

Workshop
Phase 0 Trials In Oncologic Drug Development
September 5, 2007

Natcher Conference Center
National Institutes of Health
Bethesda, MD

AGENDA

- 8:00–8:15 a.m. **Welcome**
Dr. James H. Doroshow, NCI
- 8:15–9:00 a.m. **The Exploratory IND Guidance**
Dr. David Jacobson–Kram, FDA
- 9:00–9:45 a.m. **Phase 0 Therapeutics Examples: Preclinical and Clinical Presentations**
Dr. Joseph Tomaszewski, NCI
Dr. Shivaani Kummar, NCI
- 9:45–10:30 a.m. **Phase 0 Imaging Example (Herceptin)**
Dr. Steve Larson, Memorial Sloan–Kettering Cancer Institute
- 10:30–10:45 a.m. Break
- 10:45–12:00 noon **Panel Discussion**
Clinical Trial Design/Biostatistics/Ethics/Recruitment
- Clinical Trial Design: Dr. Anthony Murgo, NCI
- Biostatistics: Dr. Larry Rubinstein, NCI
- Ethics: Dr. David Wendler, NIH
Dr. Holly Taylor, Berman Bioethics Institute
Ms. Deborah Collyar, Patient Advocates in
Research (PAIR)
- Recruitment: Dr. Martin Gutierrez, NCI
- Noon–1:00 p.m. **Lunch—On Your Own**

- 1:00–2:00 p.m. **Small Molecule PD and Imaging Talks—Models and Assay Development**
- Dr. Ralph Parchment, SAIC
Dr. Robert Kinders, SAIC
Dr. Melinda Hollingshead, NCI
Dr. Susan Galbraith, BMS
Dr. David Mankoff, University of Washington
- 2:00–3:00 p.m. **Regulatory Issues in Phase 0 Imaging**
- Dr. Jerry Collins, NCI
Dr. Karen Kurdziel, NCI
Dr. Paula Jacobs, NCI
Dr. Anthony Shields, Karmanos Cancer Institute
- 3:00–3:45 p.m. **Think Tank
Moderated Discussion**
Moderator—Dr. Joseph Tomaszewski, NCI
- 3:45–4:30 p.m. **Pharmacodynamic Paradigms in Early-Phase Cancer Clinical Trials**
- Dr. Hilary Calvert, Newcastle University, UK
- 4:30–4:35 p.m. **Closing**
Dr. James H. Doroshow, NCI