



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 Friday, November 6, 2015 3:00 – 5:00 PM CT Room: Guggenheim 1

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

I. Scientific Presentations (15 minutes each)

- A. Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation with Breast Reconstruction
Study Chair: Matthew Poppe, MD Presenter: Atif Khan, MD
- B. Exercise Mini-Forum
 1. Conducting Lifestyle Intervention Research in the Alliance: Opportunities and Challenges
Jennifer Ligibel, MD
 2. The Exercise-Oncology Program at MSKCC
Lee Jones, PhD
 3. Objective Measures of Physical Performance and Function during Cancer Chemotherapy
William A. Wood, Jr., MD
 4. Pre-Transplant Geriatric Assessment and Biologic Markers of Fitness
Ashley Rosko, MD

II. New Idea Presentations (5 minutes each)

- A. Preoperative Extended Chemotherapy vs Chemotherapy Plus Hypofractionated Radiation Therapy for Borderline Resectable Adenocarcinoma of the Head of the Pancreas
*Study Chair: Matthew Katz, MD
QOL Presenter: Joleen Hubbard, MD*
- B. Evaluation of Illness and Treatment Understanding, Quality of Life, and End of Life Care in Patients with Advanced Diffuse Large B-cell Lymphoma
Kelly Trevino, PhD
- C. Illness Understanding and Quality of Life in Follicular Lymphoma Patients: A Longitudinal Examination
Kelly Trevino, PhD

III. Liaison Presentations (10 mins each)

- A. Gastrointestinal Update
Hanna Sanoff, MD & Deb Schrag, MD
- B. Prevention
Ivana Croghan, PhD
- C. Radiation Oncology
Terence Sio, MD

IV. Notation Items

- A. Study Tracker
- B. Publications Since the May 2015 Alliance Meeting
Health Outcomes – Primary Committee Manuscripts
 - Atherton, PJ, Watkins-Bruner, DW, Gotay, C, Moinpour, CM, Satele, DV, Winter, KA, Schaefer, PL, Movsas, B and Sloan, JA. "The Complementary Nature of Patient-Reported Outcomes and Adverse Event Reporting in Cooperative Group Oncology Clinical Trials: A Pooled Analysis (NCCTG N0591)." *J Pain Symptom Manage.* 2015 Oct; 50(4): 470-479.e479. PMID: 26031708. (Study ID: N0591)

- Bennett, AV, Keenoy, K, Shouery, M, Basch, E and Temple, LK. "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." Accepted 10/9/2015. *Quality of Life Research*. (Study ID: NCT01458509, CALGB CCOP-funded pilot)
- Dueck, AC, Singh, J, Atherton, P, Liu, H, Hines, S, Loprinzi, CL, Perez, EA, Mincey, BA, Tan, A, Burger, K, Zhao, C, Diekmann, B and Sloan, JA. "Endpoint Comparison for Bone Mineral Density Measurements in North Central Cancer Treatment Group Cancer Clinical Trials N02C1 and N03CC (Alliance)." *Osteoporosis International*. 2015 Jul; 26(7): 1971-1977. PMID: 25749740. PMCID: PMC4484303. (Study ID: N02C1 and N03CC)
- Dueck, AC, Mendoza, TR, Mitchell, SA, Reeve, BB, Castro, KM, Rogak, LJ, Atkinson, TM, Bennett, AV, Denicoff, AM, O'Mara, AM, Li, Y, Clauser, SB, Bryant, DM, Bearden, JD, 3rd, Gillis, TA, Harness, JK, Siegel, RD, Paul, DB, Cleeland, CS, Schrag, D, Sloan, JA, Abernethy, AP, Bruner, DW, Minasian, LM and Basch, E. "Validity and Reliability of the US National Cancer Institute's Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)." *JAMA Oncol*. 2015 Aug 13. PMID: 26270597. [Epub ahead of print]

Health Outcomes – Primary Committee Abstracts

- Atkinson, TM, Satele, DV, Sloan, JA, Mehedint, D, Lafky, JM, Basch, EM and Dueck, AC. "Comparison Between Clinician- and Patient-reporting of Baseline (BL) and Post-BL Symptomatic Toxicities in Cancer Cooperative Group Clinical Trials (NCCTG N0591 [Alliance])." *ASCO Meeting Abstracts*. 2015 May 18, 2015; 33(15_suppl): 9520. Poster Discussion. http://meeting.ascopubs.org/cgi/content/abstract/33/15_suppl/9520. (Study ID: N0591)
- Dueck, AC, Mitchell, SA, Rogak, LJ, Ginos, B, Sargent, DJ, Shi, Q, Farma, JM, Eng, C, Crane, C, Kennecke, H, O'Mara, AM, Minasian, LM, Schrag, D and Basch, E. "A cluster-randomized study of clinician-patient shared vs standard reporting of symptomatic adverse events using PRO-CTCAE nested in a multicenter trial of multimodal therapy for rectal cancer (Alliance N1048 PROSPECT)." *Qual Life Res*. 2015; 24(Suppl1): 1-191 (abstract 192). Oral Presentation. (Study ID: N1048)
- Qin, R, Tan, AD, Sloan, JA, Johnson, DR, Lesser, GJ, Anderson, SK and Laack, NN. "Quality of life analysis of NCCTG N0877 (Alliance): Phase II Trial of Either Dasatinib or Placebo Combined with Standard Chemoradiotherapy for Newly Diagnosed Glioblastoma Multiforme (GBM)." *ASCO Meeting Abstracts*. 2015 May 18, 2015; 33(15_suppl): e17715. Publication Only. http://meeting.ascopubs.org/cgi/content/abstract/33/15_suppl/e17715. (Study ID: N0877)
- Schrag, D, Dueck, AC, Naughton, MJ, Niedzwiecki, D, Earle, C, Shaw, JE, Grothey, A, Hochster, HS, Blanke, CD and Venook, AP. "Cost of Chemotherapy for Metastatic Colorectal Cancer with Either Bevacizumab or Cetuximab: Economic Analysis of CALGB/SWOG 80405." *ASCO Meeting Abstracts*. 2015 May 18, 2015; 33(15_suppl): 6504. Oral Presentation. http://meeting.ascopubs.org/cgi/content/abstract/33/15_suppl/6504. (Study ID: 70502, 80405)

Health Outcomes – Secondary Committee Manuscripts

- Pachman, DR, Qin, R, Seisler, D, Smith, EM, Beutler, AS, Ta, LE, Lafky, JM, Wagner Johnston, ND, Ruddy, KJ, Dakhil, S, Staff, NP, Grothey, A and Loprinzi, CL. "Clinical Course of Oxaliplatin-Induced Neuropathy: Results From the Randomized Phase III Trial N08CB (Alliance)." *J Clin Oncol*. 2015 Oct 20; 33(30): 3416-3422. PMID: 26282635. PMCID: PMC4606060. (Study ID: N08CB)
- Park, H, Qin, R, Smith, TJ, Atherton, PJ, Barton, DL, Sturtz, K, Dakhil, SR, Anderson, DM, Flynn, K, Puttabasavaiah, S, Le-Lindqwister, NA, Padula, GD and Loprinzi, CL. "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): 627-632. PMID: 25423327. PMCID: PMC4442087. (Study ID: N10C2)

Health Outcomes – Secondary Committee Abstracts

- Navari, RM, Qin, R, Ruddy, KJ, Liu, H, Powell, SF, Bajaj, M, Dietrich, LL, Lafky, JM and Loprinzi, CL. "Olanzapine for the Prevention of Chemotherapy-induced Nausea and Vomiting (CINV) in Patients Receiving Highly Emetogenic Chemotherapy (HEC): Alliance A221301, A Randomized, Double-blind, Placebo-controlled Trial." *J Clin Oncol*. 2015 Oct; 33(suppl 29S): abstr 176. Oral and Poster Presentation. <http://meetinglibrary.asco.org/content/155048-165>. (Study ID: A221301)
- Ruddy, KJ, Pachman, D, Qin, R, Seisler, DK, Smith, EML, Puttabasavaiah, S, Novotny, PJ, Ta, LE, Beutler, AS, Wagner-Johnston, ND, Staff, N, Grothey, A, Dakhil, SR and Loprinzi, CL. "A Comparison of the Natural History of Oxaliplatin- and Paclitaxel-induced Neuropathy (NCCTG N08C1, N08CB/Alliance)." *ASCO Meeting Abstracts*. 2015 May 18, 2015; 33(15_suppl): 9564. Poster Presentation. http://meeting.ascopubs.org/cgi/content/abstract/33/15_suppl/9564. (Study ID: A151505, N08C1, N08CB)

- Smith, EML, Yang, J, Banerjee, T, Loprinzi, C, Cavaletti, G, Bridges, C, Haupt, R, Kanzawa, G, Knoerl, R, Lee-Ekblad, D and Prasertsri, N. "The Reliability, Validity, and Sensitivity of the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire-Chemotherapy-induced Peripheral Neuropathy (QLQ-CIPN-20)." Accepted Abstract. 2016 Midwest Nursing Research Society. (Study IDs: N06CA, N08C1, N08CA, N08CB)
- Zimmerman, C, Atherton, P, Pachman, D, Seisler, D, Wagner-Johnston, N, Dakhil, S, Lafky, J, Qin, R, Grothey, A and Loprinzi, C. "Venlafaxine to Prevent Oxaliplatin-Induced Neuropathy? A Pilot Randomized Placebo Controlled Trial." *Support Care Cancer*. 2015 June; 23(Suppl 1): S152 (abstract 112-106-P). Poster Presentation. http://mascc2015.kenes.com/Documents/10.1007_s00520-015-2712-y.pdf. (Study ID: MC11C4, CALGB CCOP-funded pilot)
- Zimmerman, CT, Atherton, PJ, Pachman, DR, Seisler, DK, Wagner-Johnston, ND, Dakhil, SR, Lafky, JM, Qin, R, Grothey, A and Loprinzi, CL. "Venlafaxine to Prevent Oxaliplatin-induced Neuropathy?: A Pilot Randomized Placebo-controlled Trial." *ASCO Meeting Abstracts*. 2015 May 18, 2015; 33(15_suppl): e20734. http://meeting.ascopubs.org/cgi/content/abstract/33/15_suppl/e20734. Publication Only. (Study ID: MC11C4, CALGB CCOP-funded pilot)

V. Other Business

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

¹Statistician

²Liaison

³Patient Advocate