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

1. **Title:** Randomized Phase 2 Study of MLN8237, an Aurora A Kinase Inhibitor, plus Weekly Paclitaxel or Paclitaxel Alone in Patients with Recurrent Ovarian, Fallopian Tube or Primary Peritoneal Cancer, Preceded by a Phase I Portion in Patients with Ovarian or Breast Cancer
   
   a. **Trial Objective:** To assess PFS after treatment with the combination of MLN8237 and weekly paclitaxel or weekly paclitaxel alone in patients with recurrent OC, and to compare PFS of the populations enrolled to these 2 treatment arms. Secondary objectives include response rate and its duration, overall survival and more precisely define toxicities. Archived tissue and blood will be analyzed for predictive markers of response.
   
   b. **Eligibility:** Women 18 years or older with an ECOG performance status of 0 or 1 and have histologically confirmed diagnosis of ovarian, fallopian tube or primary peritoneal cancer. Up to 4 prior regimens is permitted as long as at least one of them contained a platinum agent and a taxane. Patients must be less than 12 months out from their last platinum based therapy.
   
   c. **Treatment:** Arm 1 (Combination Arm) Alisertib 40 mg PO BID 3 days on, 4 days off for 3 weeks w/ Paclitaxel 60 mg/m2 on Days 1, 8, 15 Arm B-(single agent) weekly paclitaxel at 80 mg/m2 on days 1, 8, 15
   
   d. **Contact:** Cynthia Perez at 215-955-9626 or Cynthia.Perez@jefferson.edu

2. **Title:** A Randomized, Open-Label, Phase 2 Study of the IDO Inhibitor, INCB024360 versus Tamoxifen for Subjects with Biochemical-Recurrent-Only Epithelial Ovarian Cancer, Primary Peritoneal Carcinoma, or Fallopian Tube Cancer Following Complete Remission with First-Line Chemotherapy

   a. **Trial Objective:** To determine efficacy based on progression free survival (PFS) of INCB024360 versus tamoxifen among subjects with CA-125 elevation following complete remission with first-line chemotherapy for advanced disease
b. **Eligibility:** The subject must be able to give written informed consent and female, age 18 years or older who have had histologically confirmed FIGO Stage III or IV EOC, PPC, or FTC. The subject must have had a complete response to a single, prior first-line regimen which must have been a platinum-containing regimen, and subject is currently in clinical and radiological remission based on Response Evaluation Criteria in Solid Tumors (RECIST 1.1) criteria. Subjects who received maintenance paclitaxel or bevacizumab are eligible for enrollment provided they have discontinued therapy at least 4 weeks from randomization for prior taxane or at least 8 weeks from prior bevacizumab. Subjects must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1.

c. **Treatment:** This is a randomized, open-label, Phase 2 study of INCB024360 versus tamoxifen in women with histologically confirmed Federation of International Gynecologists and Obstetricians (FIGO) Stage III or IV epithelial ovarian cancer (EOC), primary peritoneal cancer (PPC), or fallopian tube carcinoma (FTC) who have had biochemical-recurrence defined as an increasing CA-125 level that is > upper limit of normal (ULN) and successively increasing on 2 consecutive measurements at least 4 weeks apart without evidence of disease. Approximately 110 subjects will be randomized 1:1 to receive INCB024360 300 mg twice daily (BID) or tamoxifen 20 mg BID.

d. **Contact:** Cynthia Perez at 215-955-9626 or Cynthia.Perez@jefferson.edu

**Now Open for Network Participation**

**CALGB80702,** *A phase III trial of 6 versus 12 treatments of adjuvant FOLFOX plus celecoxib or placebo for patients with resected stage III colon cancer*

**Pending Studies for Network Participation:**

**NSABP-50-I/ GBG77 (KATHERINE) Trial:** *A Randomized, Multicenter, Open-Label Phase III Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine versus Trastuzumab as Adjuvant Therapy for Patients with HER-2Positive Primary Breast Cancer Who Have Residual Tumor Present Pathologically in the Breast or Axillary Lymph Nodes Following Preoperative Therapy*
NSABP B-51, 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

RTOG1205, Randomized Phase II Trial of Concurrent Bevacizumab and Re-Irradiation Versus Bevacizumab Alone as Treatment for Recurrent Glioblastoma

RTOG1216, Randomized Phase II/III Trial of Surgery and Postoperative Radiation Delivered with Concurrent Cisplatin versus Docetaxel versus Docetaxel and Cetuximab for High-Risk Squamous Cell Cancer of the Head and Neck

SWOG1207, Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer

SWOG1216, 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

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:
RTOG0539 - Protocol Revisions
ECOG1305 - QA consent
SWOG0777 - Revision #17
NSAPB B-43 - Closed to Accrual at TJU, remains open at JKCCN
ECOG1512 - New Approval
CALGB80702 - New Approval
CALGB80702 - Amend #5
ECOG2805 - Addendum #12
NSAPB B-49 - Closed to Accrual at TJU, remains open at JKCCN

Please contact Rashada Dawson for any clinical trial document repository questions or concerns.

RTOG Update:
The RTOG Meeting Semiannual meeting will be held at the Philadelphia Loews Hotel, Philadelphia PA from June 13 – 16, 2013. If you are planning to attend the meeting, please make sure that you register for the meeting by June 10th. You may complete the online registration form for the meeting at the following link: http://www.rtog.org/AboutUs/RTOGMeetings/UpcomingMeetingInfo.aspx
Registration for the meeting must be completed by Monday, June 10th.

R1014, “A Phase II Study of Repeat Breast Preserving Surgery and 3D-Conformal Partial Breast Re-Irradiation (PBrI) for Local Recurrence of Breast Carcinoma” will close to patient accrual at 5 PM EST Tuesday, June 18th because the study has met its accrual objective. Data collection and site IRB renewal for closed studies must continue until the study is terminated.

Please contact Joshua Schoppe at 215-955-0448 or at Joshua.schoppe@jeffersonhospital.org with any RTOG related issues.
**CTSU Update:**
The CTSU was recently notified that the U.S. Food and Drug Administration (FDA) posted an update version of the Statement of Investigator, Form FDA 1572. The new OMB expiration date for this form is April 30, 2015. For trials requiring study-specific 1572 forms, the CTSU will no longer accept submissions containing the previous version as of July 1, 2013. Attached is link to the updated form on the FDA’s website:
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf Please feel free to contact the CTSU Regulatory Office Help Desk at 1-866-651-CTSU if you have any questions.

Please contact Joshua Schoppe with any CTSU related issues.

**ECOG Update:**
**Upcoming Performance Monitoring:** The next Performance Monitoring data cut-off date of **June 30, 2013** is approaching. Any data received on or before June 30, 2013 will be included in the upcoming Performance Monitoring. Data received after June 30, 2013 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 institution must have a score of 90% or better on each component.

The May 2013 issue of "**News from ECOG-ACRIN**" is now available http://archive.constantcontact.com/fs156/1110677545555/archive/1113554009463.html

**E1512, A Randomized Phase II Trial of Erlotinib, Cabozantinib, or Erlotinib plus Cabozantinib as 2nd or 3rd Line Therapy in Patients with EGFR Wild-type NSCLC** was activated at TJU on April 25, 2013. It is open to all ECOG

**E1Z11, A Cohort Study to Evaluate Genetic Predictors for Aromatase Inhibitor Musculoskeletal Symptoms (AIMSS)** was activated by ECOG on May 8, 2013. The study will be available to all JKCCN members through CTSU. If interested please send your regulatory documents to the attention of Joshua Schoppe.

Please contact Joshua Schoppe with any ECOG related issues.

**NSABP Update:**

**P-5: Statin Polyp Prevention Trial in Patients with Resected Colon Cancer:** The Nurse/CRA Guidelines have been revised to include information related to the expanded eligibility criteria. Please refer to this document as you screen for P-5. [https://members.nsabp.pitt.edu/P5_Nurse-CRA_Guidelines.pdf](https://members.nsabp.pitt.edu/P5_Nurse-CRA_Guidelines.pdf)

**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: On 5/20/2013 an email blast was posted for B-43. It focuses on important fast facts for the trial. [https://members.nsabp.pitt.edu/B43_Email_Blast_0513.pdf](https://members.nsabp.pitt.edu/B43_Email_Blast_0513.pdf)

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

**Jefferson Oncology Group (JOG) Update:**

Save the date for the Annual Investigators Meeting on October 10th at Sheraton in Valley Forge.
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, Jefferson Campus: June 26, 2013
GOG Semi-Annual Meeting, San Antonio, TX: July 18-20
CRA Quarterly Meeting, Jefferson Campus: September 11, 2013
JOG Annual Meeting, Sheraton Valley Forge, PA, October 10, 2013
ECOG-ACRIN Meeting, Fort Lauderdale, FL: November 15-17, 2013
CRA Quarterly Meeting, Jefferson Campus: December 18, 2013
NRG Meeting, San Diego, CA, February 6-9, 2014

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