


**SWOG SDMC Update**  
*Statistics and Data Management Center*

**Rodney Sutter, CCRP**  
Program Director, Therapeutic Studies  
SWOG Data Operations Center  
Seattle, WA

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***Thank you, Hope!***

- Travel Support Opportunity
  - 20 SWOG CRAs
  - Celgene added funding for 4-5 more
  - Max of \$1500 per award
- Future Initiative?
  - Currently Spring, 2018 only
  - Hopeful to continue efforts for future travel

**THE HOPE FOUNDATION**

*Because answers to cancers come from clinical trials*

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**CTCAE v5.0**

- Released on November 27, 2017
- SAE Reporting via CTEP-AERS
  - Effective April 1, 2018
  - Exceptions: S1505, S1612 and S1619
- AE Reporting
  - New trials will use v5.0 effective May 1, 2018
- Active Trials
  - Some active trials will convert to v5.0 by July 31, 2018
    - ✓ S1505, S1612 and S1619
  - All other active trials will continue utilizing CTCAE v4.0

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## CTCAE v5.0

- Updates between v4.0 and v5.0 consist of:
  - Clarification to grade descriptions
  - Clarification to term definitions
  - Addition of terms and/or grades
  - Deletion of terms and/or grades
  - Primary SOC changes
- Future protocol revisions when implemented
- Resources:
  - CTEP website: <https://ctep.cancer.gov/>
  - Kari Williams: [kwilliams@swog.org](mailto:kwilliams@swog.org)

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## RAVE Study Migrations

- Updated and/or New Forms
  - Pushed out at random
  - Study and forms accessible
  - Minimal impact
- Medidata Recommends Locking
  - Planned notifications
  - Later in the day whenever possible
  - Provide feedback!

S1605
 Upcoming Scheduled Rave Downtime: S1605 (Phase II Trial of Abiraterone in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer) will be temporarily unavailable in Rave starting at 2PM PST (5PM EST) on Friday, March 23rd due to study migrations. Rave data will be available again at 12AM on Saturday March 24th. Please note that PATIENTS CAN STILL BE REGISTERED IN OPEN DURING THIS TIME. However, data access, data entry, and viewing and responding to queries in Rave will be unavailable to sites and SWOG data coordinators during this time.

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## Legacy Studies → RAVE

- Studies activated prior to Medidata Rave
  - Many closed, but still open to follow-up
- Subset of forms in Rave (no longer available in CRA WB)
  - Follow-Up Form
  - Notice of Death
  - Consent Withdrawal
  - Lost to Follow-Up
  - Late Effects
- Initial studies already identified, S1011 – *Released*
  - S0016, S0033, S0221, S9921, S0307

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## Expectation and IPR Report

Policy #33 defining IPR criteria – updated October, 2017

- **IFS (Initial Forms Set):** *Expand* to include all baseline forms, reports, *specimens* and source documents
- **Follow-Up:** *Consolidate* 'follow-up, on tx' and 'follow-up, off tx' measures. *Rename* into 'Vital Status Update'
- **Post-baseline Forms:** *Include post-baseline forms*, report or other protocol-specified document that has an outstanding expectation within the last 13 months
- **Specimen Submission:** *Include post-baseline specimens* for which an expectation has been posted

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## Expectation and IPR Report

Expectation Report now lists which performance category an overdue expectation contributes to:

- Initial Forms Set (IFS)
- Follow-Up (FUP)
- Post-baseline Forms (FORM)
- Specimen Submission (SPEC)

DATE	EXPECTATION	DAYS OVER DUE	P	S
11/06/2017	FACT-SIRI	114	FORM	
	Circle 3 FACT-SIRI			
	Cover Sheet for Questionnaires			
11/06/2017	Circle 3 Cover Sheet	114	FORM	
13/07/2017	Adverse Events Form	85	FORMFUP	
	Period beginning 09/15/2017			
13/07/2017	Treatment Exam	85	FORMFUP	
	Period beginning 09/15/2017			
13/06/2017	Diagnosis Assessment Exam	84	FORMFUP	
	Period beginning 09/15/2017			
07/09/2018	EQ-5D-VL Health Questionnaire	32		
	Circle 4 EQ-5D-VL			
07/09/2018	FACT-SIRI	32		
	Circle 4 FACT-SIRI			
07/09/2018	Cover Sheet for Questionnaires	32		
	Circle 4 Cover Sheet			
04/05/2018	12 Month Follow-up			
	Status Update			
12/18/2017	Adverse Events Form	73	FORMFUP	
	Period beginning 1/23/2018			
07/15/2018	Treatment Exam	46		
	Period beginning 07/18/2017			
07/15/2018	Follow-up off tx	44	IFS	
11/08/2017	Onstudy form	34	IFS	
	Baseline			
11/08/2017	Prevaling Pathology Report	34	IFS	
	Baseline			
13/05/2017	Tissue Submission	87	SPEC	
	Tissue Details			

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## Expectation and IPR Report

Contact us if you identify any problems with your reports!

- We can explain why something is showing up, **OR...**
- You may have found a real problem we need to investigate
- Expectation Report: [expectationreportquestion@crab.org](mailto:expectationreportquestion@crab.org)
- IPR Report: [pgoodman@fredhutch.org](mailto:pgoodman@fredhutch.org)

**New IPR criteria will be enforced starting May, 2018**

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## SWOG Query Report

- Separate from Expectation Report and IPR
  - Expectation Report → Forms
  - Query Report → Queries on Forms
- Future component of Site Performance
- Initiating a monthly email to Head CRAs
- Located in the Reports link on the CRA WB:

Reports

Please select the reports you wish to display:

Expectation and IPR Reports

Query Reports ←

Ineligible Patients Report

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## Differences from DQP

	SWOG Query Report	DQP
What's posted?	All queries	Overdue queries
Overdue definition	Don't currently measure	Calculated from date posted. Due within 15 days
What's included?	Queries from Data Coordinators Queries from Auditors	Queries from Data Coordinators Queries from Auditors/Monitors Medidata Rave System queries + non-conformant data
How to access	SWOG CRA Workbench	CTSU
Which studies?	All Rave studies + All legacy studies	All Rave studies

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## Queries in RAVE

- Marking Groups: Site from DM, Site from Auditor, etc.
- Implement additional query tracking in RAVE vs. email
- Nationwide:
  - Queries specific to specimens submitted to the solid tumor, myeloma and lymphoma repository
  - Last Fall: Pilot Study – S1201
  - Added S1406 and LungMAP
  - April, 2018 → **All Active Studies**

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**Questions?**



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**SDMC Training**

8:25 – 8:40	Stages of NMIBC & Associated Biology	Peter Black, MD
8:40 – 8:50	S1602, S1605 Data Management & FAQs	Joseph Sanchez Sean O'Bryan
8:50 – 9:00	FDA Trials – Differences from Standard SWOG Trials	Melissa Plets
9:00 – 9:05	Q and A	All
9:05 – 9:15	S1404 Updates	Krystle Pagarigan

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**Please Welcome,**

**Peter Black, MD**  
*BC Cancer Agency – Vancouver Centre  
 S1605 Study Chair*

**Stages of NMIBC & Associated Biology**

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