


S1404: GENERAL DATA MANAGEMENT UPDATES

SWOG 2018 SPRING GROUP MEETING

*Krystle Pagarigan, BS
Clinical Research Data Coordinator
SWOG Statistics and Data Management Center (SDMC)*

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, 2015 April 15, 2016 September 15, 2016

No eligibility checklist is needed

A signed and dated copy of protocol section 5.0 OR the S1404 Eligibility Checklist is acceptable

Only a signed and dated copy of the S1404 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, please submit a copy of the S1404 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

The image shows a portion of a clinical trial eligibility checklist. It includes a header with the protocol name 'S1404' and a section for patient information. The main body of the form consists of numerous checkboxes and text boxes for screening criteria, such as 'Is the patient's performance grade (PG) at least 1?', 'Is the patient's ECOG performance grade at least 1?', and 'Is the patient's hemoglobin level at least 10 g/dL?'. At the bottom, there is a section for 'Patient Reported Outcomes' and a 'Page 1 of 5' indicator.

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 must 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 patient
- 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**

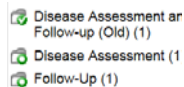
- Centralized monitoring occurs on the first two patients who were randomized after October 2016 and at a site previously not audited
- Common S1404-related issues:
 - Late upload of the eligibility checklist and local pathology review form
 - Using section 5 of the protocol instead of the eligibility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

**New to S1404:
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.



	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 S1404:
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:
 1. 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 S1404:
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 melanomaquestion@crab.org or at 206-652-2267