New Featured Trials Actively Recruiting at the Sidney Kimmel Cancer Center at Jefferson University:

1. **Title:** Phase II Study of Bendamustine, Bortezomib, and Dexamethasone (BBd) for Newly Diagnosed Patients with Multiple Myeloma
   
   a. **Objective:** Overall response rate (ORR) following 4 cycles of the combination regimen BBd and ORR (partial remission or better) to induction therapy following 4 cycles of the combination regimen BBd.
   
   b. **Treatment Experimental:** Bendamustine, Bortezomib, Dexamethasone: Patients receive bendamustine hydrochloride IV over 30 minutes on days 1, 8, and 15; bortezomib SC on days 1, 8, 15, and 22; and dexamethasone PO on days 1, 8, 15, 22, and 28. Treatment repeats every 35 days for 4 courses in the absence of disease progression or unacceptable toxicity. Patients achieving less than a VGPR or with more than 10% bone marrow plasmacytosis may receive 2 additional courses. NOTE: Patients requiring immediate reduction in paraprotein during course 1 only receive bendamustine hydrochloride IV over 30 minutes on days 1 and 2; bortezomib IV on days 1, 4, 8, 11, 15, and 18; and dexamethasone PO on days 1-7.
   
   c. **Eligibility:** New diagnosis of multiple myeloma with no prior history of treatment (Exceptions include corticosteroids, bisphosphonates, single agent cyclophosphamide, < 21 days of the first cycle of a planned regimen, measurable serum paraprotein on SPEP or serum free light chains and ratio, smoldering myeloma, monoclonal gammopathy of undetermined significance (MGUS), or plasma cell leukemia are excluded
   
   d. **Contact:** Jennifer Cloud at 877-656-2891 or Jennifer.cloud@jefferson.edu

**Now Open for Network Participation:**

**A041202**, A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL)

**Pending Studies for Network Participation:**

**EA1910**, A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-negative B lineage Acute Lymphoblastic Leukemia in Adults
EA2212, A Randomized, Double-Blinded, Placebo-Controlled Phase II Study of Adjuvant Everolimus Following the Resection of Metastatic Pancreatic Neuroendocrine Tumors to the Liver

EA2511, Phase I and Randomized Phase II Double Blind Clinical Trial of Cisplatin and Etoposide in Combination with Veliparib (ABT-888) or Placebo as Frontline Therapy for Extensive Stage Small Cell Lung Cancer- ECOG Members only

B-52, A Randomized Phase III Trial Evaluating Pathologic Complete Response Rates in Patients with Hormone Receptor-Positive, HER2-Positive, Large Operable and Locally Advanced Breast Cancer Treated with Neoadjuvant Therapy of Docetaxel, Carboplatin, Trastuzumab, and Pertuzumab (TCHP) with or Without Estrogen Deprivation

B-55, A Randomized, Double-Blind, Parallel Group, Placebo-Controlled Multi-Center Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy

N0577, Phase III Intergroup Study of Temozolomide Alone Versus Radiotherapy with Concomitant and Adjuvant Temozolomide Versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma

R1306, A Randomized Phase II Study of Individualized Combined Modality Therapy for Stage III Non-Small Cell Lung Cancer (NSCLC)

S1304, A Randomized Phase II Study of CO-eXpression ExtrapolationN (COXEN) with Neoadjuvant Chemotherapy for Localized, Muscle-Invasive Bladder Cancer

Please contact Joshua Schoppe at 215-955-0448 or Joshua.Schoppe@jefferson.edu if your site is interested in participating in any of these trials.

**Regulatory Update:**

**EA2212**
- Add #2-3: *Reconsent all subjects*
- R0631- Amend #7

**EA2511**
- Addenda #4-5: *reopen to accrual*

**B-52**
- Amend #9
- R1122-Amend #5

**B-55**
- Amend #6

**N0577**
- Amend #5

**R1306**
- Amend #6

**S1304**
- Amend #7

**E1412**
- Add #10

**E7208**
- Add #12

**R-04**
- Add #5

**E1305**
- Add #17: *Reconsent all subjects*

**E5508**
- Amend #10

**E2804**
- Amend #4

**R0937**
- Amend #4

**E041202**
- Initial Approval

**B-47**
- Amend #5

**E1305**
- Add #12

**E5508**
- Add #10
Please contact Joshua Schoppe for any regulatory update inquiries.

CTSU Update
The Alliance for Clinical Trials in Oncology, in conjunction with the National Cancer Institute (NCI) and ECOG-ACRIN Cancer Research Group, today launched the Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials, or ALCHEMIST – three trials to identify patients with early-stage lung cancer who have tumors that contain uncommon genetic changes and evaluate whether drug treatments aimed at those changes can improve their survival. As lead network group, the Alliance will coordinate two of the three trials, including the ALCHEMIST screening trial and the adjuvant treatment trial for patients with epidermal growth factor receptor (EGFR) mutations. All of the NCI-supported National Clinical Trials Network (NCTN) groups are participating in the trials.

The three trials of ALCHEMIST are:

ALCHEMIST - Screening component (A151216)
Coordinated by the Alliance | Principal Investigators: Pasi A. Jänne, MD, PhD and Geoffrey Oxnard, MD, Dana-Farber Cancer Institute, Boston. [http://www.cancer.gov/clinicaltrials/NCT02194738](http://www.cancer.gov/clinicaltrials/NCT02194738)

ALCHEMIST - EGFR Treatment component (A081105)
Coordinated by the Alliance | Principal Investigator: Ramaswamy Govindan, MD, Washington University, St. Louis. [http://www.cancer.gov/clinicaltrials/NCT02193282](http://www.cancer.gov/clinicaltrials/NCT02193282)

ALCHEMIST - ALK Treatment component (E4512)
Coordinated by ECOG-ACRIN | Principal Investigator: David Gerber, MD, University of Texas Southwestern Medical Center at Dallas. [http://www.cancer.gov/clinicaltrials/NCT02201992](http://www.cancer.gov/clinicaltrials/NCT02201992)

Participants enrolled in ALCHEMIST need to have been diagnosed with lung adenocarcinoma or other types of non-squamous, non-small cell lung cancer (or NSCLC), and must be planning to undergo surgery or have already undergone surgical removal of their tumors. In the ALCHEMIST screening trial, tissue from the participant’s surgical resection will be tested in a central laboratory for genetic changes in two specific genes – EGFR and anaplastic lymphoma kinase (ALK).

CIRB IT Integration Questions and Answers
Over the last several weeks you have received a variety of communications regarding the CIRB IT Integration efforts. This memo reiterates the purpose of this effort from the CIRB perspective and highlights the important questions that have been asked during this transition.
What is happening with CIRB username and password account access?
The NCI CIRB is converting its systems to utilize the Cancer Therapy Evaluation Program (CTEP) Identity and Access Management (IAM) system. CTEP IAM is a web-based application that provides user accounts and website access to Investigators, Research Staff and IRB Staff participating in NCI-sponsored clinical trials.

Why is the CIRB doing this?
The CIRB and CTSU have been working together to establish a link between systems. This integration simplifies many processes for users, such as:

• Alleviating the use of multiple usernames and password currently required to access various NCI systems by reducing a user’s login to one username and password across systems;
• Exchanging CIRB enrollment information and institution contact information between NCI systems by allowing Regulatory Support System (RSS) to share contact information with the CIRB; and
• Alleviating the burden for submitting the CTSU Acknowledgement Form and the CTSU IRB Certification Form for trials open with the NCI CIRB at your institution, thereby simplifying the regulatory submission process for institutions utilizing the CIRB as their IRB of Record.

What does this mean to you?
In order to continue to access the CIRB review documents or Worksheets in IRBManager, all Key Personnel will require a CTEP Person ID and active CTEP IAM account to maintain access.

Do you need to access CIRB applications?
If you answer “Yes” to any of the three criteria below, then you will require both a CTEP Person ID and an active CTEP IAM account.

1. Do you require access to IRBManager to support completion of the Worksheets?
2. Do you currently have access to and use the Participant’s Area of the NCI CIRB website for CIRB study review documents?
3. Do you require access to CTSU website to access CIRB study review documents?

If your answer is “No” to all three criteria above, then no CTEP Person ID or CTEP IAM account is needed and no further action is required.

What are the benefits of the CIRB/CTSU Integration?
The following changes are a result of the CIRB/CTSU Integration:

• Streamlined regulatory submission process for institutions using the CIRB;
• Direct web-service feed of NCI CIRB protocol and institution participation approval information into RSS;
• Management of NCI CIRB roster in RSS; and
• Access to the new CIRB Site Preference feature on the CTSU website

A041202, *A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (>/= 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL)*, is now open to accrual. The online geriatric assessment training module for A041202-EL1 is now available to all NCTN groups. The training module may be accessed on the member side of the Alliance website (www.allianceforclinicaltrialsinoncology.org). In order to gain access to the member side of the Alliance website, the user must have an active CTEP-IAM account that is linked to at least one of the NCTN group rosters. To login, select “Member Login” on the Alliance homepage and enter the CTEP-IAM account username and password. After logging in, the training module can be found under education and training > online training and under “For Site Staff.” *At least one member of the research team at your institution must complete the online training on the geriatric assessment procedures before enrolling any patients to the Geriatric Assessment correlative (A041202-EL1).*

*Please contact Joshua Schoppe for any CTSU update inquiries.*

**ECOG-ACRIN Update**

The next **Performance Monitoring** data cut-off date of *September 30, 2014* is approaching. Any data received on or before *September 30, 2014* will be included in the upcoming Performance Monitoring. Data received after *September 30, 2014* 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.

**ECOG-ACRIN Group Meeting website open:** We are happy to announce the opening of the ECOG-ACRIN Fall Group meeting website. The fall meeting will be held at the JW Marriott/Ritz-Carlton Grande Lakes, 4040 Central Florida Parkway, Orlando, FL from November 13-15 (Thursday-Saturday). You can register for the meeting by following this link: [https://www.regonline.com/builder/site/Default.aspx?EventID=1573167](https://www.regonline.com/builder/site/Default.aspx?EventID=1573167)

Please contact Joshua Schoppe for any ECOG-ACRIN update inquiries.

**NRG Update**

**RTOG 1005, 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: Amendment 4: On the first title page, a sentence was added beneath the title specifying NRG Oncology as leading the trial with participation of the network of NCTN researchers: the Alliance, ECOG-ACRIN, and SWOG.

NRG-G1001, Randomized Phase III Study of Focal Radiation Therapy for Unresectable, Localized Intrahepatic Cholangiocarcinoma: ***PRE-ACTIVATION: This Study is Not Yet Open to Patient Enrollment***

NSABP B-43, NSABP B-47, and NSABP B-52: Updated Investigator's Brochure (IB) for Herceptin® (Trastuzumab), Version 14, dated October 2013. Please contact the Pharmaceutical Monitoring Branch to obtain a copy of this updated IB.

Please contact Christine Bonaccorso at 215-955-7954 or Christine.Bonaccorso@jefferson.edu with any related NRG issues.

JOG Meeting
Please mark your calendars for our annual JOG Investigators Meeting.
Date: Thursday, October 9, 2014
Time: 5:15pm-8:30pm
Place: The Sheraton Valley Forge Hotel in King of Prussia
The topic for this year is Hematologic Malignancies. We hope you will plan to attend. If interested please RSVP to Rita Carlino at rita.carlino@jefferson.edu or 215-955-2412

Upcoming Events:
CRA Quarterly Meeting: TJU campus, September 19
JOG Meeting: The Sheraton Valley Forge Hotel in KOP, October 9, 2014
JKCCN Navigator Meeting: TJU campus, November 7th,
ECOG Meeting: Orlando, FL, November 13-15
CRA Quarterly Meeting: TJU Campus, December 12,
NRG Meeting: San Diego, CA, February 5-8

Changes in the research environment, technological advances, and a greater understanding of related ethical concerns have made the issue of informed consent in research increasingly complex. This RCF will examine consent related challenges faced by IRBs, investigators, and other members of the research community. The conference will foster thought provoking topics and stimulating discussions, and provide creative solutions to these challenges.

This dynamic two-day event will be co-hosted by the Children's Hospital of Philadelphia, the University of Pennsylvania, Drexel University, Temple University, Thomas Jefferson University, and the Wills Eye Hospital.

The conference will be held at the Sheraton Philadelphia Society Hill Hotel at 1 Dock St., Philadelphia, PA 19106 in the Old City section of Philadelphia.

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

Please provide feedback and any suggestions to Joshua Schoppe at 215-955-0448 or email Joshua.schoppe@jeffersonhospital.org

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.