RTOG 0213, A Phase I/II Trial Of A COX-2 Inhibitor, Celebrex™ (Celecoxib), With Limited Field Radiation For Intermediate Prognosis Patients With Locally Advanced Non-Small Cell Lung Cancer, With Analysis Of Prognostic Factors Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

As mandated by CTEP, RTOG 0213 has been amended to replace CTC version 2.0 with the CTEP Active Version of CTCAE. Changes were made to the following sections:

- Section 7.2.2, footnote below the table
- Section 7.3
- Appendix V: Sections "B", "D" and "E"
SUMMARY OF CHANGES

Update, February 11, 2005

RTOG 0213, “A Phase I/II Trial Of A COX-2 Inhibitor, Celebrex™ (Celecoxib) With Limited Field Radiation For Intermediate Prognosis Patients With Locally Advanced Non-Small Cell Lung Cancer, With Analysis Of Prognostic Factors”

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

RTOG 0213 has been updated as follows:

Title Page: Corrected Benjamin Movsas, M.D.’s contact information.

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”.

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

Amendment 4, Version Date: January 11, 2005

RTOG 0213, A Phase I/II Trial Of A COX-2 Inhibitor, Celebrex™ (Celecoxib), With Limited Field Radiation For Intermediate Prognosis Patients With Locally Advanced Non-Small Cell Lung Cancer, With Analysis Of Prognostic Factors

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

RTOG 0213 has been amended as follows:

NCI requires that the risks associated with celecoxib (Celebrex™) be amended to “include the results of the cardiovascular risk analysis and to inform patients in lay terms of the results”.

In Appendix I, NCI’s suggested language has been added to the risks associated with celecoxib as a paragraph under the bulleted list of “Less Likely, But Serious” risks.

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

Revision 3, Version Date: May 21, 2004

RTOG 0213, A Phase I/II Trial Of A COX-2 Inhibitor, Celebrex™ (Celecoxib), With Limited Field Radiation For Intermediate Prognosis Patients With Locally Advanced Non-Small Cell Lung Cancer, With Analysis Of Prognostic Factors

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

RTOG 0213 was revised to allow physicians to treat patients at 3 Gy per fraction to 45 Gy or 2 Gy per fraction to 60-66 Gy.

The following sections were revised for this change: The Schema, Sections 6.1.1, 6.1.8, 6.1.10, and Appendix I (“What Is Involved In The Study?” and “How Long Will I Be In The Study?”).

The following additions were made for this change: Four paragraphs and a table were added to Section 1.2, and references for these additions were added as citations 68-76. The first paragraph was added to Section 13.4.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Update, May 14, 2004

RTOG 0213, “A Phase I/II Trial Of A COX-2 Inhibitor, Celebrex™ (Celecoxib) With Limited Field Radiation For Intermediate Prognosis Patients With Locally Advanced Non-Small Cell Lung Cancer, With Analysis Of Prognostic Factors”

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu>

RTOG 0213 has been updated as follows:

Section 7.1.8 — Updated Pfizer’s contact information.

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”.

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

Update, April 21, 2004

RTOG 0213, “A Phase I/II Trial Of A COX-2 Inhibitor, Celebrex™ (Celecoxib) With Limited Field Radiation For Intermediate Prognosis Patients With Locally Advanced Non-Small Cell Lung Cancer, With Analysis Of Prognostic Factors”

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

RTOG 0213 has been updated as follows:

Section 7.1.8 – Deleted sentence pertaining to Appendix VIA (Celebrex™ Drug Order Request Form) to make this section consistent with the previous update of April 13, 2004.

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”.

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

Update, April 13, 2004

RTOG 0213, “A Phase I/II Trial Of A COX-2 Inhibitor, Celebrex™ (Celecoxib) With Limited Field Radiation For Intermediate Prognosis Patients With Locally Advanced Non-Small Cell Lung Cancer, With Analysis Of Prognostic Factors”

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

RTOG 0213 has been updated as follows:

Index Page — Made “Appendix VI - Study Agent Shipment Forms” singular as Appendix VIA was deleted.

Sections 5.1, 7.1.8, and Appendix VI clarify that Appendix VI is used for initial drug shipment only.

Deleted Appendix VIA — Appendix deleted as this form was used for drug re-supply only, and now the drug re-supply form is located on the RTOG website at: http://www.rtog.org/pdf_reports.html?members/reports=0213Pfizer_Clinical_Re-supply_Request_Form_sites.doc.

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”.

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

Update, March 15, 2004

RTOG 0213, “A Phase I/II Trial Of A Cox-2 Inhibitor, Celebrex™ (Celecoxib) With Limited Field Radiation For Intermediate Prognosis Patients With Locally Advanced Non-Small Cell Lung Cancer, With Analysis Of Prognostic Factors”

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

The manufacturer of Celebrex™ is now Pfizer (versus Pharmacia). RTOG 0213 has been updated to reflect this change as follows:

Sections 7.1.7, 7.1.8, 7.1.9, 7.4, 7.4.2.1, 7.4.2.2, and Appendix VII — Changed “Pharmacia” to “Pfizer” to reflect the new company name;

Section 7.1.8 – Provided Pfizer contact information;

Appendix VIA – Provided the Re-supply Request form provided by Pfizer.

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”.

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

Revision 2, Version Date: August 26, 2003

RTOG 0213, A Phase I/II Trial Of A COX-2 Inhibitor, Celebrex™ (Celecoxib), With Limited Field Radiation For Intermediate Prognosis Patients With Locally Advanced Non-Small Cell Lung Cancer, With Analysis Of Prognostic Factors

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

IRB Review Requirements:
( ) Full board review required
( ) Expedited review allowed, but site IRB requirements take precedence.
( ) No review required

RTOG 0213 has been revised as follows:

Title Page — The NSC number, “[NSC# 719627]”, was deleted from the protocol title as celecoxib is not supplied by the NCI for this study; the title also was corrected on the Schema Page, and in Appendices IA & VIA, and the number was deleted from Section 7.1.

Eligibility Checklist — Question 5, page 2 was updated to RTOG standard.

Section 2.1 was revised to specify that celecoxib will be administered for “two years”.

Section 5.1 was revised to specify that sites in the U.S. will submit the Study Agent Shipment Form to the CTSU Regulatory Office versus RTOG Headquarters; this change also was made in Section 7.1.8 and Appendix VI.

Section 10.3.1 — The e-mail address for LDS Hospital was updated.

Section 10.4 was updated to RTOG standard, which includes the current reimbursement for submission of serum.

Section 12.0 — The address and text for data submission were updated to RTOG standard.

Section 12.1 — The schedule for submission of the Treatment Summary Form was revised.

Appendix IA — The following changes were made to the sample consent:
Under “What About Confidentiality”, Health Canada has been listed as an organization that may inspect and/or copy research records. This applies to Canadian participants only;

Under “What Are My Rights As A Participant”, the last paragraph was corrected;

Under “Signature”, the lines for signatures were updated to RTOG standard; this change also was made to the signature section of Appendix IB.

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

Revision 1, Version Date: October 3, 2002

RTOG 0213, A PHASE I/II TRIAL OF A COX-2 INHIBITOR, CELEBREX™ (CELECOXIB), [NSC# 719627] WITH LIMITED FIELD RADIATION FOR INTERMEDIATE PROGNOSIS PATIENTS WITH LOCALLY ADVANCED NON-SMALL CELL LUNG CANCER, WITH ANALYSIS OF PROGNOSTIC FACTORS

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

IRB Review Requirements:
( ) Full board review required
(X) Expedited review allowed
( ) No review required

RTOG 0213 has been revised as follows:

Section 2.0 — Sections 2.3 and 2.4 have been revised to correctly correspond to the study endpoints in Sections 13.1.2.3 and 13.1.2.4.

Section 3.1.4 was revised to include patients who refuse chemotherapy. It was originally intended that these patients be eligible for this study, and this is a correction to the eligibility criteria. This change also was made to the Eligibility list on the Schema page and to the Eligibility Checklist, page 1, question 4.

Section 11.1 — The superscript “f” was added to “Blood samples for angiogenesis factor and cytokine analysis” at the timepoint, “Weekly During RT” to correspond to footnote “f”.

Section 13.2.1.1 — The parenthetical phrase, “excluding nausea, vomiting, and alopecia”, was added to further define grade 3 or 4 nonhematologic dose limiting toxicities.

Appendix IA — After discussion with the medical director of Pharmacia, manufacturer of Celebrex™, the study chairs determined that “Decrease in blood tests that measure how well your heart is working” should be deleted from “Risks Associated With Celebrex™”. This risk is not a side effect of Celebrex™, and is not included in Section 7.1.4 of the protocol.
A revised protocol is available (no password required) on the RTOG website: http://www.rtog.org/
SUMMARY OF CHANGES

Update, August 16, 2002

RTOG 0213, A PHASE I/II TRIAL OF A COX-2 INHIBITOR, CELEBREX™ (CELECOXIB), [NSC# 719627] WITH LIMITED FIELD RADIATION FOR INTERMEDIATE PROGNOSIS PATIENTS WITH LOCALLY ADVANCED NON-SMALL CELL LUNG CANCER, WITH ANALYSIS OF PROGNOSTIC FACTORS

Study Chair: Elizabeth Gore, M.D., (414) 805-4465, FAX (414) 805-4369, bethgore@mcw.edu

IRB Review Requirements:
(   ) Full board review required
(   ) Expedited review allowed
(X) No review required

RTOG 0213 has been updated as follows:

The Celebrex™ Drug Order Request Form has been appended to the protocol as Appendix VIA. This form is not provided in the forms packet for this protocol. The following sections have been updated for this change: Section 7.1.8: The parenthetical reference to the appendices for the Celebrex™ Shipment Forms for U.S. Sites has been corrected to “Appendix VI, VIA”, the parenthetical reference “in the forms packet” has been deleted, and the Celebrex™ Drug Order Request Form is now correctly referenced as “Appendix VIA”; Appendix VIA has been added.

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 “Updated Edition”, not as a revision. IRB review is not required; however, this change must be reported to site IRBs.

An updated protocol (PDF version) can be accessed on the RTOG website, www.rtog.org