution					V
Alliance	Clinical Research Associate (CRA)	Institution					V
Alliance	Co-Principal Investigator	Institution					
Alliance	Cytogeneticist	Institution					
Alliance	Fellow/Post Doc	Institution					V
Alliance	Imaging Coordinator	Institution					V
Alliance	Institutional Lab Tech	Institution					٧
Alliance	Investigator	Institution					V
Alliance	Laboratory Colordinator	Institution					V
Alliance	Laboratory Director	Institution					
Alliance	Lead Clinical Research Professional (CRP)	Institution	٧				
Alliance	Nurse Practioner	Institution			_		V
Alliance	Oncology Nurse	Institution or Protocol					V
Alliance	Pathology Coordinator	Institution					V
Alliance	Pharmacist	Institution or Protocol					V
Alliance	Pharmacy Coordinator	Institution					V
Alliance	Physician Assistant	Institution					√
Alliance	Principal Investigator	Institution					
Alliance	Radiation Oncology Coordinator	Institution or Protocol					V
Alliance	Rave CRA	Institution or Protocol			V		V
Alliance	Read Only	Institution or Protocol			V		V
Alliance	Registrar	Institution		V			V
Alliance	Repository Lab Tech	Institution					V
Alliance	Secondary Lead CRP	Institution	V				
Alliance	Site Investigator	Institution			V		
Alliance	Surgical Coordinator	Institution or Protocol					V
Alliance	Surgical CRA	Institution					V
Alliance	Transplant Coordinator	Institution					V
Alliance	SLA (Senior Lab Admin)	Protocol			V		
Alliance	CRA (Lab Admin)	Protocol			V		

Resources

- Network Site Roles Table
 - List of roles and access for each Network roster.
- Help Sheet
 - Quick reference sheet on how to add and remove roles.
- Site Roles Video
 - Slightly outdated and CTSU centric however the mechanics are the same across all rosters.



LEAD PROTOCOL ORGANIZATION (LPO) DOCUMENTS

LPO Documents Tab

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

A071102 | Add to My Protocols

A Phase II/III Randomized Trial of Veliparib or Placebo in Combination with Adjuvant Temozolomide in Newly Diagnosed Glioblastoma with MGMT Promoter Hypermethylation

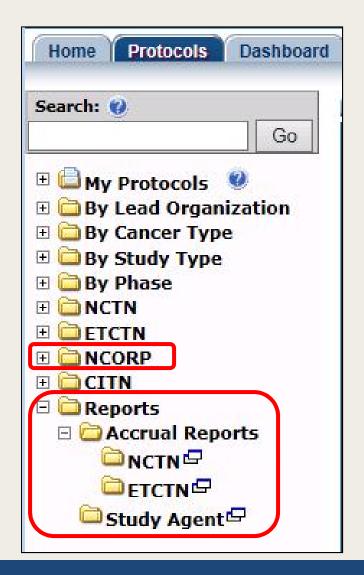
#	Document Title	Document Date	Format	Post Date
Pro	otocol			
1	Protocol Document (NCI Version Date 03/20/2015)	04/15/15	PDF	04/16/15
2	Update #1 □	04/15/15	PDF	04/16/15
3	Memorandum: Activation Notice	12/15/14	PDF	12/18/14
4	Memorandum: Adverse Event Reporting 🗗	12/15/14	PDF	12/18/14
Ed	ucation and Promotion Materials			
1	Time & Events □	12/15/14	PDF	12/18/14
2	Schema &	04/15/15	PDF	04/16/15
3	Study Calendar 🗗	04/15/15	PDF	04/16/15
4	SAE Training Presentation for CRAs	02/25/15	PDF	02/27/15
5	SAE Training Webinar - Recorded 02/25/2015			
6	SAE User Guide for CRAs	03/09/15	PDF	03/23/15
Ca	se Report Forms			
1	Data collection for this study will be done exclusively through Medidata Rave. Please see the data submission section of the protocol for further instructions. The Ray system can be accessed through the iMedidata portal at https://login.imedidata.com .			
2	All Forms Packet 🗗	03/01/15	PDF	03/02/15
3	Forms Submission Schedule	03/01/15	PDF	03/02/15
Sit	te Registration Documents			
1	CTSU IRB Certification Form 🗗		PDF	12/18/14



ADDITIONAL CTSU UPDATES

CTSU Website

- New folders have been added to navigation tree in the Protocols tab.
 - NCORP folder displays all NCORP sponsored trials, sorted by LPO.
 - Reports folder searchable reports for:
 - Protocol Accrual Reports for NCTN and FTCTN
 - Study Agent Reports



CTSU Bi-Monthly Broadcast

Direct links have been added to take users to trial updates for NCTN, ETCTN, NCORP, and other NCI-supported networks.

CLICK HERE TO SKIP TO NCTN TRIAL UPDATES

*** CLICK HERE TO SKIP TO NCORP TRIAL UPDATES ***

*** CLICK HERE TO SKIP TO ETCTN TRIAL UPDATES ***

*** CLICK HERE TO SKIP TO TRIAL UPDATES FOR OTHER
NCI-SUPPORTED NETWORKS ***

SECTION II - NCTN TRIAL UPDATES

*** NCTN PROTOCOL PRE-ACTIVATIONS (i.e. LPO Activation) ***

Pre-Activation of Protocol EA8141
 Pre-Activation Date: 04/01/15

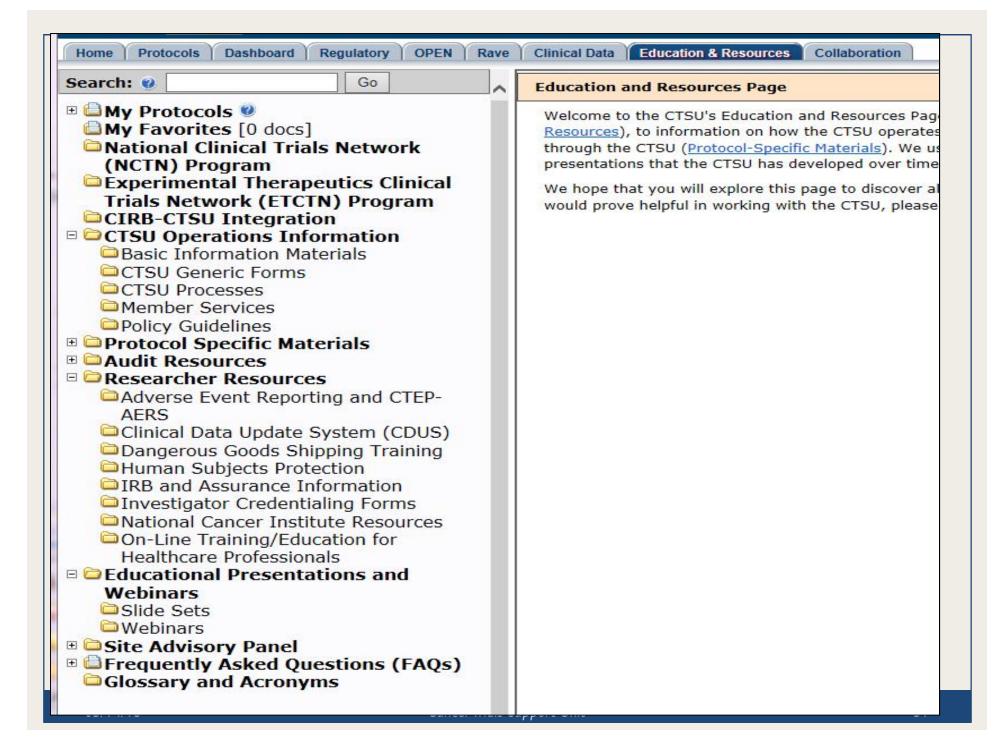
Protocol Title: A Prospective Phase II Trial of Neoadjuvant Systemic Chemotherapy Followed by Extirpative Surgery for Patients with High Grade Upper Tract Urothelial Carcinoma

*** NCTN PROTOCOL ACTIVATIONS ***

Activation of Protocol NRG-GY001

Activation Date: 04/01/15

Protocol Title: A Phase II Trial of Cabozantinib (XL-184) (NSC #761968) in Women with Recurrent, Clear Cell Carcinoma of the Ovary, Fallopian Tube, or Peritoneum



Questions?

- CTSU Help Desk
 - Email:

ctsucontact@westat.com

- Phone: I-888-823-5923

