The Clinical Research E-News

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Now Open:
RTOG 0937, Randomized Phase II Study Comparing Prophylactic Cranial Irradiation Alone to Prophylactic Cranial Irradiation and Consolidative Extra-Cranial Irradiation for Extensive Disease Small Cell Lung Cancer (ED-SCLC)

Coming soon:
CALGB10403, An Intergroup Phase 2 Clinical Trial for Adolescents and Young Adults with Untreated Acute Lymphoblastic Leukemia (ALL)

NSABP FC-6, A Phase II Study to Determine the Surgical Conversion Rate in Patients Receiving Neoadjuvant mFOLFOX7 Plus Cetuximab for Unresectable Wild-Type K-RAS Colorectal Cancer with Metastases Confined to the Liver

RTOG 0929, A Randomized, Phase I/II Study of ABT-888 in Combination with Temozolomide in Recurrent (Temozolomide Resistant) Glioblastoma

RTOG 1014, A Phase II Study of Repeat Breast Preserving Surgery and 3D-Conformal Partial Breast Irradiation (PBRI) for Local Recurrence of Breast Carcinoma

GOG 248, A Randomized Phase II Trial of Temsirolimus or the Combination of Hormonal Therapy Plus Temsirolimus in Women with Advanced, Persistent, or Recurrent Endometrial Carcinoma
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:** The following study has had a recent consent form change and updated letter posted on the repository website: SWOG0500

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

**CTSU Update:**
CALGB80405, *A Phase III Trial of Irinotecan / 5-FU / Leucovorin or Oxaliplatin / 5-FU / Leucovorin with Bevacizumab, or Cetuximab (C225), or with the Combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum*, released Update #8 on July 20, 2010 to update the risk factors associated with cetuximab. This update **DOES NOT** mandate local suspension of accrual.

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

**ECOG Update:**
E2805, *ASSURE: Adjuvant Sorafenib or Sunitinib for Unfavorable Renal Carcinoma*, will close to accrual effective 5:00pm EST **September 1, 2010** because this study is approaching its accrual goal. Patients currently on this study should be followed according to the protocol. Quality of Life
evaluations, follow-up, sample submissions and disease and cardiac imaging studies should continue during the follow-up period as specified in the protocol.

*Please see this week's E-Newsletter supplement that details ECOG's response to the recent FDA findings in regard to Bevacizumab.*

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

**NSABP Update:**
**NSABP R-04, A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion of 5-Fluorouracil with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum,** will close to accrual at 4:00 pm EST on Monday August 16, 2010. Please keep this in mind as you continue to screen for potential patients and obtain informed consent. NSABP will not grant extensions beyond that deadline. Accrual as of August 4th is 1598 patients; 8 are still required to reach the accrual goal of 1606 patients.

An excellent resource for **B-43** is now available: Nurse/CRA Frequently Asked Questions: [https://members.nsabp.pitt.edu/B-43.asp](https://members.nsabp.pitt.edu/B-43.asp)

If you have an NSABP related question please contact Vicki Squire at [vicki.squire@jeffersonhospital.org](mailto:vicki.squire@jeffersonhospital.org) or at 215-503-5641.

**RTOG Update:**
**RTOG 1014, "A Phase II Study of Repeat Breast Preserving Surgery and 3D-Conformal Partial Breast Re-Irradiation (PBRI) for Local Recurrence of Breast Carcinoma,"** is now available in CTSU's OPEN patient registration system. Jefferson is in the process of opening this trial.
The stage 1B cohort of RTOG 0627, "Phase II Trial of Dasatinib in Patients with Recurrent Glioblastoma Multiforme," will close to patient accrual at 5pm EST on Tuesday, August 10, because it has accrued the required number of patients. This protocol will be suspended while data from the stage 1B cohort are analyzed to determine whether there is sufficient evidence of response to proceed to the next stage of accrual.

Jefferson Oncology Group (JOG) Update:
If your site has any JOG inquiries please contact either Josh Schoppe or Vicki Squire.

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:
JKCCN CRA Meeting, Philadelphia, PA: September 15
SoCRA Annual Conference, Dallas, TX: September 24-26
Geriatric Oncology Conference, Philadelphia, PA: November 4
ECOG Fall Meeting, Ft. Lauderdale, FL.: November 5-7

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