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)

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.

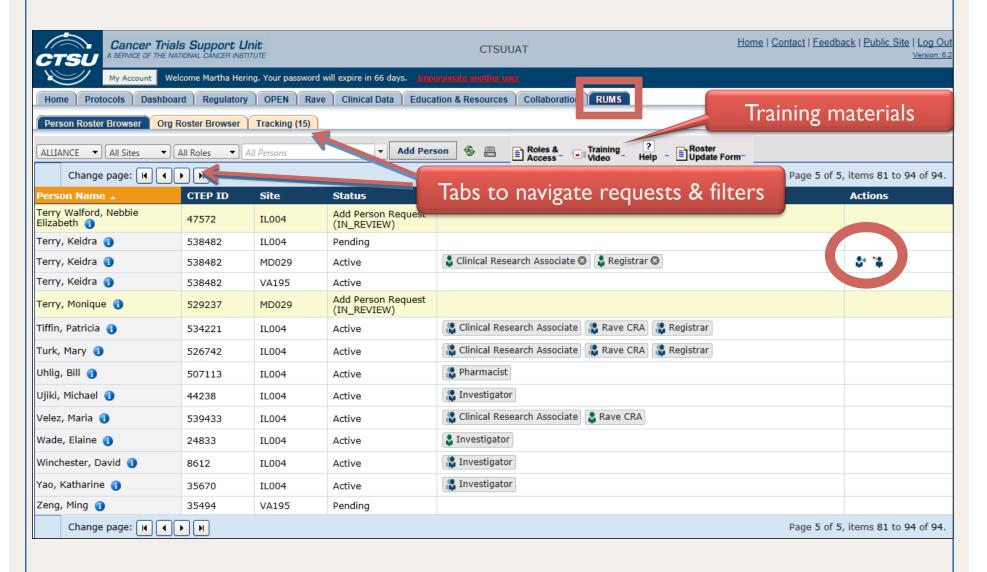- With the exception of the Rave-related and Registrar roles, roles are roster owner specific.

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.
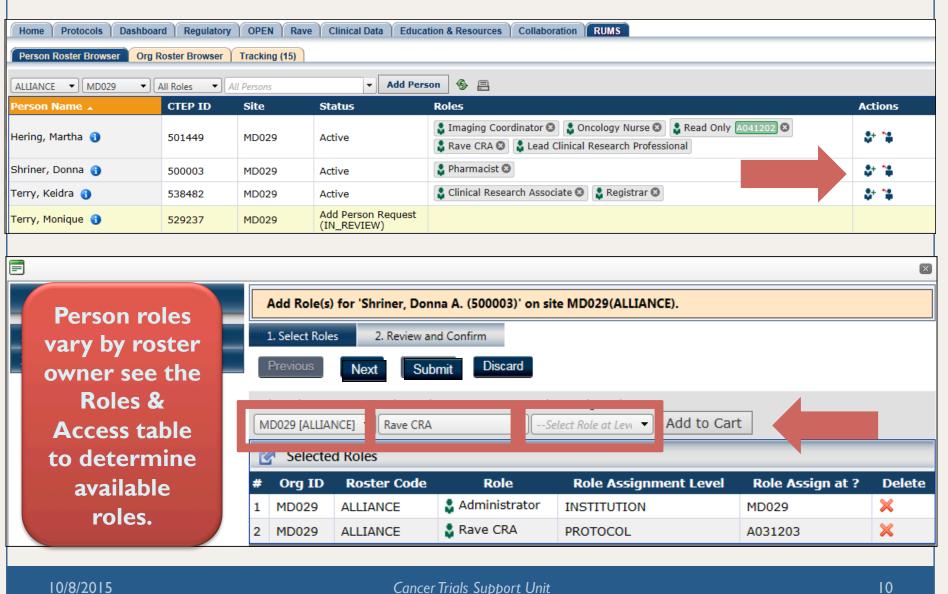
Possible RUMS Functions

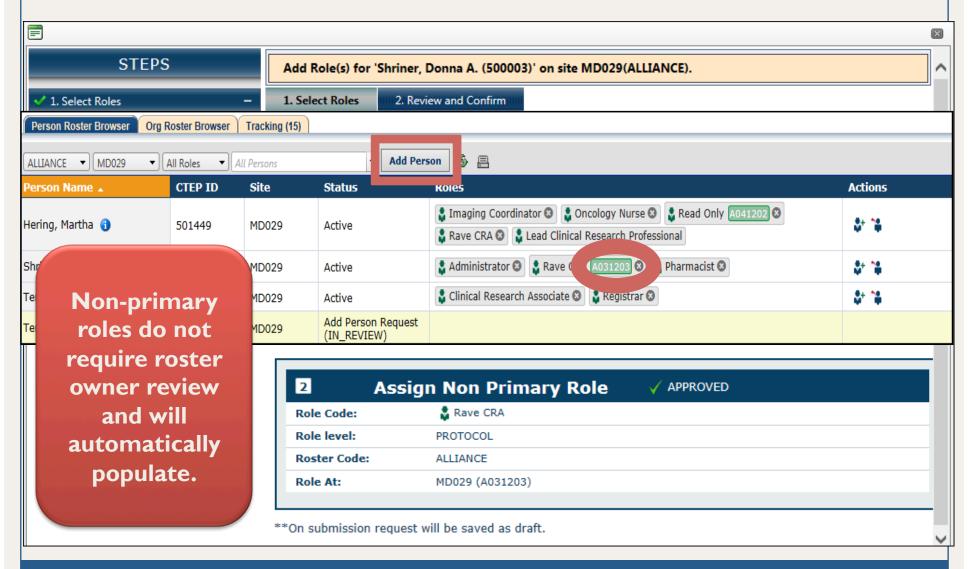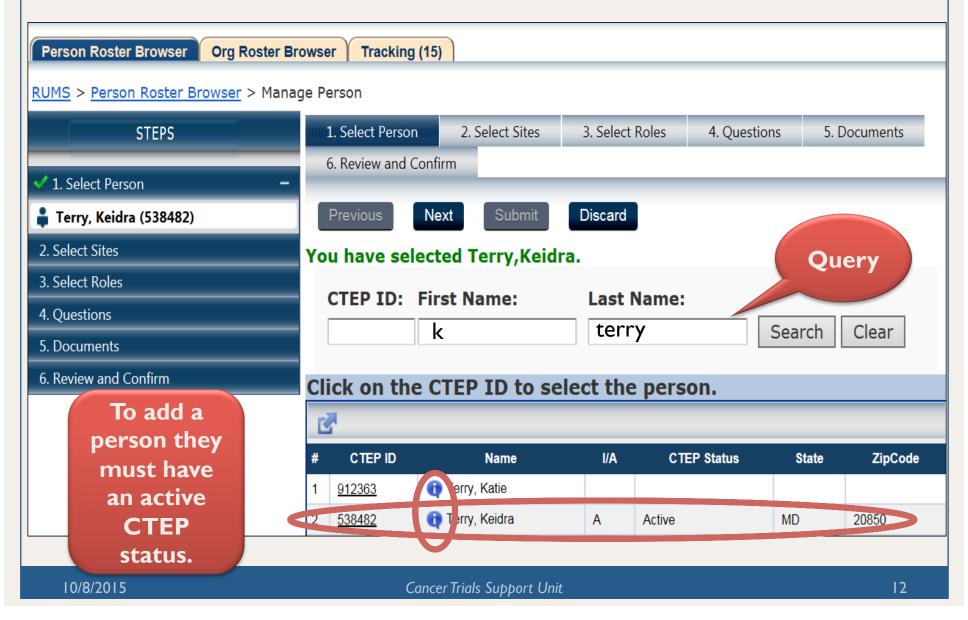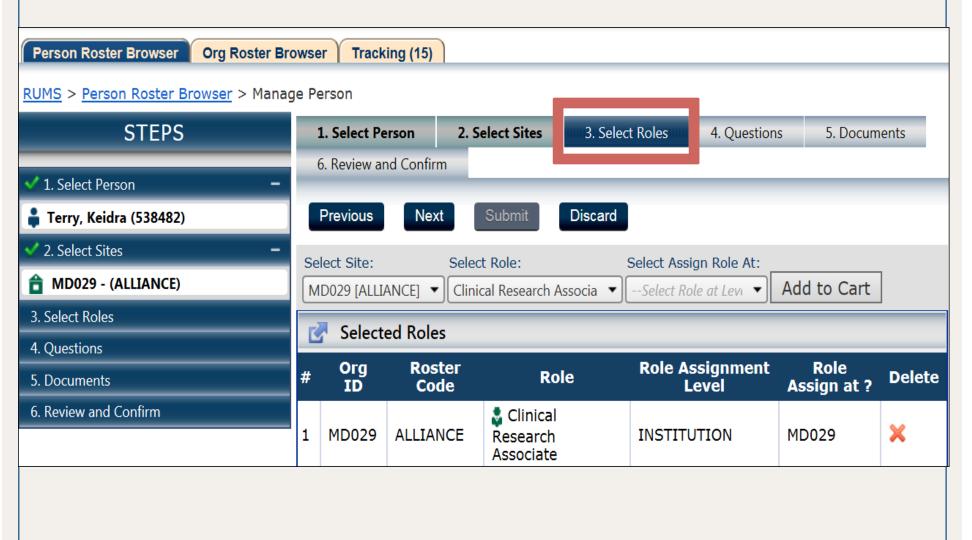| NCTN Member Type	Action	Allowed	Roster Owner Review
Main Member	Add or withdraw non-primary person role	X	No
Main Member	Request to add primary role to self	X	Yes
Main Member	Request to add or withdraw a person	X	Yes
Main Member	Request to add or withdraw affiliate, sub-affiliate, LAPS AA, LAPS ASA	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

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 Leve ▼ | Add to Cart |

📋 Selected Roles

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

Confirming Changes

STEPS

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

✓ 1. Select Roles   —   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	👥⁺ 👥
Shr...		MD029	Active	👤 Administrator ⊗ 👤 Rave C... A031203 ⊗ ...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

Adding Persons (cont.)

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 ❓				🟢 UpdateAccessInternal.doc ✖ Remove

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

Confirm Person Addition

STEPS

✓ 1. Select Person
👤 Terry, Keidra (538482)

✓ 2. Select Sites
🔒 MD029 - (ALLIANCE)

✓ 3. Select Roles
Clinical Research Associate @MD029

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

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 Su...
Person Name:	Terry, Keidra	

ALL GOOD?

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

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

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).   No

Documents:

Document Title	File Name	Uploaded By	Uploaded On
HST Training Certificate - Assoc ❓	UpdateAccessInternal.docx		

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)

Status Filter: All Open Status ▾ | Apply Filter

Person Roster Requests | Org Roster Requests

Review status of requests for persons and organizations.

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	✕
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	✎ ✕
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	✕
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	✎ ✕
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		Someone already has this role	❓

REGULATORY UPDATES FOR CIRB AND LOCAL IRBs

How Can I Better Manage Regulatory Submissions?

Sites Using the CIRB

Ensure site preferences are set.

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.

CTSU 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

Subscribing to Notifications

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

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

Review Subscription

| # | Notification | ency | Subscriptions Settings | Delete |
No record were found that

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)

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

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 <u>not</u> 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.

Education and Promotion Materials	
1	Study Calendar
2	Schema
3	SAE Training Presentation for CRAs
4	SAE Training Webinar - Recorded 02/25/2015
5	SAE User Guide for CRAs

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.

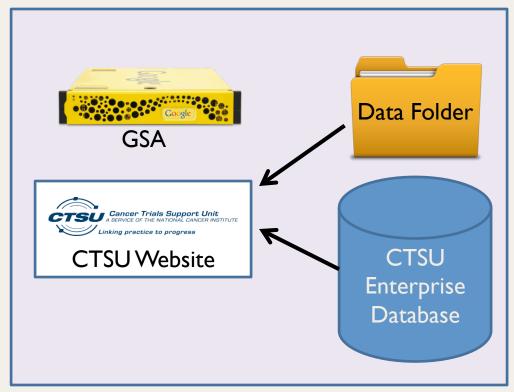****Delinquent form information will only be available for those Rave studies that use the Rave Calendaring functionality ****

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~

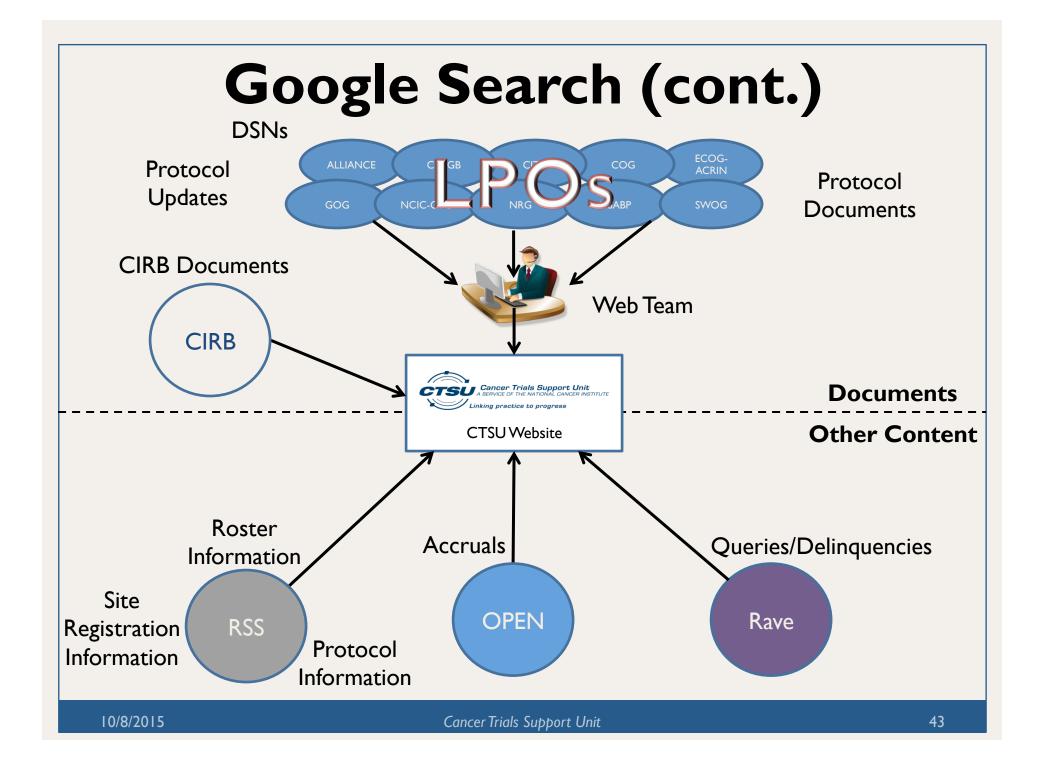# Google Search

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

GSA

Data Folder

CTSU Website

CTSU Enterprise Database

Google Search (cont.)

DSNs

Protocol Updates

Protocol Documents

CIRB Documents

LPOs

ALLIANCE   CALGB   CITN   COG   ECOG-ACRIN

GOG   NCIC-CTG   NRG   NSABP   SWOG

Web Team

CIRB

Documents

Other Content

CTSU — Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE
Linking practice to progress

CTSU Website

Roster Information

Accruals

Queries/Delinquencies

Site Registration Information

RSS

Protocol Information

OPEN

Rave

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 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