MINUTES
RTOG DATA MONITORING COMMITTEE
June 18, 2003

RTOG Committee Members:

Joseph Aisner, M.D. Chair
Walter J. Curran, Jr., M.D. (Ex Officio)
Marie Diener-West, Ph.D.
Dorthy Donahue, R.N.
Boris Freidlin, Ph.D. (Ex Officio)
Eli Glatstein, M.D.
Mitchell Machtay, M.D. (Ex Officio)
Scott Saxman, M.D. (Ex Officio)
Charles B. Scott, Ph.D. (Ex Officio)
Elin Sigurdson, M.D.

Other attendees:

Ross Abrams, M.D.
Brian A. Berkey, M.S.
Michelle DeSilvio, Ph.D.
Leonard Lucey
Thomas F. Pajak, Ph.D.
William F. Regine, M.D.
Suzanne R. Swann, Ph.D.
Kathryn Winter, M.S.
Thomas Wudarski

RTOG 9704

Dr. Pajak presented accrual, pretreatment characteristics, toxicity data for this trial. It was activated on July 20, 1998 and closed July 26, 2002, and as of this date 538 patients have been accrued. The average monthly accrual was 11.2 cases. This was a protocol-planned analysis The DMC recommended early reporting of toxicity and survival results. The results will be presented to the appropriate committees at the RTOG Semi-Annual Meeting in Montreal, June 2003. The Group Chair concurred with this recommendation.

RTOG 9903

Dr. Pajak presented accrual, pretreatment characteristics, toxicity data for this trial. It was activated on June 30, 2000 and as of this date 129 patients have been accrued. The average monthly accrual is 3.8 cases. There were no toxicity issues identified. The protocol calls for a review of the sample size based on the assumption that, the risk of failure among the patient groups was equal, when 150 patients were entered. The DMC recommended an assessment of the hemoglobin response and requested a power calculation for the local-regional and survival objectives. The Group Chair concurred with this recommendation.

OPEN RTOG PHASE III TRIALS

Dr. Scott reviewed accrual and toxicity data for the following Phase III trials:

Study	Description
9512	H&N: T2 Vocal Cords
9804	Breast: DCIS
9811	GI: Anal Canal
9813	Brain: Ana. Astro. (Phase I/II)
9902	Prostate: High Risk
9903	H & N: Anemic Patients
9910	Prostate: TAS
0011	Prostate: High Risk pT3NO
0014	Prostate: Advanced Hormone Naive
0018	Brain: Thalidomide for Metastases
0122	Cancer Cachexia/CCOP
0126	Prostate: 3D
0129	H&N: Stage III/IV
0214	Lung: PCI for NSCC
0215	Erectile Dysfunction/CCOP

The DMC concluded that there was no need to modify any protocol as a result of unexpected or excessive toxicity.

Study specific notes:

9512 The study will close to accrual July 2003

9804 The DMC set an accrual target to be reached by January 2004, and recommended a hold on a proposed amendment until that time.

9811 Accrual on target

9813 Accrual will be closely monitored since the FDA mandated that the study be completed by the end of 2004.

9902 The DMC set an accrual target to be reached by January 2004, and requested a report on thrombolitic events at next DMC meeting

9903 Patient accrual will be reviewed in January 2004 along with ancillary data requested by the DMC

9910 Accrual on target

0011 The DMC set an accrual target to be reached by January 2004

0014 Will establish accrual target in 2004

0118 DMC requested a report on vascular events at the next meeting

0122 Accrual on target

0126 Will establish accrual target in 2004, IMRT issues pending

0129 Accrual on target

0214 DMC requested a report on the number of IRB approved sites and will establish an accrual target in 2004

0215 Slow accrual noted as well as the change in eligibility criteria.

The DMC discussed the request from a member institution to unblind the treatment regime for a patient on RTOG 9601. The DMC recommended that when a treatment decision needs to be made, the RTOG will authorize the unblinding of the patient treatment regime for this patient. The Group Chair concurred with this recommendation.

The next DMC meeting will be scheduled for February 2004.

The meeting was adjourned.