SWOG SDMC Update

Statistics and Data Management Center

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SDMC Update

General SDMC Updates — **Rodney Sutter**

Central Monitoring — **Jourdain Hayward**

S1919: *Phase II, Multi-Arm, **R**andomized **U**mbrella **S**tudy to Evaluate the **T**herapeutic Efficacy and Safety of **I**mmune-Oncology Drug **C**ombinations in Metastatic Breast Cancer **(RUSTIC)***

Study Trial Design & Statistical Issues	**Bill Barlow**
Logistical Details, Access, Registration, etc.	**Jacqueline Scurlock**
Rave Instance Differences	**Katie Minichiello**

CDASH Training for CRAs — **Dani Weatherbee**

CRA Newsletter

- First edition published in September!
- Quarterly, posted to the CRA Workbench

- Newsletter Introduction
- Group Meeting Information
- NCORP Workshop
- Best Practices
- Updated ORP Manual
- Consent Withdrawal
- Active/Accruing Studies
- Disease Committee Members

- Feel free to submit suggestions! CRAnewsletter@crab.org

Mentoring Workshops

- Four Hour Workshop Addressing the Following Topics:
  - Clinical: Practice, Research and Trials
  - SWOG Protocol Implementation Process
  - Reports and Tools to Support Data Quality
  - Data Coordinator Review at the SDMC
  - Statistical Considerations for Clinical Trials
  - Central Monitoring for Registration Trials
  - Regulatory and SAE Reporting
  - CRA Tools: CTSU, Patient Transfers, CRA WB, Source Docs
  - Site Readiness for FDA Inspection
- Open Forum Table: How to qualify, how to request

Study-Specific Meetings

- **S1316** Protocol Meeting: ***Thursday, 10/03 at 2:30***
  - Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction, activated 03/09/2015
- **S1803** Kick-Off Meeting: ***Thursday, 10/03 at 5:00***
  - Phase III Myeloma Trial, 1000+ patients, activated 06/27/2019
- **S1919** Training session: ***Friday, 10/04 at 8:00***
  - Phase II Umbrella Breast Trial (RUSTIC). Target date for activation: Early, 2020
- **S1820** Kick-Off Meeting: ***Friday, 10/04 at 9:30***
  - A Randomized Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors Compared to a Healthy Living Education Control. Target date for activation: Fall, 2019

SWOG Reports – CRA WB

Reports

Please select the reports you wish to display:

Site Management Reports

Expectation and IPR Reports

Query Reports

Ineligible Patients Report

SWOG Patients in Follow-up

Accrual Reports

SWOG-credited Registrations – site-specific, patient listing

SWOG-credited Registrations by Race and Sex - summary

SWOG Disease Committee Accrual Reports

Study Management

Serious Adverse Events (SAE) for a Given Study

List of Studies with NO Required Follow-Up

List of studies for S9808 - Long Term Follow-Up Protocol

Study-wide Unblinding Report

S0820 (PACES) Potential Patients

SWOG Facilities

Approved SWOG Bone Marrow Transplant Facilities

Approved SWOG Radiation Therapy Facilities

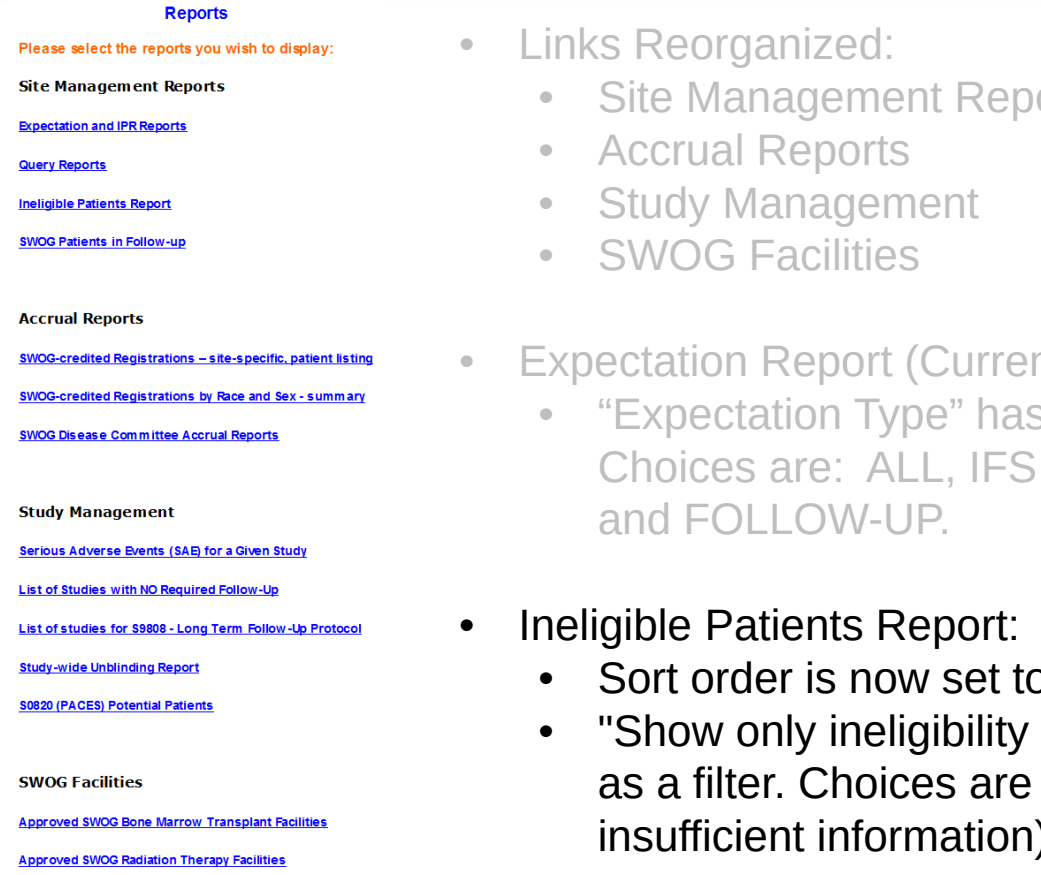
- Links Reorganized:
  - Site Management Reports
  - Accrual Reports
  - Study Management
  - SWOG Facilities

SWOG Reports – CRA WB

- Links Reorganized:
  - Site Management Reports
  - Accrual Reports
  - Study Management
  - SWOG Facilities

- Expectation Report (Current):
  - “Expectation Type” has been added as a filter in the dropdown. Choices are: ALL, IFS (Initial Forms Set), FORM, SPECIMEN and FOLLOW-UP.

SWOG Reports – CRA WB



- Links Reorganized:
  - Site Management Reports
  - Accrual Reports
  - Study Management
  - SWOG Facilities

- Expectation Report (Current):
  - “Expectation Type” has been added as a filter in the dropdown. Choices are: ALL, IFS (Initial Forms Set), FORM, SPECIMEN and FOLLOW-UP.

- Ineligible Patients Report:
  - Sort order is now set to “Note Date” (descending) by default
  - "Show only ineligibility code" has been added in the dropdown as a filter. Choices are All, N (Ineligible), NI (Ineligible, insufficient information) and NR (Ineligible, reversible).

ORP GM Travel – 2019

- Continued travel opportunities!
  - We were able to provide travel for up to 10 ORP members for both meetings in 2019
  - We had 14 applicants for Spring and 70 for Fall
  - Watch for CRA Newsletter announcements for the Spring meeting

THE HOPE FOUNDATION FOR CANCER RESEARCH

Please Welcome,

Jourdain Hayward

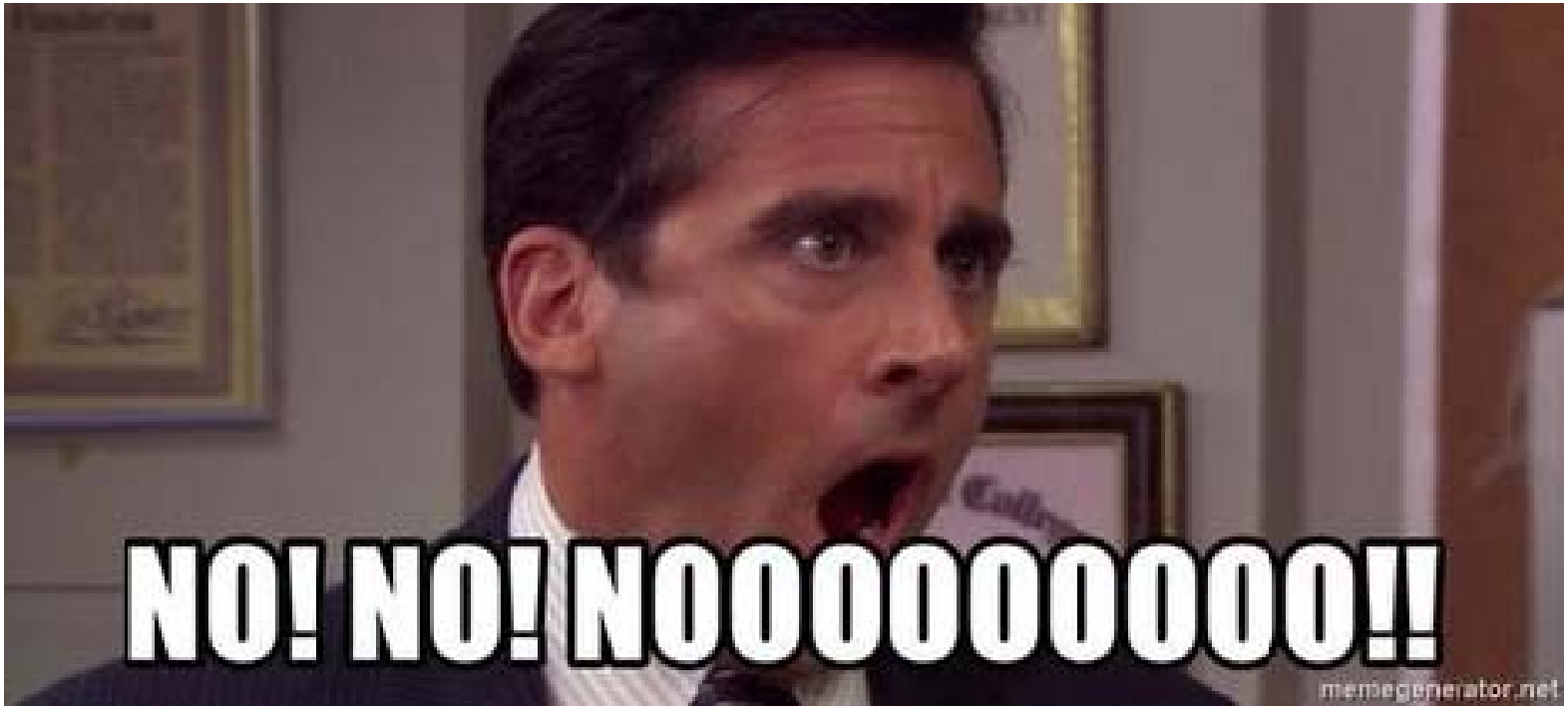
Central Monitor

SWOG Central Monitoring

SWOG Central Monitoring

Risk-based Monitoring at the Statistics and Data Management Center (SDMC)

You may be feeling like this after hearing from us…



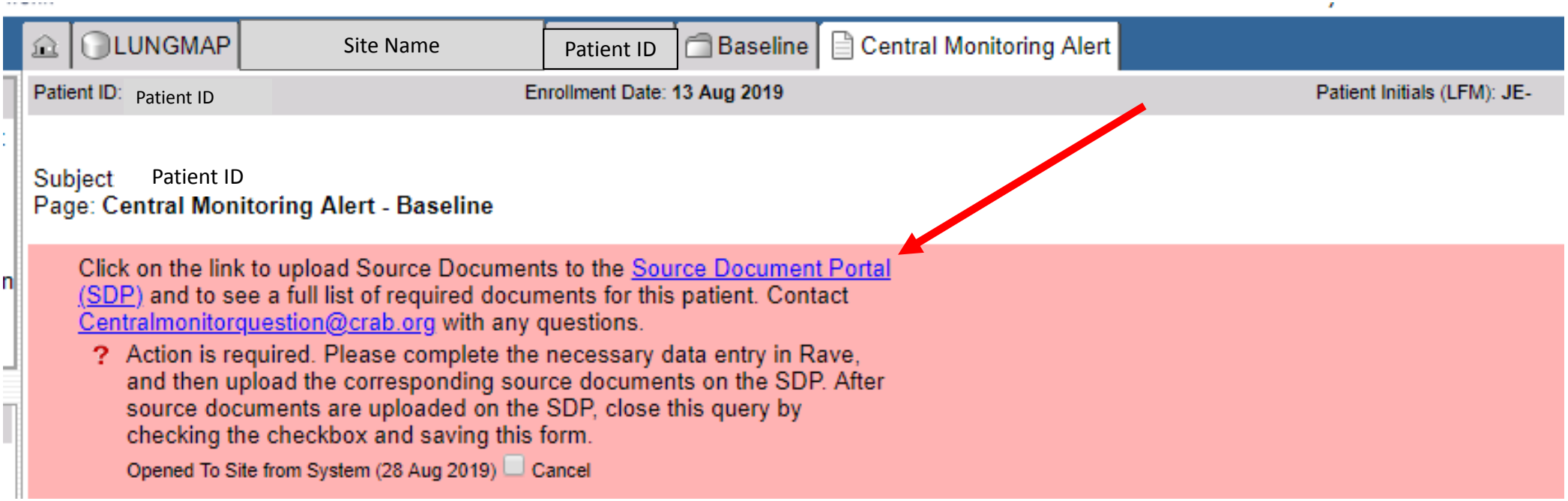
Why?

- Data Quality
- In following the FDA's guidance for industry[1] as a means to verify:
  - Rights and well-being of human subjects are protected
  - Reported trial data are accurate, complete, and verifiable from source documents.
  - The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).
- With the increased probability of an FDA inspection, SWOG's Registration Trials present a need for additional monitoring outside what is already in place.

Remote Data Verification Will Utilize the Following:

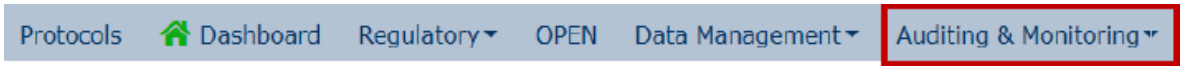
- Source documents uploaded to RAVE per your SWOG protocol.
- Source documents uploaded to CTSU in the Source Document Portal (SDP) per your SWOG protocol.
- SWOG monitors will compare data reported to the eCRF against the source documents to ensure data accuracy and integrity.

SDP Access via Medidata RAVE:

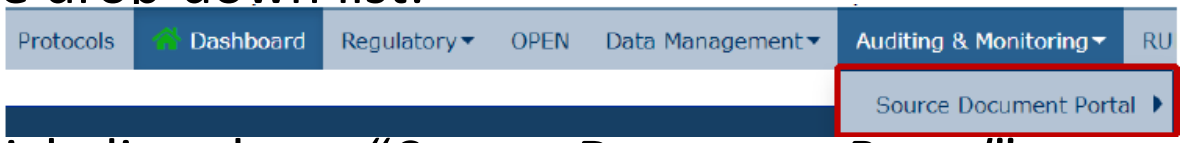


SDP Access via CTSU website:

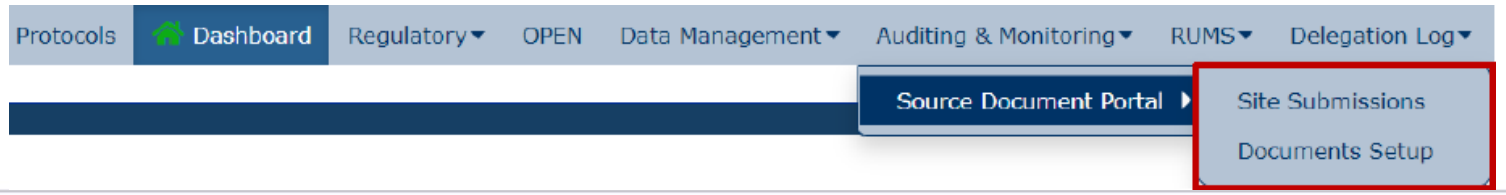
1. Log on to CTSU using your CTEP-IAM account information
2. There will be a tab across the top called "*Auditing & Monitoring*"



3. Hover over this tab and you will be able to see "*Source Document Portal*" in the drop-down list:



4. You can click directly on "*Source Document Portal*" or you can navigate further to be able to go to the Site Submissions landing page:



Primary Method

#	Site	Protocol	Patient	# of Documents Expected	# of Documents Uploaded	# of Missing Documents	# of Days Past Date of Data Entry in Rave
1	NCI Code	LUNGMAP	123456	2	0	2	51*

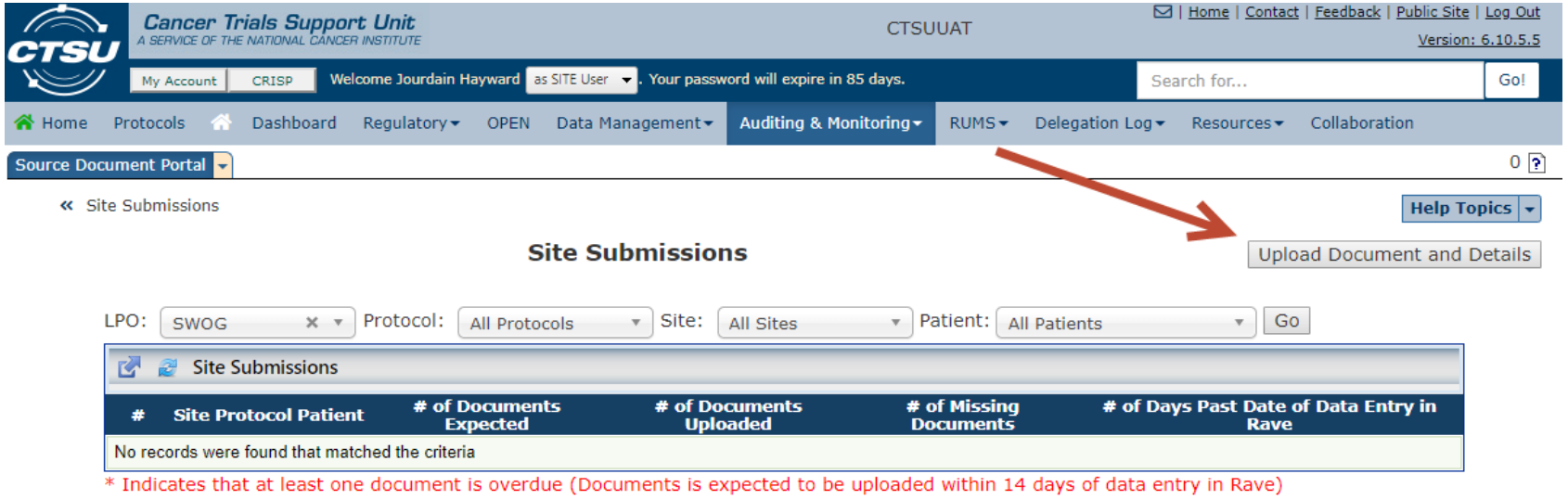
* Indicates that at least one document is overdue (Documents is expected to be uploaded within 14 days of data entry in Rave)

Protocol: LUNGMAP Site: CA087 Patient: 123456 Go

#	Protocol	Site	Patient	Document Types	Visit Type	Expected Date	Action
1	LUNGMAP	NCI Code	123456	History & Physical	Enrollment Forms	10-May-2019	
2	LUNGMAP	NCI Code	123456	Informed Consent	Enrollment Forms	10-May-2019	

Secondary Method

- For uploading additional documents not initially listed or to supplement what you've already uploaded (i.e. additional source documents requested by study monitor).



Tips for Successful Document Uploads in the SDP

- Ensure PHI are thoroughly redacted.
- Review your SWOG protocol (typically section 18)
- Review the email notification distributed to your site's Head CRA that provides details and instructions for the review process.
- Review reference documents provided by SWOG:
  - *Best Practices for SWOG Studies* (updated July 2019)
  - *CTSU Source Document Portal User Guide* (SWOG-created)
- Contact the SWOG monitoring team with questions: centralmonitorquestion@crab.org

References/Citations

- 1: E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1). March, 2018.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