EORTC
European Organisation for Research and Treatment of Cancer
AISBL International Non-Profit Association under Belgian law IVZW

EORTC Data Center
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +32 2 774 16 11
Fax : +32 2 772 35 45
E-mail : eortc@eortc.be
Web : http://www.eortc.be

QART start up letter for study 22042 - 26042

Brussels, March 20, 2007

Dear Study Investigator,

We thank you for your interest in this phase II and observation study on adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma led by the EORTC Radiation Oncology and Brain Tumor groups.

This trial has specific requirements to assess and ensure the quality of radiotherapy (RT) delivered to every patient. The quality assurance (QA) for RT in this study will be done for every patient case jointly with the Advanced Technology Consortium (ATC), through their Image-Guided Therapy QA Center (ITC), which is located in the USA. Because of this extended QA program, you will be asked to sign a form (see appendix 1) to clearly state that you are able and willing to comply with this amount of QA in RT.

The following steps are **mandatory** for your participation in this trial:

1. The **EORTC FACILITY QUESTIONNAIRE** aiming to assess the techniques and infrastructure of each institute has to be completed. Please submit it online as soon as possible at http://www.eortc.be/facilityquest, **if you have not done so**. This questionnaire is not specific for the 22042-26042 study, but is mandatory.

2. A **DRY RUN** is compulsory for the 22042-26042 study. There is no requirement that the patient whose data are used for the submission test be treated according to EORTC 22042-26042. This test set can be from a data set for a patient who was previously seen and/or treated (in some other way). The only requirement is that the CT scan, tumor/target volumes and critical normal structure contours be made compliant with 22042-26042 and that protocol compliant treatment plans be generated and the appropriate data submitted to the ITC. The immobilization device requirement is waived for this test data set. All patient identifying data for the test data must be removed before submission. **The case number for this test patient on the DDSI form (see below) is CR (credential run)**.

3. When the Dry Run was successfully carried out, you can go on with the submission of your first case for this protocol. This will be a **RAPID REVIEW** of the treatment plan

of the first patient that an institution registers. The rapid review of this first patient case will not hold patient treatment as it must be completed within the first 5 days after data have been received by EORTC-ATC.

4. The **INDIVIDUAL CASES REVIEW** will check the data for all patient(s) entered in the trial. These patient cases will have to be submitted to ATC once per year.

Instructions and data required for the submission of digital treatment planning information on this protocol are provided below.

DIGITAL DATA SUBMISSION PROCEDURES

SUBMITTING DIGITAL DATA VIA THE INTERNET

First of all, you have to obtain an institutional SFTP Account. Contact the ITC (itc@castor.wustl.edu) and request an SFTP account for digital data submission. Include your name, institution's name and your full contact address. Please obtain your SFTP account on time. **Allow 3 business days to process your account request**.

An online Digital Data Submission Information (DDSI) Form (see http://atc.wustl.edu/forms/DDSI/ddsi-eortc.html) for ATC-supported EORTC protocols is available and must be filled in for each individual patient data submission. Access to the DDSI form requires a username ("EORTC-forms") and password (data4itc"). This form has to contain the patient SeqID and is to accompany all digital data submissions to the ITC, whether for protocol case data or for credentialing (data submission capability test) data submissions. SeqID will be given by the EORTC Data Center at the time of patient registration.

Digital patient treatment planning data in DICOM RT (or RTOG Data Exchange) format must be submitted to ITC using Secure FTP (SFTP) instead of "normal" FTP to the **ITCsubmit.wustl.edu** server. There is an instructional page for SFTP uploads on the ATC web site (http://atc.wustl.edu/home/news/SFTP.html) which includes instructions for configuring several SFTP client programs. Please note that your firewall must allow outgoing connections on port 22 (SSH2) in order to connect to the SFTP server (ITCsubmit.wustl.edu, IP address 128.252.17.87). If this is not the case, you may have to ask for an institutional authorization to your local firewall administrator.

Please use the following steps to submit data via FTP:

1. Connect via SFTP client program to the ITCsubmit.wustl.edu server (IP address 128.252.17.87) and login with the provided username and password.
2. Change to the "incoming" directory. ("cd incoming")
3. Create a new sub-directory within "incoming" with a name that is pertinent to the data that you are submitting ("mkdir Case01423totalplan"). **Please do not use spaces or punctuation marks other than "-", "_" and "." in naming files and directories. Also, as the local investigator, you have the responsibility to ensure that all patient data are anonymized on the institutional level prior to submission!**
4. Submit DDSI form online at http://atc.wustl.edu/forms/DDSI/ddsi-eortc.html.
5. Send an e-mail to itc@castor.wustl.edu to indicate that you have uploaded data. Please identify the study group (EORTC), protocol (22042), and case number (SeqID) for the submission as well as your contact information.
6. In order for ATC to confirm that your data have been received and imported correctly, please send CT images showing structure contours and color isodose curves in three orthogonal planes along with total dose DVHs. DVHs may be screen dumps sent via e-mail as JPEG files to the address itc@castor.wustl.edu.

REQUIRED PROTOCOL DIGITAL DATA

Digital data submitted to ITC must include the following in accordance with the appropriate protocol requirements:

1. **Protocol compliant planning images** (e.g. a maximum CT slice thickness of 3 mm for a good quality of DRR and margin definition); see also EORTC 22042-26042, 5.1.3. Treatment planning;
2. **Protocol compliant structure contours** for GTV, CTV and PTVs, and all critical normal structures. They must be contoured on all slices in which each structure exists and include skin on ALL CT cuts; see also EORTC 22042-26042, 5.1.3. Definition of target volumes;
3. **Treatment plan specification** (DICOM RT Plan file or RTOG Data Exchange Beam Geometry files) **for each fraction group** (concurrently treated set of beams). Note that plans involving boost fields may consist of multiple fraction groups.
4. **3D dose distribution** (absolute) **for each fraction group** (concurrently treated set of beams) delivering a protocol compliant dose. Dose is to be calculated with heterogeneity corrections and submitted separately for each fraction group (EORTC 22042-26042, 5.1.8 Dose calculation and reporting). Of note, the calculation grid size (voxel size) of the 3D dose distributions and the DVHs should be the same (2-5 mm^3); dose prescription has to be provided (i.e Simpson 1-3 60 Gy; Simpson 4-5, 70 Gy);
5. **Color isodose images** (3 planes) in absolute dose for each phase of treatment (concurrently treated beams) and for the total treatment;
6. **DVHs for the total dose plan** in absolute dose for the GTV, CTV and PTV and for the following organs at risk (see protocol section 5.1.3): brain stem, optic chiasm, both optic nerves, pituitary gland, both eyes and both inner ears (cochleae), whenever appropriate depending on the location of the primary tumor; It is imperative that there be reasonable agreement between the OAR-DVH computations from each participating institution and those of the ITC. Therefore, any discrepancy (between submitting institution and the ITC) in excess of +5% in total volume or +5% (relative to the absolute structure volume) of the volume calculated to be at or above the appropriate TD 5/5 dose will need to be resolved prior to successfully completing the Dry Run Test. DVH's for the total dose for item 4 (summed fraction groups from item 4) for PTV and all critical normal structures (EORTC 22042-26042, 5.1.7 Normal tissue sparing & 5.1.8 Dose reporting). Of note, the calculation grid size of the 3D dose distributions and the voxel size of DVHs should be the same (2-5 mm^3). These DVH's should be sent by email (**to itc@castor.wustl.edu**) in a **JPEG** screen captures.

DIGITAL DATA FORMAT

For digital data submission, an institution's treatment planning system must have the capability of exporting data in one of two formats:

- DICOM 3.0 in compliance with the ATC's DICOM 3.0 Conformance Statement
- RTOG Data Exchange Format, Version 3.20 or later (specifications at http://itc.wustl.edu/exchange_files/tapeexch400.htm); or

All commercial systems that are known to have this capability are listed on the ATC web site (see http://atc.wustl.edu/credentialing/atc_compliant_tps.html).

NOTE:

1. **Please email to itc@castor.wustl.edu** alerting the ITC staff that your data have been submitted
2. Any corrections to previously submitted digital data should be discussed with the ITC prior to such submission.
3. A reasonable number of isodose lines which can be used to determine that the digital dose and anatomy data are properly aligned relative to each other. The prescription dose for the high-dose PTV should be displayed. If the hard copy isodose lines are in percentage, the conversion factor to absolute dose (Gy or cGy) for all delivered fractions must be indicated.
4. No credentialing plan (dry run) will be approved that results in a Major Variation. Plans with No Variation or Minor Variations will be approved (assuming no other significant areas of protocol non-compliance).

Summary (submitting patient data to ITC)

What?	Where?
1. Patient registration	At the Data center by phone or online as usual
2. SeqID allocation	At the end of the registration process
3. Fill the online DDSI form	See: http://atc.wustl.edu/forms/DDSI/ddsi.html
4. Send CT study, target volumes & OARs, Color 3D Dose distributions	As a SFTP, see: (http://atc.wustl.edu/home/news/SFTP.html)
5. DVHs	Email to itc@castor.wustl.edu

If you have any question, please do not hesitate to contact damien.weber@hcuge.ch or pascal.ruyskaert@eortc.be (IT support) or edwin@mvhphysics.netkonect.co.uk.

Sincerely yours,

On behalf of the QA-ROG Committee,

Damien WEBER
Study Coordinator

Elena MUSAT
EORTC ROG Coordinating Physician

Tom BUDIHARTO
E. van der Schueren QA Fellow

Appendix 1

QART Compliance Statement Form

EORTC *Study: 22042 - 26042*
Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma: a Phase II and observation study
Version 1.0, February 2007

I, the undersigned declare that I will comply with the requested QA in RT for this study. I have read the QA start up letter and I am aware of the extended QA in RT that is requested in this study. I am also aware of the fact that patient data must be anonymized prior to their submission to ITC (USA) in order to be compiled for analysis.
I will conduct the QA in RT in this protocol and any subsequent amendments.

Please tick all applicable boxes:

I have the necessary tools in my TPS to export Structure and Plan data to the ITC SFTP server. ▶

I have the necessary tools in my TPS to provide anonymous (deletion of the patient's name) patient data to the ITC SFTP server. ▶

If my institution does not have the anonymization tools, I am willing to install software developed for this purpose (provided for free). ▶

NAME Principal Investigator: .....

EORTC Institution number: .....

Signature Date: .....

Please complete and return this form, **as soon as possible**, to Marianne Pierart at the EORTC Data Center: fax number **+32 2 7713810** no later than **April 15Th, 2007.**