Now Open:
CALGB 90802, Randomized Phase III trial comparing everolimus plus placebo versus everolimus plus bevacizumab for advanced renal cell carcinoma progressing after treatment with tyrosine kinase inhibitors

NSABP B-47, A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of TC or Four Cycles of AC Followed by Four Cycles of Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Normal Invasive Breast Cancer

RTOG0912, A Randomized Phase II Study of Concurrent Intensity Modulated Radiation Therapy (IMRT), Paclitaxel and Pazopanib/Placebo, for the Treatment of Anaplastic Thyroid Cancer

Coming soon:
ACOSOG Z1041, A Randomized Phase III Trial Comparing a Neoadjuvant Regimen of FEC-75 Followed By Paclitaxel Plus Trastuzumab With a Neoadjuvant Regimen of Paclitaxel Plus Trastuzumab Followed by FEC-75 Plus Trastuzumab in Patients with HER-2 Positive Operable Breast Cancer

E2108, A Randomized Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Women with Metastatic Breast Cancer
E2408, A 3-Arm Randomized Phase II Trial of Bendamustine-Rituximab (BR) Followed by Rituximab vs Bortezomib-BR (BVR) Followed by Rituximab vs BR Followed by Lenalidomide/Rituximab in High Risk Follicular Lymphoma

E2906, Phase III randomized trial of Clofarabine as induction and post-remission therapy vs. standard Daunorubicin and Cytarabine induction and intermediate dose Cytarabine post remission therapy, followed by Decitabine maintenance vs. observation in newly diagnosed acute myeloid leukemia in older adults (age >60 yrs)

E3108, A Phase II Prospective Trial Correlating Progression Free Survival with CYP2D6 Activity in Patients with Metastatic Breast Cancer Treated with Single Agent Tamoxifen.

E7208, A Randomized Phase II Study of Irinotecan and Cetuximab with or without the Anti-angiogenic Antibody, Ramucirumab (IMC-1121B), in Advanced, K-ras Wild-type Colorectal Cancer Following Progression on Bevacizumab-Containing Chemotherapy.

GOG 252, A Phase III Clinical Trial of Bevacizumab with IV Versus IP Chemotherapy, in, Ovarian, Fallopian Tube and Primary Peritoneal Carcinoma

GOG 262, A Randomized Phase III Trial of Every-3-weeks Paclitaxel versus Dose Dense Weekly Paclitaxel in Combination with Carboplatin Plus Concurrent and Consolidation Bevacizumab in the Treatment of Primary Stage III or IV Epithelial Ovarian, Peritoneal or Fallopian Tube Cancer

NSABP C-11, A Phase III Study Evaluating the Role of Preoperative Chemotherapy and Bevacizumab in Patients with Potentially Resectable Hepatic Colorectal Metastases
RTOG 0724, Phase III Randomized Study of Concurrent Chemotherapy and Pelvic RT With or Without Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy


RTOG 0839, Randomized Phase II Study of Pre-operative Chemoradiotherapy +/- Panitumumab followed by Consolidation Chemotherapy in Potentially Operable Locally Advanced (Stage IIIA, N2+) Non-Small Cell Lung Cancer

RTOG 0929, A Randomized Phase I/II Study of ABT-888 in Combination with Temozolomide in Recurrent (Temozolomide Resistant) Glioblastoma

RTOG 1008, A Randomized Phase II Study of Adjuvant Concurrent Radiation and Chemotherapy Versus Radiation Alone in Resected High-Risk Malignant Salivary Gland Tumors

SWOG 1007, A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less.

If your site is interested in participating in any of these studies please contact Rolma Gano at 215-955-7954 or Rolma.gano@jeffersonhospital.org.
Regulatory Update:
C80405 Update #11 R0815 Amendment #1 & 2
E5103 Update #5, Addendum #8 R1010 Update #1
E5202 CLOSURE
GOG 258 Revision #5
NSABP B-46-I, Amendments #1-3

*Patients on E5103 who are currently being treated on study or within 30 days of receiving protocol related treatment should be re-consented.*

Please contact Rolma Gano with any repository or other regulatory related questions.

CTSU Update:
N0147, *A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer*, recently released a memorandum to all investigators and clinical research associates on March 8, 2011. The purpose of this memorandum is to provide clarifications regarding the collection of blood and recurrent tissue based on Addendum 12 for N0147. Arm G patients do not need to be re-consented for Addendum 12. Patients on Arms A & D who are still returning for follow-up visits in the Observation phase are to be re-consented for both the additional collection of blood and the recurrent tissue. Patients on Arms A & D who are being followed annually in the Event Monitoring phase are to be re-consented only if they have had a recurrence of their colorectal cancer AND have available tissue that has been resected from their 1st surgery following recurrence. Changes to the consent based on Addendum 12 occur on pages 3, 5, 9-12, and 17-19. Please refer to CTSU webpage for more information on the rationale of the extra tissue and blood collection.
CALGB 40502, *A Randomized Phase III Trial of Weekly Paclitaxel Compared to Weekly Nanoparticle Albumin Bound Nab-Paclitaxel or Ixabepilone with or without Bevacizumab as First-Line Therapy for Locally Recurrent or Metastatic Breast Cancer*, has released a memorandum in regards to the use of Avastin. In light of the recent publication of the results of three phase III breast trials and the Federal Drug Administration recommendation to withdraw the previously awarded accelerated approval for the combination of weekly paclitaxel and bevacizumab, the CALGB 40502 study has been amended to make the use of bevacizumab optional in combination with each of the three treatment arms. For those physicians who elect to prescribe bevacizumab for their patients enrolled on CALGB 40502, bevacizumab will continue to be supplied by the Pharmaceutical Management Branch of the NCI for the duration of the protocol enrollment.

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

ECOG Update:
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*, recently released Addendum 8 which updates the risks to Epirubicin. All patients currently receiving active protocol treatment or who have received protocol treatment in the past 30 days should be re-consented. Changes to the ICF took place on page 9.

Important Announcement from Robert L. Comis, ECOG Chairman: “I am very pleased to announce that we have signed a Letter of Intent (LOI) to merge the ECOG program with the cancer related scientific programs of the American College of Radiology Imaging Network (ACRIN) in a new alliance. Over the next several months we will be discussing how best to integrate our
business, scientific and administrative programs with the intent to develop a single grant submission when the new cooperative group grants submission guidelines become available in 2012.” A press release has been posted on the ECOG Webpage and can be found at the following link:

ECOG Spring Meeting being held in Boston, MA from June 10th-12th. Registration for the meeting is now OPEN and will be done completely online. To register for the Group Meeting, please use the following link:
https://www.regonline.com/ECOG_spring2011

E2108, A Randomized Phase III Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Patients with Metastatic Breast Cancer, will be featuring in an upcoming webinar taking place on April 11th from 11am to 12pm. The webinar will include a brief presentation followed by an open question and answer forum. Additionally, ECOG will provide information on screening and eligibility concerns, as well as educational resources available to support this trial. This is a great opportunity for sites and patient advocates to learn more about this exciting protocol! If interested, please RSVP by sending an email to Lauren DiFerdinando at ldiferdinando@ecogchair.org.

Performance Monitoring: The next Performance Monitoring data cut-off date of March 31, 2011 is approaching. Any data received on or before March 31 will be included in the upcoming Performance Monitoring. Data received after March 31 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.

If you have an ECOG related question please contact Joshua Schoppe.
NSABP Update:
P-5, Statin Polyp Prevention Trial in Patients with Resected Colon Cancer: In an effort to increase awareness of P-5, the NSABP had a news release on March 15th. Jefferson participated in that effort with our own press release on March 23rd. Jefferson along with our cancer network sites is one of 400 participating sites. A physician to patient letter is available to use for recruitment of subjects. It can be viewed on our document repository. The version which allows for entry of site and patient specific information can be obtained from Vicki Squire.

Look for news coming out of the NSABP Group Meeting in our early April e-newsletter.

If you have an NSABP related question please contact Vicki Squire at vicki.squire@jeffersonhospital.org or at 215-503-5641.

RTOG Update:
RTOG 0627, "Phase II Trial of Dasatinib in Patients With Recurrent Glioblastoma Multiforme," is permanently closed to patient accrual. Data analysis from the stage 1B cohort did not show sufficient evidence of response to proceed to the next stage of accrual.

RTOG 0915, “A Randomized Phase II Study Comparing 2 Stereotactic Body Radiation Therapy (SBRT) Schedules for Medically Inoperable Patients with Stage I Peripheral Non-Small Cell Lung Cancer,” closed to patient accrual March 22nd, as the study has met its accrual objective.

Please contact Joshua Schoppe or Vicki Squire with any RTOG related issues.
Jefferson Oncology Group (JOG) Update:
If your site has any JOG inquiries please contact either Joshua Schoppe or Vicki Squire.

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:
NSABP Group Meeting, Boca Raton, FL: March 24-27
JKCCN/KCC All Day Annual Scientific and Clinical Symposium
JOG Annual Investigators Meeting: Philadelphia, PA: April 11th:
Topic: Treatment in Thoracic Malignancies
ECOG Semiannual Meeting, Boston, MA: June 10-12
CRA Quarterly Meeting, Philadelphia, PA: June 15th

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