



Alliance for Clinical Trials in Oncology
Date Thursday, November 2, 2017
Loews Hotel Chicago O'Hare
Cassatt C D
Time 10:30 am – 12:30 pm

Health Outcomes Committee Meeting Agenda

Meeting available by teleconference: Dial 800-501-8979, Access Code: 9060180

Chairs: Amylou Dueck, PhD and Michelle Naughton, PhD
Vice-Chairs: Ronald Chen, MD and Gita Thanarajasingam, MD

Time	Description/Title	Presenter
10:30	Welcome and Announcements	Amylou Dueck, PhD Michelle Naughton, PhD
Guest Presentation		
10:35	Tobacco Use and Cessation Among Cancer Patients, Tobacco Use and Cancer Chemoprevention and Screening, Clinical Trials	Stephanie Land, PhD
Pilot Project/Junior Investigator Final Results		
11:05	A Prospective Pilot Study to Evaluate and Correlate Early Lean Muscle Loss with Functional Activity in Metastatic Gastrointestinal and Lung Cancer Patients	Eric Roeland, MD
10:25	Supporting Head and Neck Cancer Survivors in Making Shared Decisions for Lung Cancer Screening	Kimberly Dukes, PhD presenting on behalf of Nitin Pagedar, MD & Richard Hoffman, MD
Study Updates		
11:45	A221208: Randomized Phase II Study: Corticosteroids + Bevacizumab vs. Corticosteroids + Placebo (BeSt) for Radionecrosis after Radiosurgery for Brain Metastases	Paul Brown, MD
12:00	A151729: Impact of Age and Performance Status on Toxicity over Time in Patients with Advanced NSCLC Receiving Chemotherapy	Melisa Wong, MD
12:15	AFT-28: Direct Oral Anticoagulants (DOACs) versus LMWH +/- Warfarin for VTE in Cancer: A Randomized Effectiveness Trial (CANVAS Trial)	Deborah Schrag, MD

12:20	Methodology Working Group Updates	Jeffrey Sloan, PhD
12:30	Adjourn	

Notation Items

I. Reminder Jimmie Holland Lecture

Friday, November 3, 8:30 – 9:30 AM CT

Avedon A – D

Title: Communication Skills Training for Oncology Clinicians: Development, Implementation and Impact

Presenter: Patricia A. Parker, Ph.D.

II. Study Tracker

III. Publications Since May 2017 Meeting

Health Outcomes Primary Publications:

- Basch, E., A. C. Dueck, L. J. Rogak, L. M. Minasian, W. K. Kelly, A. M. O'Mara, A. M. Denicoff, D. Seisler, P. J. Atherton, E. Paskett, L. Carey, M. Dickler, R. S. Heist, A. Himelstein, H. S. Rugo, W. M. Sikov, M. A. Socinski, A. P. Venook, D. J. Weckstein, D. E. Lake, D. D. Biggs, R. A. Freedman, C. Kuzma, J. J. Kirshner and D. Schrag (Aug 01 2017). "Feasibility Assessment of Patient Reporting of Symptomatic Adverse Events in Multicenter Cancer Clinical Trials." *JAMA Oncol* **3**(8): 1043-1050. PMID: 28208174. PMC5553624. (Study ID: C70501).
- Enzinger, A., J. Wind, L. Frank, N. McCleary, C. Cronin, H. Sanoff, K. Van Loon, K. Matin, A. Bullock, N. Meropol, H. Uno and D. Schrag (May 2017). "Understanding the benefits of palliative chemotherapy (PC): do patients hear what they want to hear?" *J Clin Oncol* **35**(suppl; abstr 6575). (Study ID: NCT02282722 (CCP Junior Faculty Award)). Poster Presentation.
- Hacker, E. D., A. M. Fink, T. Peters, C. Park, G. Fantuzzi and D. Rondelli (May/Jun 2017). "Persistent Fatigue in Hematopoietic Stem Cell Transplantation Survivors." *Cancer Nurs* **40**(3): 174-183. PMID: 27333126. PMC5177539. (Study ID: CALGB CCOP Pilot).
- Hacker, E. D., I. Kim, C. Park and T. Peters (Jul/Aug 2017). "Real-time Fatigue and Free-Living Physical Activity in Hematopoietic Stem Cell Transplantation Cancer Survivors and Healthy Controls: A Preliminary Examination of the Temporal, Dynamic Relationship." *Cancer Nurs* **40**(4): 259-268. PMID: 27922918. PMC5459685. (Study ID: CALGB CCOP Pilot).
- Thanarajasingam, G., A. Dueck, P. J. Novotny, T. E. Witzig, T. M. Habermann, G. S. Nowakowski, C. R. Flowers, N. L. Bartlett, K. A. Blum, B. N. Pitcher, S.-H. Jung, P. J. Atherton, A. Tan, J. A. Sloan and J. P. Leonard (Aug 2017). "Beyond Maximum Grade: A Novel, Longitudinal Toxicity Over Time (ToxT) Adverse Event (AE) Analysis of Lenalidomide in Follicular Lymphoma (FL) in CALGB 50401 (Alliance)" *International Conference on Malignant Lymphoma 2017*. (Study ID: A151617, C50401). Poster Presentation.

Health Outcomes Secondary Publications:

- Barton, D. L., J. A. Sloan, L. T. Shuster, P. Gill, P. Griffin, K. Flynn, S. A. Terstriep, F. N. Rana, T. Dockter, P. J. Atherton, M. Tsai, K. Sturtz, J. M. Lafky, M. Riepl, J. Thielen and C. L. Loprinzi (Sep 18 2017 Epub ahead of print). "Evaluating the efficacy of vaginal dehydroepiandrosterone for vaginal symptoms in postmenopausal cancer survivors: NCCTG N10C1 (Alliance)." *Support Care Cancer*. PMID: 28921241. PMCTBD. (Study ID: N10C1).
- Brown, P. D., K. V. Ballman, J. H. Cerhan, S. K. Anderson, X. W. Carrero, A. C. Whitton, J. Greenspoon, I. F. Parney, N. N. I. Laack, J. B. Ashman, J. P. Bahary, C. G. Hadjipanayis, J. J. Urbanic, F. G. Barker, 2nd, E. Farace, D. Khuntia, C. Giannini, J. C. Buckner, E. Galanis and D. Roberge (Aug 2017). "Postoperative stereotactic radiosurgery compared with whole brain radiotherapy for resected metastatic brain disease (NCCTG N107C/CEC.3): a multicentre, randomised, controlled, phase 3 trial." *Lancet Oncol* **18**(8): 1049-1060. PMID: 28687377. PMC5568757. (Study ID: N107C).
- Dukes, K. and A. Seaman (November 29 Accepted 2017). ""Let's Take a Peek": Looking at, for, and away from future cancers." *American Anthropological Association Annual Meeting*. (Study ID: NCORP-funded Pilot Project). Oral Presentation.
- Jatoi, A., P. D. Steen, P. J. Atherton, D. F. Moore, K. M. Rowland, N. A. Le-Lindquist, C. S. Adonizio, A. J. Jaslawski, J. Sloan and C. Loprinzi (Aug 01 2017). "A double-blind, placebo-controlled randomized trial of creatine for the cancer anorexia/weight loss syndrome (N02C4): an Alliance trial." *Ann Oncol* **28**(8): 1957-1963. PMID: 28475678. PMC Journal - In Process. (Study ID: N02C4).
- Le-Rademacher, J., R. Kanwar, D. Seisler, D. R. Pachman, R. Qin, A. Abyzov, K. J. Ruddy, M. S. Banck, E. M. Lavoie Smith, S. G. Dorsey, N. K. Aaronson, J. Sloan, C. L. Loprinzi and A. S. Beutler (Jun 20 2017 Epub

ahead of print). "Patient-reported (EORTC QLQ-CIPN20) versus physician-reported (CTCAE) quantification of oxaliplatin- and paclitaxel/carboplatin-induced peripheral neuropathy in NCCTG/Alliance clinical trials." *Support Care Cancer*. PMID: 28634656. PMCTBD. (Study ID: N08CA, N08CB).

- Ligibel, J. A., W. T. Barry, C. Alfano, D. L. Hershman, M. Irwin, M. Neuhouser, C. A. Thomson, L. Delahanty, E. Frank, P. Spears, E. D. Paskett, J. Hopkins, V. Bernstein, V. Stearns, J. White, O. Hahn, C. Hudis, E. P. Winer, T. A. Wadden and P. J. Goodwin (Sep 21, 2017 Epub ahead of print). "Randomized phase III trial evaluating the role of weight loss in adjuvant treatment of overweight and obese women with early breast cancer (Alliance A011401): study design." *NPJ Breast Cancer* 3: 37. PMID: 28948213. PMC5608692. (Study ID: A011401).
- Shapiro, C. L., J. P. Moriarty, S. Dusetzina, A. L. Himelstein, J. C. Foster, S. S. Grubbs, P. J. Novotny and B. J. Borah (Oct 12 2017 Epub ahead of print). "Cost-Effectiveness Analysis of Monthly Zoledronic Acid, Zoledronic Acid Every 3 Months, and Monthly Denosumab in Women With Breast Cancer and Skeletal Metastases: CALGB 70604 (Alliance)." *J Clin Oncol*: Jco2017737437. PMID: 29023215. PMC Journal - In Process. (Study ID: 70604).
- Sio, T. T., P. J. Atherton, W. K. Zhen, Y. I. Garces, D. J. Ma, A. Ganti, S. E. Schild and R. C. Miller (October 15-18 2017). "A pilot, randomized trial of daily lisinopril vs placebo to prevent radiation-induced pulmonary distress (Alliance MC1221)." *World Conference on Lung Cancer*. (Study ID: MC1221). Poster Presentation.

Committee Members			
¹ Amylou Dueck, PhD (Co-Chair)	² Ivana T. Croghan, PhD	¹ Luke J. Huebner, MS	Deborah Schrag, MD
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