

# S1404: Study Updates

**Diana Heaney**

***SWOG Data Operations Center***

# Overview

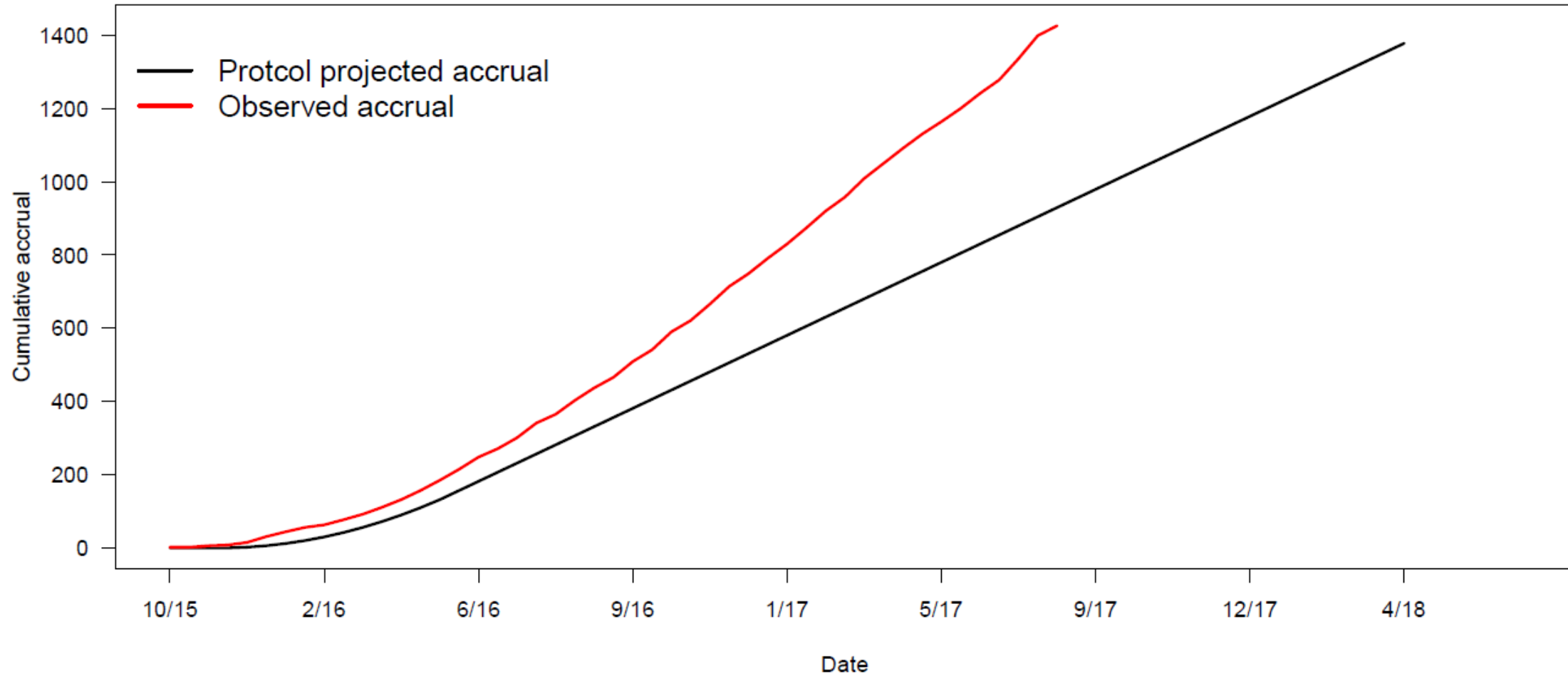
- Study Timeline
- Recent and Upcoming Updates to Rave
- Data Submission Efforts
- Resources

# Study Timeline

- Activated 10/15/2015
  - Ipilimumab added to protocol 4/15/2016
- Step 1 closed 8/15/2017
  - 1,426 registered to Step 1
  - 1,345 randomized to Step 2
- Final analysis will tentatively be done Spring 2019

# Study Timeline



S1404 accrual







# Rave Updates – Lab Values Form



- Treatment Cycle folders will start out with only one laboratory values form
- There is now a checkbox at the bottom of the form that will generate additional forms on an as-needed basis
- Rave was updated 8/22/2017, so this will apply to any Treatment Cycle folders generated after that date


# Rave Updates – Lab Values Form




**Pregnancy test** ☐ Positive ☐ Negative ☐  

Sample collection date  ...  ☐  


*Check this box to add an additional Lab Values form* ☐ ☐  





**Comments**  ☐  

 **Cycle 01**

-  Treatment (Control arm)
-  Adverse Events: Assessment
-  Laboratory Values



 **Cycle 01**

-  Treatment (Control arm)
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-  Laboratory Values

# Rave Updates – Site(s) of Relapse Form

- Brain MRI was added as a requirement at relapse 11/1/2016
- To ensure that we are capturing this information, we will soon be adding a field to the Site(s) of Relapse form
- This will also be used to verify TRIAD submissions

# Rave Updates – Site(s) of Relapse Form

**Was a MRI of the brain performed at recurrence?** ☐ Yes ☐ No

*If Yes, Date of MRI of the brain:*   /   /

*If No, Specify the reason:* \_\_\_\_\_



# Rave Updates – Disease Assessment Form

- Modifying how disease assessment information is captured in Rave
- Will be creating a new form to use for documenting any disease assessments that are done
- This will require a protocol amendment, so please continue to follow section 14.4g for current guidelines

**SWOG**  
**S1404 DISEASE ASSESSMENT FORM**

Patient Identifier  Study Identifier  Registration Step

Patient Initials \_\_\_\_\_ (L, F M)

**Instructions:** Please submit at each scheduled follow up disease assessment, as outlined in section 9.0, until relapse or progression, and at time of progression/relapse. In addition, upload all corresponding radiology reports, via the source documentation follow-up form, and all corresponding images via TRIAD. Answer all questions and explain any blank fields or blank dates in the **Comments** section.

**DISEASE ASSESSMENT**

Was disease status (for this cancer) evaluated during this reporting period? ☐ Yes ☐ No

If No, Explain why: \_\_\_\_\_

If Yes, Complete the following:

Date of last disease assessment:  /  /

Assessment Type (mark all that apply):

- ☐ X-Ray/Scan (CT, PET-CT, MRI, Ultrasound, etc.)  
☐ Physical exam  
☐ Other, Specify: \_\_\_\_\_

If X-Ray/Scan, Please provide the date of each X-Ray/Scan performed during the reporting period:

X-Ray/Scan	Date
	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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# Data Submission Efforts – New Reports

- Tighter study deadlines means there is a greater need for timely and accurate data submission
- Want to ensure that queries are being seen and addressed
- Email notifications based on outstanding queries from the DQP
  - Total number of outstanding system queries, outstanding queries from data management and non-conformant errors

# Data Submission Efforts – New Reports

- Working on developing a comprehensive report that will pull from many sources to summarize all data submission needs
- Report will likely include, but not be limited to:
  - Queries open  $\geq 30$  days
  - Non-conformant data outstanding for  $\geq 30$  days
  - Forms that are  $\geq 60$  days delinquent
  - Patients with outstanding eligibility issues
- Aiming to launch in the next couple of months

# Resources and Contact Information

- Documents available on the protocol page at SWOG.org and CTSU.org
  - SWOG Best Practices Memo
  - CTTC Training Presentations
  - S1404 Tips for Data and Specimen Submission
- Expectation Report
- Data Quality Portal

# Resources and Contact Information

- SWOG Data Coordinators
  - [MelanomaQuestion@crab.org](mailto:MelanomaQuestion@crab.org)
  - (206) 652-2267
- Study Chairs
  - [S1404SCQuestion@swog.org](mailto:S1404SCQuestion@swog.org)
- Auditors & monitors – here to help!
  - [centralmonitorquestion@crab.org](mailto:centralmonitorquestion@crab.org)
- IROC contact for TRIAD submission
  - [SWOG1404@irocoho.org](mailto:SWOG1404@irocoho.org)
  - [Triad-support@aci.org](mailto:Triad-support@aci.org)

# Thank you!

