RTOG Report to ATC

Radiation Therapy Oncology Group

ATC • AdvancedTechnologyConsortium
Providing support in quality assurance and data management for radiation therapy clinical trials

RTOG
Radiation Therapy Oncology Group

Image-Guided Therapy Center
An Advanced Technology Clinical Trials QA and Support Center

THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER
Making Cancer History™

AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE
Radiological Physics Center

RCET
University of Florida Radiation Oncology

QARC
Quality Assurance Review Center

acr
American College of Radiology

Radiation Therapy Oncology Group

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

REGISTER

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

Tomotherapy

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Institution Approval Letter for RTOG – 0236

Radiation Therapy Oncology Group

American College of Radiology
1818 Market Street, Suite 1600
Philadelphia, PA 19103-3604
(215) 574-3189
(800) 227-5463 Ext. 4189
(215) 928-0153 Fax

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

Supported by the Division of Cancer Treatment and Diagnosis, National Cancer Institute

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RTOG 0236 Accrual List

Radiation Therapy
Oncology Group

Institution	Inst. #	Patients
Thomas Jefferson University Hospital	0601	1
Washington University	2101	4
Princess Margaret Hospital	2215	6
Indiana University Medical Center	8001	2
	TOTAL	**13**

As of 6/20/2005

Radiation Therapy
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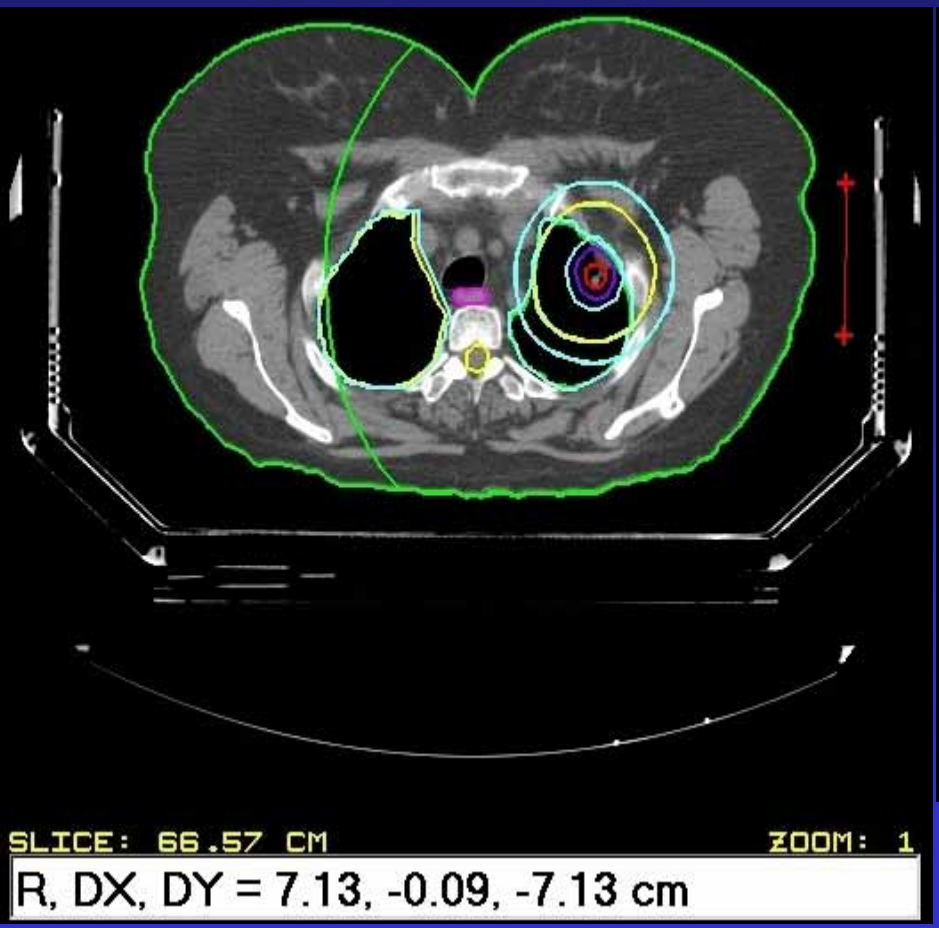
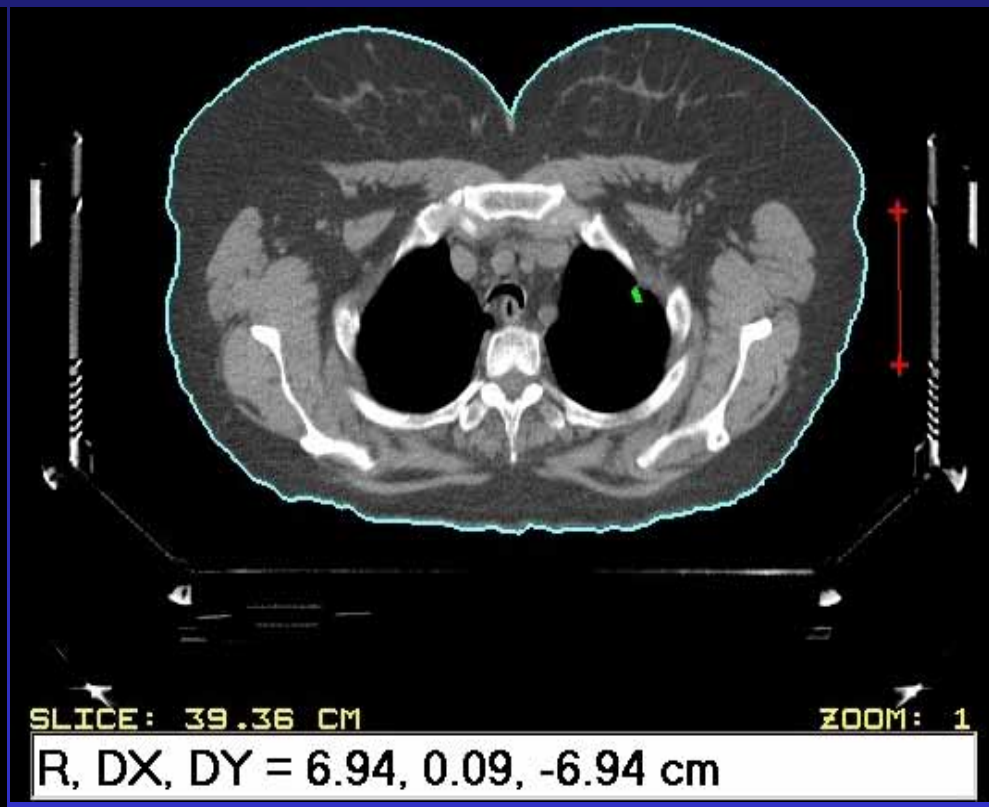
Wash U. – St. Louis





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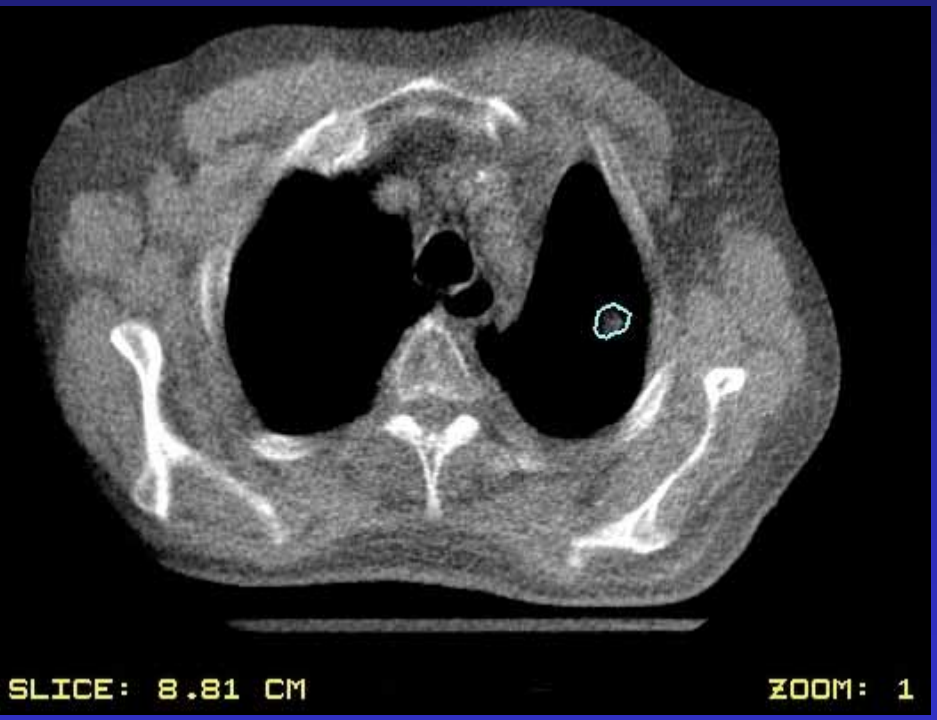

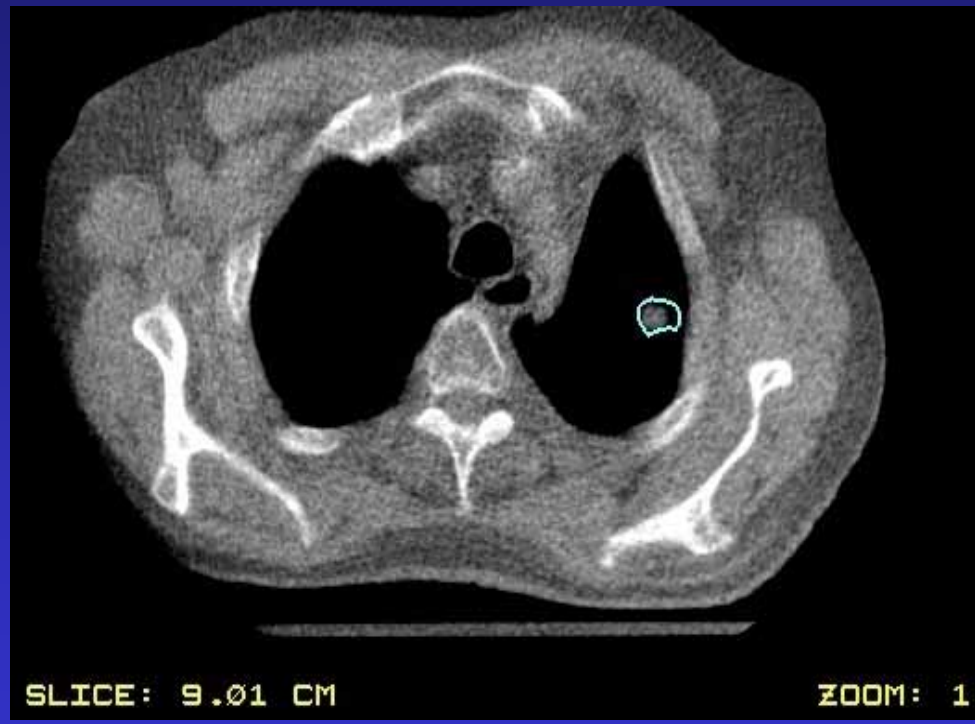

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RTOG Protocol 0236

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.

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