



CTSU Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE
Linking practice to progress

**THE CENTRAL MONITORING
PORTAL AND CTSU
WEBSITE UPDATES**

OISHI SYMPOSIUM

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Agenda

- Central Monitoring Portal (CM): Using the Source Document Portal (SDP)
- Website Updates

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

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Introduction

- What is Central Monitoring (CM)?
 - Performed by Lead Protocol Organizations (LPOs) to ensure protocol compliance by sites
 - Remote review of source documents against data entered in Rave
- What is the Source Document Portal (SDP)?
 - An application on the CTSU website in the Auditing & Monitoring tab used to support the collection of source documents for CM review
 - The SDP was previously named the Central Monitoring Portal (CMP)

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Source Document Portal 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

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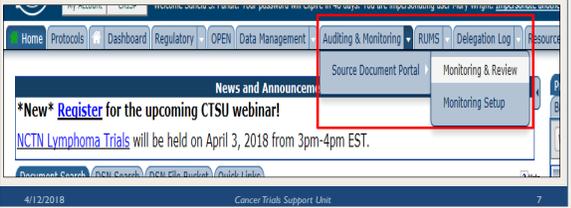
SDP- Roles and Access

- Everyone with access to the CTSU website may view 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
 - Site Investigator (changing to Rave Investigator in early May)
 - CRA (LabAdmin) (changing to Rave CRA (LabAdmin) in early May)

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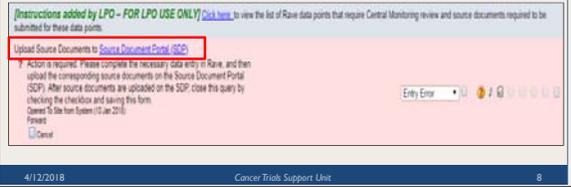
Navigating to SDP: Option 1 - CTSU Website

- Log in to the CTSU members' website
- Click on the 'Auditing & Monitoring' tab drop-down
- Click on 'Monitoring & Review' to access the Site Submissions screen to track and upload



Navigating to SDP: Option 2 - Rave

- Log in to Rave EDC
- Select Study, Site, Subject, as needed
- Click on the subject visit/folder to access forms located inside
- Click on the 'Central Monitoring Alert' Form to open
- Click on the 'Source Document Portal (SDP)' link on the form to access SDP on the CTSU website



Central Monitoring 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, an open query and instructions to upload source documents



Using the SDP

- Identify study using SDP for CM: In May 2018 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 LPO
 - In Rave, data queries issued by LPO monitor

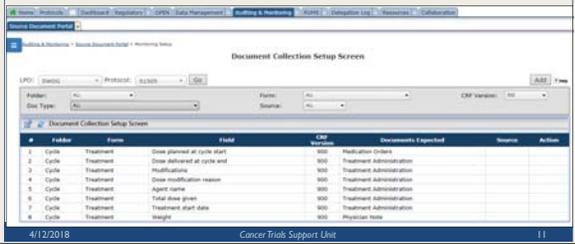
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Document Collection Setup Screen

- Sites have Read-Only access to view documents that are expected to be uploaded on the SDP for each study (as determined by the LPO leading the study)
- Information may be filtered by LPO or Protocol



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Source Document Portal Screen

- Lists all documents uploaded on the SDP
- Those with appropriate Rave roles may upload source documents
- May filter by LPO, Protocol, Site, or Patient



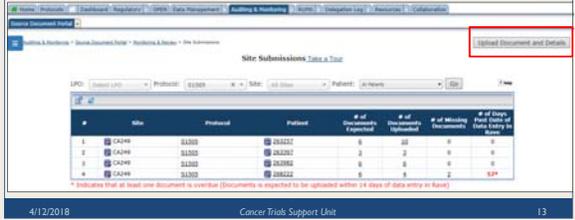
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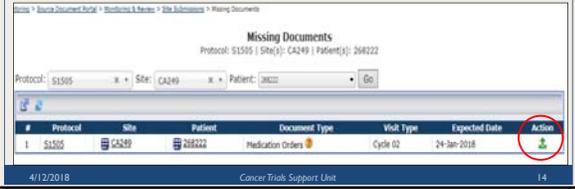
Site Submissions Screen

- 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 missing document count to access the upload icon



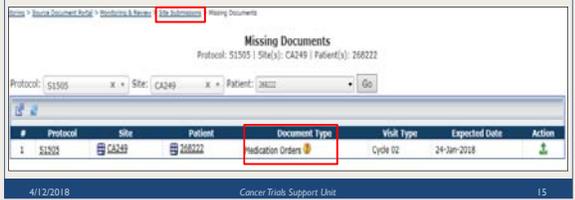
Missing Document Screen (1)

- Ability to filter by Protocol, Site, or Patient
- Displays all expected documents and details for the patient – Protocol, Site, Patient, Document Type, Visit Type, Expected Date
- Click on the green icon in the Action column to upload document



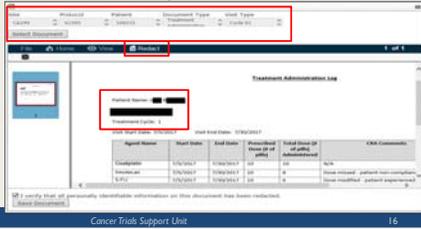
Missing Document Screen (2)

- Click on the query icon to view details of document rejected by the LPO (i.e., document will be rejected if LPO identifies PII)
- Click on Site Submissions link at the top to return to the Site Submissions screen



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



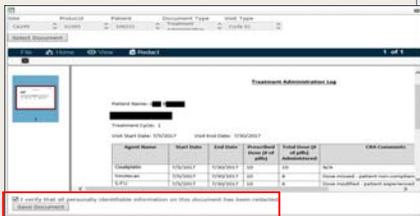
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Upload, Redact & Save Document (2)

- 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 and the document saved successfully message will appear



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Reminders!

- Use the link in Rave to access SDP and vice-versa
- Documents uploaded must be in PDF and for a single patient and visit
- Redact all PII from source document and add Patient Study ID before saving on the SDP
- Submitting the documents via the SDP is not the end of the CM process
 - Submitted documents may be rejected, if not legible or PII was not redacted
 - corrected documents need to be re-upload on the SDP
- Monitor the SDP and the Delinquency Notification email sent to the Primary Site Contacts

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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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WEBSITE UPDATES

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Protocols > Documents tab (I)

- Redesigned in December 2017 to support uniform document postings for CIRB studies
 - CTSU is only website to host CIRB reviewed documents; LPOs provide links to CTSU
 - Protocol and Consents are always at top of page
 - CIRB section houses all CIRB reviewed materials: amendments, patient materials, consent translations and certificates, reviews, action letters, etc.
 - Supplemental section contains LPO communication
 - Full details of contents: Resources > CTSU Ops Info > Education and Reference > Uniform Document Posting
- Additional design changes being considered in conjunction with CTSU Site Advisory Panel and NCI

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New Dashboard Portlet

- DTL's Awaiting CI Approval
 - Default portlet in protocol profile
 - Lists all DTL's at associated sites waiting for Clinical Investigators signature

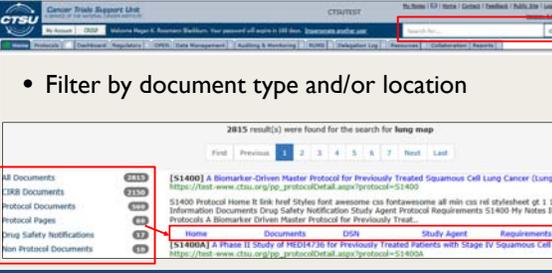


Action column will navigate to DTL

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New Search Results

- Enhanced search results using search bar
- Filter by document type and/or location



2815 result(s) were found for the search for lung map

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?? Questions ??



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