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

1. **Title:** *A Phase 1b, Open-Label, Non-Randomized Multicenter Study of Birinapant in Combination with Conatumumab in Subjects with Relapsed Epithelial Ovarian Cancer, Primary Peritoneal Cancer or Fallopian Tube Cancer*
   
a. **Eligibility:** 1) Pathologically confirmed ovarian cancer (epithelial ovarian, cancer, primary peritoneal cancer, or fallopian tube cancer) that are second line platinum resistant or platinum sensitive subjects who are unable to receive further platinum based therapy. Subjects may have had a maximum of 3 prior systemic chemotherapy regimens (excluding hormonal and investigational). 2) Subjects with Cancer that progresses within 6 months of completion of first line platinum-based therapy are excluded.

   b. **Objective:** To determine the safety of birinapant when administered in combination with conatumumab, to define the maximum tolerated dose (MTD) of birinapant when administered in combination with conatumumab, and, to determine the recommended Phase 2 dose of birinapant when administered in combination with conatumumab.

   c. **Contact:** Cynthia Perez, CCRP at 877-656-712 or Cynthia.perez@jefferson.edu

2. **Title:** *A Phase I/II Study of Romidepsin in Combination With Abraxane in Patients With Metastatic Inflammatory Breast Cancer*
   
a. **Eligibility:** 1) Patients must have histologically or cytologically confirmed breast carcinoma with a clinical diagnosis of IBC based on the presence of inflammatory changes in the involved breast, such as diffuse erythema and edema (peau d'orange), with or without an underlying palpable mass involving the majority of the skin of the breast. Pathological evidence of dermal lymphatic invasion should be noted but is not required for diagnosis. 2) Patients must have demonstrated metastatic disease and not received >2 lines of systemic therapy for metastatic disease.

   b. **Objective:** To assess the safety of the combination of romidepsin plus Abraxane (paclitaxel albumin-stabilized nanoparticle formulation) delivered weekly. (Phase I)
To determine the maximum tolerated dose (MTD) of romidepsin with full dose weekly Abraxane to define a recommended phase II doses of the combination. (Phase I) To assess the progression-free survival (PFS) in patients with human epidermal growth factor receptor 2 (HER2) negative, newly diagnosed metastatic inflammatory breast cancer treated with the combination of romidepsin and Abraxane. (Phase II).

c. Contact: Cynthia Perez, CCRP at 877-656-712 or Cynthia.perez@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

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

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

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-IIIB NSCLC

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

Regulatory Update:

R1119- Final Report
JOG63- Amend
R0924- Amend
R0913-Amend # 4&5
R1106- Final Report
R0617- Amend #1
R0848- Amend #5, re-open

Please contact Rashada Dawson for any regulatory update inquiries.

NCTN Update:

On April 8, 2014, CTSU announced it would move forward with changing the access paradigm for OPEN, Rave, and protocol documents from CTSU roster control to control based upon the participating organization rosters. The proposed transition which was to occur over the weekend of April 12-13 but was postponed to May 5, 2014 as internal reports showed that over 2000 persons would lose access to Rave studies and protocol documents. All clinical site staff needing access to Rave and OPEN must have the appropriate access roles at each site and on each roster to which they are associated (e.g., Rave at
sites 1, 2, and 3 on the NRG and the ECOG-ACRIN roster). Please use the Site Roles application under the Regulatory tab to verify that you are aligned on all associated rosters at the appropriate sites and have the appropriate roles.

Please contact Joshua Schoppe at 215-955-0448 or at Joshua.schoppe@jefferson.edu with any NCTN related issues.

ECOG-ACRIN Update:
The ECOG-ACRIN Cancer Research Group (ECOG-ACRIN) and Syndax Pharmaceuticals, Inc have begun patient recruitment for **E2112, a randomized phase III clinical trial of Syndax’s entinostat in treatment of patients with advanced breast cancer**. The trial will evaluate whether the addition of entinostat to endocrine therapy ( exemestane) improves progression-free survival and/or overall survival in men and postmenopausal women with hormone receptor-positive, human epidermal growth factor 2-negative advanced breast cancer who have previously progressed on a nonsteroidal aromatase inhibitor. Please contact Rashada Dawson if your site is interested in participating in this new trial.

The **Therapeutic Studies Subcommittee** of the ECOG-ACRIN Data Safety Monitoring Committee (DSMC) met by conference call on April 22, 2014 to review all ongoing phase III and randomized phase II therapeutic studies coordinated by ECOG-ACRIN. Their recommendations have been posted at: [http://www.ecog.org/ecoginst/DMC.html](http://www.ecog.org/ecoginst/DMC.html)
Please contact Mary Steele at the Operations Office – Boston at (617-632-3610) with questions.

Please contact Joshua Schoppe with any ECOG-ACRIN related issues.
NRG Update:
The **NRG Oncology Semi Annual Meeting** will be held July 10 – 13, 2014, in Chicago, Illinois. The link to the meeting registration is here: [http://www.nrgoncology.org/AboutUs/Meetings/NRGOncologyJuly2014Meeting/Registration.aspx](http://www.nrgoncology.org/AboutUs/Meetings/NRGOncologyJuly2014Meeting/Registration.aspx)

Message from the NRG Oncology Group Chairs:  As many of you know, the NCTN Lead Protocol Organizations (LPOs) have received their grant awards from the NCI and, like most of the other LPOs, NRG Oncology's grant funding is significantly less than the sum of our legacy group awards. Because of the reduced funding we have made adjustments in our Operations and Statistics & Data Management budgets including staff reductions and process changes. One area of concern is the cost of our semiannual meeting which accounts for nearly $800,000 of our operating budget, most of which is not supported by our grant. While we continue to work with our corporate partners to help defray these costs, we do not expect to be able to meet all of our meeting expenses with external funding. In order to continue to provide many of the meeting services that our members value, including continental breakfasts, coffee breaks, the reception, meeting area WiFi, and free-of-charge CME programs, we are instituting a $100 registration fee for all physician and PhD investigator members and a $50 registration fee for all other members. The registration fee will begin with the July 2014 NRG Oncology semiannual meeting in Chicago.

**RTOG 1008, A Randomized Phase II Study of Adjuvant Concurrent Radiation and Chemotherapy Versus Radiation Alone in Resected High-Risk Malignant Salivary Gland Tumors**, Amendment 6: The required timeframe for the CBC/differential, serum creatinine, total bilirubin, and AST or ALT was expanded from 4 to 8 weeks to provide more flexibility to sites, and clarifications were made in Section 6.0.
RTOG 1010, A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of Her2-Overexpressing Esophageal Adenocarcinoma: The Current Accrual listed on the RTOG Website on the Protocol Information Page for RTOG 1010 reflects the total accrual to STEP 1 (HER2 screening). This study will continue to accrue until 160 cases have completed STEP 2 registration. The current accrual to RTOG 1010 - STEP 2 registration is 133 as of 4/30/14.

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/. This page contains links to the Remote Access Portal as well as the clinical trial document repository.

Upcoming Events:
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