Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE

Linking practice to progress

MULTI-GROUP AUDITS, THE CENTRAL MONITORING PORTAL, AND OTHER CTSU UPDATES

OISHI SYMPOSIUM

Agenda

- Multi-Group Audits

- Central Monitoring Portal

- Website and Administrative Updates

MULTI-GROUP AUDITS

Multi-Group Audits (1)

- Three-year pilot program with Multi-Group Audits (MGAs) expected to start in early winter 2018.

- Clinical sites that are members of more than one NCTN Adult Group may be subject to audit visits by two or more Groups *at the same time*. This is expected to:

  – Ease the audit burden for clinical sites over time.

  – Increase efficiency and standardization of audit practices across Groups.

Multi-Group Audits (2)

- Process and procedures have been developed by a committee (CTMB, CTSU, NCTN Groups, DCP).

- Eligible clinical sites:
  - Can be NCTN Group members, NCORPs, or LAPS.
  - Selection related to accrual, Network Group audit schedules, expected audit duration, and other attributes.
  - Will generally be those that enroll a moderate number of patients (i.e., ~25 accruals credited to a single Group across the organization per year).

Implications for Sites (1)

- MGA will be introduced at the time of audit visit scheduling.
  - Interaction with staff from the participating Groups, and the *CTSU Audit Coordinator* during the MGA scheduling process.

- Each auditing Group will send an audit team and will audit the patients/accruals credited to them.

- An MGA visit will follow the same process as any other audit visit (other than there being more than one Group present).

Implications for Sites (2)

- A *CTSU Audit Facilitator* will be in attendance.

  – Assists with on-site coordination; serves as resource; looks for opportunities for increased efficiency and consistency across Groups.

  – May participate as an auditor at the Group's request.

- Each Group will conduct its own exit interview and generate its own audit report.

For more information: refer to the [Multi-Group Audit Overview document](#) under the Resources tab of the CTSU members website.

MGA Timeline

Group 1 and 2 schedule audit*

→

Group 1 and 2 conduct audit*

→

Group 1 communicates audit findings

Group 2 communicates audit findings

*Note: Group audits will remain separate, but will be coordinated to occur at the same time

CENTRAL MONITORING PORTAL (CMP)

Cancer Trials Support Unit

Central Monitoring Portal Introduction

- An application on the CTSU website, also accessible from Rave.

- Upload source documents for Central Monitoring (CM) review; electronically redact Personal Identifying Information (PII).

- Shows documents expected, uploaded and missing for each patient identified for CM review.

- Tracks all CM activities for all protocols, regardless of LPO.

CMP Goals

- Develop a streamlined process for performing data monitoring remotely:
  - Enable upload of source documents to a central location to be accessible for monitors to review against data in Rave.
  - Electronically capture the Central Monitoring (CM) review activity in Rave.

- Provide an efficient way for sites to manage document submission for CM review.

- Provide an easy way for sites to identify the patient\visit for which source documents are required for CM review.

Process for CRAs

- Enter data in Rave.

- Click on CMP link on the 'Central Monitoring Alert' form (new) in Rave or directly login to the CMP from the CTSU website to upload source documents.

- Redact and upload source documents as PDFs on the CMP; PII can be redacted in the document browser.

- Review and respond to queries:

  - On CMP for source documents rejected by the Lead Protocol Organization (LPO).

  - Issued by LPO monitor in Rave.

Central Monitoring Alert Form

- A trigger in Rave indicating a source document upload is required on the CMP.

- Displays for any visit/folder in Rave that has Electronic Case Report Forms (eCRFs) with data points that require CM review (e.g., cycle 1 and cycle 2).

- Form contains a link to the CMP, an open query and instructions to upload source documents.

Subject: 263358
Page: **Central Monitoring Alert - Cycle**

[Instructions added by LPO – FOR LPO USE ONLY] Click here: to view the list of Rave data points that require Central Monitoring review and source documents required to be submitted for these data points.

Upload Source Documents to Central Monitoring Portal (CMP)

? Action is required. Please complete the necessary data entry in Rave, and then upload the corresponding source documents on the CMP. After source documents are uploaded on the CMP, close this query by checking the checkbox and saving this form.
Opened To Site from System (22 Aug 2017)
Forward
☐ Cancel

Printable Version View PDF Icon Key
CRF Version 659 - Page Generated: 22 Aug 2017 10:53:52 Eastern Daylight Time

Save Cancel

Site Submissions Screen

- Viewable by everyone.
  - Those with a specific role (e.g., Rave CRA) can view/upload documents.
  - Those with no specific role will only have read-only access and cannot view the uploaded source documents.
- Data can be filtered by LPO, Site, Protocol and Patient.

Upload Doc & Details

Site Submissions

LPO: SWOG   Site: All Sites   Protocol: S1505   Patient: All Patients   Go

Site	Protocol	Patient	# Documents Expected	# Documents Uploaded	# Missing Documents	# Days for Missing Documents
CA249	S1505	263397	8	2	7	21
CA249	S1505	263257	16	4	13	21
MN054	S1505	264086	10	4	6	45

Document Browser

- Click on 'Upload Document and Details' on the CMP to access the Document browser.

- Provides PII redaction capability.

Items To Note

- Uploaded documents must be a PDF for a patient and visit; source documents for multiple visits in one file will not be accepted.

- Rely on the "Central Monitoring Alert" Form in Rave to identify the patients, visits, and data points for source documents required for upload.

- Use the link provided in Rave to access CMP.

- Use the link provided in CMP to access Rave.

- Do not ignore email reminders and alerts on CMP.

Training

- The CM Portal will contain context sensitive help on every screen.

- CM updates will also be announced in the CTSU Bi-Monthly Broadcast and CTSU Newsletter.

- The CTSU will schedule webinar for sites in late October.

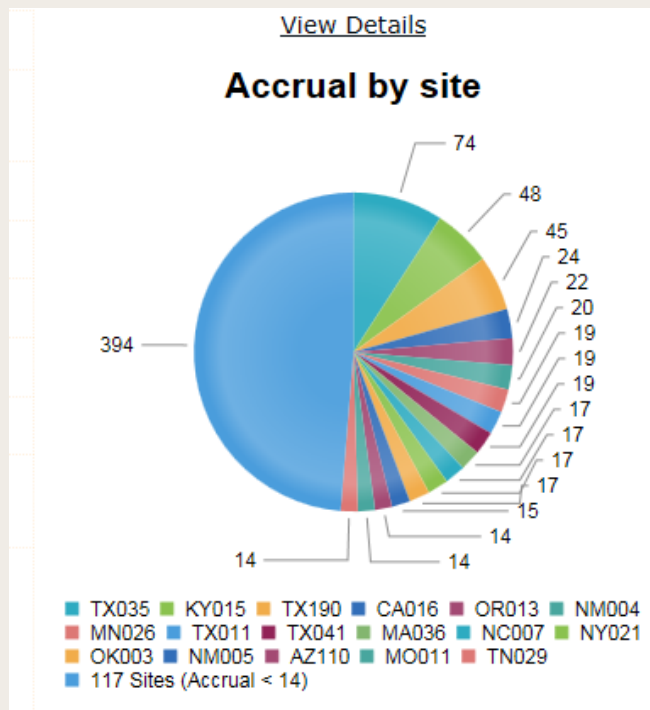# WEBSITE AND ADMINISTRATIVE UPDATES

Upcoming Changes

Unified Protocol Postings

- Display a single version of the CIRB approved protocol and consent form.

  - LPOs will link to the CIRB version posted on the CTSU website.

  - Protocol-specific webpages will have an updated layout on CTSU website.

  - Eliminate duplicate postings under multiple tabs.

- Slated for fall 2017.

Accrual Graphs

- Coming Soon - Accrual Graph and Details
  - On Protocol-Specific Home Pages

Protocol Specific Requirement (PSR) Changes

- Provide user friendly requirement descriptions and instructions on compliance.

- Will display in the Regulatory tab under the Site Registration and Protocol Requirements subtabs.

- Will implement for new studies, and subset of legacy studies.

- Slated for implementation winter 2018.

TRIAD Access

- The following roles will be migrated:

  - TRIAD Site User role to IROC roster when the clinical site is aligned to the IROC provider.

  - TRIAD Site User role to individual's other affiliated rosters.

  - CTSU Admin to the IROC roster for the aligned IROC provider.

- Allow individuals at the IROC provider to maintain roster via RUMS.

CTSU Site Roster

- Will phase out after TRIAD roles are migrated.

- Point of contact will be based upon designated primary person on participating or credited roster – may be several.

- Impacts the distribution of CTSU targeted broadcast and cross-network communications.

NCTN NAVIGATOR
Specimen Resource Locator

- Overview: NCI's NCTN Navigator is a resource for investigators interested in conducting research on specimens that have been banked in CTEP sponsored completed cancer clinical trials.

- Project Goals
  - Publish inventory of available biospecimens from NCI-CTEP supported NCTN trials.
  - Standardize / harmonize definition of "available" biospecimens.
  - Provide a streamlined, consistent process for external investigators to get more information about and submit a proposal for use of available biospecimens.
  - Provide a centralized review of all proposals for requests for biospecimens

Navigator Pilot Phase
Volunteer Investigators

- We need investigators to participate in the Navigator Pilot. If you are interested in participating, please contact the CTSU @ ctsucontact@Westat.com

Reports and Reminders

CTSU Report and Information Subscription Portal (CRISP)

- Allows subscriptions to a variety of e-mail alerts.

- Located on main tool bar.

- Includes:

  - Enrollment Updates: multi-step enrollments, accrual updates and step changes

  - Person Roster: changes at selected rosters

  - Protocol Updates: protocols in selected area of interest

  - Regulatory Updates: expiring approvals, changes site registration status, IRB approval received, registration status change on selected protocols

Accrual Reports

- Located at the bottom of the Protocol Browser Tree.

- Categories: NCTN, ETCTN, NCORP and AYA.

- Filters: protocol status and phase.

- Keyword search.

- Group by: study type, disease, Lead Org.

- Export to: PDF, CSV or Excel or print.

Data Quality Portal (DQP)

- One Stop Shopping
  - Access all Rave studies
  - Direct 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 and Reports

- Metric Tables
  - Grid/Table layout and export features
- Metric Reports
  - Graphic layout, aging report, and totals by form and site
- Timeliness Reports
  - Quarterly updates for query and timeliness

Resources

Resources (1)

- Patient Subtab
  - Relocated from Clinical Data Tab (CDT) to Rave/DQP
  - Provides summary of all registration steps
- Study Agent Report
  - Located in Protocol Browser tree
- NCI Funding Sources
  - Lists available funds per protocols
  - Located under funding tab for each protocol

Resources (2)

- OPEN Reports
  - Located under Reports subtab in OPEN
  - Funding Report: entered reimbursements for QOL and Biospecimens
  - Accrual Map and Charts

- Tags
  - Upcoming feature which allows you to add notes to the website

?? Questions ??