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

New Featured Trials Actively Recruiting at the Kimmel Cancer Center at Jefferson:

1. Title: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Phase 3 Study of the Safety, Tolerability, and Efficacy of CMX001 for the Prevention of Cytomegalovirus (CMV) Infection in CMV-seropositive (R+) Hematopoietic Stem Cell Transplant Recipients
   a. Objective: The primary efficacy endpoint of this study will be the incidence of clinically significant CMV infection through Week 24 post transplant [Time Frame: 24 weeks].
   b. Treatment: Placebo Comparator: CMX001 placebo BIW, Drug: Brincidofovir (CMX001), Active Comparator: CMX001 100mg and 100 mg CMX001 BIW. Drug: Brincidofovir (CMX001).
   c. Eligibility: Subjects will be adult allogeneic HSCT recipients aged ≥ 18 years-old (or as applicable, per local law) who were CMV seropositive before transplantation and CMV viremia negative post transplant. Subjects will be adult allogeneic HSCT recipients aged ≥ 18 years-old (or as applicable, per local law) who were CMV seropositive before transplantation and CMV viremia negative post transplant.
   d. Contact: Deborah Kilpatrick, RN at 877-656-7115 or Deborah.kilpatrick@jefferson.edu

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*

**EA 2131**, *A Phase I and Randomized, Double-Blinded Phase II Study of nab-Paclitaxel/Gemcitabine plus AZD1775 or Placebo in Treatment-Naïve Metastatic Adenocarcinoma of the Pancreas*

**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 2511**, *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*

**ECOG3311**, *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*

**GOG-0286B**, *A Randomized Phase II/III Study of Paclitaxel/Carboplatin/Metformin (NSC#91485) Versus Paclitaxel/Carboplatin/Placebo as Initial Therapy for Measurable Stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer*
NSABP-B-52, A Randomized Phase III Trial Evaluating Pathologic Complete Response Rates in Patients with Hormone Receptor-Positive, HER2-Positive, Large Operable and Locally Advanced Breast Cancer Treated with Neoadjuvant Therapy of Docetaxel, Carboplatin, Trastuzumab, and Pertuzumab (TCHP) with or Without Estrogen Deprivation

NSABP-B-55, A Randomised, Double-Blind, Parallel Group, Placebo-Controlled Multi-Centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy

N0577, Phase III Intergroup Study of Temozolomide Alone Versus Radiotherapy with Concomitant and Adjuvant Temozolomide Versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma

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

RTOG1308, Phase III Randomized Trial Comparing Overall Survival after Photon Versus Proton Chemoradiotherapy for Inoperable Stage II-IIIIB NSCLC

Please contact Joshua Schoppe at 215-955-0448 or Joshua.Schoppe@jefferson.edu if your site is interested in participating in any of these trials.
Regulatory Update:
C80702 - Patient Material
PACCT-1 - Addendum #8
E5103 - Addendum #11
R1205 - Amend #2 & 3
E1505 - Addendum #13
E3085 - Addendum #6
R0241 - Final Report
E1208 - Addendum #6
R0920 - Amend #7
R1005 - Amend #3
R0848 - Pt Material
E2804 - Addendum #16
R0938 - Amend #3
R1014 - Amend #3

Please contact Joshua Schoppe for any regulatory update inquiries.

NCTN Update:
CIRB Signatory Institutions: Signatory Institutions are required to inform the CTSU which CIRB-enrolled institutions are participating in studies opened via the CIRB. To accomplish this, the CTSU has designed a new application called the Site Preference feature on the CTSU website that will allow the CTSU to load and maintain participation information provided by CIRB Signatory Institutions. The settings loaded by the CTSU are viewable by individuals on the CIRB roster of the Signatory Institution. Should a Signatory Institution feel their established site preference setting does not best reflect their network of CIRB institutions, the CTSU should be notified right away. For example, a Signatory Institution may obtain a new Affiliate/Component Institution or terminate an existing Affiliate/Component Institution; therefore, causing site preference levels to change. To change a site preference setting previously established, call or email the CTSU Regulatory Office at 866-651-CTSU or CTSURegPref@ctsu.coccg.org.

Please contact Joshua Schoppe at 215-955-0448 or at Joshua.schoppe@jefferson.edu with any NCTN related issues.
ECOG-ACRIN Update:
PACCT-1, Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment: The TAILORx Trial: Protocol Notice for Quality of Life Data Needed for Final Analysis was released on July 10, 2014. In anticipation of the final analysis on the Quality of Life (QOL) component, the ECOG-ACRIN Operations Office is requesting that a priority be placed on faxing all outstanding QOL forms and Data Clarification Forms (DCFs) to (617) 632-2444, Attention to: TAILORx DM.

The clinical study report for the following ECOG-ACRIN protocol is now available: E2804 – The BeST Trial: A Randomized Phase II Study of VEGF, RAF Kinase and MTOR Combination Targeted Therapy (CTT) with Bevacizumab, Sorafenib and Temsirolimus in Advanced Renal Cell Carcinoma: To access the report, please use the following link: http://www.ecog.org/ecoginst/finalreports/E2804_clin_study_rpt.pdf

The next Performance Monitoring data cut-off date of September 30, 2014 is approaching. Any data received on or before September 30, 2014 will be included in the upcoming Performance Monitoring. Data received after September 30, 2014 will be considered late. It is important to remember that data timeliness will be evaluated by assessing two components: The rate of CRF submitted and the rate of survival follow-up. To avoid penalties, each evaluable ECOG-ACRIN institution must have a score of 90% or better on each component.

Please contact Joshua Schoppe with any ECOG-ACRIN related issues.

NRG Update:
NRG Oncology PROTOCOL ACTIVATIONS: Activation of Protocol NSABP-B-55, CTSU Activation Date: 07/03/14
**Protocol Title:** A Randomised, Double-Blind, Parallel Group, Placebo-Controlled Multi-Centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy

*Activation of Protocol RTOG-0912*, CTSU Activation Date: 06/23/14

**Protocol Title:** A Randomized Phase II Study of Concurrent Intensity Modulated Radiation Therapy (IMRT), Paclitaxel and Pazopanib (NSC 737754)/Placebo, for the Treatment of Anaplastic Thyroid Cancer

**RTOG 1016,** Phase III Trial of Radiotherapy Plus Cetuximab Versus Chemoradiotherapy in HPV-Associated Oropharynx Cancer

*For Dosimetrists and Physicists,* affective Aug 4th RTOG will initiate a hard stop validation for submissions to TRIAD for RTOG 1016 ONLY. This means that if the structure names do not match the list in section 6.6 exactly - you will not be able to submit your digital RT data.

**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). Amendment 4: The interim toxicity analysis plan was modified and age was added as a stratification variable.

**R1016,** Phase III Trial of Radiotherapy Plus Cetuximab Versus Chemoradiotherapy in HPV-Associated Oropharynx Cancer, will close to patient accrual on Thursday, July 31st at 5 p.m. Eastern because the study will have met its accrual objective.
**B-43, A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma in Situ Resected by Lumpectomy:** Administrative changes resulting from the transition to NRG Oncology and NCI-requested changes were made to the protocol. The updated Fact Sheet and Pathology and Correlative Instructions for NSABP B-43 have also been posted.

**B-47, A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer:** Administrative changes resulting from the transition to NRG Oncology and NCI-requested changes were made to the protocol. The updated Fact Sheet and Pathology and Correlative Instructions for NSABP B-47 have also been posted.

**B-49, A Phase III Clinical Trial Comparing the Combination of Docetaxel Plus Cyclophosphamide to Anthracycline-Based Chemotherapy Regimens for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer:** Administrative changes resulting from the transition to NRG Oncology and NCI-requested changes were made to the protocol. The updated Fact Sheet and Pathology and Correlative Instructions for B-49 have also been posted.

Please contact Christine Bonaccorso at 215-955-7954 or Christine.Bonaccorso@jefferson.edu with any related NRG issues.

**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: TJU campus, September 19
JOG Meeting, The Sheraton Valley Forge Hotel in KOP, October 9,
JKCCN Navigator Meeting, TJU campus, November 7th,
ECOG Meeting: Orlando, FL, November 13-15
CRA Quarterly Meeting: TJU Campus, December 12,


The Office for Human Research Protections (OHRP) is co-sponsoring a Research Community Forum (RCF) with local institutions in Philadelphia, PA on Thursday and Friday, October 23rd and 24th 2014 entitled "Moving Beyond the Basics of Informed Consent."

Changes in the research environment, technological advances, and a greater understanding of related ethical concerns have made the issue of informed consent in research increasingly complex. This RCF will examine consent related challenges faced by IRBs, investigators, and other members of the research community. The conference will foster thought provoking topics and stimulating discussions, and provide creative solutions to these challenges.

This dynamic two-day event will be co-hosted by the Children's Hospital of Philadelphia, the University of Pennsylvania, Drexel University, Temple University, Thomas Jefferson University, and the Wills Eye Hospital.

The conference will be held at the Sheraton Philadelphia Society Hill Hotel at 1 Dock St., Philadelphia, PA 19106 in the Old City section of Philadelphia.
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