The Clinical Research E-News

ISSUE 22: November 11, 2009

Now Open:
RTOG 0815, A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy with or without Short-Term Androgen Deprivation Therapy for Patients with Intermediate-Risk Prostate Cancer.

Coming soon:
E1508, A Randomized Phase II Study of Cisplatin and Etoposide in Combination with either Hedgehog Inhibitor GDC-0449 or IGF-1R MOAB IMC-A12 for Patients with Extensive Stage Small Cell Lung Cancer.

E4508, Three-Arm Randomized Phase II Study of Carboplatin and Paclitaxel in Combination with Cetuximab, IMC-A12 or Both for Advanced Non-Small Cell Lung Cancer Patients Who Will Not Receive Bevacizumab-based Therapy will be opened to the JKCCN network only.

SWOG0819, A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) will be opened to the JKCCN network only.

NSABP B-46-I / USOR 07132: A Phase III Clinical Trial Comparing the Combination of TC Plus Bevacizumab to TC Alone and to TAC for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer.
RTOG 0621, *Adjuvant 3DCRT/IMRT in Combination with Androgen Suppression and Docetaxel for High Risk Prostate Cancer Patients Post-Prostatectomy: A Phase II Trial*.

If your site is interested in participating in any of these studies please contact Kelly Shipman at 215-955-2135 or Kelly.shipman@jeffersonhospital.org.

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

- B-44-I (BETH trial) Spanish consent
- R0825 amendments #1, amendment #2, and the 9/29/09 update
- R0619 update 10/13/09
- S0600 amendment #2
- E1505 consent
- E1305 consent
- R0232 consent
- R0534 consent
- R0526 consent

If any of these studies pertain to your site please visit the repository at: [http://www.kimmelcancercenter.org/kcc/JKCCN/file-repository/](http://www.kimmelcancercenter.org/kcc/JKCCN/file-repository/). Please contact Kelly Shipman at with any repository or other regulatory related questions.

**Quality Assurance Update:** Please contact Kelly Shipman with any QA related issues.
CTSU Update:

S0600, Phase III Trial of Irinotecan-Based Chemotherapy Plus Cetuximab (NSC-714692) with or without Bevacizumab (NSC-704865) as Second-Line Therapy for Patients with Metastatic Colorectal Cancer who have Progressed on Bevacizumab with either FOLFOX, OPTIMOX or XELOX, has been reactivated as of October 15, 2009. Amendment #2 has been approved by the TJUH IRB. This amendment changes the design of the protocol.

Oncology Patient Enrollment Network (OPEN) has expanded from ACOSOG Z1041, B-42 and S0777 to include PACCT-1 and E1505 as of November 4, 2009. If your sites participate in any of these trials remember to go to OPEN https://open.ctsu.org when you are ready to enroll your next patient. Remember you must have been given the registrar role in order to enter new enrollments in the OPEN system. Please contact your site’s CTSU administrator to have your role updated.

N0723, MARVEL, Marker Validation of Erlotinib in Lung Cancer- A Phase III Biomarker Validation study of Second-line Therapy in Patients With Advanced Non-Small Cell Lung Cancer (NSCLC) Randomized to Pemetrexed Versus Erlotinib, will be closing soon due to slow accrual.

If you have a CTSU related question please contact Joshua Schoppe at 215-955-0048 or Joshua.schoppe@jeffersonhospital.org.

ECOG Update:

E5103, A Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide followed by Paclitaxel with Bevacizumab or Placebo in Patients with Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer, was reviewed by the ECOG data monitoring committee on October 21, 2009. This study includes requirements for cardiac monitoring and early stopping rules for excessive cardiac toxicity. A monitoring rule on the rate of clinical CHF had
been met and accrual had been suspended on September 24, 2009. The DMC reviewed the data on cardiac toxicity. The DMC recommended the consent form be modified to reflect the current information on the risk of clinical CHF and the study then be reopened to accrual. Intensive monitoring of cardiac toxicity will continue. ECOG is currently drafting an amendment to reflect the DMC’s finding and the study is expected to reopen to accrual in the first quarter of 2010.

**E5597, Phase III Chemoprevention Trial of Selenium Supplementation in Persons with Resected Stage I Non Small Cell Lung Cancer**, was closed to accrual on November 5, 2009. The Eastern Cooperative Oncology Group’s Data Monitoring Committee (DMC) reviewed E5597 and determined the study was not likely to meet its endpoint. Therefore, the DMC recommended the study be closed to new accrual and the intervention be stopped.

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

**NSABP Update**: There are no new updates. If you have an NSABP related question please contact Vicki Squire at vicki.squire@kimmelcancercenter.org or at 215-503-5641.

**RTOG Update:**

**RTOG 0415**, "A Phase III Randomized Study of Hypofractionated 3D-CRT/IMRT Versus Conventionally Fractionated 3D-CRT/IMRT in Patients with Favorable-Risk Prostate Cancer," was closed to accrual on November 6, 2009.

The phase II component of **RTOG 0537**, "A Phase II/III Study Comparing Acupuncture-like Transcutaneous Electrical Nerve Stimulation (ALTENS) Versus Pilocarpine in Treating Early Radiation-Induced Xerostomia," was closed to accrual on October 23, 2009.
RTOG 0822, "A Phase II Evaluation of Preoperative Chemoradiotherapy Utilizing Intensity Modulated Radiation Therapy (IMRT) in Combination with Capecitabine and Oxaliplatin for Patients with Locally Advanced Rectal Cancer," will close to patient accrual at 5pm EST on Friday, November 13.

Important Reminder: When completing the neurocognitive assessment for your patients participating in RTOG 0424, 0525, 0534, 0614, and 0825, please submit to RTOG Headquarters the summary form only. The summary form contains the scores from the evaluations. Please keep the worksheets in the patient's record for audit purposes. Any worksheets submitted to Headquarters will be returned to you.

Please contact Kelly Shipman with any RTOG related issues.

Jefferson Oncology Group (JOG) Update: There are no new JOG updates, please contact Vicki Squire or Joshua Schoppe for any JOG related issues.

Upcoming Events:
JOG Investigator Conference Call: November 11, 2009
Dial-in instructions: Call 1-866-423-7434
When prompted enter the participant code 5031600 followed by #

Quarterly CRA meeting- Special Holiday Event:
Date: Wednesday, December 9, 2009
Time: 9:00am
Place: Room 202 Bluemle
Agenda: includes "JKCCN Interactive Game Show Live." Back by popular demand!
Lunch: at LaScala
RSVP: to Vicki Squire by 11/30/09 and please indicate your menu choice: cheese ravioli, rib eye sandwich or chicken parmigiano
NSABP Group Meeting, Atlanta, GA: November 20-21, 2009
JKCCN Quarterly CRA Meeting: December 9, 2009
RTOG Group Meeting, Tampa, FL: Jan. 14-17, 2010

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_eneWSletter.html

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