

Credentialing for study 22042 - 26042

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 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.

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**.