

Prostate Cancer End Points Workshop  
June 21-22, 2004  
Bethesda Marriott - Bethesda, MD

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**AGENDA**

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**Monday, June 21, 2004, AM**

**Introductory Overview: End Points to Measure Therapeutic Efficacy in Prostate Cancer**

8:00 – 8:20	<b>Regulatory Perspective</b>	<u>Richard Pazdur</u>
8:20 – 8:55	<b>Relevance of Prostate Cancer Clinical States to End Points and PSA End Point Application Methodologies</b>	<u>Howard Scher</u>
8:55 – 9:10	<b>Statistical Issues in the Validation of Surrogate Endpoints</b>	<u>Stuart Baker</u>
9:10 – 9:20	<b>Prostate Cancer Specific Mortality – Issues in its Use in Surrogate Validation</b>	<u>Peter Albertsen</u>
9:20 – 9:30	Clarification Questions to Presenters	
9:30 – 9:45	<b>Bone Scan – Issues in Application for Disease Assessment</b>	<u>Steve Larson</u>
9:45 – 9:55	<b>Bone Scan – Application Experience in Clinical Trials</b>	<u>Kevin Carroll</u>
9:55 – 10:05	Break	
10:05 – 10:25	<b>Patient Reported Outcomes</b>	<u>Derek Raghavan</u>
10:25 – 10:35	Clarification Questions to Presenters	
10:35 – 11:40	<b>Formal Questions for Discussion</b>	Discussion Leaders: <u>Anthony D’Amico,</u> <u>Howard Scher &amp;</u> <u>Peter Scardino</u>
11:40 – 12:10	<b>Audience Questions</b>	
12:10 – 12:55	Lunch	

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**Monday, June 21, 2004, PM**

**End Points for Clinical Trials in Primary Treatment  
(Neoadjuvant & Adjuvant) of M0 Disease & Hormone Sensitive M1 Disease**

12:55 – 1:10	<b>Hormone Sensitive Disease – Regulatory End Point History of Approved Therapies</b>	<u>George Benson or Donna Griebel</u>
1:10 – 1:30	<b>Early disease: It's Scope &amp; Associated End Point Issues</b>	<u>Peter Scardino</u>
1:30 – 1:50	<b>Increasing PSA after Primary Treatment</b>	<u>Anthony D'Amico</u>
1:50 – 2:00	Clarification Questions to Presenters	
2:00 – 2:20	<b>Examination of End Points – Increasing PSA after Primary Treatment Including Adjuvant</b>	<u>Howard Sandler</u>
2:20 – 2:30	Clarification Questions to Presenter	
2:30 – 2:50	<b>Examination of End Points in the Adjuvant Casodex EPC Trials Experience</b>	<u>Kevin Carroll</u>
2:50 – 3:00	Clarification Questions to Presenter	
3:00 – 3:10	Break	
3:10 – 3:30	<b>Examination of End Points in Advanced Disease (D2) – Casodex Experience</b>	<u>Laurence Collette</u>
3:30 – 3:40	Clarification Questions to Presenter	
3:40 – 3:50	<b>Examination of End Points in the Primary Hormonal Treatment of Advanced Disease (D2) – SWOG Experience</b>	<u>Cathy Tangen</u>
3:50 – 4:00	Clarification Questions to Presenter	
4:00 – 5:15	<b>Formal Questions for Discussion</b>	Discussion Leaders: <u>Mario Eisenberger,</u> <u>Barry Kramer, &amp;</u> <u>Howard Sandler</u>
5:15 – 5:45	<b>Audience Questions</b>	

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**Tuesday, June 22, 2004, AM**

**Hormone Refractory Disease  
(M0 with PSA Rising Post Hormone Therapy and M1)**

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|---------------|--|---|
| 8:00 – 8:30   | <b>Introductory Comments and Overview of Regulatory End Point History of Approved Therapies</b>            | <u>Bhupinder Mann</u>   |
| 8:30 – 8:50   | <b>End Points and Trial Design for Evaluating Second-Line Chemotherapy – Post Docetaxel</b>                | <u>Mario Eisenberger</u>  |
| 8:50 – 9:00   | Clarification Questions to Presenter   |   |
| 9:00 – 9:20   | <b>Examination of End Point Applications in the Abbott Atrasentan Trials</b>                               | <u>Perry Nisen</u>  |
| 9:20 – 9:40   | <b>Examination of End Points in the Aventis Docetaxel Trial</b>  | <u>Martin Roessner</u>  |
| 9:40 – 10:00  | <b>Examination of End Points in the SWOG Docetaxel Trial</b>   | <u>Daniel Petrylak</u>  |
| 10:00 – 10:20 | Clarification Questions to Abbott, Aventis, & SWOG Presenters  |   |
| 10:20–10:30   | Break  |   |
| 10:30–12:15   | <b>Formal Questions for Discussion</b>   | Discussion Leaders:<br><u>Steven George,</u><br><u>Philip Kantoff,</u> &<br><u>Derek Raghavan</u> |
| 12:15–12:45   | <b>Audience Questions</b>  |   |
| 12:45 – 1:30  | Lunch  |   |
| 1:30 – 3:00   | <b>Optional Discussion Period:<br/>Wrap-Up Topics of Remaining Interest<br/>from Workshop Days 1 and 2</b> |   |
| 3:00          | Adjourn  |   |

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## PANELISTS & SPEAKERS

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### **Peter C. Albertsen, MD**

Division of Urology  
University of Connecticut Health Center  
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Urol

### **E. David Crawford, MD**

Prof. of Surgery & Radiation Oncology  
Head, Urologic Oncology  
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Urol

### **Anthony V. D'Amico, MD**

Chief, Genitourinary Radiation Oncology  
Assoc. Professor of Radiation Oncology  
Depts. of Cancer Onc and Rad Onc  
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Rad Onc

### **Mario A. Eisenberger, MD**

Professor, Oncology & Urology  
Johns Hopkins Univ  
Baltimore, MD 21231  
Int Med, Med Onc

### **Stephen L. George, PhD**

Dir., Biostatistics & Information Systems  
Duke University Medical Center  
Durham, NC 27710-0001  
Biostats/Epid

### **Philip W. Kantoff, MD**

Chief, Division of Solid Tumor Oncology  
Dir of the Lank Ctr for GU Oncology  
Dana Farber Cancer Institute  
Dir, Prostate Cancer Prog. & Prostate  
Cancer SPORE at Dana Farber  
Harvard Cancer Center  
Professor of Medicine  
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### **Eugene Kazmierczak – patient rep**

Sierra Vista, AZ 85650

### **Eric A. Klein, MD**

Head, Section of Urologic Oncology  
Cleveland Clinic Foundation  
Cleveland, OH 44195  
Urol/Surg

### **Barry Kramer, MD, MPH**

National Institutes of Health (NIH)  
Office of the Director  
Office of Disease Prevention  
Rockville, MD 20852  
Med Onc

### **Alison Martin, MD**

National Cancer Institute (NCI), NIH  
Cancer Therapy Evaluation Program  
Rockville, MD 20892-7436  
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### **Judd Moul, MD**

Director, Dept of Defense  
Center for Prostate Disease Research  
Rockville, Maryland 20852  
Urol

### **Derek Raghavan, MD, PhD, FACP (Co-chair)**

Chair & Director  
Cleveland Clinic Taussig Cancer Center  
Cleveland Clinic Foundation  
Cleveland, OH, 44195  
Med Onc/Hem

### **Mack Roach III, MD, FACP**

Professor Rad Onc and Urology  
Vice Chair Radiation Oncology,  
Director of Clinical Research  
Department of Radiation Oncology  
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San Francisco, CA 94143-1708  
Int Med, Med Onc, Rad Onc

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## PANELISTS & SPEAKERS

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### **Howard M. Sandler, MD**

Clinical Div Dir and Residency Dir  
Assoc Prof, Dept of Rad Onc  
University of Michigan Medical Center  
Ann Arbor, MI 48109-0010  
Rad Onc

### **Peter T. Scardino, MD**

Chairman, Dept. of Urology  
Mem. Sloan-Kettering Cancer Ctr.  
New York, NY 10021  
Urol/Surg

### **Howard I. Scher, MD**

Chief, Genitourinary Oncology Service  
Sidney Kimmel Ctr for Prostate and  
Urologic Cancers  
Mem. Sloan-Kettering Cancer Ctr.  
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### **Siu-Long Yao, MD – Industry Rep**

Aventis Pharmaceuticals, Inc.  
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Bridgewater, NJ 08807  
Med Onc, Hem, Int Med

### **FDA Representatives:**

#### **George Benson, MD**

Urology Team Leader  
Division of Reproductive and Urologic  
Drug Products, CDER

#### **Susan Ellenberg, PhD**

Director  
Office of Biostatistics and Epidemiology,  
CBER

#### **Donna Griebel, MD**

Deputy Director  
Division of Reproductive and Urologic  
Drug Products, CDER

### **Steven Hirschfeld, MD, PhD**

Division of Clinical Evaluation &  
Pharmacology/Toxicology, OCTGT,  
CBER

### **Patricia Keegan, MD**

Division Director  
Division of Therapeutic Biological  
Oncology Products, CDER

### **Bhupinder Mann, MBBS**

Medical Officer  
Division of Oncology Drug Products,  
CDER

### **Richard Pazdur, MD (Co-chair)**

Division Director  
Division of Oncology Drug Products,  
CDER

### **Daniel Shames, MD**

Division Director  
Division of Reproductive and Urologic  
Drug  
Products, CDER

### **Rajeshwari Sridhara, PhD**

Acting Statistical Team Leader  
for Division of Oncology Drug Products,  
CDER

### **Grant Williams, MD**

Deputy Director  
Division of Oncology Drug Products,  
CDER

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