

National Cancer Institute  
National Institutes of Health  
Department of Health and Human Services

**Patient-Reported Outcomes Assessment in Cancer Trials:  
*Evaluating and Enhancing the Payoff to Decision Making***

Marriott Bethesda North Hotel and Conference Center  
September 20-21, 2006

**Agenda**

**Wednesday, September 20, 2006**

8:30 a.m. – 8:45 a.m.     *Opening/Introductions*

**Steven B. Clauser, Ph.D.**  
Chief  
Outcomes Research Branch  
Division of Cancer Control and Population Sciences  
National Cancer Institute

8:45 a.m. – 9:15 a.m.     *Patient-Reported Outcomes Assessment in Clinical Trials: Overview and Charge*

**Rachel Ballard-Barbash, M.D., M.P.H.**  
Associate Director  
Applied Research Program  
Division of Cancer Control and Population Sciences  
National Cancer Institute

**Peter Greenwald, M.D., Dr.PH.**  
Director  
Division of Cancer Prevention  
National Cancer Institute

9:15 a.m. – 10:00 a.m.     *Issues and Challenges With Integrating Patient-Reported Outcomes in Clinical Trials Supported by National Cancer Institute-Sponsored Clinical Trials Networks*

**Maria Sgambati, M.D. [Chair]**  
Program Director  
Community Oncology and Prevention Trials Research Group  
Division of Cancer Prevention  
National Cancer Institute

**Deborah Watkins Bruner, R.N., Ph.D.**  
Professor  
School of Nursing  
University of Pennsylvania

10:00 a.m. – 10:15 a.m. Break

10:15 a.m. – 12:15 p.m. *Patient-Reported Outcomes Assessment in Phase III Cancer Treatment Trials: Part I*

- A Case Study Analysis of Issues and Challenges for Integrating Patient-Reported Outcomes in Phase III Cancer Clinical Trials

**Jeffrey S. Abrams, M.D. [Chair]**

Chief  
Clinical Investigations Branch  
Division of Cancer Treatment and Diagnosis  
National Cancer Institute

**Patricia A. Ganz, M.D.**

Professor  
University of California at Los Angeles Schools of Medicine and Public Health  
Division of Cancer Prevention and Control Research  
Jonsson Comprehensive Cancer Center

**Carolyn C. Gotay, Ph.D.**

Professor  
Cancer Research Center of Hawaii  
University of Hawaii

- Question and Answer Session

12:15 p.m. – 1:30 p.m. Lunch

1:30 p.m. – 2:45 p.m. *Patient-Reported Outcomes Assessment in Phase III Cancer Treatment Trials: Part II*

**Jeffrey S. Abrams, M.D. [Chair]**

Chief  
Clinical Investigations Branch  
Division of Cancer Treatment and Diagnosis  
National Cancer Institute

- Lessons for Trial Sponsors and Investigators

**Carolyn C. Gotay, Ph.D.**

Professor  
Cancer Research Center of Hawaii  
University of Hawaii

**Patricia A. Ganz, M.D.**

Professor  
University of California at Los Angeles Schools of Medicine and Public Health  
Division of Cancer Prevention and Control Research  
Jonsson Comprehensive Cancer Center

- Round Table Discussion/Reactions

**Discussants:**

**David Cella, Ph.D.**

Professor  
 Psychiatry and Behavioral Sciences, and Institute for Healthcare Studies,  
 Feinberg School of Medicine, Northwestern University  
 Director  
 Center on Outcomes, Research and Education (CORE)  
 Evanston Northwestern Healthcare

**Pamela J. Goodwin, M.D., M.Sc., F.R.C.P.C.**

Senior Scientist  
 Samuel Lunenfeld Research Institute Marvella Koffler Chair in Breast Cancer  
 Research  
 Professor of Medicine  
 University of Toronto  
 Mount Sinai Hospital

**James Hayman, M.D.**

Associate Professor and Director  
 Clinical Division  
 Department of Radiation Oncology  
 University of Michigan

- Question and Answer Session

2:45 p.m. – 3:15 p.m.

*Funding Patient-Reported Outcomes Assessment in Cancer Clinical Trials*

**Andrea Denicoff, R.N., M.S., A.N.P. [Chair]**

Nurse Consultant and Coordinator of Palliative Care Initiatives  
 Clinical Investigations Branch  
 Division of Cancer Treatment and Diagnosis  
 National Cancer Institute

**Carol M. Moinpour, Ph.D.**

Behavioral Scientist  
 Southwest Oncology Group Statistical Center  
 Associate Member  
 Division of Public Health Sciences  
 Fred Hutchinson Cancer Research Center

- Question and Answer Session

3:15 p.m. – 3:30 p.m.

Break

3:30 p.m. – 5:00 p.m. *Patient-Reported Outcomes Assessment in Cancer Symptom Management Trials*

**Ann O’Mara, Ph.D., R.N. [Chair]**

Program Director  
Community Clinical Oncology Program  
Division of Cancer Prevention  
National Cancer Institute

**Jeff A. Sloan, Ph.D.**

Professor of Oncology and Health Services Research  
Mayo Clinic College of Medicine  
Mayo Clinic – Division of Biostatistics

**Lawrence Berk, M.D., Ph.D.**

Vice Chair  
Radiation Therapy Oncology Group (Cancer Control)  
Associate Professor and Medical Director of Radiation Oncology Moffitt  
Clinic at Tampa General Hospital  
H Lee Moffitt Cancer Center  
University of South Florida

**Joseph A. Roscoe, Ph.D.**

Research Associate Professor  
Department of Radiation Oncology  
Behavioral Medicine Unit  
University of Rochester Cancer Center

**Michael J. Fisch, M.D., M.P.H. [Discussant]**

Medical Director  
M.D. Anderson Cancer Center Community Clinical Oncology Program  
Research Base  
Chair  
Eastern Cooperative Oncology Group Symptom Management Committee  
Associate Professor  
General Oncology and Palliative Care  
The University of Texas M.D. Anderson Cancer Center

- Question and Answer Session

5:00 p.m. – 6:00 p.m. *Poster Session/Reception*

- Poster Session Theme: *Enhancing Patient-Reported Outcomes in Cancer Trials*

6:00 p.m. *Adjournment*

**Thursday, September 21, 2006**

8:00 a.m. – 9:30 a.m.     *Phase I and Phase II Cancer Clinical Trials: What Can Patient-Reported Outcomes Do for You?*

**Lynne I. Wagner, Ph.D. [Chair]**

Clinical Research Scientist  
Assistant Professor  
Institute for Health Services Research and Policy Studies  
Northwestern University

**Lari Wenzel, Ph.D.**

Associate Professor  
General Internal Medicine  
University of California, Irvine

**Edward G. Shaw, M.D.**

Professor and Chairman  
Department of Radiation Oncology  
Wake Forest University School of Medicine  
Director  
Clinical Research Program Comprehensive Cancer Center of Wake Forest University

**David Cella, Ph.D. [Discussant]**

Professor  
Psychiatry and Behavioral Sciences, and Institute for Healthcare Studies  
Feinberg School of Medicine, Northwestern University  
Director  
Center on Outcomes, Research and Education (CORE)  
Evanston Northwestern Healthcare

- Question and Answer Session

9:30 a.m. – 9:45 a.m.     Break

9:45 a.m. – 10:50 a.m.     *International Perspectives on Issues and Challenges To Integrating Patient-Reported Outcomes in Cancer Trials*

**Bryce B. Reeve, Ph.D. [Chair]**

Program Director  
Outcomes Research Branch  
Division of Cancer Control and Population Sciences  
National Cancer Institute

**Michael D. Brundage, M.Sc., F.R.C.P.C., M.D.**

Professor of Oncology and Community Health and Epidemiology  
Medical Director, Radiation Oncology  
Queen's University Cancer Research Institute

**Neil K. Aaronson, Ph.D.**

Head

Division of Psychosocial Research and Epidemiology

The Netherlands Cancer Institute

Chairman

Quality of Life Group

European Organization for Research and Treatment of Cancer

**Andrew Bottomley, Ph.D.**

Head

Quality of Life Unit

European Organization for Research and Treatment of Cancer, Belgium

- Question and Answer Session

10:50 a.m. – 12:15 p.m. *Industry and U.S. Food and Drug Administration Perspectives on Patient-Reported Outcomes in Cancer Trials*

**Dennis Revicki, Ph.D. [Chair]**

Senior Vice President and Director

Center for Health Outcomes Research

United BioSource Corporation

**Kathleen Gondek, Ph.D.**

Head

Global Health Economics and Outcomes Research

Therapeutic Areas, North America

Bayer Pharmaceuticals

**Laurie B. Burke, R.Ph., M.P.H.**

Director

Study Endpoints and Label Development Team

Office of New Drugs

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

**Edwin P. Rock, M.D., Ph.D.**

Medical Officer

Division of Oncology Drug Products

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

- Question and Answer Session

12:15 p.m. – 1:15 p.m. *Lunch*

1:15 p.m. – 1:35 p.m.

*National Cancer Institute's Clinical Trials Working Group and Its Implementation Process*

**Edward Trimble, M.D., M.P.H. [Chair]**

Head

Gynecologic Cancer Therapeutics and Quality of Cancer Care Therapeutics  
Clinical Investigations Branch  
Cancer Therapy Evaluation Program  
Division of Cancer Treatment and Diagnosis  
National Cancer Institute

**James H. Doroshow, M.D.**

Director

Division of Cancer Treatment and Diagnosis  
Chairman  
Clinical Trials Working Group  
National Cancer Institute

1:35 p.m. – 3:20 p.m.

*Enhancing Patient-Reported Outcomes Assessment in Cancer Trials*

A panel of experts will discuss issues related to these broad themes:

- Identifying when, where, and how Patient Reported Outcomes (PRO) assessment is likely to add significant value to the findings from a cancer trial and therefore should be recommended.
- Developing guidance for the cost-effective conduct of PRO assessment in trials to maximize the useful information obtained while holding respondent and administrative burdens to acceptable levels.
- Specifying how the research agenda in cancer outcomes measurement and evaluation can best inform decisionmaking on the use of PROs in cancer trials.

Panel Members:

**Neil K. Aaronson, Ph.D.**

Head

Division of Psychosocial Research and Epidemiology  
The Netherlands Cancer Institute  
Chairman  
Quality of Life Group  
European Organization for Research and Treatment of Cancer

**Jan C. Buckner, M.D.**

Professor of Oncology

Mayo Clinic College of Medicine  
Chair  
North Central Cancer Treatment Group  
Chair  
Mayo Clinic Cancer Research Consortium

**Susan L. Butler**

Ovarian Cancer National Alliance  
Ovarian Cancer Coalition of Greater Washington

**Patricia A. Ganz, M.D.**

Professor  
University of California at Los Angeles Schools of Medicine and Public Health  
Division of Cancer Prevention and Control Research  
Jonsson Comprehensive Cancer Center

**Kathleen Gondek, Ph.D.**

Head  
Global Health Economics and Outcomes Research  
Therapeutic Areas, North America  
Bayer Pharmaceuticals

**Pamela S. Hinds, Ph.D., R.N., F.A.A.N.**

Director  
Division of Nursing Research  
St. Jude Children's Research Hospital

**Paula Kim**

President and Founder  
TRAC-Translating Research Across Communities

**Joseph Lipscomb, Ph.D. [Moderator]**

Quality of Life Science Advisory Committee  
American Cancer Society  
Professor  
Health Policy and Management  
Georgia Cancer Coalition Distinguished Cancer Scholar  
Rollins School of Public Health  
Emory University

**Lori Minasian, M.D., F.A.C.P.**

Chief  
Community Oncology and Prevention Trials Research Group  
Division of Cancer Prevention  
National Cancer Institute

**Edwin P. Rock, M.D., Ph.D.**

Medical Officer  
Division of Oncology Drug Products  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

**Julia Rowland, Ph.D.**

Director  
Office of Cancer Survivorship  
Division of Cancer Control and Population Sciences  
National Cancer Institute

**Edward Trimble, M.D., M.P.H.**

Head

Gynecologic Cancer Therapeutics and Quality of Cancer Care Therapeutics

Clinical Investigations Branch

Cancer Therapy Evaluation Program

Division of Cancer Treatment and Diagnosis

National Cancer Institute

3:20 p.m. – 3:30 p.m.

Wrap-Up and Adjournment