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

E1809, Randomized Phase II Trial of Docetaxel with or without PSATRICOM Vaccine in Patients with Castrate-Resistant Metastatic Prostate 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:**

- S0819: Revision #9
- S0500: Revision #7
- S1007: Step 1 consent
- C-11: new consent
- C10403: new consent
- R0517: amendment #5
- R0534: new consent
- E2603: Update #3
- E2905: Addendum #5 + consent

*None of these studies require a re-consent.* Please contact Rolma Gano with any repository or other regulatory related questions.

**CTSU Update:**

Due to a national shortage of paclitaxel, the GOG has instituted the following recommendations concerning patients currently being treated on GOG studies. These recommendations are to be used only if the site does not have paclitaxel available for use. We expect this shortage to require deviation from the protocol for 1-2 cycles only. *We request that sites not initiate new patients on studies for which they do not have drug supply to initiate and complete their treatment per protocol.*

- **For GOG 252 and 262:** Substitute docetaxel at 55-75 mg/m2 IV every 3 weeks (see dose modification tables in protocols). Omit day 8 IP paclitaxel (if applicable). For carboplatin containing regimens, reduce carboplatin AUC by one unit when giving docetaxel.
- **For GOG 258 and 249:** Substitute docetaxel at 55 - 75 mg/m2 IV every 3 weeks. Reduce carboplatin AUC by one unit when giving docetaxel.
Please contact Joshua Schoppe with any CTSU related issues at 215-955-0448 or Joshua.Schoppe@jeffersonhospital.org

**ECOG Update:**

**E1508**, *A Randomized Phase II Study of Cisplatin and Etoposide in Combination with Either Hedgehog Inhibitor GDC-0449 or IGF-1R MoAB*, will close to accrual on August 12, 2011. Patients currently on this study should be followed according to the protocol.

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

**NSABP Update:**

The **STAR trial**, *a Study of Tamoxifen and Raloxifene (STAR) for the Prevention of Breast Cancer (NSABP P-2)*, will officially close to follow up on May 31, 2012, at which time a 10 year follow up analysis will be performed. Please continue to submit all relevant data to NSABP.

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

**RTOG Update:**

**R0436**, *A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation for Patients With Esophageal Cancer Who Are Treated Without Surgery*, has re-opened to accrual. RTOG and The Food and Drug Administration (FDA), through their ongoing safety review, identified a disproportionate number of deaths and serious adverse events in patients over the age of 75 participating in RTOG 0436. An amendment was previously released to address these safety concerns, which changed the eligibility criteria to exclude patients $\geq$ 75 years of age.
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:**
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