Center Stage:

**Congratulation to Edith Mitchell, MD!**
Dr. Mitchell, a Sidney Kimmel Cancer Center Physician and Researcher was named the next President of the National Medical Association

**NEW FEATURED TRIAL AT THE SIDNEY KIMMEL CANCER CENTER AT JEFFERSON UNIVERSITY:**

**Title:** A Phase III Prospective Double blind Placebo Controlled Randomized Study of Adjuvant MEDI4736 in Completely Resected Non-Small Cell Lung Cancer

**Sponsor:** NCIC CTG TRIAL: BR.31

**PI:** Rita Axelrod, MD

**Objective:** Compare Disease free survival (DFS) for patients with NSCLC that is PD-L1 positive

MEDI4736 is a novel IgG1-kappa PD-L1 inhibitor

- Condition: Non-Small Cell Lung Cancer
- Intervention: Drug: MEDI4736
- Drug: Placebo
- Phase: Phase 3

* Randomization will be 2:1 to the active treatment arm.

**Stratification:**
- stage (IIB (> 4cm), II, IIIA)
- adjuvant platinum based chemotherapy (> 300 mg/m2 cisplatin/equivalent** vs. < 300 mg/m2 vs. no chemotherapy)
- accruing center

Coordinator: Courtney Brant, MBA-HCM
Clinical Research Coordinator
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Sidney Kimmel Cancer Center
Clinical Research Management Office
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Fax: (215) 923-9974  Pager: 877-656-5581
Email: courtney.brant@jefferson.edu
NEW OPEN CLINICAL TRIALS AT TJU:

BN001: Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation with Concomitant and Adjuvant Temozolomide in Patients with Newly Diagnosed Glioblastoma
PI: Wenyin Shi, MD

PENDING FOR NETWORK PARTICIPATION:

EA8141: A Prospective Phase II Trial of Neoadjuvant Systemic Chemotherapy Followed by Extirpative Surgery for Patients with High Grade Upper Tract Urothelial Carcinoma

EAY131: Molecular Analysis for Therapy Choice (MATCH)

EA1131: A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Observation in Patients with Residual Triple-Negative Basal-Like Breast Cancer Following Neoadjuvant Chemotherapy

BR002: A Phase IIIR/III Trial of Standard of Care Therapy with or Without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer

<table>
<thead>
<tr>
<th>Regulatory Update</th>
<th>CTSU (RUMS) cont.</th>
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<tbody>
<tr>
<td>7/1/15 SELECT-1-Amendment revisions to consent form only</td>
<td>available in RUMS and which roles have update privileges for the CTSU and the NCTN groups. Also on the RUMS toolbar there is an icon for a Training Video and under the Help Icon a User Guide. NCTN and CTSU sites will no longer have access to the Site Roles application to make updates.</td>
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<tr>
<td>7/2/15 ECOG 2511 Closure Ltr</td>
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<tr>
<td>7/14/15 NRG LU001-Amendment Ltr changes to protocol &amp; consent</td>
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<td>7/17/15 RTOG 0839-Amendment temp closed to accrual effective 6/5/15 for protocol specific toxicity review</td>
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<tr>
<td>7/23/15 ECOG 1412 Accrual Suspension Letter</td>
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CTSU Update:
The Roster Update Maintenance System (RUMS) was released to NCTN sites on August 7, 2015. The RUMS allows site users to maintain roles by site and roster request the addition or withdraw of associates and investigators to a roster, and request the addition or withdraw of affiliate and sub-affiliate sites under a Main Member. RUMS appears as a tab on the CTSU members’ website. All users will be able to view information associated with sites and rosters to which they are affiliated, and users with the appropriate role at a site for a roster owner will be able to request roster-related updates. The Roles and Access document under the Site Roles tab lists roles

CTSU Dashboard Educational Documents: New CTSU Dashboard educational documents are now available! The Dashboard Tab is available to everyone and provides dynamic information that is personalized for each user. Data shown on the Dashboard is derived from various associations, such as affiliated sites, open protocols, and assigned roles.
NCIC CTG Study MA17R: The NCIC CTG MA.17R trial has recently been amended to allow for a time-driven analysis as described in Administrative Update #2, with the final analysis planned for Fall 2015. We thank you for all of your hard work in making this trial a success. In order to effectively plan for timelines of the final analysis for MA.17R, as well as to prepare for data cleaning for this analysis, we are calling for any outstanding data for this trial. The data cut-off date was 2015-Jul-01. All visits, recurrences, and deaths up to and including 2015-Jul-01 should have been submitted to NCIC CTG by 2015-Aug-17. Please resolve all outstanding data queries as soon as possible.

Reactivation of CODEL Trial (N0577) for Patients with Anaplastic Glioma or Low Grade Glioma: We would like to bring your attention to the re-activation of Alliance N0577 – the CODEL trial, Phase III Intergroup Study of Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade Gliom (N0577). There are currently no competing trials for this study population (newly diagnosed Grade II and III codeleted gliomas). Given the continued importance of this trial and the changes to simplify the trial design, we strongly urge you to consider the CODEL trial for your eligible patients. The trial will be open to accrual for considerable period of time (approximately 5 years) and therefore this is an excellent time for your sites to participate.

ECOG-ACRIN Update

ECOG-ACRIN (MATCH) cont.
more than 20 different study drugs or drug combinations, each targeting a specific gene mutation, in order to match each patient in more than 20 different study drugs or drug combinations, each targeting a specific gene mutation, in order to match each patient in the trial with a therapy that targets a molecular abnormality in their tumor. Each patient will initially enroll for screening, during which samples of their tumor will be biopsied and sequenced to detect genetic abnormalities that may be driving tumor growth and might be targeted by one of a wide range of drugs being studied. If a molecular abnormality is detected for which there is a substudy available, patients will be further evaluated to determine if they meet the specific eligibility requirements within that arm. Once enrolled, patients will be treated with the targeted drug regimen for as long as their tumor shrinks or remains stable. Trial investigators plan to screen at least 3,000 patients during the full course of the trial with the goal of enrolling approximately 1,000 patients in the various treatment arms (with up to 35 patients each). The trial’s design calls for at least one-quarter of the enrolled patients to have rare cancers (defined as cancers other than non– small cell lung, prostate, breast, or colon cancers). Participants must be age 18 or older, with solid tumors or lymphomas that have advanced following at least one line of standard systemic therapy, or with tumors for which there is no standard treatment.

Two endpoints will be evaluated: overall response rate (ORR; primary endpoint) and 6-month PFS (secondary endpoint). Within molecularly targeted subpopulations, an ORR of 16%-25% or higher and a 6-month PFS of 35% or higher will be considered promising results. NCI-MATCH is a “highly coordinated effort,” study co-chair Barbara A. Conley, MD, of NCI, said. The study was co-developed by NCI and the ECOG-ACRIN Cancer Research Group, is part of the NCI-sponsored National Clinical Trials Network (NCTN), and is being led by ECOG-ACRIN. The principal investigators who will lead the substudies are situated throughout the NCTN and its participating network groups: ECOG-ACRIN, the Alliance for Clinical Trials in Oncology, NRG Oncology, and SWOG. Patient advocates were engaged in the development of the trial and will help oversee the protocol and other aspects of the study.

ECOG-ACRIN Update
ACTIVATION OF PROTOCOL EAY131, Molecular Analysis for Therapy Choice (MATCH) Notice: EAY131 has been reviewed and approved by the NCI Central Institutional Review Board (CIRB), and only sites utilizing the CIRB as their IRB of record will be able to participate in the trial. The phase II NCI-MATCH trial will incorporate

**E1412, Randomized Phase II Open Label Study of Lenalidomide R-CHOP (R2CHOP) vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma, was temporarily suspended to accrual effective May 22, 2015. As previously announced, E1412 Step 1 remains temporarily SUSPENDED due to meeting its original accrual goal. However, please be advised that the study is currently in the process of being revised to increase accrual. E1412 is anticipated to re-open to accrual in September 2015.**

**ECOG-ACRIN Leukemia Bank Move:** The ECOG-ACRIN Leukemia Translational Research Laboratory and Tissue Bank (LTR/LTB) at Montefiore in Bronx, NY will move to a new facility effective August 10, 2015. Please DO NOT send any specimens to the new location for receipt prior to the effective date. Effective August 10, 2015, all samples shipped to the LTR/LTB are to be submitted to the new address:

Elisabeth Pairet, Ph.D.
Department of Oncology
Hofheimer 3rd Floor,
Leukemia Oncology Laboratory
111 East 210th Street
Bronx, NY 10467
Phone (NEW): 718-920-4100
Fax: 718-920-1161
Email: epairetta@earthlink.net

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**ECOG-ACRIN cont.**

**ECOG-ACRIN Upcoming Performance Monitoring:** The next Performance Monitoring data cut-off date of **September 30, 2015** is approaching. Any data received on or before September 30, 2015 will be included in the upcoming Performance Monitoring. Data received after September 30, 2015 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-ACRIN institution must have a score of 90% or better on each component.

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**NRG Audit update**
On behalf of Dr. Maria Werner-Wasik, thank you to all the TJU NRG affiliates who completed and submitted their site’s CAPA by the 8/7/2015 deadline. Overall, TJU and its affiliates successfully completed the 2015 NRG audit.

**GOG-02290, A randomized phase II study with a phase I lead- in to assess the antitumor efficacy of the MEK inhibitor Trametinib alone or in combination with GSK2141795, an AKT inhibitor in patients with recurrent or persistent endometrial cancer, closed to accrual July 18, 2015 and Amendment 5; version date: May 29, 2015.**

**RTOG 0839, Randomized Phase II Study of Pre-operative Chemoradiotherapy +/- Panitumumab (IND #110152) Followed by Consolidation Chemotherapy in Potentially Operable Locally Advanced (Stage IIIA, N2+) Non-Small Cell Lung Cancer.** After review by the NRG Oncology Data Monitoring Committee (DMC) of the study results of interim analysis and the most recent toxicity data, the DMC recommended that due to a poor benefit-risk profile, the trial be closed to patient accrual effective immediately, and treatment with panitumumab is discontinued.
Upcoming Events:

- **JOG Investigators Meeting**: King of Prussia PA, October 15\textsuperscript{th}
- **ECOG-ACRIN** Semi-Annual Meeting: Orlando FL, November 12\textsuperscript{th}-14\textsuperscript{th}
- **CRA Meeting**: Jefferson Campus, December 16\textsuperscript{th}

**The Clinical Research E-News** Archive is now located on the Sidney Kimmel Cancer Center webpage under the JKCCN Member Area: http://www.kimmelcancercenter.org/jkccn/e-newsletters.html

Sidney Kimmel Cancer Network Homepage: http://www.kimmelcancercenter.org/jkccn/. This page contains links to the Remote Access Portal as well as the clinical trial document repository.

**Contact Information:**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Cynthia Perez at 215-955-9923 or <a href="mailto:cynthia.perez@jefferson.edu">cynthia.perez@jefferson.edu</a></td>
<td>NRG Update inquiries or suggestions for future Clinical Research E-Newsletters</td>
</tr>
<tr>
<td>Joshua Schoppe at 215-955-0448 or <a href="mailto:joshua.schoppe@jefferson.edu">joshua.schoppe@jefferson.edu</a></td>
<td>ECOG-ACRIN Update inquiries, CTSU, or CIRB</td>
</tr>
<tr>
<td>Rashada Dawson at 215-955-2135 or <a href="mailto:rashada.dawson@jefferson.edu">rashada.dawson@jefferson.edu</a></td>
<td>Pending Studies or Regulatory Update inquires</td>
</tr>
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*For urgent clinical trial questions or assistance please page: 877-656-9004*