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# **NCTN GROUP MEETINGS**

Fall 2015

# Agenda

- Roster Update Management System (RUMS)
- Regulatory Updates
- CTSU Report and Information Subscription Portal (CRISP)
- OPEN and T&UM Updates
- Serious Adverse Event (SAE) Integration
- Upcoming Features: National Coverage Analysis, Data Quality Portal, Google Search, Site Registration Portal, Webinars, Protocol Tree



## THE ROSTER UPDATE MANAGEMENT SYSTEM (RUMS)

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# Is There An Easier Way To Manage Roster Data?

# The Roster Update Management System (RUMS)

RUMS is an application hosted on the CTSU website that allows the management of institution and person roster data through a direct link with the Regulatory Support System (RSS).



# RUMS Features

- Supports common and roster-specific attributes.
- Supports document collection.
- Contains training information, including a video and user guide.
- Highly configurable for roster owner-specific requirements.
- Deep-linking capabilities to NCORP-SYS.

# RUMS Business Rules

- Persons with an active CTEP-IAM can access and view roster data for their associated sites.
- Persons with primary roles at the site for the roster owner may request changes.
- All person records being requested for update must have an active or approved CTEP ID.
- With the exception of the Rave-related and Registrar roles, roles are roster owner specific.

# **RUMS Business Rules (cont.)**

- Roster owners may configure which roles are available in RUMS and which actions site users can take on their roster.
- NCORP sites will continue to use NCORP-SYS to add persons and sites.
- Lead Academic Participating Sites (LAPS) and Lead Academic Organizations (LAOs) must contact CTEP to add or withdraw sites.

# Possible RUMS Functions

NCTN Member Type	Action	Allowed	Roster Owner Review
Main Member	Add or withdraw non-primary person role	X	No
Main Member	Request to add primary role to self	X	Yes
Main Member	Request to add or withdraw a person	X	Yes
Main Member	Request to add or withdraw affiliate, sub-affiliate, LAPS AA, LAPS ASA	X	Yes
NCORP	Add or withdraw non-primary person role	X	No
NCORP	Request to add primary role to self	X	Yes
NCORP	Request to add or withdraw a person	N/A	N/A
NCORP	Request to add or withdraw site under the NCORP	N/A	N/A
LAPS	Add or withdraw non-primary person role	X	No
LAPS	Request to add primary role to self	X	Yes
LAPS	Request to add or withdraw a person	X	Yes
LAPS	Request to add or withdraw site under LAPS grant	N/A	N/A

# RUMS Tutorial

**CTSUSU** Cancer Trials Support Unit  
A SERVICE OF THE NATIONAL CANCER INSTITUTE

Home | Contact | Feedback | Public Site | Log Out  
Version: 6.2

My Account Welcome Martha Hering. Your password will expire in 66 days. [Impersonate another user](#)

Home Protocols Dashboard Regulatory OPEN Rave Clinical Data Education & Resources Collaboration **RUMS**

Person Roster Browser Org Roster Browser Tracking (15)

ALLIANCE All Sites All Roles All Persons Add Person Roles & Access Training Video Help Roster Update Form

Change page: Page 5 of 5, items 81 to 94 of 94.

Person Name	CTEP ID	Site	Status	Actions
Terry Walford, Nebbie Elizabeth	47572	IL004	Add Person Request (IN_REVIEW)	
Terry, Keidra	538482	IL004	Pending	
Terry, Keidra	538482	MD029	Active	Clinical Research Associate Registrar
Terry, Keidra	538482	VA195	Active	
Terry, Monique	529237	MD029	Add Person Request (IN_REVIEW)	
Tiffin, Patricia	534221	IL004	Active	Clinical Research Associate Rave CRA Registrar
Turk, Mary	526742	IL004	Active	Clinical Research Associate Rave CRA Registrar
Uhlig, Bill	507113	IL004	Active	Pharmacist
Ujiki, Michael	44238	IL004	Active	Investigator
Velez, Maria	539433	IL004	Active	Clinical Research Associate Rave CRA
Wade, Elaine	24833	IL004	Active	Investigator
Winchester, David	8612	IL004	Active	Investigator
Yao, Katharine	35670	IL004	Active	Investigator
Zeng, Ming	35494	VA195	Pending	

Change page: Page 5 of 5, items 81 to 94 of 94.

Training materials

Tabs to navigate requests & filters



# Adding Person Roles

Home Protocols Dashboard Regulatory OPEN Rave Clinical Data Education & Resources Collaboration RUMS

Person Roster Browser Org Roster Browser Tracking (15)

ALLIANCE MD029 All Roles All Persons Add Person

Person Name	CTEP ID	Site	Status	Roles	Actions
Hering, Martha	501449	MD029	Active	Imaging Coordinator, Oncology Nurse, Read Only A041202, Rave CRA, Lead Clinical Research Professional	
Shriner, Donna	500003	MD029	Active	Pharmacist	
Terry, Keidra	538482	MD029	Active	Clinical Research Associate, Registrar	
Terry, Monique	529237	MD029	Add Person Request (IN_REVIEW)		



Person roles vary by roster owner see the Roles & Access table to determine available roles.

Add Role(s) for 'Shriner, Donna A. (500003)' on site MD029(ALLIANCE).

1. Select Roles 2. Review and Confirm

Previous Next Submit Discard

MD029 [ALLIANCE] Rave CRA --Select Role at Lev Add to Cart

Selected Roles

#	Org ID	Roster Code	Role	Role Assignment Level	Role Assign at ?	Delete
1	MD029	ALLIANCE	Administrator	INSTITUTION	MD029	X
2	MD029	ALLIANCE	Rave CRA	PROTOCOL	A031203	X



# Confirming Changes

**STEPS**  
Add Role(s) for 'Shriner, Donna A. (500003)' on site MD029(ALLIANCE).

1. Select Roles    2. Review and Confirm

Person Roster Browser    Org Roster Browser    Tracking (15)

ALLIANCE    MD029    All Roles    All Persons    **Add Person**

Person Name	CTEP ID	Site	Status	Roles	Actions
Hering, Martha	501449	MD029	Active	Imaging Coordinator, Oncology Nurse, Read Only A041202, Rave CRA, Lead Clinical Research Professional	
Shriner, Donna A.		MD029	Active	Administrator, Rave CRA, <b>A031203</b> , Pharmacist	
Te...		MD029	Active	Clinical Research Associate, Registrar	
Te...		MD029	Add Person Request (IN_REVIEW)		

**Non-primary roles do not require roster owner review and will automatically populate.**

**2 Assign Non Primary Role**    APPROVED

**Role Code:** Rave CRA

**Role level:** PROTOCOL

**Roster Code:** ALLIANCE

**Role At:** MD029 (A031203)

\*\*On submission request will be saved as draft.

# Adding Persons

Person Roster Browser   Org Roster Browser   Tracking (15)

RUMS > Person Roster Browser > Manage Person

**STEPS**

- 1. Select Person
- 2. Select Sites
- 3. Select Roles
- 4. Questions
- 5. Documents
- 6. Review and Confirm

1. Select Person   2. Select Sites   3. Select Roles   4. Questions   5. Documents

6. Review and Confirm

Previous   Next   Submit   Discard

**You have selected Terry,Keidra.**

**CTEP ID:**   **First Name:**   **Last Name:**

        Search   Clear

**Query**

**Click on the CTEP ID to select the person.**

#	CTEP ID	Name	I/A	CTEP Status	State	ZipCode
1	<a href="#">912363</a>	Terry, Katie				
2	<a href="#">538482</a>	Terry, Keidra	A	Active	MD	20850

**To add a person they must have an active CTEP status.**

10/8/2015   Cancer Trials Support Unit   12

# Adding Persons (cont.)

Person Roster Browser   Org Roster Browser   Tracking (15)

RUMS > Person Roster Browser > Manage Person

**STEPS**

1. Select Person ✓  
 Terry, Keidra (538482)

2. Select Sites ✓  
 MD029 - (ALLIANCE)

3. Select Roles

4. Questions

5. Documents

6. Review and Confirm

1. Select Person   2. Select Sites   **3. Select Roles**   4. Questions   5. Documents

6. Review and Confirm

Previous   Next   Submit   Discard

Select Site: MD029 [ALLIANCE]   Select Role: Clinical Research Associa   Select Assign Role At: --Select Role at Lev   Add to Cart

**Selected Roles**

#	Org ID	Roster Code	Role	Role Assignment Level	Role Assign at ?	Delete
1	MD029	ALLIANCE	Clinical Research Associate	INSTITUTION	MD029	

# Adding Persons (cont.)

RUMS > Person Roster Browser > Manage Person

Home Protocols Dashboard Regulatory OPEN Rave Clinical Data Education & Resources Collaboration RUMS

Person Roster Browser Org Roster Browser Tracking (15)

RUMS > Person Roster Browser > Manage Person

## STEPS

- ✓ 1. Select Person -  
Terry, Keidra (538482)
- ✓ 2. Select Sites -  
MD029 - (ALLIANCE)
- ✓ 3. Select Roles -  
Clinical Research Associate @MD029 (ALLIANCE)
- ✓ 4. Questions -  
REQUIRED: 1 of 1 answered  
OPTIONAL: 4 of 5 answered
- 5. Documents
- 6. Review and Confirm

1. Select Person 2. Select Sites 3. Select Roles 4. Questions 5. Documents

6. Review and Confirm

Previous Next Submit Discard

Document Title	File Name	Uploaded By	Uploaded On	Action
HST Training Certificate - Assoc ?				<ul style="list-style-type: none"><li>● UpdateAccessInternal.doc</li><li>✗ Remove</li></ul>

6. Please enter the date your HST training expires (mm/dd/yyyy).

# Confirm Person Addition

**STEPS**

- 1. Select Person
- 2. Select Sites
- 3. Select Roles
- 4. Questions
- 5. Documents
- 6. Review and Confirm

1. Select Person ✓

Terry, Keidra (538482)

2. Select Sites ✓

MD029 - (ALLIANCE)

3. Select Roles ✓

Clinical Research Associate @MD029

Person Roster Browser | Org Roster Browser | Tracking (15)

RUMS > Person Roster Browser > Manage Person

**STEPS**

- 1. Select Person
- 2. Select Sites
- 3. Select Roles
- 4. Questions
- 5. Documents
- 6. Review and Confirm

1. Select Person ✓

Terry, Keidra (538482)

2. Select Sites ✓

MD029 - (ALLIANCE)

3. Select Roles ✓

Clinical Research Associate @MD029 (ALLIANCE)

4. Questions ✓

REQUIRED: 1 of 1 answered

OPTIONAL: 4 of 5 answered

Previous Next Submit Discard

You are about to submit 2 requests. Please review before you click SUBMIT button.

**1 Add Associate to ALLIANCE** Ready To Submit

Person Name: Terry, Keidra

**ALL GOOD?**

Previous Next Submit Discard

✓ All requests have been submitted successfully. [Return to Person Roster Browser.](#)

**1 Add Associate to ALLIANCE** ✓ IN\_REVIEW

Person Name: Terry, Keidra

Person Code: 538482

Institution: MD029

Roster Code: ALLIANCE

Please enter the date your HST training expires (MM/DD/YYYY)

**Documents:**

Document Title	File Name	Uploaded By	Uploaded On
HST Training Certificate - Assoc ?	<a href="#">UpdateAccessInternal.docx</a>		

**2 Assign Non Primary Role** Ready To Submit

Role Code: Clinical Research Associate

Role level: INSTITUTION

Roster Code: ALLIANCE

Role At: MD029

# Request Tracking

Person Roster Browser   Org Roster Browser   **Tracking (17)**

**Review status of requests for persons and organizations.**

Status Filter: All Open Status   **Apply Filter**

**Person Roster Request**   Org Roster Requests

**Edit Requests**

#	Request ID	Request Date	Operation	Roster	Site	Site Name	CTEP ID	Name	Person Type	Role			
1	81850	06/29/2015 10:41:46	Assign Non-Primary Role	ALLIANCE	MD029	MedStar Franklin Square Medical Center/Weinberg Cancer Institute	538482	Terry, Keidra	Associate	Clinical Research Associate	INSTITUTION	ON_HOLD	X
2	81849	06/29/2015 10:41:43	Add Associate	ALLIANCE	MD029	MedStar Franklin Square Medical Center/Weinberg Cancer Institute	538482	Terry, Keidra	Associate			IN_REVIEW	X
3	81845	06/26/2015 08:01:53	Assign Non-Primary Role	ALLIANCE	MD029	MedStar Franklin Square Medical Center/Weinberg Cancer Institute	529237	Terry, Monique R.	Associate	CRA (LabAdmin)	PROTOCOL	ON_HOLD	X
4	81844	06/26/2015 08:01:52	Add Associate	ALLIANCE	MD029	MedStar Franklin Square Medical Center/Weinberg Cancer Institute	529237	Terry, Monique R.	Associate			IN_REVIEW	X
5	81838	06/24/2015 15:44:09	Assign Primary Role	ALLIANCE	MD029	MedStar Franklin Square Medical Center/Weinberg Cancer Institute	500003	Shriner, Donna A.	Associate	Lead Rese Prof			<b>Someone already has this role</b>



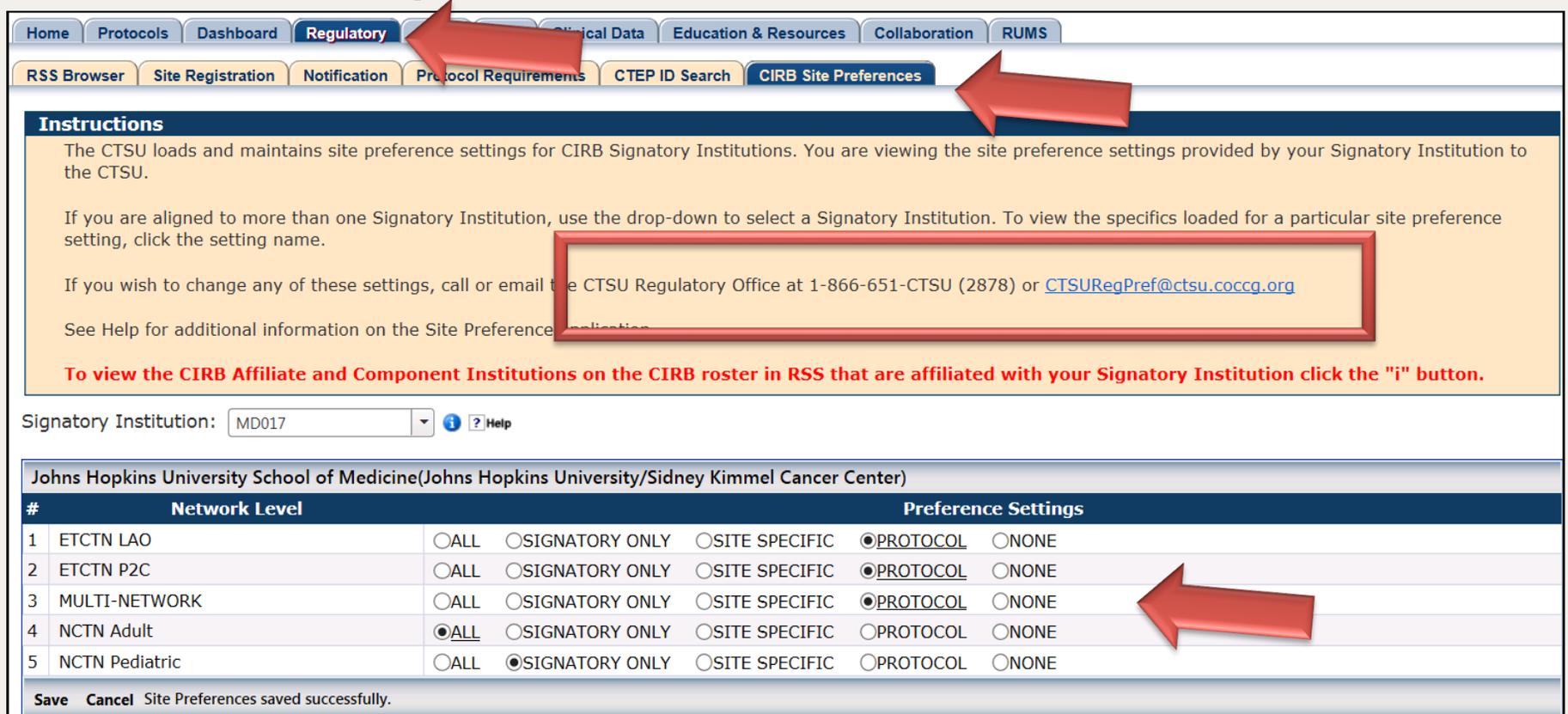
## REGULATORY UPDATES FOR CIRB AND LOCAL IRBs

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# How Can I Better Manage Regulatory Submissions?

# Sites Using the CIRB

Ensure site preferences are set.



**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-CTSUs (2878) or [CTSUSRegPref@ctsu.cocccg.org](mailto:CTSUSRegPref@ctsu.cocccg.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: MD017   Help

Johns Hopkins University School of Medicine(Johns Hopkins University/Sidney Kimmel Cancer Center)

#	Network Level	Preference Settings				
1	ETCTN LAO	<input type="radio"/> ALL	<input type="radio"/> SIGNATORY ONLY	<input type="radio"/> SITE SPECIFIC	<input checked="" type="radio"/> PROTOCOL	<input type="radio"/> NONE
2	ETCTN P2C	<input type="radio"/> ALL	<input type="radio"/> SIGNATORY ONLY	<input type="radio"/> SITE SPECIFIC	<input checked="" type="radio"/> PROTOCOL	<input type="radio"/> NONE
3	MULTI-NETWORK	<input type="radio"/> ALL	<input type="radio"/> SIGNATORY ONLY	<input type="radio"/> SITE SPECIFIC	<input checked="" type="radio"/> PROTOCOL	<input type="radio"/> NONE
4	NCTN Adult	<input checked="" type="radio"/> ALL	<input type="radio"/> SIGNATORY ONLY	<input type="radio"/> SITE SPECIFIC	<input type="radio"/> PROTOCOL	<input type="radio"/> NONE
5	NCTN Pediatric	<input type="radio"/> ALL	<input checked="" type="radio"/> SIGNATORY ONLY	<input type="radio"/> SITE SPECIFIC	<input type="radio"/> PROTOCOL	<input type="radio"/> NONE

**Save** **Cancel** Site Preferences saved successfully.

# Additional Tips for CIRB Sites

- Contact the CIRB as soon as possible when institutions need to be added or withdrawn from the Signatory.
- Contact the CTSU Regulatory Office to set preferences for newly added sites, or to add a site to an existing approval under the Signatory site.
- For additional information, review the slide set on the CTSU website under the Education and Resources tab > CIRB-CTSU Integration.

# Sites Using a Local IRB

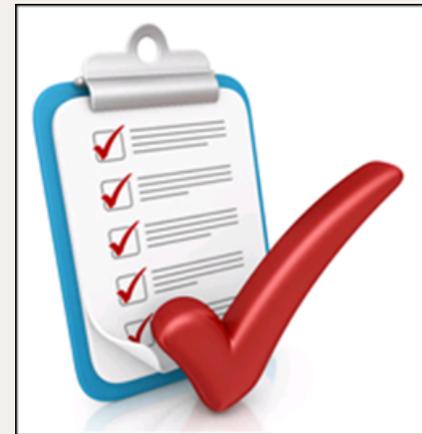
Submit to the CTSU Regulatory Office one or a combination of the following three documents:

- CTSU IRB Certification;
- IRB Approval Letter; *or*
- Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption Form.

# Using a Local IRB (cont.)

The documents submitted should include:

- Protocol number and title (short title okay);
- Protocol version date or version number;
- Institution name and CTEP ID;
- Assurance number;
- PI name and CTEP ID;
- Review type; *and*
- Date of approval and expiration date.



# Using a Local IRB (cont.)

- Ensure the approval is signed by the IRB signatory.
- If the local IRB signs electronically submit a copy of the IRB policy (one time only).
- Approvals must be in English.
- For contingent approvals, submit subsequent letters showing final IRB approval.



## CTSUS REPORT AND INFORMATION SUBSCRIPTION PORTAL (CRISP)

**Can I get protocol updates  
emailed to me?**

# CTSU Report and Information Subscription Portal (CRISP)

CRISP allows CTSU website users to subscribe and manage e-mail notifications.

Available Subscriptions	Subscriptions in Development
Summary of multi-step enrollments	Newly posted protocol-related documents
Summary of changes to person roster	Accrual notifications for my site
New protocols in my area of interest	Summary of incomplete patient enrollments
Expiring IRB approvals	Unused slot reservations
Changes to Site Registration statuses	New data on a user dashboard portlet

# Accessing CRISP

CTSU Information Subscription Portal

CTSU Information Subscription Portal

Add New

My Subscriptions Inactive Subscriptions View Subscribed Messages History

#	Notification Subject	Frequency	Subscriptions Settings	Action
1	IRB Approval Expiring in 30 Days	WEEKLY	Site Ctep Id <b>ALL</b>	
2	New Protocols in Your Area of Interest	DAILY	Disease Name <b>Breast Cancer</b> <b>CNS Metastases (see Metastatic Cancer)</b> <b>CNS Primary</b> <b>Gastrointestinal Cancer</b> <b>Gynecologic Cancer</b> <b>Miscellaneous Neoplasm</b>	
3	Summary of Multi-step Enrollments at all Sites	MONTHLY	Site Ctep Id <b>ALL</b>	
4	Summary of Changes to the Selected Person Rosters	DAILY	Roster Owner <b>CTSU</b> Site Ctep Id <b>ALL</b>	

# Subscribing to Notifications

CTSU Information Subscription Portal

## Add Subscriptions Wizard

1. Select Notifications    2. Configure Subscriptions    3. Review and Confirm

Previous    **Next**    Submit    Discard



**Enrollment Updates**

1	<input type="radio"/>	Summary of Multi-step Enrollments at all Sites	Provides a summary of multi-step enrollments at your selected sites
---	-----------------------	--	---

**Person Roster Updates**

1	<input type="radio"/>	Summary of Changes to the Selected Person Rosters	Lists all roster additions/withdrawals including person role changes made to the selected roster during your specified time range
---	-----------------------	---	---

**Protocol Updates**

1	<input checked="" type="radio"/>	New Protocols in Your Area of Interest	Lists all upcoming studies in your selected area of interest or disease category
---	----------------------------------	--	--

**Regulatory Updates**

1	<input type="radio"/>	IRB Approval Expiring in 30 Days	Lists all IRB approvals due to expire within 30-days
2	<input type="radio"/>	Site Registration Status Changes	Provides a summary of Site Registration Status Changes

# Setting Notification Preferences

## Add Subscriptions Wizard

1. Select Notifications

2. Configure Subscriptions

3. Review and Confirm

Previous

Next

Submit

Discard

You are subscribing to **New Protocols in Your Area of Interest** notification. Please select value(s) for each list below, click **Add to Cart** and then click **Next**.

Select Frequency:

DAILY

Select Area of Interest:

4 items checked

Add to Cart

Review Subscription

# Notification

No records were found that r

- Adrenocortical
- Brain Cancer
- Breast Cancer
- CNS Metastases  
(see Metastatic Cancer)
- CNS Neoplasms  
(Primary Tumor)
- CNS Primary
- Carcinoid
- GI Stromal Tumor

Frequency	Subscriptions Settings	Delete

# Review & Submit

## Add Subscriptions Wizard

1. Select Notifications

2. Configure Subscriptions

3. Review and Confirm

Previous

Next

Submit

Discard

✓ You have subscribed successfully.

### Selected Notifications

#	Notification	Frequency	Subscriptions Settings
1	Lists all upcoming studies in your selected area of interest or disease category	DAILY	Disease Name Brain Cancer CNS Metastases (see Metastatic Cancer) CNS Neoplasms (Primary Tumor)



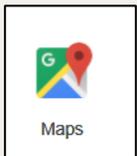
## OPEN AND THE TRANSFER & UPDATE MODULE (T&UM)

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# What's New In OPEN?

# T&UM Updates

- T&UM is being used for SWOG, Alliance, and ECOG-ACRIN trials; NRG usage is expected in mid-October.
- New updates:
  - An ‘archive’ folder has been added to the T&UM’s History Tab to view patients that have been transferred from a site.
  - Google Maps has been integrated into the T&UM Help Tool. The Google Map will display on the left side of the screen, a list of possible Receiving Institutions (complete with their addresses) will display on the right side of the screen.



# Google Maps in T&UM

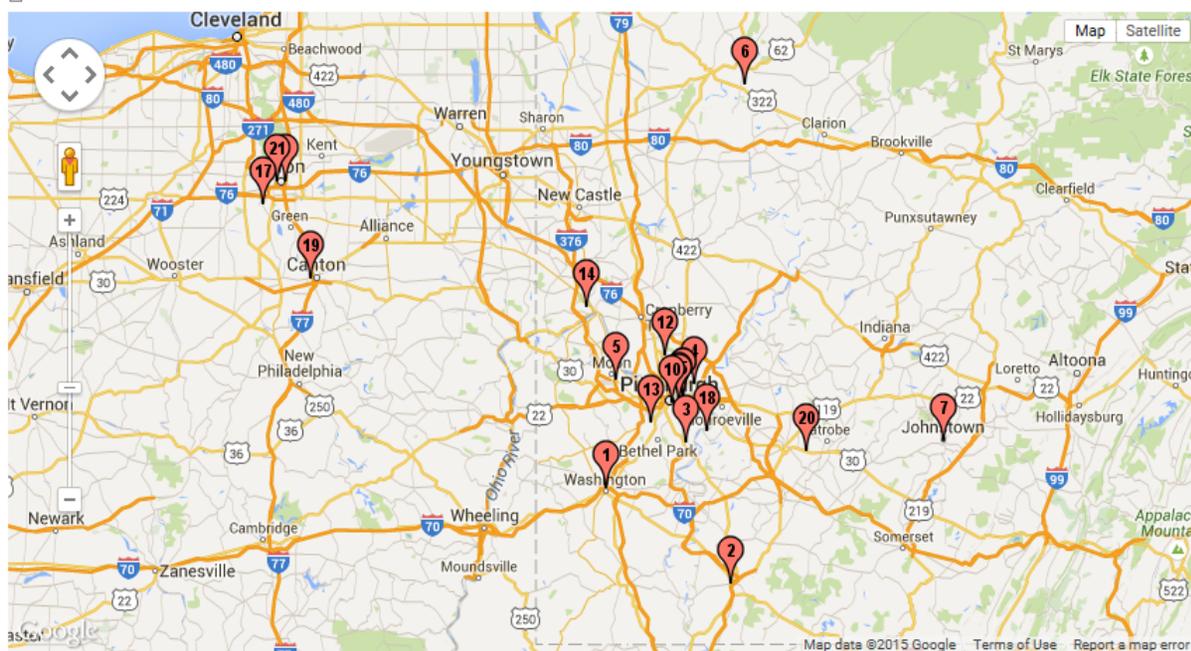
In Progress | Create New | History | Configuration | **Help Tool** | Sync

## Help Tool for Locating Receiving Institutions

- This tool is designated to assist users with identifying potential receiving sites for patient transfers. **Transferring sites must initiate a conversation with potential receiving sites on accepting patient transfers, and confirm agreement prior to initiating the the institution change process in the T&UM tab of OPEN.**
- To filter results, enter a value within a text-entry field (above a column's name) and click the search button.
- Click the "Details" button to view the contact information for persons at an institution.
- If further assistance is needed with finding an appropriate receiving institution, please contact the Lead Protocol Organization's Help Desk.

\* Protocol:  \* Zip Code:  \* Radius:

### Map of Receiving Institutions



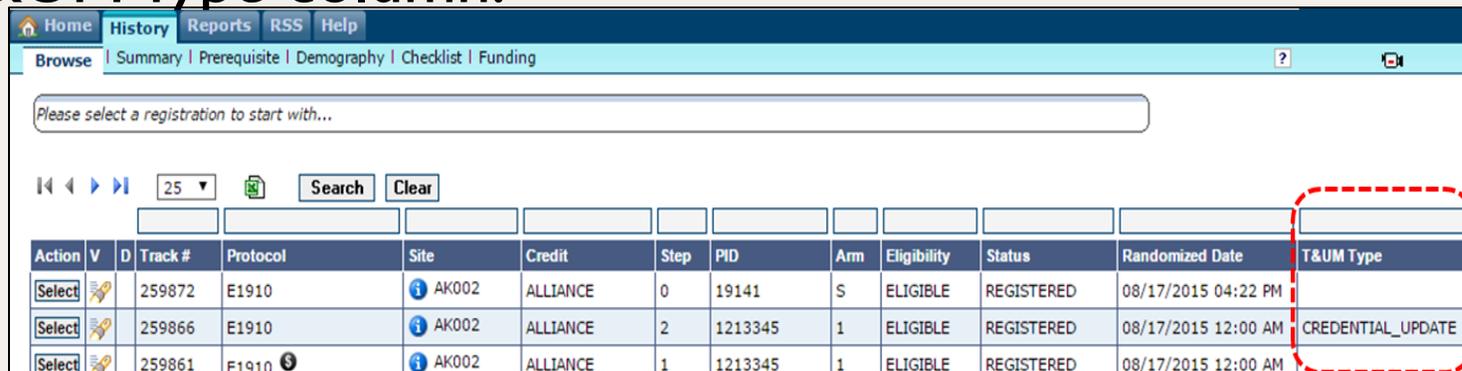
- PA146 [Details](#)  
1 **UPMC Washington Hospital Radiation Oncology**  
155 Wilson Avenue, Washington, PA 15301
- PA371 [Details](#)  
2 **UPMC Uniontown Hospital Radiation Oncology**  
51 Brewer Drive, Uniontown, PA 15401
- PA263 [Details](#)  
3 **UPMC Jefferson Regional Radiation Oncology**  
565 Coal Valley Road, Pittsburgh, PA 15236
- PA122 [Details](#)  
4 **UPMC-Saint Margaret**  
815 Freeport Road, Pittsburgh, PA 15215
- PA353 [Details](#)  
5 **UPMC-Coraopolis/Heritage Valley Radiation Oncology**  
1600 Coraopolis Heights Road, Moon Township, PA 15108
- PA137 [Details](#)  
6 **UPMC Cancer Center at UPMC Northwest**  
100 Fairfield Drive, Seneca, PA 16346
- PA270 [Details](#)  
7 **UPMC-Johnstown/John P. Murtha Regional Cancer Center**  
337 Somerset Street, Johnstown, PA 15901
- PA015 [Details](#)  
8 **University of Pittsburgh Cancer Institute (UPCI)**

Navigation icons | 25 |

Protocol	Site	Site Name	Status	Comments	Distance(Mile(s))	City	State	Zip Code	Country	Contact Information
S1007	PA020	UPMC-Shadyside Hospital	Approved		0	Pittsburgh	PA	15232	US	<a href="#">Details</a>
S1007	PA015	University of Pittsburgh Cancer Institute (UPCI)	Approved	Add from packet	0	Pittsburgh	PA	15232	US	<a href="#">Details</a>
S1007	PA014	UPMC-Presbyterian Hospital	Approved		1	Pittsburgh	PA	15213	US	<a href="#">Details</a>
S1007	PA011	UPMC-Magee Womens Hospital	Approved		1	Pittsburgh	PA	15213	US	<a href="#">Details</a>

# Additional OPEN Updates

- A “T&UM Type” column was added to the Browse subtab (under the History tab) so OPEN users can identify which patient enrollments involved approved T&UM requests. The type of T&UM request is indicated in the T&UM Type column.



The screenshot shows a web application interface with a navigation bar (Home, History, Reports, RSS, Help) and a subtab (Browse). Below the navigation bar is a search bar and a table of patient enrollments. The table has the following columns: Action, V, D, Track #, Protocol, Site, Credit, Step, PID, Arm, Eligibility, Status, Randomized Date, and T&UM Type. The T&UM Type column is highlighted with a red dashed box.

Action	V	D	Track #	Protocol	Site	Credit	Step	PID	Arm	Eligibility	Status	Randomized Date	T&UM Type
Select			259872	E1910	AK002	ALLIANCE	0	19141	S	ELIGIBLE	REGISTERED	08/17/2015 04:22 PM	
Select			259866	E1910	AK002	ALLIANCE	2	1213345	1	ELIGIBLE	REGISTERED	08/17/2015 12:00 AM	CREDENTIAL_UPDATE
Select			259861	F1910	AK002	ALLIANCE	1	1213345	1	ELIGIBLE	REGISTERED	08/17/2015 12:00 AM	

- A custom edit check was added to the demography screen which validates whether the Zip Code value matches the list of valid US Zip Codes, (when the Country of Residence is “US”).

# Update to the Funding Screen

A Comments column was added to the funding screen, so that notes can be added (for internal use only) regarding each per-case funding entry. Comments are not sent to the LPOs.

Selected Tracking # 259874 [Details](#) [Summary](#)

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
S1207	256816	RM-	1	Blinded	IL036	Santa-Maria, Cesar	REGISTERED	08/18/2015

**Funding Report**

**Protocol Funding:**

- Enter the completion date for each funding type once completed.
- Completion dates cannot be prior to the enrollment date. If 2 was completed prior to enrollment date, please enter enrollment date in date field.
- Completion dates cannot be changed after 7 calendar days of initial entry.

Funding Type	Funding Type #	Specify	Date Completed (MM/DD/YYYY)	Comments (300 Characters)
Quality of Life		Quality of Life - Limited to NCORP sites only	<input type="text"/>	Does not apply for this patient. <input type="button" value="Clear"/>



## SERIOUS ADVERSE EVENTS (SAE) INTEGRATION

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# What Do Updates To The SAE Reporting Process Mean To My Site?

# SAE Integration Phases

The SAE integration project is being rolled out in Rave in two phases- Rules Evaluation (RE) and Full:

- **RE integration** provides the ability to enter Adverse Events (AEs) in Rave and return a real-time recommendation of whether to complete an expedited report based on protocol specific rules.
- **Full integration** provides the additional capability to generate expedited reports directly in Rave.

# The Steps for Using RE

1. A set of NCI and protocol specific business rules are setup to evaluate the AEs.
2. Routine AEs (treatment or follow-up) are entered into Rave.
3. AEs are evaluated via an automated process.
4. A recommendation is returned to Rave indicating whether or not an expedited report is expected.
5. Expedited reporting, if recommended, is performed by site users in CTEP-AERS.

# Current Status of SAE Integration

- Pilot studies for the RE integration have started with Alliance, Theradex and ECOG-ACRIN.
- The CTSU plans to begin piloting the full SAE integration by late 2015.
- If you participate in a protocol piloting the SAE integration, additional information is available on the protocol specific webpage in the LPO Documents Tab under Education and Promotion.

Education and Promotion Materials	
1	<a href="#">Study Calendar</a> 
2	<a href="#">Schema</a> 
3	<a href="#">SAE Training Presentation for CRAs</a> 
4	<a href="#">SAE Training Webinar - Recorded 02/25/2015</a>
5	<a href="#">SAE User Guide for CRAs</a> 



**UPCOMING FEATURES!**

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# **What New Tools Are Being Implemented To Help Site Efficiency?**

# National Coverage Analysis

- CTSU is working with the Network Groups and Research Bases to provide National Coverage Analysis (CA) support for NCI supported trials.
- A working group is in place to:
  - Define the roles and responsibilities for developing CA documents,
  - Establish a process for creating the CA for NCTN and NCORP protocols,
  - Pilot CA documents for specified protocols on the CTSU website.
- A coverage analysis for the MATCH trial will be available on the CTSU website in November.



# Data Quality Portal (DQP)

The Data Quality Portal (DQP) will provide a single platform to access query and delinquency information for all CTEP Rave protocols via the CTSU website.

- DQP access will be integrated with RSS to control data that is displayed.
- Form delinquency and query information will be retrieved from all nine CTEP Rave URLs.

*\*\*\*Delinquent form information will only be available for those Rave studies that use the Rave Calendaring functionality \*\*\**

# DQP (cont.)

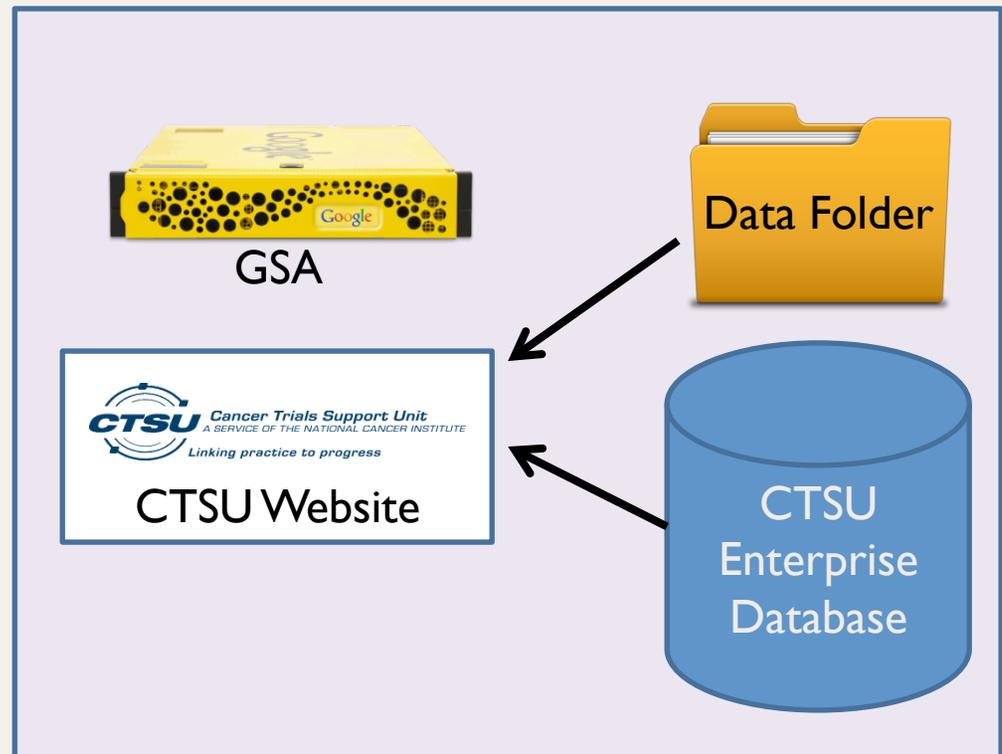
- The DQP will contain 2 modules, a 'Queries Module' (*discrepancies*) and a 'Delinquencies Module' (*forms*).
- Using both modules together, users will be able to track and manage data quality and timeliness for Rave studies:
  - Review summary reports,
  - Deep-link directly to Rave forms:
    - Enter data for missing forms,
    - Manage open queries/ discrepancies.



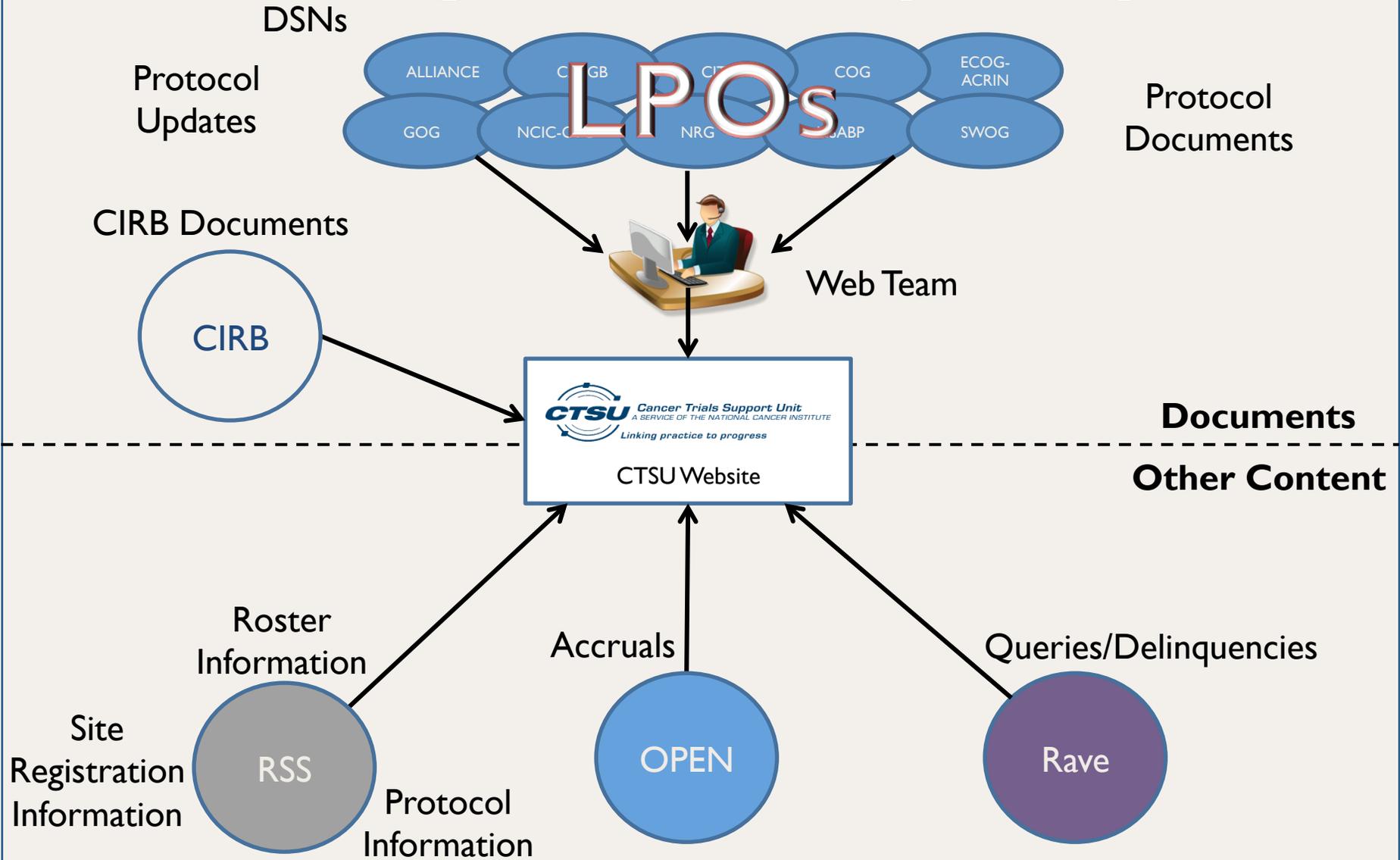
*~The DQP will be available in early 2016~*

# Google Search

The Google Search Appliance (GSA) is a mechanism that utilizes Google to make documents posted on the CTSU website easily searchable.



# Google Search (cont.)



# Google Search (cont.)

The CTSU website is a repository of documents which contain large amounts of information that is currently not searchable using the existing functionality.

Content	Number on Website	Monthly Downloads (July 2015)
LPO Documents	20,696	50,972
DSN Documents	12,243	6,454
CIRB Documents	15,080	24,981
Non-Protocol Documents	140	200

# Site Registration Portal

- The site registration portal will streamline and modernize the submission of regulatory information to the CTSU.
- The portal will be a subtab located under the Regulatory tab on CTSU website.
- Provides the ability to upload and submit site registration documentation (by corresponding site and study number) directly to the CTSU Regulatory Office and RSS.
  - A fax option will still exist with enhancements to include a dynamic cover sheet using a barcode indicating the sites and protocols contained in the fax.

# Site Registration Portal (cont.)

- The status of site registration documents will be viewable and trackable directly on the CTSU website.
- Person and institution documentation will also be submitted via the portal.
- There will also be an option to respond to queries from the regulatory office directly from the website.



# Webinars

- This initiative started in April 2015 with the “Access to NCTN AYA Trials” Webinar.
- Goal of the webinars is to address key concerns that affect accrual to NCI-supported trials, and raise awareness of trials among NCTN sites.
- Upcoming Webinars:
  - EAY131 MATCH webinar – Early Fall 2015
  - Lung-MAP/ALCHEMIST webinar – October 27<sup>th</sup>, 2015
  - Sister Breast Studies (NSABP B-51/RTOG-1304, A011202, E1131) – December 2015

# Webinars (cont.)

- Upcoming webinars will be announced via:
  - The CTSU website under the “CTSU News” Box or “Announcements” section
  - The Bi-Monthly Broadcast
  - CTSU Newsletter
- An archive of the webinars will be maintained:
  - In the E&R tab of the website under “Educational Presentations and Webinars”



# Changes to the Protocol Tree

**Available Now**

Home Protocols Dashboard Regulatory OPEN Rave Clinical Data Education & Resour

- My Protocols
  - By Site
  - By Lead Organization
  - By Cancer Type
  - By Study Type
  - By Phase
  - AYA Studies**
    - ALLIANCE
      - A031102
    - COG
      - AEWS1031
      - AEWS1221
      - AOST1322
      - ARST1321
    - ECOG-ACRIN
      - E1609
      - EAY131
  - NCTN
  - ETCTN
  - NCORP
  - CITN
  - Reports
    - Accrual Reports**
      - NCTN
      - ETCTN
      - NCORP
      - AYA Studies
    - Study Agent

All

**AYA Accrual Report**

The Adolescent and Young Adult (AYA) Accrual Report for AYA protocols supported by the CTSU in which all p website (protocols will display a LPO Documents folder available funding information or CIRB documents will r

Protocol Status:  Phase:

Keywords (optional):  Group by:

AYA Accrual Report

#	Protocol Number	Lead Group	Protocol Status	Protocol Title	Phase	Activation Date	Title
1	AEWS1031	COG	Active	A Phase III Randomized Trial of Adding Vincristine-Topotecan-Cyclophosphamide to Standard Chemotherapy in Initial Treatment of Non-Metastatic Ewing Sarcoma	III	11/22/2010	E16