

EUROPEAN ORGANISATION
FOR RESEARCH AND TREATMENT OF CANCER
LUNG CANCER COOPERATIVE GROUP (LCCG)

STATUTES (*FINAL VERSION 01, 23 March, 2001*)

1. Aims of the LCCG Group

The aims of the Lung Cancer Co-operative Group are to conduct, develop, co-ordinate and stimulate research on treatment of patients with intra-thoracic malignancies, including lung, pleural and thymic cancer. To fulfil this, the LCCG will conduct mainly prospective studies and promote both translational research and multi-disciplinary diagnosis and therapy policies.

2. Functions and mandates of Group Officers and Committees

2.1 Group Officers

Group officers are representatives from active member-institutions, elected by active members for a period of office of 3 years. One re-election for the same position is allowed for a maximum of three more years.

The Officers of the LCCG are: Chairman, Past-Chairman, Vice-Chairman, Chairmen of sub-committees, Secretary, Treasurer and Quality Assurance (QA) Co-ordinator. Together, these officers form the **Executive Board of the LCCG**, which performs the annual membership review together with the Data Centre representatives. Their functions and mandates are as follows:

2.1.1 Chairman:

The Chairman is responsible for the strategy and aims of the LCCG, the co-ordination between all members of the group, between the LCCG and other Co-operative Groups of the EORTC and between the LCCG and the EORTC Board. With the Secretary, he/she is responsible for providing a yearly report on the activities of the group for submission to the EORTC. Further details of the responsibilities of the Chairman are specified in the "Summary of EORTC Group Chairmen Tasks and Responsibilities" available at the EORTC Data Centre. 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. The re-election for a second three-year term should be exceptional, requires approval by the EORTC Board and should be justified by the LCCG Steering Committee.

2.1.2 Past-Chairman:

The Past-Chairman is responsible for supporting the new Chairman in all functions for 3 years.

2.1.3 Chairman-Elect:

The Chairman-Elect will be appointed at least 1 year before starting his/her term.

2.1.4 Chairmen of sub-committees:

Within the LCCG, surgery, radiotherapy, chemotherapy and pathology are represented by a committee Chairman. The Chairman of each sub-committee is responsible for the link between the LCCG and other EORTC disease oriented groups, other study groups or medical organisations. Their function is to promote the design and implementation of new and original work of the LCCG. The Pathology committee Chairman is also responsible for the pathology review in those studies requiring it and linking the LCCG with the EORTC Pathology Study Group as well as for stimulating biological research in the LCCG.

He/she is elected for a term of 3 years and may be re-elected every 3 years without a limit in time.

2.1.5 Secretary:

The Secretary is responsible for the administrative co-ordination of the LCCG, organisation of elections, organisation of the twice-yearly meetings and the distribution of the minutes (within one month) to all active, probationary and corresponding members. 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.

2.1.6 Treasurer:

The Treasurer is responsible for the monitoring and management of the Group financial assets, income and expenditures. He/she is responsible for presenting an updated overview of the account to the LCCG during the business meetings. 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 every 3 years without a limit in time.

2.1.7 Chairman of Quality Assurance:

The Chairman of the QA is responsible for the preparation and execution of QA programmes and the co-ordination 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 LCCG will be submitted by the QA Chairman to the Group Executive board and to 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.

2.2 *Steering Committee*

2.2.1 Composition

The Steering Committee consists of the following members:

- *from the LCCG:* the group Officers and the active Investigators who are Study Co-ordinators.
- *from the EORTC Data Centre:* 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 Chairman of the Quality Control agrees to enforce the quality control measures as laid down in the EORTC Data Center Procedures with regard to data collection and data quality from member institutions.

2.2.2 Mission

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

Internal rules

- Define the strategies of the Group
- Screening the proposed agenda and planning the efficient conducting of the group meetings
- Reviewing proposed protocols before they are presented to all members
- Reviewing 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 formalise, in full collaboration with the Chairman of the QA, a full review process for the application of new candidates for (probationary) membership of the group (see chapter 3).

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 LCCG.

External relationships

- Promoting and co-ordinating all actions towards intergroup collaboration, 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.

2.2.3 Meetings

The meetings are organised separately and only open for Steering Committee members. They are held at least prior to each group General Assembly meeting but additional meetings can be organised if the Executive Board of the LCCG decides to do so. The Steering Committee meeting consists of financial, strategic and organisational matters.

All Steering Committee members should be able to be reached through e-mail on issues which need to be addressed urgently and require to be solved before the next meeting.

3. Quality Assurance

3.1 Composition

The Quality Control Committee (QCC) consists of:

- QA Chairman
- LCCG Members (4-5) from different institutions and representing different specialities
- Data Centre representative

3.2 Mission

The QCC will need to review the quality assurance questionnaire received from new applicants. The Chairman will report to the Steering Committee during the next meeting. The Steering Committee might decide to send at least 2 representatives to the new centre before acceptance of the application. This visit should be organised and covered by the applicant.

Before a probationary member becomes active member, they will be asked to bring 3 patient files to the group meeting where its application for active membership is to be reviewed. The Data Centre will then bring copies of the CRF's and the 2 sets will be compared by the QCC before the Executive Board decides on the acceptance of the applicant institution to active membership. A site visit might be scheduled at the applicants institution before acceptance of active membership.

3.3 Quality Assurance Meetings

The QCC will meet at least once a year and the meeting is organised prior to a business meeting.

- Evaluation of new applicants
- Evaluation of the quality control of probationary members before they become active member.

Additional meetings are organised by the Chairman of the QA in order to cope with the minimal requirements of the Quality assurance procedures (see 4.5.1).

4. Procedures

4.1 Membership

Members of the EORTC LCCG 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 listings. The secretary should then keep the Steering Committee and the Data Centre informed of this list.

All membership criteria are based on number of patients entered.

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 LCCG, 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. Membership implies adherence to the good clinical practice guidelines (ICH/GCP). If, after a period of 2 years, the probationary member does not fulfill the requirements for active membership, the reasons should be evaluated. The Executive Board 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 regularly attend (at least once a year) or send a representative to the twice-yearly Group meetings.

Probationary members have no voting rights within the LCCG nor they participate in financial decisions.

- Active members

Active member institutions are expected to contribute *at least 10 patients per year* over the preceding *2 years* in LCCG trials. Membership implies adherence to the good clinical practice guidelines (ICH/GCP). When for one year an active member contributes less than 10 patients per year, he/she will regress to probationary membership. The active member has to regularly attend (at least once a year) or

send a representative to the twice-yearly group meetings. Active members participate in the business meetings, have the right to candidate and vote for the election of officers of the group and participate in its financial decisions.

- Associate members

Are institutions which are member of the Group but do not fulfill the criteria of Probationary Membership. They 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 LCCG.

- 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. They 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 LCCG.

- 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 LCCG.

- 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 board on the basis of a written motivation by the applicant . They have no vote right within the LCCG.

The Executive Board 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 probationary or associate members and conversely). The list is produced by the Data Centre and reviewed by the executive board who approves the new membership affiliations. The executive board will besides figures of accrual also

take into account the quality of the data as assessed by the QA and attendance at meetings by the member or his/her representative. 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 Centre of the updated membership status of all institutions.

4.2 Voting rights

Active members and honorary members have the right to vote for the election of the LCCG officers. Each active member-institution has one vote for the election of the officers. If two or more representatives are present in one institution, that institution will have for each 10 patients accrued in a LCCG trial during the last year an extra vote (maximum number of votes will not exceed number of active members for that institution).

4.3 Meetings

- Business meetings

The meetings are organised twice-yearly. At least one of them is organised at the Data Centre in Brussels. The business meeting is open to active members, probationary members, associate members, foreign members, honorary members and consultant members. A business meeting consists of an overview of administrative, strategic and general issues; a presentation of descriptive data of ongoing trials, presentations on results of closed trials and outline of trials to be activated. The content of this meeting is confidential and not for publication.

- Scientific meetings

The meetings are held at least once a year, generally following a business meeting. It can also be held combined with a conference, to stimulate the presentation and exchange of results of clinical and basic research with other groups or colleagues, not necessarily LCCG members. Representatives of pharmaceutical companies can receive "ad hoc" invitations to this meeting.

- Independent Radiology review meetings

This meeting is trial-based and is held on request of the study co-ordinator and/or pharmaceutical company. Two independent radiologists are appointed to assess radiological responses. Study participants, study co-ordinator, Data Centre representative(s) and a representative of the pharmaceutical industry supporting the trial can attend the meeting.

4.4 Coordinatorship

— 4.4.1 New protocols

A new protocol outline development is initiated by active members on request by any member of the Group during an official business meeting or on request by the Chairman of the group. New studies must fit into the research program approved by the LCCG and should not be competing with current trials. Upon acceptance by the LCCG Steering Committee, a protocol writing committee is formed, consisting of the initiating member (who will become the study co-ordinator of the new protocol) and other experts if required. The Chairman of the specific sub-committee and the Data Centre team will help designing the new protocol. Other study co-ordinators can be assigned to one single trial if this is felt as needed.

4.4.2 Study Co-ordinators

The study co-ordinator(s) will have a major role in protocol development, central initiation and follow-up of the study in close collaboration with the Data Centre, participation in the study conduct and he/she will be responsible for the writing of abstracts and papers according to the rules for publication.

Study co-ordinators 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:

- Submission of the protocol and/or amendment to the NTC-PRC after full agreement on the protocol and/or amendment from the Data Centre team and Chairman of the specific sub-committee.
- Support the Data Centre in designing the study specific forms.

- The correct execution of the protocol, with the help of the Data Centre and for resolving any difficulties which may arise during the study (accrual issues, questions raised by participating institutions, etc.).
- The central evaluation of the patient charts at the EORTC Data Centre. Funding are provided by the group for two visits a year, however, costs should be kept as minimal as possible.
- The preparation of appropriate publication material, obtaining agreement of all authors concerned.

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A study co-ordinator 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).

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 co-ordinate concurrently more than 2 studies.

4.5 Quality Assurance Procedures

4.5.1 Minimum requirements

The minimal requirements for QA within EORTC Co-operative Groups include:

- Nomination of a responsible investigator (QA Chairman) and creation of a Quality Control (QC) committee
- Writing of a report to the EORTC Quality Assurance Committee on an annual basis.
- Regarding individual institutions, minimal requirements for QA include data timeliness, ratio eligible / registered patients in the trials, and quality of data per institution (compliance with protocol requirements like submissions of pathology slides and radiology evaluations for independent review).

4.5.2 Trial-oriented procedures

Quality control procedures

The procedures implemented within the QA Programme of the LCCG 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.

QA of patient and treatment data

EORTC LCCG trials are designed according to the ICH/GCP guidelines. Quality of data is reviewed by the Quality Control Committee. With regard to phase III trials, study co-ordinators are urged to follow narrowly the quality of data collected at the Data Centre.

4.6 Application for membership of the LCCG

A new centre should send a written application to the Chairman of the group, giving details of the institute and its Oncology / Pulmonology 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 together with his/her CV. A copy of that letter should be sent to the Medical Advisor of the LCCG at the EORTC Data Centre.

— If the applicant works in a centre that is already a member-institution, a letter of recommendation of a representative of that institution should accompany the application.

A representative of an active member-institution who changes hospital can apply for immediate active membership of his new institution for 2 years but need to complete a new lung application form for administrative reason.

The Chairman will inform the Secretary, Treasurer and QA Chairman of the new application. The Secretary will sent the quality assurance questionnaire to the new applicant to be completed and returned as soon as possible to the QA Chairman of the group. A copy of the QA questionnaire must be sent to the Medical Advisor at the Data Centre. All new applications received will be discussed at the next Executive Board meeting. The Executive board has 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 centre doesn't have the necessary infrastructure or for other reasons. Applicants will receive an invitation to the next business meeting. They can be asked to present their centre and activities. Every application approved by the Executive board will be transmitted to the Medical Advisor of the LCCG at the EORTC Data Centre, including the list of trials allowed to participate in. A standard information package (including the lung application form, one-page overview of the ongoing protocols for which the applicant is allowed to participate in and a copy of the LCCG statutes) will be sent by the Data Centre to the new applicant.

The applicant should return to the Data Centre as soon as possible the completed application form and the trials he/she is interested in to participate together with his/her current CV and the current referential laboratory values of his institution.

4.7 Publication Policy.

The final publication and abstracts will be written by the study Co-ordinator(s) on the basis of the statistical final analysis performed at the EORTC Data Centre. The study Co-ordinator works in close co-operation with the EORTC Data Centre. Data will not be released from the Data Centre without permission of the study Co-ordinator(s) and the Group Chairman. A draft manuscript will be completed no later than 4 months after final analysis. The final draft will be circulated to all co-authors, possible pharmaceutical company, and then submitted to a scientific journal.

Data may not be used in oral or written form (abstracts, interim publications or presentations) without being approved by the LCCG Chairman, the study Co-ordinator(s) and the Data Centre.

All publications and oral presentations undertaken on behalf of the group will have EORTC Lung Cancer Co-operative Group in their title or in their authorship and the final content must be approved by the Chairman and Secretary of the group, study Co-ordinator, as well as by the EORTC LCCG Statistician and Medical Advisor.

Authorship is assigned by the study Co-ordinator(s) and Chairman and includes as co-authors who have actively participated in the study.

- the study Co-ordinator(s) (first author)
- for phase II studies, the names of the representatives of the member institutions which have contributed 10% or more of the eligible patients on which the publication is based. For phase III studies, the cut-off is 5%.
- the LCCG Chairman (last author)
- 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 Co-ordinator and Chairman.
- the names of the EORTC DC representatives (minimal 2) of the LCCG

- on request, the name of one representative per pharmaceutical company in sponsored studies *.
- all other participants to the study will be acknowledged in an appendix of the publication

* In sponsored studies, more names of pharmaceutical company representatives can be mentioned in the "Acknowledgements" depending on the agreement and involvement made with the company.

Publications in co-operation with other EORTC Co-operative 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.

If the study Co-ordinator(s) for some reason cannot comply with the deadline of 4 months, another investigator, who contributed a major part in the study, will be appointed by the Chairman of the group and will be the new first author.

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 Centre for information and inclusion in the group bibliography. All accepted abstracts and publications must also be sent to all co-authors.

4.8 Finances

The yearly balance has to be approved by the LCCG Chairman and at least one active member of the group. The treasurer is responsible for the presentation of an overview of the account of the LCCG at each business meeting or when required.

The LCCG funds consist of:

- Yearly EORTC grant
- Financial contributions of pharmaceutical industry, related to the conduct of a certain trial. These are negotiated by the LCCG Chairman, the study Co-ordinator and the Data Centre. All financial contributions will be centrally handled by the treasurer and allocated according to decisions taken by the

Steering Committee. In principle the investigator fee for these trials will be not less than 50 % of the amount received per patient by the sponsor.

- Other sources

In general, secretarial costs and costs enquired for the functioning of the group (organisation of group meetings) will be covered.

The LCCG expenditures consist of:

Limited financial support is available for the following purposes:

- Costs for EORTC LCCG Statistician and Data Manager to attend the business group meetings. The costs of the EORTC Medical Advisor will alternatively be supported by the EORTC DC and the LCCG group.
- Representatives of active member institutions who are asked to perform quality control studies or review of data at participating centres
- Study co-ordinator visits to the Data Centre (on the basis of two visits per year)
- Non-members who are invited to group meetings to give specialist presentations
- Group officers in mission
- Liaison persons in mission
- Investigators fees for non-sponsored trials will depend on the health of the finances of the LCCG. This fee is typically intended to help institutions that have a large accrual and are economically weaker. The decision of the fee will be reassessed every year and discussed during the Steering Committee meetings.

Proposed expenditures should have the prior approval of the Treasurer.

In the framework of investigators fees, 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.

5. Relationship of the LCCG with the Central Office at the Data Centre

The Chairman of the LCCG is member of the EORTC General Assembly for the duration of the mandate. For all trials, sponsored or not, optimal communication between Chairman, study Co-ordinators and the Director General of the EORTC Data Centre is mandatory to provide adequate insurance coverage.

6. Liaison with other EORTC groups or bodies

In order to improve the relationship with other EORTC Co-operative 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 LCCG 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 cooperative 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 Co-operative 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.

7. Relationship with pharmaceutical companies

Contact with pharmaceutical companies should only be entered into by the study Co-ordinator 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 Medical Advisor and Statistician at the Data Centre should be involved up-front in any negotiations.

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

Approved by the Steering Committee of the EORTC LCCG,
on, 1999

EORTC, Brussels, Belgium

The Chairman: G. Giaccone

The Secretary: J. Van Meerbeeck

The Treasurer: P. Baas