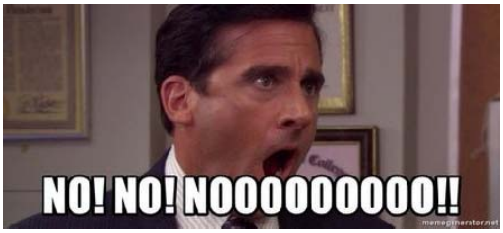
SWOG Central Monitoring

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

You may be feeling like this after hearing from us...



2

Why?

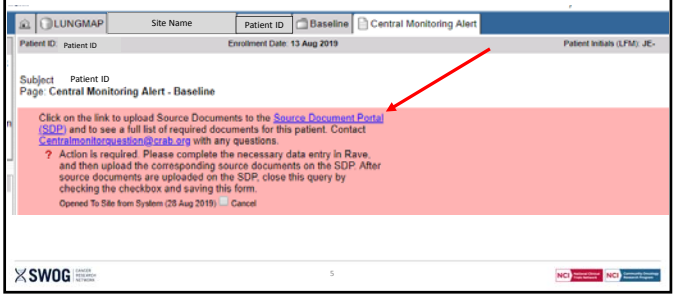
- Data Quality
- In following the FDA's guidance for industry[1] as a means to verify:
  - Rights and well-being of human subjects are protected
  - Reported trial data are accurate, complete, and verifiable from source documents.
  - The conduct of the trial is in compliance with the currently approved 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.

3

Remote Data Verification Will Utilize the Following:

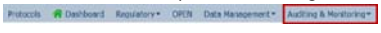
- Source documents uploaded to RAVE per your SWOG protocol.
- Source documents uploaded to CTSU in the Source Document Portal (SDP) per your SWOG protocol.
- SWOG monitors will compare data reported to the eCRF against the source documents to ensure data accuracy and integrity.

SDP Access via Medidata RAVE:

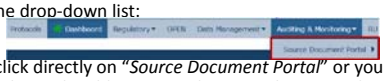


SDP Access via CTSU website:

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)

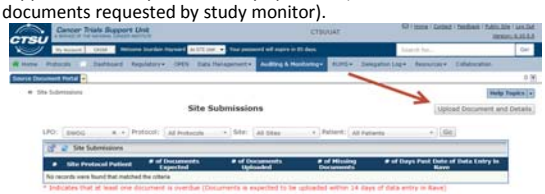
Protocol: LUNGMAP Site: CA087 Patient: 123456 Go

#	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	

SWOG 7

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).



SWOG 8

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

SWOG 9

References/Citations

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