



Cancer Control Program Health Outcomes Committee

200 First Street, SW
Rochester, MN 55905
P: 507-266-9202
F: 507-284-1803

www.allianceforclinicaltrialsinoncology.org

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: Louvre 1

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

I. Welcome

II. ACS CRP Education Committee (5 minutes)
Nancy You, MD

III. 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

IV. 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
Jane Perlmutter, PhD & Coleen Crespo-Elliott

V. CCDR Update (25 minutes)
George Chang, MD and Caprice Greenberg, MD

VI. Reminder: Jimmie Holland Lecture 3:30-4:30 PM Friday, November 7, Cassatt Ballrooms
Quality of Life in Oncology Trials: 30 Years and Where Have We Come?
David Cella, PhD

VII. Notation Only: Study Tracker



ALLIANCEStudyTrack
er_HOC_31Oct2014.

VIII. Other Business

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

¹Statistician

²Liaison

³Patient Advocate

Health Outcomes Committee (HOC) Publications Since May 2014

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 **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)