New Trials Opened at the Kimmel Cancer Center at Jefferson:

1. **New Multiple Myeloma Clinical Trial Announcement: A Multicenter, Single-Arm, Open-Label Treatment Use Program for Pomalidomide in Combination with Low Dose Dexamethasone in Subjects with Relapsed or Refractory Multiple Myeloma**
   a. **Eligibility:** Inclusion Criteria: Must have documented diagnosis of relapsed or relapsed/refractory multiple myeloma and have measurable disease (serum M-protein \( \geq 0.5 \) g/dL or urine M-protein \( \geq 200 \) mg/24 hours) per the IMWG criteria. Must be refractory to both lenalidomide and a proteasome inhibitor and have documented progression during or within 60 days after completion of the last lenalidomide and a proteasome inhibitor therapy. Exclusion Criteria: Peripheral neuropathy \( \geq \) Grade 2. Non-secretory multiple myeloma. Any anti-myeloma drug therapy or radiation within the past 14 days of initiation of study treatment
   b. **Treatment:** Oral POM at 4 mg on Days 1-21 of a 28-day cycle, Oral DEX at 40 mg/day (\( \leq 75 \) years old) or 20 mg/day (\( > 75 \) years old) on Days 1, 8, 15 and 22 of a 28-day cycle
   c. **Contact:** Cathy Harriman at pager 878-656-9517 or cathy.harriman@jefferson.edu

2. **New Clinical Trial Announcement: A Phase I Study of TL32711 in Combination with Gemcitabine in Patients with Advanced Solid Tumors**
   a. **Eligibility:** Histologically or cytologically confirmed solid tumors that are advanced or metastatic for which gemcitabine-based treatment is considered standard therapy. Patient must consent to the use of their archival tumor tissue for protocol use if available. Patients with at least one measurable site of disease as defined by RECIST version 1.1 that has not been previously irradiated. Life expectancy \( \geq \) 3 months.
   b. **Treatment:** This is a single-arm, open-label, Phase I dose-escalation study of TL32711 in combination with gemcitabine consisting of 2 parts. Part A is the dose exploration portion, “3+3” dose escalation design to determine the MTD. Part B
(expansion cohort) will enroll 10 or more advanced solid tumor patients to further characterize the tolerability of the study combination.

c. **Contact:** Briana Shields at pager 878-656-7116 or Briana.Shields@jefferson.edu

**Pending Studies 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*

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

**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*

If your site is interested in participating in any of these studies please contact Joshua Schoppe at 215-955-0448 or at Joshua.schoppe@jeffersonhospital.org.

**Regulatory Update:**

- B-30- Final Report
- JOG61- Amend#4
- S1207- Initial Approval
- E2108- Amend #4
- FB-5- IB
- R1106- Amend #2
- E3903- Amend
- P-5- Amend #3
- C-07- Final Report
- C90203- Closure Letter
- R0912- Temp closure
- R1175- Update #2
- E2809- Update #3
- C-08- Final Report
- B-34- Final Report
Regulatory Notice: Key Personnel. The addition of non-essential key personnel, ie those persons not involved in treatment related protocol activities will only be added or removed from a study at the time of annual review.

Please contact Rashada Dawson at 215-955-2135 or Rashada.Dawson@jeffersonhospital.org with any repository related questions.

CTSU Update:
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, has been pre-activated by SWOG and is available through CTSU. This study will open to accrual shortly. If your site is interested, please submit your site’s regulatory paperwork at your earliest convenience.

Please contact Joshua Schoppe with any CTSU related issues.

ECOG Update:
Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment: The TAILORx Trial, Addendum #7 is in the process of IRB review. Please note that this addendum includes the activation of ancillary study EL112LAB, North American Breast Cancer groups Biospecimen Bank for Determinants of Late Relapse in Operable Breast Cancer. 0.1 cancer control credit is available for patients who consent and submit samples. Please let us know if your site is interested in participating.

E5103: A Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide followed by Paclitaxel with Bevacizumab or Placebo in Patients with Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer, Addendum
#10 is in the process of IRB review. Please note that this addendum includes the activation of ancillary study EL112LAB, North American Breast Cancer groups Biospecimen Bank for Determinants of Late Relapse in Operable Breast Cancer. 0.1 cancer control credit is available for patients who consent and submit samples. Please let us know if your site is interested in participating.

**ECOG Core Committee:** The CRA Core Committee has openings for new members. The committee's purpose is to develop committee policy, provide educational materials and programs, and coordinate efforts with all scientific, modality, and ad hoc committees within ECOG-ACRIN. The applications are due by May 1, 2013. If you are interested please contact the ECOG Core Committee Chair, Joshua Schoppe, at your earliest convenience.

**Performance Monitoring:** The next Performance Monitoring data cut-off date of March 31, 2013 is approaching. Any data received on or before March 31, 2013 will be included in the upcoming Performance Monitoring. Data received after March 31, 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.*

**Travel Funds Available for the Spring 2013 ECOG-ACRIN Group Meeting:** The ECOG CRA CORE Committee has limited funds available for travel assistance to the Spring ECOG-ACRIN Group meeting to be held May 16 – 18, 2013 in Atlanta, GA. These funds are intended to facilitate attendance to the ECOG-ACRIN meetings for CRAs with no other form of travel support. Only one candidate per institution will be supported. CRAs interested in applying for funds can download an application form from the ECOG web page at the link below: [http://www.ecog.org/ecoginst/cragroup.html](http://www.ecog.org/ecoginst/cragroup.html) or contact
Christine Jerome via email christine.jerome@fccc.edu no later than March 29th, 2013.

Please contact Joshua Schoppe with any ECOG related issues.

**NSABP Update:**

**Pre-Activation of B-51:** A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chest wall 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- This new NSABP protocol can now be viewed on their Members Website. Please review the protocol to determine your interest and contact Vicki Squire if you have questions.

**Activation of B-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- Several JKCCN sites have completed pre-site visits for this trial and will be moving forward with essential documents. The protocol will be posted on the Division of Industry Trials of the NSABP Members Website this week. If you plan to participate, please take the time to read the protocol, since only a summary of the trial has been available up to this date.

**MPR-1:** NSABP Patient Registry and Biospecimen Profiling Repository- The goal of the trial is to run genetic profiles on the tissue from patients with metastatic colorectal cancer. These genetic profiles will be used to design protocols for cohorts of patients with matching genetic profiles. Several months ago we polled for interest in this trial. Many sites looked at their tumor registry numbers to determine their interest in participating. Then the NSABP
decided to offer the trial to the Jefferson campus only. Now that decision has been reversed, the NSABP is encouraging satellite sites to participate. Please contact Vicki Squire if you are interested in participating in this trial.

P-5: Statin Polyp Prevention Trial in Patients with Resected Colon Cancer-
The NSABP has prepared a media release for this trial. It can be viewed on the Members Website. Please contact Vicki Squire if you would like to use this release. It requires IRB approval.

B-39/RTOG0413: A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer- If you have this trial open at your institution, please go to the Members Website to view a recent Email Blast regarding the effort to move the trial to completion.

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

RTOG Update:
Permanent Closure Notice: R0436, A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation for Patients With Esophageal Cancer Who Are Treated Without Surgery- Following the evaluation of the RTOG 0436 study data and discussions with the RTOG Data Monitoring Committee, this study was permanently closed to accrual on February 8, 2013. No additional study cetuximab will be provided. Reminder: Data collection and site IRB renewal for closed studies must continue until the study is terminated.

R0524, A Phase I/II Trial Of A Combination Of Paclitaxel And Trastuzumab With Daily Irradiation Or Paclitaxel Alone With Daily Irradiation Following
Transurethral Surgery For Non-Cystectomy Candidates With Muscle-Invasive Bladder Cancer, closed to accrual on February 22, 2013, as the HER2 negative cohort has met its accrual objective and due to the HER2 positive cohort not meeting targeted accrual goals. Reminder: Data collection and site IRB renewal for closed studies must continue until the study is terminated.

**Pre-Activation:** R1216, 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 - Note: Per the new NCI Protocol Setup and Assignments Policy (effective 10/1/12), this study has been granted the status of “Pre-Activation.” This status is used to permit the release of the Cancer Therapy Evaluation Program (CTEP)-approved protocol to our member sites for submission to their local IRBs. Please contact Joshua Schoppe if your site is interested in opening.

**R1016**, Phase III Trial of Radiotherapy Plus Cetuximab versus Chemoradiotherapy in HPV-Associated Oropharynx Cancer: The quality of life (QOL) component of the study has met its accrual objective (400 patients; as specified in Section 13.7 of the protocol) and that component is now closed to accrual. The Behavioral Risk Assessment Survey System (BRASS optional) will be collected on all patients that consent to it. Note: RTOG 1016 remains open to accrual to the treatment and translational research components.

**R1005**, A Phase III Trial of Accelerated Whole Breast Irradiation with Hypofractionation plus Concurrent Boost Versus Standard Whole Breast Irradiation plus Sequential Boost for Early-Stage Breast Cancer- The cosmesis subset for patients not receiving chemotherapy has met its accrual and will be closed to further enrollment at close of business on Friday March 8th, 2013. This closure date will be noted in the next protocol amendment. The cosmesis subset for patients that are receiving chemotherapy will continue.
to accrue until its target is met. *Please note that this closure broadcast is for the non-chemotherapy cosmesis subset only. The study as a whole is still accruing.*

Please contact Joshua Schoppe with any RTOG related issues.

Jefferson Oncology Group (JOG) Update:
No studies, please check back next month

**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, Webinar: March 20, 2013 10:00-11:30AM
- ECOG-ACRIN Meeting, Atlanta, GA: May 14-16, 2013
- CRA Quarterly Meeting, Jefferson Campus: June 26, 2013
- CRA Quarterly Meeting, Jefferson Campus: September 11, 2013
- ECOG-ACRIN Meeting, Fort Lauderdale, FL: November 15-17, 2013
- CRA Quarterly Meeting, Jefferson Campus: December 18, 2013

*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*