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APPENDIX I: Head and Neck Cancer Group Statutes

EUROPEAN ORGANISATION
FOR RESEARCH AND TREATMENT OF CANCER
HEAD AND NECK CANCER GROUP (HNG)

STATUTES (*VERSION 01.09, 2001-09-26*)

I. Objectives of the Group

The aims of the Head and Neck Cancer Group are to conduct, develop, coordinate and stimulate research, on a clinical basis, in head and neck cancer patients. To fulfil this, the HNCG will conduct mainly prospective studies and promote both translational research and multi-disciplinary diagnosis and therapy policies.

II. Functions and mandates of Group Officers and Committees

II.1. Group Officers

The four Officers of the HNCG are: Chairman, Secretary, Treasurer and Quality Assurance (QA) Coordinator. Their functions and mandates are as follows:

II.1.1. Chairman:

The Chairman is responsible for coordination between all members of the group and between the HNCG and other Groups of the EORTC. With the Secretary, he/she is responsible for providing a yearly report on the activities of the group for submission to the EORTC. The Chairman of the group automatically becomes a full member of the EORTC General Assembly for the duration of his mandate.

He/she is elected for a term of 3 years and may be re-elected once for a second three-year term if approved by the EORTC Board.

II.1.2 Secretary:

The Secretary is responsible for the organization of the twice-yearly meetings and the distribution of the minutes to the membership. With the Chairman, he/she is responsible for providing a yearly report on the activities of the group for submission to the EORTC.

He/she is elected for a term of 3 years and may be re-elected once for a second three-year term.

II.1.3 Treasurer:

The Treasurer is responsible for the monitoring and management of the Group financial assets, income and expenditures. Yearly declarations of expenditure must be submitted to the EORTC Executive Treasurer. Expenditures should have the prior approval of the Treasurer.

He/she is elected for a term of 3 years and may be re-elected once for a second three-year term.

II.1.4. Quality Assurance Coordinator:

The QA Coordinator is responsible for the preparation and execution of QA programmes and the coordination of the quality control procedures with the Quality Control Unit of the EORTC Data Centre and the QA Committee of the EORTC. Yearly reports on the QA Programme of the HNCG will be submitted by the QA Coordinator to the Group Steering Committee and the EORTC QA Committee.

He/she is elected for a term of 3 years and may be re-elected once for a second three-year term.

Group officers are not allowed to cumulate functions during their mandate, except as liaison person with other groups or bodies of the EORTC.

II.2. Steering Committee

1.1. II.2.1. Composition

The Steering Committee consists of the following members:

- *from the HNCG:* the Chairman, Past-Chairman, Secretary, Treasurer, Quality Control Coordinator, and Chairmen of the Group sub-committees (see section).
- *from the EORTC Data Center:* the Group Medical Advisor, and Group Statistician.

It is expected that all members of the Steering Committee, and especially those coming from the largest countries, have an active role in recruiting institutions within their respective countries.

The Steering Committee together with the Quality Control Coordinator agrees to enforce the quality control measures as laid down in the EORTC Data Centre Procedures Manual (page 63) with regard to data collection and data quality from member institutions.

1.2. II.2.1. Mission

The mission of the Steering Committee concerns the implementation of internal rules and the development of external relationships.

II.2.1.1. Internal rules

- Screening the proposed agenda and planning the efficient conducting of the group meetings
- Previewing proposed protocols before they are represented to the membership
- Previewing scientific articles before their publication
- Discussing financial matters

Accepting new members and monitoring the membership status*

*: With respect to Membership acceptance and monitoring, the objectives of the steering Committee are to develop and formalize, in full collaboration with the QA Coordinator, a full review process for

the application of new candidates for (probationary) membership of the group. Its mission also covers the re-evaluation of probationary members before they apply for active membership and a comprehensive monitoring of the participation of active members to EORTC activities. These review processes have to comply with the statutes of the EORTC and of the HNCG

II.2.1.2. External relationships

- Promoting and coordinating all actions towards inter-group collaborative works, both within and outside the EORTC
- Appointing liaison persons with other EORTC groups or units
- Developing the integration of the Group activities in the field of translational research.

1.3. II.2.3. Meetings

Twice yearly, in Fall and Spring, the Steering Committee holds a meeting prior to the group General Assembly meeting. In between the Steering Committee can be consulted through mail and/or email on issues which need to be addressed urgently and require to be solved before the next Spring or Autumn meeting.

II.3. Sub-committees

The HNCG includes various sub-committees, which are discipline-oriented. These sub-committees cover at least four scientific areas: surgery, pathology, medical oncology and radio-oncology

The chairman of a sub-committee is elected among each sub-committee members. He/she is elected for a term of 3 years and may be re-elected once for a second three-year term.

III. Procedures

III.1. General considerations

Members of the EORTC HNCG are institutions. Each institution should provide the Group Secretary with the name of a Representative (or Contact Person) which will be the liaison between the Group or the EORTC and the Institution for matters such as payments, data timeliness lists... The secretary should then keep the Steering Committee and the Data Center informed of this list.

All membership criteria are based on number of patients entered, irrespective of eligibility or evaluability.

Institutions can be:

- Probationary members

Any institution active in the field of clinical and experimental oncology who agrees to comply with the rules of the EORTC and of the EORTC HNCG, can apply for probationary membership. A new member institution is admitted as a Probationary Member of the Group for 2 years and is expected to contribute *at least 5 patients* each year for two consecutive years, to become an active member*. If, after a period of 2 years, the probationary member does not fulfill the requirements for active membership, the reasons should be evaluated. The Steering Committee may then decide to prolong the probationary period by 1 year. In the event of a probationary member contributing less than 5 patients per year, but recruiting in certain trial(s) to which this low accrual is deemed to be of value, the probationary membership period can be extended for the duration of these trials. Probationary Members agree to participate in the quality control of the Group and to send a representative to regularly attend the twice-yearly Group meetings.

*: Institutions will be asked to bring 3 patient files to the group meeting where its application for active membership is to be reviewed. The Data Center will then bring copies of the CRF's and the 2 sets will

be compared by the QA coordinator and the Data Manager before the Steering Committee decides on the acceptance of the applicant institution to active membership.

- Active members

Active member institutions are expected to contribute *at least 5 patients per year* over the preceding *2 years* in HNCG trials. A representative should attend regularly the twice-yearly group meetings.

Active members have all voting rights within the HNCG

- Associate members

Are institutions which are member of the Group but do not fulfill the criteria of Active Membership. Representatives of these institutions will be invited to the group meetings and will receive information on the study in which they participate but they have no vote right within the HNCG.

- Foreign members

These are institutions which are not member of the Group but are authorized to participate in one or several of the Groups trials. Representatives of these institutions will be invited to the group meetings and will receive information on the study in which they participate but they have no vote right within the HNCG.

- Honorary members

Members elected by the group in respect of their past contribution to the activities of the group but who do not recruit patients in the studies anymore. They have the right to vote for elections within the HNCG.

- Consultant members

Are other types of specialists advising the group on specific issues or aspects of research but who cannot recruit patients in the studies (eg: pathologists, basic researchers,...). This membership is attributed by the Steering Committee on the basis of a written motivation by the applicant . They have no vote right within the HNCG.

The Steering Committee of the Group will be consulted at the end of each month of January in order to review the figures of accrual of the institutions and evaluate the modifications to the membership of the institutions (also for active members becoming associate members and conversely). The list is produced by the Data Center and reviewed by the Steering Committee who approves the new membership affiliations. It is then the responsibility of the Secretary of the Group to inform each institution of its new membership and to inform the EORTC Data Center of the updated membership status of all institutions.

III.2. Meetings

The Group meetings are organized twice-yearly and consist of:

- sub-committee meetings attended by members active in the relevant discipline
- the Steering Committee meeting attended by its members only
- the business meeting attended by active members
- the open plenary session attended by active, probationary and honorary members, observers, consultants, and invited speakers. Representatives of pharmaceutical companies can receive “ad hoc” invitations to open plenary sessions.

III.3. Coordinatorship

1.4. III.3.1. New protocols

A new protocol outline development is initiated by active members on request by the Group or by its Sub-Committees during an official meeting or on request by the Chairman of the group. The initiating member will become the study coordinator of the new protocol and is responsible for the presentation of data to the meetings of the group and for the writing of abstracts and papers according to the rules for publication.

A protocol which is specifically developed in a sub-committee should first be discussed by this sub-committee before being presented to the Steering Committee and finally to all Group members. For this the protocol outline reviewed by the sub-committee will be sent to the Secretary of the group, at least 6 weeks before the group meeting. The Secretary will then distribute the protocol outline to the members of the Steering Committee before it is presented to members of the group.

After approval by the Steering Committee and the group, the study coordinator, with the collaboration of the Writing Committee members, will develop the full protocol and submit it to the EORTC Protocol Review Committee. New full protocols should be open in between group meetings if they are ready.

1.5. III.3.2. Study Coordinators

Study coordinators are designated by the group and hold office for the duration of a protocol. They should actively take part in the study. They are responsible for:

- the correct execution of the protocol, with the help of the Data Centre and for resolving any difficulties which may arise during the study,
- the central evaluation of the patient charts at the EORTC Data Center

- the preparation of appropriate publication material, obtaining agreement of all authors concerned.

III.3.3. A study coordinator may be removed from function (after decision by the Steering Committee) if he/she is unable to support the study following the rules of the Data Centre (EORTC Data Centre Procedures Manual, page 63).

III.3.4. In order to distribute better the responsibilities of the activities of the group over the members of the group and promote the active participation of younger members, it is strongly recommended that an investigator doesn't coordinate concurrently more than 3 studies.

III.4. Quality Assurance Procedures

1.6. III.4.1. Minimum requirements

The minimal requirements for QA within EORTC Groups include:

- nomination of a responsible investigator (called QA Coordinator) or creation of a Quality Control (QC) subcommittee*
- writing of a report to the EORTC Quality Assurance Committee on an annual basis.
- Regarding individual institutions, minimal requirements for QA include data timeliness and quality of data per institution.

*: Due to the size of the HNCG, the Steering Committee will appoint a QA Coordinator and will act as QC Sub-Committee both for Quality Assurance and Membership.

III.4.2. Trial-oriented procedures

III.4.2.1. Quality control procedures

The procedures implemented within the QA Programme of the HNCG are, within the framework of EORTC trials, as follows:

- individual case reviews (ICR)
- on-site whenever necessary
- dummy-runs
- electronic investigations on human resources and department infrastructure in participating institutions.

1.7.III.4.2.2. QA of patient and treatment data

With regard to phase III trials, study coordinators are urged to follow narrowly the quality of data collected at the Data Centre.

1.8.III.4.2.3. Application for membership of the HNCG

A new centre should send a written application to the Chairman of the group, giving details of the institute and its Head and Neck department (members of staff, numbers of new patients treated per year, specialist treatments, equipment, etc.) as well as data on investigator motivation to join the group.

The Chairman will inform the Secretary, Treasurer, QA Coordinator and Steering Committee members of the application. An application form for membership should be completed (administrative information on the centre concerned) and sent to the Data Centre.

All applications received between the group meetings are discussed at the next following Steering Committee meeting. Upon formal approval of the application by the Membership and Steering Committee, the Secretary will inform the applicant

and provide him/her with the Statutes of the group, information on methods of patient entry and the QA programme for all participating institutions. The EORTC Data Centre will also be informed. The QA coordinator will contact the applicant as soon as the new centre has registered 5 patients in any of the groups studies. Regarding the radiotherapy department of the new institution, their responsables will be asked to complete an infrastructure questionnaire (Internet) and to take part in the mailed TL dosimetry programme for beam calibration.

1.9.III.4.2.4. Starting randomization for a new centre

Since the application of a new institution to register patients in a Group study should be viewed as an application to become member of the Group, new applicants are authorized to participate to all studies. The Steering Committee is however reserved the right to limit the participation of a new institution to a subset of studies, for instance by restricting the access to early phases or sponsored studies if the center doesn't have the necessary infrastructure or for other reasons. This decision should then be motivated and justified by the Steering Committee and the QA Coordinator.

III.5. Publication Policy.

All publications and oral presentations undertaken on behalf of the group will have EORTC in their title and the content must be approved by the Chairman and Secretary of the group and the study coordinator, as well as by the study statistician and medical advisor.

Authorship is assigned by the study coordinator and Chairman and includes:

- the study coordinator (usually first author)
- for phase II studies, the names of the representatives of the member institutions which have contributed 10% or more of the cases on which the publication is based. For phase III studies, the cut-off is 5%.

- the names of the representatives who have provided a major scientific contribution to the design or support of the study at the discretion of the study coordinator and Chairman.
- the names of the EORTC DC representatives (minimal 2) of the group.
- on request, the name of one representative per pharmaceutical company in sponsored studies*.

* In sponsored studies, more names of pharmaceutical company representatives will be mentioned in the "Acknowledgements".

All draft publications (full papers and abstracts) must be sent to the Steering Committee for approval. The members are obliged to react within 14 days to the Chairman who will then inform the author of any proposed changes, etc.

Publications in cooperation with other EORTC Groups will follow the same rules, and will meet with the agreement of the representatives of both groups. All publications concerning group studies must list all the participating centres in an acknowledgement section.

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

References and, if available, copies, of all publications (abstracts, papers, chapters in books), including oral communications and posters, should be sent to the Secretary of the group and to the Data Center for information and inclusion in the group bibliography.

The study coordinator works in close cooperation with the EORTC Data Centre. He/she may reject any data from a participating centre if it is unsatisfactory. Data will not be released from the Data Centre without the permission of the Study Coordinator and the Chairman of the group. Data may not be used in oral or written form without the permission of the study coordinator.

III.6. Elections

Active members of the group have the right to vote in the election of group officers and subcommittee chairmen. For the election of officers, candidates may be proposed by all active member institutions. Voting will take place by postal ballot and the results of the election will be made known during the business meeting.

III.7. Finances

III.7.1. All financial matters are decided by the Treasurer and Steering Committee.

III.7.2. Limited financial support is available for the following purposes:

- representatives of active member institutions who are asked to perform quality control studies or review of data at participating centres
- study coordinator visits to the Data Centre (on the basis of reimbursement of 1 class train travel)
- non-members who are invited to group meetings to give specialist presentations
- Group officers in mission
- Liaison persons in mission

Proposed expenditures should have the prior approval of the Treasurer.

III.7.3. In the framework of sponsored clinical studies, investigators from individual institutions will be asked to provide the Group's Treasurer with a non personal bank account number, for payment of their contribution and on the basis of the arrangement defined by the Group and the pharmaceutical company.

IV. Liaison with other EORTC groups or bodies

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 HNCG has to establish a list of Liaison Members.

The Steering Committee will therefore appoint liaison persons with other EORTC groups or units (for instance, the Quality of Life study group, the Radiotherapy Group, the Early Clinical Study Group, or the Health Economics Unit) and with other groups outside the EORTC. A person may remain liaison person for an unlimited period of time.

It is expected that representatives attend regularly their respective Group meetings, give regular information on other group activities, participate in the elaboration of common programmes in a positive, multidisciplinary approach. It is recommended that the liaison persons attend at least one meeting of the group they liaise with every year.

Liaison person functions can be cumulated with other mandates of Group Officers.

V. Relationship with pharmaceutical companies

Contact with pharmaceutical companies should only be entered into by the study coordinator and the group Chairman. 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 will vary in each case in the light of 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.

Administrative data and data on toxicity can be provided to a pharmaceutical company during the active period of the trial. Data may be transferred after approval by the study coordinator, even before the closure of the study and publication by the group. The Company however has no right to publish the results before the final publication by the group.

Simultaneous negotiations between the group and the EORTC Data Centre should be organized when a new sponsored protocol is being designed, to ensure

satisfactory support for the group and the investigators, as well as the Data Centre (see EORTC Directory, Guidelines for Statutes of Groups).

Approved by the Steering Committee of the EORTC HNCG,
on November 15, 2001

EORTC, Brussels, Belgium

The Chairman: J. Bernier

The Secretary: J.B. Vermorken

The Treasurer: G. Andry