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CTSU Updates for NRG

July 16, 2020

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Agenda

1. COVID-19 Information
2. Source Document Portal (SDP) / CTEP-AERS Integration
3. OPEN Updates
4. Provider Association and the Roster Update Management System (RUMS)
5. ePRO
6. Finding Help

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COVID-19 Information

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COVID-19 Information Page

- Contains all information received by the CTSU in one place
- Announcements organized by:
  - NCI & other government entities (only appears on the COVID-19 page)
  - Networks (e.g., NCTN)
    - Lead Protocol Organization (LPO)
      - General announcements
      - Protocol-specific announcements
- Documents are posted in the order they are received
- Network announcements are also posted to other locations on the website
  - E.g., protocol-specific announcements are posted to protocol updates and protocol-specific webpages

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Location

- Accessed from the COVID-19 Info Page button located on the CTSU banner/header

- NCI/CTEP hosts a CTEP Coronavirus Guidance Page;
  The link is available from the Important Notice on the CTSU website

IMPORTANT NOTICE
COVID-19 Information
Announcements from NCI and the LPOs will be posted as they are received. Use the COVID-19 button located at the top of the CTSU members' website to access the COVID-19 Information page. (login to members' website required). Additional information from NCI is available on the CTEP Coronavirus Guidance page. (posted

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CTSU COVID-19 Information Page

COVID-19 Information Page

As the CTSU receives information related to the COVID-19 pandemic it will be posted to this page. This information will also appear in LPO Updates, Protocol Updates, and/or the protocol-specific webpages, as appropriate.

This page is organized by the organization that sent the communication, and the most recent announcements appear first.

Instructions for Reporting COVID-19 Related Protocol Deviations

NCI and Other Government Entities

The memos listed in this section are posted to the CTEP Coronavirus Guidance page. Please check the CTEP Coronavirus Guidance page for additional information.

1. Memorandum: Updated Interim Guidance for Patients on Clinical Trials Sponsored by the NCI Cancer Therapy Evaluation Program: Shipment of Oral IND Agents to Clinical Trial Subjects (June 2, 2020)
2. Guidance for Collection of Adverse Events Related to COVID-19 Infection (March 25, 2020)
3. Memorandum: Additional Guidance for Clinical Trial Activities Affected by the Novel Coronavirus (March 23, 2020)
4. FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic
5. Guidance for NIH-Funded Clinical Trials and Human Subjects Studies Affected by COVID-19 (Notice Number: NOT-OD-20-87)
6. Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19 (Notice Number: NOT-OD-20-86)
7. Memorandum: Interim Guidance for Patients on Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program and the NCI Community Oncology Research Program (NCORP) (March 13, 2020)

NCTN/NCORP

Alliance

General Announcements

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Reporting COVID-Related Protocol Deviations

- New posting lists instructions on reporting COVID-19-related protocol deviations
- Grid organized by LPO
- Located on COVID-19 Info page and Resources > CTSU Operations Information > Education & Reference

Instructions for Reporting COVID-19 Related Protocol Deviations

LPO	Instructions for Reporting COVID-19 Related Protocol Deviations	Rave Form/Folder	Method
ABTC	Sites should record deviations using the paper deviation log which is located under the COVID policy on the ABTC website (Document Area - General Information > COVID-19 Documents). Once available, instructions will be provided for sites to upload the log into Rave each month.	NA	Paper Deviation Log; site to upload monthly to Rave once Rave form is available
Alliance	The Alliance has implemented a single Rave study, ALLIANCE_COVID-19-Reporting, for the centralized collection of all COVID-19 pandemic-related data for patients on Alliance clinical trials.	Two Rave forms in the Master Study (ALLIANCE_COVID-19-Reporting):	Rave Master Study (ALLIANCE_COVID-19-Reporting)

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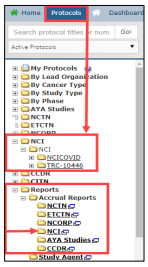
NCI COVID Protocols

- NCI is sponsoring two COVID-related protocols
  - NCICOVID: *NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study*
  - TRC-10446: *Tocilizumab in Hospitalized Cancer Patients with Coronavirus 2019 (SARS-CoV-2) and Severe Complications of Coronavirus Disease 19 (COVID-19)*
- Located in the new NCI folder in the protocol tree
- New NCI node in Accrual Reports



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NCICOVID Trial Webinar

- Webinars were conducted in May/June on NCICOVID
- Recording, slides, and Q&A are in NCICOVID protocol-specific page >Documents > Education & Promotion

#	Document Title	Document Date
Education and Promotion Materials		
1	Study Calendar	01-May-2020
2	Schema	01-May-2020
3	CLASS: Specimen Tracking Training Guide	
4	Specimen Tracking: User Guide v3.0	
5	Specimen Tracking: ETCTN and CTMS Training	
6	Specimen Kit Management User Guide	27-May-2020
7	NCCAPS Communication Resources for Study Sites - Word Version	19-Jun-2020
8	NCCAPS Communication Resources for Study Sites - PDF Version	19-Jun-2020
9	NCI Social Media Resources	19-Jun-2020
10	Coronavirus Study Visual	15-Jun-2020
11	NCICOVID Overview - Slides - June 2, 2020	02-Jun-2020
12	NCICOVID Overview - Recording - June 2, 2020	02-Jun-2020
13	NCICOVID Overview - Q and A from Sites - June 2, 2020	02-Jun-2020

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Source Document Portal (SDP) / CTEP-AERS Integration

New Submission Process for Supporting Documents

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Overview

- The Source Document Portal (SDP) will be used to collect supporting documentation for Adverse Events (AE) reports beginning late summer/early Fall, 2020
- **Current process** is to check the box(es) on the *Additional Information* screen indicating which documents will be faxed to the AE Review Team when submitting supporting documents for an AE report in the Cancer Therapy Evaluation Program - Adverse Event Reporting System (CTEP-AERS)
- **New process** will be direct upload of supporting documents on SDP via a hyperlink on the *Submission* screen (rather than fax)
- Persons with Rave roles will be able to access the *Safety Ticket Documents* screen in the SDP

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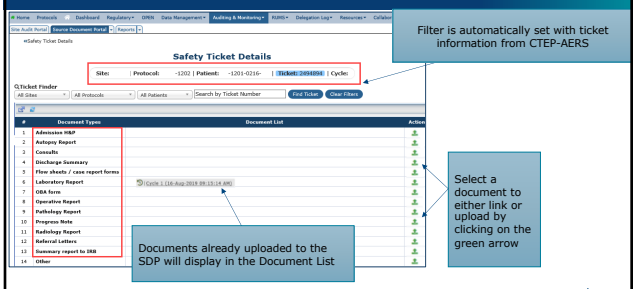
Landing page from CTEP-AERS



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Best Practices

- Skip the SDP link/upload step if the AE report does not require any supporting documentation
- Site staff responsible for reporting in CTEP-AERS will also be responsible for uploading supporting documents in the SDP
- All communication between site staff and AE reviewers will continue to be via email

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Upload vs. Document Linking

- If a document is required to support the information on an AE report, first check if the document already exists in the SDP
  - If the required document appears on the *Safety Ticket Documents* screen, link the document to the ticket rather than uploading a duplicate document
- The current fax-based process for sending supporting documents to the AE review team will remain in place for non-RSS managed protocols

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Multiple Supporting Documents

- There is flexibility with document uploads
  - More than one version of a document type (e.g., two laboratory reports for the same cycle as the ticket)
  - Documents from a cycle other than the cycle on which the AE occurred (e.g., a laboratory report for a different cycle than the ticket)

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OPEN Updates

New Features

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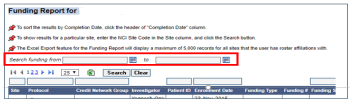
OPEN Updates

- Sites in a follow-up status can now view historical data in OPEN and enter funding data for their enrollments
- Updates to the funding screens and funding reports
  - Ability to search funding between specific date ranges in the funding report (*see right*)



  - Increased number of records that can be exported to excel for the funding report
  - New column for collect type (mandatory, mandatory request, conditional, optional) in the OPEN funding screen

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Provider Association and The Roster Update Management System (RUMS)

New Features & Reminders

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Provider Institution Roster –The Basics

- Providers are entities that provide essential research-related services to the enrolling institution
- Types of Providers in RSS
  - Radiation/Imaging – originate with the Imaging and Radiation Oncology Core (IROC)
  - Targeted Radio Pharmacy (TRF) – originate with the Pharmaceutical Management Branch (PMB) for CTEP IND studies
- Providers may be at the enrolling institution or a separate entity that works via an agreement with the enrolling institution
  - Ex. 1: John Hopkins University/Sidney Kimmel Cancer Center (MD017)/(RTF-1652)
  - Ex. 2: Community Hospital linked to provider at an Academic Center

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Provider Institution Roster –Additional Facts

- Has a CTEP Identifier
- Cannot be claimed on a network roster
- A provider may link to many enrolling sites, or an enrolling site may link to many providers
- Can be credentialed for modalities to comply a protocol-specific requirement (PSR) for the enrolling site
- Will be available on the Delegation of Tasks Log (DTL)

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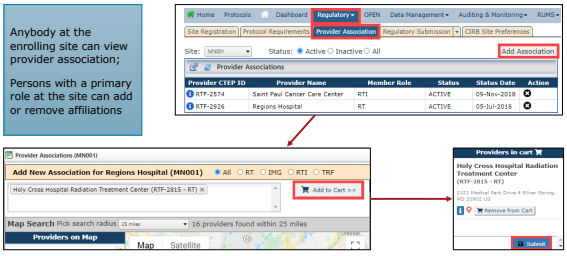
Provider Association Application

Anybody at the enrolling site can view provider association;

Persons with a primary role at the site can add or remove affiliations



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Provider Person Roster

- For TRFs entered by PMB staff from radiopharmacy licensure and supporting documents
  - Viewable on the DTL for TRF Providers associated with the enrolling site
- For Radiation/Imaging Providers managed in RUMS
  - Have access to TRIAD for studies using the full IROC integration or for credentialing purposes
  - *Note – you will need to maintain the TRIAD Site User role on the enrolling site for legacy studies*

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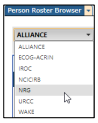
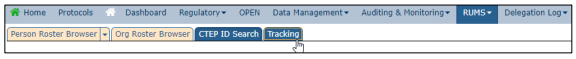
RUMS Reminders

- If on multiple rosters, select the correct one
- Use the button for detailed person info, including registration (RCR) documents and required trainings
- Use the CTEP ID search feature to look up CTEP IDs
- Person roles can be added in bulk across rosters and sites
- Persons with the RUMS Update Person role for CIRB may request the addition of CIRB affiliates and components from RUMS
- Remember to check the status of person requests under the Tracking section





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electronic Patient Reported Outcomes (ePRO)

Helpful Information: Access, Education & Training, Hints, and Support

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ePRO Access for Rave Protocols

- **Staff requirements:**
  - Rave CRA role
  - On a participating site roster in RSS
- After completion of required trainings, may:
  - Enter study data in Rave
    - eLearning needed: *EDC Essentials for Clinical Research Coordinators*
    - Link: *Rave EDC*
  - Register patients in ePRO
    - eLearning needed: *Registering Your Subject in an ePRO Study*
    - Link: *Patient Cloud Registration*

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ePRO Training

- Statement displays in protocol-specific home page on the study title banner indicating ePRO online training required

- Accessed in iMedidata
  - If required for a study, *eLearning* link appears in place of the *Rave EDC* link
  - Once certified, the *eLearning* link will be replaced by the *Rave EDC* link
- Only taken by a site user one time for one protocol and certification satisfies the requirement for all subsequent ePRO studies in Rave for that person
- All staff with the Rave CRA role for a Rave study that is using ePRO must take the ePRO eLearning, regardless of whether they will be enrolling patients in ePRO

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ePRO Patients and the App

- Patient registration in ePRO
  - Patient must be enrolled in OPEN
  - Site staff performing registration must have Rave CRA role;
    If a DTL is required, must be an approved Rave CRA on the DTL
- Patient access to ePRO
  - ePRO forms can only be accessed using a patient's own approved device (or site device if available for a study)
  - There is no access via a web browser
- ePRO app versions

Patient Cloud ePRO for older studies
(A221602, NRG-GU005, NRG-GU006, EAA173, 10021, 10107)

Patient Cloud is used for all remaining studies

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ePRO Helpful Hints

- Identify if a Rave study is using ePRO by checking the *Supported By* matrix on the CTSU website protocol-specific home page
- For ePRO issues/support contact the study data manager (will forward issues as appropriate)
- ePRO educational materials are in Documents > Education and Promotion for protocols using ePRO

Supported By:

CIRB	DTL	OPEN	Rave	TSDV	IROC/ TRIAD	DQP	ePRO	SAE Int	CM
✓	✗	✓	✓	✓	✓	✓	✓	✗	✗

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Finding Help

Help Topics

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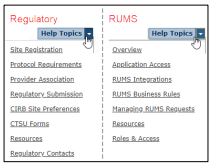
Help Topics Button

- **Help Topics** are replacing User Guides
- Content is unique to the page being viewed
- Navigate using drop-downs or click on button to access whole page
- Current availability
  - Members' home page
  - Dashboard
  - Regulatory
  - SDP, RUMS, DTL
  - DQP (*Coming Soon!*)



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Thank You

Any questions?

Please contact the CTSU Help Desk if you have questions after the session at:

- Email: **ctsucontact@westat.com**
- Phone: 1-888-823-5923

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