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

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: Registration Step = Specimen/Material Type = Lab =

Submission Timepoint =

Apply Reset

Registration Step	Submission Timepoint	Specimen or Material Type			Material Requirements	Lab
1	Baseline, Prior to tx start	Tissue from primary site	Blocks	5-10 mm3 FFPE block	Preferred	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, Prior to tx start	Tissue from primary site	Unstained Slides	30 (5 micron) positive charge unstained slides	Alternate	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, Prior to tx start	Tissue from distant site	Blocks	5-10 mm3 FFPE block	Preferred	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, Prior to tx start	Tissue from distant site	Unstained Slides	30 (5 micron) positive charge unstained slides	Alternate	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, Prior to tx start	Tissue from local site	Blocks	5-10 mm3 FFPE block	Preferred	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, Prior to tx start	Tissue from local site	Unstained Slides	30 (5 micron) positive charge unstained slides	Alternate	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, <= 2 days prior Ipi tx	Blood	Serum	4 mL in Plastic SST, Frozen	Only option	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, <= 2 days prior Ipi tx	Blood	Whole Blood	9 mL in plastic EDTA, refrig	Preferred	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, <= 2 days prior Ipi tx	Blood	Whole Blood	9 mL in Cryotube, refrig	Alternate	201 - SWOG Specimen Repository Columbus, OH

Specimen Tracking – Updates

- Specimens that cannot be submitted
  - Indicate this in Specimen Tracking
  - Resolves the Expectation

- Specimen Manager
  - Show only those not submitted

- Chooser
- Log a Specimen
- Specimen Manager
- View/Update Consent Answers
- Notify that Specimen Cannot be Submitted
- Reports
- Administration
- Contact Us

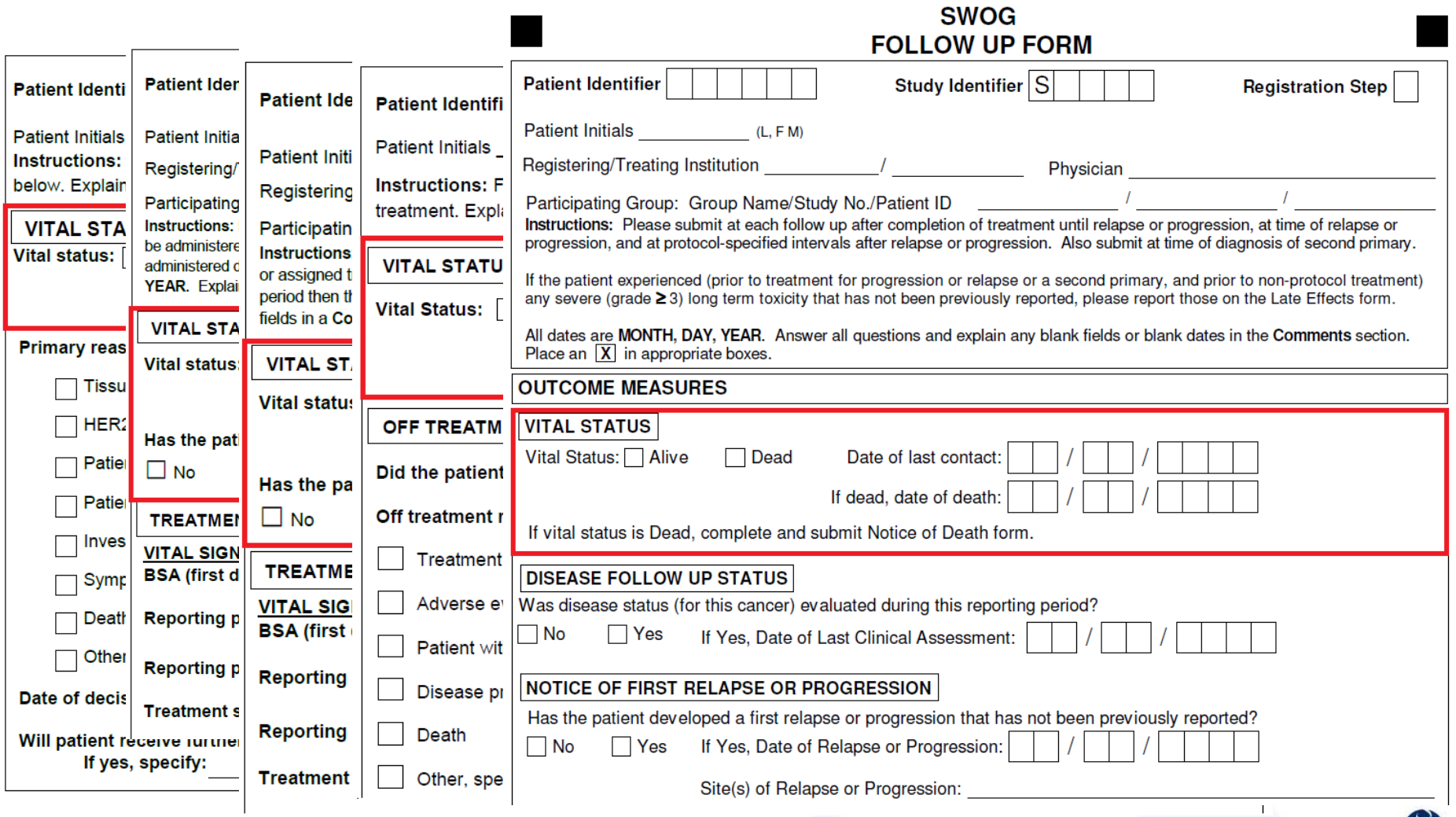
Show:

Patient Number: | Specimen Number: | Status: ☐ Not Shipped ☐ Shipped (not received) ☐ Received ☑ Not Collected | Receiving Lab #: | Apply | Reset

Study Number: | Shipment Number:

Click to delete specimen	Patient	Study	Specimen Number	Specimen	Timepoint	Collection Date	Receiving Lab	*Select specimen to ship*	Status	Shipment Number	Ship Date	Received Date	Condition
	197934	S0356	Not collected	Blood - Whole Blood -	Baseline								
	200152	S0106	Not collected	Bone Marrow - Stained touch prep - Stained biopsy touch preps	Baseline, Within 30 days of reg:only pts reg before 10/15/06								
	200152	S0106	Not collected	Bone Marrow - Stained smear - Wright-Giesma stained aspirate smear	Baseline, Within 30 days of reg:only pts reg before 10/15/06								

Last Contact Date and Status



SWOG
FOLLOW UP FORM

Patient Identifier ☐☐☐☐☐☐ Study Identifier S☐☐☐☐ Registration Step ☐

Patient Initials _____ (L, F M)

Registering/Treating Institution _____/ _____ Physician _____

Participating Group: Group Name/Study No./Patient ID _____ / _____ / _____

Instructions: Please submit at each follow up after completion of treatment until relapse or progression, at time of relapse or progression, and at protocol-specified intervals after relapse or progression. Also submit at time of diagnosis of second primary.

If the patient experienced (prior to treatment for progression or relapse or a second primary, and prior to non-protocol treatment) any severe (grade ≥ 3) long term toxicity that has not been previously reported, please report those on the Late Effects form.

All dates are **MONTH, DAY, YEAR.** Answer all questions and explain any blank fields or blank dates in the **Comments** section. Place an [X] in appropriate boxes.

OUTCOME MEASURES

VITAL STATUS

Vital Status: ☐ Alive ☐ Dead Date of last contact: ☐☐ / ☐☐ / ☐☐☐☐

If dead, date of death: ☐☐ / ☐☐ / ☐☐☐☐

If vital status is Dead, complete and submit Notice of Death form.

DISEASE FOLLOW UP STATUS

Was disease status (for this cancer) evaluated during this reporting period?

☐ No ☐ Yes If Yes, Date of Last Clinical Assessment: ☐☐ / ☐☐ / ☐☐☐☐

NOTICE OF FIRST RELAPSE OR PROGRESSION

Has the patient developed a first relapse or progression that has not been previously reported?

☐ No ☐ Yes If Yes, Date of Relapse or Progression: ☐☐ / ☐☐ / ☐☐☐☐

Site(s) of Relapse or Progression: _____

Vital Status Form – *New!*

SWOG

VITAL STATUS FORM

Patient Identifier ☐☐☐☐☐☐ **Study Identifier** S☐☐☐☐ **Registration Step** ☐

Patient Initials _____ (L, F M)

Page: Vital Status

Instructions: Please complete this form when contact is made with the patient for any reason. This form should be submitted prior to any other data entry related to that visit. Date is in **DD MON YYYY** format.

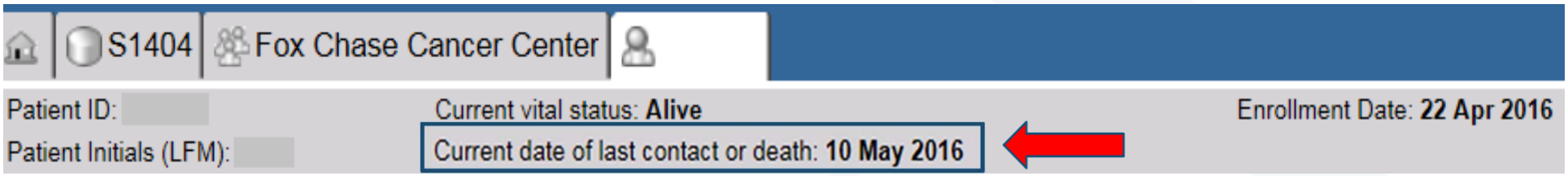
Vital Status *(If dead, please submit Notice of Death)* ☐ Alive ☐ Dead

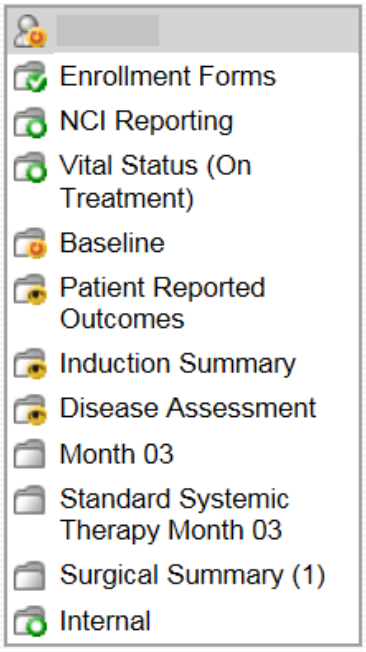
Date of last contact *(If dead, please enter date of death)* ☐☐ ☐☐☐ ☐☐☐☐

Comments

Vital Status Form – *New!*

- Banner page in Rave updated





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

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

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

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

Data Operations – *Moving!*

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