

UPDATE OF PROTOCOLS SUPPORTED BY THE ATC (as of June 7, 2006)

a. Protocols that have been completed that were supported by ATC Method 1:

- RTOG 94-06: Phase I/II Dose Escalation Study Using 3DCRT for Adenocarcinoma of the Prostate. (54 institutions credentialed; 1084 patients registered to study; study closed; data analysis continues).
- RTOG 93-11: Phase I/II Dose Escalation Study Using 3DCRT in Patients with Inoperable NSCLC. (26 institutions credentialed; 180 patients registered to study; study closed; data analysis continues).
- RTOG 98-03: Phase I/II Radiation Dose Escalation Study Applying 3DCRT in Supratentorial Glioblastoma Multiforme. (46 institutions credentialed; 210 patients registered to study; study closed; data analysis continues).
- RTOG 0022: Phase I/II Study of 3DCRT and IMRT for Oropharyngeal Cancer. (32 institutions credentialed; 69 patients registered to study; study closed, data analysis continues).
- RTOG 0225: Phase I/II Study of Conformal And Intensity Modulated Irradiation for Nasopharyngeal Cancer (36 institutions credentialed; 68 patients registered to study; study closed, data analysis continues).
- RTOG 0319: Phase I/II to Evaluate 3DCRT Irradiation Confined to Region of the Lumpectomy Cavity for Stage I/IIA Breast Carcinoma. (opened: 8/15/2003, accrual goals: 46; 31 institutions credentialed; 58 patients registered to study; study closed 4/30/04).

b. Protocols that are active and being supported by ATC Method 1:

- RTOG 0117: Phase I/II dose intensification study using 3DCRT and concurrent chemotherapy for patients with inoperable, non-small cell lung cancer (opened: 7/13/2001, accrual goals: 73; 48 institutions credentialed; 40 patients registered to study).
- RTOG 0126: Phase III randomize study of high dose 3DCRT/IMRT versus standard dose 3DCRT/IMRT in patients treated for localized prostate cancer. (opened: 3/21/2002, accrual goals: 1520; 135 institutions credentialed (62 IMRT); 921 patients registered to study (208 IMRT)).
- RTOG 0232: Phase III Study Comparing Combined External Beam Radiation & Transperineal Interstitial Permanent Brachytherapy with Brachytherapy alone (opened: 6/11/2003, accrual goals: 1520; 65 institutions credentialed. 210 patients registered to study).

- RTOG 0234: A Phase II Randomized Trial of Surgery Followed by Chemoradiotherapy Plus C225 (Cetuximab) for Advanced Squamous Cell Carcinoma of the Head and Neck (opened: 4/20/2004, accrual goals: 230 (ATC to collect data for IMRT cases only; 46 (IMRT) institutions credentialed. 165 patients registered to study.).
- RTOG 0236: Phase II Extracranial Stereotactic Radioablation in Treatment of Patients with Medically Inoperable Stage in NSCLC (opened: 5/26/04, accrual goals: 52; 7 institutions credentialed; 46 patients registered to study).
- RTOG 0321: Phase I/II Prostate: High Dose Brachytherapy and External Beam. (opened: 7/30/04, accrual goals: 110 (Recently Closed); 18 institutions credentialed; 129 patients registered to study).
- NSABP B39/RTOG 0413: Phase III Partial Breast Irradiation (opened: 3/28/05, accrual goals: 3000; 322 institutions credentialed (264 3DCRT, 189 Mammosite, 32 Multi-cath); 1446 patients registered to study (488 3D, 158 Mammosite, 62 Multi-cath).
- RTOG 0415: Phase III Rand Conventional Fx 3DCRT/IMRT vs Hypo Fx 3DCRT/IMRT in Prostate Ca (accrual goals: 706)
- RTOG 0418: Phase II IMRT + / - chemo for post-op endometrial or cervical Ca (opened: 3/20/06, accrual goals: 92; 55 institutions credentialed; 0 patients registered to study).
- RTOG 0421: Phase III Trial for Previously Irradiated Head and Neck Cancer: Reirradiation with or without Chemo (opened: 4/27/05, accrual goals: 240; 40 institutions credentialed; 13 patients registered to study).
- RTOG 0438: Phase I Unresect. Primary Bil Hepatobil. Ca & Liver Mets Extracranial Stereotactic RT (opened: 11/3/05, accrual goals: 18; 1 institutions credentialed; 1 patients registered to study).
- RTOG 0515: Phase II NSCLC Volume definition+/- PET (opened: 2/24/06, accrual goals: 48, 0 institutions credentialed; 0 patients registered to study)
-
- RTOG 0521: Phase III Trial for localized High Risk Prostate Cancer: Androgen Suppressioin with Radiation vs. Radiation with Chemotherapy and Prednisone. (opened: 12/8/05, accrual goals: 600 (ATC only receiving IMRT cases); 55 institutions credentialed; 16 patients registered to study).
- RTOG 0522: Phase III Trial Comparing Radiation and Cisplatin with/without Cetuximab for Advanced Head and Neck Cancer. (opened: 3/28/05, accrual goals: 720; 46 institutions credentialed for IMRT; 17 patients registered to study).

- JCOG 0403: Phase II Study of Stereotactic Body Radiation Therapy in Patients with T1N0M0 Non-Small Cell Lung Cancer (opened: 2005, accrual goals: 165; 13 institutions credentialed. 67 patients registered to study).

c. Protocols that are active and being supported by the ATC Method 3:

- NCIC MA20: Phase III study of regional radiation therapy in early breast cancer. (NCIC CTG Data Warehouse released for clinical QA use May 30, 2005. Currently, all MA.20 centers are being re-credentialed (As of March 1, 2006 ATC Teleconference 8 have been credentialed and 2 are in progress; 33 cases have been submitted using Method 3 for rapid or final review. (Note accrual data will be updated monthly on the ATC Teleconference).

d. Pending RTOG Studies – ATC Resources Requested/Committed – As of 8/29/05

- RTOG 0526: Phase II Salvage Brachy Hi Risk Prostate (accrual goals: approximately 150)
- RTOG 0539: Phase II Meningioma feasibility (accrual goals: not determined at this time)
- RTOG 0516: SCLC PET Staging (accrual goals: not determined at this time)
- RTOG 0529: Phase II Mitomycin+ Cis +IMRT in Anal Ca (accrual goals: under 100)