Patient-Reported Outcomes Assessment in Cancer Trials:

Evaluating and Enhancing the Payoff to Decision Making

September 20-21, 2006

Marriott Bethesda North
Hotel and Conference Center
North Bethesda, MD

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Where we have been

The PROACT Conference follows many relevant initiatives and meetings focused on improving the measurement, understanding, and value of Patient-Reported Outcomes in cancer clinical trials.

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Enhancing PRO Methods and Measurement

- In 2002, the Mayo Clinic in Rochester sponsored the *Symposium on the Clinical Significance of Quality-of-Life Measures in Cancer Patients*.
- In 2004, the NCI and the Drug Information Association co-sponsored the conference: *Advances in Health Outcomes Measurement: Exploring the Current State and the Future of Item Response Theory, Item Banks, and Computer-Adaptive Testing*

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Improving Symptom Measurement Research

- In 2002, NIH State of the Science Conference on *Symptom Management in Cancer: Pain, Depression, and Fatigue*
- In 2005, NCI Division of Cancer Prevention workshop: *Current State of the Science in QOL in Symptom Management Trials: Challenges and Future Directions*

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FDA Guidance Document on PROs

- In February, 2006, the FDA released their draft guidance for industry for use of PROs in medical product development to support labeling claims.
- Later in February: Mayo Clinic sponsored conference: *FDA Guidance on Patient Reported Outcomes: Discussion, Dissemination, and Operationalization*
- In June: the International Society for Quality of Life Research sponsored the conference: *Patient Reported Outcomes and FDA Regulatory Guidance Meeting*

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Where we are going

- ***The PROACT Conference feeds off the findings from these initiatives to examine how PROs can be more effectively incorporated into cancer trials***
- ***- in ways that yield valuable information about the impact of interventions while not imposing an undue data-collection burden on clinical investigators and patients.***

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PROACT Scientific Program Committee Members

Jeffrey S. Abrams, M.D. *National Cancer Institute, DCTD*	*Lori Minasian, M.D.,F.A.C.P.* *National Cancer Institute, DCP*
Deborah Watkins Bruner, Ph.D. *Fox Chase Cancer Center*	*Ann O'Mara, Ph.D., R.N.* *National Cancer Institute, DCP*
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Joseph Lipscomb, Ph.D. *Emory University*	*Edward Trimble, M.D., M.P.H.* *National Cancer Institute, DCTD*

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PROACT Conference Aims

- Serve as a platform for informing the NCI Clinical Trials Working Group implementation process
- Identify “best practices” for the application of PRO measures in a range cancer clinical trials
- Examine where, when, and how the measurement of PROS can yield valuable information for decisions about cancer care.
- Inform the research agenda on improving the application of PRO measures in clinical trials generally.

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Key PROACT Conference Questions

- What do we know now about the use, usefulness, and perceived value of HRQOL in cancer trials?
- What are the challenges and impediments to a broader embrace of HRQOL measures in trials?
- Where do we go from here?

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PROACT Conference Learning Resources

- Perspectives from NCI Leadership
- Case Studies and Lessons Learned from NCI-sponsored Clinical Trials
- Perspectives from Industry, International Groups, and the FDA
- Reactor/Round Table Discussions
- Poster Session/Reception/Networking
- Questions and Comments from YOU!

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Conference Agenda - Wednesday

- Perspectives from NCI Leadership
  - Division of Cancer Control and Population Sciences, Division of Cancer Prevention
- Perspectives from the NCI-sponsored, Clinical Trials Networks
  - Deborah Watkins Bruner, RN, Ph.D.
- Phase III Cancer Treatment Trials
  - Patricia Ganz, M.D., Carolyn Gotay, Ph.D.
- Cancer Symptom Management Trials
  - Ann O'Mara, Ph.D., R.N., Jeff Sloan, Ph.D., Lawrence Berk, M.D., Ph.D., Joseph Roscoe, Ph.D.
- Poster Session/Reception

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Conference Agenda - Thursday

- Opportunities for Phase I and Phase II Cancer Clinical Trials
  - Lynne Wagner, Ph.D., Lari Wenzel, Ph.D., Edward Shaw, M.D.
- International Perspectives on Issues and Challenges
  - NCI Canada & European Organization for Research and Treatment in Cancer
- Industry and Regulatory Perspectives
  - PHARMA HOC & Food and Drug Administration
- Perspectives from NCI Leadership
  - James Doroshow, M.D
- Reactor Panel – Questions, Comments and Discussion
  - Joseph Lipscomb, Ph.D. (Chair)