



CANCER TRIALS SUPPORT UNIT (CTSUS)

CTSUS WEBSITE AND OPEN UPDATES

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Alliance Meeting
May 14, 2015

Agenda

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





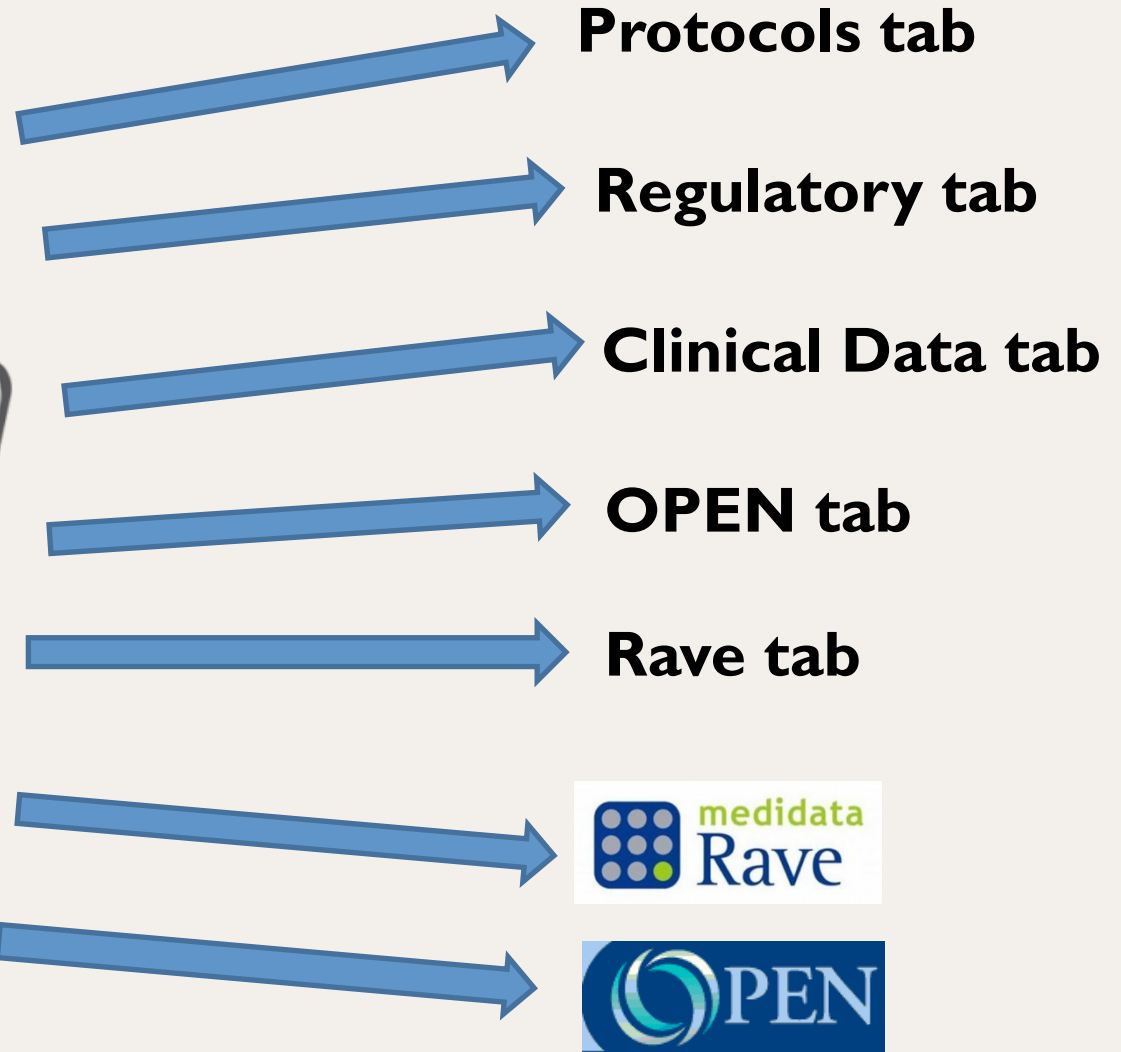
CTSU WEBSITE DASHBOARD

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.



Paradigm Shift From



Paradigm Shift To

With
CTSUS
Dashboard



The screenshot displays several data tables from the CTSU dashboard:

- Protocol Updates:** A table with columns for Protocol ID, Update, and Post Date. It lists updates such as "Revision #1" for protocol BCSC-26-02 and "New Investigator Letter" for protocol BT02-1115.
- CTEP Status Notifications at all sites:** A table with columns for Name, CTEP ID, Person Type, Status, Days to Suspension, CTEP Reg Exp Date, and Site(s). It lists individuals like "Pinnip, John William" and "Lacey, James V." with their respective statuses.
- Unviewed DSNs for Studies at CTSU:** A table with columns for Protocol Number, Drug, Post Date, SAE Number, Adverse Events, and Action. It currently shows "No records were found that matched the criteria."
- Newly Posted Protocols:** A table with columns for CTSU Activation Date, Protocol Number, LPO, Title, Disease, and Target Accrual. It lists a protocol for "Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Lung Cancer".
- Site Registration at all sites:** A table with columns for Site, Protocol, Site Name, Comments, Missing Requirements (if applicable), and Registration Status. It shows registration details for sites NCI028 and NCI029.

Protocols tab

Regulatory tab

Clinical Data tab

OPEN tab

Rave tab



Protocol Accrual Summary at all sites

#	Protocol	Target Accrual	Accrual at Site(s) on
1	9177	153	0
2	E3311	377	1
3	NSABP-B-43	2000	

Unviewed DSNs for Studies at all sites

Post Date	SAE Number	Adverse Events	Action

Newly Posted Protocols

#	CTSU Activation Date
1	09/08/2014
2	09/17/2014
3	09/24/2014
4	10/08/2014
5	10/17/2014
6	10/27/2014

Protocol Updates at CA006

#	Protocol	Update	Post Date
1	NSABP-B-43	URGENT UPDATE: Memorandum: Central HER2 Testing To Resume for NSABP B-43	10/24/2014
2	NSABP-B-43	Memorandum: HercepTest Kit Shortage	10/10/2014
3	NSABP-B-43	Important Information: Memorandum: Shortage of HercepTest Kits for Central HER2 Testing Prior to Enrollment	10/03/2014
4	9177	Amendment #5 and Amendment #6	09/25/2014

- **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

Coming Soon!

- Pending Rave Queries

In-Progress Enrollments

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

#	Site	Protocol	Date	Tracking#	Last User
1	MN054	<u>E5508</u>	10/10/2014	<u>204712</u>	
2	MN014	<u>E3A06</u>	10/13/2014	ZU	

Deep-link to OPEN patient enrollment page in a new browser tab

Multi-Step Enrollments

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

If you are aware that a given patient is not going to move onto the next step, please complete the appropriate documentation and/or contact study LPO

All Sites ▾ All Protocols ▾ Last 30 Days ▾

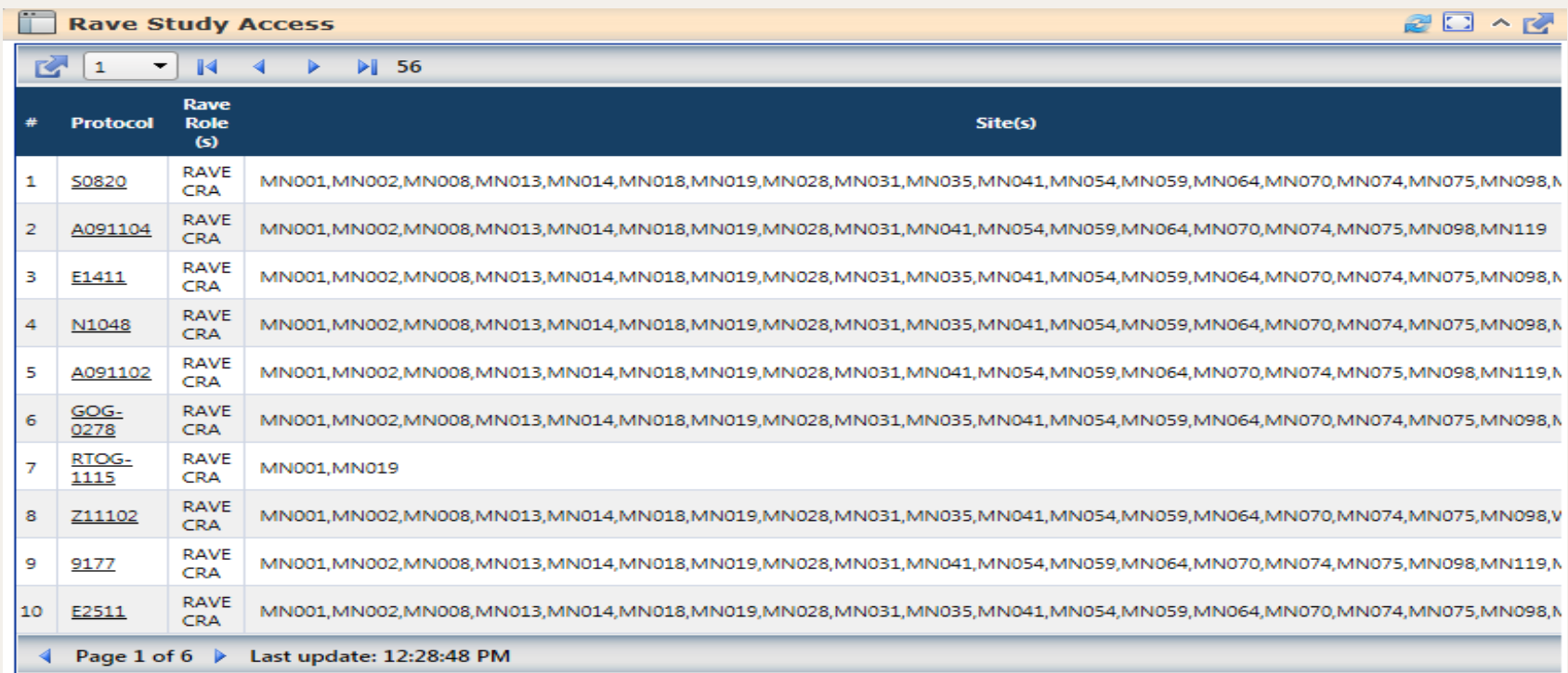
1 ▾ 11 records

#	Site	Protocol	Patient ID	Step	Date	# Days Since Last Step	Arm	Investigator
1	MN001	RTOG-1010	1010-473	1	10/13/2014			
2	MN014	A041202	9101022	1	10/09/2014			

Deep-link to OPEN patient page in a new browser tab

Rave Study Access

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



The screenshot shows a web application window titled "Rave Study Access". The window contains a table with 10 rows of study access information. The table has four columns: "#", "Protocol", "Rave Role(s)", and "Site(s)". The "Rave Role(s)" column consistently shows "RAVE CRA" for all studies. The "Site(s)" column lists various site identifiers for each study. The table is displayed on page 1 of 6, with a last update time of 12:28:48 PM.

#	Protocol	Rave Role(s)	Site(s)
1	S0820	RAVE CRA	MN001,MN002,MN008,MN013,MN014,MN018,MN019,MN028,MN031,MN035,MN041,MN054,MN059,MN064,MN070,MN074,MN075,MN098,M
2	A091104	RAVE CRA	MN001,MN002,MN008,MN013,MN014,MN018,MN019,MN028,MN031,MN041,MN054,MN059,MN064,MN070,MN074,MN075,MN098,MN119
3	E1411	RAVE CRA	MN001,MN002,MN008,MN013,MN014,MN018,MN019,MN028,MN031,MN035,MN041,MN054,MN059,MN064,MN070,MN074,MN075,MN098,M
4	N1048	RAVE CRA	MN001,MN002,MN008,MN013,MN014,MN018,MN019,MN028,MN031,MN035,MN041,MN054,MN059,MN064,MN070,MN074,MN075,MN098,M
5	A091102	RAVE CRA	MN001,MN002,MN008,MN013,MN014,MN018,MN019,MN028,MN031,MN041,MN054,MN059,MN064,MN070,MN074,MN075,MN098,MN119,M
6	GOG-0278	RAVE CRA	MN001,MN002,MN008,MN013,MN014,MN018,MN019,MN028,MN031,MN035,MN041,MN054,MN059,MN064,MN070,MN074,MN075,MN098,M
7	RTOG-1115	RAVE CRA	MN001,MN019
8	Z11102	RAVE CRA	MN001,MN002,MN008,MN013,MN014,MN018,MN019,MN028,MN031,MN035,MN041,MN054,MN059,MN064,MN070,MN074,MN075,MN098,V
9	9177	RAVE CRA	MN001,MN002,MN008,MN013,MN014,MN018,MN019,MN028,MN031,MN041,MN054,MN059,MN064,MN070,MN074,MN075,MN098,MN119,M
10	E2511	RAVE CRA	MN001,MN002,MN008,MN013,MN014,MN018,MN019,MN028,MN031,MN035,MN041,MN054,MN059,MN064,MN070,MN074,MN075,MN098,M

Page 1 of 6 Last update: 12:28:48 PM

Protocol Updates

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

User can search for a specific protocol

#	Protocol		
1	GOG-0275	Revision #5	
2	NSABP-B-52	B-52 Amendment #3 Activation Instructions and Investigators Letter	04/20/2015
3	A041202	Memorandum: Alliance A041202 Monthly CRA Teleconference Invitation	04/16/2015
4	A041202	Memorandum: Alliance A041202 Update #2 Booklet reordering Instructions for Substudy A041202-EL1	04/16/2015
5	A041202	Update #2	04/16/2015
6	A071102	Update #1	04/16/2015
7	S0931	Revision #4	04/15/2015
8	S1007	Memorandum: Forms Update	04/15/2015
9	NRG-CC002	Revision #1	04/13/2015
10	E5508	Memorandum: E5508 Step 1 Accrual to Close May 8, 2015	04/08/2015

Page 1 of 5 Last update: 1:40:18 PM

Site Registration

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

Site Registration at all sites

All Sites ▾ All ▾ Go

Pin Sites
All Sites
CTSU
NCICIRB

All
All, but Closed
Approved
Closed
Disapproved
Pending

User can search for a specific protocol

#	Site	Comments	Requirement (if applicable)	Registration Status
		NCT Central	No treatment	

Unviewed DSNs

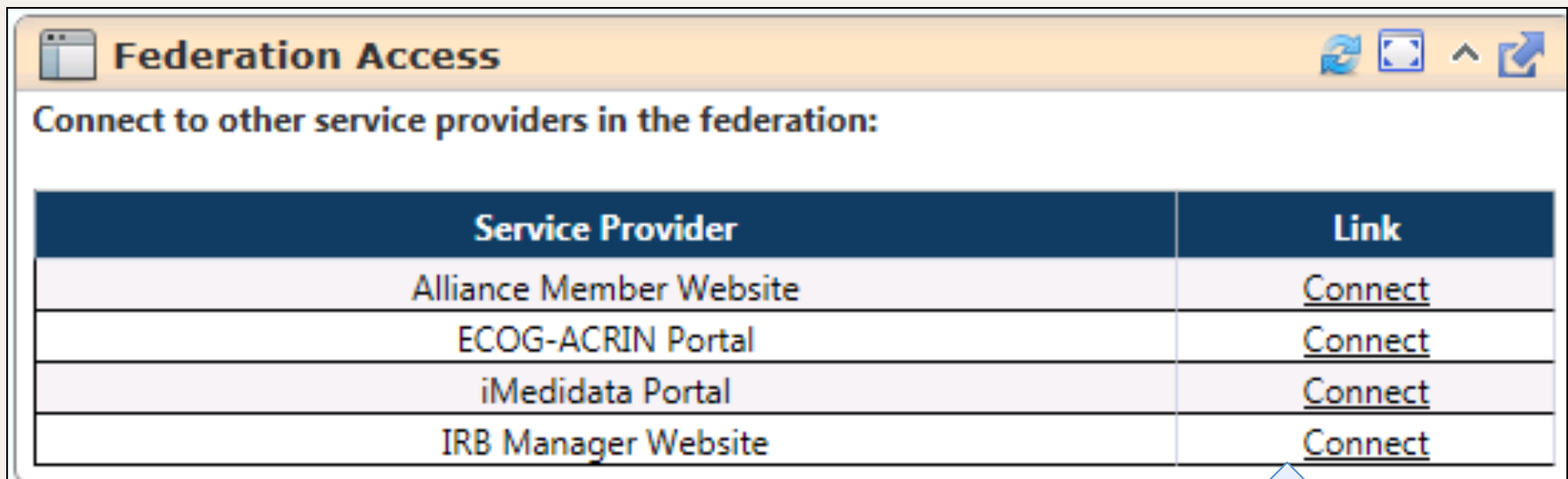
Displays a list of all unviewed Drug Safety Notifications specific to all protocols open at your site(s).

#	Protocol Number	Drug	Post Date	SAE Number	Adverse Events	Action
1	N1174	<u>Bevacizumab</u>	10/08/2014	<u>2971421</u>	intracranial hemorrhage (Gr. 5)	★

**Opens SAE document
in a new browser tab**

Federation Access

Displays quick links to other applications in the Federation.



Service Provider	Link
Alliance Member Website	Connect
ECOG-ACRIN Portal	Connect
iMedidata Portal	Connect
IRB Manager Website	Connect

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.

#	Name	CTEP ID	Person Type	Status	Days to Suspension	CTEP Reg Exp Date
1		42081	IVR	Suspended !		12/15/2013
2		33410	IVR	Active	56	12/10/2014 IN036,IN090,IN186
3		23241	IVR	Active	58	12/12/2014 IN036,IN090,IN186,NICR
4		46722	IVR	Active	59	12/13/2014 IN036,IN090,IN186

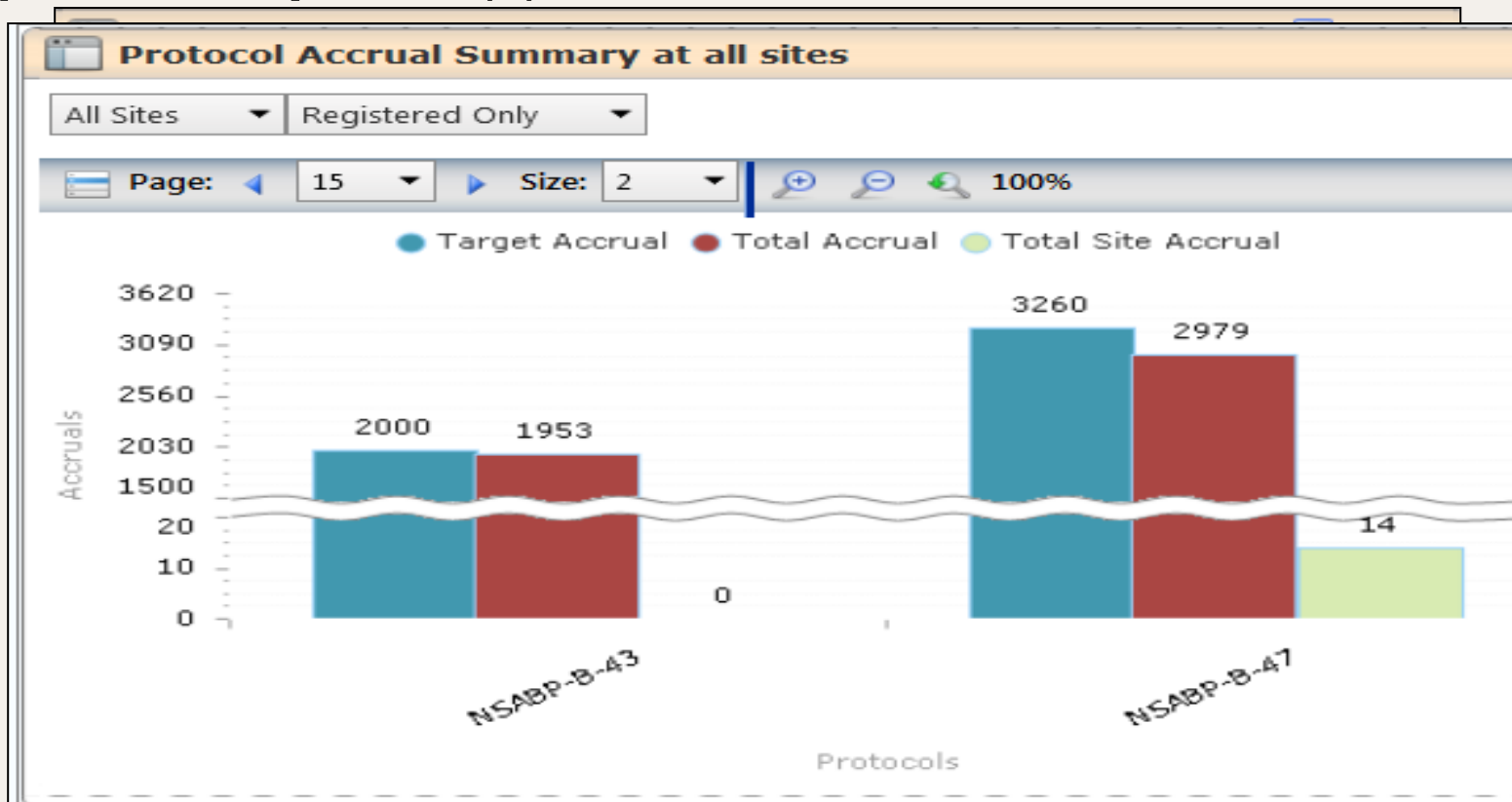
Newly Posted Protocols

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

#	CTSU Activation Date	Protocol Number	LPO	Title	Disease	Target Accrual
1	10/08/2014	  S1406	SWOG	Randomized Phase II Study of Irinotecan and Cetuximab with or Without Vemurafenib in BRAF Mutant Metastatic Colorectal Cancer	Gastrointestinal Cancer	78
2	09/24/2014	   9671	NCI	Exceptional Responders Pilot Study: Molecular Profiling of Tumors From Cancer Patients Who Are Exceptional Responders	Multiple Cancers	300
3	08/22/2014	  E1808	ECOG-ACRIN	A Randomized Phase II Trial of Sunitinib/Gemcitabine or Sunitinib in Advanced Renal Cell Carcinoma with Sarcomatoid Features	Genitourinary Cancer	100

Protocol Accrual Summary

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



Expiring IRB Approval Status

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

#	Site	Protocol	Approval Date	Expiry Date	Days to expire
1	IN051	RTOG-1205	12/18/2013	12/17/2014	64
2	IN051	NSABP-B-47	12/18/2013	12/17/2014	64
3	IN051	SCUSF-0806	12/18/2013	12/17/2014	64
4	IN051	E6508	12/18/2013	12/17/2014	64
5	IN051	GOG-0237	12/18/2013	12/17/2014	64
6	IN051	RTOG-0631	12/18/2013	12/17/2014	64
7	IN051	GOG-0256	12/18/2013	12/17/2014	64
8	IN051	NSABP-P-5	12/18/2013	12/17/2014	64
9	IN051	NCCTG-N08C3	12/18/2013	12/17/2014	64
10	IN051	NCCTG-N08C1	12/18/2013	12/17/2014	64

CTEP Profile

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

CTEP Profile: Patrichuk, Lucille (510167)

NCI Status: Active	CTEP Email : lucillepatrichuk@westat.com
CTEP-IAM Account Expires (in days): 29 Renew	Office Phone : (240) 314-2572
Password Expires (in days): 73 Change	Office fax : (301) 610-5517

#	Group/Roster	Site	Status	Roles
1	CTSU	CTSU	Active	CENTER CTSU Staff, OPEN Admin, Panel Member, Project Manager
2	NCICIRB	NCICIRB	Active	Research Staff

Site Accrual Report

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

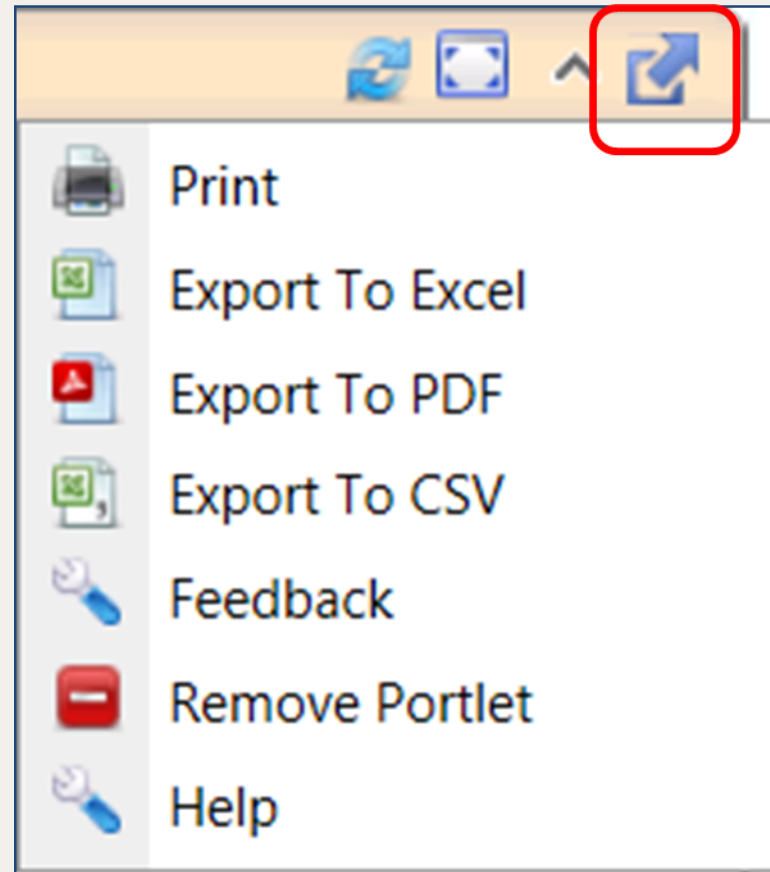
#	SITE CTEP	TRACKING NUMBER	Protocol	PATIENT ID	ENROLLMENT DATE	INVESTIGATOR
1	NJ023	209524	A221301	0001305	11/17/2014	Atari, Louis M
2	NJ023	206439	S1007	0001306	10/23/2014	Atari, Louis M
3	NJ023	205952	A221102	0001307	10/21/2014	Marston, Jill S
4	NJ023	204126	A221301	0001308	10/07/2014	Atari, Louis M
5	NJ023	196879	S0931	0001309	09/02/2014	Marston, Jill S
6	NJ023	179852	SCUSF-0806	0001310	04/24/2014	Atari, Louis M
7	NJ023	179654	S1007	0001311	04/23/2014	Atari, Louis M
8	NJ023	172829	CALGB-70807	0001312	03/04/2014	Atari, Louis M
9	NJ023	171519	S1007	0001313	02/19/2014	Atari, Louis M
10	NJ023	171452	E1Z11	0001314	02/18/2014	Atari, Louis M



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

The screenshot shows the CTSU website dashboard. At the top, there is a navigation bar with tabs for Home, Protocols, Dashboard (highlighted), Regulatory, OPEN, Rave, Clinical Data, and Education & Resources. Below the navigation bar, a message reads: "Welcome to Dashboard. Click [here](#) to watch a video tutorial." The word "here" is enclosed in a dashed box. A blue arrow points from a callout box below to this link. The callout box contains the text: "Click to open CTSU website tutorial in a separate window". Below the message, there is a video player window titled "Using the CTSU Dashboard". The video player has a navigation menu on the left with the following items: "Navigation Menu" (in red), "Introduction to the Dashboard", "Creating a Custom Profile", "Portlet Level Standard Features", and "List of Individual Portlets". The main content area of the video player is titled "CTSU Dashboard Overview" and contains the following text: "Welcome to the video series for the CTSU Website Dashboard. The CTSU Website Dashboard is an interface providing CTSU members with a single location for viewing information related to their protocols. It also allows access to all available applications under the CTEP federation. The Dashboard was developed based on website user recommendations and testing. This video series introduces the CTSU Website Dashboard and includes instructions for using its key features. First-time users will probably find it helpful to view the videos in the order shown to the left. For ongoing reference, the videos may be accessed in any order." At the bottom of the video player, there is a video control bar showing a play button, a progress bar at 00:00, and other standard video controls.



OPEN
TRANSFER & UPDATE MODULE
NOW AVAILABLE!

Types of Updates/Transfers

Action	Scenarios
Patient Transfers	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Patient demographic data needs to be changed.

Transfer & Update Module

Home Slot Reservation Enroll History **T&UM** Reports RSS Help

In Progress Create New | History | Help Tool

In-Progress T&UM Requests * Click the Select button to review a particular record. For request that have been completed, please go to


1 25 Search Clear


Action	V	Request #	Track #	Site	Study	Patient ID	Request Type	Request Status	Created By
Select		TUM-0000000220	239517	MI142	A071101	9101880-1	SITE_TRANSFER	ACCEPTED	STEINMETZS
Select		TUM-0000000217	209865	KS063	CALGB-90601	136964-1	SITE_TRANSFER	ACCEPTED	PENNELS
Select		TUM-0000000207	161444	NE047	N0877	9054948-1	SITE_TRANSFER	REQUESTED	SEVERINS
Select		TUM-0000000206	119213	NE047	8129	9054366-1	SITE_TRANSFER	REQUESTED	SEVERINS
Select		TUM-0000000205	102811	NE047	N0874	9053016-1	SITE_TRANSFER	REQUESTED	SEVERINS

T&UM – Create New Screen

Home Slot Reservation Enroll History **T&UM** Reports RSS Help

In Progress | **Create New** | History | Help Tool

 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
<input checked="" type="radio"/> 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.
<input type="radio"/> Credentialing Data Update	Update credentialing data for a patient that will remain at the same institution.
<input type="radio"/> 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.

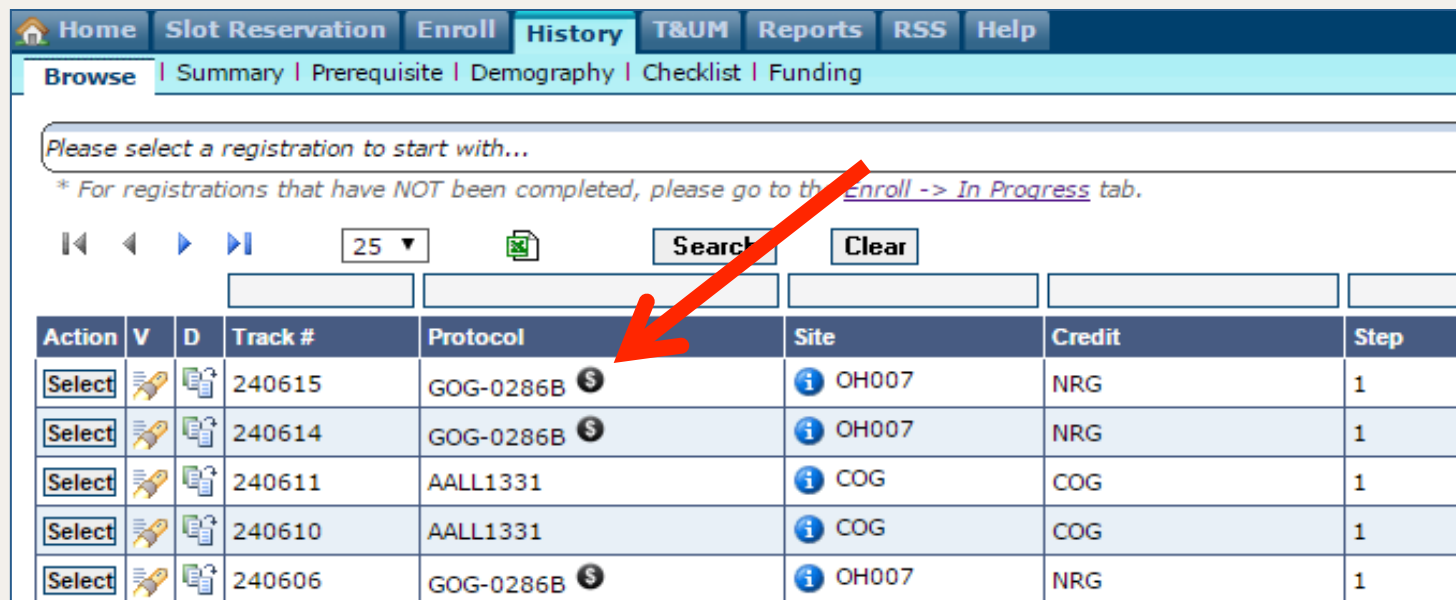




OPEN FUNDING

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.



Action	V	D	Track #	Protocol	Site	Credit	Step
Select			240615	GOG-0286B \$	OH007	NRG	1
Select			240614	GOG-0286B \$	OH007	NRG	1
Select			240611	AALL1331	COG	COG	1
Select			240610	AALL1331	COG	COG	1
Select			240606	GOG-0286B \$	OH007	NRG	1

OPEN Funding Report

Oncology Patient Enrollment Network [ABRAHAML - 04/21/15 01:00:31 PM EDT]



Funding Report for Ohio State University Comprehensive Cancer Center (OH007)

To sort the results by Completion Date, click the header of "Completion Date" column

Navigation: 1 2 3 4 5 | 25 | Search Clear

Site	Protocol	Credit Network Group	Investigator	Patient ID	Enrollment Date	Funding Type	Funding #	Funding Status	Specify	Completion Date	Completed By
OH007	A011106	ALLIANCE	[REDACTED]	9101163-1	10/20/2014 01:39 PM	Biospecimen	3	ACTIVE	Biospecimen - Serum - Serum, plasma, whole blood	10/21/2014	OSMANN
OH007	A011106	ALLIANCE	[REDACTED]	9101163-1	10/20/2014 01:39 PM	Special	1	ACTIVE	Biospecimen - Tissue - Pre-treatment core biopsy	10/21/2014	OSMANN
OH007	A011106	ALLIANCE	[REDACTED]	9101163-1	10/20/2014 01:39 PM	Biospecimen	2	ACTIVE	Biospecimen - Tissue		
OH007	A011106	ALLIANCE	[REDACTED]	9101163-1	10/20/2014 01:39 PM	Special	2	ACTIVE	Biospecimen - Tissue - Week 4 core biopsy	11/19/2014	OSMANN
OH007	A011106	ALLIANCE	[REDACTED]	9101163-1	10/20/2014 01:39 PM	Biospecimen	1	ACTIVE	Biospecimen - Other - Formalin core biopsies, frozen core biopsies, slides		
OH007	A011106	ALLIANCE	[REDACTED]	9101717-1	12/23/2014 12:22 PM	Biospecimen	1	ACTIVE	Biospecimen - Other - Formalin core biopsies, frozen core		

Funding Information Page

[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

Instructions

- 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 NCORP 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 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.
- See protocol funding sheet for more details and information about non-NCI funding.
- Click [NCTN Funding Instructions](#) for more information.

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

Display inactive funding also

NCI Funding Sources

#	Funding Source	Funding Type	Funding Type #	Specify	Collect Type	NCTN \$ Value	NCORP \$ Value	Funding Status	Collect in OPEN
1	DCTD-DCP	Screening for Intervention		H&E and paraffin block form initial surgery	Mandatory	\$500.00	\$500.00	ACTIVE	No
2	DCTD-DCP	Base Intervention			Mandatory	\$1,750.00	\$2,000.00	ACTIVE	No

Funding Documents

#	Document Title	Document Date	Format	Post Date
1	A071102 Funding Sheet	01/01/15	PDF	02/18/15

OPEN Oncology Patient Enrollment Network

OPEN is the web-based registration system for patient enrollments onto NCI-sponsored Network Group and Network Groups' registration/randomization systems for patient registration/randomization. OPEN provides access 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](#)

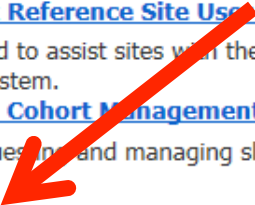
The OPEN training video has been reformatted. It is now easier to access the information you need. Just click on one of the tabs at the top of the screen for a drop down list of instructional topics, then click on the specific topic you want to view.
- [Guidelines for OPEN Access and Crediting](#)

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 User 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 requesting and 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	NCORPPSYS 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

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

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

Documents

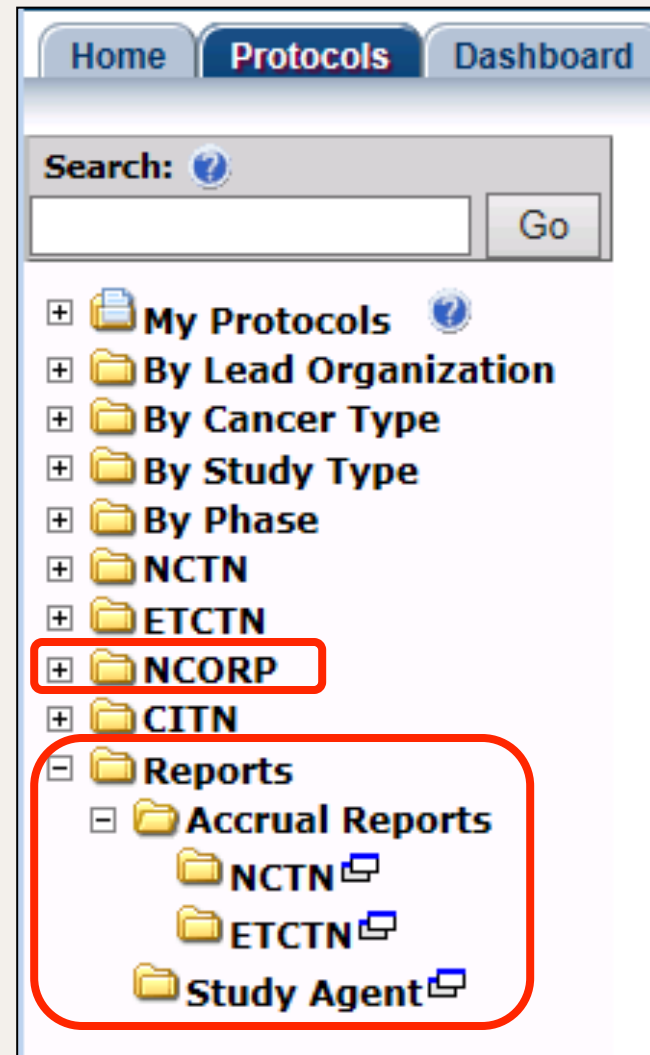
#	Document Title	Document Date	Format	Post Date
Protocol				
1	Protocol Document (NCI Version Date 03/20/2015)	04/15/15	PDF	04/16/15
2	Update #1	04/15/15	PDF	04/16/15
3	Memorandum: Activation Notice	12/15/14	PDF	12/18/14
4	Memorandum: Adverse Event Reporting	12/15/14	PDF	12/18/14
Education and Promotion 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
Case 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 Rave 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
Site Registration Documents				
1	CTSUS 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 ETCTN
 - 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) ***






























1. 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 ***

1. 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

Search:

Go

- ⊕  **My Protocols** 
-  **My Favorites** [0 docs]
-  **National Clinical Trials Network (NCTN) Program**
-  **Experimental Therapeutics Clinical Trials Network (ETCTN) Program**
-  **CIRB-CTSU Integration**
- ⊖  **CTSU Operations Information**
 -  Basic Information Materials
 -  CTSU Generic Forms
 -  CTSU Processes
 -  Member Services
 -  Policy Guidelines
- ⊕  **Protocol Specific Materials**
- ⊕  **Audit Resources**
- ⊖  **Researcher Resources**
 -  Adverse Event Reporting and CTEP-AERS
 -  Clinical Data Update System (CDUS)
 -  Dangerous Goods Shipping Training
 -  Human Subjects Protection
 -  IRB and Assurance Information
 -  Investigator Credentialing Forms
 -  National Cancer Institute Resources
 -  On-Line Training/Education for Healthcare Professionals
- ⊖  **Educational Presentations and Webinars**
 -  Slide Sets
 -  Webinars
- ⊕  **Site Advisory Panel**
- ⊕  **Frequently Asked Questions (FAQs)**
-  **Glossary and Acronyms**

Education and Resources Page

Welcome to the CTSU's Education and Resources Page ([Resources](#)), to information on how the CTSU operates through the CTSU ([Protocol-Specific Materials](#)). We use presentations that the CTSU has developed over time.

We hope that you will explore this page to discover all that would prove helpful in working with the CTSU, please

Questions?

- CTSU Help Desk
 - Email:
ctsucontact@westat.com
 - Phone: 1-888-823-5923

