



## Cancer Control Program Health Outcomes Committee

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Ethan M. Basch, M.D.  
Jeffrey A. Sloan, Ph.D.  
Co-Chairs

### Agenda Health Outcomes Full Committee Meeting Friday November 4, 2016 1:30 – 3:30 PM CT Room: Guggenheim 1

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

#### I. Welcome & Announcements

- A. QOL Study Chairs
- B. Leadership

#### II. Study Results/Updates (5 minutes)

- A. A Breast In-Visit Decision Engagement (ABIDE) to Reduce Uninformed Decision Making for Contralateral Prophylactic Mastectomy in Women with Newly Diagnosed Localized Breast Cancer  
*Katharine Yao, MD*

#### III. New Concepts (10 – 15 minutes)

- A. Your Feedback on Study Result Summaries  
*Deborah Collyar*
- B. EAQ152: Communication and Education in Tumor Profiling (COMET)  
*Angela Bradbury, MD*
- C. Olanzapine for the treatment of chronic nausea and vomiting, unrelated to chemotherapy or radiation, in advanced cancer patients: a pilot clinical trial  
*Rudolph Navari, MD, PhD*

#### IV. Study Results/Updates (10 – 15 minutes each)

- A. Patient Centered Videos to Enhance Informed Consent for Palliative Chemotherapy (NCT02282722)  
*Andrea Enzinger, MD*
- B. N107C/CEC.3: A Phase III Trial of Post-surgical Stereotactic Radiosurgery (SRS) Compared with Whole Brain Radiotherapy (WBRT) for Resected Metastatic Brain Disease  
*Paul D. Brown, MD*
- C. A Novel Approach to Analyzing Toxicity over Time in Lymphoma Clinical Trials: Update  
*Gita Thanarajasingam, MD*

#### V. QOL Methodology Update (10 minutes)

*Jeff Sloan, PhD*

#### VI. PCORI Updates (10 minutes each)

- A. Electronic Patient Reporting of Symptoms during Outpatient Cancer Treatment: A U.S. National Randomized Controlled Trial ("PRO-TECT")  
*Ethan Basch, MD*
- B. AFT-28: CANVAS Trial DOACs versus LMWH +/- Warfarin  
*Deb Schrag, MD*



CANVAS  
Trial\_AFT-28\_Cliniciar

## VII. Notation Items

- A. QOL Study Co-Chairs
- B. Study Tracker



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## VIII. Other Business

Committee Members				
Ethan M. Basch, MD (Co-chair)	<sup>2</sup> Deborah Collyar	<sup>2</sup> Eileen D. Hacker, PhD, APN, AOCN	Bryce B. Reeve, PhD	
Jeffrey A. Sloan, PhD (Co-chair)	<sup>2</sup> Ivana T. Croghan, PhD	Michele Y. Halyard, MD	<sup>2</sup> Shoshana M. Rosenberg, ScD	
<sup>1</sup> Amylou Dueck, PhD (V. Co-chair)	Teresa K. Deshields, PhD	Jimmie C. Holland, MD	<sup>2</sup> Kathryn J. Ruddy, MD	
Michelle Naughton, PhD, MPH (V. Co-chair)	Deborah Dickman	<sup>2</sup> Joleen M. Hubbard, MD	Lila J. Rutten, PhD, MPH	
Timothy A. Ahles, PhD	Michael A. Diefenbach, PhD	Nandita Khera, MD, MPH	<sup>2</sup> Hanna K. Sanoff, MD, MPH	
<sup>1</sup> Jacob B. Allred, MS	<sup>1</sup> Travis J. Dockter, MS	Heidi D. Klepin, MD	<sup>1</sup> Daniel V. Satele	
<sup>2</sup> Terri S. Armstrong, PhD, ANP-BC, FAANP, FAAN	Ann Marie Dose, PhD, RN, ACNS-BC, ACHPN	Leslie J. Kohman, MD	Deborah Schrag, MD	
<sup>1</sup> Pamela J. Atherton, MS	<sup>3</sup> Karen Durham	Jacqueline M. Lafky, MS	<sup>1</sup> Drew K. Seisler	
Thomas M. Atkinson, PhD	Elena Elkin, PhD	<sup>1</sup> Jennifer G. Le-Rademacher, PhD	Charles L. Shapiro, MD	
<sup>2</sup> Antonia V. Bennett, PhD	Andrea C. Enzinger, MD	<sup>2</sup> Joanne Lester, PhD, CRNP, ANP-BC, AOCN	Terence T. Sio, MD	
Anne H. Blaes, MD	Josephine L. Feliciano, MD	<sup>1</sup> Heshan Liu, MS	<sup>1</sup> Angelina D. Tan	
Victoria S. Blinder, MD	Stewart B. Fleishman, MD	<sup>1</sup> Brittney T. Major, MS	John R. Taylor, MA	
<sup>2</sup> Paul D. Brown, MD	<sup>1</sup> Jared C. Foster, PhD	Linda W. Martin, MD, MPH	Shelby A. Terstriep, MD	
Jan C. Buckner, MD	<sup>1,2</sup> Nathan R. Foster, MS	Diana C. Mehedint, MD	<sup>2</sup> Linda Veit, MPH, CCRP, CCRC	
<sup>2</sup> Jane Cerhan, PhD	Amanda Francescatti, MS	<sup>1</sup> Paul J. Novotny, MS	Srinivas Vourganti, MD	
George J. Chang, MD	Marlene H. Frost, PhD, RN	<sup>1</sup> Levi D. Pederson	Rahma M. Warsame, MD	
<sup>2</sup> Ronald C. Chen, MD, MPH	<sup>1</sup> Briant F. Fruth	Jeffrey M. Peppercorn, MD, MPH	Giles F. Whalen, MD	
Selina L. Chow, MD	<sup>2</sup> Lucy J. Gansauer, RN, MSN, CPSO, OCN	<sup>3</sup> Jane Perlmutter, PhD	William A. Wood, MD, MPH	
<sup>2</sup> Harvey J. Cohen, MD	<sup>2</sup> Apar K. Ganti, MD	Erica N. Peters, PhD	<sup>1</sup> Tyler J. Zemla, MS	

<sup>1</sup>Statistician    <sup>2</sup>Liaison    <sup>3</sup>Patient Advocate

### Primary Sponsoring Committee – Health Outcomes Manuscripts

- Atherton, P. J., K. N. Burger, L. D. Pederson, S. Kaggal and J. A. Sloan (Epub ahead of print Jun 30 2016). "Patient-reported Outcomes Questionnaire Compliance in Cancer Cooperative Group Trials (Alliance N0992)." *Clin Trials*. PMID: 27365012. (Study ID: N0992).
- Bennett, A. V., K. Keenoy, M. Shouery, E. Basch and L. K. Temple (2016). "Evaluation of Mode Equivalence of the MSKCC Bowel Function Instrument, LASA Quality of Life, and Subjective Significance Questionnaire Items Administered by Web, Interactive Voice Response System (IVRS), and Paper." *Qual Life Res* **25**(5): 1123-1130. PMID: 26590838. PMC ID: PMC4841708. (Study ID: CALGB CCOP Pilot (NCT01458509)).
- Brown, P. D., K. Jaeckle, K. V. Ballman, E. Farace, J. H. Cerhan, S. K. Anderson, X. W. Carrero, F. G. Barker, 2nd, R. Deming, S. H. Burri, C. Menard, C. Chung, V. W. Stieber, B. E. Pollock, E. Galanis, J. C. Buckner and A. L. Asher (2016). "Effect of Radiosurgery Alone vs Radiosurgery with Whole Brain Radiation Therapy on Cognitive Function in Patients with 1 to 3 Brain Metastases: A Randomized Clinical Trial." *Jama* **316**(4): 401-409. PMID: 27458945. PMC ID: PMCTBD. (Study ID: N0574).
- Thanarajasingam, G., P. J. Atherton, P. J. Novotny, C. L. Loprinzi, J. A. Sloan and A. Grothey (2016). "Longitudinal Adverse Event Assessment in Oncology Clinical Trials: the Toxicity over Time (ToxT) Analysis of Alliance Trials NCCTG N9741 and 979254." *Lancet Oncol* **17**(5): 663-670. PMID: 27083333. PMCID: PMC4910515. (Study ID: N9741, 979254).

## Abstracts

Le-Rademacher, J., A. Dueck, C. Chauhan, D. Satele and J. Sloan (2016). "Association Between Patient Perception of Oncology Clinical Trial Participation and Survival: N0392 (Alliance)." *ASCO Meeting Abstracts* **34**(suppl; abstr e18122). Publication Only. (Study ID: N0392).

## Secondary Committee – Health Outcomes

### Manuscripts

- Jatoi, A., H. Muss, J. B. Allred, H. J. Cohen, K. Ballman, J. O. Hopkins, A. Gajra, J. Lafky, A. Wolff, L. Kottschade, J. Gralow and A. Hurria (2016). "Social Support and Its Implications in Older, Early-stage Breast Cancer Patients in CALGB 49907 (Alliance A171301)." *Psychooncology* **25**(4): 441-446. PMID: 25994447. PMC ID: PMC4864498. (Study ID: A171301).
- Kottschade, L., P. Novotny, A. Lyss, M. Mazurczak, C. Loprinzi and D. Barton (2016). "Chemotherapy-induced Nausea and Vomiting: Incidence and Characteristics of Persistent Symptoms and Future Directions NCCTG N08C3 (Alliance)." *Support Care Cancer* **24**(6): 2661-2667. PMID: 26768436. PMC ID: PMC4984535. (Study ID: N08C3).
- Miller, R. C., D. G. Petereit, J. A. Sloan, H. Liu, J. A. Martenson, J. D. Bearden, 3rd, R. Sapiante, G. R. Seeger, R. B. Mowat, B. Liem, M. J. Iott and C. L. Loprinzi (2016). "N08C9 (Alliance): A Phase 3 Randomized Study of Sulfasalazine Versus Placebo in the Prevention of Acute Diarrhea in Patients Receiving Pelvic Radiation Therapy." *Int J Radiat Oncol Biol Phys* **95**(4): 1168-1174. PMID: 27354129. PMCID: PMC4955745. (Study ID: N08C9).
- Navari, R. M., R. Qin, K. J. Ruddy, H. Liu, S. F. Powell, M. Bajaj, L. Dietrich, D. Biggs, J. M. Lafky and C. L. Loprinzi (2016). "Olanzapine for the Prevention of Chemotherapy-induced Nausea and Vomiting." *N Engl J Med* **375**(2): 134-142. PMID: 27410922. (Study ID: A221301).
- Pachman, D. R., R. Qin, D. Seisler, E. M. Smith, S. Kaggal, P. Novotny, K. J. Ruddy, J. M. Lafky, L. E. Ta, A. S. Beutler, N. D. Wagner-Johnston, N. P. Staff, A. Grothey, P. M. Dougherty, G. Cavaletti and C. L. Loprinzi (2016). "Comparison of Oxaliplatin and Paclitaxel-induced Neuropathy (Alliance A151505)." *Support Care Cancer*. PMID: 27534963. (Study ID: A151505 (N08C1 and N08CB)).
- Sio, T. T., P. J. Atherton, B. J. Birkhead, D. J. Schwartz, J. A. Sloan, D. K. Seisler, J. A. Martenson, C. L. Loprinzi, P. C. Griffin, R. F. Morton, J. C. Anders, T. J. Stoffel, R. E. Haselow, R. B. Mowat, M. A. Wittich, J. D. Bearden, 3rd and R. C. Miller (2016). "Repeated Measures Analyses of Dermatitis Symptom Evolution in breast cancer patients receiving radiotherapy in a phase 3 randomized trial of mometasone furoate vs Placebo (N06C4 [alliance])." *Support Care Cancer* **24**(9): 3847-3855. PMID: 27075674. PMCID: PMC4967382. (Study ID: N06C4).

## Abstracts

- Brown, P. D., K. V. Ballman, J. H. Cerhan, S. K. Anderson, X. W. Carrero, A. C. Whitton, J. Greenspoon, I. Parney, N. N. I. Laack, J. Ashman, J.-P. Bahary, C. G. Hadjipanayis, J. Urbanic, F. G. Barker, E. Farace, D. Khuntia, C. Giannini, J. C. Buckner, E. Galanis and D. Roberge (Accepted LBA ASTRO 2016). "N107C/CEC.3: A Phase III Trial of Post-Operative Stereotactic Radiosurgery (SRS) Compared with Whole Brain Radiotherapy (WBRT) for Resected Metastatic Brain Disease." (Study ID: N107C).
- Miller, R. C., J. Le-Rademacher, T. Sio, J. L. Leenstra, G. Rine, A. Curtis, A. K. Singh, J. A. Martenson, P. J. Novotny, A. D. Tan, TBD and C. L. Loprinzi (Accepted LBA ASTRO 2016). "A Phase III, Randomized Double-Blind Study of Doxepin Rinse Versus "Magic Mouthwash" Versus Placebo in the Treatment of Acute Oral Mucositis Pain in Patients Receiving Head and Neck Radiotherapy with or without Chemotherapy (Alliance A221304)." (Study ID: A221304).