


SWOG SDMC Update

Statistics and Data Management Center


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SWOG

SDMC Update


<p>General SDMC Updates</p> <p>Central Monitoring</p> <p>S1919: <i>Phase II, Multi-Arm, Randomized Umbrella Study to Evaluate the Therapeutic Efficacy and Safety of Immune-Oncology Drug Combinations in Metastatic Breast Cancer (RUSTIC)</i></p> <p>Study Trial Design & Statistical Issues Logistical Details, Access, Registration, etc. Rave Instance Differences</p> <p>CDASH Training for CRAs</p>	<p>Rodney Sutter</p> <p>Jourdain Hayward</p> <p>Bill Barlow Jacqueline Scurlock Katie Minichiello</p> <p>Dani Weatherbee</p>
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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

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



SWOG

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



Reports

Study Management Reports

Site Management Reports

Accrual Reports

Study Management

SWOG Facilities



Please Welcome,

Jourdain Hayward
Central Monitor

SWOG Central Monitoring

