Ovarian Cancer End Points Workshop
April 26, 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 Society of Clinical Oncology
Co-sponsored by the American Association for Cancer Research

Potential Biomarker & Endpoint Research Priorities
3:45 – 4:45 p.m.

In this session of the workshop, the panelists will consider what additional research may be required to move the most promising endpoints/biomarkers along to the next step.

Discussion Leader

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Topics for Discussion

1. Review of ongoing and planned Phase III trials in ovarian cancer

2. Potential research priorities

    a. Further individual-patient-data analysis of completed first-line ovarian cancer studies to evaluate the correlation between PFS and OS

    b. Further individual-patient-date analysis of completed ovarian cancer studies to evaluate the correlation between RECIST progression criteria and GCIG CA 125 progression

    c. Evaluation of GCIG CA 125 response criteria compared to RECIST response criteria in Phase II trials of novel agents

    d. Evaluation of radiological intermediate endpoints (FDG-PET, etc.) as markers of refractory disease, persistent disease, or recurrent disease; correlation with PFS and OS

    e. Evaluation of symptom benefit for ovarian cancer-related symptoms in second-line trials