Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE

Linking practice to progress

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

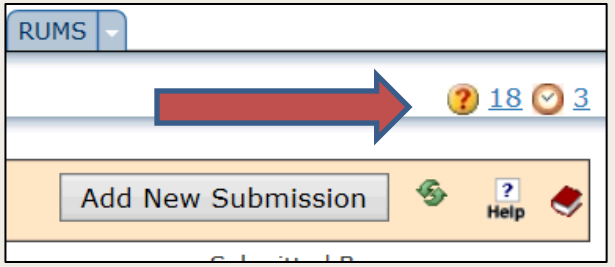
REGULATORY SUBMISSION PORTAL

Regulatory Submission Portal

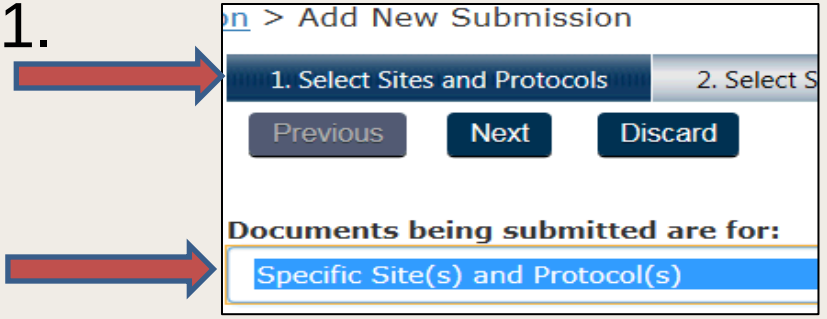
- Mandatory since February 9th, 2017.
- Recent enhancements include:
  - Ability to respond to inquiries directly via the Portal.
  - Enhanced filtering capabilities in the Tracking Table.
  - Addition of a notification area to view count/type of submissions.
  - Mandatory indexing of site registration,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

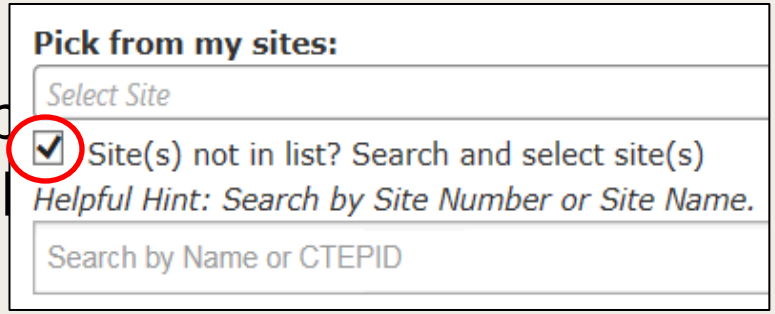


- Documentation being submitted to fulfill a specific study's regulatory requirement should be designated as *Specific Site(s) and Protocols(s)* in the first question of Step1.



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?* b able to search and select CT numbers.



- **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).
- **Urgency**

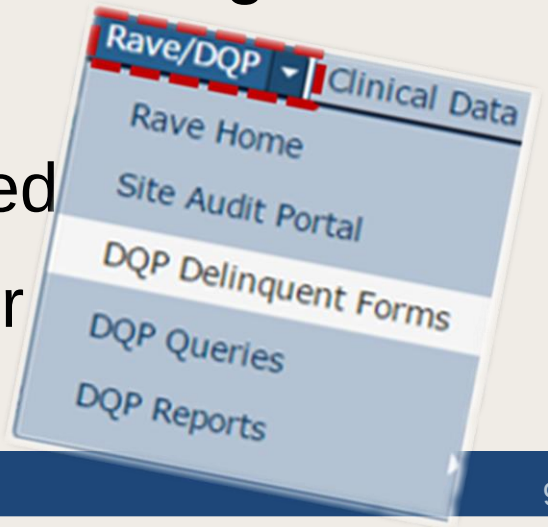
» Abuse of the priority type *urgent* reduces the speed in which the CTSU can process other regulatory submissions.

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	2) Metric Reports
✓ Grid/Table layout	✓ Graphic layout
✓ Export features	✓ Aging Report Summaries
✓ Default view	✓ Rave Totals by Form and Site

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 1st, (24 studies)
  - All NRG Rave studies
- Studies targeted for June/July 2017 release:
  - All COG Rave studies
  - All Alliance Rave studies

CENTRAL MONITORING

Goals

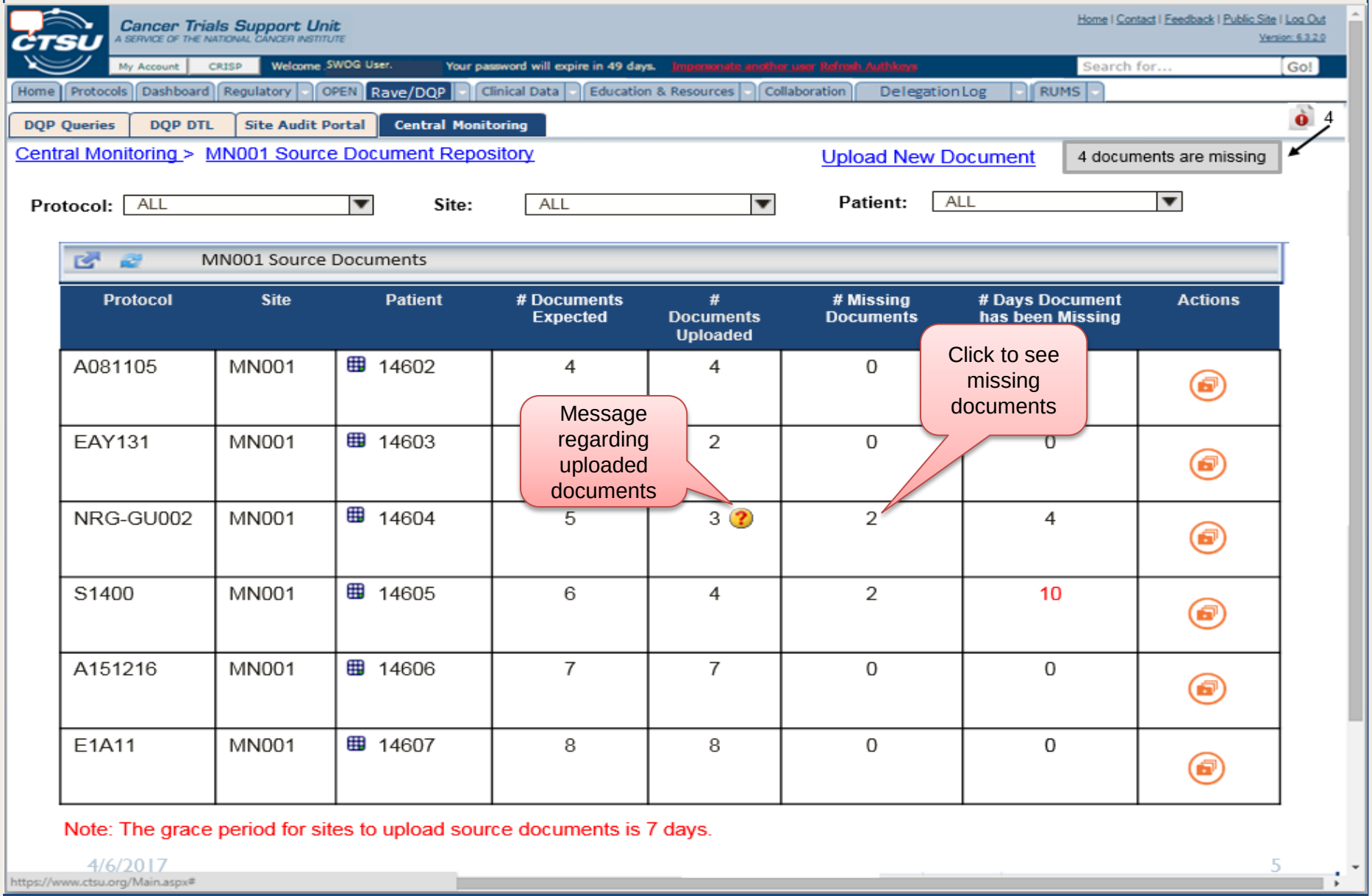
- Develop a streamlined process for performing data monitoring remotely.
  - Data review to be recorded in Rave.
  - Source documents will be uploaded in a central location and must be accessible to monitors to review against the data in Rave.
- Provide an efficient way for sites to keep track of what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



Benefits For Sites

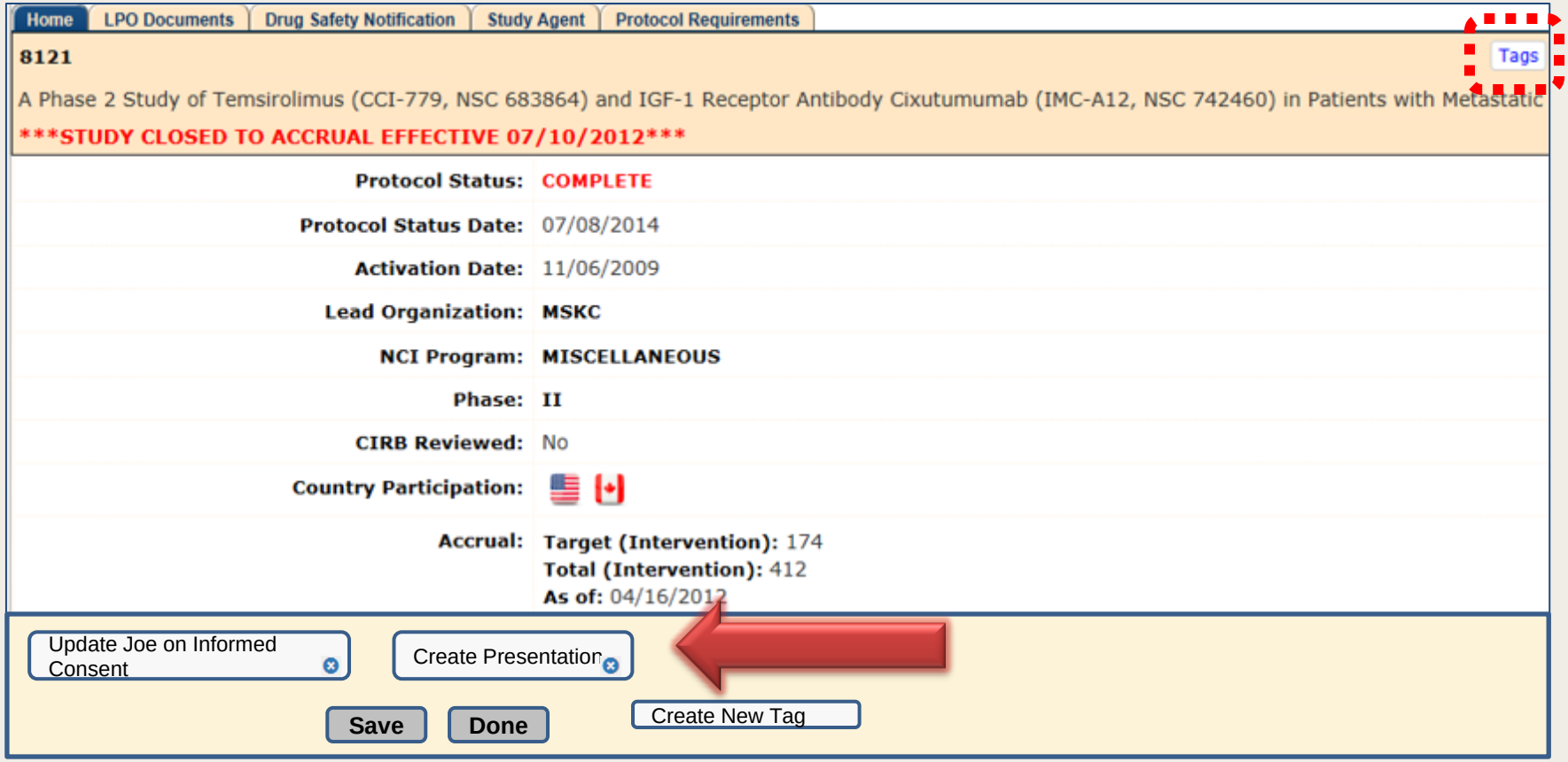
- Ability to redact Personal Identifiable Information electronically while uploading source documents.
- Reminders and Alerts for missing documents.
- Direct links to the source document.
- One place to keep tabs on all the central monitoring activities for all protocols even when led by different Lead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

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)



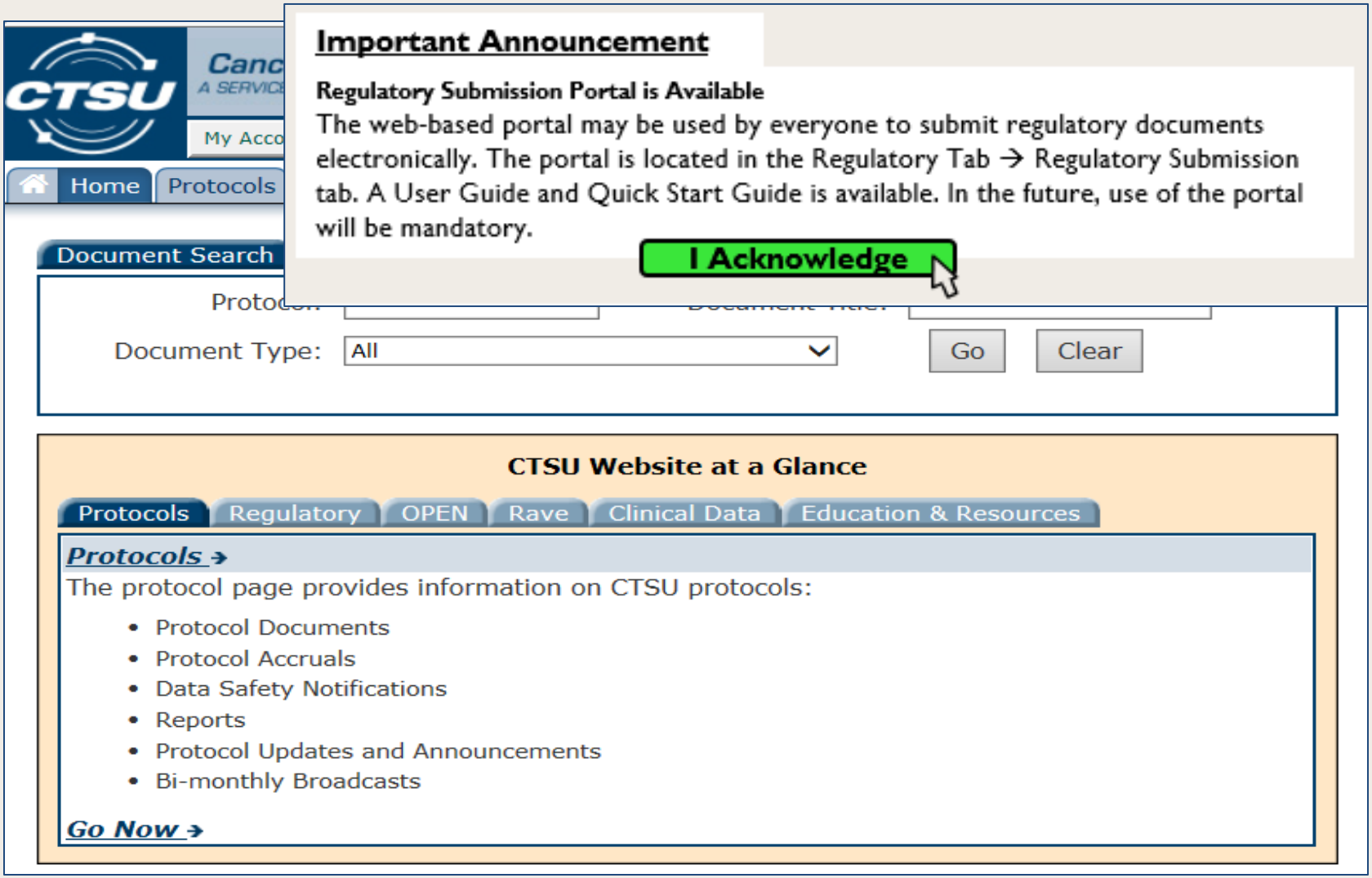
Website Tagging (3)

- 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.

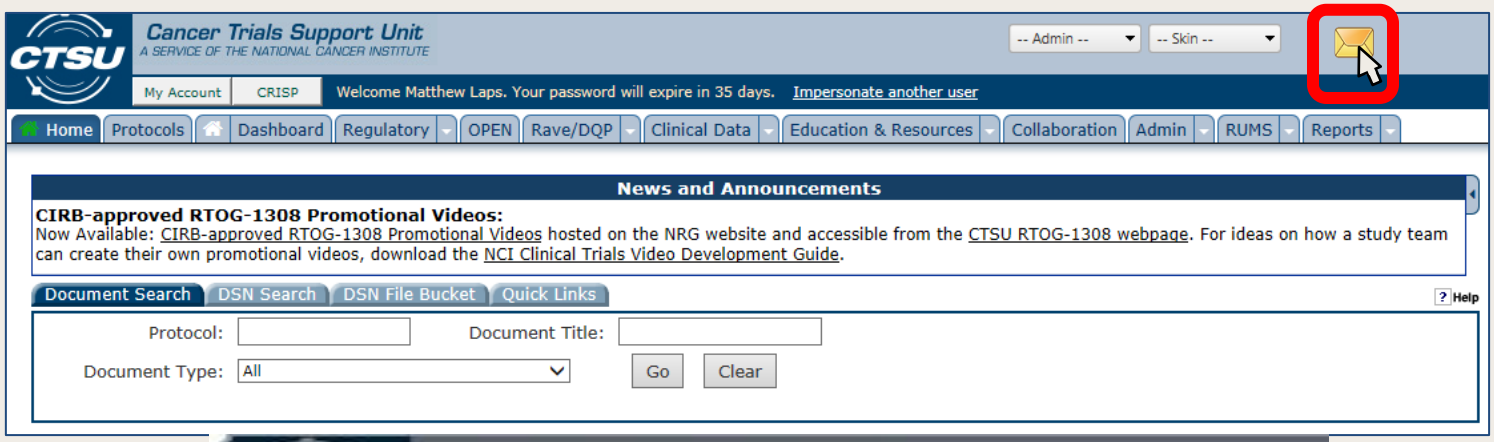
Website Alerts

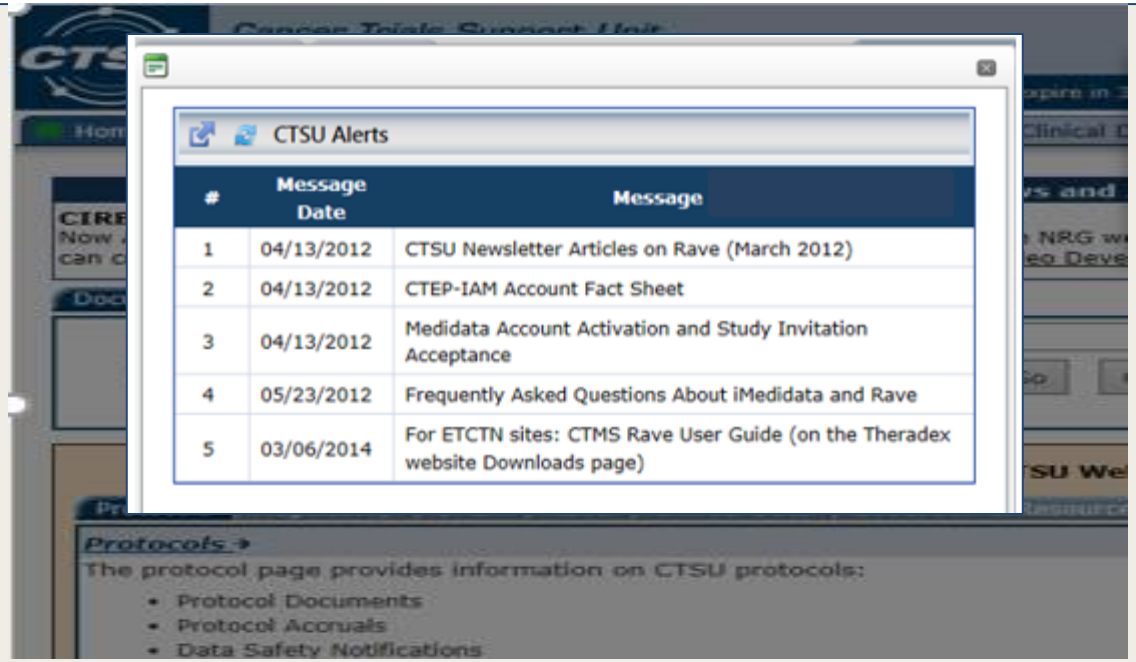
- Important messages will be displayed directly on the webpage upon sign-in.
- Messages can be acknowledged upon delivery, once acknowledged, the message will not be displayed again.
- Website alerts will be available in early summer 2017.

Examples of Alerts



Locating Past Alerts

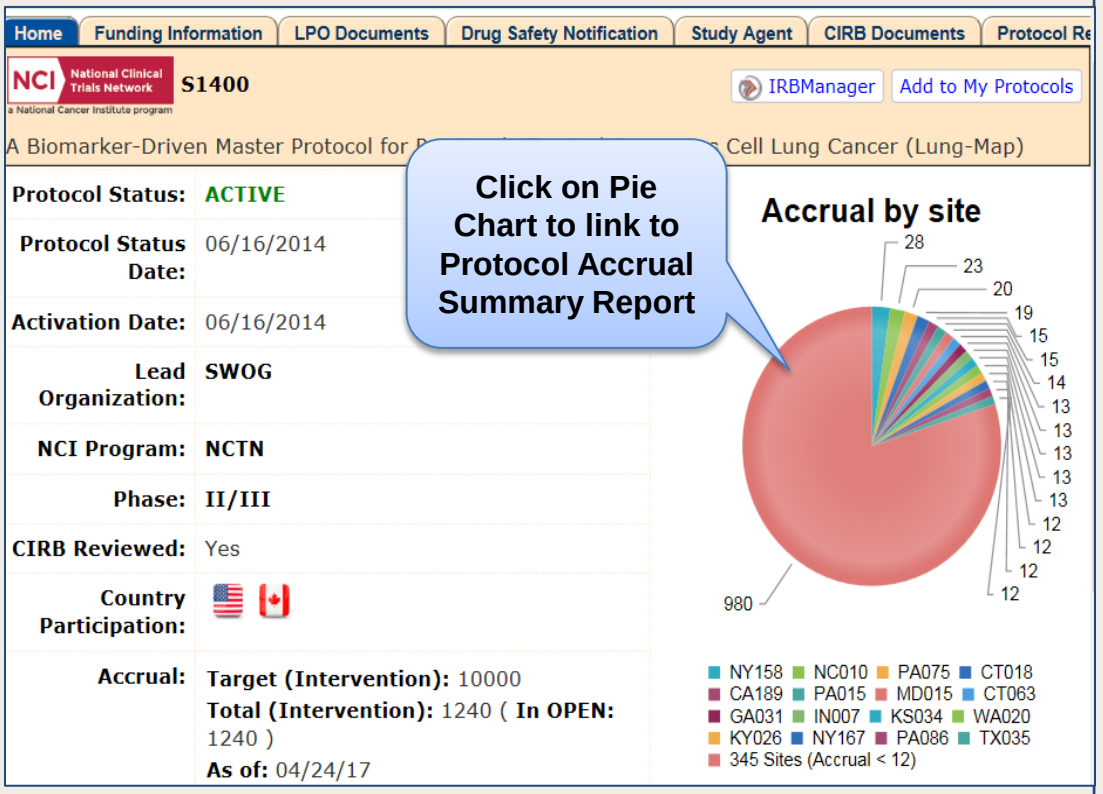


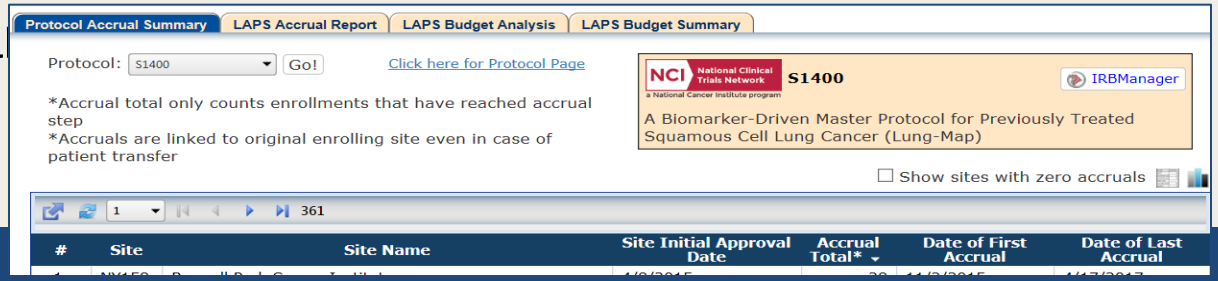


Accrual Graphs (1)

Available summer 2017

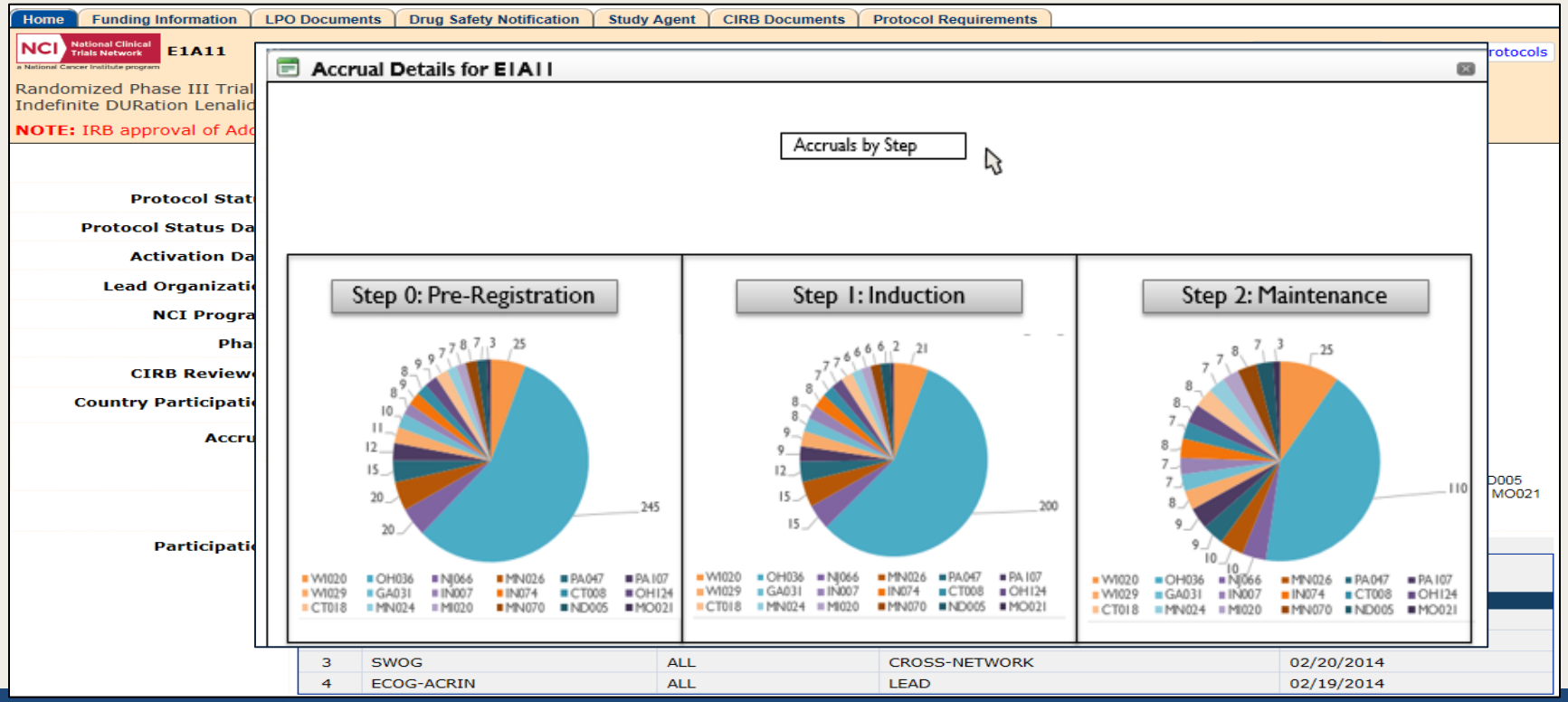
- Displays the top enrolling institutions for protocols with enrollment data in OPEN.
  - Provides name of institution, CTEP site code and number of accruals.
  - Links to Protocol Accrual Summa





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.



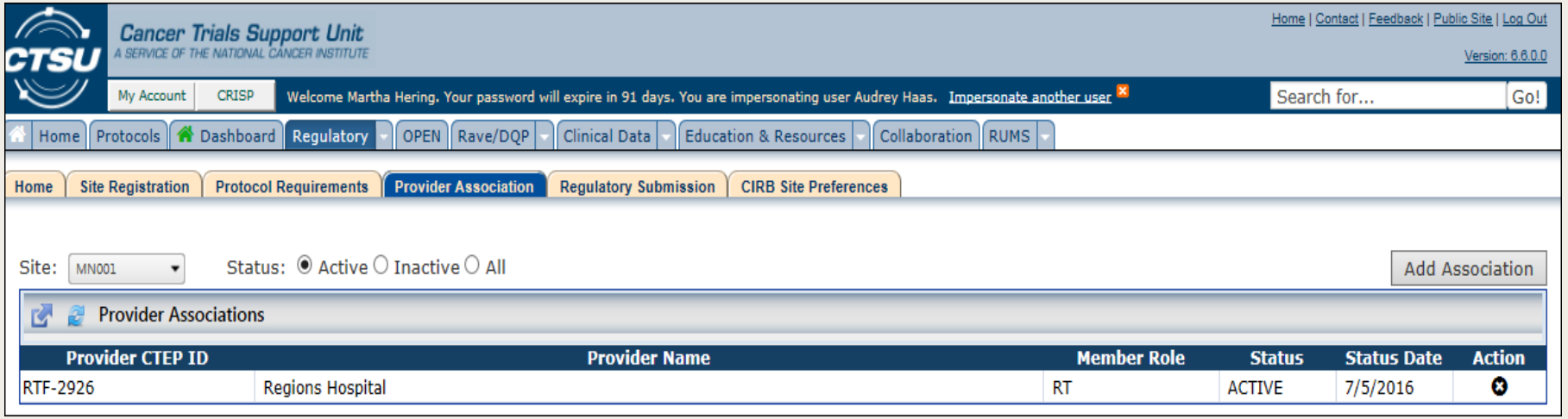
PROVIDER ASSOCIATION TAB

Provider Association Tab Summary

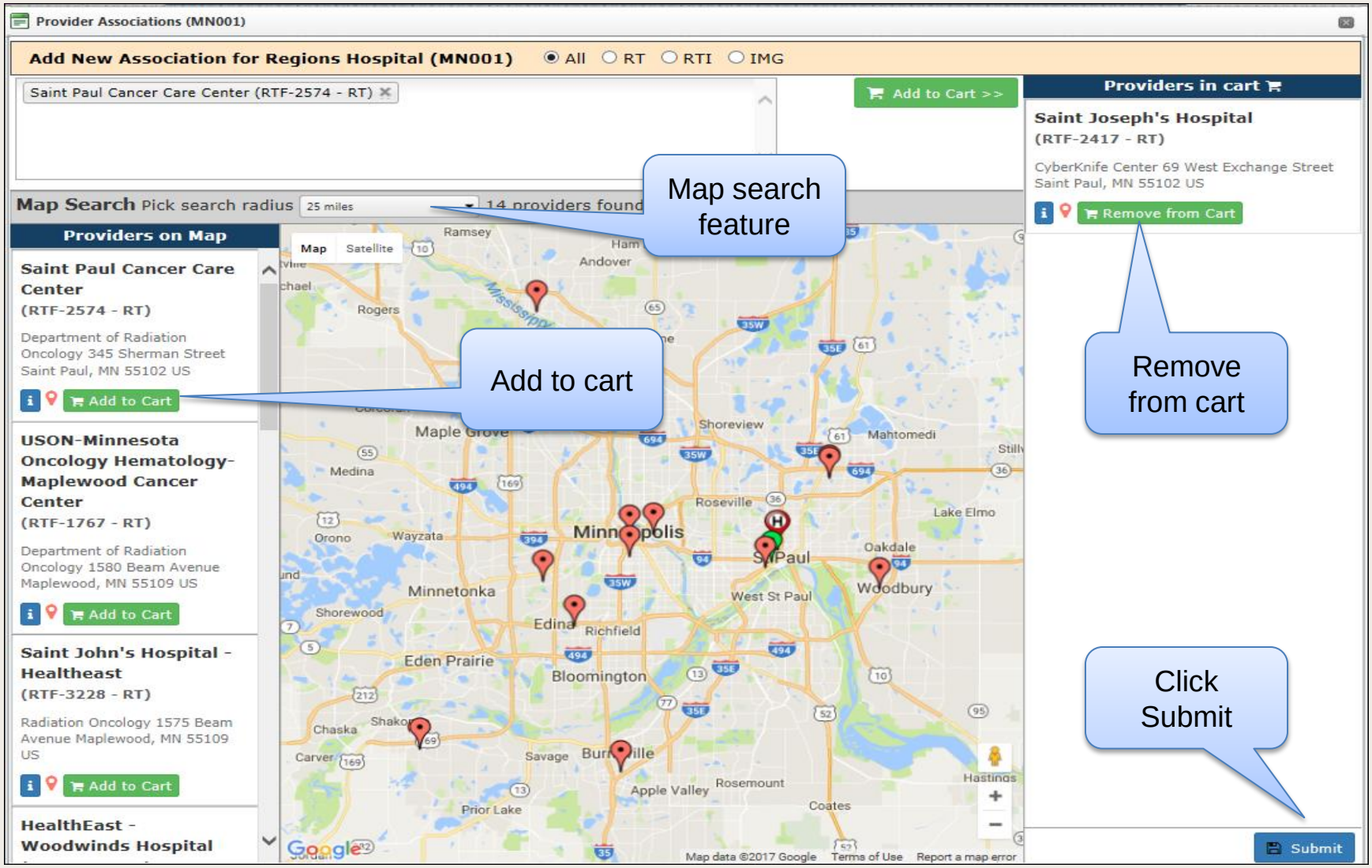
- Allows the enrolling site to manage associations with a radiation (RT) /imaging (I) provider(s).
- Complies with the protocol specific requirement (PSR) for use of an IROC participating RT/I provider.
  - Submission of the paper RTFI form will no longer be required.
- RT/Is will have unique CTEP identifiers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



Managing Associations



IROC Integration Goals

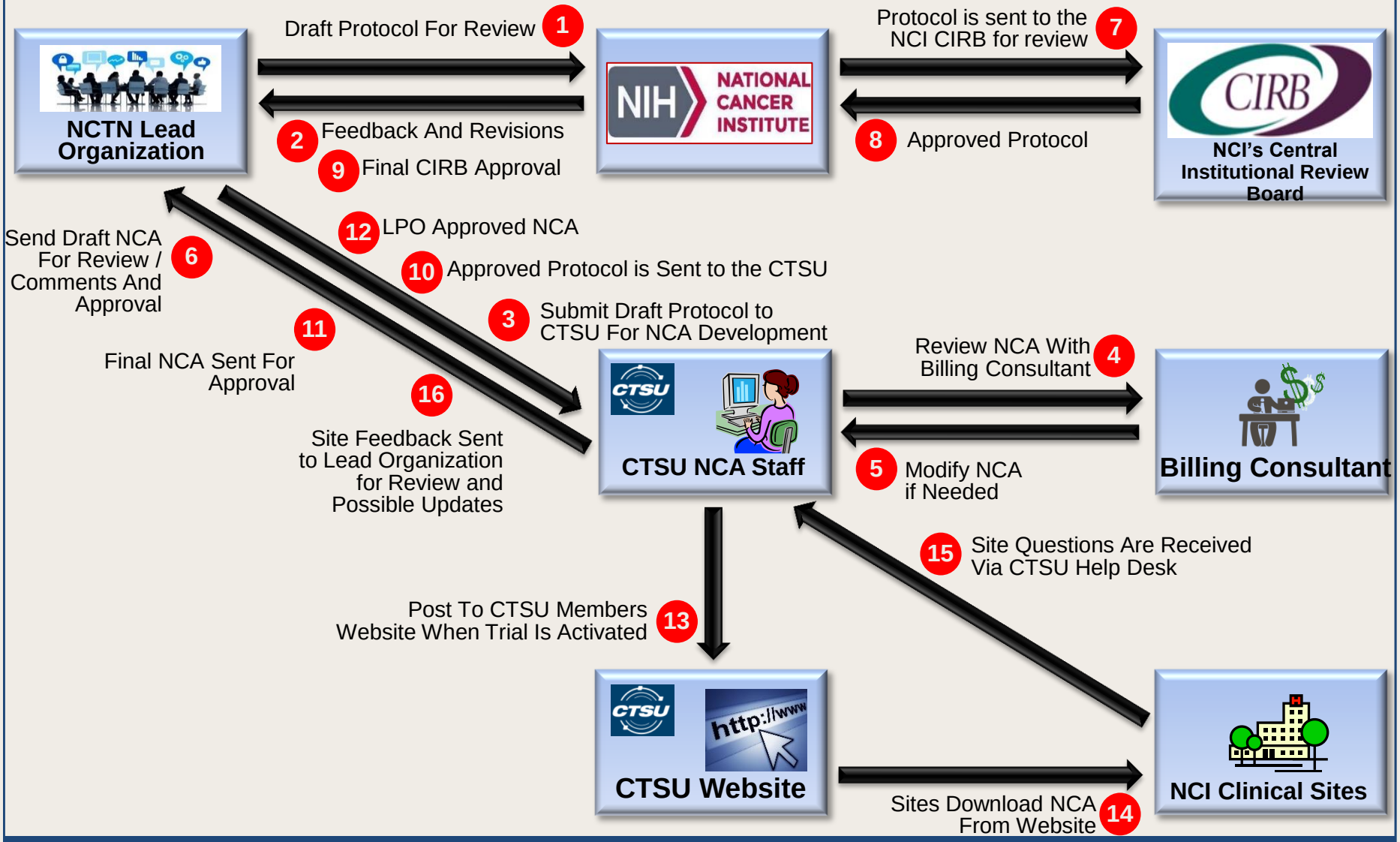
- Automatically provide RT/I credentialing information to the Regulatory Support System (RSS) to comply PSRs.
- Align TRIAD Site Users with the RT/I provider and on the participating organization rosters (instead of the CTSU roster).
- Reduce burden of submitting IROC credentialing letters through the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

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

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

esses.
  - 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.

QUESTIONS