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
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

<table>
<thead>
<tr>
<th>NCTN Member Type</th>
<th>Action</th>
<th>Allowed</th>
<th>Roster Owner Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main Member</td>
<td>Add or withdraw non-primary person role</td>
<td>X</td>
<td>No</td>
</tr>
<tr>
<td>Main Member</td>
<td>Request to add primary role to self</td>
<td>X</td>
<td>Yes</td>
</tr>
<tr>
<td>Main Member</td>
<td>Request to add or withdraw a person</td>
<td>X</td>
<td>Yes</td>
</tr>
<tr>
<td>Main Member</td>
<td>Request to add or withdraw affiliate, sub-affiliate, LAPS AA, LAPS ASA</td>
<td>X</td>
<td>Yes</td>
</tr>
<tr>
<td>NCORP</td>
<td>Add or withdraw non-primary person role</td>
<td>X</td>
<td>No</td>
</tr>
<tr>
<td>NCORP</td>
<td>Request to add primary role to self</td>
<td>X</td>
<td>Yes</td>
</tr>
<tr>
<td>NCORP</td>
<td>Request to add or withdraw a person</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>NCORP</td>
<td>Request to add or withdraw site under the NCORP</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>LAPS</td>
<td>Add or withdraw non-primary person role</td>
<td>X</td>
<td>No</td>
</tr>
<tr>
<td>LAPS</td>
<td>Request to add primary role to self</td>
<td>X</td>
<td>Yes</td>
</tr>
<tr>
<td>LAPS</td>
<td>Request to add or withdraw a person</td>
<td>X</td>
<td>Yes</td>
</tr>
<tr>
<td>LAPS</td>
<td>Request to add or withdraw site under LAPS grant</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
RUMS Tutorial

Tabs to navigate requests & filters

Training materials
**Adding Person Roles**

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

<table>
<thead>
<tr>
<th>Person Name</th>
<th>CTEP ID</th>
<th>Site</th>
<th>Status</th>
<th>Roles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hering, Martha</td>
<td>501449</td>
<td>MD029</td>
<td>Active</td>
<td>Imaging Coordinator, Oncology Nurse, Read Only, 2041262</td>
</tr>
<tr>
<td>Shriner, Donna</td>
<td>500003</td>
<td>MD029</td>
<td>Active</td>
<td>Pharmacist</td>
</tr>
<tr>
<td>Terry, Keidra</td>
<td>538482</td>
<td>MD029</td>
<td>Active</td>
<td>Clinical Research Associate, Registrar</td>
</tr>
<tr>
<td>Terry, Monique</td>
<td>529237</td>
<td>MD029</td>
<td></td>
<td>Add Person Request (IN_REVIEW)</td>
</tr>
</tbody>
</table>

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

1. Select Roles
2. Review and Confirm

- **MD029 (ALLIANCE)**
- **Rave CRA**
- **Select Role at Level**

Selected Roles:

<table>
<thead>
<tr>
<th>Org ID</th>
<th>Roster Code</th>
<th>Role</th>
<th>Role Assignment Level</th>
<th>Role Assign at?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>MD029</td>
<td>Administrator</td>
<td>INSTITUTION</td>
<td>MD029</td>
</tr>
<tr>
<td>2</td>
<td>MD029</td>
<td>Rave CRA</td>
<td>PROTOCOL</td>
<td>A031203</td>
</tr>
</tbody>
</table>
Non-primary roles do not require roster owner review and will automatically populate.

**On submission request will be saved as draft.**
To add a person they must have an active CTEP status.
Adding Persons (cont.)

1. Select Person

2. Select Sites

3. Select Roles

4. Questions

5. Documents

6. Review and Confirm

Document Title: HST Training Certificate - Assoc

Action: UpdateAccessInternal.doc

SELECTED DOCUMENT:

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

Cancer Trials Support Unit
ALL GOOD?
Review status of requests for persons and organizations.

<table>
<thead>
<tr>
<th>#</th>
<th>Request ID</th>
<th>Request Date</th>
<th>Operation</th>
<th>Roster</th>
<th>Site</th>
<th>Site Name</th>
<th>CTEP ID</th>
<th>Name</th>
<th>Person Type</th>
<th>Role</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>81850</td>
<td>06/29/2015 10:41:46</td>
<td>Assign Non-Primary Role</td>
<td>ALLIANCE</td>
<td>MD029</td>
<td>MedStar Franklin Square Medical Center/Weinberg Cancer Institute</td>
<td>538482</td>
<td>Terry, Keldra</td>
<td>Associate</td>
<td>Clinical Research Associate</td>
<td>INSTITUTION</td>
</tr>
<tr>
<td>2</td>
<td>81849</td>
<td>06/29/2015 10:41:43</td>
<td>Add Associate</td>
<td>ALLIANCE</td>
<td>MD029</td>
<td>MedStar Franklin Square Medical Center/Weinberg Cancer Institute</td>
<td>538482</td>
<td>Terry, Keldra</td>
<td>Associate</td>
<td>IN_REVIEW</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>81845</td>
<td>06/26/2015 08:01:53</td>
<td>Assign Non-Primary Role</td>
<td>ALLIANCE</td>
<td>MD029</td>
<td>MedStar Franklin Square Medical Center/Weinberg Cancer Institute</td>
<td>529237</td>
<td>Terry, Monique R.</td>
<td>Associate</td>
<td>CRA (LabAdmin)</td>
<td>PROTOCOL</td>
</tr>
<tr>
<td>4</td>
<td>81844</td>
<td>06/26/2015 08:01:52</td>
<td>Add Associate</td>
<td>ALLIANCE</td>
<td>MD029</td>
<td>MedStar Franklin Square Medical Center/Weinberg Cancer Institute</td>
<td>529237</td>
<td>Terry, Monique R.</td>
<td>Associate</td>
<td>IN_REVIEW</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>81838</td>
<td>06/24/2015 15:44:09</td>
<td>Assign Primary Role</td>
<td>ALLIANCE</td>
<td>MD029</td>
<td>MedStar Franklin Square Medical Center/Weinberg Cancer Institute</td>
<td>500003</td>
<td>Shriner, Donna A.</td>
<td>Associate</td>
<td>Lead Res Prot</td>
<td></td>
</tr>
</tbody>
</table>
How Can I Better Manage Regulatory Submissions?
Sites Using the CIRB

Ensure site preferences are set.

---

<table>
<thead>
<tr>
<th>#</th>
<th>Network Level</th>
<th>Preference Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ECTCN LAO</td>
<td>ALL, SIGNATORY ONLY, SITE SPECIFIC, PROTOCOL, NONE</td>
</tr>
<tr>
<td>2</td>
<td>ECTCN P2C</td>
<td>ALL, SIGNATORY ONLY, SITE SPECIFIC, PROTOCOL, NONE</td>
</tr>
<tr>
<td>3</td>
<td>MULTI-NETWORK</td>
<td>ALL, SIGNATORY ONLY, SITE SPECIFIC, PROTOCOL, NONE</td>
</tr>
<tr>
<td>4</td>
<td>NCTN Adult</td>
<td>ALL, SIGNATORY ONLY, SITE SPECIFIC, PROTOCOL, NONE</td>
</tr>
<tr>
<td>5</td>
<td>NCTN Pediatric</td>
<td>ALL, SIGNATORY ONLY, SITE SPECIFIC, PROTOCOL, NONE</td>
</tr>
</tbody>
</table>

Signatory Institution: MD017

CTSU Regulatory Office at 1-866-651-CTSU (2878) or CTSURegPref@ctsu.cccg.org

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.
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.
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.

<table>
<thead>
<tr>
<th>Available Subscriptions</th>
<th>Subscriptions in Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary of multi-step enrollments</td>
<td>Newly posted protocol-related documents</td>
</tr>
<tr>
<td>Summary of changes to person roster</td>
<td>Accrual notifications for my site</td>
</tr>
<tr>
<td>New protocols in my area of interest</td>
<td>Summary of incomplete patient enrollments</td>
</tr>
<tr>
<td>Expiring IRB approvals</td>
<td>Unused slot reservations</td>
</tr>
<tr>
<td>Changes to Site Registration statuses</td>
<td>New data on a user dashboard portlet</td>
</tr>
</tbody>
</table>
## Accessing CRISP

### CTSU Information Subscription Portal

<table>
<thead>
<tr>
<th>#</th>
<th>Notification Subject</th>
<th>Frequency</th>
<th>Subscriptions Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IRB Approval Expiring in 30 Days</td>
<td>WEEKLY</td>
<td>Site Ctep Id ALL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Disease Name: Breast Cancer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CNS Metastases (see Metastatic Cancer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CNS Primary</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Gastrointestinal Cancer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Gyne Oncology Cancer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Miscellaneous Neoplasm</td>
</tr>
<tr>
<td>2</td>
<td>New Protocols In Your Area of Interest</td>
<td>DAILY</td>
<td>Site Ctep Id ALL</td>
</tr>
<tr>
<td>3</td>
<td>Summary of Multi-step Enrollments at all Sites</td>
<td>MONTHLY</td>
<td>Site Ctep Id ALL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Roster Owner CTSU</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Site Ctep Id ALL</td>
</tr>
</tbody>
</table>
Subscribing to Notifications

CTSU Information Subscription Portal

Add Subscriptions Wizard

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

Previous  Next  Submit  Discard

<table>
<thead>
<tr>
<th>Enrollment Updates</th>
<th>Person Roster Updates</th>
<th>Protocol Updates</th>
<th>Regulatory Updates</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  ○  Summary of Multi-step Enrollments at all Sites</td>
<td>Provides a summary of multi-step enrollments at your selected sites</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Person Roster Updates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1  ○  Summary of Changes to the Selected Person Rosters</td>
<td>Lists all roster additions/withdrawals including person role changes made to the selected roster during your specified time range</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol Updates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1  ○  New Protocols in Your Area of Interest</td>
<td>Lists all upcoming studies in your selected area of interest or disease category</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulatory Updates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1  ○  IRB Approval Expiring in 30 Days</td>
<td>Lists all IRB approvals due to expire within 30-days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2  ○  Site Registration Status Changes</td>
<td>Provides a summary of Site Registration Status Changes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Setting Notification Preferences

Add Subscriptions Wizard

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

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:
- CNS Metastases (see Metastatic Cancer)
- CNS Neoplasms (Primary Tumor)
- CNS Primary
- Carcinoid
- GI Stromal Tumor

Add to Cart
Add Subscriptions Wizard

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

Previous  Next  Submit  Discard

You have subscribed successfully.

Selected Notifications

<table>
<thead>
<tr>
<th>#</th>
<th>Notification</th>
<th>Frequency</th>
<th>Subscriptions Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Lists all upcoming studies in your selected area of interest or disease category</td>
<td>DAILY</td>
<td>Disease Name, Brain Cancer, CNS Metastases (see Metastatic Cancer), CNS Neoplasms (Primary Tumor)</td>
</tr>
</tbody>
</table>
What’s New In OPEN?

OPEN and the Transfer & Update Module (T&UM)
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

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 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 Protocol Organization’s Help Desk.

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Site</th>
<th>Site Name</th>
<th>Status</th>
<th>Comments</th>
<th>Distance (Mile(s))</th>
<th>City</th>
<th>State</th>
<th>Zip Code</th>
<th>Country</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1007 PA020</td>
<td>UPMC-Shadyside Hospital</td>
<td>Approved</td>
<td></td>
<td></td>
<td>0</td>
<td>Pittsburgh</td>
<td>PA</td>
<td>15232</td>
<td>US</td>
<td>Details</td>
</tr>
<tr>
<td>S1007 PA015</td>
<td>UPMC University of Pittsburgh Cancer Institute (UPCI)</td>
<td>Approved</td>
<td></td>
<td></td>
<td>0</td>
<td>Pittsburgh</td>
<td>PA</td>
<td>15222</td>
<td>US</td>
<td>Details</td>
</tr>
<tr>
<td>S1007 PA014</td>
<td>UPMC-Presbyterian Hospital</td>
<td>Approved</td>
<td></td>
<td></td>
<td>1</td>
<td>Pittsburgh</td>
<td>PA</td>
<td>15213</td>
<td>US</td>
<td>Details</td>
</tr>
</tbody>
</table>
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.

• 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.
Serious Adverse Events (SAE) Integration

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.
Upcoming Features!

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

<table>
<thead>
<tr>
<th>Content</th>
<th>Number on Website</th>
<th>Monthly Downloads (July 2015)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LPO Documents</td>
<td>20,696</td>
<td>50,972</td>
</tr>
<tr>
<td>DSN Documents</td>
<td>12,243</td>
<td>6,454</td>
</tr>
<tr>
<td>CIRB Documents</td>
<td>15,080</td>
<td>24,981</td>
</tr>
<tr>
<td>Non-Protocol Documents</td>
<td>140</td>
<td>200</td>
</tr>
</tbody>
</table>
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 27th, 2015
  – Sister Breast Studies (NSABP B-51/RTOG-1304, A011202, EA1131) – 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

AYA Accrual Report

The Adolescent and Young Adult (AYA) Accrual Report for AYA protocols supported by the CTSU in which all protocols will display a LPO Documents folder. Available funding information or CIRB documents will not be shown. Available to non-AYA protocols.

<table>
<thead>
<tr>
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