S1404: GENERAL DATA MANAGEMENT UPDATES

SWOG 2018 SPRING GROUP MEETING

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Overview

- Brief History of the Trial
- Interim Analysis Timeline
- S1404 Data Management Tips
 - Eligibility checklist
 - Cycle-specific laboratory values
 - Patient-Reported Outcome
 (PRO) Questionnaires
 - Centralized Monitoring
- S1404: New and Upcoming
 - Disease Assessment form
 - S1404 Outstanding Data Reports
 - PK/ADA Requirements
 - New site resource: S1404 Data Entry and Specimen Submission Guidelines



S1404: A Brief History

- "Randomized phase III trial evaluating SoC (physician's choice of interferon alfa-2b or Ipilimumab) vs. Pembrolizumab in patients with resected Stage III (at least IIIA/N2a) or Stage IV melanoma"
- Opened in October 2015; Step 1 (screening) closed to accrual in August 2017, and Step 2 (treatment) closed to accrual November 2017.
- Accrued very quickly!
- Potential FDA registration/validated study

Interim Analysis: What this means for sites

- Big push to get Rave data ready for the interim analysis (Summer 2018)
- Final analysis should be complete by end of 2018

Data Management Tips: S1404 Eligibility Checklist

- Eligibility checklists were required starting in April 15, 2016 but were not available for download until September 15th, 2016.
 - Patients registered to Step 1 between these dates only need to have a signed and dated copy of protocol section 5
 - Patients registered after September 15, 2016 will need a copy of the official S1404 Eligibility Checklist
- If the checklist was never uploaded, please upload a copy of the official S1404 Eligibility Checklist

Data Management Tips: What do I need to submit to fulfill the Eligibility Checklist requirement? October 15, April 15, September 15, 2016 No eligibility Checklist is needed A signed and dated copy of protocol section 5.0 OR the \$1404 Eligibility Checklist is acceptable All patients must have an Eligibility Checklist uploaded. If one was never uploaded but the patient was registered after April 15, 2016, legises submit a copy of the \$1404 Eligibility Checklist, even if the patient's Step 1 registration date falls between April 15 and September 15, 2016.

Data Management Tips: S1404 Eligibility Checklist

- 5 pages total-- please respond to all questions
- Data entered on this form must be consistent with associated data on Rave Onstudy forms
 - Lab values match Onstudy: Lab Values
 - Staging matches Onstudy: Pt and Dz Description

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Data Management Tips: Cycle-specific Laboratory Values

- A cycle begins at the time the infusion starts
- Labs done on the same day, but prior to the first infusion, are considered to be labs for the previous cycle.
- As such, these labs <u>must</u> be entered on the previous cycle's laboratory values form, as they are reflective of treatment already received.

Data Management Tips: Patient Reported Outcome Questionnaires

- PRO research provides the patient's perspective in this research; it's our responsibility to ensure their views are represented accurately
- After patient completes questionnaires, immediately review responses and request any clarifications from the
- After initially entering patient responses in Rave, review your data entry before form submission
- Upload the original patient completed forms in Rave per protocol requirements for source document review

Data Management Tips: Centralized Monitoring

- Centralized monitoring occurs on the first two patients who were randomized after October 2016 and at a site previously not audited
- Common S1404-related issues:
 - Late upload of the eligibility checklist and local pathology review form
 - Using section 5 of the protocol instead of the eligibility checklist from the master form set.
- For any questions, please contact <centralmonitorquestion@crab.org>

New to \$1404: Disease Assessment form

- Implemented with the release of Revision #8 on March 1st, 2018
- To be submitted for patients who are on treatment and for patients who are off treatment prior to progression.

New to S1404: Disease Assessment form

- What about the old Adjuvant Melanoma Follow Up forms in the Follow-up and Disease Assessment Folder?
 - These forms will now roll out in a new "Follow-Up Folder" and are only required for patients who are off treatment
- As such, patients who are off treatment and have not yet experienced progression should complete BOTH the Disease Assessment form AND the Adjuvant Melanoma Follow-Up form.

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_	Follow-up (Old) (1)	

- Follow-up (Old) (1)

 Disease Assessment (1
- Follow-Up (1)

	Previous to Revision #8	Current as of Revision #8
On protocol treatment	Adjuvant Melanoma Follow- Up form every 12 weeks until disease recurrence or 2 years after randomization, and then every 6 months until Year 10	Disease Assessment form every 12 weeks until disease recurrence or 2 years after randomization, and then every 6 months until Year 10
Off protocol treatment before recurrence	Adjuvant Melanoma Follow- Up form every 12 weeks until disease recurrence or 2 years after randomization, and then every 6 months until Year 10	Disease Assessment form every 12 weeks until recurrence or 2 years after randomization, then every 6 months until Year 10 AND Adjuvant Melanoma FUP form every 6 months for 2 years, then annually until Year 10
Off protocol treatment after recurrence	Adjuvant Melanoma Follow-Up form every 6 months for two years, then annually until year 10	

New to \$1404: Outstanding Data Reports

- These emails go out to a site if one or more of the following outstanding data types are identified in the CTSU Data Quality Portal (DQP) or our database:
 - Outstanding Data Manager queries open for ≥30 days since posted.
 - 2. System queries open for ≥30 days since posted.
 - 3. Non-conformant error messages in Rave open for ≥30 days since attempted submission.
 - 4. Forms delinquent for ≥60 days.

New to \$1404: PK/ADA is no longer required

- As of 12/11/2017, PK/ADA sampling has been discontinued
- However, all samples already collected must still be submitted per instructions in S1404 section 15.4.

New to S1404: Data Entry and Specimen Submission Guidelines

- Provides data entry and specimen submission guidelines to assist with commonly-seen questions
- Compiled by the S1404 Data Coordinators
- Available in the ORP Manual, which can be found on the SWOG CRA Workbench
- This is a living document, so site input is always appreciated!

S1404 General Updates: Final Words

- Please come visit us at the ORP Open Forum!
- The S1404 Data Coordinators can be reached at <u>melanomaquestion@crab.org</u> or at 206-652-2267

