SWOG SDMC Update

Statistics and Data Management Center

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SWOG Data Operations Center
Seattle, WA
SDMC Update

General SDMC Updates
Rodney Sutter

Central Monitoring
Jourdain Hayward

S1919: *Phase II, Multi-Arm, Randomized Umbrella Study to Evaluate the Therapeutic Efficacy and Safety of Immune-Oncology Drug Combinations 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

• Links Reorganized:
  • Site Management Reports
  • Accrual Reports
  • Study Management
  • SWOG Facilities
SWOG Reports – CRA WB

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  - 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

THANK YOU!
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...

NO! NO! NOOOOOOOOOO!!

meme-generator.net
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.
Click on the link to upload Source Documents to the [Source Document Portal](#) (SDP) and to see a full list of required documents for this patient. Contact [Centralmonitorquestion@crab.org](mailto:Centralmonitorquestion@crab.org) with any questions.

Action is required. Please complete the necessary data entry in Rave, and then upload the corresponding source documents on the 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 (28 Aug 2019)  □  Cancel
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

<table>
<thead>
<tr>
<th>#</th>
<th>Site</th>
<th>Protocol</th>
<th>Patient</th>
<th># of Documents Expected</th>
<th># of Documents Uploaded</th>
<th># of Missing Documents</th>
<th># of Days Past Date of Data Entry in Rave</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NCI Code</td>
<td>LUNGMAP</td>
<td>123456</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>51*</td>
</tr>
</tbody>
</table>

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

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