

**Brain Tumor End Points Workshop**  
**January 20, 2006**  
**Bethesda North Marriott Hotel and Conference Center**  
**5701 Marinelli Road, Bethesda, MD**

Presented by the U.S. Food and Drug Administration and the American Association for Cancer Research  
Co-sponsored by the American Society of Clinical Oncology

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## **AGENDA**

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8:00 – 8:10	<b>Welcome and Introduction</b>	<u>Richard Pazdur</u>
8:10 – 8:30	<b>Regulatory Background</b>	<u>Edwin Rock</u>
8:30 – 9:00	<b>FDA-AACR Brain Tumor Endpoints Workshop</b>	<u>Howard Fine</u>
	<b><u>Clinical Trial Endpoints for Approval: Imaging Based Outcomes</u></b>	
9:00 – 9:30	<b>MR Imaging Surrogate Markers of Brain Tumor Therapeutic Response</b>	<u>James Provenzale</u>
	<b>PET Scanning with FDG in Brain Tumors – Brain Tumor Measurements in Assessing Responses to Treatment</b>	<u>Nicholas Patronas</u>
9:30 – 9:45	Break	
9:45 – 10:15	<b>Response and Progression-free Survival (PFS) Endpoints for Gliomas</b>	<u>Karla Ballman</u>
	<b>PFS: Is this a Clinically Relevant Endpoint for Clinical Trials Testing Treatments for Malignant Gliomas at Time of Progression? Report of Data from the North American Brain Tumor Consortium</b>	<u>Kathleen Lamborn</u>
10:15 – 11:30	Panelist Discussion on Imaging Based Outcomes	
11:30 – 11:40	Audience Questions/Comments	
11:40 – 12:30	Lunch	
	<b><u>Clinical Trial Endpoints for Approval: Patient Reported Outcomes (PROs)</u></b>	
12:30 – 1:00	<b>Cognitive Testing and Patient Reported Outcomes in Brain Tumor Clinical Trials</b>	<u>Christine Meyers</u>
1:00 – 1:50	Panelist Discussion on PROs	
1:50 – 2:00	Audience Questions/Comments	
2:00 – 2:15	Break	
2:15 – 3:25	<b><u>General Panel Discussion</u></b>	
3:25 – 3:35	Audience Questions/Comments	
3:35 – 3:45	<b>Workshop Summary</b>	<u>Henry Friedman</u>
3:45 – 4:00	Break	
4:00 – 5:00	<b><u>Biomarker &amp; Endpoint Research Priorities</u></b>	<u>Jeff Abrams/Tracy Lively/ Lalitha Shankar</u>
5:00	Adjournment	