





#### 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)

#### 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

# 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

#### Navigating to SDP: Option I - 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

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	Source Document Portal	Monitoring & Review	
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*New* <u>Register</u> for the upcoming CTSU webinar!		Monitoring Setup	Р B
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### 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
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# 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

#### **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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# Site Submissions Screen

- Summary of document submission statusAbility 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

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		attes that at least one	e document is overdue (Docum	ents is expected to be upto	aded within 14 days	of data entry	in Rawe)	



# 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

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# 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

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#### Upload, Redact & Save Document (1)

- On the Document Upload screen, identifying information (Site, Protocol, Patient, Document Type, and Visit Type) are prepopulated 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



- 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



#### **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  $\ensuremath{\mathsf{SDP}}$
- Monitor the SDP and the Delinquency Notification email sent to the Primary Site Contacts

## 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



# Protocols > Documents tab (1)

- 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

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