CTSU 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

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)
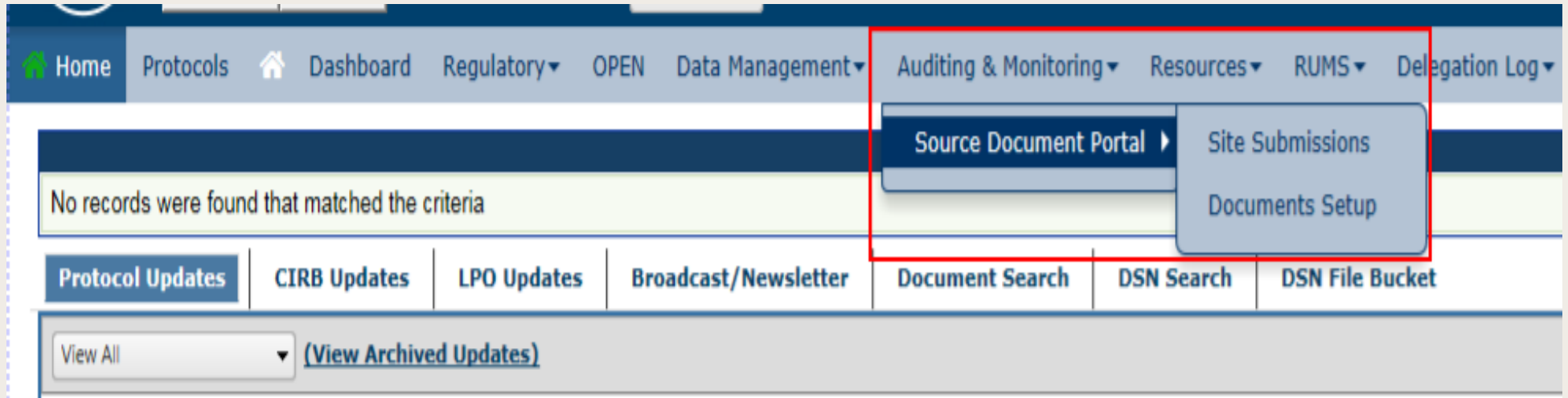
SDP - Features

- 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

| 🏠 Home | Protocols | 🏠 Dashboard | Regulatory ▾ | OPEN | Data Management ▾ | Auditing & Monitoring ▾ | Resources ▾ | RUMS ▾ | Delegation Log ▾ |

Source Document Portal ▶ | Site Submissions

Documents Setup

No records were found that matched the criteria

| **Protocol Updates** | **CIRB Updates** | **LPO Updates** | **Broadcast/Newsletter** | **Document Search** | **DSN Search** | **DSN File Bucket** |

View All ▾ (View Archived Updates)

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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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: ALLIANCE × ▾   Protocol: A031501 × ▾   Site: IL057 × ▾   Patient: 9114173 × ▾   Go

#	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

Upload, Redact, & Save Document (1)

- 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
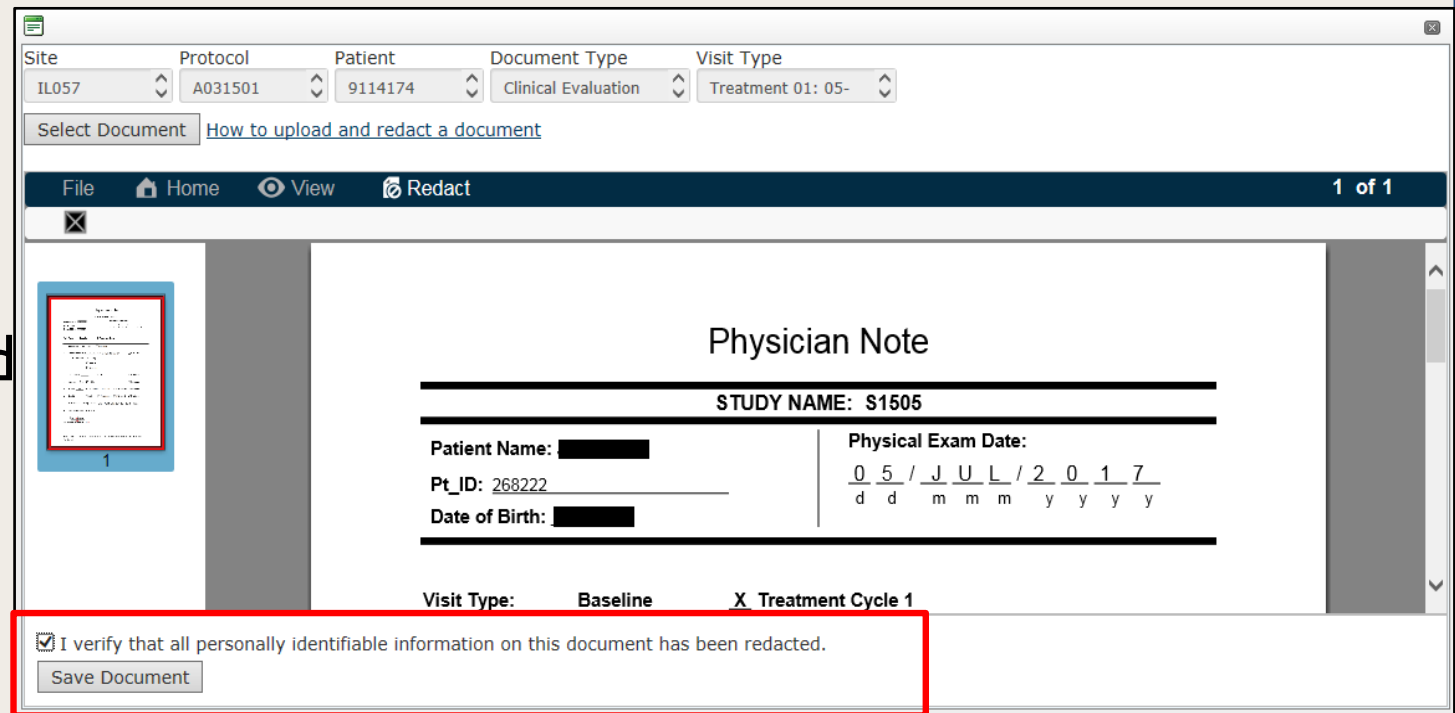
Upload, Redact, & Save Document (2)

- 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.

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

DELEGATION OF TASKS (DTL) LOG UPDATES

Recent Updates (1)

- 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

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, <u>not</u> 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

NEW WEBSITE TOOLS & GENERAL REMINDERS

Home Tab

- ## The CTSU Twitter feed has been added

- ## 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
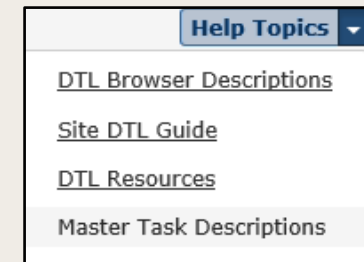
- Will eventually replace help icons on all webpages

Helpful New Tools (1)

- Translated Short Form Consents

Data Management ▾	Auditing & Monitoring ▾	RUMS ▾	Delegation Log ▾	Resources ▾	Collaboration

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
NCTN	
1	Brain Cancer Trials Portfolio
2	Breast Cancer Trials Portfolio
3	Gastrointestinal Cancer Trials Portfolio
4	Genitourinary Cancer Trials Portfolio
5	Gynecologic Cancer Trials Portfolio
6	Head and Neck Cancer Trials Portfolio
7	Leukemia Cancer Trials Portfolio
8	Lung Cancer Trials Portfolio
9	Lymphoma Cancer Trials Portfolio
10	Skin (Mainly Melanoma) Cancer Trials Portfolio
11	Adolescent and Young Adult (AYA) Cancer Trials Portfolio
ETCTN	
1	Brain Cancer Trials Portfolio
2	Breast Cancer Trials Portfolio
3	Gastrointestinal Cancer Trials Portfolio
4	Genitourinary Cancer Trials Portfolio
5	Gynecologic Cancer Trials Portfolio
6	Head and Neck Cancer Trials Portfolio
7	Leukemia Cancer Trials Portfolio
8	Lung Cancer Trials Portfolio
9	Lymphoma Cancer Trials Portfolio
10	Myeloma Cancer Trials Portfolio
11	Radiation Cancer Trials Portfolio
12	Sarcoma Cancer Trials Portfolio
13	Skin and Other Melanoma Cancer Trials Portfolio
14	Solid Tumors Cancer Trials Portfolio
15	Solid Tumors Expansion Studies Cancer Trials Portfolio

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 implements on November 15th

IROC Integration (1)

- ## 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.

REMINDER:
Please do not share your CTEP IAM password

?? Questions ??