

The Clinical Research E-News

Volume 3: ISSUE 16: September 28, 2011

Jefferson Kimmel Cancer Network: For urgent clinical trial questions or assistance please page: 877-656-9004

Now Open:

C70604, *A Randomized, Phase III Study of Standard Dosing versus Longer Dosing Interval of Zoledronic Acid in **Metastatic Cancer***

RTOG 1005, *A Phase III Trial of Accelerated Whole Breast Irradiation with Hypofractionation plus Concurrent Boost Versus Standard Whole Breast Irradiation plus Sequential Boost for **Early-Stage Breast Cancer***

Coming soon:

C90202, *A Randomized, Double-Blind, Placebo-Controlled, Phase III Study of Early Versus Standard Zoledronic Acid to Prevent Skeletal-Related Events in Men with **Prostate Cancer Metastatic to Bone***

E6508, *A Phase II Study of L-BLP25 and Bevacizumab in Unresectable Stage IIIA and IIIB **Non-Squamous Non-Small Cell Lung Cancer** after Definitive Chemoradiation*

RTOG 0933, *A Phase II Trial of Hippocampal Avoidance During Whole Brain Radiotherapy for **Brain Metastases**--RTOG CCOP Study*

RTOG 1016, *Phase III Trial of Radiotherapy Plus Cetuximab Versus Chemoradiotherapy in HPV-Associated **Oropharynx Cancer***

RTOG 1021, A Randomized Phase III Study of Sublobar Resection (+/- Brachytherapy) versus Stereotactic Body Radiation Therapy in High Risk Patients with Stage I Non-Small Cell Lung Cancer (NSCLC)

RTOG 1114, Phase II Randomized Study of Rituximab, Methotrexate, Procarbazine, Vincristine, and Cytarabine With and Without Low-Dose Whole-Brain Radiotherapy for Primary Central Nervous System Lymphoma

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.

Regulatory Update:

C90203: Update #5

S0221: Revision #7

E1505: Consent

E1508: Closure to Accrual

R1010: Amend #1

B-43: Amend #4

C70604: New Study Letter

R0920: Consent

E3805: Consent

P-5: Consent

C-11: Consent

N0577: Addendum #4

C40502 : Update #5

C80405 : Consent

R0839: Consent

E2804: Update #6

E1305: Addendum #6

S0500: Revision #8

S0777: Revision #12

C40502, R0839, and S0777 all require a re-consent for patients on active treatment or have received protocol related treatment within the last 30 days. Please contact Rolma Gano with any repository or other regulatory related questions.

Serious Adverse Event (SAE) Reporting Update: Going forward all patient hospitalizations including Emergency Room visits regardless of grading and or duration need to be reported to the Thomas Jefferson University Institutional Review Board using the eSAEy system. Please contact Joshua Schoppe with any questions at 215-955-0448 or Joshua.Schoppe@jeffersonhospital.org

CRA Meeting Update: All slides from the September 14th CRA meeting are on the clinical trial repository. Additionally a current master list of open trials is available on the repository which can be accessed with your campus key through this link: <http://www.kimmelcancercenter.org/kcc/JKCCN/file-repository/>

CTSU Update:

S0777, *A Randomized Phase III Trial of CC-5013 (Lenalidomide, NSC-703813) and Low Dose Dexamethasone (LLD) Versus Bortezomib (PS-341, NSC-681239), Lenalidomide and Low Dose Dexamethasone (BLLD) for Induction, in Patients with Previously Untreated Multiple Myeloma Without an Intent for Immediate Autologous Stem Cell Transplant, **requires a re consent*** due to the risk profile update of Lenalidomide in Revision #12. Changes occurred on pages 2-3 and 14-15 of the consent form. Please have all active patients initial and date the changed pages as well as getting all signatures on the last page.

C40502, *A Randomized Phase III Trial of Weekly Paclitaxel Compared to Weekly Nanoparticle Albumin Bound (Nab)-Paclitaxel or Ixabepilone Combined with Bevacizumab as First-Line Therapy for Locally Recurrent or Metastatic Breast Cancer, **requires a re consent*** due to the changes included in Update #5 which closed ARM C. Changes to the consent form occurred on pages 2-4, 6, and 9. Please have all active patients initial and date the changed pages as well as getting all signatures on the last page.

Please contact Joshua Schoppe with any CTSU related issues.

ECOG Update:

Protocol Notice: Shortage of Paclitaxel: This message affects the following actively accruing ECOG protocols: E1308, **E1505**, E2208, E2508, E3508, **E5508 & E6508**. ECOG has been notified that suppliers of paclitaxel are experiencing shortages of the drug. Information found at the manufacturers/suppliers websites suggest that the shortages may last until September.

Notice to Investigators Regarding the Lenalidomide Counseling Program:

ECOG has received notice from CTEP to remind sites that your site will need to have two counselors trained through Celgene's Lenalidomide Counseling Program (LCP) available to counsel all patients receiving lenalidomide supplied by the Division of Cancer Treatment and Diagnosis. Sites must document that two counselors have been trained to maintain active trial status and order drug. During audits, auditors will ask to see documentation of counselor training and monthly patient counseling. ***The deadline for this training is September 30, 2011.*** This letter affects the following **ECOG protocols: E1A05, E1A06, E3A06, E2905, E4A03** and can be accessed via the following link:

http://www.ecog.org/ecoginst/notices/Notices_PIs_LCP.PDF

FALL 2011 ECOG GROUP MEETING – Registration is now open!! The meeting will be held at the Westin Diplomat Resort and Spa in Hollywood, FL from Nov 11-13, 2011. Meeting registration will be done completely online. There are no registration fees for the meeting for ECOG members. To register for the Group Meeting, please use the following link:

https://www.regonline.com/ECOG_fall2011

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*, follow-up reminder for the current (and final) 18 MONTH QOL Assessment Point. Please remind your patients that we appreciate their continued participation in this trial as we come to the final assessment with them.

Upcoming Performance Monitoring: The next Performance Monitoring data cut-off date of **September 30, 2011** is quickly approaching. Any data received on or before **September 30, 2011** will be included in the upcoming Performance Monitoring. Data received after September 30, 2011 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. This message is only a reminder concerning the upcoming Performance Monitoring. Data should be submitted according to normal procedures.

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

NSABP Update:

P-5: *Statin Polyp Prevention Trial in Patients with Resected Colon Cancer*, Amendment #2 and a patient-directed brochure will be IRB approved within the next two weeks. Look for the approvals on our repository.

B-35: *A Clinical Trial Comparing Anastrozole with Tamoxifen in Postmenopausal Patients with Ductal Carcinoma in Situ (DCIS) Undergoing Lumpectomy with Radiation Therapy*: NSABP requests immediate attention to submission of treatment data (Form T). Form Ts are to be submitted once for each patient for any of the following reasons:

- When tamoxifen/anastrozole is completed at the end of 5 years

- When tamoxifen/anastrozole is permanently discontinued for any reason (there is no OFF Form for B-35)
- If the patient never begins tamoxifen/anastrozole

B-39/ R0413: *A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer:* Beginning on September 23, 2011, form submission of the NSABP B-39 Adverse Event Form (Form AE) will become online only via Coordinator on Line. Other means of submission will not be accepted after 9/23/11.

C-11: *A Phase III Study Evaluating the Role of Perioperative Chemotherapy in Patients with Potentially Resectable Hepatic Colorectal Metastases:* A slide presentation and new documents, "Frequently Asked Questions" and "Protocol Overview", were posted on the NSABP Members Website on 9/13/11. These are not for patient use.

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

RTOG Update:

RTOG has recently activated several Phase III trials of interest. Please let us know if you site would like to participate in any of the following trials:

- **RTOG 0924**, *Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial*
- **RTOG 1005**, *A Phase III Trial of Accelerated Whole Breast Irradiation with Hypofractionation plus Concurrent Boost Versus Standard Whole Breast Irradiation plus Sequential Boost for **Early-Stage Breast Cancer***

- **RTOG 1016**, *Phase III Trial of Radiotherapy Plus Cetuximab Versus Chemoradiotherapy in HPV-Associated Oropharynx Cancer*
- **RTOG 1021**, *A Randomized Phase III Study of Sublobar Resection (+/- Brachytherapy) versus Stereotactic Body Radiation Therapy in High Risk Patients with Stage I Non-Small Cell Lung Cancer (NSCLC)*

Please contact Joshua Schoppe with any RTOG related issues.

Jefferson Oncology Group (JOG) Update:

The EPIC Trial: *The Elderly and Poor Performance Status Individualized Chemotherapy Trial Randomized Phase III Multicenter Trial of Customized Chemotherapy versus Standard of Care for 1st Line Treatment of Elderly and Poor Performance Status Patients with Advanced Non-Small-Cell Lung Cancer*, if you are site is interested in participating please contact Josh or Vicki at your earliest convenience.

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:

Breast Care Coordinators Networking Meeting, Philadelphia, PA:

November 11

ECOG Semiannual Meeting, Hollywood, FL: November 11-13

CRA Quarterly Meeting, Philadelphia, PA: December 14

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