

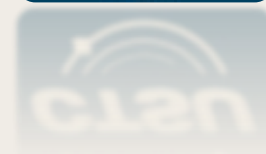
# CTSU UPDATES

SWOG Meeting  
Spring 2017  
Lucille Patrichuk

# Agenda

- Regulatory Submission Portal
- Data Quality Portal
- Central Monitoring
- CTSU Website Updates
- Provider Association Tab (*New*)
- National Coverage Analysis Updates





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# REGULATORY SUBMISSION PORTAL

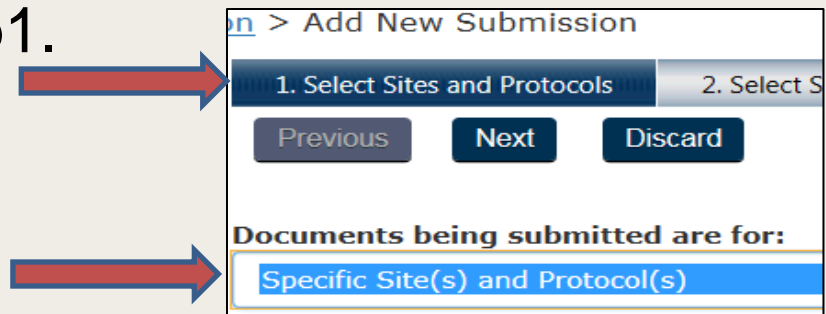
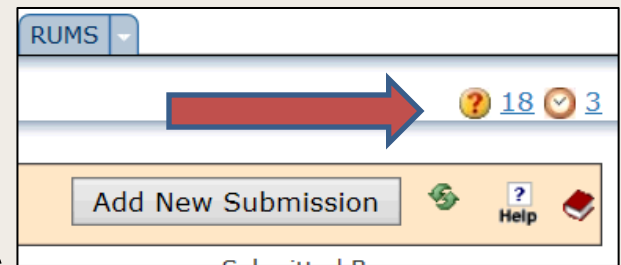
# Regulatory Submission Portal

- Mandatory since February 9<sup>th</sup>, 2017.
- Recent enhancements include:
  - Ability to respond to inquiries directly via the Portal.
  - Enhanced filtering capabilities in the Tracking Table.
  - Addition of a notification area to view count/type of submissions.
  - Mandatory indexing of site registration, institution, and person submissions.

# Regulatory Submission Portal

## Tips

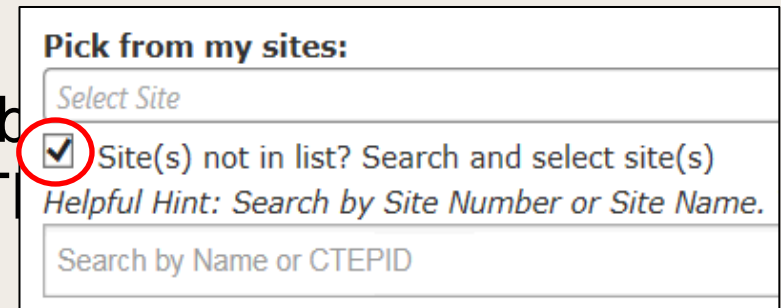
- Barcode cover pages may only be used **once** and will deactivate after 30 days if not submitted.
- Use the notification area above the “Add New Submission” button to identify packets which have *Inquiry with Site* and *Not Received* statuses.
- Documentation being submitted to fulfill a specific study’s regulatory requirement should be designated as *Specific Site(s) and Protocol(s)* in the first question of Step1.



# General Regulatory Tips (1)

- **Indexing**

- Avoid processing delays by ensuring site CTEP ID and protocol number(s) provided on the Portal match your regulatory documentation.
- Administrative users must check the *Site(s) not in list?* button to be able to search and select CTEP numbers.



Pick from my sites:

Select Site

☒ Site(s) not in list? Search and select site(s)

Helpful Hint: Search by Site Number or Site Name.

Search by Name or CTEPID

- **IRB Numbers**

- Provide your IRB number in the message field of the Portal if it is not indicated within your approval documentation.

# General Regulatory Tips (2)

- **Closures**

- Local IRB closure approval documentation must indicate justification of the closures in order to be processed. *OR*
- Include the CTSU Optional Form 1: Withdraw from Protocol Participation (anyone may sign; IRB-signatory not necessary).



» Abuse of the priority type *urgent* reduces the speed in which the CTSU can process other regulatory submissions.



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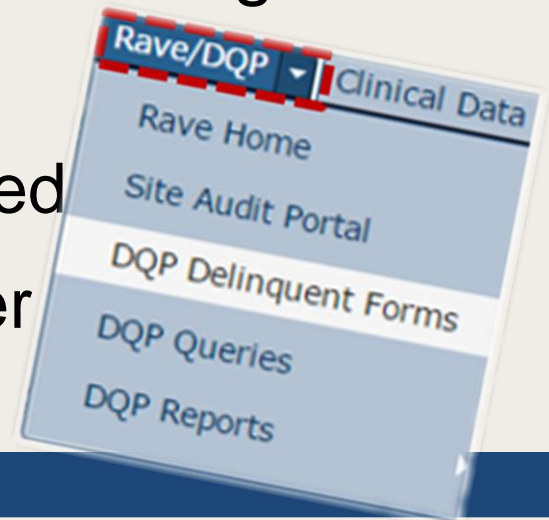
# DATA QUALITY PORTAL




# Data Quality Portal (DQP)

## What is it?

- The DQP is a single platform accessed via the CTSU Website providing access to query and form delinquency information for all CTEP Rave studies, including the ability to link directly to Rave forms for management of data.
  - CTEP IAM account required
  - Staff must be on site roster



# DQP Benefits

- One Stop Shopping
  - Access all Rave studies
  - Deep-link into Rave URLs and directly manage queries/delinquencies
  - Monitor data quality and timeliness
  - Review metrics and performance
- Standardized Experience
  - Consistent experience across LPOs and Rave studies
- Reports and Other Tools

# DQP Metrics & Reports

What Metrics & Reports are available?

## 1) Metric Tables

- ✓ Grid/Table layout
- ✓ Export features
- ✓ Default view

## 2) Metric Reports

- ✓ Graphic layout
- ✓ Aging Report Summaries
- ✓ Rave Totals by Form and

## 3) Timeliness Reports

- ✓ Demonstrate data timeliness and data quality
- ✓ Quarterly schedule

# DQP Status

- Studies released to all users:
  - All ECOG-ACRIN Rave studies
  - The NCICCR 9177 study
- Studies targeted for Spring 2017 release:
  - SWOG Rave studies – May 1<sup>st</sup>, (24 studies)
  - All NRG Rave studies
- Studies targeted for June/July 2017 release:
  - All COG Rave studies
  - All Alliance Rave studies



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# CENTRAL MONITORING

# Goals


- Develop a streamlined process for performing data monitoring remotely.
  - Data review to be recorded in Rave.
  - Source documents will be uploaded in a central location and must be accessible to monitors to review against the data in Rave.
- Provide an efficient way for sites to keep track of what documents need to be submitted for Central Monitoring.

# Central Monitoring vs. On-Site Auditing

Central Monitoring	On-Site Auditing
ALL patients enrolled on a trial will be monitored for critical data points.	10% of patients selected for audit are reviewed.
Central Monitoring is augmenting site auditing.	On-Site Auditing will continue as per the current process.
Central Monitoring is near real time data review.	On-site auditing is performed every 2-3 years.
Central Monitoring is performed to address safety concerns immediately.	On-site audit is performed to verify data.
Applicable to registration trials in Rave.	Applicable to all trials in Rave.

➤ Late summer/early fall release to sites for pilot studies.

# Central Monitoring Screen


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

[Home](#) | [Contact](#) | [Feedback](#) | [Public Site](#) | [Log Out](#)  
Version: 6.3.2.0

My Account | CRISP | Welcome SWOG User. | Your password will expire in 49 days. | [Impersonate another user](#) | [Refresh Authkeys](#)

[Home](#) | [Protocols](#) | [Dashboard](#) | [Regulatory](#) | [OPEN](#) | [Rave/DQP](#) | [Clinical Data](#) | [Education & Resources](#) | [Collaboration](#) | [Delegation Log](#) | [RUMS](#)

[DQP Queries](#) | [DQP DTL](#) | [Site Audit Portal](#) | [Central Monitoring](#)

[Central Monitoring](#) > [MN001 Source Document Repository](#)














[Upload New Document](#)

4 documents are missing

Protocol:

Site:

Patient:

MN001 Source Documents							
Protocol	Site	Patient	# Documents Expected	# Documents Uploaded	# Missing Documents	# Days Document has been Missing	Actions
A081105	MN001	 14602	4	4	0		
EAY131	MN001	 14603		2	0	0	
NRG-GU002	MN001	 14604	5	3 	2	4	
S1400	MN001	 14605	6	4	2	10	
A151216	MN001	 14606	7	7	0	0	
E1A11	MN001	 14607	8	8	0	0	

Note: The grace period for sites to upload source documents is 7 days.

4/6/2017

<https://www.ctsu.org/Main.aspx#>

April 26, 2017

5

16



# Benefits For Sites

- Ability to redact Personal Identifiable Information electronically while uploading source documents.
- Reminders and Alerts for missing documents.
- Direct links to the source document.
- One place to keep tabs on all the central monitoring activities for all protocols even when led by different Lead Protocol Organizations.



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# WEBSITE UPDATES

# Website Tagging (1)

- Tagging allows you to add personalized notes to the CTSU webpages.
- Only the person who entered the notes can see the tags.
- Notes may be tagged to any webpage.
  - Remind yourself to perform a task or resolve a query!



# Website Tagging (2)

[Home](#) [LPO Documents](#) [Drug Safety Notification](#) [Study Agent](#) [Protocol Requirements](#)

**8121** [Tags](#)

A Phase 2 Study of Temsirolimus (CCI-779, NSC 683864) and IGF-1 Receptor Antibody Cixutumumab (IMC-A12, NSC 742460) in Patients with Metastatic

**\*\*\*STUDY CLOSED TO ACCRUAL EFFECTIVE 07/10/2012\*\*\***

<b>Protocol Status:</b>	<b>COMPLETE</b>
<b>Protocol Status Date:</b>	07/08/2014
<b>Activation Date:</b>	11/06/2009
<b>Lead Organization:</b>	MSKC
<b>NCI Program:</b>	MISCELLANEOUS
<b>Phase:</b>	II
<b>CIRB Reviewed:</b>	No
<b>Country Participation:</b>	 
<b>Accrual:</b>	<b>Target (Intervention):</b> 174 <b>Total (Intervention):</b> 412 <b>As of:</b> 04/16/2012


Update Joe on Informed Consent

Create Presentation

Save

Done

Create New Tag



# Website Tagging (3)

- Tagging will be available in early summer 2017.
- Future enhancements will include:
  - Ability to share tags with other users at your site.
  - Search capabilities for tags.

# Website Alerts

- Important messages will be displayed directly on the webpage upon sign-in.
- Messages can be acknowledged upon delivery, once acknowledged, the message will not be displayed again.
- Website alerts will be available in early summer 2017.

# Examples of Alerts

The image shows a screenshot of the CTSU (Cancer Therapy Evaluation Service) website. At the top left is the CTSU logo. To its right, the text 'Cancer Therapy Evaluation Service' is partially visible, along with a 'My Account' link. Below the logo are navigation tabs for 'Home' and 'Protocols'. A 'Document Search' section is visible, featuring a search bar, a dropdown menu for 'Document Type' set to 'All', and 'Go' and 'Clear' buttons. Overlaid on the top right is a white alert box with a grey border. The alert is titled 'Important Announcement' in bold. The main text reads: 'Regulatory Submission Portal is Available. The web-based portal may be used by everyone to submit regulatory documents electronically. The portal is located in the Regulatory Tab → Regulatory Submission tab. A User Guide and Quick Start Guide is available. In the future, use of the portal will be mandatory.' At the bottom of the alert box is a green button with white text that says 'I Acknowledge', with a mouse cursor pointing at it. Below the alert box, there is a section titled 'CTSU Website at a Glance' with a light orange background. It contains a row of navigation tabs: 'Protocols', 'Regulatory', 'OPEN', 'Rave', 'Clinical Data', and 'Education & Resources'. The 'Protocols' tab is selected and highlighted. Below the tabs, the text 'Protocols →' is followed by a paragraph: 'The protocol page provides information on CTSU protocols:'. This is followed by a bulleted list: 'Protocol Documents', 'Protocol Accruals', 'Data Safety Notifications', 'Reports', 'Protocol Updates and Announcements', and 'Bi-monthly Broadcasts'. At the bottom of this section is a link that says 'Go Now →'.

**Important Announcement**

**Regulatory Submission Portal is Available**

The web-based portal may be used by everyone to submit regulatory documents electronically. The portal is located in the Regulatory Tab → Regulatory Submission tab. A User Guide and Quick Start Guide is available. In the future, use of the portal will be mandatory.

**I Acknowledge**

**CTSU Website at a Glance**

**Protocols** Regulatory OPEN Rave Clinical Data Education & Resources

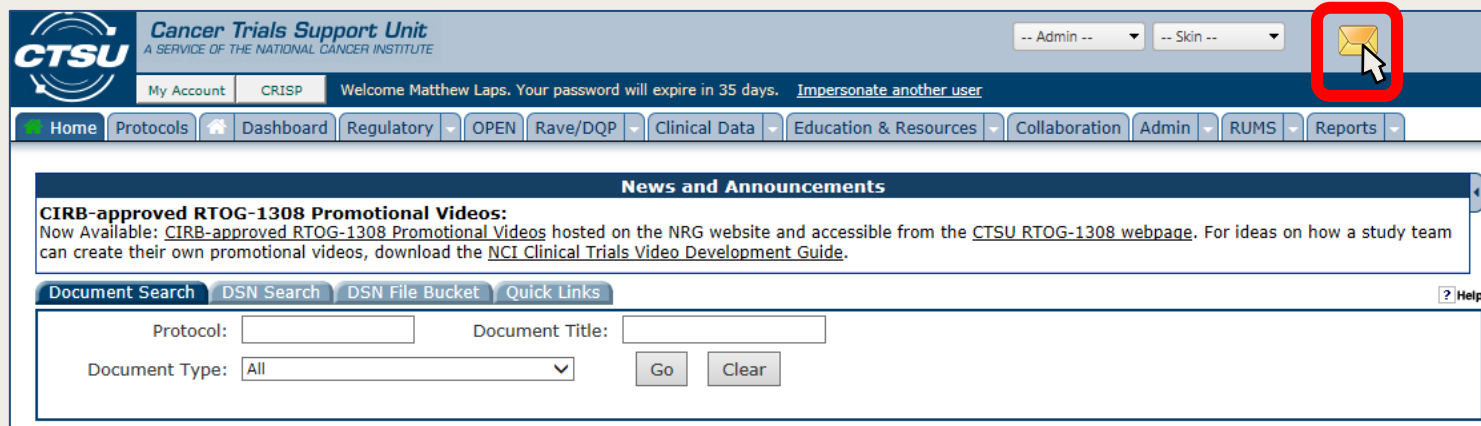
**Protocols →**

The protocol page provides information on CTSU protocols:

- Protocol Documents
- Protocol Accruals
- Data Safety Notifications
- Reports
- Protocol Updates and Announcements
- Bi-monthly Broadcasts

**Go Now →**

# Locating Past Alerts



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

-- Admin -- -- Skin --

My Account CRISP Welcome Matthew Laps. Your password will expire in 35 days. [Impersonate another user](#)

Home Protocols Dashboard Regulatory OPEN Rave/DQP Clinical Data Education & Resources Collaboration Admin RUMS Reports

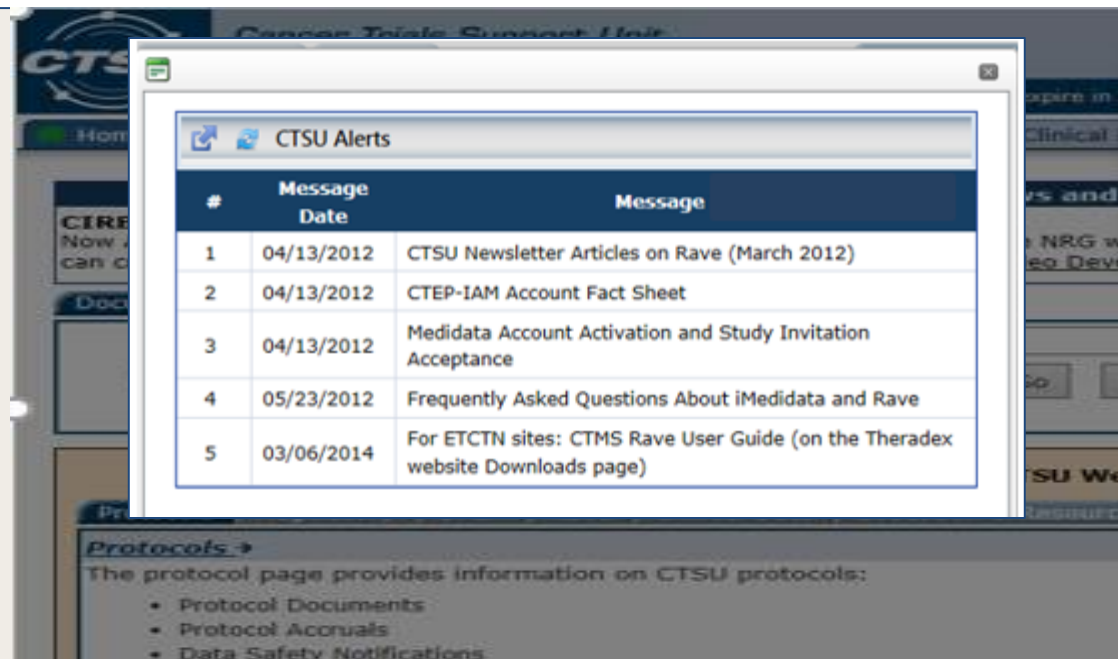
### News and Announcements

**CIRB-approved RTOG-1308 Promotional Videos:**  
Now Available: [CIRB-approved RTOG-1308 Promotional Videos](#) hosted on the NRG website and accessible from the [CTSU RTOG-1308 webpage](#). For ideas on how a study team can create their own promotional videos, download the [NCI Clinical Trials Video Development Guide](#).

Document Search DSN Search DSN File Bucket Quick Links [Help](#)

Protocol:  Document Title:

Document Type:



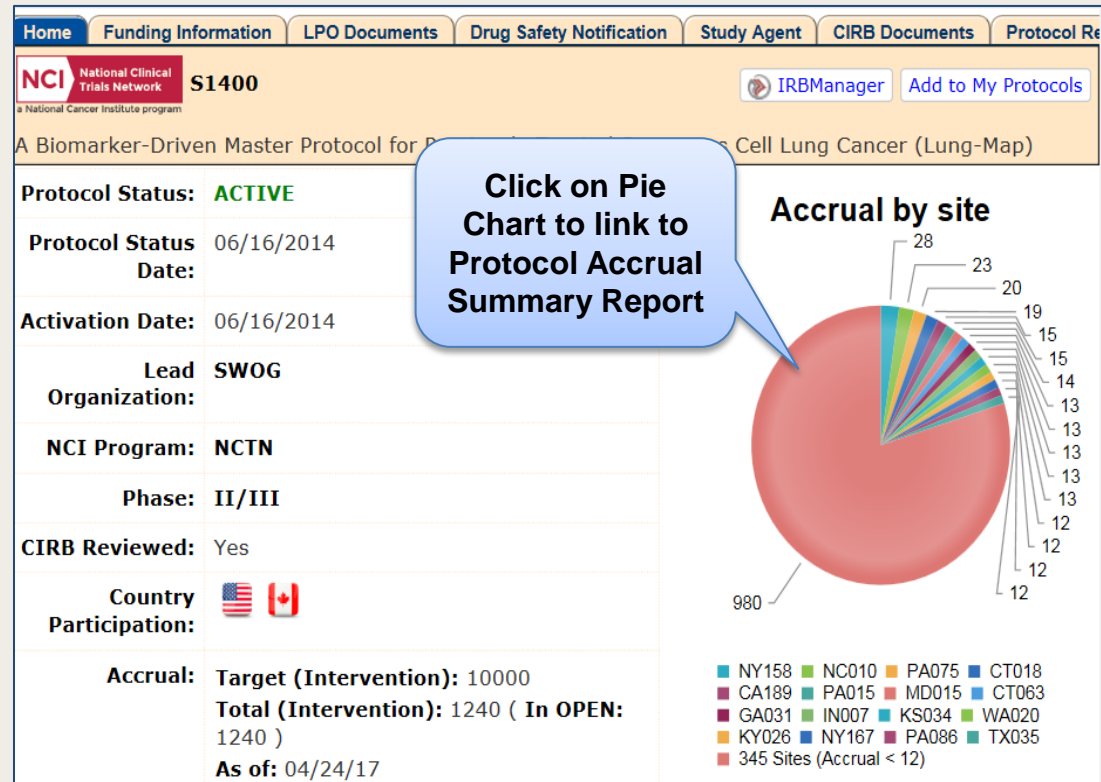
#	Message Date	Message
1	04/13/2012	CTSU Newsletter Articles on Rave (March 2012)
2	04/13/2012	CTEP-IAM Account Fact Sheet
3	04/13/2012	Medidata Account Activation and Study Invitation Acceptance
4	05/23/2012	Frequently Asked Questions About iMedidata and Rave
5	03/06/2014	For ETCTN sites: CTMS Rave User Guide (on the Theradex website Downloads page)



# Accrual Graphs (1)

Available summer 2017

- Displays the top enrolling institutions for protocols with enrollment data in OPEN.
  - Provides name of institution, CTEP site code and number of accruals.
  - Links to Protocol Accrual Summary

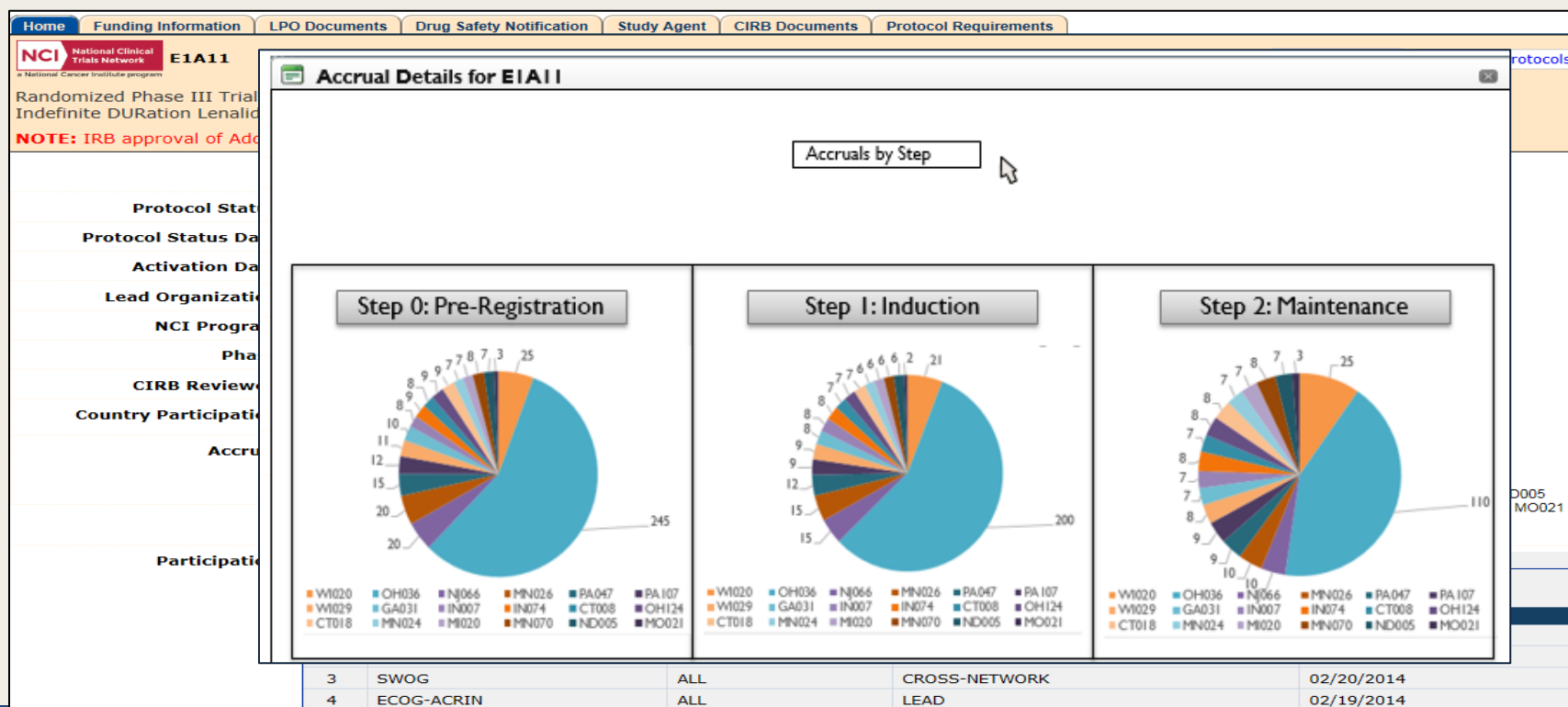


The screenshot displays the Protocol Accrual Summary report for S1400. The report shows the protocol details and a table of site accruals. The table has columns for Site, Site Name, Site Initial Approval Date, Accrual Total, Date of First Accrual, and Date of Last Accrual. The total number of sites is 361.

#	Site	Site Name	Site Initial Approval Date	Accrual Total*	Date of First Accrual	Date of Last Accrual
1	NY158	NY158	06/16/2014	28	06/16/2014	04/24/17
2	NC010	NC010	06/16/2014	23	06/16/2014	04/24/17
3	PA075	PA075	06/16/2014	20	06/16/2014	04/24/17
4	CT018	CT018	06/16/2014	19	06/16/2014	04/24/17
5	CA189	CA189	06/16/2014	15	06/16/2014	04/24/17
6	PA015	PA015	06/16/2014	15	06/16/2014	04/24/17
7	MD015	MD015	06/16/2014	14	06/16/2014	04/24/17
8	CT063	CT063	06/16/2014	13	06/16/2014	04/24/17
9	GA031	GA031	06/16/2014	13	06/16/2014	04/24/17
10	IN007	IN007	06/16/2014	13	06/16/2014	04/24/17
11	KS034	KS034	06/16/2014	13	06/16/2014	04/24/17
12	WA020	WA020	06/16/2014	12	06/16/2014	04/24/17
13	KY026	KY026	06/16/2014	12	06/16/2014	04/24/17
14	NY167	NY167	06/16/2014	12	06/16/2014	04/24/17
15	PA086	PA086	06/16/2014	12	06/16/2014	04/24/17
16	TX035	TX035	06/16/2014	12	06/16/2014	04/24/17
17	345 Sites (Accrual < 12)			980		

# Accrual Graphs (2)

- Provides link to accrual information by step for multi-step protocols.
  - Step number and description.
  - Pie chart with top enrolling sites by step.





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# PROVIDER ASSOCIATION TAB

# Provider Association Tab Summary

- Allows the enrolling site to manage associations with a radiation (RT) /imaging (I) provider(s).
- Complies with the protocol specific requirement (PSR) for use of an IROC participating RT/I provider.
  - Submission of the paper RTFI form will no longer be required.
- RT/Is will have unique CTEP identifiers 'RTF-1234'.
  - Associated RT/I may be part of the enrolling site or a separate institution.

# Access

- Any person at the enrolling site can view their provider associations.
- Persons with a primary role (same people who can update RUMS) can add or remove associations.

The screenshot displays the CTSU web application interface. At the top, the header includes the CTSU logo, the text "Cancer Trials Support Unit A SERVICE OF THE NATIONAL CANCER INSTITUTE", and navigation links: Home | Contact | Feedback | Public Site | Log Out. Below the header, a user status bar shows "Welcome Martha Hering, Your password will expire in 91 days. You are impersonating user Audrey Haas. Impersonate another user" and a search bar. The main navigation menu includes Home, Protocols, Dashboard, Regulatory, OPEN, Rave/DQP, Clinical Data, Education & Resources, Collaboration, and RUMS. A secondary menu shows Home, Site Registration, Protocol Requirements, Provider Association (selected), Regulatory Submission, and CIRB Site Preferences. The "Provider Association" section includes filters for Site (MN001), Status (Active selected, Inactive, All), and an "Add Association" button. Below these filters is a table titled "Provider Associations" with the following data:

Provider CTEP ID	Provider Name	Member Role	Status	Status Date	Action
RTF-2926	Regions Hospital	RT	ACTIVE	7/5/2016	

# Managing Associations

The screenshot displays the 'Provider Associations (MN001)' web application. At the top, there is a header bar with the title 'Add New Association for Regions Hospital (MN001)' and radio buttons for 'All', 'RT', 'RTI', and 'IMG'. Below this is a search bar containing 'Saint Paul Cancer Care Center (RTF-2574 - RT)' and an 'Add to Cart >>' button. The main interface is divided into three sections: a left sidebar, a central map, and a right sidebar. The left sidebar, titled 'Providers on Map', lists three providers: Saint Paul Cancer Care Center, USON-Minnesota Oncology Hematology-Maplewood Cancer Center, and Saint John's Hospital - HealthEast, each with an 'Add to Cart' button. The central map shows a search radius of 25 miles around Saint Paul, MN, with 14 providers found. A callout 'Map search feature' points to the map area. A callout 'Add to cart' points to the 'Add to Cart' button in the left sidebar. The right sidebar, titled 'Providers in cart', shows 'Saint Joseph's Hospital (RTF-2417 - RT)' with a 'Remove from Cart' button. A callout 'Remove from cart' points to this button. At the bottom right, a 'Submit' button is visible, with a callout 'Click Submit' pointing to it.

Provider Associations (MN001)

Add New Association for Regions Hospital (MN001) ☒ All ☐ RT ☐ RTI ☐ IMG

Saint Paul Cancer Care Center (RTF-2574 - RT)

Map Search Pick search radius 25 miles 14 providers found

**Providers on Map**

**Saint Paul Cancer Care Center**  
(RTF-2574 - RT)  
Department of Radiation Oncology 345 Sherman Street  
Saint Paul, MN 55102 US

**USON-Minnesota Oncology Hematology-Maplewood Cancer Center**  
(RTF-1767 - RT)  
Department of Radiation Oncology 1580 Beam Avenue  
Maplewood, MN 55109 US

**Saint John's Hospital - HealthEast**  
(RTF-3228 - RT)  
Radiation Oncology 1575 Beam Avenue  
Maplewood, MN 55109 US

**HealthEast - Woodwinds Hospital**

**Map search feature**

**Add to cart**

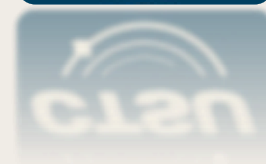
**Providers in cart**

**Saint Joseph's Hospital**  
(RTF-2417 - RT)  
CyberKnife Center 69 West Exchange Street  
Saint Paul, MN 55102 US

**Click Submit**

# IROC Integration Goals

- Automatically provide RT/I credentialing information to the Regulatory Support System (RSS) to comply PSRs.
- Align TRIAD Site Users with the RT/I provider and on the participating organization rosters (instead of the CTSU roster).
- Reduce burden of submitting IROC credentialing letters through the Regulatory Submission Portal.
- Release is planned for summer 2017



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# NATIONAL COVERAGE ANALYSIS UPDATES

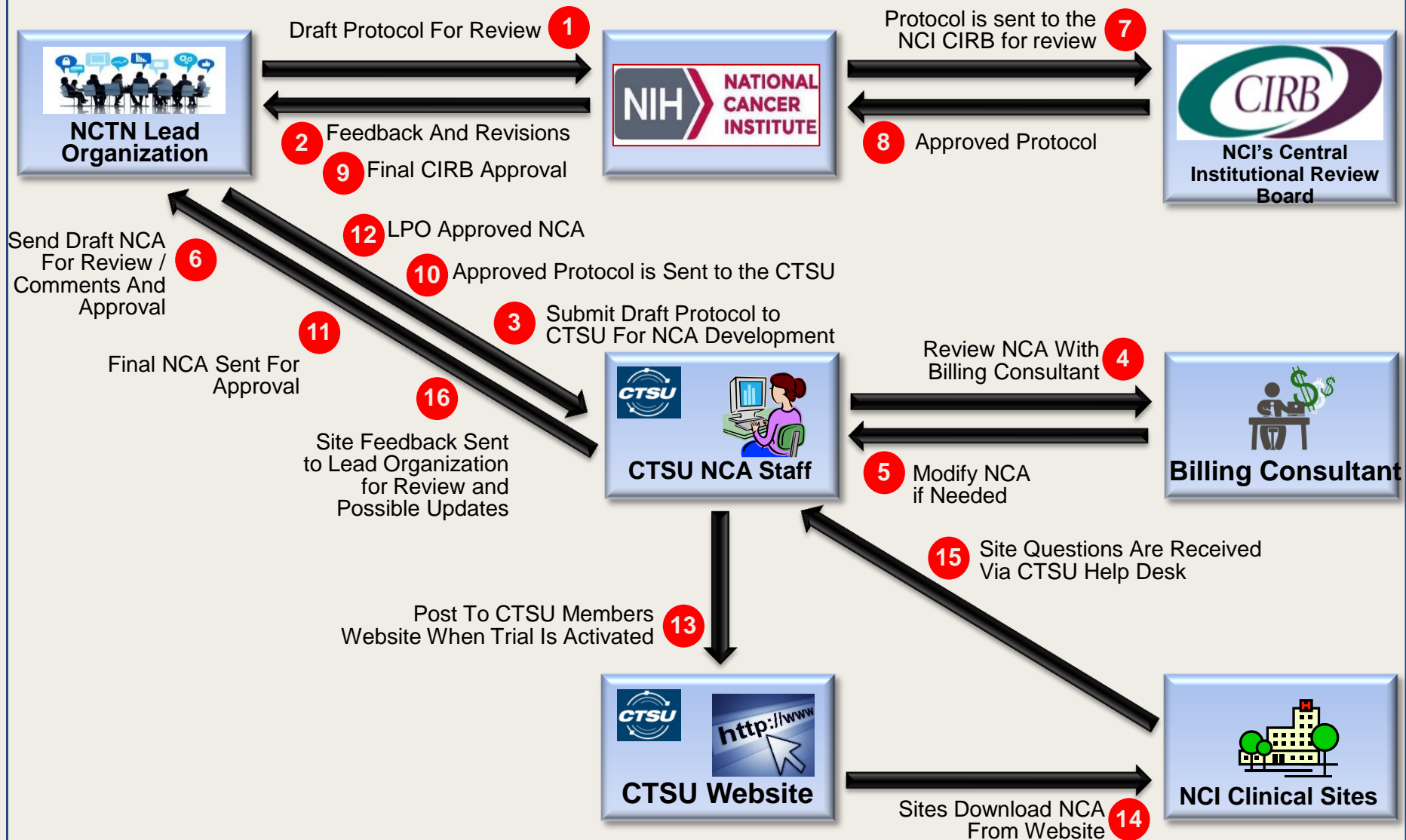


# NCA Process Updates

- CTSU continues to develop and maintain NCAs for all NCTN Phase III treatment trials, select Phase II studies, and cross network NCORP cancer control and prevention trials as well as NCTN precision medicine trials.
- Our monthly working group calls with NCI, NCTNs, Research Bases and billing consultant (Willenberg Associates) continue. These calls provide the opportunity to:
  - Share best practices to standardize protocol language and to enhance clarity of funding for tests that are billable or not billable.
  - Provide additional training regarding clinical trial billing.



# NCA Development Workflow



# New NCTN Working Group Calls

- CTSU has initiated individual monthly calls with the NCTNs. The purpose of these calls is to:
  - Track the status of NCAs in review at the group in order to improve turn around time and have NCAs posted to the CTSU website earlier.
  - Address billing issues during the protocol development phase to avoid negatively impacting trial accrual.
  - Provide the NCTNs with the opportunity to address billing questions and get guidance on funding for tests/procedures from our billing consultant.
    - Note what seems to be routine clinical care, but may not be reimbursable.
  - Provide ongoing feedback on billing issues from sites that could potentially be addressed by changes to the protocol

# Impact of the NCA Pilot to Date

- Lead Protocol Organizations (LPOs) are already embracing the changes prompted from the NCA effort. In addition to creating greater awareness of the issues with billing compliance:
  - The NCA process prompted a review of the IC to enhance the clarity and consistency in some of the language.
  - The NCA has increased awareness of the LPOs to reduce unnecessary testing (and associated costs) in protocols.
  - Initiated discussions with Centers for Medicare and Medicaid Services (CMS) to improve communications related to clinical trial billing and process improvements



# NCA Related Activities (1)

- NCI along with Kelly Willenberg presented at the CMS MAC meeting in March.
  - The presentations provided information about our NCA pilot and the feedback received from sites about the challenges they (and their patients) face as result of the lack of local harmonized coverage for NCI's national trials.
- Sites should contact their MACs about local variation of coverage that seem to conflict with the Medicare clinical trials policy (NCD 3101.1)
- CMS listing of MACs state and jurisdictions:  
[www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Who-are-the-MACs](http://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Who-are-the-MACs)

# NCA Related Activities (2)

## Next steps with CMS:

- CMS will review the NCI's CTSU NCA process for NCI trials and provide input to improve our pilot process and when finalized, it is hoped they will provide some type of acknowledgement of the process.
- NCI/CTSU will gather data from sites on baseline and other tests in NCI trials that are exceptions and do not process through the automated Medicare billing adjudication process. Specific information on local coverage determination variations will be shared with the Medical Directors during future calls.
- Continue to work with CMS to improve clarity around clinical trials coverage policy, especially for NCI national trials.

# NCA Next Steps (1)

- Conduct an assessment of the sites, investigators and trial leaders to gather feedback and work to make improvements to current NCA processes.



- A NCA survey will be available on the CTSU website in early May.
- Continue to collaborate with study leaders to conduct NCAs early in protocol development to ensure plans for tests and procedures align with the standard of care unless medically justified to differ such as careful monitoring of side effects.

# NCA Next Steps (2)



- The NCA Pilot will be part of the poster session at the ASCO meeting in June!
  - **Abstract Title:** *National coverage analyses for NCI clinical trials: A pilot project to reduce participation barriers.*
  - *Abstract Number for Publication: 6542*
  - The Poster Session is the Health Services Research, Clinical Informatics, and Quality of Care Session on Monday, 6/5/2017 1:15 PM-4:45 PM.
- Results from the NCA survey and NCA usage data will be presented.



