

TRIAL PARTICIPATION REQUEST NOTES

This notes describe the procedures for joining IRMA trial and for center accreditation.

The clinical IRMA study is promoted by a group of radiation oncology facilities of Emilia-Romagna and Marche regions, but facilities outside of these areas are welcome to participate.

Participation of each centre is subordinated to:

- a) availability of appropriate technical equipment;
- b) adequate clinical cases number;
- c) verification with dummy-run of the respect of main therapeutical procedures, according to the guidelines stated in the clinical trial and referring only to the experimental arm (see protocol attachment # 1).

Interested in centres can apply for joining study participation by completely drawing up the participation form after downloading it from site www.irmatrial.it, mailing drawn up form to fax # +390594223235 for the attention of dott. Roberto D'Amico. In participation form every centre must declare if it will include both N0 and N1, or only N0 patients; moreover, it must be clearly stated if the centre intends to deliver the boost treatment in usual treatment arm (every form-stated issue must be followed by the centre after final assenting).

Applying centre will receive a *password* for accessing site area relevant to recruitment procedure.

Material requested for dummy-run participation will be available in website area, namely:

- a) Clinical case description dummy;
- b) DICOM images for treatment planning (CD available on request);
- c) Data collection form dummy;
- d) List of records to be sent for quality control.

QA group – Accredited Evaluation and Quality Assurance Group: (Coordinator: Filippo Bertoni – Radiotherapy Oncology Modena)

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- Paola Chiovati – Health Physics - Bellaria Hospital (BO)
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