



CTSU UPDATES

Alliance Meeting
Spring 2017
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Agenda

- National Coverage Analysis (NCA) Updates
- Provider Association Tab
- Data Quality Portal (DQP)
- Central Monitoring
- Serious Adverse Event (SAE) Integration





NATIONAL COVERAGE ANALYSIS (NCA) 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.



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 Informed Consent (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 Next Steps (I)

- 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.



PROVIDER ASSOCIATION TAB

Provider Association Tab Summary

- Allows the enrolling site to manage associations with a radiation (RT) /imaging (I) providers.
- 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 CTSU logo and "Cancer Trials Support Unit A SERVICE OF THE NATIONAL CANCER INSTITUTE" are visible. The user is logged in as Martha Hering, impersonating Audrey Haas. The navigation menu includes Home, Protocols, Dashboard, Regulatory, OPEN, Rave/DQP, Clinical Data, Education & Resources, Collaboration, and RUMS. The "Provider Association" tab is selected in the sub-navigation. The main content area shows a filter for Site: MN001 and Status: Active (selected), Inactive, or All. An "Add Association" button is present. Below the filter is a table of Provider Associations.

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

Managing Associations

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**

Providers in cart

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

Map search feature

Add to cart

Remove from cart

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.



DATA QUALITY PORTAL (DQP)

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 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

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 accessible to monitors to review against the data in Rave.
- Provide an efficient way for sites to track document submission for Central Monitoring.

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



SERIOUS ADVERSE EVENT (SAE) INTEGRATION

SAE Integration – Phase I

- Evaluated routine Adverse Events (AEs) entered in Rave against adverse event reporting rules to determine the recommendation for expedited reporting.
- If recommended, expedited reporting was completed (manual login to CTEP-AERS).
- Standard Rave forms were introduced (Adverse Events and Rules Evaluation).
- Pilot was conducted on studies throughout 2015 and early 2016.
- Feedback was collected after implementation of the integration on the pilot studies.

SAE Integration – Phase 2

- Enhancements to features from Phase I were made based on pilot feedback as well as technical updates required by the NCI.
- Included updates in Rave and CTEP-AERS.
 - Changes to make it easier to create, manage, and track expedited reports.
 - Rave connects directly to CTEP-AERS for entry of expedited reporting details.
 - Data entered on the routine AE form in Rave is displayed in CTEP-AERS reducing the need for dual entry.
- Updates are currently being communicated to each Lead Protocol Organization piloting the integration.

Going Forward

- Phase 1 pilot studies are being evaluated for upgrade to the Phase 2 forms.
- Beginning spring 2017 the updated integration will be implemented in new studies where CTEP holds the Investigational New Drug (IND) application.
- A User Guide to assist with the updated forms and process will be available on the CTSU website under each participating protocol's Education and Promotion Materials section.

