GU Kick Off Meeting for S1605
SWOG Group Meeting, Friday, April 28, 2017

Central Monitoring

What's New? S1605 is a FDA registry trial, and therefore has some more stringent expectations regarding both the reporting and monitoring of this trial.

Per Protocol *section 18.2 Quality Assurance Auditing and Monitoring, Off-site monitoring,* Monitors at the Statistics and Data Management Center (SDMC) will support the risk based monitoring approach for this trial with the following actions: Off-site monitoring to include auditable elements through administration of the second course of treatment for the first 2patients registered at each site. ***Note: this review is separate from an on-site Audit.***

The Head CRA will be contacted by a SDMC monitor via email with instructions for uploading the auditable elements. Source documents are required to verify/confirm patient consent, eligibility and data entry on the specified forms in RAVE®. ***All source documents MUST be properly and completely redacted and free of PHI before uploading to Rave®.***

In preparation for centralized monitoring, a **Source Document Verification (SDV) folder** in Rave® will be created for your two patients registered where you will be able to upload source documentation to support or confirm items listed below

<u>Eligibility</u>

- Informed Consent title page, signature page and responses to Future Contact, Samples for Future Research Studies
- S1605 Registration Worksheet signed by the Registering Investigator
- Source documents to support S1605 Baseline Onstudy Patient and Disease Description form
- Source documents to support Baseline Onstudy Laboratory Values form
- Source documents to support Baseline Prior Treatment form
- Source documents to support S1605 Eligibility Form
- Source documents to support the Baseline Abnormalities Form
- H&P to include Wt
- PS
  ** if additional labs are drawn outside of the required time points, upload the source documentation for these as well*

<u>Cycle 1:</u>

- Source documents for labs drawn prior to drug infusion (See Study Calendar)
- Source documents to support S1605 Treatment Form
- Source documents to support S1605 Adverse Event Form
- H&P, PS
- Treatment Records (drug order, nursing notes, vital signs before, during and after infusion)
- Specimen shipping records

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Cycle 2:

- Source documents for labs drawn prior to drug infusion (See study calendar)
- Source documents to support S1605 Treatment Form
- Source documents to support S1605 Adverse Event Form
- H&P, PS
- Treatment Records (drug order, nursing notes, vital signs before, during and after infusion)
- Specimen shipping records

Source Documents to Support Other Forms
If applicable:

- Off Treatment Notice
- Notice of Death

Week 13

- Source documents to support S1605 Disease Assessment form
- Specimen shipping records

Week 25

Reminder: Bladder biopsy is MANDATORY for patients with any component of CIS or if the Cystoscopy and/or Cytology are suspicious (see protocol section 7.3)

- Source documents to support S1605 Disease Assessment form
- Specimen shipping records

As part of the review, the central monitor will also be reviewing the following documents that are required to be uploaded into RAVE® within 7 days of patient registration to Step 1 via the **Source Documentation Baseline Form:**

- S1605 Eligibility Criteria Form
- Radiology reports from all scans performed to assess disease at baseline
- Cytology Reports
- Operative and Pathology reports
- ECG report

The SWOG SDMC appreciates your efforts in timely data submission in Rave® for this centralized monitoring review.

Questions? Contact Dona Marrah at centralizedmonitoring@crab.org or 1-206-652-1341