SWOG SDMC Update Statistics and Data Management Center

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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 grade description
 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/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!

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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 WithdrawalLost to Follow-UpLate 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

- <u>IFS (Initial Forms Set)</u>: *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
- <u>Specimen Submission</u>: *Include post-baseline specimens* for which an expectation has been posted

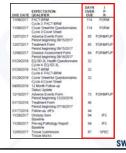
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Expectation and IPR Report

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)



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
 IPR Report: expectationreportquestion@crab.org
 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:



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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 → <u>All</u> Active Studies



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