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# CTSUS UPDATES

Alliance Fall Meeting  
November 1, 2018

# Agenda

- Central Monitoring (CM) Using Source Document Portal (SDP)
- Delegation Of Tasks Log (DTL) Updates
- Serious Adverse Event (SAE) Integration
- General Reminders



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# **CENTRAL MONITORING (CM) USING THE SOURCE DOCUMENT PORTAL (SDP)**

# Introduction

- What is Central Monitoring (CM)?
  - Performed by Lead Protocol Organizations (LPOs) to ensure protocol compliance by sites
  - Allows the LPO to review source documentation against data entered in Rave
- What is the Source Document Portal (SDP)?
  - An application on the CTSU website under the Auditing & Monitoring tab used to support the collection of source documents for CM review
  - Future expansion to support Eligibility Reviews and support reviews of Serious Adverse Events (SAEs)

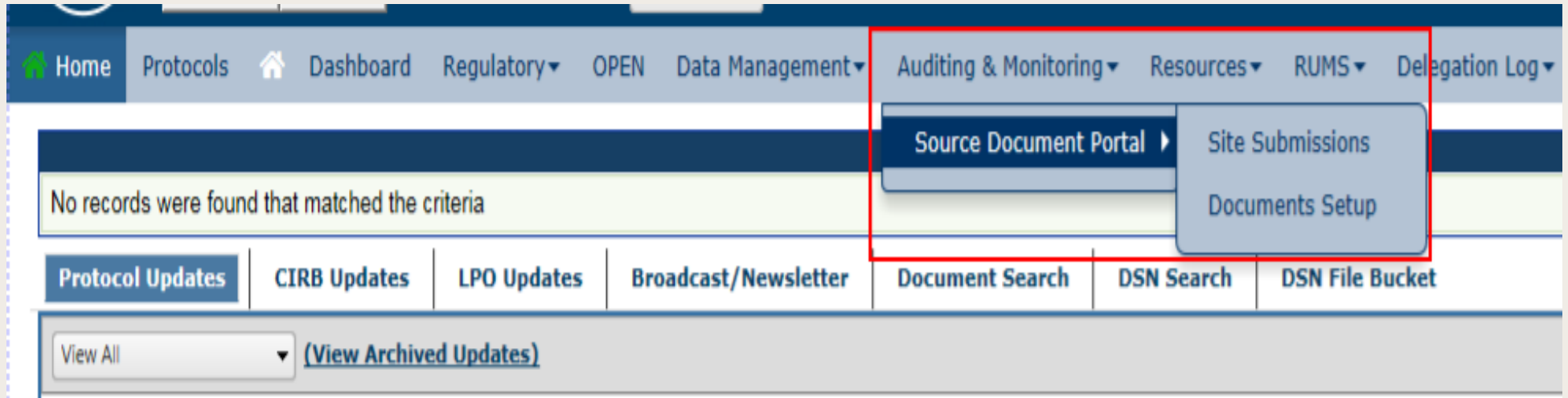
# SDP - Features

- Allows direct upload of source documents to facilitate CM activities
- Provides ability to redact Personally Identifiable Information (PII) electronically during the upload
- Is accessible via a deep-link (direct link) from Rave
- Keeps tabs on all CM activities for all protocols, regardless of the LPO
- Standard document upload process across LPOs

# SDP - Roles and Access

- Everyone with access to the CTSU website may view (read-only access) document submission information for sites with which they are associated
- The following Rave Electronic Data Capture (EDC) roles are allowed to upload and view uploaded documents:
  - Rave CRA
  - Rave Investigator
  - Rave CRA (LabAdmin)

# Navigating to SDP: Option 1 - CTSU Website



# Navigating to SDP: Option 2 - Rave

**[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 [Source Document Portal \(SDP\)](#)

? Action is required. Please complete the necessary data entry in Rave, and then upload the corresponding source documents on the Source Document Portal (SDP). After source documents are uploaded on the SDP, close this query by checking the checkbox and saving this form.  
Opened To Site from System (23 Jan 2018)



# CM Alert Form

- A trigger in Rave to indicate source document upload is required on the SDP
- 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)
- Includes two links to the SDP, and open query and instructions to upload source documents

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Opened To Site from System (23 Jan 2018)





# Using the SDP

- Identify study using SDP for CM:
  - Protocol specific webpages will indicate SDP use
- Process for CRAs:
  - Enter data in Rave
  - Upload source documents to SDP as PDFs, redact PII and save on the SDP
  - Track document submission summary on SDP
  - Review and respond to queries
    - On SDP, rejected documents by the LPO
    - In Rave, data queries issued by LPO monitor

# SDP Screen

- Lists all documents uploaded on the SDP, and can be filtered by LPO, Protocol, Site, or Patient
- Those with appropriate Rave roles may upload source documents
- Click on the Document History icon to view the date document uploaded, triaged by LPO user, who viewed the document, and date viewed

**Source Document Portal** Upload Document and Details

LPO:  Protocol:  Site:  Patient:

#	LPO	Protocol	Site	Patient	Document Type	Folder Name	Status	Updated By	Updated Date
1	ALLIANCE	A031501	IL057	9114173	Computed Tomography (CT) Report	Baseline	Triaged	Pandit, Suhela S.	04-Jun-2018
2	ALLIANCE	A031501	IL057	9114173	Imaging Technique Report	Baseline	Triaged	Pandit, Suhela S.	04-Jun-2018
3	ALLIANCE	A031501	IL057	9114173	Physician And/Or Health Care Provider Report Or Clinical Note	Baseline	Triaged	Pandit, Suhela S.	30-May-2018
4	ALLIANCE	A031501	IL057	9114173	Pathology Report	Baseline	Triaged	Pandit, Suhela S.	30-May-2018
5	ALLIANCE	A031501	IL057	9114173	Magnetic Resonance Imaging (MRI) Scan Report	Baseline	Triaged	Pandit, Suhela S.	30-May-2018
6	ALLIANCE	A031501	IL057	9114173	Laboratory Test Report	Baseline	Triaged	Pandit, Suhela S.	30-May-2018
7	ALLIANCE	A031501	IL057	9114173	Laboratory Test Report	Baseline	Uploaded	Pandit, Suhela S.	30-May-2018

# Site Submissions Screen

- Summary of document submission status
- Ability to filter by LPO, Protocol, Site, or Patient
- To upload document, click
  - ‘Upload Document and Details’ button at the top-right corner
  - # of document expected or # of missing document count to access the upload icon

Source Document Portal 168 ?

Auditing & Monitoring > Source Document Portal > Site Submissions Help Topics

### Site Submissions

Upload Document and Details

LPO: Select LPO Protocol: A031501 Site: IL057 Patient: All Patients Go

#	Site	Protocol	Patient	# of Documents Expected	# of Documents Uploaded	# of Missing Documents	# of Days Past Date of Data Entry in Rave
1	IL057	<a href="#">A031501</a>	<a href="#">9114175</a>	8	0	8	100*
2	IL057	<a href="#">A031501</a>	<a href="#">9114176</a>	8	0	8	100*
3	IL057	<a href="#">A031501</a>	<a href="#">9114177</a>	8	0	8	100*
4	IL057	<a href="#">A031501</a>	<a href="#">9114174</a>	11	1	10	100*
5	IL057	<a href="#">A031501</a>	<a href="#">9114173</a>	11	11	4	101*

\* Indicates that at least one document is overdue (Documents is expected to be uploaded within 14 days of data entry in Rave)

# Upload, Redact, & Save Document (I)

- On the 'Document Upload' screen, identifying information (Site, Protocol, Patient, Document Type and Visit Type) are pre-populated on the screen for expected documents
- Complete document identifying information, if not pre-populated
- Click 'Select Document' button to upload document
- Select 'Redact', click & drag cursor over PII to redact data

Site: IL057 Protocol: A031501 Patient: 9114174 Document Type: Clinical Evaluation Visit Type: Treatment 01: 05-

Select Document [How to upload and redact a document](#)

File Home View **Redact** 1 of 1

Physician Note

STUDY NAME: S1505

Patient Name: [REDACTED] Physical Exam Date: 05 / JUL / 2017  
Pt\_ID: 268222 d d m m m y y y y  
Date of Birth: [REDACTED]

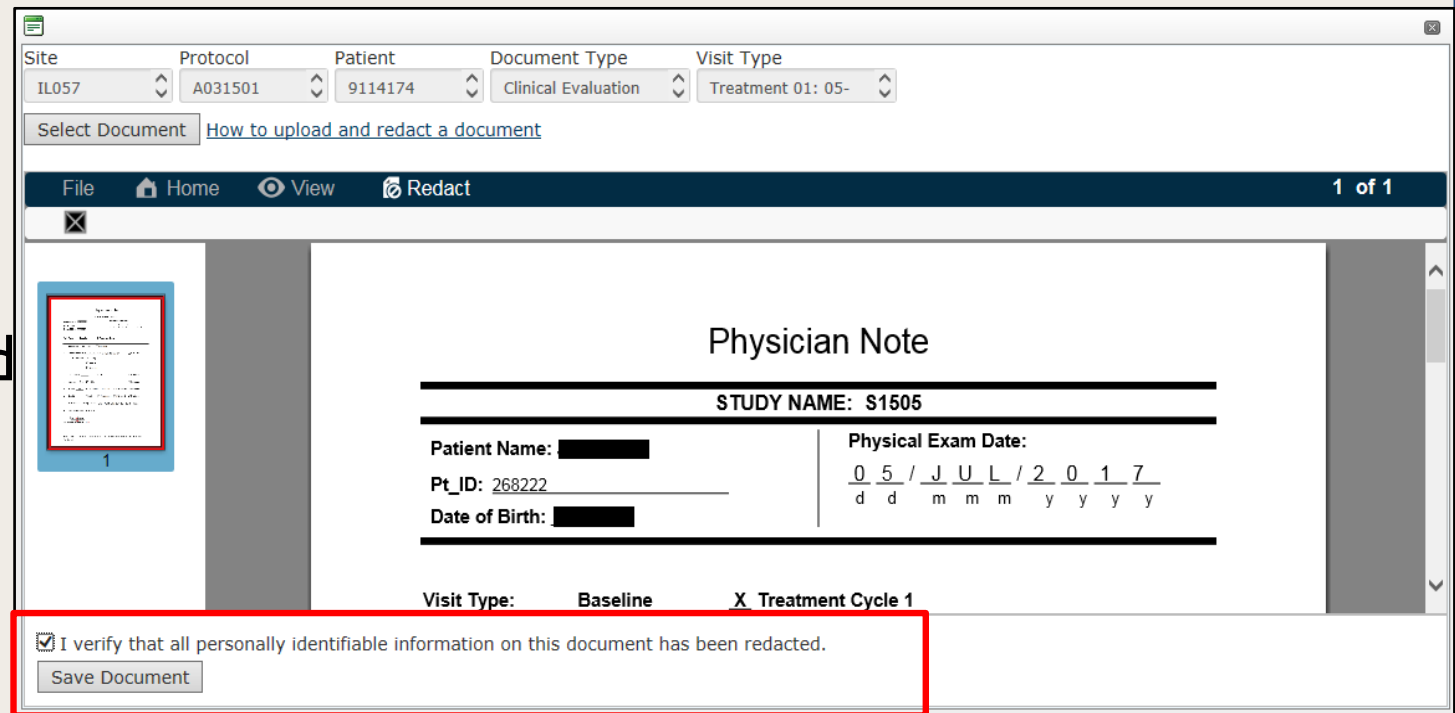
Visit Type:  Baseline  Treatment Cycle 1

I verify that all personally identifiable information on this document has been redacted.

Save Document

# Upload, Redact, & Save Document (2)

- Keyboard buttons CTRL + F brings up the search feature; use it to search for text within the uploaded document
- After document is reviewed and all PII redacted, save the document
- Check the checkbox at the bottom left of the 'Document Upload' screen to verify PII was redacted
- Click 'Save Document' to complete the upload; 'document saved successfully' message will appear.



The screenshot shows a web interface for document management. At the top, there are dropdown menus for Site (IL057), Protocol (A031501), Patient (9114174), Document Type (Clinical Evaluation), and Visit Type (Treatment 01: 05-). Below these is a 'Select Document' button and a link 'How to upload and redact a document'. A dark blue navigation bar contains 'File', 'Home', 'View', and 'Redact' icons, with '1 of 1' on the right. The main content area displays a document titled 'Physician Note' with a redaction tool overlay. The document text includes 'STUDY NAME: S1505', 'Patient Name: [REDACTED]', 'Pt\_ID: 268222', 'Date of Birth: [REDACTED]', and 'Physical Exam Date: 05 / JUL / 2017'. At the bottom, there is a checkbox labeled 'I verify that all personally identifiable information on this document has been redacted.' which is checked, and a 'Save Document' button.

# Training

- The 'Help Topics' button on SDP screens contains links to context sensitive help on every screen
- CM updates are announced in the CTSU Bi-Monthly Broadcast and CTSU Newsletter
- Slides and a recording of the training webinar are available on the CTSU website under Resources > Educational Multimedia > Webinars



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# **DELEGATION OF TASKS (DTL) LOG UPDATES**

# Recent Updates (I)

- Updates to the Help Topics and FAQs
- When cloning a DTL, only tasks in Active or Awaiting CI Approval status will be copied
- Alert message will display if task is removed that will cause the DTL to change status to Unapproved
- New DTL Summary Report - An Excel spreadsheet available for sites to easily view all DTL assignments and status
- New 'DTLs Awaiting CI Approval' portlet lists DTLs requiring a CI's signature



# Recent Updates (2)

- DTL Administrators (DTLAs) can revert Site DTLs that are *Awaiting Clinical Investigator (CI) Approval* back to an *Initiated* status
- *Initiated Delegation of Tasks Logs (DTLs)* can be deleted by the site
- **DTL Audit History**
  - Updated messages and date filter
  - Added audit history for individual task assignments
- **Revised IRB warning message**
  - No IRB on file vs. discrepancy with the IRB# on file

# Recent Updates (3)

- DTL for Canadian Sites
  - Integrated with CCTG's Roster Interface Program and Participants List Environment (RIPPLE) application
  - Canadian sites will use RIPPLE when CCTG is a study participant and holds the Clinical Trials Application (CTA)
  - All DTL information for Canadian sites will be viewable through the CTSU's DTL application



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# **SERIOUS ADVERSE EVENT (SAE) INTEGRATION**

# Rave Reminders

- AE data should be entered in Rave and sent for Rules Evaluation (RE) at the time the AE is known/reported
- If the recommendation is to report, then click the direct link in Rave to access CTEP-AERS to complete expedited reporting
  - A warning will appear when first logging into CTEP-AERS if the user did not use the direct link from Rave to access CTEP-AERS
- 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 may result in reconciliation issues as data in CTEP-AERS cannot synchronize with Rave once the expedited report has been submitted to NCI
- If entering a verbatim term, do not use any special characters (such as &)

# Site Notifications (Late RE Call)

- Anytime a modification is made to the AE form (insert, modify, delete) a query will be opened on the Expedited Reporting Evaluation form (*Send all AEs to rules evaluation*)
- If the query on the Expedited Reporting Evaluation form remains open for longer than 24 hours, an email notification is sent to the person who last modified the AE form
- The email notification states that the AEs were automatically sent to rules evaluation by the system and asks the recipient to check the recommendation on the Expedited Reporting Evaluation form

# Site Notifications (Late Report Initialization)

- Anytime a recommendation to CREATE a report is generated and displayed on the Expedited Reporting Evaluation form, the user must initialize the report in CTEP-AERS in a timely manner
  - If the Investigator feels the recommendation is not warranted per the Protocol, override the recommendation by updating CREATE to NONE in Rave and do not initialize the report in CTEP-AERS
- If the report is not initialized, and the Investigator has not overridden the recommendation, an email notification is sent to the person who last modified the AE form
- The email notification states that there is a recommendation to report but no expedited report has been initialized in CTEP-AERS



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# **NEW WEBSITE TOOLS & GENERAL REMINDERS**

# Home Tab

- The CTSU Twitter feed has been added

The screenshot shows the CTSU website home page. At the top, there are navigation tabs: Home, Protocols, Dashboard, Regulatory, OPEN, Data Management, Auditing & Monitoring, RUMS, Delegation Log, Resources, and Collaboration. Below this is a 'News and Announcements' section with a sub-section for 'Disease Portfolio Tab'. A table of updates is displayed, with columns for '#', 'Date', 'Protocol', and 'Update'. A new 'Tweets by @TheCTSU' section is highlighted with a red box, showing a tweet about ARST1431 being temporarily closed to accrual effective 8/22/18. The table data is as follows:

#	Date	Protocol	Update
1	28-Aug-2018	9984	Action Letter for Olaparib (AZD2281)
2	28-Aug-2018	9984	Amendment #6
3	28-Aug-2018	10020	Action Letter for Olaparib (AZD2281)
4	28-Aug-2018	10020	Amendment #9
5	28-Aug-2018	EAQ152	Memorandum: Addendum #6 (Version Date: 06/18/18) Activation
6	28-Aug-2018	EAQ152	Memorandum: Protocol Notice: EAQ152 (COMET) Addendum #6 Activation
7	28-Aug-2018	10031	Action Letter for Olaparib (AZD2281)
8	28-Aug-2018	10031	Amendment #8
9	28-Aug-2018	ARST1431	Memorandum: Patient/Family Letter
10	28-Aug-2018	ARST1431	Memorandum: Results from EpSSG RMS 2005 and ARST0531 and Implications for ARST1431
11	28-Aug-2018	9881	Action Letter for Olaparib (AZD2281)
12	28-Aug-2018	9881	Amendment #9
13	27-Aug-2018	NRG-BR002	Memorandum: Amendment #4 and Amendment #5
14	27-Aug-2018	NRG-BN003	Memorandum: Amendment #1
15	27-Aug-2018	A041202	Memorandum: Data Cleaning
16	27-Aug-2018	10132	Memorandum: 10132 - Notice of Requirement of Site Initiation Visit Conference Call
17	27-Aug-2018	A051301	A051301 Temporary Suspension
18	24-Aug-2018	10010	Memorandum: Teleconference Minutes - 06/26/18
19	24-Aug-2018	10030	10030 Investigator Teleconference Minutes- 08/24/18
20	24-Aug-2018	10021	Memorandum: Colorectal Cancer Cohort Permanent Closure
21	24-Aug-2018	10106	Memorandum: Site Initiation Visit - Protocol Specific Requirement
22	23-Aug-2018	S1609	S1609 - Memorandum: Reactivation of Cohort 16
23	23-Aug-2018	10150	Memorandum: Notice of Requirement of Site Initiation Visit Conference Call
24	23-Aug-2018	NSABP-B-55	Memorandum: NSABP-B-55 WebEx Reminder - Registration Deadline
25	23-Aug-2018	ARST1431	Memorandum: Temporary Closure

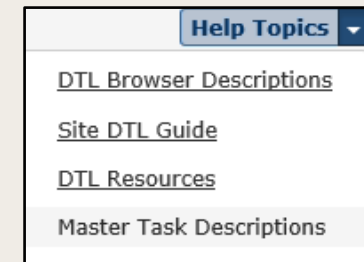
The screenshot shows a Twitter feed titled 'Tweets by @TheCTSU'. The first tweet is from @TheCTSU: 'ARST1431 is temporarily closed to accrual effective 8/22/18. View the full memorandum in Protocol Updates on the CTSU members' homepage at [ctsu.org](https://ctsu.org) (log in required)'. The second tweet is also from @TheCTSU: 'The CTSU website release 6.9.2 on 8/21/2018 includes Source Document Portal (SDP) updates/enhancements. A list of all the updates/enhancements are in the 8/22 @theCTSU Bi-Monthly Broadcast. Please visit [ctsu.org](https://ctsu.org), log in and click on the Broadcast/Newsletter tab.' Below these are retweets from 'Cancer Trials Support Unit Retweeted' and 'NCI CTEP Clinical Research'. The ETCTN logo is visible at the bottom of the feed.

- The Quick Links tab has been removed



# Help Topics Button


- Currently on DTL, RUMS, and the SDP Tabs
  - Select drop downs to navigate topics
  - Click button to open entire help page, sections expand and collapse





- Will eventually replace help icons on all webpages

**The Delegation of Tasks Log (DTL)  
Site DTL Browser Help Page**

The Site DTL Browser Help Page contains information and links to various resources and educational documents. The links under the DTL Browser Descriptions and the Site DTL Guide section will expand or collapse help text located underneath each section. The links under DTL Resources will open new webpages containing these resources. If you need assistance beyond the scope of this page, please contact the CTSU Help Desk.

**DTL Browser Descriptions** 

**Site DTL Guide** 

**DTL Resources** 

[DTL Fact Sheet](#)

[DTL Webinar Recording](#)

[DTL Slide Set](#)

[DTL Frequently Asked Questions](#)

[DTL Master Task List](#)

**Master Task Descriptions**

# Helpful New Tools (I)

- Translated Short Form Consents

#	Title
1	CIRB Approval of English and Translated Short Form Consents ★
2	Arabic - Short Form Consent ★
3	Arabic - Certificate of Accuracy ★
4	Arabic - CIRB Approval Worksheet ★
5	Creole (Haitian) - Short Form Consent ★
6	Creole (Haitian) - Certificate of Accuracy ★
7	Creole (Haitian) - CIRB Approval Worksheet ★
8	English - Short Form Consent, FOR REFERENCE ONLY ★
9	French - Short Form Consent ★
10	French - Certificate of Accuracy ★
11	French - CIRB Approval Worksheet ★
12	German - Short Form Consent ★
13	German - Certificate of Accuracy ★
14	German - CIRB Approval Worksheet ★
15	Italian - Short Form Consent ★
16	Italian - Certificate of Accuracy ★
17	Italian - CIRB Approval Worksheet ★
18	Korean - Short Form Consent ★
19	Korean - Certificate of Accuracy ★
20	Korean - CIRB Approval Worksheet ★
21	Portuguese Brazil - Short Form Consent ★
22	Portuguese Brazil - Certificate of Accuracy ★
23	Portuguese Brazil - CIRB Approval Worksheet ★
24	Russian - Short Form Consent ★
25	Russian - Certificate of Accuracy ★
26	Russian - CIRB Approval Worksheet ★
27	Spanish - Short Form Consent ★
28	Spanish - Certificate of Accuracy ★

# Helpful New Tools (2)

- Disease Portfolios

Data Management ▾ Auditing & Monitoring ▾ RUMS ▾ Delegation Log ▾ Resources ▾ Collaboration	
Disease Portfolios	
#	Title
<b>NCTN</b>	
1	<a href="#">Brain Cancer Trials Portfolio</a> ★
2	<a href="#">Breast Cancer Trials Portfolio</a> ★
3	<a href="#">Gastrointestinal Cancer Trials Portfolio</a> ★
4	<a href="#">Genitourinary Cancer Trials Portfolio</a> ★
5	<a href="#">Gynecologic Cancer Trials Portfolio</a> ★
6	<a href="#">Head and Neck Cancer Trials Portfolio</a> ★
7	<a href="#">Leukemia Cancer Trials Portfolio</a> ★
8	<a href="#">Lung Cancer Trials Portfolio</a> ★
9	<a href="#">Lymphoma Cancer Trials Portfolio</a> ★
10	<a href="#">Skin (Mainly Melanoma) Cancer Trials Portfolio</a> ★
11	<a href="#">Adolescent and Young Adult (AYA) Cancer Trials Portfolio</a> ★
<b>ETCTN</b>	
1	<a href="#">Brain Cancer Trials Portfolio</a> ★
2	<a href="#">Breast Cancer Trials Portfolio</a> ★
3	<a href="#">Gastrointestinal Cancer Trials Portfolio</a> ★
4	<a href="#">Genitourinary Cancer Trials Portfolio</a> ★
5	<a href="#">Gynecologic Cancer Trials Portfolio</a> ★
6	<a href="#">Head and Neck Cancer Trials Portfolio</a> ★
7	<a href="#">Leukemia Cancer Trials Portfolio</a> ★
8	<a href="#">Lung Cancer Trials Portfolio</a> ★
9	<a href="#">Lymphoma Cancer Trials Portfolio</a> ★
10	<a href="#">Myeloma Cancer Trials Portfolio</a> ★
11	<a href="#">Radiation Cancer Trials Portfolio</a> ★
12	<a href="#">Sarcoma Cancer Trials Portfolio</a> ★
13	<a href="#">Skin and Other Melanoma Cancer Trials Portfolio</a> ★
14	<a href="#">Solid Tumors Cancer Trials Portfolio</a> ★
15	<a href="#">Solid Tumors Expansion Studies Cancer Trials Portfolio</a> ★

# Summary of Business Rules for Site-Protocol PIs

- The Site-Protocol PI must have an active CTEP registration status.
  - An End Date will be added to the PI record on the IRB approval if the PI becomes suspended or relocated. **new**
  - End dates are set on the PI record on the IRB approval for other non-active CTEP statuses (withdrawn, deceased, disqualified and inactive).
- The IRB number on the IRB approval must match an IRB number for the Site-Protocol PI in RCR.
- The Site-Protocol PI must be rostered on a participating roster at the site and by extension have the site listed in their RCR profile. **new**
- The Site-Protocol PI must be on the CIRB Signatory roster for CIRB approvals (US sites only).
- The Site-Protocol PI must have the appropriate registration type and task access at the person and protocol level.

*New checks will be implemented on November 15th*

# IROC Integration (I)

- What is it?
  - Integrations between IROC, CTSU, and CTEP system to improve roster management of radiation/imaging (RT/I) providers, improve TRIAD access, and exchange RT/I credentialing data.
- Components
  - IROC Provider Roster
  - Provider Association Tab
  - Credentialing Data Exchange
  - Capture of subject specific providers in OPEN

# IROC Integration (2)

- Pilot starts November 1
  - EAI142, EAI151, and NRG-GY017
- New protocols with RT/I component slated for late 2018
- Reminder – make sure your site is aligned to your RT/I provider(s) via the Provider Association sub-tab on the CTSU website.

Passwords are like your pants



- DO change them regularly
- DON'T leave them on your desk
- DON'T share them with anyone

[www.bluespotcomputers.com](http://www.bluespotcomputers.com)

**REMINDER:**

**Please do not share your CTEP IAM password**

# ?? Questions ??

