The Clinical Research E-News

ISSUE 18: September 9, 2009

New Activations:

**SWOG0518**, Phase III Prospective Randomized Comparison of Depot Octreotide Plus Interferon Alpha Versus Depot Octreotide Plus Bevacizumab (NSC #704865) in Advanced, Poor Prognosis Carcinoid Patients.

**CALGB 40502**, A Randomized Phase III Trial of Weekly Paclitaxel Compared to Weekly Nanoparticle Albumin Bound (Nab)-Paclitaxel or Ixabepilone Combined with Bevacizumab as First-Line Therapy for Locally Recurrent or Metastatic Breast Cancer.

Studies that are coming soon to TJU:

**SWOG0421**, Phase III Study of Docetaxel and Atrasentan versus Docetaxel and Placebo for Patients with Advanced Hormone Refractory Prostate Cancer.

**E1508**, A Randomized Phase II Study of Cisplatin and Etoposide in Combination with either Hedgehog Inhibitor GDC-0449 or IGF-1R MOAB IMC-A12 for Patients with Extensive Stage Small Cell Lung Cancer.

**GOG249**, A Phase III Trial of Pelvic Radiation Therapy Versus Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin Chemotherapy in Patients with High Risk, Early Stage Endometrial Carcinoma.
RTOG 0813, Seamless Phase I/II Study of Sterotactic Lung Radiotherapy (SBRT) for Early Stage, Centrally Located Non-Small Cell Lung Cancer (NSCLC) in Medically Inoperable Patients.

If your site is interested in participating in any of these studies please contact Rolma Mancinow at 215-955-7954 or Rolma.mancinow@jeffersonhospital.org.

**Regulatory Update:** The following studies have had recent consent form changes posted on the repository website:

- R0617
- R0517
- S0500
- E2905
- R0436
- R0822
- E4805
- E2804
- C90203
- E2805

**R0521, R0320 and GOG218:** letters closing to accrual are posted on repository.

If any of these studies pertain to your site please visit the repository at: http://www.kimmelcancercenter.org/kcc/JKCCN/file-repository/. Please contact Rolma Mancinow at with any repository or other regulatory related questions.

**Quality Assurance Update:** No new updates. Check back in 2 weeks.

Please contact Kelly Shipman with any QA related issues at Kelly.shipman@jeffersonhospital.org or 215-955-2135.
**CTSU Update:** S0307, *Phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer*, has been re-activated for accrual by SWOG/CTSU. This revision should be reviewed shortly by the TJUH IRB, and you will be alerted when final approval has been granted.

If you have a CTSU related question please contact Joshua Schoppe at Joshua.schoppe@jeffersonhospital.org or 215-955-0448

**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*, has been revised. The addition of Addendum #4 includes changes made to reflect the addition of a Quality of Life (QOL) component and additional correlative studies. This addendum should be reviewed shortly by the TJUH IRB, and you will be alerted when final approval has been granted.

**Upcoming Performance Monitoring:** The next Performance Monitoring data cut-off date of 9/30/2009 is approaching. Any data received on or before 9/30/2009 will be included in the upcoming Performance Monitoring. Data received after 9/30.2009 will be considered late. It is important to remember that data timeliness will be evaluated by assessing two components: The rate of CRF submission 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.
FALL 2009 ECOG GROUP MEETING: Registration is now OPEN:
Meeting registration will be done completely online again for this meeting. To register for the Group Meeting, please use the following link below. Please note that the schedule is updated on an ongoing basis. The schedule provided is for current reference only and is subject to change at any time. ECOG strongly recommends that all meeting attendees check the most current schedule online before making travel arrangements, as ECOG will not be responsible for ticket change fees due to scheduling changes.
https://www.regonline.com/ECOG_Fall2009

If you have an ECOG related question please contact Joshua Schoppe.

NSABP Update:
A Recent email from NSABP regarding closure of the of the operations center and pathology lab:

The city of Pittsburgh, where NSABP headquarters is located, is hosting the G-20 Summit on September 24-25, 2009. The NSABP has considered the logistical problems that this could cause and has made the decision to close the NSABP Operations Center and the NSABP Pathology Lab offices on these days. The NSABP Biostatistical Center is planning to remain open. Please consider this important information when planning for patient randomization, treatment dates, and ordering drug by following these guidelines:
• For routine questions, call the NSABP's Division of Industry Trials at 1-800-270-3165. Please leave a detailed voice mail message and your phone number with area code (we will not be able to respond to a pager, therefore, please do not provide page numbers). Questions will be answered intermittently by the FRP nurses on these days. For BETH questions, please contact your Quintiles CRA.
• For any urgent questions that must be addressed on September 24 and 25, call 412-951-1678.
• Any patients that you wish to enroll on protocol should have all registration documents submitted prior to September 23 to allow for randomization before closure. We will not be able to randomize any patients on September 24 or 25. Online enrollment for B-46-I and B-41 studies will remain available through Coordinator Online on these dates. Online enrollment for the BETH study will remain available through ID-net on these dates.
• We recommend that you check with your individual pharmacies to ensure adequate drug supply as we will not be able to handle any drug ordering or delivery issues during these days. Orders should be placed no later than September 17, 2009. We also recommend checking your supplies for any kits required by the protocol so that any re-supply issues can be addressed prior to September 18, 2009.

Prior to closure, please address any questions related to this matter by contacting the research nurse specialist for your protocol or by calling 1-800-270-3165.

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

RTOG Update:

Important Information Regarding Storage of Specimens: Many recent RTOG protocols include the instruction in the blood collection appendix to "store [blood] samples at -80 °C until packed and shipped in dry ice." RTOG HQ has received feedback from some institutions that they do not have access to a -80 °C freezer for storage of specimens (serum, buffy coat, etc.) prior to shipment. The RTOG Biospecimen Resource has provided the following alternatives for sites without access to a -80 °C freezer. These alternatives will
be added, as appropriate, to new RTOG protocols going forward and to current RTOG protocols in future amendments:

• If a -80°C freezer is not available for storage of blood specimens prior to shipment to the RTOG Biospecimen Resource:
  • Samples can be stored short term in a -20°C freezer (non-frost free preferred) for up to 1 week (please ship out Monday-Wednesday only). OR
  • Samples can be stored in plenty of dry ice for up to one week, replenishing daily (please ship out on Monday-Wednesday only). OR
  • Samples can be stored in liquid nitrogen vapor phase (ship out Monday-Wednesday only).

Please indicate the storage conditions used and time stored on the Specimen Transmittal Form.

**Spotlight on R0813:** RTOG 0813 is a seamless phase I/II Study of Stereotactic Lung Radiotherapy (SBRT) for early stage, centrally located, non-small cell lung cancer (NSCLC) in medically inoperable patients. The primary objective of the phase I portion is to determine the maximum tolerated dose (MTD) of SBRT for centrally-located NSCLC and the efficacy of that dose in patients who are not operative candidates. The phase II portion primary objective is to estimate the local control rate at the MTD of SBRT. Please note that to be eligible to participate in this protocol you must submit the 0813 Application to Participate, which can be found on the RTOG website, due to the importance of timely data quality with regard to assigning doses to new cases (institutions with a data quality score of 80% or higher may participate). Please contact Kelly Shipman or Rolma Mancinow if you are interested in participating in this trial.
If you have an RTOG related question please contact Kelly Shipman.

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

**JOG 043:** *An Open-Label, Randomized, Phase 2 Study of R-CHOP plus Enzastaurin versus R-CHOP in the First Line Treatment of Patients with Intermediate and High-Risk Diffuse Large B-Cell Lymphoma.* The sponsor will allow additional sites. If you have interest please contact Vicki Squire.

**Upcoming Events:**

Quarterly CRA Meeting: September 16, 2009  
SWOG Group Meeting, Chicago, IL: Oct. 21-24, 2009  
ECOG Group Meeting, Baltimore, MD: November 6-8, 2009  
NSABP Group Meeting, Atlanta, GA: November 20-21, 2009  
Quarterly CRA Meeting: December 9, 2009

*The Clinical Research E-News Archive* is now located on the Kimmel Cancer Center webpage under the JKCCN Member Area:  
[http://www.kimmelcancercenter.org/kcc/JKCCN/jcn_enewsletter.html](http://www.kimmelcancercenter.org/kcc/JKCCN/jcn_enewsletter.html)

Please provide feedback and any suggestions to Joshua Schoppe at 215-955-0448 or email at [Joshua.schoppe@jeffersonhospital.org](mailto:Joshua.schoppe@jeffersonhospital.org)