

SPOTLIGHT ON TRIALS

Reducing Cancer-Related Fatigue in Patients with Glioblastoma Multiforme

Alliance A221101 A Phase III Randomized, Double-Blind Placebo-Controlled Study of Armodafinil to Reduce Cancer-Related Fatigue in Patients with Glioblastoma Multiforme

Fatigue is one of the most common and most troublesome symptoms for primary brain tumor patients throughout the course of the disease.^{1,2} This condition has long been under-recognized, under-diagnosed, and undertreated.³⁻⁶

Cancer Related Fatigue (CRF) is a concerning issue in patients with cancer due to its high prevalence and negative effects on quality of life. Fatigue is a subjective experience. Sufferers may exhibit symptoms that are physical (physical weakness or tiredness), emotional (depression), motivational (lack of initiative or motivation), cognitive (impairment of cognitive function), and social (reduced ability to sustain social relationships).⁷ In a survey evaluating Health-Related Quality of Life (HRQOL) in a variety of primary brain tumor patients at various times in the trajectory of their illness, 42 percent reported “quite a bit low” or “very low” energy levels.^{8,9}

Radiation therapy is the most common treatment modality for all brain tumor grades, and has been the treatment evaluated in the glioblastoma multiforme (GBM) patient population in relation to fatigue. Lovely and colleagues reported that more than 80 percent of primary brain tumor patients

report fatigue during radiation therapy.¹⁰ Fatigue has been reported to occur as early as within one week of the first radiation treatment and tends to increase with the number of radiation fractions.¹¹ Fatigue occurring during radiation therapy may continue into the post-radiation period.

Besides treatment factors, fatigue is often due to the tumor itself. The mechanism of direct tumor-related fatigue is poorly understood and presumed to be a combination of the tumor biology itself, surrounding edema, and location. A prospective trial assessing quality of life in high-grade glioma patients found one third of patients had clinically significant fatigue at baseline before initiation of radiotherapy. In addition, this study found fatigue to be an independent predictor of overall survival.¹²

The effects of cancer treatments on cognitive function have commanded increasing attention from researchers in the past decade.¹³⁻¹⁷ Cognitive deficits identified by cancer survivors consist of a range of difficulties including memory and concentration problems that can emerge during cancer treatment and/or months after completion.¹⁴ Deficits that occur as a result of cancer or its treatment vary widely and may be subtle or dramatic, temporary or permanent, and stable or progressive.¹⁸⁻²¹ Pathological evidence shows adverse effects of radiation on white matter tracts and cerebral vasculature of the brain. These

continued on next page

Spotlight on Trials

continued from page 1

changes are secondary to damaged oligodendrocytes resulting in axonal demyelination, and disruption of vascular endothelial cells contributing to coagulative necrosis, vessel wall thickening, and focal mineralization. Chronic radiation toxicity is also believed to involve alterations in neurogenesis as well as metabolic abnormalities and inflammatory responses.²²⁻²⁵

Armodafinil is a novel psychostimulant that has shown promise as a cognitive enhancer in normal adults and patient populations, including schizophrenia and attention deficit hyperactivity disorder.²⁶⁻²⁹ Commonly prescribed to treat MS-related fatigue, armodafinil is also an alertness-promoting agent that reduces lapses of attention and vigilance that are caused by sleep deprivation and fatiguing disorders.^{26, 30-32} It has been suggested that the nootropic effects of armodafinil may be magnified among people with pronounced fatigue and pre-existing cognitive difficulties.^{33,34} As cancer patients frequently suffer from significant fatigue and neuropsychological deficits, armodafinil has the potential to an effective cognitive enhancer in this population. Despite this, no published studies have examined the use of armodafinil to treat fatigue or cognitive impairment in patients with cancer.

In this randomized phase III trial, Alliance researchers will evaluate if armodafinil can reduce cancer-related fatigue in patients with GBM. The interventional study aims to determine preliminary efficacy of armodafinil in treating moderate fatigue compared to placebo using patient reported fatigue in patients with GBM. Other fatigue endpoints such as usual fatigue and activity interference will also be assessed. In addition, evaluation of the tolerability of two different doses of armodafinil, and assessment of the effect of armodafinil on cognitive function and global quality of life will be performed. This study will also explore the correlation between

the Brief Fatigue Inventory (BFI), Patient-Reported Outcomes Measurement Information System (PROMIS), and Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) measures, as well as the relationship of fatigue and cognitive difficulties.

Patients will be randomized to one of three treatment arms: Arm I: Patients receive lower-dose armodafinil orally once daily on days 1-28; Arm II: Patients receive placebo orally once daily on days 1-28; and Arm III: Patients receive higher-dose armodafinil orally once daily on days 1-28. In all arms, treatment repeats every 28 days for two courses.

Patients eligible to participate in this trial include those with GBM who are clinically stable and have completed radiation therapy more than 28 days and less than 24 months prior to enrollment. Those patients also with a greater than 6 score on the worst fatigue question of the BFI, and those who have undergone surgery (gross total or subtotal resection) or biopsy and will have been treated with concurrent radiation therapy and chemotherapy as standard of care for glioblastoma. (Radiation must be completed, but chemotherapy is allowed.) Patients with a history of or currently taking medications for attention deficit hyperactivity disorder, severe anxiety disorder, schizophrenia, or substance abuse by patient record and/or self report will be excluded. In addition, those patients currently using any other pharmacologic agents or nonpharmacologic interventions to specifically treat fatigue including psychostimulants, antidepressants, acupuncture, etc. are ineligible to participate in this study.

About 330 people will take part in this study.

The study protocol for Alliance A221101 is available on the CTSU menu (ctsu.org). Refer to the protocol for complete information about the trial design and patient eligibility.

continued on next page

Spotlight on Trials

continued from page 2

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Navigating the Alliance Website

Helpful Tips for Accessing Information Online



The Alliance for Clinical Trials in Oncology website is an official publication of the Alliance that represents the Alliance electronically to the public and our members 24 hours a day. The website is designed to share specific information about the Alliance and our research to those touched by cancer, scientists and clinicians, community and institutional networks, collaborators and others.

The official address of the Alliance website is www.AllianceforClinicalTrialsinOncology.org.

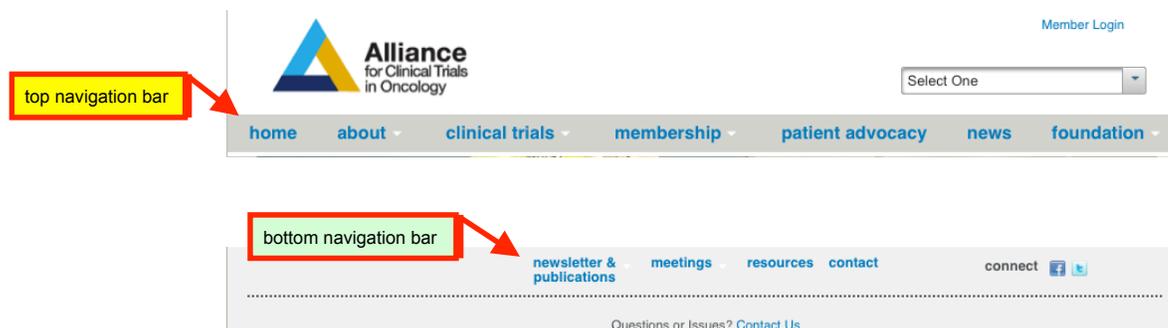
Two sides, one site.

[Public pages](#) are used to inform and educate potential patients about clinical trials, and provide general information about the Alliance to the public.

[Member pages](#) include applications and documentation on managing clinical trials within the Alliance, and are secured by user IDs and passwords.

How to find what you need.

Information on the website is organized within easy-to-use menus (or [navigation bars](#)) at the top and bottom of each page.



Need help.

Send all questions, suggestions or concerns about the site to info@allianceNCTN.org.

[See pages 5-8](#) to learn more about navigating public and member pages, and how the site is managed.



Navigating the Alliance Website

Helpful Tips for Accessing Information Online

PUBLIC PAGES

Finding what you need

- A: Mission, vision, governance and history
- B: Trials portfolio
- C: Public inquiries about concepts and specimen bank
- D: Institutional membership; individual participation
- E: Patient advocacy
- F: News about the Alliance and cancer research

- G: Alliance for Clinical Trials in Oncology Foundation: research awards and how to donate
- H: Newsletters, bibliographies and public summaries (*plain language study results*)
- I: Alliance meeting dates
- J: Links to cancer-related sites and other groups
- K: Contacts for general inquiries and website help

The screenshot shows the website's layout with the following navigation elements:

- Top Navigation Bar:** home, about, clinical trials, membership, patient advocacy, news, foundation. A yellow box highlights this bar.
- Member Login:** A dropdown menu labeled "Select One" with a "Member Login" link above it.
- Hero Image:** A photograph of four medical professionals in white coats. Red boxes A-F point to specific elements: A (Alliance logo), B (clinical trials), C (news), D (membership), E (patient advocacy), and F (hero image).
- Content Area:**
 - UPCOMING COMMITTEE MEETINGS:**
 - 2013 Group Meeting: open to all Alliance members, November 7-10, 2013* at InterContinental Chicago O'Hare.
 - 2014 Committee Meetings: open to Alliance committee members only.
 - ANNOUNCEMENTS:**
 - NCI Branch Revises Clinical Trial Audit Guidelines: Effective January 1, 2013, the National Cancer Institute's Clinical Trials Monitoring Branch (CTMB) instituted revised guidelines...
- Bottom Navigation Bar:** newsletter & publications, meetings, resources, contact, connect. A red box highlights this bar.
- Footer:** Questions or Issues? [Contact Us](#)

Navigating the Alliance Website

Helpful Tips for Accessing Information Online



MEMBER PAGES

Getting access to what you need

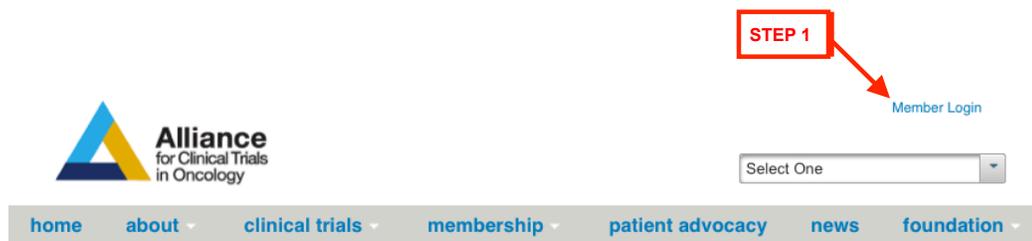
To access member-specific information, all Alliance members must have a National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) Identity and Access Management (IAM) username and password.

How to get CTEP-IAM username and password. Visit CTEP-IAM website: <https://eapps-ctep.nci.nih.gov/iam>; click Request New Account

How to log onto the member side.

Follow these two easy steps to get access to the member side.

STEP 1 Click [Member Login](#) in the upper right corner of Alliance home page



STEP 2 Enter your [CTEP-IAM username](#) and [password](#)

REMEMBER Once logged in, you can move freely between public and member pages.



Navigating the Alliance Website

Helpful Tips for Accessing Information Online

MEMBER PAGES

Finding what you need

- A: Trials portfolio, funding sheets, concept submission and biospecimen requests forms, study summaries
- B: Access to BioMS
- C: Online Alliance education and training resources (*under construction*)
- D: Contact lists and descriptions of Alliance Programs and committees; resources for committee chairs
- E: Alliance governance, policies and procedures, membership information, frequently used documents
- F: General news for Alliance members
- G: Important announcements for Alliance members
- H: Last three applications used or pages viewed
- I: Access to legacy group websites and information
- J: Directory listing of Alliance members
- K: Newsletters, bibliographies and public summaries (*plain language study results*)
- L: Alliance meeting dates, schedules, meeting presentations, travel policies and procedures
- M: Contacts for Alliance administrative offices, emergency technical support

The screenshot shows the Alliance for Clinical Trials in Oncology website interface. At the top left is the Alliance logo. At the top right, it says 'LOGGED IN AS: Jamilah Owens (Log out)' with a dropdown menu. Below the logo is a top navigation bar with links: home, protocols, education & training, committees, member services, and news. A yellow box labeled 'top navigation bar' points to this area. Below the navigation bar is a blue 'Welcome' banner. Below the banner are two main content areas: 'ANNOUNCEMENTS' and 'RECENTLY USED APPLICATIONS'. The 'ANNOUNCEMENTS' section features a notice about the suspension of Cohort 3. Below this is a 'NEWS' section with two articles. At the bottom of the page is a bottom navigation bar with links: legacy sites, directory, newsletter & publications, meetings, contact, and connect (with social media icons). A yellow box labeled 'bottom navigation bar' points to this area. Various letters (A-M) are placed on the page with arrows pointing to specific elements: A points to 'protocols', B to 'BioMS' (implied), C to 'education & training', D to 'committees', E to 'member services', F to 'news', G to the 'ANNOUNCEMENTS' section, H to the 'RECENTLY USED APPLICATIONS' list, I to 'legacy sites', J to 'directory', K to 'newsletter & publications', L to 'meetings', and M to 'contact'.

Navigating the Alliance Website

Helpful Tips for Accessing Information Online



WEBSITE GOVERNANCE

Web Operations Manager

This individual is responsible for the day-to-day function and operation of all Alliance web presences, including the website and wikis (*team or committee-specific websites*).

Alliance Website Team

This team comprises members from all functional units within the Alliance plus IS staff, Web Operations Manager and Web Content Administrators, and is responsible for web development and management. This team reports to the Alliance Program Operations Committee.

Website Content

All requests for website revisions or additions should be submitted to the Web Operations Manager by e-mail at info@allianceNCTN.org

- Minor requests (*such as bugs, broken links and information updates*) are handled directly by the Web Operations Manager.
- Requests for new menu items or new pages are sent to the Alliance Program Operations Committee for review and approval.

Website Feedback

For all questions, suggestions or concerns about the website, send an e-mail to info@allianceNCTN.org.

Alliance Appoints New Committee Leaders



Leonard



Galinsky



Watson



Cheson

The Alliance Board of Directors met and made three appointments during the 2013 Alliance Committee Meetings held March 14-17 in Chicago, IL. Appointments include: **John P. Leonard, MD**, of Weill Cornell Medical College, Chair of the Lymphoma Committee, and **Ilene A. Galinsky, MSN, ANP-C**, of the Dana-Farber Cancer Institute, Vice Chair of the Oncology Nursing Committee; **Mark Watson, MD, PhD**, of Washington University School of Medicine, has been appointed Principal Investigator of the Alliance Biorepository Grant.

Dr. Leonard replaces **Bruce D. Cheson, MD**, Professor of Medicine, Head of Hematology and Director of Hematology Research at Lombardi Comprehensive Cancer Center at Georgetown University. Dr. Leonard received his MD from the University of Virginia. He currently serves as an attending physician at New York Weill Cornell Medical Center, New York Presbyterian Hospital, and as Associate Dean for Clinical Research at Weill Cornell Medical College. Dr. Leonard joined CALGB in 1998. He served on the CALGB Board of Directors and the Executive Committee from 2006 and 2009, respectively, until being elected to the Alliance Board of Directors in 2011. He also serves as a member of the Study Concept Review Committee. He has served as Vice Chair of the Lymphoma Committee since 2008.

Ms. Galinsky is a Senior Research Nurse Practitioner in the Leukemia Program at Dana-Farber Cancer Institute. She graduated from Northeastern University with a BSN in 1988 and returned to earn a MSN in 2003. Ms. Galinsky has been an active member of the Oncology Nursing Committee since 1998 for CALGB and now the Alliance. She is an accomplished research nurse with more than 40 abstracts and publications on the treatment and management of patients with hematologic malignancies and bone marrow failure. She is also an experienced lecturer and mentor to nurses and clinical research staff.

Dr. Watson is a member of the Group Banking Committee and has led the development of BioMS and caTissue. He is currently Director of Alliance Biorepository Systems. Dr. Watson received his MD, PhD from Washington University in St. Louis, where he currently serves as Associate Professor in the Department of Pathology and Immunology in the

Division of Clinical Pathology. Dr. Watson served as the Director of the Central Specimen Bank for ACOSOG from 1999 until 2011. His research interest is in characterization of genes associated with solid tumor development and cancer informatics.

New Alliance Service Center Offers Broader Services

The new Alliance Service Center opened March 29, 2013, and replaces the CALGB Help Desk. Center services include triage support for Alliance information systems, along with user authorization, access, connectivity and password resets. The center is available 8 am to 5:30 pm ET (7 am to 4:30 pm CT) Monday through Friday, excluding holidays. Below is a list of key contacts.

Alliance Service Center

Hours: 8 am - 5:30 pm ET (7 am - 4:30 pm CT)

Monday - Friday, excluding holidays

Phone: 877-442-2542

E-mail: AllianceServiceCenter@allianceNCTN.org

Patient Registration (OPEN) and Regulatory Documents

Contact CTSU Regulatory Office

Phone: 866-651-2878

Fax: 215-569-0206

For Protocol-related Questions

See: Protocol contacts in the protocol

Expedited Adverse Event Reporting

Visit: <http://ctep.cancer.gov/reporting/adeers.html>

Medidata Rave Portal

Visit: <https://login.imedidata.com>

OPEN (Oncology Patient Enrollment Network)

Visit: <https://open.ctsu.org>

BioMS User Support

Hours: 9 am - 8 pm ET (8 am - 7 pm CT)

Monday - Friday

Phone: 855-552-4667 or 855-55-BioMS

E-mail: bioms@allianceNCTN.org

FAQs: <http://tinyurl.com/alliance-Bioms-FAQs>

Training Schedule:

<http://tinyurl.com/alliance-Bioms-Training>

PROFESSIONAL DEVELOPMENT

Accelerating Anticancer Agent Development and Validation Workshop

Bethesda North Marriott Hotel
May 8-10, 2013

Co-sponsors: U.S. Food and Drug Administration, National Cancer Institute, American Association of Cancer Research, American Society of Clinical Oncology, Susan G. Komen for the Cure and Duke University

This workshop is a unique learning experience for all investigators and patient advocates involved in the design and conduct of oncology clinical trials. It is an especially valuable tool for individuals with limited experience in the regulatory aspects of drug development. The goal of the workshop is to expedite the development of anticancer agents so that they can be made available to patients at an accelerated rate.

This workshop is ideal for those early to mid-career academic scientists and patient advocates. Partial and total registration scholarships are available to these groups.

How to register. Online registration is open at www.acceleratingworkshop.org. Early enrollment is encouraged as the audience is intentionally kept small to enhance the exchange of ideas. For additional questions, please contact Mary Ruemker, Conference Manager, by phone at (919) 448-7593.

ALLIANCE AWARDS PROGRAM

Nomination Deadline: 2013 Achievement Award

The Alliance for Clinical Trials in Oncology Foundation is seeking nominations for the **2013 Richard L. Schilsky Cancer and Leukemia Group B Award**. The annual award acknowledges the significant contributions of an individual to cooperative group research.

The deadline for nominations is April 22, 2013.

Interested? Please submit a letter by e-mail that describes the contributions of the nominee to: Denise Brennan, Interim Treasurer of the Alliance for Clinical Trials in Oncology Foundation, at Dcollinsbrennan@partners.org.

Application Deadline: 2013 Alliance Scholar Award

The Alliance for Clinical Trials in Oncology Foundation invites applications for the **2013 Alliance Scholar Award**. Applications must be submitted by midnight CT May 6, 2013.

Interested? Visit the Alliance website (AllianceforClinicalTrialsinOncology.org) under Foundation (Awards) for application requirements.

Future Meeting Dates

2013 Group Meeting

November 7-9, 2013
Open to Alliance members

2014 Committee Meetings

May 8-10, 2014*
Open to Alliance committee members only

**date changed from March 27-29, 2014*

Group Meeting

November 6-8, 2014
Open to Alliance members

All meetings will be held at the
InterContinental Chicago O'Hare
5300 N. River Road, Rosemont, IL

For meeting and travel inquiries,
contact Katherine Faherty
e-mail: kefaherty@partners.org
phone: 617-525-3022

For more information on the Alliance
and updates about meetings, visit
AllianceforClinicalTrialsinOncology.org

Did You Know ...

If you're an Alliance member and are making a presentation on behalf of the Alliance, **templates for presentations and scientific posters** are available on the **Alliance website** at AllianceforClinicalTrialsinOncology.org. Just log onto the member side and find the templates under **Member Services** (*top right corner*) in the Frequently Used Documents section.

Call for Photos! New Alliance Website

Want to see your institution featured prominently on the new Alliance website?

If so, send us your photos. We welcome photos of all Alliance members and institutions. Just send them to us with a confirmation that all individuals pictured have given their consent for web posting to *Alliance News* at jowens@uchicago.edu. Also, make sure to include a caption with the date, location, and names of individuals in the photos.