The Clinical Research E-News

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

Now Open for Network Participation
RTOG 1216, Randomized Phase II/III Trial of Surgery and Postoperative Radiation Delivered with Concurrent Cisplatin Versus Docetaxel and Cetuximab for High Risk Squamous Cell Cancer of the Head and Neck

Pending Studies for Network Participation:
ALLIANCE 041202, A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL)

ECOG 1910, A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-negative B lineage Acute Lymphoblastic Leukemia in Adults

ECOG 2212, A Randomized, Double-Blinded, Placebo-Controlled Phase II Study of Adjuvant Everolimus Following the Resection of Metastatic Pancreatic Neuroendocrine Tumors to the Liver

ECOG 2515, Phase I and Randomized Phase II Double Blind Clinical Trial of Cisplatin and Etoposide in Combination with Veliparib (ABT-888) or Placebo as Frontline Therapy for Extensive Stage Small Cell Lung Cancer- ECOG
Members only
ECOG 3311, Phase II Randomized Trial of Transoral Surgical Resection followed by Low-dose or Standard-dose IMRT in Resectable p16+ Locally Advanced Oropharynx Cancer.

ECOG 3612, A randomized Phase II Trial of Ipilimumab with or without Bevacizumab in Patients with Unresectable Stage III or Stage IV Melanoma-ECOG Members only

RTOG1306, A Randomized Phase II Study of Individualized Combined Modality Therapy for Stage III Non-Small Cell Lung Cancer (NSCLC)

Please contact Rashada Dawson at 215-955-2135 or Rashada.Dawson@jeffersonhospital.org if your site is interested in participating in any of these trials.

Regulatory Update:
E2804- Addendum #15
E1609- amend revisions to protocol only
B-49- amend revisions to protocol only
R1114- Amend #4
R9501- Final Report

Please contact Rashada Dawson for any regulatory update inquiries.

CTSU Update:
Accountability of NCI-Supplied Oral Agents: The Pharmaceutical Management Branch of the NCI has announced that effective March 1, 2014, use of the new NCI Investigational Agent Accountability Record for Oral Agents (Oral DARF) is mandatory. The policy and a copy of the new NCI
Investigational Agent Accountability Record for Oral Agents (Oral DARF) may be obtained at
Questions or comments regarding accountability and storage of investigational agents should be addressed to the Pharmaceutical Management Branch by telephone (240-276-6575) or email PMBafterhours@mail.nih.gov.

**S1216, A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 With Androgen Deprivation Therapy + Bicalutamide in Patients With Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer**, new information: for all participating sites: serum submission for androgen testing to ARUP Laboratories, Lab #208, is being temporarily suspended. Effective February 1, 2014

**E1412, Randomized Phase II Open Label Study of Lenalidomide R-CHOP (R2CHOP) vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma,** is now available to all CTSU member sites. Effective January 22, 2014. This study has been approved by the TJU IRB. Please contact Rashada Dawson if your site is interested in participating in this trial.

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

**ECOG Update:**
The latest issue of the e-newsletter is now available. To view the January 2014 issue of “News from ECOG-ACRIN,” click here:
http://archive.constantcontact.com/fs156/1110677545555/archive/1116270183104.html  This e-newsletter appears every two months. Scientific committee leaders, research support committee leaders and senior staff may submit

**E1Z11**, *A Cohort Study to Evaluate Genetic Predictors of Aromatase Inhibitor Musculoskeletal Symptoms (AIMSS)*, will close to new Caucasian/Other races cohort effective February 24, 2014. Please note that the Asian cohort and the African-American cohort of this study will both remain open to accrual. Enrollment to these important minority cohorts is strongly encouraged.

**E3F05**, *Phase III Study of Radiation Therapy with or without Temozolomide for Symptomatic or Progressive Low-Grade Gliomas*, has been suspended to new accrual, effective February 3, 2014. New accrual to E3F05 has been suspended due to updated findings from RTOG 98-02. This recent analysis showed that study participants who received PCV after radiation therapy lived longer compared to those receiving radiation therapy alone. A Physician letter containing additional information regarding this suspension is now available.

**E2410**, *A Phase II Trial of Response-Adapted Therapy Based on Positron Emission Tomography (PET) for Bulky Stage I and II Classical Hodgkin Lymphoma (HL)*, has closed to new accrual, effective January 24, 2014. The study has failed to meet its accrual targets. Therefore, E2410 is closing due to slower than expected accrual.

Please contact Joshua Schoppe with any ECOG related issues.

**NSABP Update:**

**B-32**, *A Randomized, Phase III Clinical Trial To Compare Sentinel Node Resection To Conventional Axillary Dissection In Clinically Node-Negative Breast Cancer Patients*: This trial was closed to follow up effective February 14, 2014. The presentation of the long term results of B-32 was named "Best
of ASCO" for its "high-impact and practice-changing" research results. Read more at: http://www.nsabp.pitt.edu/B32_Best_of_ASCO.pdf

**B-51/RTOG 1304**, *A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy*: Two slide presentations have been posted on the NSABP Members Website, "Overview" and "Radiotherapy Requirements":

https://members.nsabp.pitt.edu/Treatment_Slide_Presentations_Open.asp

Screening Logs for **NSABP B-50-I** and **FC-7** should be faxed at the beginning of each month to this new fax number: 412-697-6618. For questions regarding screening logs contact 1-800-270-3165.

Please contact Vicki Squire with any NSABP related issues at 215-503-5641 or Vicki.squire@jeffersonhospital.org

**RTOG Update:**
**RTOG Newsletter Posted:** Inside the Winter 2014 RTOG Newsletter: an overview of the recently submitted NRG Oncology NCORP grant, a conversation with Adam Dicker, MD, PhD about exciting translation research plans on the horizon for NRG Oncology, a highlight of the recently activated RTOG 1308 trial, the first phase III randomized trial to compare patient survival after photon versus proton chemoradiation for patients with stage III non-small cell lung cancer and more!

http://www.rtog.org/LinkClick.aspx?fileticket=rBp_0O6J8X8%3d&tabid=360

**NRG Oncology Statistical Reports for Semiannual Meeting:** The NRG Oncology Statistical Reports, containing standard summaries of RTOG trials as well as GOG and NSABP studies from our new partners, are available for
download on the NRG Oncology Web site. The Statistics and Data Management Center (SDMC) staff collaborated to produce a common format for this first combined report representing the entire portfolio of active NRG Oncology studies. In the future, we will continue to work to improve the NRG Oncology report with respect to content and usability. Special thanks to individuals from the three legacy SDMCs who worked hard to bring this material together. To access the statistical reports navigate to the NRG Oncology Web site (www.nrgoncology.org) and select the NRGONCOLOGY MEMBER LOGIN link located in the upper right corner.

Username: nrgmeeting
Password: n1r2g345.

Please contact Joshua Schoppe with any RTOG related issues.

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:
CRA Quarterly Meeting: Webcast: March 21
ECOG Meeting: Chicago, IL, May 8-10
CRA Quarterly Meeting: June 11
NRG Meeting: Chicago, IL, July 10-13
CRA Quarterly Meeting: September 19
ECOG Meeting: Orlando, FL, November 13-5
CRA Quarterly Meeting: December 12
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