

Appendix 1 – Statutes of the EORTC Leukemia group



STATUTE OF THE EORTC LEUKEMIA GROUP

- 1. Aim of the Group:** to promote the study of leukemias and related malignancies with regard to their natural history, diagnosis, treatment and sequelae of treatment.
- 2. Membership:** the Group has 3 categories of members:
 - Probationary members (PM): these are new centers asking for membership. They are required to enter a minimum of 5 patients in at least one phase III trial. This membership status will last for only one year at the end of which the center will either become an Active member or, in case of non compliance with this requirement and/or poor quality of data, will be asked by the Board to leave the Group. One representative of the center has to attend both general meetings annually.
 - Active members (AM): these centers are required to enter a minimum of 5 patients per year in at least two phase III trials. The quality of data is an additional parameter to be taken into consideration and only centers fulfilling both criteria will have their Active member status renewed yearly by the Board. Active members should be represented during the business meeting and have the right to vote.
 - Core members (CM): these are Active members characterized by an accrual of a minimum of 10 patients per year in at least two phase III trials during 3 consecutive years with the highest standards of quality of the data. They constitute the core of the Group and are members of the Board.
- 3. Officers:**
 - Chairman: the Chairman is elected by Active members during the business meeting, and serves for only one 3-year term. He/She will be responsible in all matters that are related to the proper operation of the Group. The task of the Chairman is to coordinate activities of the Group and to take care of the planning of new studies. He/She is responsible for the functionality of the Group and the sub-committees. He/She also represents the Group in the council of the EORTC.
 - Chairman-Elect: The Chairman-Elect is elected by Active members during the business meeting. He/She shall perform the duties of the Chairman in the absence or incapacity of the Chairman, and shall become Chairman if the office of Chairman shall become vacant. Should the Chairman-Elect become Chairman

through a vacancy in the office, he/she shall be permitted to serve as Chairman for the remainder of the unexpired term and his/her own term.

- Secretary: the Secretary is elected by Active members during the business meeting, and serves for only one 3-year term. He/She will conduct the correspondence and perform all duties that pertain to the office of the Secretary. He/She is responsible for the organization of the two annual meetings of the Group and the distribution of the minutes to the members and the EORTC Secretary General for publication in the newsletter.
- Treasurer: the Treasurer is elected by Active members during the business meeting. He/She will be responsible for the collection, receipt, custody and disbursement of all funds and securities of the Group. During the annual business meetings, the Treasurer will make a report of the financial condition of the Group.
- Board: the Board is the administrative body of the group. It will deliberate upon and advise the Chairman concerning the long range development and policies of the group and other actions and activities which the Board determines to be in the best interest of the group. The Board consists of the Chairman, the Chairman-Elect, the Secretary, the Treasurer, the Chairpersons of the sub-committees, the past Chairmen of the group, and the representatives of the Core members.

4. Meetings: there will be at least two group meetings per year, each consisting of a business meeting and a general meeting. The location of the meetings is decided by the Board.

- Business meeting: will be attended by the Board members, representatives of Active members, study coordinators, sub-committee chairpersons, datamanagers and statisticians of the group. During the meeting long and short term planning and organizative problems will be discussed. Plans are accepted by majority of votes. When voting is required for decision making, each Active member has one vote per institution.
- General meeting: in the general meeting ongoing protocols are discussed based on the information from the Data Center. Plans generated and decisions taken during the business meeting will be presented and discussed. The general meeting should include 1-2 scientific presentations by members of the group or invited speakers.

5. Sub-committees: the Group has two permanent sub-committees: Pathology sub-committee, Cytogenetic/Molecular sub-committee, but more can be established if and when required. Each sub-committee is headed by a Chairperson appointed by the Board. Upon appointment, He/She becomes member of the Board. Chairpersons must give annual reports to the Board and to the assembly during the business meeting about sub-committee activities and programs.

6. Study Coordinators: are appointed by the Board and hold office for the duration of a specific protocol. They are responsible for the “writing process” of the given study and have the task, in cooperation with the Data Center, to judge the eligibility and the evaluability of the patients included. He/She is responsible for the final presentation and publication of the study of which He/She will be the first author. Problems occurring during a study must be discussed with the study coordinators.

- 7. Publications and Authorship:** all Group publications will have “EORTC-LG” in their title and must preliminary be approved by the Chairman of the Group, the study coordinator(s), datamanager(s) and statistician.

Authorship will include:

- a) the study coordinator(s);
- b) the names of responsible physicians from contributing centers selected on the basis of a scoring system, developed by the Data Center, taking into account the following parameters: number of patients accrued, data timeliness and quality of submitted data;
- c) the datamanager and statistician;
- d) the Chairman of the Group.

Authors must belong to centers, members of the Group. In a note, participating centers with responsible physicians, sub-committee members, and members of the Board who have participated in the development and coordination of the protocol must be mentioned. Individual members or sub-committees may write articles on special subjects, but not before the main manuscript on the study, as a whole, has been accepted for publication. Preliminary publications are allowed on specific aspects, provided that they do not concern the end points of the study and they should fulfil the above mentioned rules. The name(s) of the study coordinator(s) must be included in the authorship.

Papers should be circulated to all members of the Group participating in the study prior to submission.

Presentations (oral, poster) at national/international meetings by individual members must be approved by the Board and the study coordinator(s). The abstract will be written by the author who is going to present the data with the addition “on behalf of the EORTC Leukemia Group”. The abstract will include the names of contributors selected on the basis of the above mentioned scoring system. The number of authors may be limited by space available for the abstract.

Publications in cooperation with other EORTC, national or international Groups will follow the same rules and will meet the agreement of the representatives of the collaborating Groups. Abstracts must be sent to all authors and the Chairman and Secretary of the Group.

- 8. Cooperation with other Groups:** trials may be run in cooperation with other national or international Groups. The trials must be approved by the EORTC Protocol Review Committee and must have been discussed within the Group as normal Group trials. The title must include “in cooperation with the EORTC Leukemia Group”.

- 9. Financial aspects:** the funds for the Group organization and activities are accorded by the Board. Financial support will be available for the following activities:

- a) per patient fee (eligible patients entered in a given trial);
- b) special projects of the sub-committees;

- c) participation of members in special meetings to give presentations on behalf of the Group;
- d) invitation of leading non-member experts for the Group meetings;
- e) visits to the Data Center by study coordinators.

Expenses will have to be cleared beforehand with the Treasurer of the Group.

10. Relations with the Industries: financial relationships may be established with pharmaceutical industries, always in cooperation with the Data Center. The pharmaceutical industries have no right to include patient files in their own databases. During the running of a trial, contacts between the pharmaceutical industries and individual contributors should only take place through the study coordinator(s). Data can be provided through the study coordinator(s) to the industries only after the closing of the trial and after at least one official presentation of the results to the Group.

In case of financial support given by the pharmaceutical industry, only the Chairman of the Group will be entitled to conclude officially a contract on behalf of the Group. All financial contributions will be put in the Group' bank account in Brussels and allocated after decisions taken during the Business meeting.

March 2000

R. Willemze, Chairman

S. Amadori, Secretary