SUMMARY OF CHANGES
Amendment 6, Version Date: September 9, 2009
(Broadcast 9/17/09)

RTOG 0236 "A 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"

Study Chair: Robert D. Timmerman, MD; 214-645-7637; Robert.Timmerman@UTSouthwestern.edu

RTOG 0236 has been amended as follows:

Patient follow up has been amended from a total of 4 years to include annual follow up for the patient's lifetime. The primary analysis of RTOG 0236 presented at IASLC 2009 in August 2009, demonstrated very promising results. With a median follow-up time of 30.1 months, median survival had not yet been reached. When this study was developed, it had not been anticipated that this would happen. In order to fully capture the promising outcomes of this study, such as a median survival time estimate with complete 95% confidence interval and desirable 5-year survival rates, it is necessary to prolong the follow-up time to be greater than 4 years. Because it is unclear how these patients will continue to respond to their treatment, it is necessary to follow all patients until death.

The following sections were amended for this change: Section 11.1, footnote "e"; Section 11.2.4; Section 12.2, the schedule for the Follow-up Form (F1); and in Appendix I, under "What is involved in the study?" and "How long will I be in the study?".

Other Changes

Title page: Dr. Gore's e-mail address was updated.
RTOG 0236 "A 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"

Study Chair: Robert D. Timmerman, M.D., 214-645-7637, Robert.Timmerman@UTSouthwestern.edu

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RTOG 0236 has been amended as follows:

**Section 5.1:** Because this section had been erroneously revised in Amendment 4 to address IMRT pre-registration requirements, the text of this section was changed back to its original wording. Specifically:

- The phrase *for IMRT Treatment Approach* was deleted from the heading.
- The sentence *In order to utilize IMRT, the institution must have met technology requirements and have provided baseline physics information* was changed to *Institutions must be credentialed by the Advanced Technology Consortium (ATC) prior to enrolling patients on this study.*
- The sentence *This information is available on the Advanced Technology Consortium (ATC) web site: http://atc.wustl.edu* was deleted.
- The sentence *The ATC in part comprises RTOG RT Quality Assurance, the Image-Guided Therapy Center (ITC) at Washington University, and the Radiological Physics Center (RPC) at MD Anderson Cancer Center* was changed to *As it pertains to this study, the ATC includes the Image-Guided Therapy Center (ITC) at Washington University, St. Louis; the Radiological Physics Center (RPC) at MD Anderson Cancer Center; and RTOG RT Quality Assurance.*

An amended protocol is available (no password required) on the RTOG Web site, [www.rtog.org](http://www.rtog.org).
SUMMARY OF CHANGES
Amendment 4, Version Date: November 21, 2005

RTOG 0236 "A 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"

Study Chair: Robert D. Timmerman, M.D., 214-645-7637, Robert.Timmerman@UTSouthwestern.edu

RTOG 0236 has been amended as follows:

Section 5.1: The pre-registration requirements were revised to make them specific to IMRT.

Section 13.3: In the third paragraph, "...an overall significance level of no more than 0.10\textsuperscript{24}..." was changed to "an overall Type I error rate of no more than 0.10\textsuperscript{42}." In the three-item list that follows, the numbers of cases of unacceptable toxicities and numbers of evaluable patients have been revised. In the fourth paragraph, "...the rejection rule of 14 or more patients with unacceptable toxicities out of the total sample of 33 evaluable patients. This will insure an overall significance level of 0.05 for the final conclusion" was changed to "...the rejection rule of 17 or more patients with unacceptable toxicities out of the total sample of 49 evaluable patients. This will insure an overall significance level of 0.10 for the final conclusion." The sentence "If more than 49 of the 52 accrued patients..." was added. In the fifth paragraph, the phrase "(corresponding to 14 or more patients with unacceptable toxicities)" was deleted after "...the unacceptable toxicity rate exceeds 25%.

An amended protocol is available (no password required) on the RTOG Web site, www.rtog.org
SUMMARY OF CHANGES
Amendment 3, Version Date: June 14, 2005

RTOG 0236 “A 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”

Study Chair: Robert D. Timmerman, M.D., 214-645-7637, Robert.Timmerman@UTSouthwestern.edu

RTOG 0236 has been amended as follows:

Title page: James Galvin’s degree was changed to D.Sc.

Section 3.1.8:

- The first bulleted item was amended to read “…within 4 weeks prior to study entry.”
- The second bulleted item was amended to read “Evaluation by an experienced thoracic cancer clinician within 8 weeks prior to study entry.” This change was also made in Section 11.1 in the third line under “Assessments.”
- The fourth bulleted item was amended to specify that PFTs must be done within 8 weeks prior to study entry. For consistency, a new footnote g was added in Section 11.1 to reflect this change.
- In the sixth bulleted item, “unless medically contraindicated,” was added for consistency with footnote b of Section 11.1.

Section 3.2.3 was amended to include “or synchronous primary or prior malignancy in the past 2 years other than nonmelanomatous skin cancer or in situ cancer.” The corresponding change was made to the Eligibility Checklist, page 1, Question # 10.

Section 11.1: In footnote b, “preferably” was added to match the text in the sixth bullet in Section 3.1.8. A superscript b was added to the X in the Pre-Study Entry column in the CT Scan row. Old footnote g is now footnote h to keep alphabetical order.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
RTOG 0236, “A 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”

Study Chair: Robert D. Timmerman, M.D., 214-645-7637, Robert.Timmerman@UTSouthwestern.edu

RTOG 0236 has been revised as follows:

Title page: Dr. Timmerman’s contact information was updated, and the 800 number for RTOG Headquarters was added.

Section 5.0: A note was added stating that institutions will receive 2 case accrual credits for each patient enrolled on the study.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Revision 1, Version Date: August 6, 2004

RTOG 0236, “A 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”

Study Chair: Robert D. Timmerman, M.D., 317-274-1190, rtimmerman@iupui.edu

RTOG 0236 has been revised as follows:

Title page: The RTOG Headquarters 800 number was deleted, as this number is no longer current. The number also was deleted in Section 6.10.

The following changes were made in Section 11.1:

- In the “Follow Up” column in the table, footnote “b” was deleted for the chest x-ray and the PFTs;
- The text of footnotes “b”, “c”, and “e” was revised for clarity.

Section 12.1.3: The timeframe for the Follow-up CT Scans was revised for clarity.

Section 12.2: The address for RTOG Headquarters was updated.

Section 13.2: The fourth sentence was revised to correct a calculation error in the number of events required.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org