

**STATUTES OF THE GASTROINTESTINAL TRACT
CANCER COOPERATIVE GROUP
EORTC-GI GROUP**

Version 1, October 1985
Version 2, September 1997
Version 3, April 2001

STATUTES OF EORTC-GI GROUP

1. Objectives of the group

1. To co-ordinate clinical research in gastrointestinal cancer by formulating and performing clinical trials.
2. To support scientific research in gastrointestinal cancer.
3. To broadcast information thus acquired at biannual meetings and by publication in suitable scientific journals, monographs and newsletters.

2. Membership and application for membership

Anybody active in the field of clinical and experimental gastrointestinal tract oncology who agrees to comply with the rules can apply for membership. A new probationary member is nominated for two years. If during this two year period he has substantially contributed to the work of the group as stated in the by-laws, he becomes an active member. The exact number of patients required to become an active member will be determined by the group in the by-laws. Non-EORTC members can participate to the EORTC-GI trials as foreign members.

3. Officers of the EORTC GI GROUP

These shall comprise the chairman, past-chairman, secretary, treasurer, the study coordinators and the chairmen of the committees of the GI group. The chairman and the secretary are elected by the active members. The officers, with the exception of the study coordinators, are chosen among the active members.

Officers of the GI group are not allowed to be study coordinator of a non-EORTC multicenter protocol that is competing for the same target population as an active EORTC-GI protocol.

4. Committee of the EORTC GI GROUP

There may be, at any time, a number of committees of the group. Their exact make up and number is to be decided at the biannual group meetings.

5. Board of the group

The board of the group will consist of the chairman, the secretary, the past-chairman (if still an active member), the treasurer, the chief statistician, the data manager, and the chairmen of the committees. It will meet 2-4 times a year. The representative(s) of the GI group in the board of the EORTC and the chairman of the quality control committee are members of the board of the GI group.

6. Decisions

The chairman and secretary have the mandate to take operational decisions if needed; important operational decisions and strategic issues will be discussed in the board and decided in the business meeting. The business meeting can only be attended by active members. The chairman has a casting vote. They elect the officers of the EORTC-GI group. One representative of each active institute can vote.

BY LAWS

1. Membership

There are two types of membership: active and probationary.

An active member is defined as an institution that has entered at least 6 evaluable patients per year in active EORTC GI group protocols during the previous two years. Centers entering fewer than this number for two consecutive years lose their status as active members. The institution must ensure that a high proportion of patients entered are evaluable. Centers that, for two years, successively, have more than 25% of inevaluable cases due to overdue forms, have ineligible patients, or have major protocol violation lose their status as active members.

Probationary membership is for new members, or active members who for various reasons may have failed to maintain their active membership by not accruing 6 patients the previous year. The probationary membership status may exist for two years. If the probationary member has 6 patients for two consecutive years he will become an active member. If a probationary member fails to obtain active membership after two years, his position will be reviewed by the Clinical Trial Committee (CTC) who may ask for their resignation. Reapplication may be made at any time via the usual application procedure outline below. A review of the membership will be carried out by the CTC at the beginning of each year.

Active members enjoy the following privileges:

1. The receipt of all relevant communications emanating from the EORTC.
2. The opportunity to write and co-ordinate protocols.
3. They will receive the Data Center Report.
4. The opportunity to present material from group protocols at national and international meetings after agreement with the protocol co-ordinator and the CTC.
5. Active members will receive financial support from the group to aid their participation in group activities, whenever possible.

6. Right to vote and to elect the members of the CTC.

Probationary members will enjoy the following rights:

1. They will receive all relevant information concerning the EORTC GI group activities which the CTC feel they may require, including the Data Center Report.
2. They have the opportunity to achieve active membership as outlined above.
3. They have the opportunity to present material from group protocols at local meetings provided they have contributed 10% of the patients in the trial and have discussed and agreed such a presentation with the study co-ordinator and the CTC.

Advisers or consultants

Clinicians or other scientists who, because of their specialised interest in some aspects of gastrointestinal cancer, contribute or have contributed to the work of the group, may be invited by the group to become adviser to the group. Because of their speciality or for other reasons they may be unable to contribute patients to protocols. They may, however, by their specialist knowledge, contribute or have contributed greatly to the work of the group. Such advisers or consultants will be nominated by the board and will enjoy privileges of membership.

2. Officers of the EORTC GI GROUP

Chairman

The chairman is elected by the active members for a period of three years in accordance with the statutes of the EORTC. The chairman of the group shall have overall responsibility for the whole group and will represent the group, when necessary, to the board or the council of the EORTC. He will also represent the group at international meetings and will chair all bi-annual meetings during tenure of office.

To facilitate his task the chairman has the benefit of a casting vote.

Secretary

The secretary is elected by the active members for a period of three years in accordance with the statutes of the EORTC. The secretary is responsible for the transmission of information to members of the group and for organising meetings of the whole group and the CTC in co-operation with the chairman.

Treasurer

This post may be occupied for three years and is renewable.

Study co-ordinators

These must be appointed from the active members and there should be one protocol co-ordinator to each protocol. He is responsible for running that protocol, for twice yearly visits to the data center to collect information received and, when a protocol is completed, for writing the final report and the first publication of the results of that trial. He is also responsible for the initial presentations and results of that trial at a suitable international meeting. A study co-ordinator may co-ordinate a maximum of one phase II study and one phase III study at the same time. He has the right to reject data from a center if this appears unsatisfactory, resulting in the exclusion of that center from the study. The center concerned has the right of appeal to CTC. The study co-ordinator may also request the data center to refuse further randomisation of cases from centers not participating satisfactorily in a given protocol.

3. Committee of the EORTC GI GROUP

There may be, at any time, a variable number of committees of the group, examples are: chemotherapy committee, radiotherapy committee, surgical committee, laboratory research and quality control committee. Each committee will consist of active specialists in that particular field and will, amongst themselves, select a chairman. The committees shall send written reports or all their meetings to the secretary of the group.

Candidates for a place of responsibilities in the committees are put up by the active members convened in a plenary session. The candidate will be elected by a majority.

NEW PROTOCOLS

An outline of proposals for new trials must be submitted to the GI-group chairman by electronic mail. The chairman will submit the proposal to the board members and should respond within 2 weeks.

The proposals for new trials will then be submitted to the committee and must be approved by the business meeting. The outline is then submitted to the PRC and, if approved, a full protocol is prepared by the study coordinator and the drafting committee.

RULES FOR RUNNING A TRIAL

The study coordinator is responsible, with the data center and the chairman, for the smooth running of the protocol and for solving any difficulties arising during the study.

He should also:

- visit the data center when appropriate to review the data.
- ensure that all documents which have been used to measure tumor response are available.
- organize a panel of specialists for the review of radiological, ultrasound and CT-scan documents.
- Organize a panel for the review of all responding cases. This panel should be constituted of at least two oncologists not actively involved in the trial, active members or members of the GI tumor group or of other EORTC groups.

PUBLICATION AND AUTHORSHIP

Papers will be written by the drafting committee of the trial nominated by the active members.

Authorship includes:

- the study coordinator, the drafting committee.
- the names of all members who have contributed 10% or more of the available cases included in the report.
- the data manager.
- the statistician.
- the EORTC gastrointestinal group.
- all other members contributing cases to the study will be acknowledged in a footnote.
- all abstracts and final papers will be submitted to the editorial board.

No paper will be submitted for presentation or publication without the approval of the editorial board.

FORMAT OF THE BI-ANNUAL MEETINGS

The meetings will be held twice a year. Alternate meetings will be accompanied by a scientific symposium organised by a local organising committee. Meetings may last for two days and will usually be held on Friday and Saturday with an appropriate social programme. Meetings can be extended as appropriate.

The following items must appear on the agenda:

1. Apologies for absence.
2. Approval of the minutes of the previous meeting.
3. Chairman's report.
4. Secretary's report.
5. Treasurer's report.
6. Review of publications "in preparation".
7. Report from committee chairmen or advisers.
8. Data center report.
9. New protocols and ideas.
10. Other items as appropriate.