

EORTC RADIATION ONCOLOGY GROUP (ROG)

STATUTES

December 2006

1. Aims of the Group

The aims of the Radiation Oncology Group (ROG) are to conduct, develop, coordinate and stimulate research on a clinical basis in radiation therapy in cancer patients. To fulfil this aim, the Radiation Oncology Group will conduct mainly prospective clinical trials.

2. Membership of the ROG

An institution becomes EORTC affiliated as soon as it enters patients in studies of at least 3 EORTC Cooperative Groups up to a total of at least 75 patients over 3 years. Members of the EORTC ROG are institutions (mainly radiation oncology departments). The ROG recognizes individual membership of several physicians, physicists or technologists from a single institution/department. The EORTC recognizes these as associate EORTC members.

All applications for membership are handled by the EORTC, which passes specific applications for membership of the ROG to the ROG Membership Committee who reviews and approves the application.

2a **Probationary members:**

Any institution active in the field of clinical and experimental oncology, which agrees to comply with the rules, can apply for membership of the ROG. Applicants will be given probationary membership status on joining the group, for a period of 2 years, during which 10 evaluable patients must be entered in ROG studies.

Probationary members agree to participate in the quality assurance activities of the group and to send a representative to attend regularly the twice-yearly group meetings.

2b **Active members:**

Institutions become active after completion of 2 years as probationary members having entered the required number of patients. To remain an active member, institutions are expected to contribute at least 15 patients over a 3 year period in ROG trials. A representative should attend regularly the twice-yearly group meetings. Active member institutions have the right to vote in the election of the Chairperson and Secretary of the group.

2c **Active-consultant members:**

Individuals (physicists, biologists, pathologists...) who are active in the support of the work of the group. The EORTC will give these persons active status,

although it is understood that they are not entering patients in clinical studies. They have the right to vote in the election of group officers. Their membership status will be reviewed on an annual basis.

2d Observers:

Observers are potentially interested institutions or laboratories which may participate in the open group meetings. This status will be reviewed annually by the Officers, namely the Chairperson, the Secretary and the Treasurer. Observers will receive an invitation to the meetings but will only receive a copy of the minutes of the meeting upon request.

2e Honorary members:

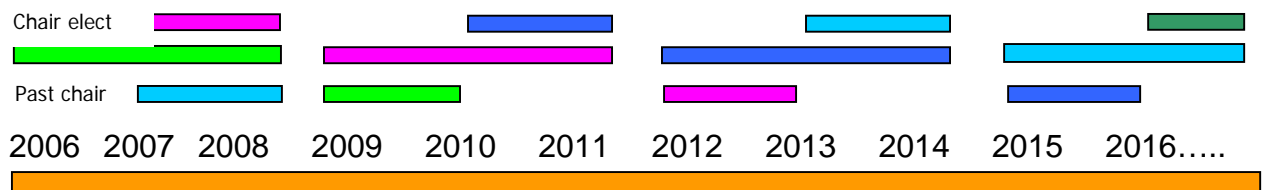
A representative of a member institution can receive the title of honorary member for exceptional services rendered to the group.

3. Officers of the group

Chairperson: is **elected** by the active members of the group for a term of 3 years. However, under exceptional circumstances, he/she may be re-elected once for a second three-year term (on approval by the EORTC Board).

A new Chair will be elected 18 months before the end of the term of office of the sitting Chair. The Chair-elect will work alongside the sitting Chair until the end of the sitting Chair's term of office and will be a member of the Executive. At the end of the sitting Chair's term of office, the Chair-elect takes the chair and the sitting Chair becomes the Past Chair, also with a place in the Executive.

Elections for Chair-elect take place 18 months prior to the year of election of a new EORTC Board which will be renewed in the years 2009, 2012, 2015 etc. Therefore the election of the ROG Chair-elect will take place in 2007, during the month of June. (and further in 2010, 2013, 2016..)



Secretary: is **elected** by the active members of the group for a term of 3 years. He/she may be re-elected once for a second three-year term. The Secretary is responsible for the coordination of the organisation of the twice-yearly meetings by the local organizer and the distribution of the minutes to the membership. The Secretary is also responsible for seeing that tasks agreed during the Executive and Steering Committee meetings or Group Meetings are carried out within the time agreed.

The Secretary and Chairperson are responsible for coordination between all members of the group and between the ROG and other Groups of the EORTC. They are responsible for providing a yearly report on the activities of the group for submission to the EORTC Data Centre. The implementation of any recommendations issued by the

EORTC Scientific Audit Committee (SAC) with regard to the working of the group is also their responsibility.

Treasurer: is **co-opted** by the Steering Committee for a term of 3 years. He/she may be re-co-opted once for a second three-year term. He/she is responsible for the day to day financial affairs of the group in collaboration with the EORTC accounting department and is involved in all study budget negotiations.

4. Specialist Committees and Functions

Executive Committee

The Executive consists of the group chair, chair-elect, past chair, secretary, treasurer, QA committee chair (and a Radiotherapy Physicist if not QA-chair) and, if applicable, any ROG member of the EORTC Board. The Executive Committee is supported by the administrator. It has the task of ensuring continuity of the work in hand. Data Centre representatives may be invited to attend the Executive Committee meetings on an ad hoc basis.

Steering Committee:

The Steering Committee consists of: The Executive Committee, Study Coordinators, Working party Coordinators (1 representative in the case of shared working party chairs), Committee Chairs (Membership Committee, Publications Committee, Public Relations and Website Committee), the Chair of the Radiotherapy Technologists Group, the full EORTC Data Centre Team, and the designated young scientist. Those study coordinators from other groups (in the case of intergroup studies) may attend the Steering Committee meetings.

The Steering Committee together with the QA Team agree to enforce the quality assurance measures as stipulated in the protocols of the group and to help ensure that participating institutions adhere to the EORTC quality measures with regard to data collection.

The Steering Committee discusses and decides the main strategy of the group, approves financial plans, as advised by the Executive.

Working Parties:

Specialist working parties may be set up within the group with the specific purpose of discussing new ideas for clinical research. These working parties may have meeting time during the group meetings and will report on their discussions during the plenary session. The chair (or joint chair) is/are chosen by the members of the working party and automatically becomes a member of the steering committee. In the case of joint working party chairs, only one will attend the steering committee meetings (to be agreed between them).

ROG Membership Committee:

The chair of the membership committee is nominated for a period of 3 years (nomination may be renewed) by the Executive and approved by the Steering

Committee. He/she chooses other members of the committee from active institutions (the number of committee members at his/her discretion).

The Membership Committee chair is responsible for tracking membership performance, receiving new applications for membership from the EORTC and sending these out for review by the membership committee members. The mandate of the committee also covers the re-evaluation of probationary members before active membership status is obtained. Finally it is aimed at a comprehensive monitoring of the participation of active members to EORTC activities.

Publications Committee:

The chair of the publications committee, nominated by the Executive and approved by the Steering Committee for a period of 3 years (nomination may be renewed), may co-opt members as necessary, according to the nature of the material to be reviewed, but must have at least 2 permanent committee members. He/she receives for approval all scientific papers, abstracts and other draft documents (excluding posters and slide presentations) prior to publication on behalf of the ROG. Quarterly reporting to the Executive Committee is required, giving information on the material received and the outcome of the review.

Quality Assurance (QA) Team:

The QA Team consists of: a Chair person and representatives of the following specialties: clinical radiotherapy, radiotherapy technology, radiation physics, the EORTC Coordinating Physician, the “Emmanuel van der Schueren” (EVDS) Fellow. The members of this team (except for the Data Centre Coordinating Physician, and the EVDS Fellow) are nominated by the Executive and approved by the Steering Committee and are responsible for the preparation and execution of quality assurance programs in radiotherapy and for the coordination of the quality assurance procedures with the Quality Assurance Unit of the EORTC Data Centre and the Quality Assurance Committee of the EORTC. The QA team is responsible for review of the QA section of every new ROG (or joint ROG) protocol and for advising the study coordinator on QA matters in his/her particular protocol.

The QA Team holds bi-annual meetings. It advises the study coordinator on dummy runs (DR), individual case reviews (ICR) and other QA measures where appropriate within the framework of ROG or joint trials, with site visits when necessary. It reports to the EORTC QA Committee on an annual basis. It is also responsible, together with the study coordinators, for an optimal radiotherapy quality within any ROG trial.

Nominating Committee:

This ad hoc committee consists of the Group Chair, the past Chair, the Secretary and any ROG member who is a member of the EORTC board. Its purpose is to receive the names of candidates for presentation to the active membership for election of group officers. Should any one of the aforementioned have the intention to stand for election, then he/she will have to withdraw from this committee.

Study Coordinators: are formally designated by the Chairperson and hold office for the duration of a protocol. They are expected to actively take part in the study and are

responsible for leading the design of the protocol and its correct execution, with the help of the Data Centre and ROG QA team, and for resolving any difficulties which may arise during the study. They are expected to take part in negotiations for financial support (from pharmaceutical companies or other bodies) together with representatives of the Data Centre with advice from the ROG QA Team and for submission of the outline and final full protocol to the Protocol Review Committee of the EORTC. They are also responsible for the design and implementation of QA activities within their protocol, in cooperation with the ROG QA Team. They are responsible for the preparation of appropriate publication material, obtaining agreement of all authors concerned.

A study coordinator may be removed from function after decision by the Executive Committee and confirmation by the Steering Committee and QA Team if he/she is unable to support the study following the rules of the Data Centre.

Study coordinators are members of the Steering Committee.

The responsibilities of the study coordinator is given in Chapter 6 of the EORTC Investigators Handbook.

The Radiation Technologists Group

This autonomous group within the ROG conducts its own meetings and manages its own membership. Meetings may be organized during the ROG meeting (parallel sessions). The chair of the Radiation Technologists Group is a member of the ROG Steering committee and the ROG QA Team.

5. Elections

Active members of the group have the right to vote in the election of group officers*. For the election of officers, candidates may be proposed by all active member institutions and those with active-consultant status. The nominating committee recommends candidates whose names will be put forward for election by the active members. Voting will take place by postal ballot and the results of the election will be made known during the next following meeting.

Active member institutes, where several individuals are present, will be asked to agree jointly on their vote.

6. Functioning of the Group

Format of the meetings: the group meetings are organised twice-yearly and consist of working party meetings and an open plenary session. The time allotted for the meeting will allow sufficient time for presentations and discussion.

* The number of votes allocated to a centre is based on a percentage of the total number of patients entered in ROG trials over the three years preceding the election; the votes will be weighted as follows: 1-5 % of the total entered = 1 vote, 5-10% = 2 votes, >10% = 3 votes.

The Executive will meet two to three times per year either physically or by telephone conference outside the twice-yearly group meetings.

The Steering Committee will hold a meeting prior to the group meeting with the purpose of:

- Screening the proposed agenda and planning the efficient conducting of the group meeting.
- Previewing proposed protocols before they are presented to the membership.
- Discussion of financial matters.
- Receive reports from the specialist committees, the QA team, the study coordinators, and working party coordinators with regard to the status of work in hand.

7. Representation of the group in the EORTC General Assembly

The Chairperson of the group automatically becomes a full member of the EORTC General Assembly for the duration of his mandate.

8. Publications and authorship

All scientific papers and abstracts undertaken on behalf of the group will have “EORTC” in their title and the content must be approved by the Secretary of the group and the Publications Committee.

Authorship is assigned by the study coordinator and Chairperson and usually includes (depending on the content of the paper – end points, secondary end points, side studies, QA etc.):

- the study coordinator (usually first author)
- those who have contributed substantially to the specific work described in the paper
- the names of the representatives of the member institutions which have contributed 5% or more of the cases on which the publication is based (10% in the case of abstracts). Where a member institution has contributed >10% of the cases, two authors can be named, depending on the rules of the journal with regard to authorship.
- the names of the representatives who have provided a major scientific contribution to the design or support of the study
- the names of the Coordinating Physician and Statistician of the group
- all participants in the part of the study described in the manuscript are mentioned in the manuscript.

Disclosure of results and publication policy are given in EORTC Policy Document [POL009](#).

All draft manuscripts (including abstracts) must be sent to all the co-authors in advance for approval. Comments must be returned to the submitting author within 21 days. All draft publications and abstracts must be sent also to the Publications Committee for

approval. The members are obliged to react within 14 days to the author with any proposed changes, etc.

The Executive Committee may appoint a new first author if he/she fails to complete the article within 6 months of receiving the complete data.

Recognition of any particular external funding should be mentioned.

9. Relationship with commercial companies and other academic partners

Contact with commercial companies should in the first instance be undertaken by not only the study coordinator and the Group Chairperson, but also a representative of the EORTC Data Centre. Negotiations between the company and representatives of the group and the Data Centre should result in agreement on the amount of financial support for the group for its own functioning and the amount which will be paid directly to the Data Centre in relation to the study to be undertaken. The amount of this support might vary depending on the expectations of the company with regard to the data to be provided. In all cases, the Data Centre should be involved up-front in any negotiations.

With regard to permission to use data before final publication of a study, the rules are stated in EORTC Policy Document [POL009](#). The ROG Steering Committee must also give its approval in cases where the permission request comes from a non-committee member. The rules for data sharing with other academic partners are specified in [POL008](#).

Simultaneous negotiations between the group and the EORTC Data Centre should be organised when a new sponsored protocol is being designed, to ensure satisfactory support for the group (i.e. QA activities) and the investigators, as well as the Data Centre.

10. Quality Assurance (QA)

The minimal requirements for Quality Assurance (QA) within EORTC Groups include:

1. nomination of a responsible investigator
2. creation of a QA committee
3. implementation of the above two points in the statutes of the group

The minimum requirements for radiotherapy centres entering patients in ROG studies are laid down by the QA Team and are kept up to date. These are available on the website of the group. They are part of the Facility Questionnaire which must be completed and submitted by all membership applicants, and which must be updated by participating centres on a regular basis.

With regard to phase III trials, study coordinators are urged by the Executive Committee to follow closely the quality of data collected at the Data Centre. Regarding individual institutions, minimal requirements for QA include data timeliness and quality of data per institution and completion and regular update of the ROG Facility Questionnaire.

11. Relationship with other EORTC Groups

In order to improve the relationship with other EORTC Groups, aiming at having more constructive interdisciplinary programmes, avoiding unnecessary competitive trials and also to accrue more patients in a shorter period of time, the Radiation Oncology Group designates two members to officially represent the ROG in each of the relevant disease oriented groups.

12. Data Management and Review

The study coordinator works in close cooperation with the Data Centre Team. They may reject any data from a participating centre if its quality is unsatisfactory.

Data will not be released from the Data Centre without the permission of the Study Coordinator and the Chairperson of the group.

Data may not be used in oral or written form without the permission of the study coordinator and the group chair.

Data release and publication follow the general EORTC policy ([POL008](#) and [POL009](#)).

13. New protocols

New protocols are proposed by active members on their own initiative or on request by the Group during an official meeting or on request by the Chairperson of the group. The proposing member will usually become the study coordinator of the new protocol and is responsible for the presentation of data at the meetings of the group and for the writing of abstracts and papers according to the rules for publication.

The QA Team will be involved in the design of a new protocol from the beginning so that adequate QA measures are included.

An outline of the proposed study (using the EORTC Template) is discussed during the working party meetings.

Further protocol development will follow the general EORTC policy ([POL16](#)).

14. Access to clinical study participation

This is only possible through membership of the ROG. A new centre wishing to participate in studies of the group must apply formally to the EORTC for membership (membership@eortc.be). The [EORTC Investigators Handbook](#), Chapter 2.2 describes membership rules and obligations.

15. **Financial Affairs**

All daily financial matters are taken care of by the Treasurer while the Treasurer and Executive decide jointly on strategic financial matters, with the approval of the Steering Committee.

The group's funds consist of: all financial contributions from commercial companies in support of trials of the group and the group's administration and other sources (e.g. grants from the EORTC Academic Research Fund, EU project grants, donations).

Limited financial support is available for the following purposes:

- representatives of active member institutions who are asked to perform quality assurance studies or review of data at participating centres
- study coordinators' visits to the Data Centre (on the basis of reimbursement of 1st class train travel, or economy air travel)
- non-members who are invited to group meetings to give specialist presentations.

Proposed expenditure must have the prior approval of the Treasurer.

16. **Application for membership of the Radiation Oncology Group**

- All applications are handled by the EORTC. Applicants should apply to membership@eortc.be and they will be supplied with the necessary forms for completion.
- Applications are reviewed by the EORTC Membership Committee and individual applicants are reviewed by the ROG Membership Committee
- All members of the group agree to comply with the rules of membership and to take part in the QA activities involved in each study.

Appended to these statutes: EORTC [POL008](#), [POL009](#) and [POL16](#)

Statutes of the EORTC Radiation Oncology Group, December 2006

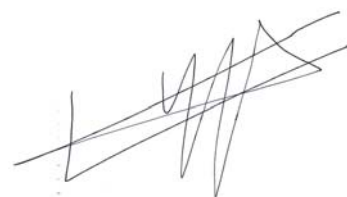
**Approved by the Steering Committee of the EORTC Radiation Oncology Group on
December 12, 2006**



Chairperson: K. Haustermans



Secretary: P. Poortmans



Treasurer: V. Grégoire