The Clinical Research E-News

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

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

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 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)
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:**

- R0617: Amend #9
- GOG262: Revision #2
- R0912: temporary closed
- E4805: Final Closure
- C90802: Update #1

- R0436
- E2906: Update #3
- E4A03: Addendum #13
- R0929: temporary closed

*Patients on R0617 need to be re-consented even if they are in follow-up. The long term safety risks for the high dose radiation arms in the opinion of the TJU IRB needs to be disseminated to all active patients. None of the other studies require a re-consent.* Please contact Rolma Gano with any repository or other regulatory related questions.

**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 trained CTEP registered counselors for Lenalidomide counseling. Sites should make every attempt to complete counselor training by the updated deadline of *September 30, 2011*.

**CALGB Studies:** CALGB Data and Safety Monitoring Board (DSMB) Report is now available on the protocol documents list for the following CALGB studies: CALGB-10603, CALGB-30506, CALGB-30607, CALGB-30610, CALGB-30801, CALGB-40101, CALGB-40502, CALGB-40503, CALGB-

Please contact Joshua Schoppe with any CTSU related issues at 215-955-0448 or Joshua.Schoppe@jeffersonhospital.org

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

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

**NSABP Update:**
Revised worksheets for protocol treatment and adverse event forms have been posted for **C-11 and B-47**.

**B-43:** Amendment #4 has been posted. The essential element of the amendment is the elimination of FISH analysis on IHC1+ DCIS. FISH analysis of IHC1+ DCIS specimens was discontinued as of April 11, 2011 because the FISH positive rate for IHC1+ specimens was only 0.36%. This means patients whose DCIS is IHC1+ are ineligible. IHC2+ will continue to be referred to a central lab for FISH analysis.

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

**RTOG Update:**
**R0617**, *A Randomized Phase III Comparison of Standard-Dose (60 Gy) Versus High-Dose (74 Gy) Conformal Radiotherapy with Concurrent and Consolidation Carboplatin/Paclitaxel +/- Cetuximab in Patients With Stage IIIA/IIIB Non-Small Cell Lung Cancer*, was amended to remove the high dose radiation therapy arms. *Amendment #9 was approved by the TJU IRB on August 12, 2011 and all active patients need to be re-consented and informed of the safety risk of the high dose radiation.*

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/](http://www.kimmelcancercenter.org/jkccn/). This page contains links to the Remote Access Portal as well as the clinical trial document repository.

**Upcoming Events:**

**CRA Quarterly Meeting**, Philadelphia, PA: September 14
Breast Care Coordinators Networking Meeting, Philadelphia, PA: November 11
ECOG Semiannual Meeting, Hollywood, FL: November 11-13

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