

RTOG Report to ATC



RTOG Headquarters Report

RTOG Protocols supported by the ATC (as of June 14, 2007)

- 3D-CRT Protocols
 - Closed Protocols (4)
 - 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; Target Accrual – 46 (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 June 14, 2007)

- 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)
 - Active Protocols (7)
 - 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; 58 patients registered to study; Target Accrual – 73
 - 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)
 - 234 institutions credentialed (163 IMRT); 1248 patients registered to study (661 3D-CRT, 272 IMRT); Target Accrual – 1520

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 14, 2007)

- 3D-CRT Protocols (cont.)
 - RTOG 0413/NSABP B39: Phase III Study of Whole Breast RT versus Partial Breast Irradiation
 - 553 institutions credentialed (382-3DCRT, 266 Mammosite, 45 Multi-Cath); 2739 patients registered to study (950 3DCRT, 253 Mammosite, 74 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
 - 156 institutions IMRT credentialed; 172 patients registered to study; Target Accrual – 1067
 - 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.
 - 4 institutions credentialed; 15 patients registered to study; Target Accrual – 48

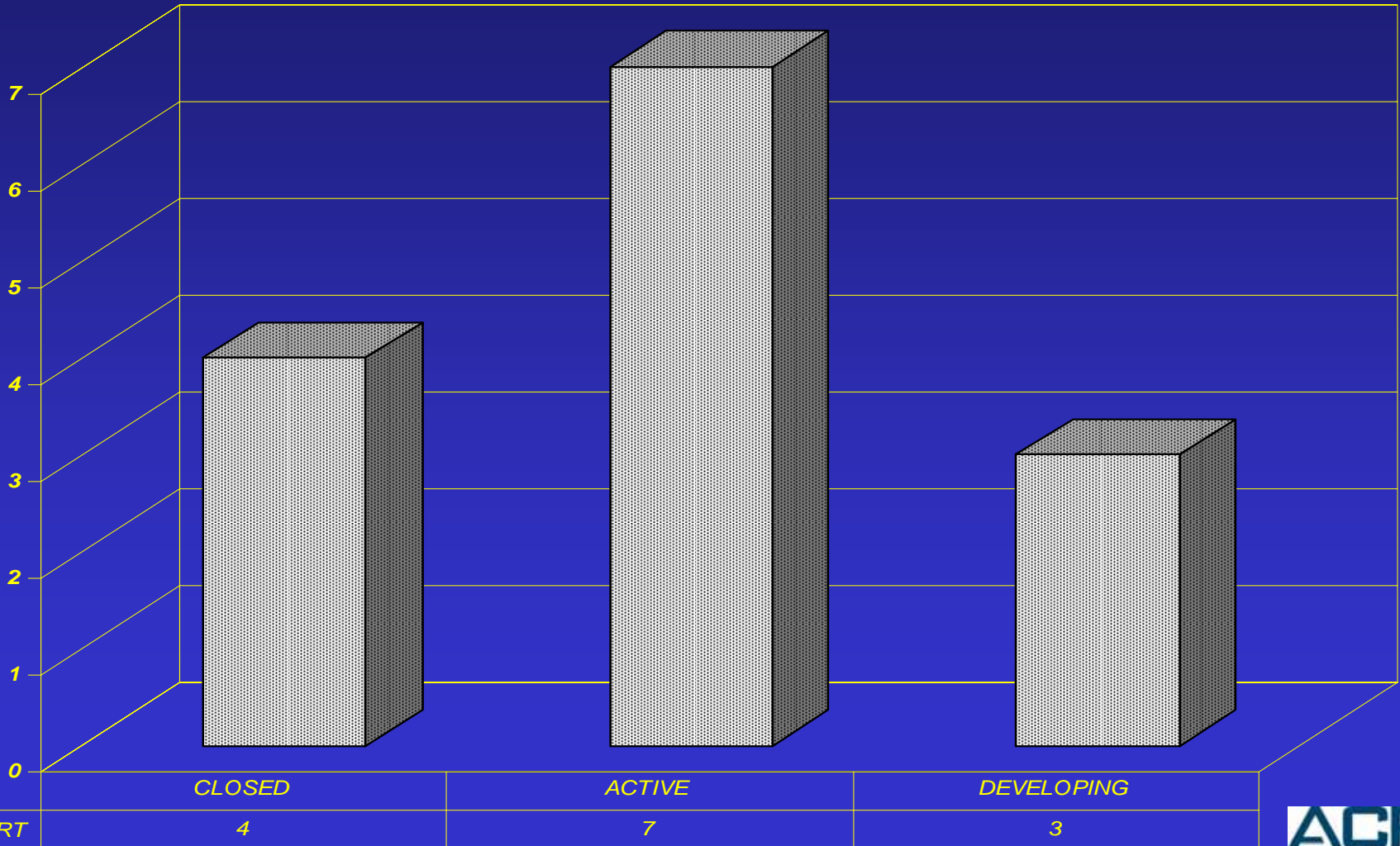
RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 14, 2007)

- 3D-CRT Protocols (cont.)
 - RTOG 0521: Phase III study of Androgen Suppression (AS) and Radiation Therapy (RT) vs AS and RT followed by Chemotherapy with Docetaxel and Prednisone for Localized, High-Risk Prostate Cancer
 - 161 institutions credentialed (149 IMRT Phantom, 7 IMRT Benchmark, 5 3D-CRT); 165 patients registered to study; Target Accrual – 600
 - RTOG 0522: Phase III study of Concurrent Accelerated Radiation and Cisplatin Versus Concurrent Accelerated Radiation, Cisplatin, and Cetuximab (C225) [Followed by Surgery for Selected Patients] for Stage III and IV Head and Neck Carcinomas
 - 137 institutions IMRT credentialed; 42 PET Participants; 215 patients registered to study; Target Accrual – 720
 - 3D-CRT Developing Protocols (3)
 - RTOG 0436: Phase III Esoph., Cetux./Cis/RT vs. Cis./Taxo/RT; 3D-CRT
 - RTOG 0617: Phase II/III study of Cetuximab in Combination with Concurrent 3D-CRT and Chemotherapy in Patients with Stage IIA/B Non-Small Cell Lung Cancer (NSCLC)
 - RTOG 0622: Phase II Study Samarium 153 Prostate; IMRT/3DCRT

RTOG Headquarters Report (cont.)

3D-CRT PROTOCOLS



RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 14, 2007)

- IMRT Protocols
 - Closed Protocols (3)
 - 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 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 0234: A Phase II Study of Surgery followed by Chemoradiotherapy Plus C225 (Cetuximab) for Advanced Squamous Cell Carcinoma of the Head and Neck
 - 87 institutions credentialed; 238 patients registered to study; Target Accrual – 230

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 14, 2007)

- IMRT Protocols (cont.)
 - Active Protocols (9)
 - 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)
 - 234 institutions credentialed (163 IMRT); 1248 patients registered to study (661 3D-CRT; 272 IMRT); Target Accrual – 1520
 - RTOG 0415: Phase III study of Hypofractionated 3D-CRT/IMRT versus Conventionally Fractionated 3D-CRT/IMRT in Patients Treated for Favorable-Risk Prostate Cancer
 - 156 institutions IMRT credentialed; 172 patients registered to study; Target Accrual – 1067
 - 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
 - 103 institutions credentialed; 74 patient registered to study; Target Accrual – 92
 - RTOG 0421: Phase III Head & Neck: Re-irradiation (GCSF)/IMRT
 - 77 institutions credentialed; 15 patients registered to study, Target Accrual – 240

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 14, 2007)

- **IMRT Protocols (cont.)**
 - RTOG 0435: Phase III Study Unresectable H&N; IMRT/3D-CRT
 - 105 institutions credentialed; 6 patients registered to study; Target Accrual – 298
 - RTOG 0521: Phase III study of Androgen Suppression (AS) and Radiation Therapy (RT) vs AS and RT followed by Chemotherapy with Docetaxel and Prednisone for Localized, High-Risk Prostate Cancer
 - 161 institutions credentialed (149 IMRT Phantom, 7 IMRT Benchmark, 5 3D-CRT); 165 patients registered to study; Target Accrual – 600
 - RTOG 0522: Phase III study of Concurrent Accelerated Radiation and Cisplatin Versus Concurrent Accelerated Radiation, Cisplatin, and Cetuximab (C225) [Followed by Surgery for Selected Patients] for Stage III and IV Head and Neck Carcinomas
 - 137 institutions IMRT credentialed; 42 PET Participants; 215 patients registered to study; Target Accrual – 720

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 14, 2007)

- **IMRT Protocols (cont.)**
 - RTOG 0529: Phase II Study Trial Evaluating Capecitabine, Cisplatin and IMRT (plus Cetuximab) in Carcinoma of the Anal Canal
 - 106 institutions credentialed; 15 patients registered to study; Target Accrual – 59
 - RTOG 0615: Phase II study of Radiotherapy (IMRT) and Concurrent Cisplatin (CDDP) followed by Adjuvant Cisplatin and 5FU + Bevacizumab (BV) for Patients with Locally Advanced Nasopharyngeal Carcinoma (NPC)
 - 108 institutions credentialed; 0 patients registered to study; Target Accrual – 46

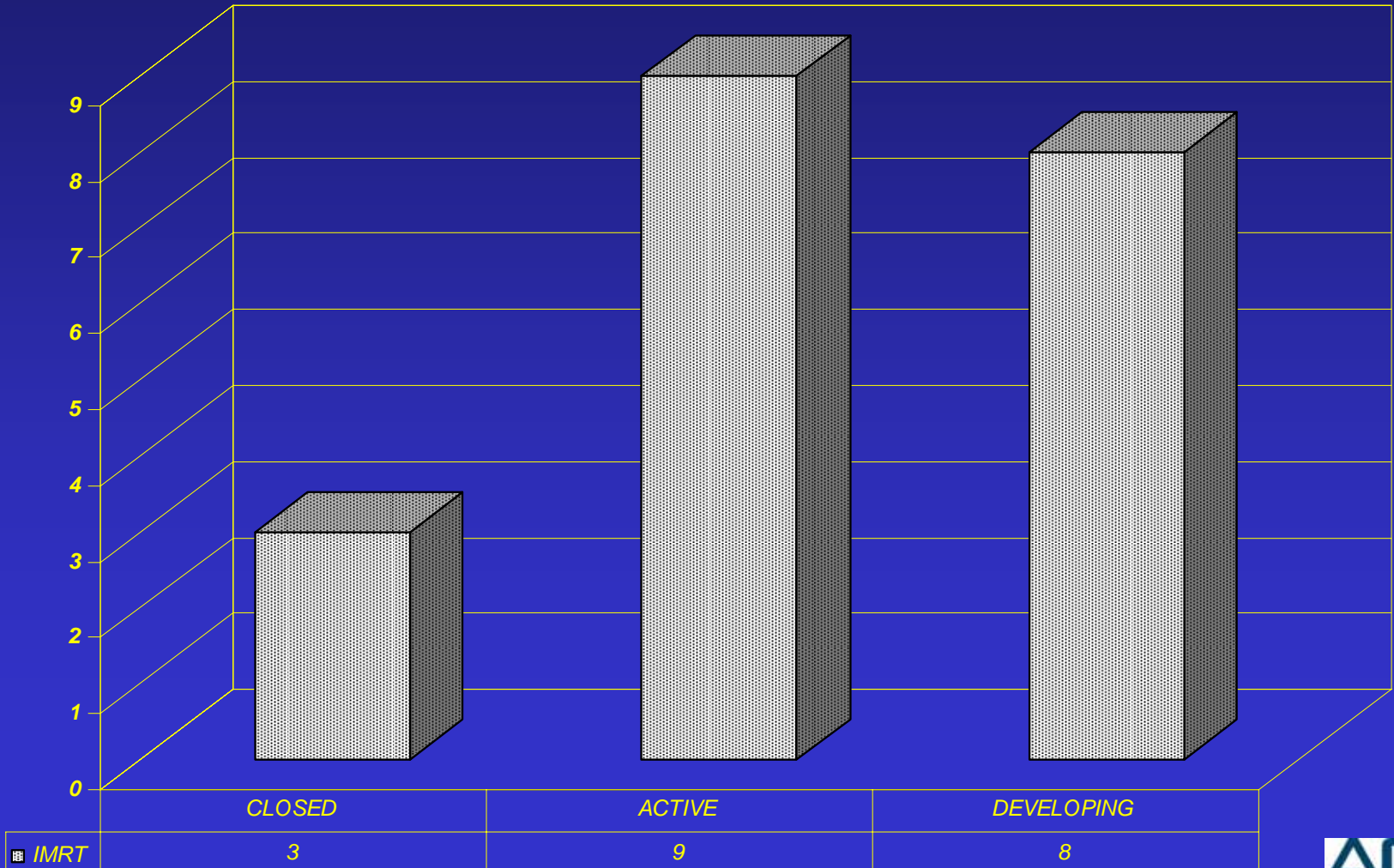
RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 14, 2007)

- **IMRT Developing Protocols (8)**
 - RTOG 0534: Phase III trial of PBRT alone vs NC-STAD+PBRT vs NC-STAD+WPRT for Patients with a Rising PSA after Radical Prostatectomy, IMRT
 - RTOG 0539: Phase II Feasibility study of IMRT for Intermediate- and High-Risk Meningiomas, and of Observation for Low-Risk Meningiomas
 - RTOG 0619: Phase II IMRT, Chemo, ZD6474 for high-risk post op H&N
 - RTOG 0621: Phase II Prostate RT/AS & Docetaxel; IMRT
 - RTOG 0622: Phase II Prostate Samarium 153; IMRT/3DCRT
 - RTOG 0623: Phase II Combined Modality with Growth Factor in SCLC; IMRT
 - RTOG 0628: Phase II IMRT Locally Advanced Rectal
- **Symptom Management**
 - Phase III Dose Escalation Trial for Non-Operable Spinal Cord Compression due to Metastasis Comparing 30 Gy versus 39 Gy Utilizing SBRT/IMRT Techniques

RTOG Headquarters Report (cont.)

IMRT PROTOCOLS



RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 14, 2007)

- Brachytherapy Protocols
 - Active Protocols (5)
 - RTOG 0116: Phase I/II Study of Extended Field External Irradiation and Intracavitary Brachytherapy Combined with Chemotherapy (Weekly Cisplatin-Arm 1) and Amifostine (Weekly Cisplatin and Amifostine-Arm 2) in Carcinoma of the Cervix with Positive Para-Aortic or High Common Iliac Lymph Nodes
 - RTOG 0232: Phase III Study Comparing Combined External Beam Radiation & Transperineal Interstitial Permanent Brachytherapy with Brachytherapy alone (IMRT added 6/2005)
 - 78 institutions Brachytherapy credentialed (66 IMRT); 290 patients registered to study; Target Accrual – 1520
 - RTOG 0413/NSABP B39: Phase III Study of Whole Breast RT versus Partial Breast Irradiation
 - 553 institutions credentialed (382-3DCRT, 266 Mammosite, 45 Multi-Cath); 2739 patients registered to study (950 3DCRT, 253 Mammosite, 74 Multi-Cath)

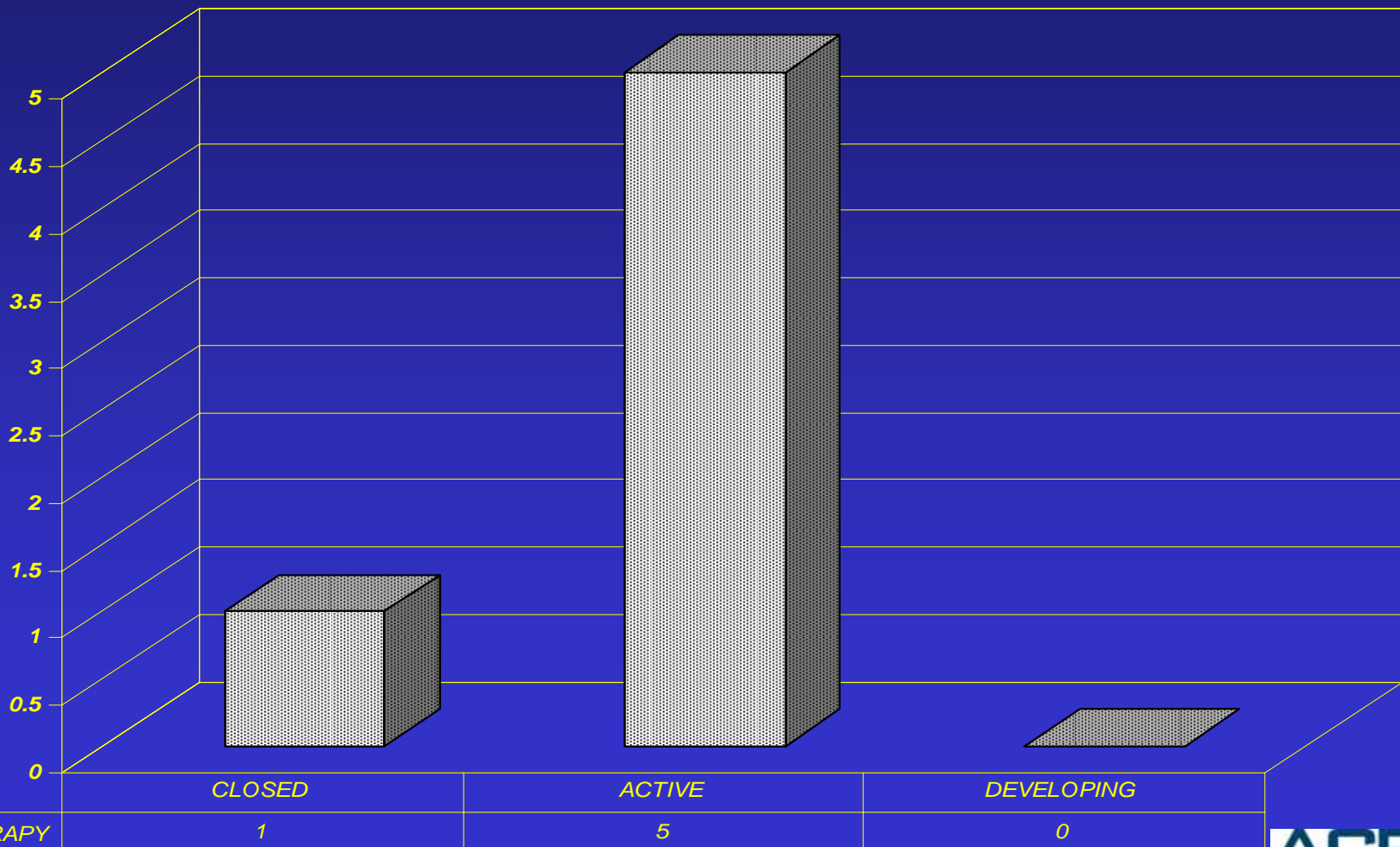
RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 14, 2007)

- **Brachytherapy Protocols (cont.)**
 - RTOG 0417: Phase II Study of Iressa in Combination with Definitive RT and Cisplatin Chemo in Locally Advanced Cervical Cancer, Optional Brachy/CT
 - institutions credentialed; 6 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
 - Closed (1)
 - RTOG 0321: Phase I/II Prostate: High Dose Brachytherapy and External Beam
 - 18 institutions credentialed; 129 patients registered to study; Target Accrual – 110

RTOG Headquarters Report (cont.)

BRACHYTHERAPY PROTOCOLS



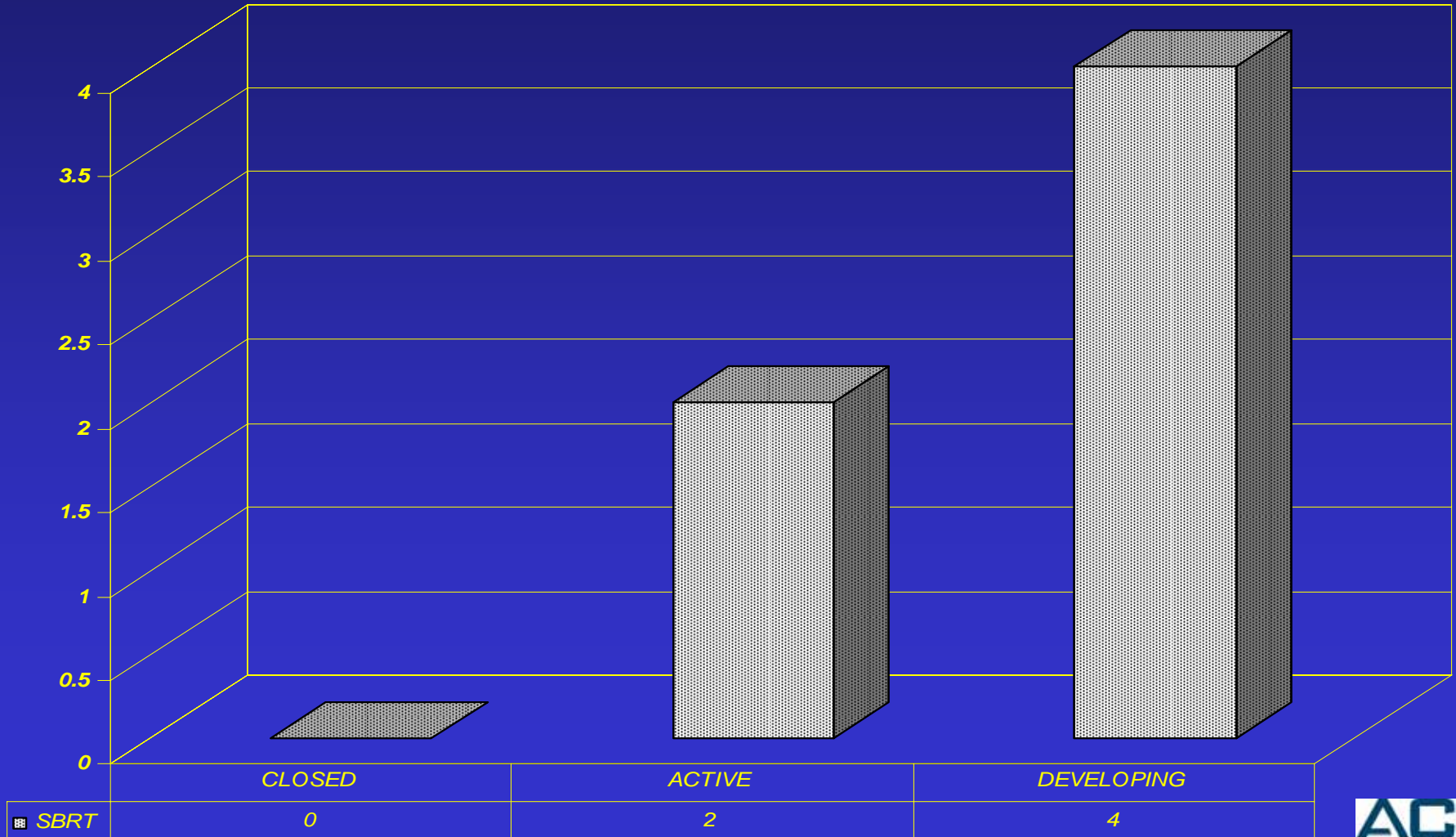
RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of June 14, 2007)

- SBRT Protocols
 - Active Protocols (2)
 - RTOG 0236: Phase II Study of Extracranial Stereotactic Radioablation in Treatment of Patients with Medically Inoperable Stage in NSCLC
 - 9 institutions credentialed; 5 Pending; 59 patients registered to study; Target Accrual – 59
 - RTOG 0438: Phase I Trial of Highly Conformal Radiation Therapy for Patients with Unresectable Hepatobiliary Cancer and Liver Metastases
 - 1 institution credentialed; 3 Pending; 7 patient registered to study; Target Accrual – 18
 - Developing (4)
 - RTOG 0618: Phase II Trial of Stereotactic Body Radiation Therapy (SBRT) for Patient with Operable Early Stage Non-Small Cell Lung Cancer
 - RTOG 0624: Phase II SBRT + Erlotinib or Sorafinib in Inoperable NSCLC
 - RTOG 0631: Phase II Stereotactic Radiosurgery for Spine Mets
 - RTOG 0633: Phase I SBRT Inoperable NSCLC

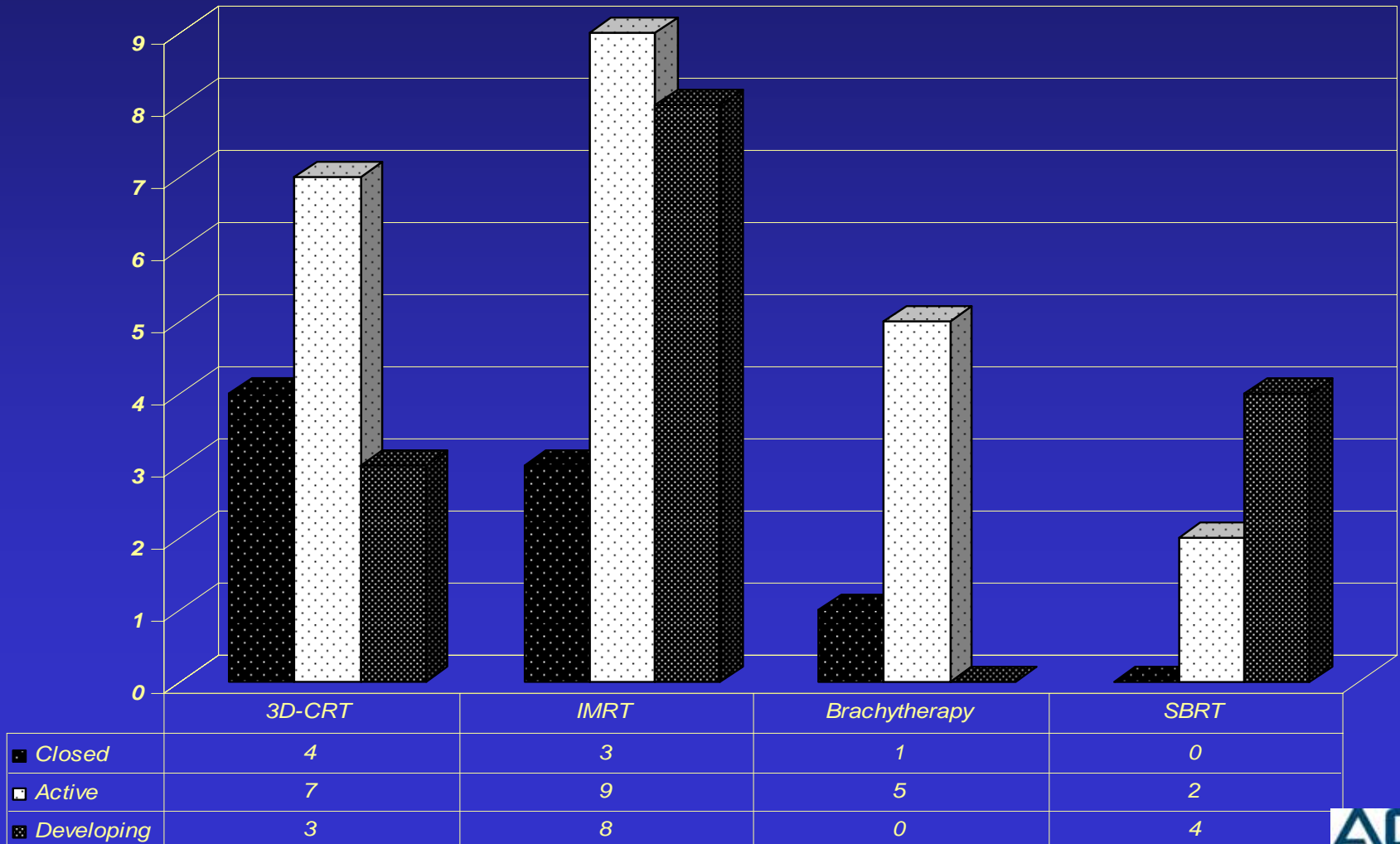
RTOG Headquarters Report (cont.)

SBRT PROTOCOLS

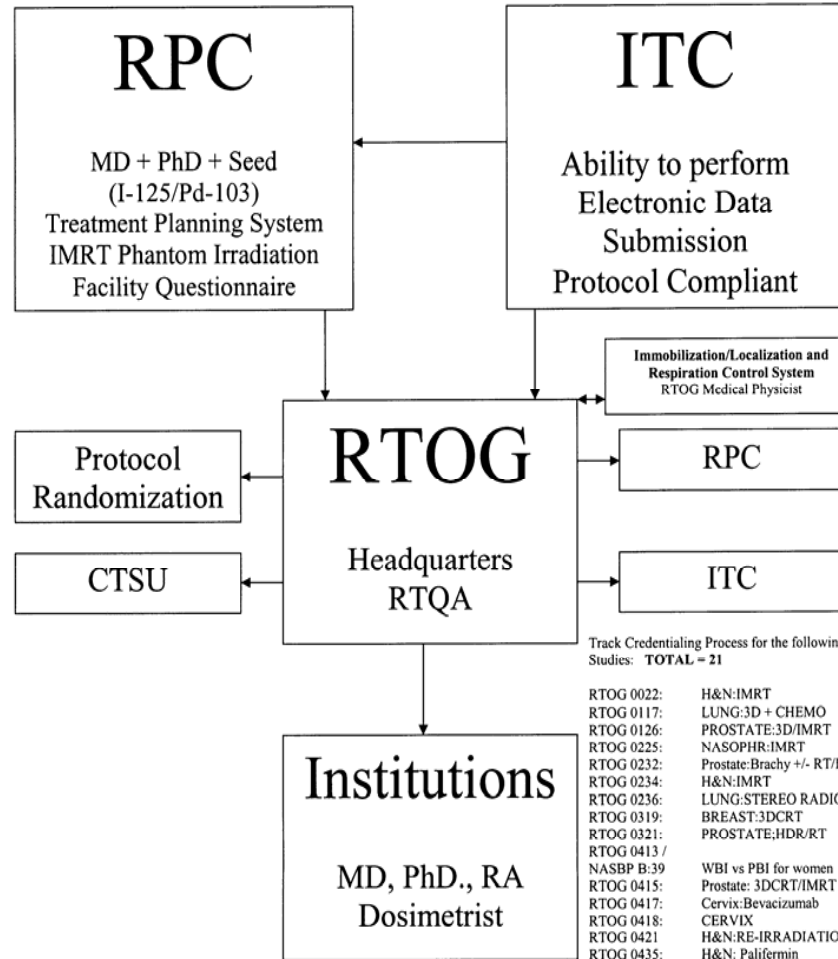


RTOG Headquarters Report (cont.)

ALL PROTOCOLS



RTOG 0232
Prostate – Brachytherapy
IMRT
Credentialing Process Notification



Track Credentialing Process for the following
Studies: **TOTAL = 21**

- RTOG 0022: H&N:IMRT
- RTOG 0117: LUNG:3D + CHEMO
- RTOG 0126: PROSTATE:3D/IMRT
- RTOG 0225: NASOPHR:IMRT
- RTOG 0232: Prostate:Brachy +/- RT/IMRT
- RTOG 0234: H&N:IMRT
- RTOG 0236: LUNG:STEREO RADIOAB
- RTOG 0319: BREAST:3DCRT
- RTOG 0321: PROSTATE:HDR/RT
- RTOG 0413 /
NASBP B:39 WBI vs PBI for women
- RTOG 0415: Prostate: 3DCRT/IMRT
- RTOG 0417: Cervix:Bevacizumab
- RTOG 0418: CERVIX
- RTOG 0421: H&N:RE-IRRADIATION
- RTOG 0435: H&N: Palifermin
- RTOG 0438: GI:STEREOTACTIC RADIOAB
- RTOG 0515: NSCLC: Vol. def. PET
- RTOG 0521: PROSTATE:3DCRT/IMRT
- RTOG 0522: H&N:3DCRT/IMRT (PET Opt.)
- RTOG 0529: ANAL CANAL:IMRT
- RTOG 0615: NASOPHARYNX:IMRT

**TOTAL
STUDIES = 21**

Institution Approval Letter for RTOG – 0232



Date

Principal Investigator, M.D.
Institution – RTOG # ; NCI # ; RTF #
Department of Radiation Oncology
Address
City, State, Zip

Dear Dr. :

The Credentialing process by the Radiological Physics Center (RPC) for prostate brachytherapy and Electronic Data Submission to the Image-Guided Therapy Center (ITC) for RTOG-0232 – A Phase III Study Comparing Combined External Beam Radiation and Transperineal Interstitial Permanent Brachytherapy with Brachytherapy Alone for Selected Patients with Intermediate Risk Prostatic Carcinoma has been successfully met.

You are now approved to enter patients onto RTOG Prostate Implant Protocol 0232. A change in Radiation Oncologist, Physicist, treatment planning system, nuclide or seed model will require recredentialing by the RPC and/or ITC.

Sincerely,

Elizabeth A. Martin
Director, R.T. Quality Assurance

cc: Physicist
Research Associate
RTOG Randomization
ITC
RPC
CTSU

a leader in defining more effective cancer therapies



RTOG 0236

Phase II Trial of Stereotactic Body Radiation Therapy (SBRT) in the Treatment of Patients with Medically Inoperable Stage I/II Non-Small Cell Lung Cancer

SCHEMA

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Stereotactic Body Radiation Therapy (SBRT),
20 Gy per fraction for 3 fractions over 1½-2
weeks, for a total of 60 Gy

Institution Approval Letter for RTOG – 0236

RTOG
Radiation Therapy
Oncology Group

Date

, M.D.
Institution – RTOG # ; NCI # ; RTF #
Department of Radiation Oncology
Address
City, State, Zip

Dear Dr. :

Your institution has successfully completed the Lung Phantom Irradiation Dosimetry Test, Facility Questionnaire, Immobilization/Localization and Respiration Control Systems Test.

You can now enter patients on to RTOG Protocol 0236.

The Dry Run / Rapid Review will be reviewed on the actual case. The dosimetry will be reviewed and the study chair will determine if this and the drawn structures are protocol compliant and sufficient for the patient to go ahead with treatment. Since this test case (Dry Run / Rapid Review) is the first case entered from your institution, the scanning parameters, the structure outline, and the dosimetry will have to be according to protocol in order to pass the Dry Run / Rapid Review **PRIOR TO DELIVERING ANY PROTOCOL TREATMENT**. The plan will be reviewed centrally at the ITC, and suggestions regarding protocol compliance will be forwarded to your institution. The treatment plan for subsequent patients enrolled from your site will not be required to be centrally reviewed prior to treatment, but will be reviewed for protocol compliance at a later date.

However, the Immobilization/Localization and Respiration Control Systems Test must be repeated for the first 4 cases submitted from your institution and the results reviewed by James Galvin, D.Sc., Medical Physics Co-Chair. The data for the first patient entered must be reviewed and approved before you enter a second patient, and the results of the Immobilization/Localization and Respiration Control Systems Study for this patient must be approved prior to entering a third patient. At this point, any additional number of patients can be entered. You will have to send forward the results of the Immobilization/Localization and Respiration Control Systems Study for the third and fourth patients entered. Please refer to the attached information.

Sincerely,

Elizabeth A. Martin
Director, R.T. Quality Assurance

cc: Physicist
Research Associate
James Galvin, D.Sc.
RTOG Randomization
ITC
RPC

a leader in defining more effective cancer therapies



RTOG Protocol 0236

Immobilization/Localization and Respiration Control Systems Study

This study must be performed on a single patient, and approval received from RTOG Headquarters, before you attempt to enter your first patient on RTOG Protocol 0236. A similar study must be performed for the first patient entered on this protocol, and approval must be received from Headquarters prior to entering a second patient. This same procedure must be followed before entering a third patient. A fourth patient can be entered at the same time as the third, as well as, additional patients can also be entered at this time. However, the results of the Immobilization/Localization and Respiration Control Systems Study for the third and fourth patients entered on this protocol must be sent forward for review as quickly as possible. This information will be analyzed, but no further communication will be sent from RTOG Headquarters except in those situations where problems are detected. If problems are found, you could be asked to stop entering patients until the issue is resolved. In situations where no problems are found, the Immobilization/Localization and Respiration Control Systems Study will be discontinued after you have sent the data forward for the fourth patient you have entered on this protocol.

Status of RTOG 0236

Institution	RPC Acceptable	Letter Sent	Immobilization Acceptable	IRB	Patient Accrual
Cleveland Clinic Foundation	Yes	05/01/2006	Yes	07/01/2007	9
Duke University Medical Center	Yes	Pending			
Indiana University	Yes	12/30/2004	Yes	3/21/2008	13
Mayo Clinic	Yes	Pending			
Medical College of Wisconsin	Yes	Pending		5/8/07	
Mount Sinai Medical Center	Yes	Pending			
OSF Saint Francis Medical Center	Yes	Pending		6/7/07	
Princess Margaret Hospital	Yes	12/30/2004	Yes	12/16/2007	13
Richard Roudebush VA Medical Center	Yes	Pending		05/25/2006	
Thomas Jefferson University	Yes	03/03/2005	Yes	07/19/2007	2
University of Florida	Yes	Pending		11/16/2005	
University of Rochester	Yes	11/07/2005	Took 1 st case off protocol	08/25/2007	1
University of Texas MD Anderson Cancer Center	Yes	12/23/2005	Yes	09/20/2007	1
University of Wisconsin Hospital	Yes	09/07/2005	Waiting for 1 st case	08/20/2007	
UT Southwestern Medical Center	Yes	05/20/2005	Yes	09/19/2007	5
Virginia Commonwealth University	Yes	Pending			
Wake Forest University Health Sciences	Yes	Pending			
Washington University	Yes	12/30/2004	Yes	02/19/2008	15

Total number of institutions = 18 (9 approved; 9 pending)

RTOG 0438

Phase I Trial of Highly Conformal Radiation Therapy for Patients with Liver Metastases

SCHEMA

All Patients will receive 10 fractions Monday-Friday for 2 weeks at the following levels; Dose escalation by 0.5 Gy to maximum of 50 Gy, as follows:

Dose level	<u>Level I</u>	† <u>Level II</u>	<u>Level III</u>	<u>Level IV</u>
Dose per fraction	3.5 Gy	4.0 Gy	4.5 Gy	5.0 Gy
Total dose	35 Gy	40 Gy	45 Gy	50 Gy

†Protocol Treatment Begins at Level II

Institution Approval Letter for RTOG – 0438

RTOG
Radiation Therapy
Oncology Group

Date

_____, M.D.
Institution – RTOG # _____ ; NCI # _____ ; RTF # _____
Department of Radiation Oncology
Address
City, State, Zip

Dear Dr. :

Your institution has successfully completed the Liver Phantom Irradiation Dosimetry Test, Facility Questionnaire, Immobilization/Localization and Respiration Control Systems Test.

You can now enter patients on to RTOG Protocol 0438.

The Dry Run / Rapid Review will be reviewed on the actual case. The dosimetry will be reviewed and the study chair will determine if this and the drawn structures are protocol compliant and sufficient for the patient to go ahead with treatment. Since this test case (Dry Run / Rapid Review) is the first case entered from your institution, the scanning parameters, the structure outline, and the dosimetry will have to be according to protocol in order to pass the Dry Run / Rapid Review **PRIOR TO DELIVERING ANY PROTOCOL TREATMENT**. The plan will be reviewed centrally at the ITC, and suggestions regarding protocol compliance will be forwarded to your institution. The treatment plan for subsequent patients enrolled from your site will not be required to be centrally reviewed prior to treatment, but will be reviewed for protocol compliance at a later date.

However, the Immobilization/Localization and Respiration Control Systems Test must be repeated for the first 2 cases submitted from your institution and the results reviewed by James Galvin, D.Sc., Medical Physics Co-Chair. The data for the first patient entered must be reviewed and approved before you enter a second patient, and the results of the Immobilization/Localization and Respiration Control Systems Study for this patient must be approved prior to entering a third patient. At this point, any additional number of patients can be entered. You will have to send forward the results of the Immobilization/Localization and Respiration Control Systems Study for the third and fourth patients entered. Please refer to the attached information.

Sincerely,

Elizabeth A. Martin
Director, R.T. Quality Assurance

cc: Physicist
Research Associate
James Galvin, D.Sc.
RTOG Randomization
ITC
RPC

a leader in defining more effective cancer therapies



RTOG Protocol 0438

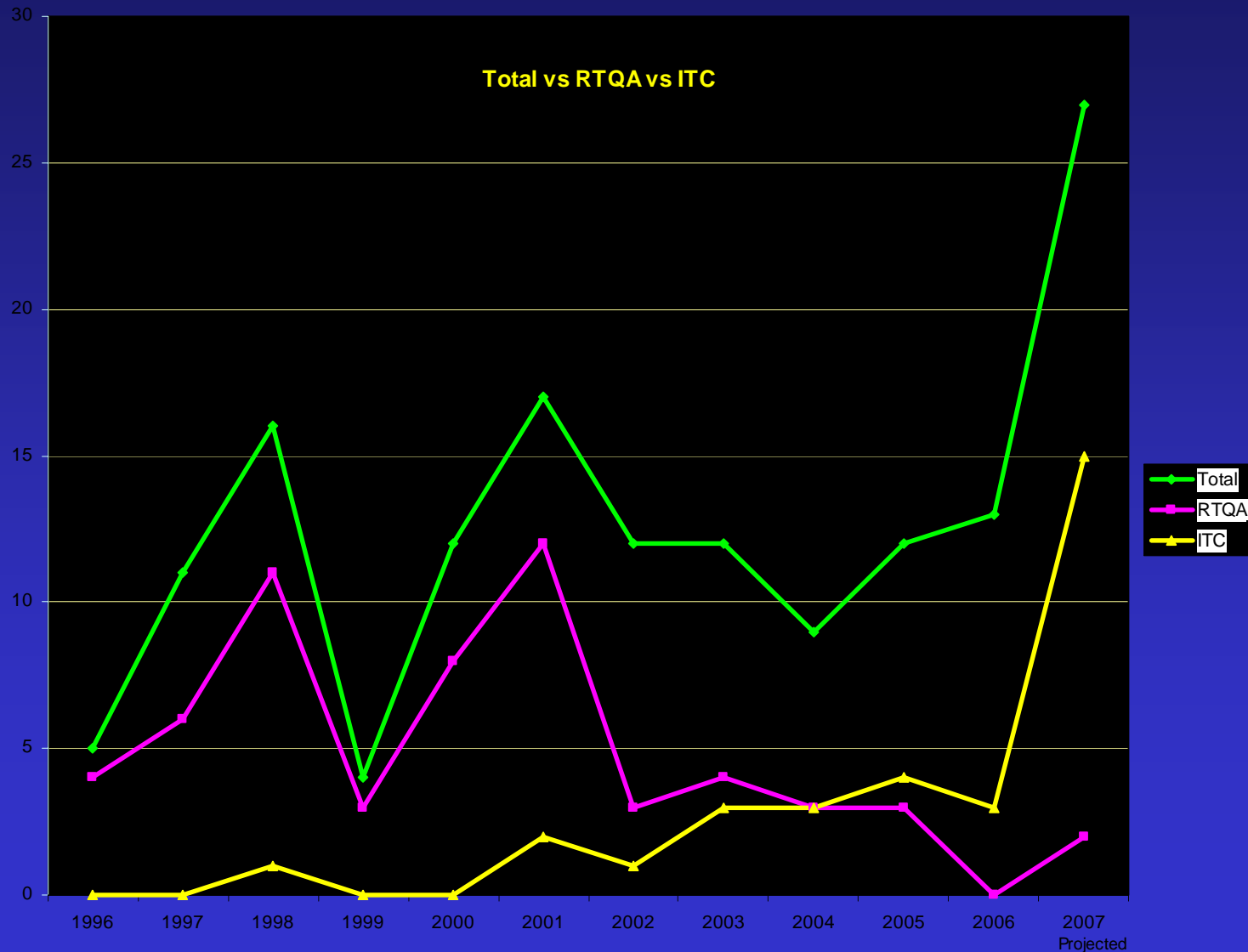
Immobilization/Localization and Respiration Control Systems Study

This study must be performed on a single patient, and approval received from RTOG Headquarters, before you attempt to enter your first patient on RTOG Protocol 0438. A similar study must be performed for the first patient entered on this protocol, and approval must be received from Headquarters prior to entering a second patient. This same procedure must be followed before entering a third patient. However, once approval has been given to enter the third patient on the protocol, no additional Immobilization/Localization data needs to be gathered.

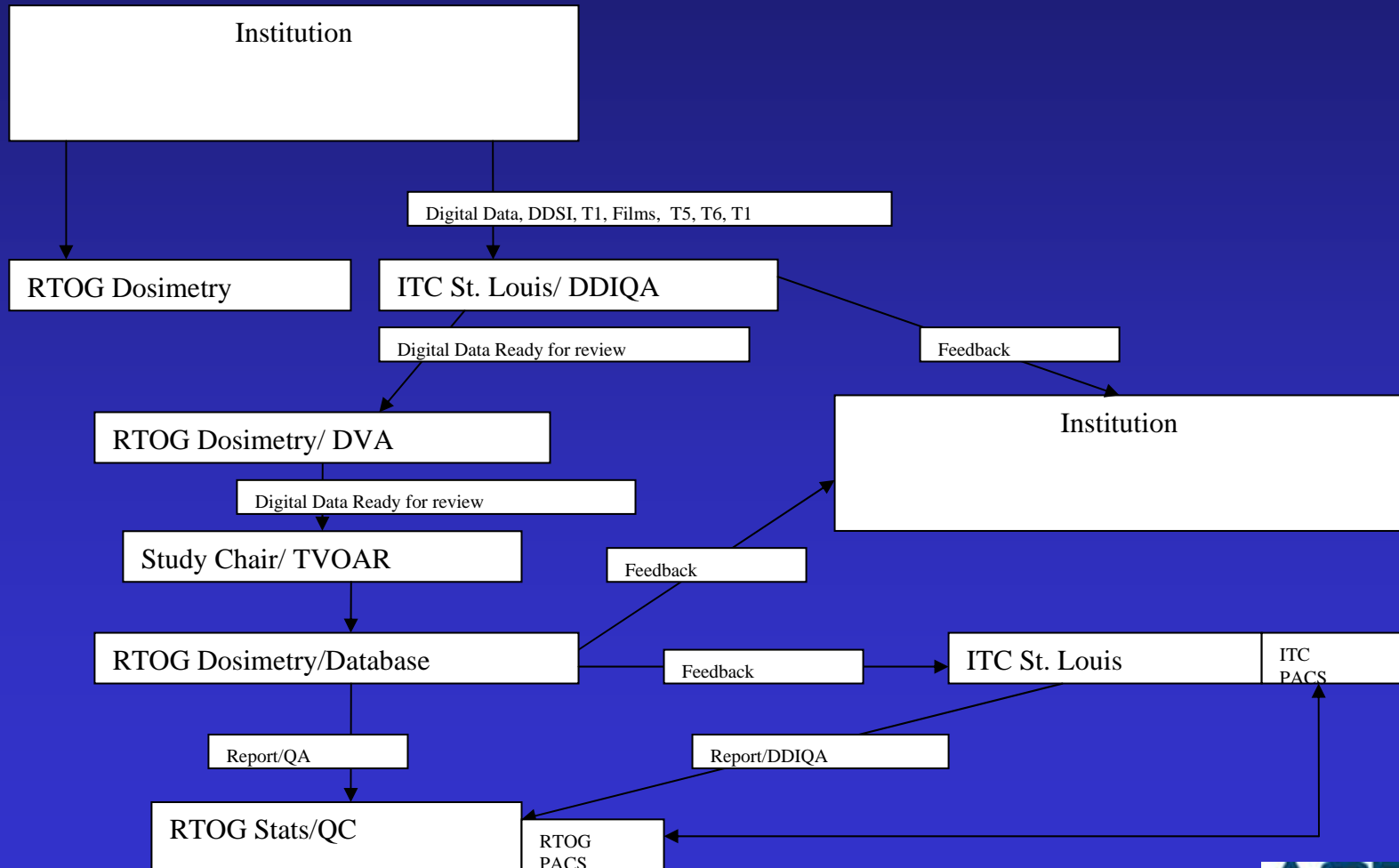
Status of RTOG 0438

Institution	RPC Acceptable	ITC Acceptable	Letter Sent	Notes	IRB	Patient Accrual
University of Rochester	Yes	Pending	10/12/2006		01/04/2008	
Princess Margaret Hospital	Yes	Yes	01/30/2006	6/2/06 passed 1 st case 9/20/06 passed 2 nd case	10/21/2007	3
Cleveland Clinic Foundation	Yes	Pending	Pending		07/12/2007	
OSF Saint Francis Medical Center	Yes	Pending	Pending		05/09/2008	

Active Protocols RTQA



Work Flow Diagram



R. T. Quality Assurance Staff



Back Row L/R: Betty O'Meara; Denise Manfredi; Nancy Linnemann; Tammy McGlade
Front Row L/R: Joanne Hunter; Lorraine Quarles; Julie McIlvaine

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 Philadelphia, PA, Loews Philadelphia Hotel, Thursday, June 21, 2007 at 4:00pm – 7:00pm.
- ATC meeting at the RTOG Semi-Annual Meeting in San Diego, CA, Manchester Grand Hyatt, Thursday, June 17, 2008 at 4:00pm – 7:00pm.