

The Clinical Research E-News

Volume 2: ISSUE 1: January 13, 2010

Coming soon:

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 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.*

RTOG 0621, *Adjuvant 3DCRT/IMRT in Combination with Androgen Suppression and Docetaxel for High Risk **Prostrate Cancer** Patients Post-Prostatectomy: A Phase II Trial will be opened to the JKCCN only.*

AZ1071, *A Phase II Study Evaluating the Role of Sentinel Lymph Node Surgery and Axillary Lymph Node Dissection Following Preoperative Chemotherapy in Women with Node Positive **Breast Cancer (T1-4, N1-2, M0)** at Initial Diagnosis*

E1208, *A Phase III Randomized, Double-Blind Trial of Chemoembolization with or without Sorafenib in Unresectable **Hepatocellular Carcinoma (HCC)** in Patients with and without Vascular Invasion.*



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**.*

E3903, *Ancillary Laboratory Protocol for Collecting Diagnostic Material on Patients Considered for ECOG Treatment Trials for **Leukemia or Related Hematologic Disorders**.*

E3F05, *Phase III Study of Radiation Therapy with or without Temozolomide for Symptomatic or Progressive **Low-Grade Gliomas**.*

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 0539, *Phase II Trial of Observation for Low-Risk **Meningiomas** and of Radiotherapy for Intermediate- and High-Risk **Meningiomas**.*

RTOG 0631, *Phase II/III Study of Image-Guided Radiosurgery/SBRT for **Localized Spine Metastasis**.*

RTOG 0834, *A Phase III Trial on Concurrent and Adjuvant Temozolomide Chemotherapy in Non-1p/19q deleted **Anaplastic Glioma**.*

RTOG 0848, *A Phase III Trial Evaluating Both Erlotinib and Chemoradiation as Adjuvant Treatment for Patients with Resected Head of **Pancreas Adenocarcinoma**.*



S0521, *A Randomized Trial of Maintenance Versus Observation for Patients with Previously Untreated Low and Intermediate Risk Acute Promyelocytic Leukemia (APL), Phase III.*

If your site is interested in participating in any of these studies please contact Rolma Gano at 215-955-7954 or Rolma.mancinow@jeffersonhospital.org.

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

E5103 (re-consent)

E1505

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 Gano with any repository or other regulatory related questions.

Quality Assurance Update:

As part of the JKCCN Quality Assurance Program, we will soon be e-mailing another round of overdue data listings, the purpose of which is to remind you to please continue submitting your study data on time. On-time data submission may affect your ability to participate in certain limited-institution trials. For example, RTOG 0813 is a phase I trial that requires at least 80% on-time data submission for participation. Thank you for your continued on-time data submission efforts!

Please contact Kelly Shipman with any QA related issues at 215-955-2135 or Kelly.shipman@jeffersonhospital.org.



CTSU Update:

The **OPEN system** is now available for the following studies: **E1505, PACCT-1, S0777, and ACOSOG Z1041**. You must be designated in the Registrar role on the CTSU roster to be able to use the system to register and randomize patients. Please contact your site's CTSU Administrator to ensure you have been given the role of "Registrar."

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, IS OPEN TO NEW ACCRUAL*. The TJUH IRB has reviewed and approved Addendum #5 for this study. Addendum #5 includes a revision to the consent form requested by the Data Monitoring Committee (DMC) in order to reflect the current information on the risk of clinical congestive heart failure. All patients in follow up and active treatment will need to be re-consented. Pages 11 and 12 in the newly issued consent will need to be reviewed and initialed by all patients currently on study or in follow up. The signature page will need to be completed as well per the TJU IRB re-consent policy.

PACCT-1, *Program for the Assessment of Clinical Cancer Tests (PACCT-1), Trial Assigning Individualized Options for Treatment: The TAILORx Trial*, Addendum #5 has been reviewed and approved by the CIRB. The CIRB approval has been submitted to the TJU IRB but not yet reviewed. Addendum #5 adds a Quality of Life Component to the study which will not be mandatory but will count for additional cancer control credits. Notification will be sent out once this Addendum is approved by the TJU IRB.



E2205, *A Phase II study to Measure Response Rate and Toxicity of Neo-adjuvant Chemoradiotherapy with Oxaliplatin (OX) and Infusional 5-Fluorouracil (5-FU) Plus Cetuximab Followed by Post-Operative Docetaxel and Cetuximab in Patients with Operable Adenocarcinoma of the Esophagus*, closed to accrual effective January 8, 2009.

ECOG Coordinating Center will be closed Monday January 18, 2010, for the Martin Luther King, Jr. holiday.

ECOG has developed a Spanish version of "A Guide to Clinical Trials for Cancer Patients" to inform patients and their families with an overview of clinical trials and to provide basic information about this treatment option. The brochure language is exactly the same as the English version, as it describes the various trials patients can participate in, suggests and lists important questions patients should ask their physician, and lists benefits and risks associated with participating in a trial. If you would like to request copies for distribution, contact Donna Griggs, Communications Manager at 215-789-3636 or dgriggs@ecogchair.org. Or, you can download and print copies from the following link. <http://www.ecog.org/general/clinguide.html>

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

NSABP Update: B-42 closed to accrual on January 6, 2010. A total of 8 patients were accrued to the Registration Program and a total of 24 patients were accrued to the randomized trial. Hematology and Oncology Associates of Northeastern PA (NEPA) randomized the most patients with Riddle Memorial Hospital and Associates in Hematology and Oncology tying for the second largest accrual. This was an important trial in the realm of hormonal therapy for breast cancer. We can be proud of our level of participation. Your hard work is appreciated!



Screening Logs for BETH and all Foundation Research Program trials (FC-4, FB-6) are due on the first of each month. Please include all screened patients and any information you think may be helpful to the NSABP. If you have any questions regarding these logs, please contact Vicki Squire.

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

RTOG Update:

The **RTOG Semi-Annual meeting** will take place January 14-17, 2010, in Tampa, FL. For those of you who are unable to attend this meeting, I will be bringing back plenty of updates back to share in the next edition of the JKCCN E-Newsletter. Please note that two Semi-Annual Meeting sessions will be broadcast as webinars:

- Research Associates Scientific Session: Friday, January 16, 1-3pm ET
- Health Services Research Outcomes (HSRO) & Symptom Management Committee Session: Saturday, January 17, 10am-noon ET

To participate in the webinars you must register ahead of time at <http://www.signup4.net/public/ap.aspx?EID=RTOG10E&OID=130>. After you register you will be sent a confirmation e-mail with instructions on how to log in to the session(s). It is also recommended that you run the diagnostic test at this time to ensure you have the correct software to participate in the webinar.

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

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



Jefferson Kimmel Cancer Center Network Homepage:
<http://www.kimmelcancercenter.org/jkccn/>. Our homepage has a new link!
This new page contains links to the SAE system as well as the clinical trial document repository.

Upcoming Events:

RTOG Group Meeting, Tampa, FL: Jan. 14-17, 2010

JOG Conference Call: Feb. 10, 2010 at 5:00pm

JKCCN Personalized Medicine Symposium, Philadelphia, PA: Mar 12, 2010

JKCCN Quarterly CRA Meeting, TJU: Mar 24, 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/jkccn/e-newsletters.html>

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