SUMMARY OF CHANGES
Update: April 20, 2012
(Broadcast: April 20, 2012)

RTOG 0622, A Phase II Trial of Samarium 153 Followed by Salvage Prostatic Fossa 3D-CRT or IMRT Irradiation in High-Risk, Clinically Non-Metastatic Prostate Cancer After Radical Prostatectomy

Study Chair Richard K. Valicenti, MD, MA; 916-734-7888; richard.valicenti@ucdmc.ucdavis.edu

---

RTOG 0622 has been updated as follows:

Title Page: Contact information for Dr. Prisciandaro was removed. Dr. Prisciandaro is no longer medical physicist co-chair for this study.

Section 5.3: Updated web link for Password Authorization Form.

Section 10.2.2 and Appendix VI (Biospecimen Collection): The street address for the RTOG Biospecimen Resource was updated.

Appendix I (Sample Consent): Under "Where can I get more information", the NCI's TTY number is no longer in service and was deleted.

SUMMARY OF CHANGES
Amendment 4: March 9, 2011
(Broadcast: March 29, 2011)

RTOG 0622, A Phase II Trial of Samarium 153 Followed by Salvage Prostatic Fossa 3DCRT or IMRT Irradiation in High-Risk, Clinically Non-Metastatic Prostate Cancer After Radical Prostatectomy

Study Chair: Richard K. Valicenti, MD, MA; (916) 734-7888; richard.valicenti@ucdmc.ucdavis.edu

---

RTOG 0622 has been amended as follows:

Global: All web links and related descriptions to sub-pages of the RTOG web site were updated.

Title Page: Dr. Hunt's e-mail address was updated; protocol document history table added.

Section 1.1.1: *Buffy coat* was replaced with *whole blood* in the subsection title and in the paragraph, per RTOG Biospecimen Resource new collection procedures.

Section 3.1.1: The first bulleted item was revised from *Postoperative PSA rising above 2.0 ng/ml* to *Postoperative PSA rising above 1.0 ng/ml*. Also, a third bulleted item was added: *Postoperative PSA rising above 0.2 ng/ml with nodal disease*. Corresponding changes were made to the following sections:

- **Schema page**, Patient Population
- **Eligibility Checklist**, page 1, question 1

Section 5.0

- **5.2.1.1:** This subsection regarding translation of regulatory documents was added, per RTOG standard.
- **5.3:** The RTOG web support e-mail address in the next to last paragraph was updated.

Sections 9.1.3.4 and 9.1.4.4: References to administration of flutamide and bicalutamide *prior to or during radiotherapy* were removed; hormone therapy in this trial is for patients with rising PSA after completion of prostatic fossa RT only.

Section 10.0

- **10.2.1.1 and 10.2.1.4:** First sentence, *at least one* added before *paraffin-embedded tissue block*; *skin punch* replaced with *punch tool*. The last sentence beginning, *"As this is a post-surgical study…"* added to 10.2.1.1. In the specimens collected when column of the table, "pre-treatment biopsy" replaced with "prostatectomy surgical specimens".
- **10.2.1.2 and 10.2.1.4:** Updated per new RTOG Biospecimen Resource procedures: Whole blood will be collected instead of buffy coat. Time point of study added as information to be included on the Specimen Transmittal Form. *Buffy coat* replaced with *whole blood* in the last sentence of **Section 10.1**.
- **10.2.1.3:** *"Frozen specimens"* was added to the first sentence, for clarity. The biospecimen shipping days for Canadian sites (Monday-Tuesday) were added.
- **10.3:** The RTOG reimbursement text was updated. The updated text includes a web address for the Reimbursement and Case Credit Schedule located on the RTOG web site.

Section 13.4.1: Third sentence, *20%* replaced with *25%*.

Appendix I (Sample Consent):

- Under, *About Using Tissue for Research*, in the last two sentences of the second paragraph, the title of the information sheet was updated and the NCI web site address was updated to the current web link.
- Under *Making Your Choice*, questions 1 and 3 and their response choices were updated according to the current RTOG format.

Appendix II (Study Parameter Table): The first two rows (*Path/Histo* and *Prostatectomy*) and the note denoted by an asterisk (*) in the second row were deleted from the table.

Appendix VI (Biospecimen Collection): Updated per the RTOG Biospecimen Resource current procedures. The protocol **Index page** was revised accordingly.

SUMMARY OF CHANGES
Amendment 3: March 8, 2011
(Broadcast: March 29, 2011)

RTOG 0622, A Phase II Trial of Samarium 153 Followed by Salvage Prostatic Fossa 3DCRT or IMRT Irradiation in High-Risk, Clinically Non-Metastatic Prostate Cancer After Radical Prostatectomy

Study Chair: Richard K. Valicenti, MD, MA; (916) 734-7888;
richard.valicenti@ucdmc.ucdavis.edu

RTOG 0622 has been amended as follows:

As mandated by NCI-CTEP, **Section 7.12** (first paragraph) has been amended to require the use of CTCAE, version 4, for grading of all adverse events reported via AdEERS as of April 1, 2011.

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

Other Changes
Section 7.12: The RTOG web address in the third paragraph was updated; the fifth paragraph regarding 24-hour telephone notification to CTEP was added.

Section 7.12.3: Amended as required per current NCI-CTEP reporting requirements for acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) via AdEERS.

SUMMARY OF CHANGES
Amendment 2: April 9, 2010
(Broadcast: April 22, 2010)

RTOG 0622, A Phase II Trial of Samarium 153 Followed by Salvage Prostatic Fossa 3DCRT or IMRT Irradiation in High-Risk, Clinically Non-Metastatic Prostate Cancer After Radical Prostatectomy

Study Chair Richard K. Valicenti, MD, MA; (916) 734-7888;
richard.valicenti@ucdmc.ucdavis.edu

RTOG 0622 has been amended as follows:

The following criterion was added to **Section 11.8** (Criteria for Discontinuation of Protocol Treatment): "Progression of disease as defined as two consecutive rises in PSA more than 30% above baseline obtained prior to the administration of Samarium-153".

Section 12.2: Updated per RTOG standard; updated ITC e-mail address in 12.2.1.

SUMMARY OF CHANGES
Amendment #1: September 29, 2009
(Broadcast October 8, 2009)

RTOG 0622, A Phase II Trial of Samarium 153 Followed by Salvage Prostatic Fossa 3DCRT Or IMRT Irradiation in High-Risk, Clinically Non-Metastatic Prostate Cancer After Radical Prostatectomy

Study Chair Richard K. Valicenti, MD, MA; (916) 734-7888;
richard.valicenti@ucdmc.ucdavis.edu

RTOG 0622 has been amended as follows:

The PSA Doubling Time (PSADT) criterion was deleted from the eligibility criteria. The following sections of the protocol were revised as a result:

- Schema page, "Patient Population"
- Eligibility Checklist, page 1, question 1
- Section 1.0 (Introduction)
- Sections 3.1.1 and 3.1.2 (Eligibility)

Title page: The contact information for the Principal Investigator, Dr. Valicenti, has been updated. Dr. Hunt is now the Senior Statistician for the study.

Section 5.1: The pre-registration requirements for 3D-CRT and IMRT were updated per RTOG standard.

Section 5.3: The RTOG web support address in the next to last paragraph was updated.

Section 6.5.1: The "scoring" categories were revised to correspond with the Compliance Criteria table in Section 6.8.

Section 7.12.1: The web address for the NCI Adverse Event Reporting Requirements document was updated.

Section 7.12.4: In the first sentence, "routine" was revised to "expedited".

Section 10.0

- The "Note" was added at the beginning of the section to emphasize to participating sites that patients must be offered the opportunity to participate in the specimen submission component of the study.
- **10.2.1.3**: This section was added to provide additional information to participating sites regarding the storage of specimens.
- **10.4**: The web address for the RTOG Patient Tissue Consent Frequently Asked Questions sheet was updated.

Section 11.2.1: The weekly testosterone assessment during radiotherapy was deleted. Corresponding changes also were made to **Appendix I** (first bulleted item under "During the study") and **Appendix II** ("Weekly" column under "During Samarium & RT Treatment").

Section 11.3.2: "Either" was deleted between "by" and "CT scan".

Section 12.2: The web address for the Digital Data Submission Form was updated.

Appendix II: Changes were made as described above for Section 11.2.1; also, the biopsy for patients with evidence of biochemical failure or growth of a palpable abnormality was deleted from the assessments.

Appendix III: REFERENCES to the Karnofsky scale were deleted per RTOG standard for studies using the Zubrod scale.

Appendices VI, VII, and VIII: Were updated per RTOG Biospecimen Resource standards for specimen collection and shipping.

SUMMARY OF CHANGES
Update: April 3, 2008

RTOG 0622, A Phase II Trial of Samarium 153 Followed by Salvage Prostatic Fossa 3D-CRT or IMRT Irradiation in High-Risk, Clinically Non-Metastatic Prostate Cancer After Radical Prostatectomy

Study Chair Richard K. Valicenti, MD, MA; (215) 955-5936;
richard.valicenti@mail.tju.edu

RTOG 0622 has been updated as follows:

Title page: Study chair contact information format was made consistent with RTOG standard.

Section 5.2.2: Note regarding preregistration study agent requirements for international sites was added to meet RTOG standard.

Section 7.4: Note regarding preregistration study agent requirements for international sites was added to meet RTOG standard.

Appendix II: Footnote was removed as no longer RTOG standard; adverse event reporting is already covered in Sections 11.2-3.

Note: These are editorial/administrative changes to the protocol. NCI requires that these changes be documented on the protocol title page as "Update Date."