

SWOG SDMC Update

Statistics and Data Management Center

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SDMC Updates

8:15 – 9:15

General SDMC Updates	Rodney Sutter
RECIST 1.1 and SWOG Protocol Section 10.0	Louise Highleyman
S1304: Expanded Data Collection	Rachael Sexton
LungMap Updates	Mary Redman

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Specimen Tracking – Updates

- Log a Specimen:
 - Filtering Tool and Material Requirements

Step 2 of 3: Choose the specimen that you are logging from the list below.

Show: Specimen/Material Type: Lab:
 Submission Management: Apply Reset

Registration Step	Substitutions/Management	Specimen or Material Type	Material Requirements	Lab
1	Available, Print to be used	Specimen from primary site Blocks	0-10 vials 100% tissue	SWOG, Spectrum, Quest, etc.
1	Available, Print to be used	Specimen from primary site Unprocessed tissue	0-10 vials 100% tissue (change unprocessed tissue)	SWOG, Spectrum, Quest, etc.
2	Available, Print to be used	Specimen from distant site Blocks	0-10 vials 100% tissue	SWOG, Spectrum, Quest, etc.
2	Available, Print to be used	Specimen from distant site Unprocessed tissue	0-10 vials 100% tissue (change unprocessed tissue)	SWOG, Spectrum, Quest, etc.
3	Available, Print to be used	Specimen from distant site Blocks	0-10 vials 100% tissue	SWOG, Spectrum, Quest, etc.
3	Available, Print to be used	Specimen from distant site Unprocessed tissue	0-10 vials 100% tissue (change unprocessed tissue)	SWOG, Spectrum, Quest, etc.
4	Available, vials 100% tissue	Block	0 vials in Plastic, 100% tissue	SWOG, Spectrum, Quest, etc.
4	Available, vials 100% tissue	Whole Blood	0 vials in plastic EDTA, 100% tissue	SWOG, Spectrum, Quest, etc.
4	Available, vials 100% tissue	Whole Blood	0 vials in 100% tissue, 100% tissue	SWOG, Spectrum, Quest, etc.

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Vital Status Form – New!

- Banner page in Rave updated

Patient ID: S1404 Fox Chase Cancer Center
 Patient Initials (LFM): Current vital status: Alive Current date of last contact or death: 10 May 2016 Enrollment Date: 22 Apr 2016

- Folder Structure
 - Vital Status Folder near the top
 - Will contain two sub-folders
 - Vital Status (On Treatment)
 - Vital Status (Off Treatment)

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Vital Status Form – New!

- Reduce repetitive data entry for CRAs!
- Removes complexities of collecting LCD and Status from multiple forms
- More efficient to track this variable for SDTM mapping
- **Site staff will need to update this form *first***
- Will be introduced in 2 new GU studies:
 - S1802 (activated)
 - S1806 (in development)
- New activations

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Data Operations – Moving!

- Physical Move: Friday, Oct 19 – Sunday, Oct 21
- **CLOSED** on Friday, Oct 19
- **Scheduled Downtime: 9:00 a.m. PT (12:00 p.m. ET) on Friday, 10/19 through Sunday, 10/21**
 - **OPEN:** Unavailable for SWOG-coordinated trials
 - **CRA Workbench:** Unavailable for pre-Rave data submission and queries, access to Expectation and IPR reports
 - **Specimen Tracking System:** Unavailable
 - **Data Operations Staff:** Unavailable – by phone and email

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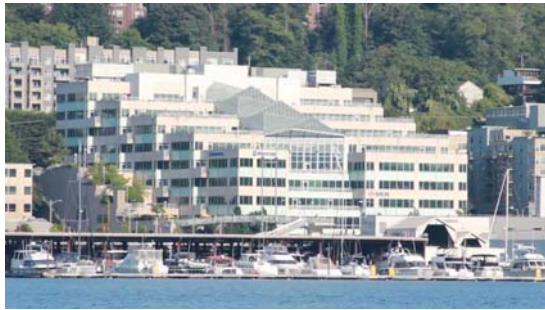
Data Operations – Moving!

- Things to make note of:
 - **RAVE:** No impact. Entered data will be uploaded to the SWOG database on Monday, Oct 22
 - Data on servers are backed up regularly
 - Plan ahead – Work up new patients earlier that week, log and ship specimens before or after scheduled downtime
 - All systems expected back up by **12:00 a.m. PT on Monday, Oct 22**

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Data Operations – Moving!



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Data Operations – Moving!

- Forward this information to applicable staff
- Any concerns or questions prior to the outage may be directed to: datamanagement@crab.org

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Please Welcome,

Louise Highleyman
SWOG Data Coordinator

**RECIST 1.1 and
SWOG Protocol Section 10.0**

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