



Alliance for Clinical Trials in Oncology

Date Friday, November 2, 2018

Loews Hotel Chicago O'Hare

Room Guggenheim 1

Time 4:30 pm – 6:30 pm

Health Outcomes Committee Meeting Agenda

- Meeting available by teleconference: Dial 800-501-8979, Access Code: 9060180
- Slide presentations will not be posted on the Alliance website, but can be requested from the CCP Program Manager (lafky.jacqueline@mayo.edu).

Chairs: Amylou Dueck, PhD and Michelle Naughton, PhD

Vice-Chairs: Ronald Chen, MD and Gita Thanarajasingam, MD

Time	Description/Title	Presenter
4:30	Welcome and Announcements	Amylou Dueck, PhD Michelle Naughton, PhD
4:35	Health Outcomes Committee Accomplishments	Amylou Dueck, PhD Michelle Naughton, PhD
	Study Presentation	
4:45	AFT-28: Direct Oral Anticoagulants (DOACs) Versus LMWH +/- Warfarin for FTE in Cancer: A Randomized Effectiveness Trial (CANVAS Trial)	Deb Schrag, MD
4:50	A231602CD: Assessing financial difficulty in patients with blood cancers	Rena Conti, MD
	New Pilot Project Presentation	
5:00	Curcumin for Breast Cancer Survivors with Aromatase Inhibitor-induced Joint Arthropathy: A Randomized Double-blinded Controlled Pilot Study	Lisa Yee, MD and Maryam Lustberg, MD
	Mini-Symposium on Improving Adverse Event Assessment: The Lancet Haematology Commission	
5:15	The Imperative for Change in Toxicity Assessment and The Lancet Haematology Commission	Gita Thanarajasingam, MD
5:25	Beyond Maximum Grade: Capturing Patient Input to Understand the Tolerability of Cancer Treatment	Lori Minasian, MD, FACP

Time	Description/Title	Presenter
5:40	Beyond Maximum Grade: Assessment of Long-Term Toxicity in Cancer Survivors	Carrie Thompson, MD
5:55	Remarks from the Patient Perspective on Adverse Event Assessment	Jane Perlmutter, PhD
6:00	Discussion and Brainstorming	Amylou Dueck, PhD Michelle Naughton, PhD
6:20	Methodology Working Group Update	Jeff Sloan, PhD
6:30	Adjourn	

Notation Items

I. Study Tracker

II. Publications Since May 2018 Meeting

Health Outcomes Primary Publications:

- Basch, E., A. C. Dueck, L. J. Rogak, S. A. Mitchell, L. M. Minasian, A. M. Denicoff, J. K. Wind, M. C. Shaw, N. Heon, Q. Shi, B. Ginos, G. D. Nelson, J. P. Meyers, G. J. Chang, H. J. Mamon, M. R. Weiser, T. Kolevska, B. B. Reeve, D. W. Bruner and D. Schrag (Sep 11 2018 Epub ahead of print). "Feasibility of Implementing the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events in a Multicenter Trial: NCCTG N1048." *J Clin Oncol*: Jco2018788620. PMID: 30204536. PMCJournal - In Process.
- Krok-Schoen, J. L., M. J. Naughton, G. S. Young, J. Moon, E. D. Paskett and D. M. Post (May 20 2018). "Increasing Adherence to Adjuvant Hormone Therapy among Breast Cancer Patients: A Smart Phone App-Based Pilot Study." *J Clin Oncol* **36**(15_suppl): abstr e12523. Publication Only.
- Naughton, M. J., D. K. Seisler, J. A. Sloan, H. Liu, J. Le-Rademacher, J. Oliveri, J. M. Armer, G. Unzeitig, M. Schwartz, M. Melnik, J. R. Taylor and E. D. Paskett (Accepted). "Health-related quality of life outcomes for The LEAP Study - CALGB 70305 (Alliance): a lymphedema prevention intervention trial for newly diagnosed breast cancer patients." *ISOQOL Annual Meeting 2018*. Poster Presentation.

Health Outcomes Secondary Publications:

- Armer, J. M., K. V. Ballman, L. McCall, N. C. Armer, Y. Sun, T. Udmuangpia, K. K. Hunt, E. A. Mittendorf, D. R. Byrd, T. B. Julian and J. C. Boughey (Jul 6 2018 Epub ahead of print). "Lymphedema symptoms and limb measurement changes in breast cancer survivors treated with neoadjuvant chemotherapy and axillary dissection: results of American College of Surgeons Oncology Group (ACOSOG) Z1071 (Alliance) substudy." *Support Care Cancer*. PMID: 29980907.
- Barginear, M., A. C. Dueck, J. B. Allred, B. Craog, H. J. Cohen, R. A. Freedman, H. Hurria, G. Kimmick, J. G. Le-Rademacher, S. Lichtman, H. B. Muss, L. N. Shulman, J. M. Lafky and A. Jatoi (Accepted 8/31/2018). "Age and the Risk of Paclitaxel-Induced Neuropathy in Women with Early-Stage Breast Cancer (Alliance A151411): Results from 1881 patients from Cancer and Leukemia Group B (CALGB) 40101 " *The Oncologist*.
- Boughey, J. C., K. Ballman, L. McCall, H. Kuerer, K. K. Hunt and J. M. Armer (May 20 2018). "Factors associated with lymphedema in patients/women with node positive breast cancer treated with neoadjuvant chemotherapy and axillary dissection on a prospective clinical trial ACOSOG Z1071 (Alliance)." *J Clin Oncol* **36**(15_suppl): abstr 513. Poster Discussion.
- Gounder, M. M., M. R. Mahoney, B. A. V. Tine, V. Ravi, S. Attia, H. A. Deshpande, A. A. Gupta, M. M. Milhem, R. M. Conry, S. Movva, M. J. Pishvaian, J. Crawford, T. Sabagh, R. G. Maki, W. D. Tap, R. A. Lefkowitz, N. P. Agaram, J. J. Wright, A. C. Dueck and G. K. Schwartz (May 20 2018). "Phase III, randomized, double blind, placebo-controlled trial of sorafenib in desmoid tumors (Alliance A091105)." *J Clin Oncol* **36**(15_suppl): abstr 11500. Oral Presentation.

- Li, D., L. M. McCall, O. M. Hahn, C. A. Hudis, H. J. Cohen, H. B. Muss, A. Jatoi, J. M. Lafky, K. V. Ballman, E. P. Winer, D. Tripathy, B. Schneider, W. Barry, M. N. Dickler and A. Hurria (Sep 2018). "Identification of risk factors for toxicity in patients with hormone receptor-positive advanced breast cancer treated with bevacizumab plus letrozole: a CALGB 40503 (alliance) correlative study." *Breast Cancer Res Treat* **171**(2): 325-334. PMID: 29789969. PMC6076849.
- Ligibel, J. A., W. T. Barry, C. M. Alfano, D. L. Hershman, M. L. Irwin, M. Neuhouser, C. A. Thomson, L. Delahanty, E. Frank, P. Spears, E. D. Paskett, J. O. Hopkins, V. Bernstein, V. Stearns, J. R. White, T. Wadden, P. J. Goodwin, L. A. Carey, A. Partridge and E. P. Winer (May 20 2018). "The Breast Cancer Weight Loss (BWEL) trial: Randomized phase III trial evaluating the role of weight loss in adjuvant treatment of overweight and obese women with early-stage breast cancer (Alliance A011401)." *J Clin Oncol* **36**(15_suppl): abstr TPS598. Poster Presentation.
- Pacyna, J. E., J. A. Sloan, S. P. Kim, H. Sedlacek and J. C. Tilburt (Oct 20 2018). "Lessons learned from implementing the first Alliance NCORP Research Base Cancer Care Delivery Research (CCDR) trial A191402CD." *Journal of Clinical Oncology* **36**(supple 30): abstr 175. Poster Presentation.
- Pacyna, J. E., S. Kim, K. Yost, H. Sedlacek, D. Petereit, J. Kaur, B. Rapkin, R. Grubb, E. Paskett, G. J. Chang, J. Sloan, E. Basch, B. Major, P. Novotny, J. Taylor, J. Buckner, J. K. Parsons, M. Morris and J. C. Tilburt (Aug 6 2018). "The comparative effectiveness of decision aids in diverse populations with early stage prostate cancer: a study protocol for a cluster-randomized controlled trial in the NCI Community Oncology Research Program (NCORP), Alliance A191402CD." *BMC Cancer* **18**(1): 788. PMID: 30081846. PMC6080528.
- Paskett, E. D., J. Le-Rademacher, J. M. Oliveri, M. J. Naughton, J. M. Armer, H. Liu, D. K. Seisler, J. R. Taylor and J. A. Sloan (Accepted). "The LEAP Study: Effects of a lymphedema prevention intervention on swelling, range of motion and quality of life." *IPOS Annual Meeting 2018*. Oral Presentation.
- Phipps, A. I., Q. Shi, T. J. Zemla, E. Dotan, S. Gill, R. M. Goldberg, S. Hardikar, B. Jahagirdar, P. J. Limburg, P. A. Newcomb, A. Shields, F. A. Sinicrope, D. J. Sargent and S. R. Alberts (Jun 2018). "Physical Activity and Outcomes in Patients with Stage III Colon Cancer: A Correlative Analysis of Phase III Trial NCCTG N0147 (Alliance)." *Cancer Epidemiol Biomarkers Prev* **27**(6): 696-703. PMID: 29563133. PMC5984710.
- Seaman, A. T., K. Dukes, R. M. Hoffman, A. J. Christensen, N. Kendell, A. L. Sussman, M. Velez-Bermudez, R. J. Volk and N. A. Pagedar (Oct 2018). "The complicated 'Yes': Decision-making processes and receptivity to lung cancer screening among head and neck cancer survivors." *Patient Educ Couns* **101**(10): 1741-1747. PMID: 29709410. PMC6119119.
- Sio, T. T., M. J. Blanchard, P. J. Novotny, S. H. Patel, J.-C. M. Rwigema, L. D. Pederson, L. A. McGee, M. E. Gamez, G. R. Seeger, J. A. Martenson, Y. Grover, M. A. N. Wittich, Y. I. Garces, R. L. Foote, R. C. Miller and M. Y. Halyard (Accepted). "N-Acetylcysteine Rinse for Thick Secretion and Mucositis of Head and Neck Chemoradiotherapy (Alliance MC13C2): A Double-Blind Randomized Clinical Trial." *ESTRO Annual Meeting 2018*. Poster Presentation.
- Wong, M. L., J. Gao, G. Thanarajasingam, J. A. Sloan, A. C. Dueck, P. J. Novotny, A. Jatoi, A. Hurria, W. A. Wood, J. L. Feliciano, L. C. Walter, C. Miaskowski, T. E. Stinchcombe and X. Wang (Accepted). "Comparison of Chemotherapy Toxicity Over Time According to Age and Performance Status in Patients with Advanced Non-Small Cell Lung Cancer: A Toxicity Over Time Analysis of CALGB 9730 (Alliance A151729)." *SIOG Annual Meeting 2018*. Poster Presentation.
- Wood, W. A., T. Xianming, N. S. Grover, A. M. Stover, A. Kannappan, P. M. Carr, R. Burkes, T. C. Shea, A. A. S., S. M. Devine, J. A. Ligibel, A. V. Bennett and E. M. Basch (Oct 20 2018). "Objective measures of performance status in cancer: A pilot Alliance study." *Journal of Clinical Oncology* **36**(suppl 30): abstr 284. Poster Presentation.

Committee Members as of October 8, 2018			
¹ Amylou Dueck, PhD (Co-chair)	Cristina M. Checka, MD	¹ Brenda Ginos	² Shoshana M. Rosenberg, ScD
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