

RTOG Report to ATC



RTOG Headquarters Report

RTOG Protocols supported by the ATC (as of April 9, 2009)

- 3D-CRT Protocols
 - Closed Protocols (9)
 - RTOG 0319: Phase I/II Study to Evaluate 3D-CRT Irradiation Confined to Region of the Lumpectomy Cavity for Stage I/IIA Breast Carcinoma
 - 31 institutions credentialed; 58 patients registered to study (study closed, data analysis continues)
 - RTOG 93-11: Phase I/II Dose Escalation Study Using 3D Conformal Radiation Therapy in Patients with Inoperable NSCLC
 - 27 institutions credentialed; 180 patients registered to study (study closed, data analysis continues)
 - RTOG 94-06: Phase I/II Dose Escalation Study Using 3D Conformal Radiation Therapy for Adenocarcinoma of the Prostate
 - 54 institutions credentialed; 1084 patients registered to study (study closed, data analysis continues)

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- 3D-CRT Protocols (cont.)
 - RTOG 98-03: Phase I/II Radiation Dose Escalation Study Applying Conformal Radiation Therapy in Supratentorial Glioblastoma Multiforme
 - 46 institutions credentialed; 210 patients registered to study (study closed, data analysis continues)
 - RTOG 0117: Phase I/II Dose Intensification Study using 3D-CRT and Concurrent Chemotherapy for Patients with Inoperable, Non-Small Cell Lung Cancer
 - 51 institutions credentialed; 63 patients registered to study (study closed, data analysis continues)
 - RTOG 0515: A Comparative study of Gross Tumor Volume Definition with or without PET Fusion for Patients with Non-Small Cell Lung Carcinoma, 3D-CRT.
 - 10 institutions credentialed; 52 patients registered to study (study closed, data analysis continues)

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- 3D-CRT Protocols (cont.)
 - RTOG 0126: Phase III Randomized Study of High Dose 3D-CRT/IMRT versus Standard Dose 3D-CRT/IMRT in Patients treated for Localized Prostate Cancer (9/18/03 IMRT allowed)
 - 307 institutions credentialed (301 IMRT); 1534 patients registered to study (494 IMRT) (study closed, data analysis continues)
 - RTOG 0435: Phase III Study Unresectable H&N; IMRT/3DCRT
 - 179 institutions credentialed; 21 patients registered to study (study closed, data analysis continues)
 - RTOG 0522: Phase III RT + Cis vs RT + Cis + C225; 3D-CRT/IMRT
 - 344 institutions credentialed; 123 PET Participants; 942 patients registered to study; Target Accrual – 720

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- 3D-CRT Protocols (cont.)
 - Active Protocols (12)
 - RTOG 0413/NSABP B39: Phase III Study of Whole Breast RT versus Partial Breast Irradiation
 - 473 institutions credentialed (385 3DCRT, 283 Mammosite, 41 Multi-Cath); 3416 patients registered to study (1300 3DCRT, 324 Mammosite, 100 Multi-Cath)
 - RTOG 0415: Phase III study of Hypofractionated 3D-CRT/IMRT versus Conventionally Fractionated 3D-CRT/IMRT in Patients Treated for Favorable-Risk Prostate Cancer
 - 405 institutions credentialed; 820 patients registered to study (359 IMRT); Target Accrual – 1067
 - RTOG 0436: Phase III Esophagus, Cetux/Cis/RT vs Cis/Taxo/RT; 3D-CRT
 - 74 institutions credentialed; 35 patients registered to study; Target Accrual – 420

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- 3D-CRT Protocols (cont.)
 - RTOG 0521: Phase III High Risk Prostate; 3D-CRT/IMRT
 - 380 institutions credentialed (370 IMRT); 536 patients registered to study; Target Accrual – 600
 - RTOG 0534: Phase III RT Whole Pelvis vs Prostate Bed in High Risk Patients; 3D-CRT/IMRT
 - 231 institution credentialed; 58 patients registered to study; Target Accrual – 1764
 - RTOG 0615: Phase II of Concurrent Chemoradiotherapy using 3D-CRT or IMRT + Bev for nasopharyngeal Cancer
 - 220 institutions credentialed; 46 patients registered to study; Target Accrual – 46
 - RTOG 0617: Phase III High Dose 3DCRT in (Taxo/Cis) NCSLC
 - 160 institutions credentialed; 70 patient registered to study; Target Accrual – 512

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- **3D-CRT Protocols (cont.)**
 - RTOG 0619: Phase II IMRT, Chemo, ZD6474 for High Risk Post Op H&N
 - 28 institutions credentialed; 0 patients registered to study; Target Accrual – 170
 - RTOG 0621: Phase II Prostate RT/AS & Docetaxel; IMRT
 - 138 institutions credentialed; 19 patients registered to study; Target Accrual – 76
 - RTOG 0622: Phase II Study Samarium 153 Prostate; IMRT/3DCRT
 - 126 institutions credentialed; 2 patients registered to study; Target Accrual – 76
 - RTOG 0623: Phase II Combined Modality with Growth Factor in SCLC; 3D-CRT
 - 10 institutions credentialed; 5 patients registered to study; Target Accrual – 44
 - RTOG 0630: Phase II IGRT Large Size Soft Tissue Sarcoma; 3D-CRT/IMRT
 - 23 institutions credentialed; 21 patients registered to study; Target Accrual – 102

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

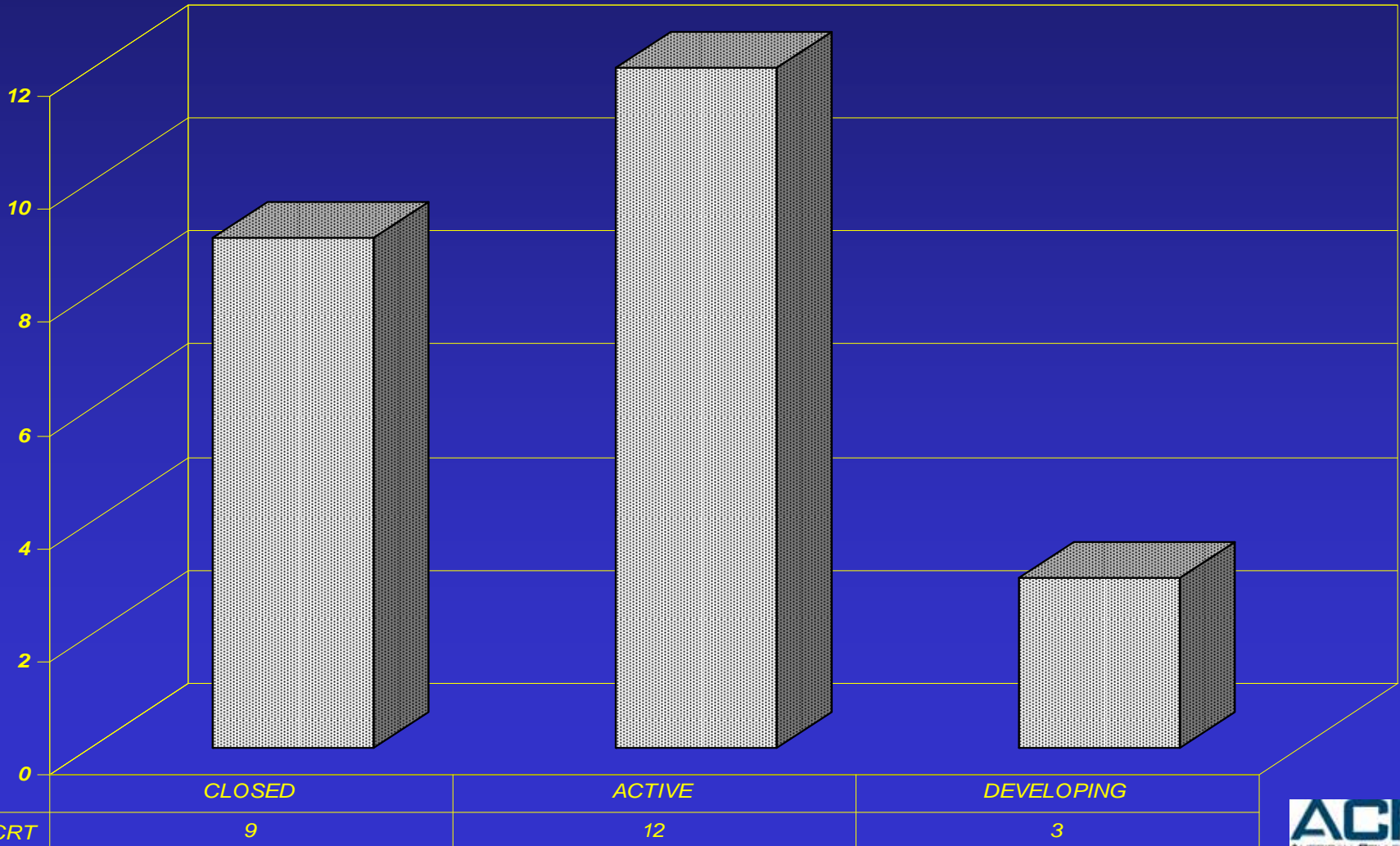
- 3D-CRT Protocols (cont.)

3D-CRT Developing Protocols (3)

- RTOG 0715: Phase II Study of Recurrent Breast 3DCRT
- RTOG 0724: Phase III Post-Operative Stage I/II Cervical with RT/Carbotaxol; 3D-CRT/IMRT
- RTOG 0825: Phase III Double-Blind RT/TMZ Bev vs RT/TMZ Placebo; 3D-CRT/IMRT

RTOG Headquarters Report (cont.)

3D-CRT PROTOCOLS



RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- IMRT Protocols
 - Closed Protocols (8)
 - RTOG 0022: Phase I/II Study of Conformal and Intensity Modulated Irradiation for Oropharyngeal Cancer
 - 36 institutions credentialed; 69 patients registered to study (study closed, data analysis continues)
 - RTOG 0126: Phase III Randomized Study of High Dose 3D-CRT/IMRT versus Standard Dose 3D-CRT/IMRT in Patients treated for Localized Prostate Cancer (9/18/03 IMRT allowed)
 - 307 institutions credentialed; 1534 patients registered to study (494 IMRT) (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 Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- **IMRT Protocols (cont.)**

- RTOG 0234: A Phase II Study of Surgery followed by Chemoradiotherapy Plus C225 (Cetuximab) for Advanced Squamous Cell Carcinoma of the Head and Neck
 - 89 institutions credentialed; 238 patients registered to study (96 IMRT) (study closed, data analysis continues)
- RTOG 0418: Phase II Study of Intensity Modulated Radiation Therapy (IMRT) to the Pelvis +/- Chemotherapy for Post-Operative Patients with Either Endometrial or Cervical Carcinoma
 - 210 institutions credentialed; 106 patients registered to study (study closed, data analysis continues)
- RTOG 0421: Phase III Head & Neck: Re-irradiation (GCSF)/IMRT
 - 80 institutions credentialed; 15 patients registered to study (study closed, data analysis continues)

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- IMRT Protocols (cont.)
 - RTOG 0435: Phase III Study Unresectable H&N; IMRT/3D-CRT
 - 179 institutions credentialed; 21 patients registered to study (study closed, data analysis continues)
 - RTOG 0529: Phase II Study Trial Evaluating Capecitabine, Cisplatin and IMRT (plus Cetuximab) in Carcinoma of the Anal Canal
 - 365 institutions credentialed; 63 patients registered to study (study closed, data analysis continues)

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- IMRT Protocols (cont.)
 - Active Protocols (12)
 - RTOG 0415: Phase III study of Hypofractionated 3D-CRT/IMRT versus Conventionally Fractionated 3D-CRT/IMRT in Patients Treated for Favorable-Risk Prostate Cancer
 - 405 institutions credentialed (359 IMRT); 820 patients registered to study; Target Accrual – 1067
 - RTOG 0521: Phase III High Risk Prostate; 3D-CRT/IMRT
 - 380 institutions credentialed (370 IMRT); 536 patients registered to study; Target Accrual – 600
 - RTOG 0522: Phase III RT + Cis vs RT + Cis + C225; 3D-CRT/IMRT
 - 344 institutions credentialed; 123 PET Participants; 942 patients registered to study; Target Accrual – 720
 - RTOG 0534: Phase III RT Whole Pelvis vs Prostate Bed in High Risk Patients; 3D-CRT/IMRT
 - 231 institutions credentialed; 58 patients registered to study; Target Accrual – 1764

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- IMRT Protocols (cont.)

- RTOG 0615: Phase II of Concurrent Chemoradiotherapy using 3D-CRT or IMRT + Bev for nasopharyngeal Cancer
 - 220 institutions credentialed; 46 patients registered to study; Target Accrual – 46
- RTOG 0617: Phase III High Dose 3DCRT in (Taxo/Cis) NSCLC
 - 160 institutions credentialed; 70 patients registered to study; Target Accrual – 512
- RTOG 0619: Phase II IMRT, Chemo, ZD6474 for High Risk Post Op H&N
 - 28 institution credentialed; 0 patients registered to study; Target Accrual – 170
- RTOG 0621: Phase II Prostate RT/AS & Docetaxel; IMRT
 - 138 institutions credentialed; 19 patients registered to study; Target Accrual – 76

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- **IMRT Protocols (cont.)**

- RTOG 0622: Phase II Prostate Samarium 153; IMRT/3DCRT
 - 126 institutions credentialed; 2 patients registered to study; Target Accrual – 76
- RTOG 0623: Phase II Combined Modality with Growth Factor in SCLC; IMRT
 - 10 institutions credentialed; 5 patients registered to study; Target Accrual – 64
- RTOG 0630: Phase II IGRT Large Size Soft Tissue Sarcoma; 3D-CRT/IMRT
 - 23 institutions credentialed; 21 patients registered to study; Target Accrual – 102
- RTOG 0822: Phase II IMRT Cape & Oxal in Locally Advanced Rectal Cancer
 - 379 institutions credentialed; 29 patients registered to study; Target Accrual – 75

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- **IMRT Developing Protocols (9)**
 - RTOG 0539: Phase II Feasibility study of IMRT for Intermediate- and High-Risk Meningiomas, and of Observation for Low-Risk Meningiomas
 - RTOG 0713: Phase III IMRT Breast
 - RTOG 0714: Phase III Resectable Pancreas IMRT 5-FU/Gem₊erlot
 - RTOG 0724: Phase III Stage I/II cervix; IMRT
 - RTOG 0848: Phase III Resectable Pancreas IMRT
 - RTOG 0823: Phase I Lapatinub/Cape + IMRT for Pancreas Cancer
 - RTOG 0838: Phase II IMRT + 5FU, MMC, Cetux for Squamous Cell Anal Canal
 - RTOG 0920: (formerly 0811) Phase III Intermediate H&N Cancer IMRT + or – C225 (IGRT Optional)
 - RTOG 0921: (formerly 0846) IMRT + Cis + Avastin in High Risk Endometrial Cancer

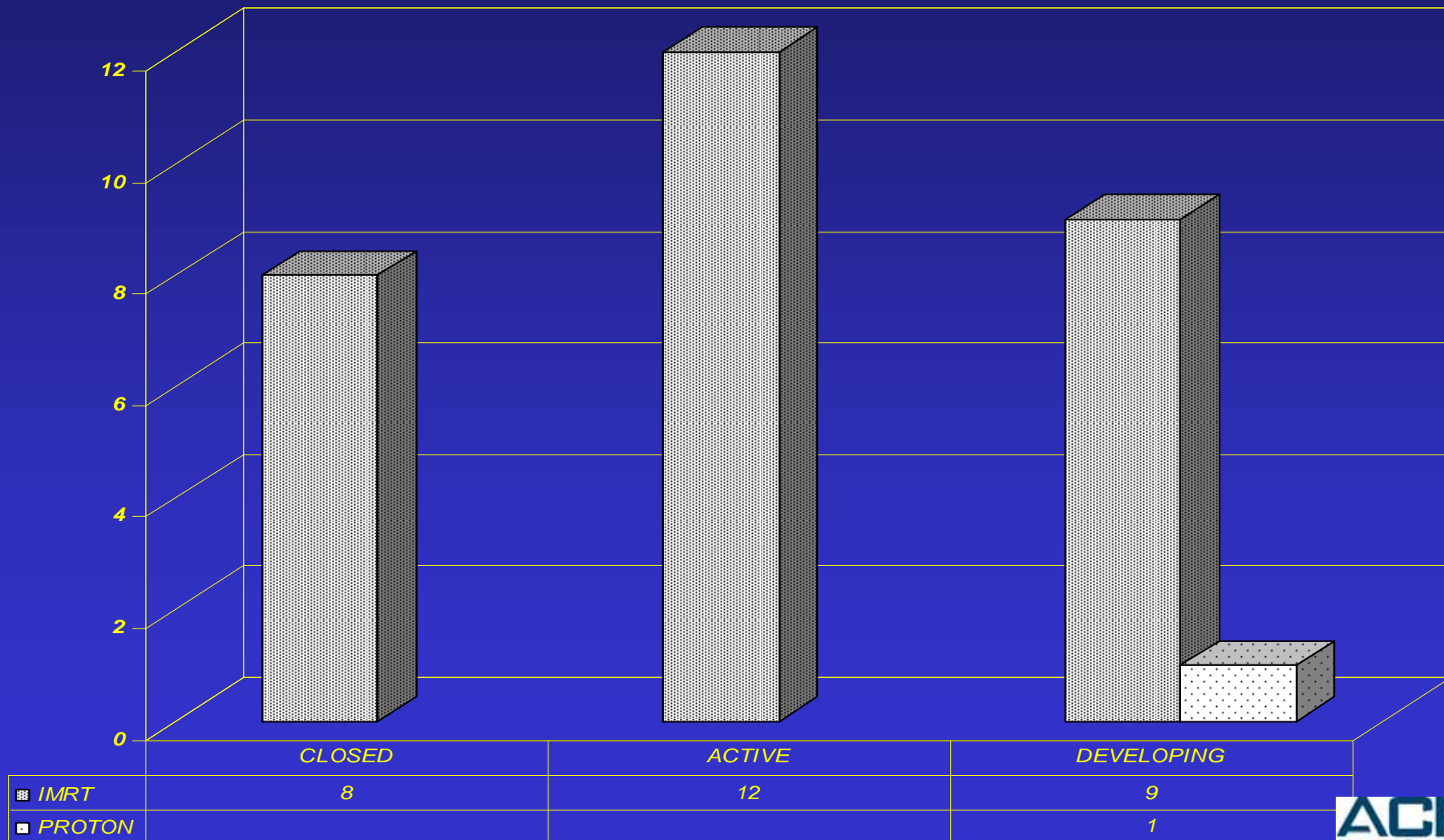
RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- Proton Developing Protocol (1)
 - RTOG 0814: Proton Beam Phase II in Locally Advance Prostate Cancer

RTOG Headquarters Report (cont.)

IMRT PROTOCOLS



RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- Brachytherapy Protocols

- Closed Protocols (2)

- RTOG 0116: Phase I/II Extended Field External Irradiation and Intracavitary Brachytherapy Comb with Chemotherapy (Weekly Cisplatin-Arm 1) and Amifostine (Weekly Cisplatin & Amifostine-Arm 2) in Carcinoma of Cervix with Positive Para-Aortic or High Common Iliac Lymph Nodes
- RTOG 0321: Phase I/II Prostate: High Dose Brachytherapy and External Beam
 - 40 institutions credentialed; 129 patients registered to study (study closed, data analysis continues)

- Active Protocols (4)

- RTOG 0232: Phase III Comparing Combined External Beam Radiation & Transperineal Interstitial Permanent Brachytherapy with Brachytherapy alone (IMRT added 6/2005)
 - 87 institutions Brachytherapy credentialed (81 IMRT); 426 patients registered to study; Target Accrual – 1520

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- **Brachytherapy Protocols (cont.)**
 - RTOG 0413/NSABP B39: Phase III Study of Whole Breast RT versus Partial Breast Irradiation
 - 473 institutions credentialed (385 3DCRT, 283 Mammosite, 41 Multi-Cath); 3416 patients registered to study (1300 3DCRT, 324 Mammosite, 100 Multi-Cath)
 - RTOG 0417: Phase II Study of Iressa in Combination with Definitive RT and Cisplatin Chemo in Locally Advanced Cervical Cancer, Optional Brachy/CT
 - 38 patient registered to study; Target Accrual – 57
 - RTOG 0526: Sequential Cohort Phase II trial of Two Dose Levels of Transperineal Ultrasound-Guided Brachytherapy for Locally Recurrent Prostate Adenocarcinoma following External Beam Radiotherapy
 - 150 institutions credentialed; 17 patients registered to study; Target Accrual – 96

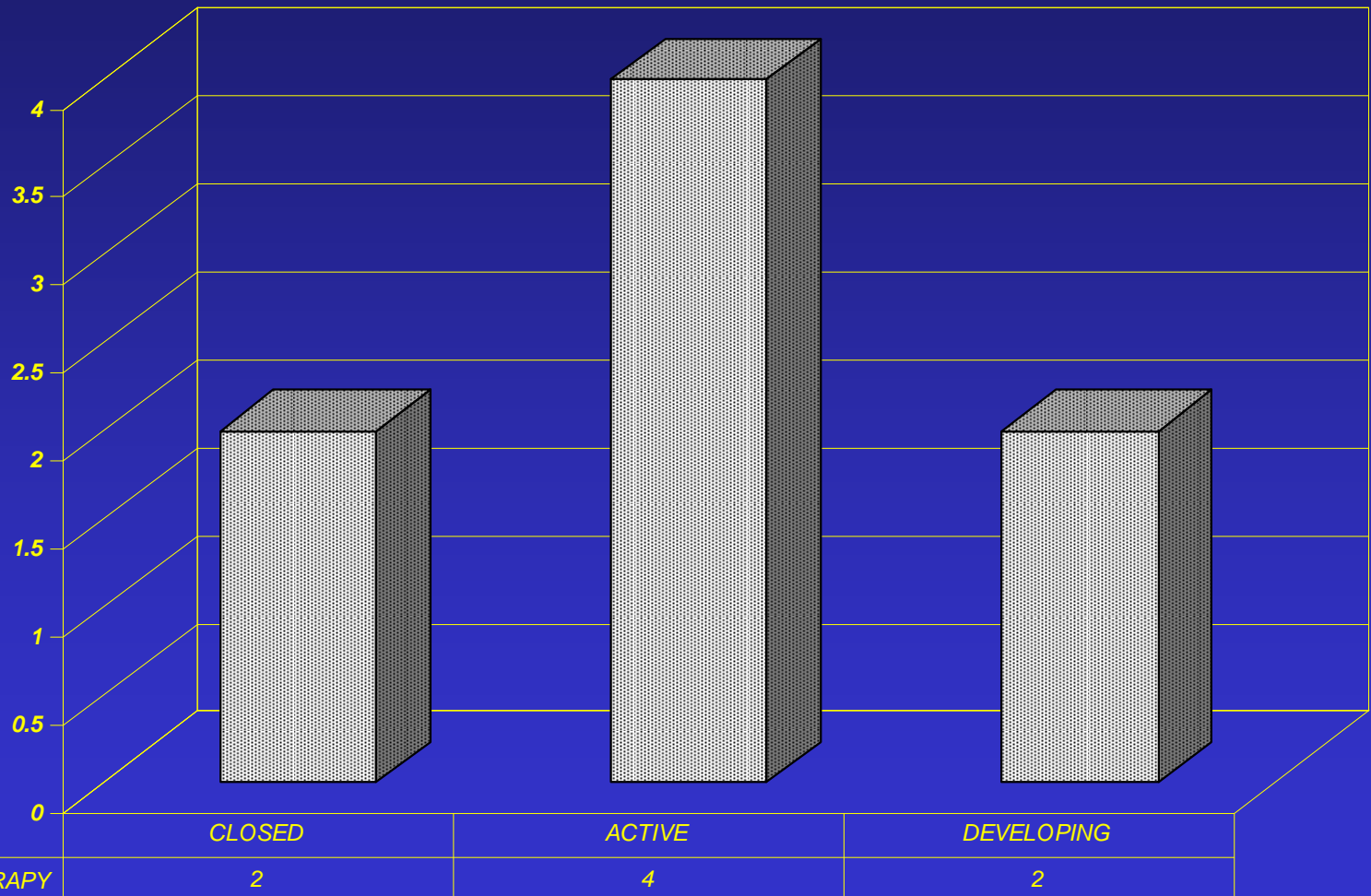
RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of April 9, 2009)

- Brachytherapy Protocols (cont.)
 - Developing (2)
 - RTOG 0816: Phase II HDR Brachy Prostate
 - RTOG 0818: Brachy Fractionation for Vaginal Length

RTOG Headquarters Report (cont.)

BRACHYTHERAPY PROTOCOLS



RTOG Headquarters Report (cont.)

IGRT in RTOG Protocols (as of April 9, 2009)

IGRT Protocols

- Lung (4 = 1 Closed; 1 Development; 3 Open)
 - RTOG 0236: Phase II Study of Extracranial Stereotactic Radioablation in Treatment of Patients with Medically Inoperable Stage in NSCLC
 - 9 institutions credentialed; 10 Pending; 59 patients registered to study (study closed, data analysis continues)
 - RTOG 0618: Phase II SBRT for Patients with Operable Early Stage NSCLC
 - 12 institutions credentialed; 4 patients registered to study; Target Accrual – 33
 - RTOG 0617: Phase III High Dose 3DCRT in (Taxo/Cis) NSCLC (Encourages IGRT / Opening 11/27/2007) – Target Accrual 512
 - 160 institutions credentialed; 70 patient registered to study; Target Accrual – 512
 - RTOG 0813: Phase I SBRT Inoperable NSCLC; IGRT
 - 0 institutions credentialed; 0 patients registered to study; Target Accrual – 94
 - RTOG 0915: Phase II SBRT Inoperable NSCLC; IGRT (Developing)

RTOG Headquarters Report (cont.)

IGRT in RTOG Protocols (as of April 9, 2009)

– Liver

- RTOG 0438: Phase I Trial of Highly Conformal Radiation Therapy for Patients with Unresectable Hepatobiliary Cancer with Liver Metastases
 - 3 institutions credentialed; 24 patients registered to study; Target Accrual – 18

– Sarcoma

- RTOG 0630: Phase II IGRT Large Size Soft Tissue Sarcoma
 - 23 institution credentialed; 21 patient registered to study; Target Accrual – 102

– H&N

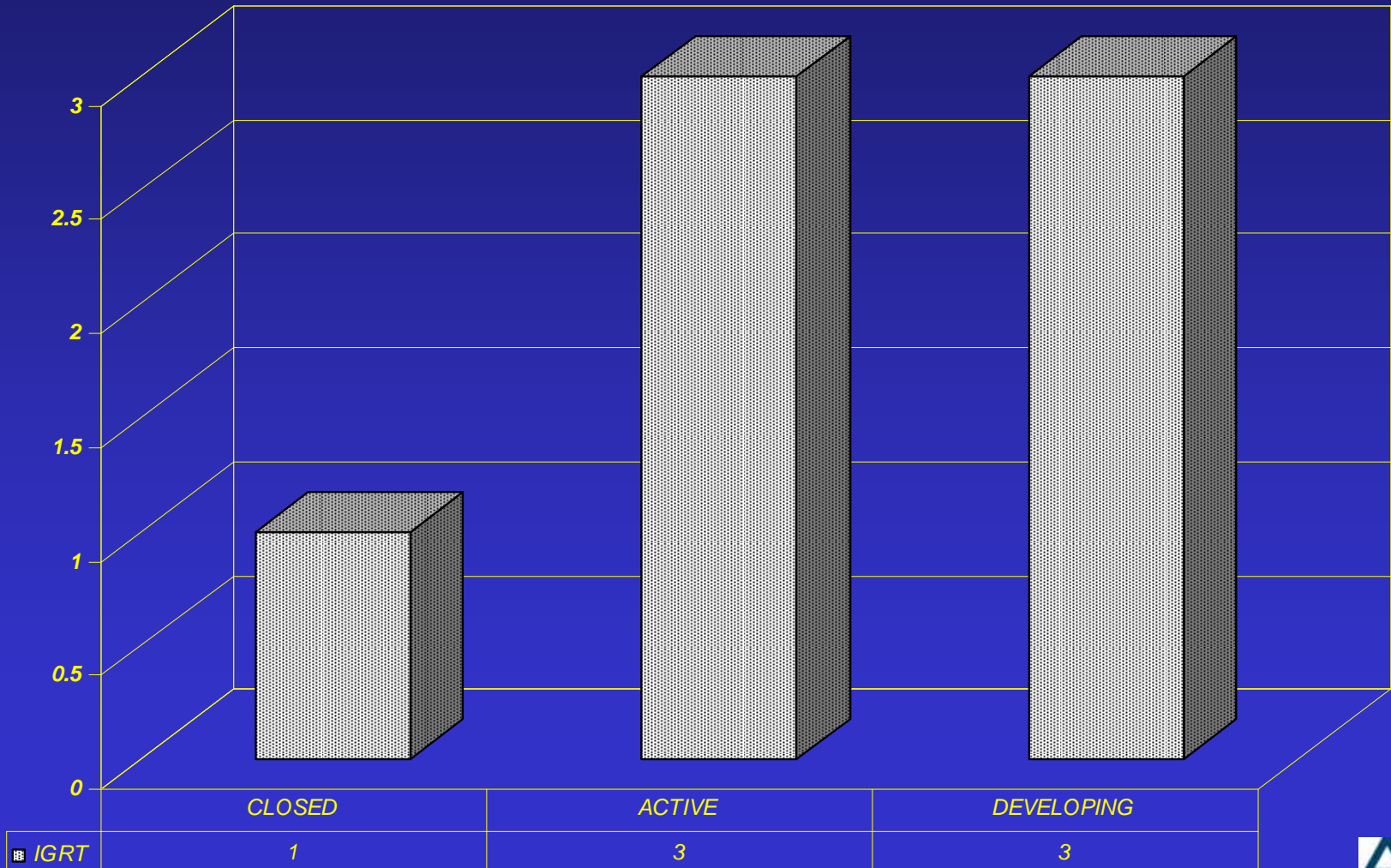
- RTOG 0920: (formerly 0811) Phase III Intermediate H&N Cancer IMRT + or – C225 (IGRT Optional)

– Spine Mets

- RTOG 0631: Phase II Stereotactic Radiosurgery for Spine Mets (Developing) – Target Accrual 77

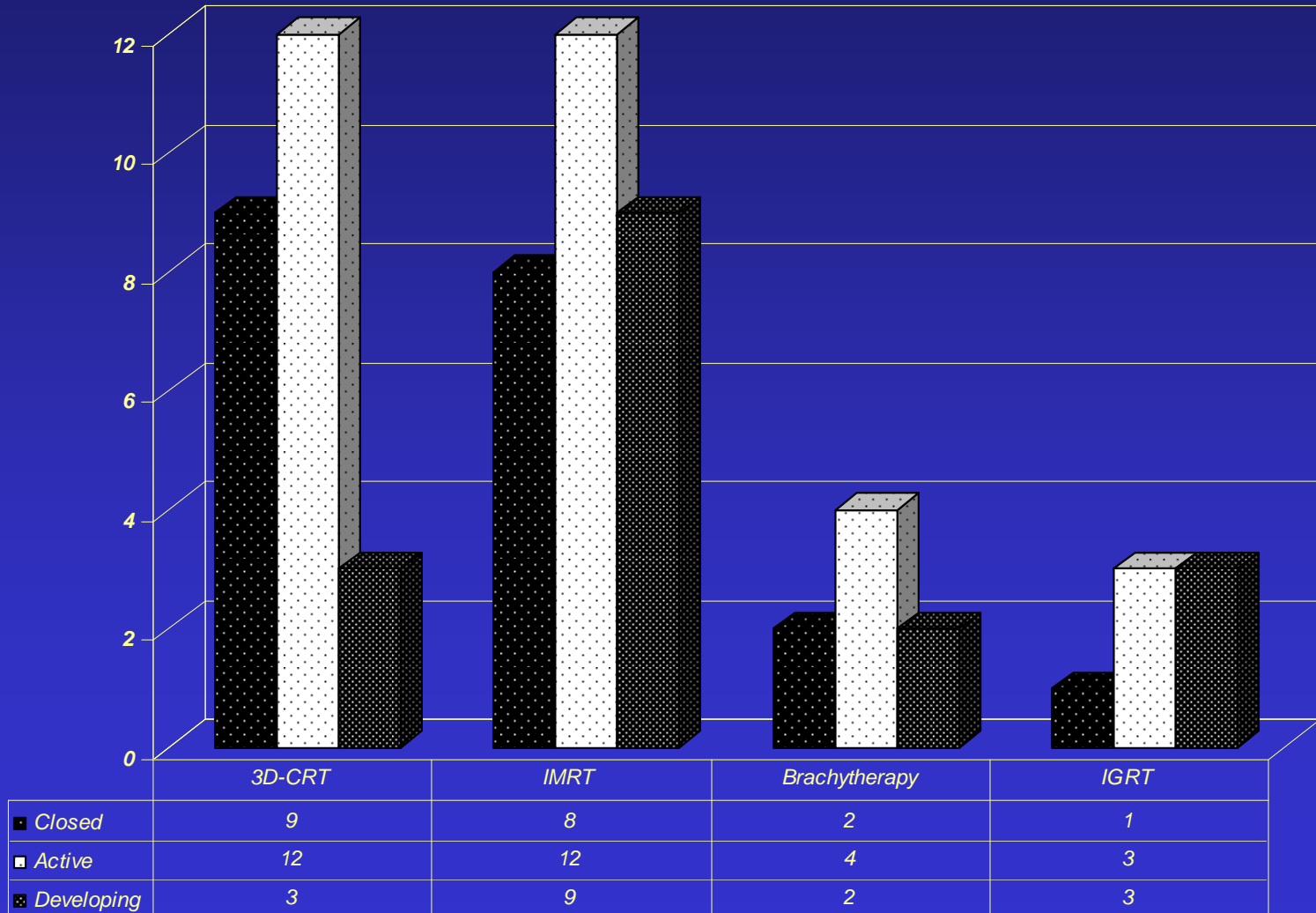
RTOG Headquarters Report (cont.)

IGRT PROTOCOLS



RTOG Headquarters Report (cont.)

ALL PROTOCOLS



ATC Meeting Schedule

- Bi-weekly teleconferences are held on Friday for RTOG/ITC/RPC Specific issues. (Monthly RTOG 0522 Protocol Update call)
- ATC meeting at the RTOG Semi-Annual Meeting in Chicago, IL.