RTOG 0229, "A Phase II Trial Of Neoadjuvant Therapy With Concurrent Chemotherapy And High Dose Radiotherapy Followed By Surgical Resection And Consolidative Therapy For Locally Advanced Non-Small Cell Lung Carcinoma"

Study Chair: Mohan Suntharalingam, M.D., 410-328-6080, msunthar@umm.edu

RTOG 0229 has been amended as follows:

As mandated by CTEP, Sections 6.14, 7.6, and 8.4.1 have been amended to require the use of CTCAE, version 4 for grading of all adverse events as of July 1, 2011.

Note: References to CTCAE, v. 3.0 remain in the protocol. These are appropriate, as treatment decisions for patients enrolled on this study were based on that version.

Other Changes
Section 7.6.6: This section was amended as required by CTEP to instruct sites to report AML or MDS via AdEERS.
SUMMARY OF CHANGES
Update Date: June 14, 2007

RTOG 0229, A Phase II Trial of Neoadjuvant Therapy With Concurrent Chemotherapy And High Dose Radiotherapy Followed By Surgical Resection And Consolidative Therapy For Locally Advanced Non-Small Cell Lung Carcinoma

Study Chair: Mohan Suntharalingam, M.D., 410-328-6080, msunthar@umm.edu

Dr. Krasna's contact information was updated on the title page, in Section 5.1, and in Appendix V.

NOTE: This is an editorial/administrative change to the protocol. NCI now requires that these changes be documented on the protocol title page with the date of the update noted as "Update Date," not as a revision.
RTOG 0229, ""A Phase II Trial Of Neoadjuvant Therapy With Concurrent Chemotherapy And High Dose Radiotherapy Followed By Surgical Resection And Consolidative Therapy For Locally Advanced Non-Small Cell Lung Carcinoma".

Study Chair: Mohan Suntharalingam, M.D., 410-328-6080, msunthar@umm.edu

RTOG 0229 has been amended as follows:

Section 8.3.1: The procedure defining the parameters of mediastinal reassessment/evaluation was added for clarity.

Section 8.5.3: "Deviations Major" has replaced "Deviations Unacceptable" for consistency with the RTOG protocol template; and under the same heading "Inadequate nodal sampling" was deleted. For clarity, a note was added to define the "Determination of Evaluable Cases."

An amended protocol is available (no password required) on the RTOG Web site, www.rtog.org
RTOG 0229, "A Phase II Trial Of Neoadjuvant Therapy With Concurrent Chemotherapy And High Dose Radiotherapy Followed By Surgical Resection And Consolidative Therapy For Locally Advanced Non-Small Cell Lung Carcinoma".

Study Chair: Mohan Suntharalingam, M.D., 410-328-6080, msunthar@umm.edu

RTOG 0229 has been amended as follows:

Section 3.2.4: The section was amended to clarify that patients with unintentional weight loss > 5% within 6 months prior to study entry are not eligible for the study.

An amended protocol is available (no password required) on the RTOG Web site, www.rtog.org
SUMMARY OF CHANGES
Update Date: September 27, 2005

**RTOG 0229**, A Phase II Trial of Neoadjuvant Therapy With Concurrent Chemotherapy And High Dose Radiotherapy Followed By Surgical Resection And Consolidative Therapy For Locally Advanced Non-Small Cell Lung Carcinoma

**Study Chair**: Mohan Suntharalingam, M.D., (410)328-6080, msunthar@umm.edu

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**Appendix V** – Updated to clarify that Dr. Krasna will fax the questionnaire to RTOG Headquarters and the institution after he reviews the form, whether or not he gives his approval. A checkbox was added for questionnaires that are not approved. Also, boxes for filling in CTEP and RTOG institution numbers have been added to the top corners of the form.

NOTE: This is an editorial/administrative change to the protocol. NCI now requires that these changes be documented on the protocol title page with the date of the update noted as “Update Date,” not as a revision.

An updated protocol is available (no password required) on the RTOG website: [http://www.rtog.org/](http://www.rtog.org/)
RTOG 0229, ““A Phase II Trial Of Neoadjuvant Therapy With Concurrent Chemotherapy And High Dose Radiotherapy Followed By Surgical Resection And Consolidative Therapy For Locally Advanced Non-Small Cell Lung Carcinoma”.

Study Chair: Mohan Suntharalingam, M.D., 410-328-6080, msunthar@umm.edu

RTOG 0229 has been amended as follows:

Eligibility Checklist: Question 15 was amended to ask the following: Is baseline FEV1 at least 2 liters? If not, is the projected post-operative FEV1 greater than 800 cc?

Section 3.1.8 was amended to specify that a VQ scan is required for patients with baseline FEV1 less than 2 liters.

Section 3.1.11: A VQ scan, if applicable, within 8 weeks prior to study entry was added to the last item in the list of pretreatment evaluations.

Section 11.1: VQ scan and footnote l were added to the study parameters.
SUMMARY OF CHANGES
Update Date: June 23, 2005

RTOG 0229, A Phase II Trial of Neoadjuvant Therapy With Concurrent Chemotherapy
And High Dose Radiotherapy Followed By Surgical Resection And Consolidative
Therapy For Locally Advanced Non-Small Cell Lung Carcinoma

Study Chair: Mohan Suntharalingam, M.D., (410)328-6080, msuntha@umm.edu

Title Page – Corrected Dr. Suntharalingam’s e-mail address (msuntha@umm.edu) and
fax number (410-328-6911).

NOTE: This is an editorial/administrative change to the protocol. NCI now requires that
these changes be documented on the protocol title page with the date of the update noted
as “Update Date”, not as a revision.

An updated protocol is available (no password required) on the RTOG website:
http://www.rtog.org/
SUMMARY OF CHANGES
Amendment 1, Version Date: February 21, 2005

RTOG 0229, “A Phase II Trial Of Neoadjuvant Therapy With Concurrent Chemotherapy And High Dose Radiotherapy Followed By Surgical Resection And Consolidative Therapy For Locally Advanced Non-Small Cell Lung Carcinoma”.

Study Chair: Mohan Suntharalingam, M.D., 410-328-6080, msunthar@umm.edu

RTOG 0229 has been amended as follows:

Title page: The 800 number for RTOG Headquarters was added.

Appendix I: On the first page, “Appendix IA” was corrected to “Appendix I”. In the first paragraph under “What Is Involved In The Study?”, the phrase, “you will receive radiation therapy once a week”, was corrected to “you will receive radiation therapy once a day”.

Appendix V: A note about a requirement for participation in the study was added after Question 6. The box for Dr. Krasna’s approval was reformatted.

An amended protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Update Date: December 21, 2004

RTOG 0229, A Phase II Trial of Neoadjuvant Therapy With Concurrent Chemotherapy And High Dose Radiotherapy Followed By Surgical Resection And Consolidative Therapy For Locally Advanced Non-Small Cell Lung Carcinoma

Study Chair: Mohan Suntharalingam, M.D., (410)328-6080, msunthar@umm.edu

Section 5.1 – Updated to reflect that the credentialing form, Appendix V, must now be faxed directly to Dr. Krasna. Dr. Krasna will then fax his approval to RTOG and the institution. Corresponding changes were made to Appendix V.

NOTE: This is an editorial/administrative change to the protocol. NCI now requires that these changes be documented on the protocol title page with the date of the update noted as “Update Date”, not as a revision.

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org/
SUMMARY OF CHANGES
Update Date: November 17, 2004

RTOG 0229, A Phase II Trial of Neoadjuvant Therapy With Concurrent Chemotherapy And High Dose Radiotherapy Followed By Surgical Resection And Consolidative Therapy For Locally Advanced Non-Small Cell Lung Carcinoma

Study Chair: Mohan Suntharalingam, M.D., (410)328-6080, msunthar@umm.edu

Section 3.2.4 – For clarity, this section was updated to read “Unintentional weight loss > 5%, or Zubrod performance status 2 or greater.”

NOTE: This is an editorial/administrative change to the protocol. NCI now requires that these changes be documented on the protocol title page with the date of the update noted as “Update Date”, not as a revision.

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org/