

The Clinical Research E-News

ISSUE 11: June 18, 2009

New Activations at TJU: No new activations.

Regulatory Update: The following studies have had recent *consent* form changes posted on the repository website:

**RTOG0413/NSABP B-39
GOG 218**

E2805 (ASSURE)

If any of these studies pertain to your site please visit the repository at: <http://www.kimmelcancercenter.org/kcc/JKCCN/file-repository/>. Please contact Rolma Mancinow at rolma.mancinow@jeffersonhospital.org or 215-955-7954 with any repository related questions.

Regulatory Corner: Announcing the Common Terminology Criteria for Adverse Events (CTCAE), Version 4.0! To access this new version (publish date May 29, 2009), please visit http://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm#ctc_v40. Please note: Each protocol specifies which version of the CTCAE should be applied when describing AEs. Please take note of the CTCAE version, especially for trials activated around and after 5/29/2009.

Quality Assurance Update: No new updates. Check back in 2 weeks. Please contact Kelly Shipman with any QA related issues at Kelly.shipman@jeffersonhospital.org or 215-955-2135.



CTSU Update: Recently, several changes were made to the CTSU members' website. The tabs on the CTSU home page were updated and now include a Clinical Data tab, where you can view a list of your patients enrolled through CTSU, outstanding DCFs, received forms and more. For a full description of the changes, please visit <https://members.ctsu.org/> and view the "Updates to the CTSU Members' Web Site" announcement.

If you have a CTSU related question please contact Joshua Schoppe at Joshua.schoppe@jeffersonhospital.org or 215-955-0448

ECOG Update: Upcoming Performance Monitoring: The next Performance Monitoring data cut-off date of June 30, 2009 is approaching. Any data received on or before June 30, 2009 will be included in the upcoming Performance Monitoring. *Data received after June 30, 2009* will be considered late. It is important to remember that data timeliness will be evaluated by assessing two components: The rate of CRFs submitted during active treatment and the rate of survival follow-up. To avoid penalties, each evaluable ECOG institution must have a **score of 90%** or better on each component.

Revised List of ECOG Coordinated Studies Not Needing Further Data Submission: ECOG has determined that follow-up information, including survival updates, is no longer required for the studies listed below:

E3198	E1301	E3878	E4397
E1100	E2301	E4802	E7897
E2100	E3301	E6800	E3695
E1200	E1497	E8998	E1696
E1203	E2499	E1A97	E1899
E1297	E1503	E5A93	E2803
E4201	E3501	E4A97	E2898
E6201	E1C97	E1F02	E3800



If you have any questions, please contact Kerry Higgins, Data Management Manager, at 617-632-3610.

ECOG 2805, ASSURE: Adjuvant Sorafenib or Sunitinib for Unfavorable Renal Carcinoma: Currently, in the United States and Canada, there is a shortage of technetium-99 (Tc-99m), the isotope used in MUGA scans. According to Covidien, beginning June 8, 2009 there will be a market impact reduction of approximately 50 percent due to a maintenance cycle at the HFR reactor. The June 8 reduction is estimated to last a few days. Additionally, there will be a four-week maintenance shut-down of the HFR reactor scheduled to begin mid-July. The Tc-99m shortage could affect patients on E2805. If your institution experiences a Tc-99m shortage, please refer to the Study Parameters in Section 7 of the protocol for cardiac assessment options.

If you have an ECOG related question please contact Joshua Schoppe

NSABP Update: The accrual goal for the BAHO sub study (which includes quality of life questionnaires, MD-reported cosmesis assessment, and digital photos assessments) associated with NSABP B-39/RTOG 0413 has been met. Please do not offer any additional patients the opportunity to participate in this sub study. All references to this optional sub study have been deleted from the main TJU consent form, and the separate sub study consent form has been removed from the JKCCN repository.

If you have an NSABP related question please contact Vicki Squire at vicki.squire@kimmelcancercenter.org or at 215-503-5641.

RTOG Update: Reminder, RTOG Meeting:

Registration and attendee information for the upcoming RTOG Semiannual Meeting has been posted on the RTOG website. The meeting will be held June 25-28, 2009, at the Chicago Marriott Downtown Magnificent Mile.



Information about the meeting can be found at <http://www.rtog.org/meeting/main.html> . Please take advantage of the opportunity to complete your meeting registration in advance via the website.

If you have an RTOG related question please contact Kelly Shipman.

Jefferson Oncology Group (JOG) Update: No new updates. Check back in 2 weeks. Please contact Joshua Schoppe or Vicki Squire with any JOG issues.

Reminder: JKCCN CRA Meeting: The next CRA meeting will be held at TJU on Wednesday, June 24, 2009: 9am- 1pm. The meeting will be held in the Bluemle building, room 105.

The Clinical Research E-News Archive is now located on the Kimmel Cancer Center webpage under the JKCCN Member Area:

http://www.kimmelcancercenter.org/kcc/JKCCN/jcn_eneewsletter.html

Please provide feedback and any suggestions to Joshua Schoppe at 215-955-0448 or email at Joshua.schoppe@jeffersonhospital.org