



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 May 15, 2015 2:00-5:00 PM CST

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

I. Introduction

II. Scientific Presentations (20 minutes each)

- A. PALLAS: A Randomized Phase III Trial of Adjuvant Endocrine Therapy with or without Palbociclib in Stage II-III ER+/HER2- Breast Cancer (*Erica Mayer, MD, MPH*)
- B. Comparative Effectiveness of Shared Decision Tools for Treatment of Breast Cancer (*Steven J. Katz, MD, MPH and Sarah Hawley, PhD, MPH*)
- C. Comparison Between Clinician- and Patient-Reporting of Baseline and Post-Baseline Symptomatic Toxicities in Cancer Cooperative Group Clinical Trials (NCCTG N0591) (*Thomas Atkinson, PhD*)
- D. Compliance Rate and Missing Data in Alliance Studies (*Jeff Sloan, PhD*)
- E. PRO-CTCAE: Development Update and Overview of PRO-CTCAE in Alliance Trials (*Amylou Dueck, PhD*)
- F. A Randomized Controlled Trial of Patient-reported Symptoms with Nursing Alerts for Symptom Management in Routine Medical Oncology Care (*Ethan Basch, MD*)

III. Alliance NCORP-funded Junior Investigator Project (20 minutes)

- A. Patient Centered Videos to Enhance Informed Consent for Palliative Chemotherapy (*Andrea Enzinger, MD*)

IV. Liaison Reports (10 minutes each)

- A. Breast Liaison Update (*Shari Goldfarb, MD & Jeffrey Peppercorn, MD*)
- B. CCDR Liaison Update (*Antonia Bennett, PhD*)
- C. Genitourinary Liaison Update (*Ron Chen, MD, MPH*)

V. Notation Items:

- A. Study Tracker
- B. HOC Publications Since the November 2014 Meeting (see below)
- C. Next Meeting: June 3, 2015, 4:00 PM ET/3:00 PM CT
Liaison Presentations for next meeting:
 - Publications (*Deb Collyar*)
 - Prevention (*Ivana Croghan, PhD and Joanne Lester, PhD, CRNP, ANP-BC, AOCN*)
 - Gastrointestinal (*Hanna Sanoff, MD, Joleen Hubbard, MD, and Deb Schrag, MD*)

VI. Other Business

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

¹Statistician ²Liaison ³Patient Advocate

Primary HOC Manuscripts (3):

Bingener, J., J. A. Sloan, P. J. Novotny, B. A. Pockaj and H. Nelson. Perioperative Patient-Reported Outcomes Predict Serious Postoperative Complications: a Secondary Analysis of the COST Trial. *J Gastrointest Surg*. 2015 Jan; 19(1): 65-71. PubMed PMID: 25091846; PubMed Central: PMC4289078. (Study ID: 934653)

Dueck, A. C., J. Singh, P. Atherton, H. Liu, S. Hines, C. L. Loprinzi, E. A. Perez, B. A. Mincey, A. Tan, K. Burger, C. Zhao, B. Diekmann and J. A. Sloan. Endpoint Comparison for Bone Mineral Density Measurements in North Central Cancer Treatment Group Cancer Clinical Trials N02C1 and N03CC (Alliance). *Osteoporosis International*. 2015 Mar 7 [Epub ahead of print]. PubMed PMID: 25749740; PubMed Central: In process at NIHMS 681319. (Study ID: N02C1 and N03CC)

Fernando, H. C., R. J. Landreneau, S. J. Mandrekar, F. C. Nichols, T. A. DiPetrillo, B. F. Meyers, D. E. Heron, S. L. Hillman, D. R. Jones, S. L. Starnes, A. D. Tan, B. D. T. Daly and J. B. Putnam. Analysis of longitudinal quality-of-life data in high-risk operable patients with lung cancer: Results from the ACOSOG Z4032 (Alliance) multicenter randomized trial. *J Thorac Cardiovasc Surg*. 2015 Mar; 149(3): 718-726. PubMed PMID: 25500100. (Study ID: Z4032)

Primary HOC Abstracts (3):

Atkinson, T. M., D. V. Satele, J. A. Sloan, D. Mehedint, J. M. Lafky, E. Basch and A. C. Dueck. Comparison Between Clinician- and Patient-Reporting of Baseline (BL) and Post-BL Symptomatic Toxicities in Cancer Cooperative Group Clinical Trials (NCCTG N0591 [Alliance]). ASCO Annual Meeting May 29-June 2, 2015. Poster Discussion. (Study ID: N0591)

Qin, R., A. Tan, J. A. Sloan, K. S. Anderson and N. N. Laack. Quality of Life Analysis of N0877 (Alliance): Phase II Trial of Either Dasatinib or Placebo Combined with Standard Chemo-Radiotherapy for Newly Diagnosed Glioblastoma Multiforme (GBM). ASCO Annual Meeting May 29-June 2, 2015. Publication Only. (Study ID: N0877)

Schrag, D., A. Dueck, M. Naughton, D. Niedzwiecki, C. C. Earle, C. Blanke and A. Venook. Cost-Effectiveness of Chemotherapy for Metastatic Colorectal Cancer with either Bevacizumab or Cetuximab: Economic Analysis of CALGB/SWOG 80405. ASCO Annual Meeting May 29-June 2, 2015. Oral Presentation. (Study ID: 70502 and 80405)

Secondary HOC Manuscripts (4):

- Barton, D. L., G. Thanarajasingam, J. A. Sloan, B. Diekmann, J. Fuloria, L. A. Kottschade, A. P. Lyss, A. J. Jaslowski, M. A. Mazurczak, S. C. Blair, S. Terstriep and C. L. Loprinzi. 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*. 2014 Nov 15; 120(22): 3575-3583. PubMed PMID: 25043153; PubMed Central: PMC4221473. (Study ID: N08C3)
- Beutler, A. S., A. A. Kulkarni, R. Kanwar, C. J. Klein, T. M. Therneau, R. Qin, M. S. Banck, G. K. Boora, K. J. Ruddy, Y. Wu, R. L. Smalley, J. M. Cunningham, N. A. Le-Lindqwister, P. Beyerlein, G. P. Schroth, A. J. Windebank, S. Zuchner and C. L. Loprinzi. Sequencing of Charcot-Marie-Tooth disease genes in a toxic polyneuropathy. *Ann Neurol*. 2014 Nov; 76(5): 727-737. PubMed PMID: 25164601. (Study ID: N08C1)
- Kulkarni, A. A., G. Boora, R. Kanwar, K. J. Ruddy, M. S. Banck, N. Le-Lindqwister, T. M. Therneau, C. L. Loprinzi and A. S. Beutler. RWDD3 and TECTA variants not linked to paclitaxel induced peripheral neuropathy in North American trial Alliance N08C1. *Acta Oncol*. 2014 Dec 31 [Epub ahead of print]: 1-3. PubMed PMID: 25549536. (Study ID: N08C1)
- Park, H., R. Qin, T. J. Smith, P. J. Atherton, D. L. Barton, K. Sturtz, S. R. Dakhil, D. M. Anderson, K. Flynn, S. Puttabasavaiah, N. A. Le-Lindqwister, G. D. A. Padula and C. L. Loprinzi. North Central Cancer Treatment Group N10C2 (Alliance): a double-blind placebo-controlled study of magnesium supplements to reduce menopausal hot flashes. *Menopause*. 2015 Jun; 22(6): 000-000. PubMed PMID: 25423327; PubMed Central: In process at NIHMS 629808. (Study ID: N10C2)

Secondary HOC Abstracts (9):

- Arnold, K., R. Andridge, A. Logan, L. Yee, M. Lustberg and T. Orchard. Healthy Eating Index Scores are Associated with Inflammatory Markers in Breast Cancer Survivors. *The FASEB Journal*. 2015 April 1, 2015; 29(1 Supplement): LB267. Poster Discussion.
http://www.fasebj.org/gca?allch=&submit=Go&gca=fasebj%3B29%2F1_Supplement%2FLB267. (Study ID: Pilot Project NCT01478477)
- Gajra, A., L. McCall, H. B. Muss, H. J. Cohen, A. Jatoi, K. V. Ballman, A. H. Partridge, L. Sutton, B. A. Parker, G. Magrinat, J. M. Lafky and A. Hurria. Association of patient preference for adjuvant chemotherapy (chemo) at baseline (BL) with toxicity, mental health, function, quality of life (QoL) and survival in older women with early stage breast cancer (ESBC) [CALGB 49907 Alliance]. San Antonio Breast Cancer Symposium December 8-12, 2014. Abstract nr P5-15-07. Poster Presentation.
http://www.abstracts2view.com/sabcs14/view.php?nu=SABCS13L_1453. (Study ID: 49907)
- Iott, M. J. Primary and secondary endpoint analysis of N08C9 (Alliance): A phase III randomized study of sulfasalazine versus placebo in the prevention of acute radiation enteritis. *J Clin Oncol (Meeting Abstracts)* January 2015; 33(3_suppl): 562. http://meeting.ascopubs.org/cgi/content/abstract/33/3_suppl/562. (Study ID: N08C9)
- Lustberg, M. B., T. Orchard, X. Pan, R. Reinbolt, A. Logan, J. Lester, R. M. Layman, E. Macrae, E. Mrozek, B. Ramaswamy, R. Wesolowski, M. Berger, M. Knopp, C. Loprinzi, C. L. Shapiro and L. Yee. Prevention of aromatase Inhibitor (AI)-induced joint symptoms with omega-3 fatty acid supplementation: A randomized placebo-controlled pilot study. San Antonio Breast Cancer Symposium December 8-12, 2014. Abstract nr P1-09-03. Poster Presentation. http://www.abstracts2view.com/sabcs14/view.php?nu=SABCS13L_1076. (Study ID: Pilot Project NCT01478477)
- Orchard, T. S., X. Pan, J. Lester, A. Logan, C. L. Shapiro, R. D. Jackson, M. A. Belury, L. Yee and M. B. Lustberg. Relationship of dietary and red blood cell polyunsaturated fatty acids to inflammatory markers in breast cancer survivors taking aromatase inhibitors. San Antonio Breast Cancer Symposium December 8-12, 2014. Abstract nr P1-09-30. Poster Presentation.
http://www.abstracts2view.com/sabcs14/view.php?nu=SABCS13L_1597. (Study ID: Pilot Project NCT01478477)
- Ruddy, K., D. R. Pachman, R. Qin, D. Seisler, E. M. Lavoie Smith, S. Puttabasavaiah, P. Novotny, L. E. Ta, A. S. Beutler, N. D. Wagner Johnston, N. Staff, A. Grothey, S. Dakhil and C. L. Loprinzi. A Comparison of the Natural History of Oxaliplatin- and Paclitaxel-Induced Neuropathy (NCCTG N08C1, N08CB/Alliance). ASCO Annual Meeting May 29-June 2, 2015. Poster Presentation. (Study ID: N08C1 and N08CB)

- Ruddy, K. J., G. K. Boora, R. Kanwar, A. Kulkarni, R. Qin, D. Seisler, D. Pachman, A. Grothey, C. L. Loprinzi and A. S. Beutler. Validation of single nucleotide variants previously associated with oxaliplatin-induced peripheral neuropathy: NCCTG N08CB (Alliance) Association for Clinical and Translational Science Annual Meeting April 16-18, 2015. Poster Presentation. (Study ID: N08CB)
- Zimmerman, C., P. Atherton, D. Pachman, D. Seisler, N. Wagner Johnston, S. Dakhil, J. M. Lafky, R. Qin, A. Grothey and C. L. Loprinzi. Venlafaxine to Prevent Oxaliplatin-Induced Neuropathy? A Pilot Randomized Placebo Controlled Trial. ASCO Annual Meeting May 29-June 2, 2015. Publication Only. (Study ID: Study ID: Pilot Project NCT01611155)
- Zimmerman, C., P. Atherton, D. Pachman, D. Seisler, N. Wagner Johnston, S. Dakhil, J. M. Lafky, R. Qin, A. Grothey and C. Loprinzi. Venlafaxine to Prevent Oxaliplatin-Induced Neuropathy? A Pilot Randomized Placebo Controlled Trial. MASCC/ISOO Annual Meeting June 25-27, 2015. Poster Presentation. (Study ID: Study ID: Pilot Project NCT01611155)