

The Clinical Research E-News

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Now Open:

N0577, *Phase III Intergroup Study of Radiotherapy versus Temozolomide alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with 1p/19q Codeleted Anaplastic Glioma*

RTOG0920, *A Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab for Locally-Advanced Resected **Head and Neck Cancer**.*

Coming soon:

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 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)***

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 studies have had recent *consent* form changes and updated letter posted on the repository website:

SWOG0500
R0920

E4402
R0825



R0614

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: The most common pharmacy deficiencies pertain to investigative agents not being returned in a timely manner and satellite pharmacy records not matching up with control records. Please make sure to notify your pharmacist when protocols close to accrual and when all patients have completed treatment. Also, satellite records must be maintained at any location outside of the central pharmacy that stores any agent overnight; the central pharmacy should have both sets of records on file. Thank you for your efforts toward continuous audit readiness!

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 #7 on June 15, 2010 to update the risk factors for both Arms A and B. This update was submitted to the TJU IRB for the July 22, 2010 meeting and will be reviewed as an expedited priority.

S0600, *Phase III Trial of Irinotecan-Based Chemotherapy Plus Cetuximab (NSC-714692) with or without Bevacizumab (NSC-704865) as Second-Line Therapy for Patients with Metastatic Colorectal Cancer who have Progressed on Bevacizumab with either FOLFOX, OPTIMOX or XELOX*, released



Revision 4 and an Action Letter for cetuximab on July 13, 2010. Accrual does not need to be suspended; however, all new patients must be verbally made aware of updated risks associated with cetuximab.

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

ECOG Update:

PACCT-1, *Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment: The TAILORx Trial*, will close to Pre-Registrations effective **August 20, 2010 at 5:00pm** because this study is approaching its accrual goal. Patients currently on this study should be followed according to the protocol. Quality of Life evaluations should continue during the follow-up period as specified in the protocol.

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

NSABP Update:

NSABP P-5, *Statin Polyp Prevention Trial in Patients with Resected Colon Cancer*, is **OPEN** to accrual at TJUH and available to our Cancer Network affiliates. Although P-5 is a prevention trial, accrual will be counted in the interventional or treatment category. The accrual goal is 1,740. Scott Goldstein, MD, is serving as Principal Investigator. The primary aim of the trial is to determine if the administration of 5 years of postoperative rosuvastatin affects the 5-year occurrence of adenomatous polyps of the colon or rectum, metachronous colorectal carcinoma and colon cancer recurrence in patients with resected colon cancer.

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

RTOG Update:

The National Cancer Institute (NCI) recently issued an Action Letter for protocols RTOG 0436, 0617, and 0920, because the risk profile for cetuximab was recently modified. NCI does NOT believe the modified risk information significantly alters the risk-benefit profile for patients already enrolled to these trials. New accrual is NOT being suspended because of these changes. When the TJU IRB reviews and approves the amendments associated with these protocols, the new consents will be posted on the JKCCN repository. If you enroll a patient to one of these trials prior to the new consent being issued, please verbally inform your patients of the additional risks and document that this was done.

RTOG 0614, *A Randomized, Phase III, Double-Blind, Placebo-Controlled Trial of Memantine for Prevention of Cognitive Dysfunction in Patients Receiving Whole-Brain Radiotherapy*, will close to patient accrual at 5pm today, Wednesday, July 21, because the study has met its accrual objective.

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