

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

Questions for Discussion

Monday, June 21, 2004, AM

The first session: Bone scan and PSA

Explore questions regarding these modalities. For instance:

Bone Scan

Discussion Leader

- What are the pros and cons with using bone scan findings as components of an end point?
- What are the recommended end point definitions using bone scan for:
 - Recurrence?
 - Response?
 - Progression?
- When must bone scan findings be verified by other clinical investigations?
- What is the optimal scheduling for bone scan follow-up?
- Do PSA findings help with interpretation of bone scan findings?

Anthony D'Amico

Howard Scher

Peter Scardino

Anthony D'Amico

Howard Scher

PSA

- What are the pros and cons with using PSA, and/or its time-dependant derivatives, as an end point to demonstrate drug effectiveness?
- What are PSA end points that are worthy of consideration for use in oncology trials?
For:
 - Recurrence?
 - Response?
 - Progression?
- Should any of the PSA end points be considered as validated in any setting?
- If not, what studies or what data are needed to validate PSA as an end point in various settings?

Peter Scardino

Anthony D'Amico

Howard Scher

Peter Scardino

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Questions for Discussion

Other End Points

- Is the state of the art of assessing patient-reported outcomes sufficiently developed to make it a major parameter in assessment of new agents for prostate cancer?

Discussion Leader

Anthony D'Amico

Monday, June 21, 2004, PM

The second session: Early Disease

- How should DFS be defined using existing modalities?
- Is the DFS definition different for adjuvant therapy post surgery versus adjuvant therapy post radiation therapy?
- Is DFS a surrogate for survival in any setting?
- Is DFS a sufficient end point for drug approval in any setting?

Mario Eisenberger

Barry Kramer

Howard Sandler

Barry Kramer

Tuesday, June 22, 2004, AM

The third session: Advanced Disease

- How do you define response and PFS?
 - role of bone scan
 - role of PSA, and/or its time-dependant derivatives
- How do you deal with dropouts due to PSA?
- Are symptom end points useful?
 - Is time to symptomatic progression a practical end point?
- Are composite end points useful (e.g. skeletal-related events)?

Derek Raghavan

Steven George

Philip Kantoff

Derek Raghavan