



## 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**  
**November 7, 2014**  
**10:30 AM – 12:30 PM CST**  
**Room: TBD**

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

<b>Committee Members:</b>				
Ethan M. Basch, MD (Co-chair)			Jimmie C. Holland, MD	
Jeffrey A. Sloan, PhD (Co-chair)	Deborah Collyar <sup>2</sup>		Joleen M. Hubbard, MD <sup>2</sup>	Kathryn Ruddy, MD <sup>2</sup>
<sup>1</sup> Amylou Dueck, PhD (V. Co-chair)	Coleen Crespo – Elliott <sup>3</sup>		Leesa Judd, RN, CCRP	Hanna Sanoff, MD <sup>2</sup>
Michele Y. Halyard, MD (V. Co-chair)	Ivana T. Croghan, PhD <sup>2</sup>		Karie Karolinski, BS, CCRP	Lidia Schapira, MD <sup>2</sup>
Michelle Naughton, PhD (V. Co-chair)	Katrina Croghan		Heidi Klepin, MD	Deborah Schrag, MD <sup>2</sup>
Timothy A. Ahles, PhD	Teresa K. Deshields, PhD		Leslie Kohman, MD	Iuliana Shapira, MD
Terri S. Armstrong, PhD, ANP-BC, FAANP <sup>2</sup>	Ann Marie Dose, PhD, RN, ACNS-BC <sup>2</sup>		Diana M. Kucmeroski, CCRP <sup>2</sup>	Charles L. Shapiro, MD
Thomas Atkinson, PhD	Elena Elkin, PhD		Jacqueline M. Lafky, MS	Terence Sio, MD
James D. Bearden, III, MD, FACP	Josephine L. Feliciano, MD		Joanne Lester, PhD, CRNP, ANP-BC, AOCN <sup>2</sup>	Karyn B. Stitzenberg, MD, MPH
Anne Blaes, MD	Stewart Fleishman, MD		Linda W. Martin, MD, MPH	Keith M. Swetz, MD
Victoria S. Blinder, MD	Nathan Royce Foster, MS <sup>2</sup>		Diana Mehedint, MD	John Taylor, MA
Paul D. Brown, MD <sup>2</sup>	Amanda Francescatti, MS		Michelle A. Neben Wittich, MD <sup>2</sup>	Larissa K.F. Temple, MD, FACS, FRCS
Jan C. Buckner, MD	Marlene H. Frost, PhD, RN <sup>2</sup>		Thomas H. Openshaw, MD	Shelby A. Terstriep, MD
Jack Burkhalter, PhD	Lucy Gansauer, RN, MSN, CPSO, OCN <sup>2</sup>		Jeffrey M. Peppercorn, MD <sup>2</sup>	Linda Veit, CCRP, CCRA, MPH <sup>2</sup>
Jane Cerhan, PhD <sup>2</sup>	Apar Ganti, MD <sup>2</sup>		Jane Perlmutter, PhD <sup>3</sup>	Meir Wetzler, MD <sup>2</sup>
George J. Chang, MD	Yolanda (Nina) I. Garces, MD <sup>2</sup>		Erica Peters, PhD	Giles Whalen, MD
Ronald Chen, MD, MPH <sup>2</sup>	Shari Goldfarb, MD <sup>2</sup>		Bryce B. Reeve, PhD	Jennifer Wind, MA
Harvey J. Cohen, MD <sup>2</sup>	Caprice Greenberg, MD, MPH		Paul L. Reiter, PhD	Yousuf Zafar, MD
Sean P. Collins, MD	Eileen D. Hacker, PhD, APN, AOCN <sup>2</sup>		Stephen Ristvedt, PhD <sup>2</sup>	

<sup>1</sup>Statistician

<sup>2</sup>Liaison

<sup>3</sup>Patient Advocate

### Welcome

#### I. Concept Presentations (15 minutes each)

- A. Examining Associations between Social Desirability Effects and Symptom Reporting  
*Teresa Deshields, PhD*
- B. Phase II Dignity Therapy/Life Plan in patients with pancreatic or advanced lung cancer  
*Ann Marie Dose, PhD*
- C. Impact of a Decision Intervention on Uninformed Contralateral Prophylactic Mastectomy for Early Stage Breast Cancer Patients  
*Kathy Yao, MD*

- II. **Liaison Presentations** (15 minutes each)
  - A. Cancer in the Elderly  
*Joleen Hubbard, MD and Harvey Cohen, MD*
  - B. Symptom Intervention  
*Katie Ruddy, MD*
  - C. Patient Advocate Update  
*Jane Perlmutter, PhD & Coleen Crespo-Elliott*
- III. **CCDR Update** (25 minutes)  
*George Chang, MD and Caprice Greenberg, MD*
- IV. **Reminder: Jimmie Holland Lecture 3:30-4:30 PM Friday, November 7**  
Quality of Life in Oncology Trials: 30 Years and Where Have We Come?  
*David Cella, PhD*
- V. **Notation Only: Study Tracker**– an electronic version of this will be provided when the agenda is sent to committee members in advance of the meeting; paper copies will NOT be provided at the meeting.
- VI. **Other Business** (5 minutes)

### Health Outcomes Committee (HOC) Publications

#### HOC Primary Sponsoring Committee

##### Manuscripts

- Bingener, J., J. A. Sloan, et al. (2014). "Perioperative Patient-Reported Outcomes Predict Serious Postoperative Complications: a Secondary Analysis of the COST Trial." J Gastrointest Surg. PMID: 25091846.
- Sloan, J. A., D. J. Sargent, et al. (2014). "Calibration of quality-adjusted life years for oncology clinical trials." J Pain Symptom Manage **47**(6): 1091-1099 e1093. PMID: 24246787. (2014 Jun)

##### Abstracts

- Dueck, A. C., D. W. Hillman, et al. (2014). "Quality of life (QOL) among patients (pts) with HER2+ breast cancer (bc) treated with adjuvant lapatinib and/or trastuzumab in the ALTTO study (BIG 2-06, Alliance N063D)." J Clin Oncol **32**(15\_suppl): 647. Poster presentation. (2014 Jun 11)
- Singh, J. A., D. E. Locke, et al. (2014). "Normative data and clinically significant effect sizes for single-item numerical linear analogue self-assessment (LASA) scales." J Clin Oncol **32**(15\_suppl): e17619. Publication only. (2014 Jun 11)
- Singh, J. A., D. E. Locke, et al. (2014). "Normative data and clinically significant effect sizes for single-item numerical linear analogue self-assessment (LASA) scales." ISOQOL Meeting Abstracts: Abstract 1014. Oral presentation. (October 15-18, 2014)
- Sloan, J. A., B. Major, et al. (2014). "Combining survival and toxicity effect sizes from clinical trials into an interpretable, quality-adjusted survival effect size estimate of treatment efficacy." J Clin Oncol **32**(15\_suppl): 6630. Poster presentation. (2014 Jun 11)
- Sloan, J., B. Major, et al. (2014). "Combining Survival and Toxicity Effect Sizes from Clinical Trials into an Interpretable Quality-Adjusted Survival Effect Size Estimate Of Treatment Efficacy." ISOQOL Meeting Abstracts: Abstract 1012. Poster presentation. (October 15-18, 2014)
- Sloan, J. A., M. Thong, et al. (2014). "Biologic pathways, candidate genes, and molecular markers associated with quality-of-life domains." J Clin Oncol **32**(15\_suppl): 1561. Poster presentation. (2014 Jun 11)
- Thanarajasingam, G., P. J. Novotny, et al. (2014). "A New Method to Analyze Adverse Events Longitudinally in Oncology Clinical Trials." Support Care Cancer **22**(Suppl 1): MASCC-0450. Poster presentation. (2014 Jun)
- Thanarajasingam, G., P. J. Novotny, et al. (2014). "A new method to analyze adverse events longitudinally in oncology clinical trials." J Clin Oncol **32**(15\_suppl): 3622. Poster presentation. (2014 Jun 11)

#### HOC Secondary Committee

##### Manuscripts

- Barton, D. L., G. Thanarajasingam, et al. (2014). "Phase III double-blind, placebo-controlled study of gabapentin for the prevention of delayed chemotherapy-induced nausea and vomiting in patients

- receiving highly emetogenic chemotherapy, NCCTG N08C3 (Alliance)." Cancer. PMID: 25043153. (Epub ahead of print 2014 Jul 9)
- Leal, A. D., R. Qin, et al. (2014). "North Central Cancer Treatment Group/Alliance trial N08CA-the use of glutathione for prevention of paclitaxel/carboplatin-induced peripheral neuropathy: a phase 3 randomized, double-blind, placebo-controlled study." Cancer **120**(12): 1890-1897. PMID: 24619793. (2014 Jun 15)
- Leenstra, J. L., R. C. Miller, et al. (2014). "Doxepin Rinse Versus Placebo in the Treatment of Acute Oral Mucositis Pain in Patients Receiving Head and Neck Radiotherapy With or Without Chemotherapy: A Phase III, Randomized, Double-Blind Trial (NCCTG-N09C6 [Alliance])." J Clin Oncol **32**(15): 1571-1577. PMID: 24733799. (2014 May 20)
- Mandelblatt, J. S., K. Huang, et al. (2014). "Preliminary Development and Evaluation of an Algorithm to Identify Breast Cancer Chemotherapy Toxicities Using Electronic Medical Records and Administrative Data." J Oncol Pract PMID: 25161127. (Epub ahead of print 2014 Aug 26)
- Mandelblatt, J. S., R. A. Stern, et al. (2014). "Cognitive impairment in older patients with breast cancer before systemic therapy: is there an interaction between cancer and comorbidity?" J Clin Oncol **32**(18): 1909-1918. PMID: 24841981. (2014 Jun 20)
- Park, H., R. Qin, et al. (Accepted 8/27/2014). "NCCTG N10C2 (Alliance) – A Double-Blind, Placebo-Controlled Study of Magnesium Supplements to Reduce Menopausal Hot Flashes " Menopause.
- Sheppard, V. B., L. A. Faul, et al. (2014). "Frailty and Adherence to Adjuvant Hormonal Therapy in Older Women With Breast Cancer: CALGB Protocol 369901." J Clin Oncol. PMID: 24934786. (2014 Aug 1)

### Abstracts

- Barton, D. L., J. A. Sloan, et al. (2014). "Physiologic effects of Vaginal Dehydroepiandrosterone (DHEA): Alliance Trial N10C1." Support Care Cancer **22**(Suppl 1): S223; MASCC-0049. Oral presentation. (2014 Jun)
- Barton, D. L., J. A. Sloan, et al. (2014). "Impact of vaginal dehydroepiandrosterone (DHEA) on vaginal symptoms in female cancer survivors: Trial N10C1 (Alliance)." J Clin Oncol **32**(15\_suppl): 9507. Oral presentation. (2014 Jun 11)
- Barton, D., T. Dockter, et al. (2014). Addressing the complexities of sexual health in cancer survivors. Council for the Advancement of Nursing Science, Washington, DC. September 18-20, 2014. Oral presentation.
- Fernando, H. C., R. J. Landreneau, et al. (2014). "Analysis of Longitudinal Quality of Life Data in High-risk Operable Patients with Lung Cancer: Data from Z4032 (Alliance) a Multicenter Randomized Trial." J Thoracic Cardiovascular Surg. **148**(3) Oral presentation. (2014 Sep)
- Miller, R. C., D. G. Petereit, et al. (2014). "Primary and Secondary Endpoint Analysis of N08C9 (Alliance): A Phase 3 Randomized Trial of Sulfasalazine Versus Placebo in the Prevention of Acute Radiation Enteritis." International Journal of Radiation Oncology\*Biophysics\*Physics **90**(1, Supplement): S86. Oral presentation. (2014 Sep)
- Pachman, D. R., R. Qin, et al. (2014). "Clinical course of patients with oxaliplatin-associated neuropathy: N08CB (Alliance)." J Clin Oncol **32**(15\_suppl): 3595. Poster presentation. (2014 Jun 11)
- Park, H., R. Qin, et al. (2014). "NCCTG N10C2 (Alliance): A double-blind, placebo-controlled study of magnesium supplements to reduce menopausal hot flashes." J Clin Oncol **32**(15\_suppl): 9508. Oral presentation. (2014 Jun 11)