



CTSUS UPDATES

ALLIANCE FALL MEETING

November 2, 2017
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Agenda

- Central Monitoring
- Multi-Group Audits
- Series Adverse Event (SAE) Integration
- Electronic Medical Record (EMR) Pilot
- Additional Updates



CENTRAL MONITORING

Central Monitoring Portal (CMP)

Introduction

- An application on the CTSU website, also accessible directly from Rave.
- Upload source documents required for Central Monitoring (CM) review and electronically redact Personal Identifying Information (PII).
- Displays expected, uploaded, and missing documents for each patient identified for CM review.
- Keeps tabs on all CM activities for all protocols, regardless of the Lead Protocol Organization.

CMP Goals

- Develop a streamlined process for performing remote data monitoring:
 - Enables the upload of source documents to a central location allowing the LPO to review source data against the data entered into Rave, and electronically capture the LPO review activity in Rave.
- Provide an easy way for sites to identify the patient\visit for which source documents are required for CM review.
- Provide an efficient way for sites to manage document submission for CM review.

Process for CRAs

- Enter data in Rave.
- Click on *Central Monitoring Portal (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 PII and upload source documents as PDFs on the CMP.
- Review and respond to queries.
 - On CMP for source documents rejected by the LPO.
 - Issued by LPO monitor in Rave.

Central Monitoring Alert Form

- A trigger in Rave to indicate a source document upload is required on the CMP.
- Displays for any visit/folder in Rave that has Electronic Case Report Forms (eCRFs) which data points require CM review (e.g., cycle 1 and cycle 2).
- Includes 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

CMP - 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 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 x Site: All Sites Protocol: S1505 x 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

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 required source documents.
- Use the link provided in Rave to access CMP.
- Use the link provided on 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 covered in the CTSU Bi-Monthly Broadcast and CTSU newsletter.
- The CTSU will schedule webinar for sites mid-November.



MULTI-GROUP AUDITS

Multi-Group Audits (I)

- What and When
 - Three-year pilot program with Multi-Group Audits (MGAs) expected to start in early winter 2018.
- Why
 - 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*.
 - Ease the audit burden for clinical sites over time.
 - Increase efficiency and standardization of audit practices across Groups.

Multi-Group Audits (2)

- How
 - Process and procedures have been developed by a committee of representatives from CTMB, CTSU, NCTN Groups, and DCP.
- Who
 - Eligible clinical sites:
 - Can be NCTN Group members, NCORPs, or LAPS.
 - 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 (I)

- MGA will be introduced at the time of audit visit scheduling.
- 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.

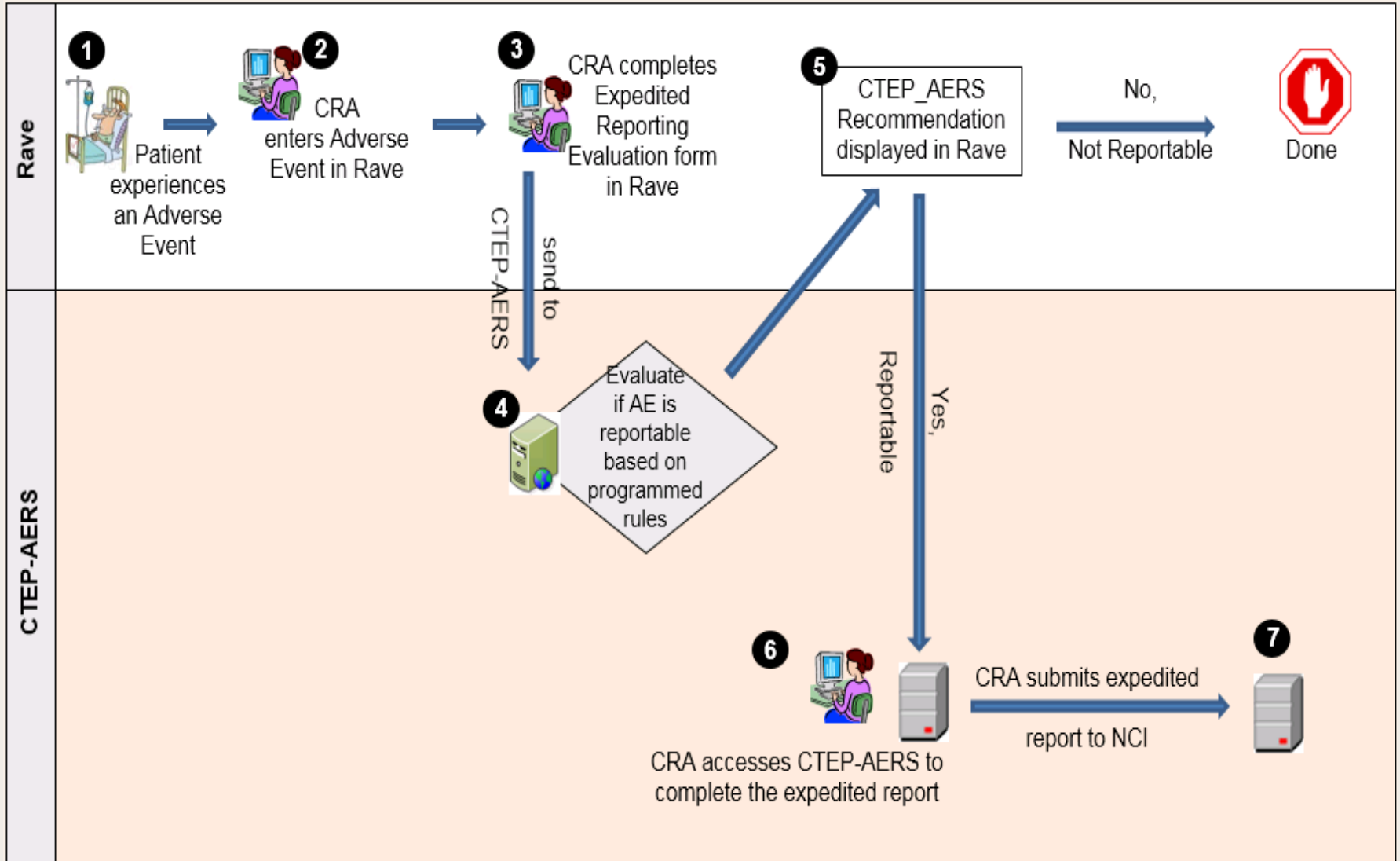


SERIOUS ADVERSE EVENT (SAE) INTEGRATION

Serious Adverse Event (SAE) Integration

- Links the system for reporting *routine* Adverse Events (AEs), Rave, with the system for the *expedited reporting* of SAEs, CTEP-AERs.
- The integration allows for a single sign-on to both systems and reduces double data entry.
- All routine AEs entered in Rave will be evaluated for possible expedited reporting, and if recommended, the system can launch CTEP-AERS directly from Rave to complete the report.

Workflow of Integration (I)



Workflow of Integration (2)

- In CTEP-AERS, the AE data that is pushed from Rave will be viewable but not modifiable.
 - Modifications to AE data will be made in Rave since it is the data source.
 - Any data modified in Rave will require the rules evaluation to be run again. This will cause the updated data to be pushed into CTEP-AERS.
 - AE Start Date and End Date/ Ongoing are required in Rave.
 - CTEP guidance for recording Adverse Events Start and End Date in Rave will be available shortly.

Expedited Reporting Recommendations

- Reporting recommendations are determined based on rules set up in CTEP-AERS using protocol requirements.
 - Exceptions are programmed into the rules (for CTEP-IND studies).
- Reporting recommendations may be overridden.
 - Example (*CREATE* > *NONE*): Laboratory abnormality is recommended as an SAE but is not considered clinically significant by the Investigator.
 - Example (*NONE*): AE is not considered reportable, but investigator determined it was significant.

SAE Report Recommendation “CREATE”

- A recommended action of CREATE indicates that an expedited report is expected based on the programmed rules setup in CTEP-AERS for the study.
- If the Investigator chooses not to report, the recommended action should be edited to NONE.
 - *Note: editing the recommendation on the Expedited Reporting Evaluation /Late AE reporting form will not affect the value of the field “SAE report recommended (derived)” on the AE / Late AE form.*


SAE Report Recommendation

“NONE”

Send all AEs for evaluation ☐ ✓ ✎ ✕

Recommended action for report *(derived)*

An expedited report is NOT recommended. If the Investigator believes an expedited report IS warranted, use the link below to move to CTEP-AERS to complete the expedited report.
Opened To Site from System (13 Mar 2017)

Click this link to complete the safety report 

Report ID *(derived)* REP0737392 ✓ ✎ ✕

[Printable Version](#) [View PDF](#) [Icon Key](#)

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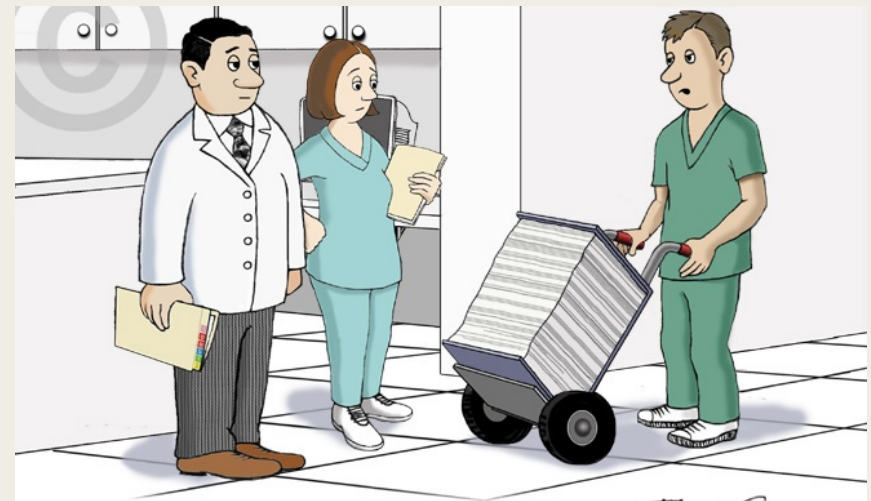
- A recommended action of NONE indicates that no expedited report is expected based on the programmed rules setup in CTEP-AERS for the study.
- If the Investigator wishes to report, the hyperlink on the Expedited Reporting Evaluation /Late AE reporting form should be used to launch CTEP-AERS.

Rave Reminders

- AE data should be entered in Rave and sent for rules evaluation at the time the AE is known/reported.
- AE data should be entered in Rave and then CTEP-AERS should be accessed to complete expedited reporting (if required) using the direct link in Rave.
 - A warning will appear if a report is initiated in CTEP-AERS prior to reporting and rules evaluation in Rave.
- AE data should be updated in Rave, not in CTEP-AERS
 - Data entered in Rave will be passed to CTEP-AERS and will only be editable in Rave.
 - A field that is entered first in CTEP-AERS and then later in Rave could result in reconciliation issues as data in CTEP-AERS will not synchronize with Rave once the expedited report has been submitted to NCI.



ELECTRONIC MEDICAL RECORDS PILOT



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Romero

"We just got an update to the user manual for our Electronic Medical Record system. Where do you want it?"

Electronic Medical Record (EMR) Study Template

- New NCI/CTSUS initiative based on feedback NCI received from physicians and site staff.
- CTSUS has developed a tool to assist sites with their EMR study set up for NCTN clinical trials.
- Currently, CRAs and other hospital staff are developing study builds for their EMR systems.

What Is an EMR Study Template?

- Clinical trials need to be set up in an institution's EMR system (if one is being used) for drug ordering, data collection and billing purposes.
- The study calendar and other details in the protocol document are abstracted into a format (usually excel) that can be used by staff in order to set the trial up in their institution's EMR system.
- The EMR study set up process:
 - Is labor intensive,
 - Cost inefficient,
 - Can delay study activation / loss of accrual,
 - Poses a high risk for deviations/medical errors,
 - Is inefficient-redundantly recreated at each institution.



EMR Study Build – Pilot Status (I)

- CTSU has developed an EMR study build template (excel spreadsheet) to use for the pilot.
- The NCTN Groups will each identify a trial for piloting.
 - NRG GU002 EMR build is currently being piloted on the CTSU and NRG websites. NRG will be contacting sites and sending out a questionnaire to assess the benefits of the template and any feedback for improvement.
 - Alliance A021502 will be the next trial for the pilot. The EMR build is complete and under review.
 - NRG HN004 will be the next NRG protocol to pilot the EMR build.

EMR Study Build – Pilot Status (2)

- Notifications about GU002 were included in the CTSU Bi-Monthly Broadcast. A021502 will be included in the Bi-Monthly when it is available.
- If you are using the GU002 build, please send your feedback to:
 - CTSU Help Desk, ctsucontact@westat.com or
 - Sara McCartney at NRG Oncology, mccartneys@nrgoncology.org or 267-940-9404.



ADDITIONAL UPDATES

Unified Document 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.
 - Update layout of the CIRB and LPO subtabs located in the Protocols tab on the CTSU website.
 - Eliminate duplicate postings under multiple tabs.
- Slated for mid-November 2017.

Updated Protocol Pages

Home Funding Information Documents Drug Safety Notification Study Agent Protocol Requirements

NCI National Clinical Trials Network **A011202** IRBManager Add to My Protocols
a National Cancer Institute program

A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy

Documents

Documents used for CIRB approval

1	Protocol Version Date 11/14/16
2	Consent Form (Protocol Version Date 11/14/16)
3	Consent Form (Protocol Version Date 11/14/16): Spanish

CIRB Documents Supplemental Documents Site Registration Documents Patient Enrollment Forms Case Report Forms Edu & Promotional Materials AE Reporting Forms Funding

Initial Reviews Amendment Reviews Continuing Reviews

Activation Notice

Correspondence

1	02/10/14: CIRB Acknowledgement of Activation (Protocol Version Date 12/30/13)
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CIRB Acknowledgement - Pre-Activation Distribution Notice

Correspondence

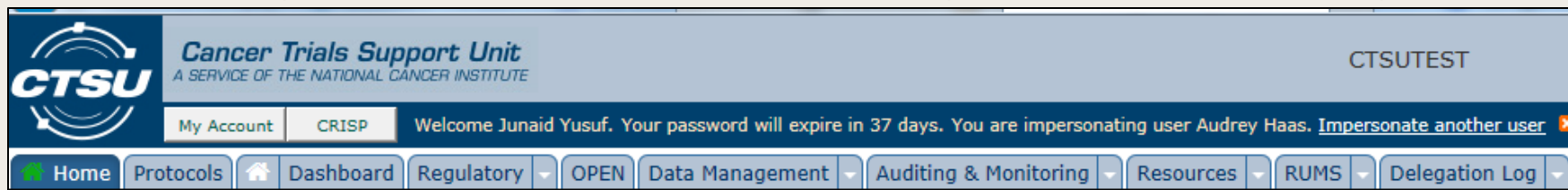
1	07/26/13: CIRB Acknowledgement of A011202 Pre-activation for IRB submission
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Support Documents

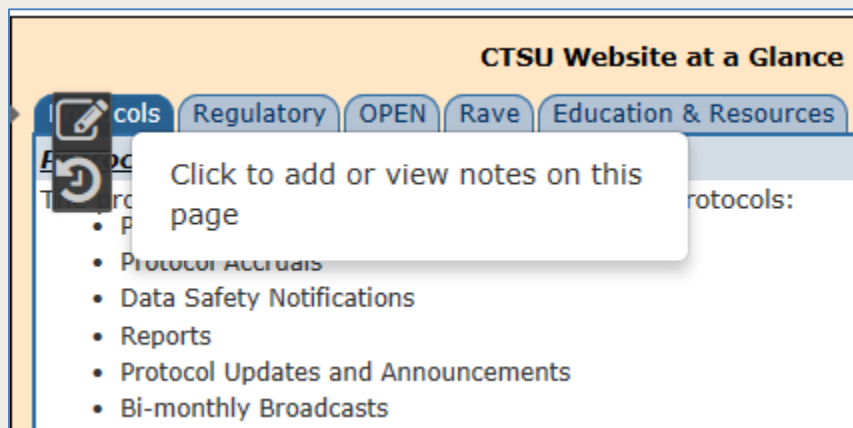
1	07/22/13: Status Notice: Pre-Activation of A011202
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Other Website Changes

- Split Rave/DQP into two tabs- “Data Management” and “Auditing & Monitoring”.



- Add ability to ‘tag’ information on the website.



National Coverage Analysis (NCA) Process Update

- The CTSU process for receiving trials for NCA development has changed.
 - CTSU is receiving the initial protocol drafts from PIO earlier to develop the NCA.
 - NCAs are sent to the LPOs earlier to alert the LPOs of potential non-billable items.
- This new process will allow the NCAs to be posted closer to study activation.

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

?? Questions ??

