

## The Clinical Research E-News

**Volume 2: ISSUE 12:** June 16, 2010

*Please Note Volume 2: Issue 13 will be delayed a week until July 7<sup>th</sup> due to the July 4<sup>th</sup> holiday.*

**Coming soon:**

**NSABP P-5**, *Statin Polyp Prevention Trial in Patients with **Resected Colon Cancer***

**NSABP FC-6**, *A Phase II Study to Determine the Surgical Conversion Rate in Patients Receiving Neoadjuvant mFOLFOX7 Plus Cetuximab for Unresectable Wild-Type K-RAS **Colorectal Cancer** with Metastases Confined to the Liver*

**RTOG0920**, *A Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab for Locally-Advanced Resected **Head and Neck Cancer**.*

**RTOG 0937**, *Randomized Phase II Study Comparing Prophylactic Cranial Irradiation Alone to Prophylactic Cranial Irradiation and Consolidative Extra-Cranial Irradiation for **Extensive Disease Small Cell Lung Cancer (ED-SCLC)***

**RTOG 0915**, *Randomized Phase II Study Comparing 2 Stereotactic Body Radiation Therapy (SBRT) Schedules for Medically Inoperable Patients with **Stage I Peripheral Non-Small Cell Lung Cancer***

**ECOG 1697**, *Phase III Randomized Study of Four Weeks High Dose IFN-A2B in Stage T2B NO, T3A-B NO, T4A-B NO, and T1-4, N1A, 2A, 3 (microscopic) **Melanoma***



**CALGB10403, *An Intergroup Phase II Clinical Trial for Adolescents and Young Adults with Untreated Acute Lymphoblastic Leukemia (ALL)***

If your site is interested in participating in any of these studies please contact Rolma Gano at 215-955-7954 or [Rolma.gano@jeffersonhospital.org](mailto:Rolma.gano@jeffersonhospital.org).

**Regulatory Update:** The following study has had recent *consent* form change and updated letter posted on the repository website:

ECOG 1508

If this study pertain to your site please visit the repository at: <http://www.kimmelcancercenter.org/kcc/JKCCN/file-repository/>. Please contact Rolma Gano with any repository or other regulatory related questions.

**Quality Assurance Update:**

Audit Tip: To avoid a major deficiency at time of audit, please ensure the same method of disease evaluation is used throughout the course of treatment. As was discussed at today's JKCCN CRA meeting, if, for example, CT is used for baseline disease assessment, then CT must be used at all subsequent assessment time points.

Please contact Kelly Shipman with any QA related issues at 215-955-2135 or [Kelly.shipman@jeffersonhospital.org](mailto:Kelly.shipman@jeffersonhospital.org).

**CTSU Update:**

Please contact Joshua Schoppe with any CTSU related issues at 215-955-0448 or [Joshua.Schoppe@jeffersonhospital.org](mailto:Joshua.Schoppe@jeffersonhospital.org)

**ECOG Update:**

**E1508**, *A Randomized Phase II Study of Cisplatin and Etoposide in Combination with Either HedgeHog (HH) Inhibitor GDC-0449 or IGF-1R MoAB(IMC-A12) for Patients with Extensive Stage Small Cell Lung Cancer (SCLC)*, is currently **Re-Opened** to new accrual with the TJUH IRB approval of Addendum #4. The addendum updates the risk profile of IMC-A12.

**Performance Monitoring:** The next Performance Monitoring data cut-off date of June 30, 2010 is approaching. Any data received on or before **June 30, 2010** will be included in the upcoming Performance Monitoring. Data received after June 30, 2010 will be considered late. It is important to remember that data timeliness will be evaluated by assessing two components: The rate of CRF submitted 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.

If you have an ECOG related question please contact Joshua Schoppe.

**NSABP Update:**

**NSABP P-5**, *Statin Polyp Prevention Trial in Patients with Resected Colon Cancer*, will soon be open to accrual at TJUH and available to our cancer network affiliates. Although P-5 is a prevention trial, accrual will be counted in the interventional or treatment category. The accrual goal is 1,740. Scott Goldstein, MD, is serving as principal investigator. The primary aim of the trial is to determine if the administration of 5 years of postoperative rosuvastatin affects the 5-year occurrence of adenomatous polyps of the colon or rectum, metachronous colorectal carcinoma and colon cancer recurrence in patients with resected colon cancer.

If you have an NSABP related question please contact Vicki Squire at [vicki.squire@jeffersonhospital.org](mailto:vicki.squire@jeffersonhospital.org) or at 215-503-5641.



**RTOG Update:**

On June 23, 2010 sites participating in RTOG 0436 will begin using the CTSU OPEN registration system for patient enrollment. The RTOG web registration system for RTOG 0436 will no longer be available. In order to access OPEN, site staff will need to be registered with CTEP and have a valid and active CTEP-IAM account. This is the same account (user ID and password) used for the CTSU members' web site. Additionally, staff must be aligned with an institution on an organization roster in RSS (CTSU roster, Cooperative Group roster, or other network roster). Please make sure your RTOG group roster is up-to-date by contacting [RTOG\\_Membership@acr-arrs.org](mailto:RTOG_Membership@acr-arrs.org), and that your CTSU RSS roster is up to date by visiting the CTSU web site.

**Publication Spotlight:** The New England Journal of Medicine recently published an analysis of study data from RTOG 0129, "A Phase III Trial of Concurrent Radiation and Chemotherapy (Followed by Surgery for Residual Primary/N2-3 Nodal Disease) for Advanced Head & Neck Carcinomas." Investigators completed a retrospective analysis of the human papillomavirus (HPV) status of the oropharyngeal tumors based on in-situ hybridization. The results found that oropharyngeal cancer patients whose tumors test positive for HPV live longer than patients whose tumors test negative (82.4% vs. 57.1% at 3 years). Survival benefit was seen irrespective of assigned cancer treatment and traditional prognostic factors such as tumor stage and age.

The next RTOG Semiannual meeting will be held June 17-20, 2010, at the Loews Philadelphia Hotel in Philadelphia, PA. General information about the meeting can be found at <http://rtog.org/meeting/main.html>. On-site registration will be available.

**Jefferson Oncology Group (JOG) Update:**

If your site has any JOG inquires please contact either Josh Schoppe or Vicki Squire.



***Jefferson Kimmel Cancer Center Network Homepage:***  
<http://www.kimmelcancercenter.org/jkccn/>. This page contains links to the Remote Access Portal as well as the clinical trial document repository.

**Upcoming Events:**

**Otolaryngology Grand Rounds**, Philadelphia, PA: 5:30pm, June 16  
“FDG PET/CT in Head and Neck Cancer”

**RTOG Semiannual Meeting**, Philadelphia, PA: June 17-20

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

<http://www.kimmelcancercenter.org/jkccn/e-newsletters.html>

*Please provide feedback and any suggestions to Joshua Schoppe at 215-955-0448 or email [Joshua.schoppe@jeffersonhospital.org](mailto:Joshua.schoppe@jeffersonhospital.org)*