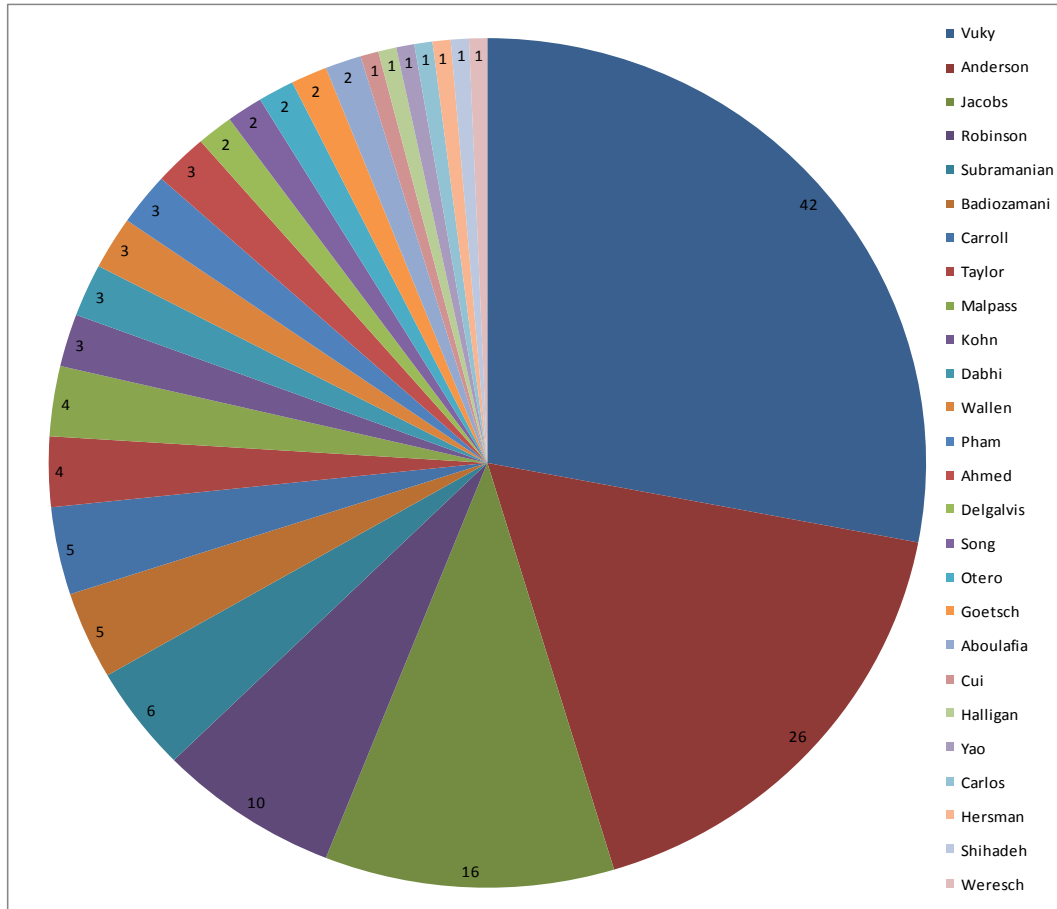


# Community Clinical Oncology Program

Benaroya Research Institute at Virginia Mason Medical Center

Volume 11 | April 2010

## Accrual by Investigator for June 2009 - March 2010



### Affiliate Sites and Investigators:

#### Valley Medical Center

Jonathan Britell, Nancy Cui, John Hersman, Richard Ingber

#### Evergreen Medial Center

Timothy Carlos, Carol Van Haelst, Aimee Kohn, Matthew Lonergan

#### Providence Cancer Center

Jeanne Anderson, Dennis Beckworth, Dale Webb, Latha Subramanian, Paul Ferucci, John Halligan, Susan Delgalvis, Jamie Blom, Mark Levandovsky

#### Fairbanks Oncology

Essam Shihadeh, Michael Carroll

#### Pacific Medical Center

Sharmila Ahmed, Vik Dabhi, Joseph Weresch

#### VMMC/BRI

David Aboulafia, Andrew Jacobs, Thomas Malpass, Henry Otero, Nanette Robinson, Huong Pham, Vincent Picozzi, Kas Badiozamani, Guobin Song, Michelle Yao, Jacqueline Vuky, Lynne Taylor, Amy Brockmeyer

## Upcoming Study: Tadalafil in Preventing Erectile Dysfunction in Patients With Prostate Cancer Treated With Radiation Therapy

In the next month, we hope to begin enrolling patients to RTOG 0831. **It is currently closed to new accrual due to problems with drug distribution.** This randomized phase III trial is studying the efficacy of tadalafil (Cialis) compared with a placebo in preventing erectile dysfunction in patients with prostate cancer treated with radiation therapy.

### Abbreviated Eligibility Criteria:

- Patients must start tadalafil/placebo within 7 days of beginning RT
- Patients must be stage T1b-T2b
- Baseline serum PSA value performed with an FDA-approved assay within the past 3 months and meets 1 of the following criteria:
  - ◊ Gleason score < 7 and PSA < 20 ng/mL
  - ◊ Gleason score ≥ 7 and PSA < 15 ng/mL
- Planned treatment must be either external radiother-

apy alone to the prostate ± seminal vesicals only at a dose of 72-79.2 Gy OR brachytherapy alone

- Patients must be potent prior to study entry
- Current or previous use of erectile aids allowed so long as patient agrees to only take drug/placebo during trial
- No hormone therapy within past 6 months
- No cancer within past 5 years
- Partner or spouse of study patient encouraged to participate in QOL part of study

### For more information:

Protocol ID: RTOG 0831 / IRB10003 / NCT00931528

Sites: VMMC, FAIR, STF

PI: Huong Pham, MD

Contact: Erica Swenson, CCRC / (206) 625-7373 x 67471

Pager: (206) 405-9815 / erica.swenson@vmmc.org

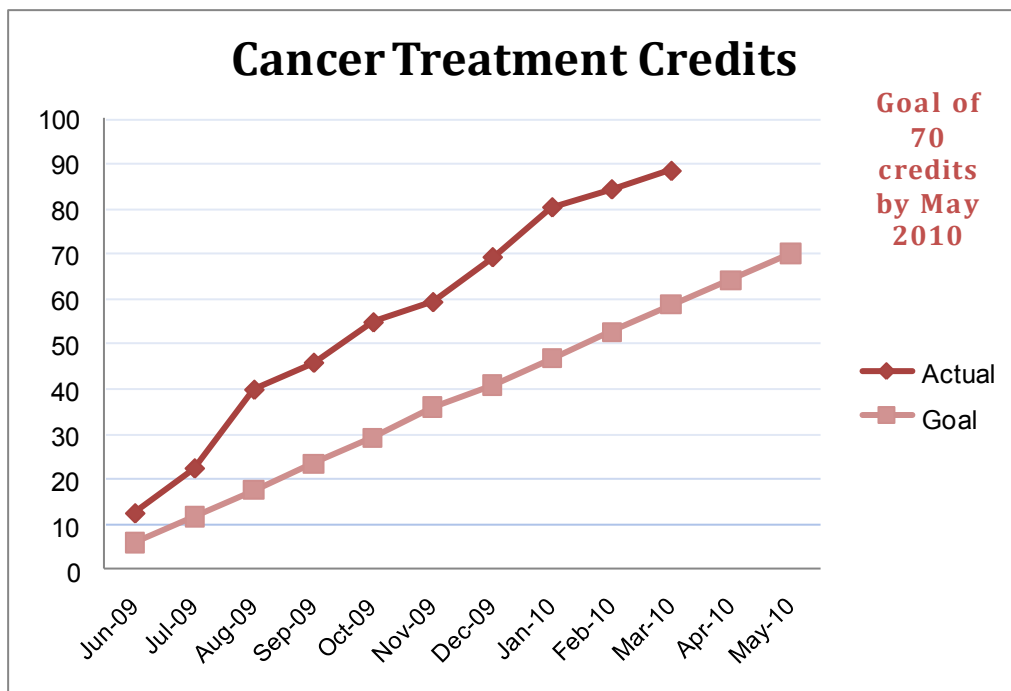
### Inside This Issue:

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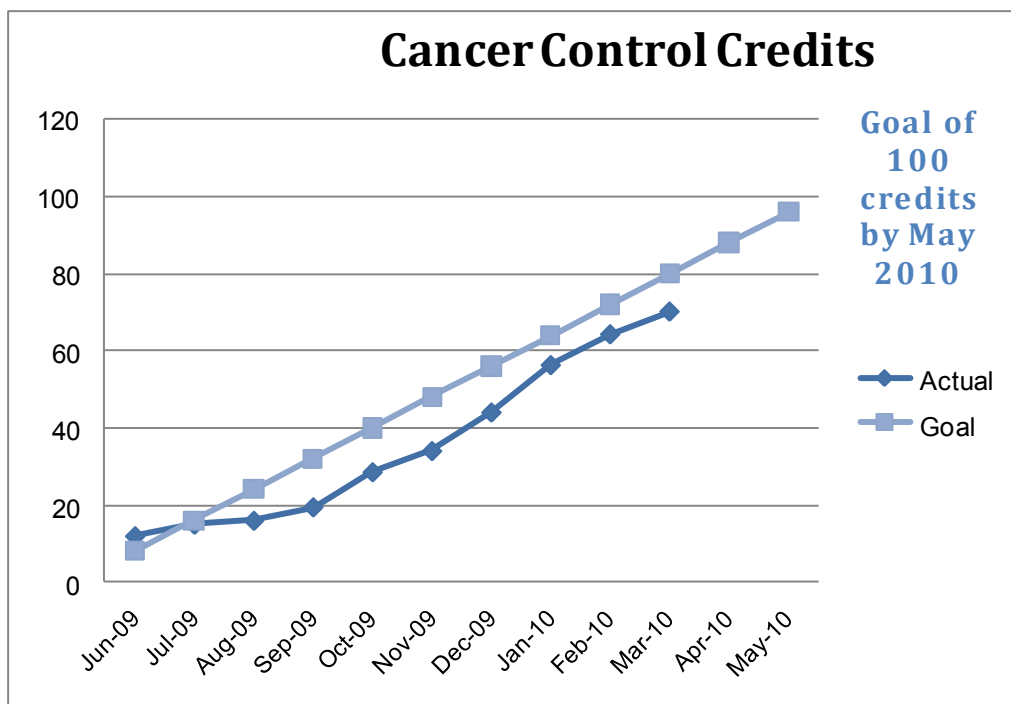
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Community Clinical Oncology Program  
1100 Ninth Avenue, M.S. D4-CRP  
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Phone: (206) 341-1044  
Fax: (206) 625-7254  
E-mail: CancerResearch@vmmc.org

## Accrual to Date Compared to Goal

The graphs on this page demonstrate accrual to date compared to goal. We have exceeded our goal for treatment credits; however, we are still lagging behind our goal in cancer control credits. Please continue your great work enrolling patients to cancer control and treatment studies.



**We met our goal for the year for Cancer Treatment Accrual!**  
**For Cancer Control we are at 70% of our goal for the year.**



## Personnel Changes

*We would like to bid goodbye to Travis Doran, who has been a research coordinator at Virginia Mason for the past two years. His studies have all been transferred to other coordinators. Please see the most recent version of the Cancer Booklet, or the attached study list, for the new study contact.*

*We also would like to welcome Dr. Amy Brockmeyer our new Gynecologic Oncology Group (GOG) principal investigator, and Jin-won Kim, our new research assistant.*

## Study Closures

**S0421**  
**CALGB 90203**

## ELECTRONIC FINANCIAL DISCLOSURE FORMS

As some of you may have noticed, we recently began a new electronic method of requesting financial disclosure forms (FDFs).

For studies that require FDFs, all key personnel (other than the principal investigator who must submit a paper FDF) are required to complete an email FDF before the study start, and annually thereafter. You may receive emails from either

Jinwon Kim, research assistant, or from research coordinators requesting that you complete an email FDF.

Please try to respond to these emails promptly, as delays significantly slow IRB approval. Ms. Kim tracks the amount of time it takes to receive a response to FDF requests and some personnel have taken over 35 days to respond even with multiple requests. However, Ms. Kim has found that elec-

tronic FDFs have expedited the FDF collection process. Please see the examples below of an initial request, and the response for an email FDF.

We would appreciate your feedback for this new process. If you have questions, comments, or suggestions please email [cancerresearch@vmmc.org](mailto:cancerresearch@vmmc.org).

### INITIAL REQUEST FOR FINANCIAL DISCLOSURE

From: Jacks, Andrea  
 To: [Redacted]  
 Cc: [Redacted]  
 Subject: Financial Disclosure, IRB09061, Randomized Study of Soy Protein and Effexor™ on Vasomotor Symptoms of Men with Prostate Cancer

Please reply to this email, and mark "X" in the appropriate space below.

TO: [Redacted]  
 RE: Financial Relationship Disclosure

PI: Jacqueline Vuky, MD  
 IRB#: IRB09061  
 Short Title: WFU97405: Randomized Study of Soy Protein and Effexor™ on Vasomotor Symptoms of Men with Prostate Cancer

Do you or your immediate family have any potential or actual financial interests, relationships or conflicts in the last mentioned study? [Link to the [VMHS, VMMC, BRI Research Conflicts of Interest Policy](#) for more details.]

Sponsor(s): National Cancer Institute, Biologics Inc.  
 Drug/Biologic: Soy Protein, Effexor™  
 Device(s): N/A

I do NOT have a Financial Interest or Relationship  
 I do have a Financial Interest or Relationship (Please complete a full [Financial Relationship Disclosure Statement](#))

### RESPONSE TO FINANCIAL DISCLOSURE

From: [Redacted]  
 To: Jacks, Andrea  
 Cc: [Redacted]  
 Subject: RE: Financial Disclosure, IRB09061, Randomized Study of Soy Protein and Effexor™ on Vasomotor Symptoms of Men with Prostate Cancer

From: Jacks, Andrea [mailto:Andrea.Jacks@vmmc.org]  
 Sent: Monday, March 29, 2010 10:38 AM  
 To: [Redacted]  
 Subject: Financial Disclosure, IRB09061, Randomized Study of Soy Protein and Effexor™ on Vasomotor Symptoms of Men with Prostate Cancer

Please reply to this email, and mark "X" in the appropriate space below.

TO: [Redacted]  
 RE: Financial Relationship Disclosure

PI: Jacqueline Vuky, MD  
 IRB#: IRB09061  
 Short Title: WFU97405: Randomized Study of Soy Protein and Effexor™ on Vasomotor Symptoms of Men with Prostate Cancer

Do you or your immediate family have any potential or actual financial interests, relationships or conflicts in the last mentioned study? [Link to the [VMHS, VMMC, BRI Research Conflicts of Interest Policy](#) for more details.]

Sponsor(s): National Cancer Institute, Biologics Inc.  
 Drug/Biologic: Soy Protein, Effexor™  
 Device(s): N/A

I do NOT have a Financial Interest or Relationship  
 I do have a Financial Interest or Relationship (Please complete a full [Financial Relationship Disclosure Statement](#))

\*\*\*\*\* CONFIDENTIALITY DISCLAIMER \*\*\*\*\*

## Cooperative Group Meeting Schedule

Date of Meeting	Research Base	Location
April 14-17, 2010	SWOG Spring	San Francisco, CA
April 22-25, 2010	NSABP Spring	San Francisco, CA
May 11-14, 2010	NCCTG Spring	Rochester, MN
June 17-20, 2010	RTOG Spring	Philadelphia, PA
July 16-18, 2010	GOG Spring	Boston, MA
October 20-23, 2010	SWOG Fall	Chicago, IL
January 28-30, 2011	GOG Fall/Winter	San Diego, CA

**There are funds available for CCOP travel.**

If you are interested in attending an upcoming meeting please e-mail Beth Edelheit or Jacqueline Vuky at : [CancerResearch@vmmc.org](mailto:CancerResearch@vmmc.org)

**Our CCOP program is made possible by support from an NCI grant and the Benaroya Research Institute, as well as contributions from our affiliate sites.**

Virginia Mason CCOP Newsletter Editor: Andrea Jacks, CCRC

Assistant Editor: Erica Swenson, CCRC

For questions, comments, or if you have a story for us, please email:

[CancerResearch@vmmc.org](mailto:CancerResearch@vmmc.org)

