

STATUTES OF THE EORTC GENITO-URINARY GROUP

June 2007

1. OBJECTIVES OF THE EORTC GU GROUP

All EORTC GU Group activities are activities divided into clinical research and laboratory research conducted by a multidisciplinary group. The objectives of the EORTC GU Group are as follows:

1. To co-ordinate and promote multidisciplinary approach to research on urological cancer treatment through clinical urological cancer trials and where possible integrating translational research programmes. To this purpose novel and innovative trials that cover studies from early drug development up to large phase III clinical trials will be designed and executed looking at strategic therapeutic questions which will influence the urological cancer-related practice or improve fundamentally the understanding of the disease. Trials are conducted within the framework of the European Organisation for Research and Treatment of Cancer (EORTC) and/or within intergroup studies.
2. To develop, stimulate and co-ordinate clinical, translational and basic research studies in urological cancer within the framework of the European Organisation for Research and Treatment of Cancer (EORTC) and/or within intergroup studies.
3. To encourage scientific research in urological cancer, support the collaboration between basic medical research scientists and clinicians and strengthen the direct interaction between basic research and clinical activities (from bench-to-bedside).
4. To broadcast information thus acquired at the biannual meetings of the EORTC GU Group and by publication in peer-reviewed scientific journals and a newsletter.
5. To support and participate in educational efforts by organizing meetings and conferences in the field of urological cancer.

2. EORTC MEMBERSHIP

Institutional membership of the EORTC is allocated by the EORTC to Institutions and is a prerequisite for EORTC Group membership. On a yearly basis the EORTC Data Center will review the activities of the Institutions during the previous 3 years. A minimum of 15 patients recruited in the previous 3 years is required for renewal of membership of an Institution. Institutions who fail to contribute at least 15 patients in 3 years will not be invited to participate in new studies. They will remain in the studies for which they are currently activated because follow-up of the randomized/registered patients is essential.

3. EORTC GU GROUP MEMBERSHIP

Membership is primarily linked to an institution. If the key person moves, the institution must come up with a suitable replacement. If available, this site remains a full member. If the person who moves wishes to remain a member, he may apply for probationary membership. Institutions applying for membership of the EORTC GU Group have to apply to the EORTC Membership Committee who will then inform the Secretary of the GU Group if their application is successful. Applicants may receive a site visit from a member of the Quality Assurance Committee of the EORTC GU Group. He/she will look at the facilities provided at the hospital and interview physicians of all specialties participating in EORTC GU Group studies (urologists, medical oncologists, radiation oncologists, radiologists, pathologists) and a written report will be sent by the visitor to the Secretary. The Executive Committee of the EORTC GU Group will then decide for a 2-year admission as an Associate Member of the EORTC GU Group.

In addition to the Central Institutional membership (see EORTC membership), the EORTC GU Group has membership rules which they use to upgrade Associate Members to Full Members.

The EORTC GU Group is a multidisciplinary group and EORTC GU Group membership is also allocated to Institutions.

Depending on the number of patients per year entered into the group's trials, Institutions can nominate Full Members and/or Associate Members. New members receive the status of Associate Member for an observational period of 2 years. During this period a minimum number of patients per year must be entered. If, within this 2-year period the Associate Member has contributed substantially to the work of the GU Group by putting the appropriate number of patients in GU studies, the Associate Member becomes a Full Member. The exact numbers of patients required will be determined by the Executive Committee of the EORTC GU Group. The status of all members of the Group will be revised at the beginning of each year by the Secretary and agreed by the Executive Committee of the EORTC GU Group. The member Institutions will be informed thereafter about their status. All members of the EORTC GU Group will receive correspondence from the GU Group.

In addition to patient numbers, the quality of protocol adherence and generated data will be subject to evaluation, and will be included in the evaluation of membership status.

4. CLASSES OF MEMBERS:

There are four classes of membership: FULL MEMBER, ASSOCIATE MEMBER, CONSULTANT and HONORARY MEMBER.

4.1. ASSOCIATE MEMBER

An Associate Member is either a new member or a Full Member who has failed to maintain full membership status by not accruing the appropriate number of points in the previous years. When the Associate Member has acquired the required number of points over a period of 1-2 years, s/he will become a Full Member.

Associate Members are considered to become Full Members after a 2-year period, during which the institution must:

1) accrue the required number of points during the previous 2 years as agreed by the Executive Committee of the EORTC GU Group, by entering new patients in open EORTC GU Group protocols.

ONE POINT is awarded for each NEW ELIGIBLE and FULLY EVALUABLE PATIENT admitted to an EORTC GU Group open protocol including intergroup trials where the GU Group is an official participant. Fractions of points can be awarded for participation in special projects or studies. Such projects, side studies, basic research, translational research, epidemiological research, etc. will be selected by the Executive Committee of the EORTC GU Group. ONE POINT is also awarded for every 10 patients in follow-up two years after randomisation. Only ONE full membership per institution is allowed due to points awarded for follow-up patients.

2) participate in at least one General Assembly of the Group each year.

If the members in an institution fail to comply with these requirements, the decision to exclude the institution will be proposed by the Secretary to the Executive Committee.

4.2. FULL MEMBER

Full membership is granted to institutions that fulfill the above-mentioned criteria continuously. Each Full Member has to attend at least one General Assembly each year.

A new responsible physician at an institution (hospital) already approved by the EORTC has to apply to the EORTC Membership Committee for membership. A Full Member who changes hospital has to apply to the EORTC Membership Committee for membership.

The Chairman, Vice-Chairman, Secretary and Treasurer of the EORTC GU Group and the chairpersons of the five disease-oriented Committees automatically become Full Members for the duration of their mandate.

4.3. HONORARY MEMBER

The Executive Committee of the EORTC GU Group can nominate Honorary Members. A member can receive the title of Honorary Member for exceptional services rendered to the GU Group. This exempts him from fulfilling the normal admission criteria in terms of accrual.

4.4. CONSULTANT

Consultants will be appointed for three years, and this term may be renewed for a further three years.

Clinicians or other scientists who, because of their specialized interest in some aspect of urological cancer, have contributed to the work of the EORTC GU Group may be invited to become Consultants.

Clinicians or other scientists who contribute to the work of the EORTC GU Group but who, because of their speciality or for other reasons, are unable to enter patients into protocols, may be invited to become Consultants to the Group. If Consultants are able to comply with the requirements of full membership, they may regain full membership status.

5. PRIVILEGES OF FULL MEMBERS

5.1. PRIVILEGES OF FULL MEMBERS

1. The opportunity to be an Officer of the EORTC GU Group.
2. The opportunity to write and co-ordinate protocols and be members of the Committees of the EORTC GU Group.
3. Receipt of the EORTC GU Group Newsletter.
4. The opportunity to present material from Group trials at national and international meetings after a written request has been sent to the chairman of the EORTC GU Group.
5. Voting rights.

5.2. PRIVILEGES OF HONORARY MEMBERS

1. Voting rights.
2. Receipt of the EORTC GU Group Newsletter.

5.3. PRIVILEGES OF CONSULTANTS

1. The opportunity to write and co-ordinate protocols and be members of the Committees of the EORTC GU Group.
2. Receipt of the EORTC GU Group Newsletter.
3. The opportunity to present material from Group trials at national and international meetings after a written request has been sent to the chairman of the EORTC GU Group.

6. RESIGNATION OR EXCLUSION OF A MEMBER

The members of the EORTC GU Group may resign any time by informing the Executive Committee of the EORTC GU Group.

Exclusion of any member may be proposed by the Executive Committee of the EORTC GU Group or by the General Assembly of Full Members and Honorary members with a majority of four-fifths of present members, if the member ceases to hold the qualifications which justified his admission, in the case of non-participation in the activities of the EORTC GU Group and in the case of serious misconduct of a nature that will harm the good reputation of the EORTC GU Group.

If a member of the EORTC GU Group is found to be involved in clinical and/or scientific misconduct or gross violation of the Statutes of the Group, the Executive Committee of the EORTC or of the GU group will decide on further actions with unanimous agreements and may terminate the membership immediately. The decisions of the Executive Committee will be presented to the Group at the next meeting for approval. The chair of the Group will inform the Data Center who must inform the Study Coordinator, the Chairman of the group, the Director of DC, the Board as well as the Quality Assurance Committee to take appropriate actions

Members who have resigned or who have been excluded shall have no claim or right over the funds of the EORTC GU Group. The institution should guarantee the follow-up of patients already randomised in trials.

7. BUSINESS MEETING

The General Assembly is the business meeting of the EORTC GU Group. Except for the exceptions by law or by the Group's Statutes, the decisions are made by a majority of the votes of the present Full Members and Honorary Members. The General Assembly will only make a statement concerning the matters that are on the agenda, except by unanimous decision. The decisions will be registered and this document will be signed by the Chairman and Secretary; the Secretary will put the decisions at the disposal of the members.

The General Assembly is, broadly, authorized to:

1. delineate a strategy and define the policy of the EORTC GU group;
2. approve the financial statement presented by the Treasurer, as well as the activity reports, the budget and accounts;
3. change the Statutes.

The General Assembly shall reassemble automatically, except where the Executive Committee of the EORTC GU Group shall decide otherwise, every six months (twice a year). Extraordinary meetings may be organised either by the Chairman or by the Executive Committee of the EORTC GU Group. The right to vote is only given to Full Members and Honorary Members, with one vote per Full Member or Honorary Member.

Minutes of the General Assembly will be included in the next Newsletter. The names of the participants are included in the minutes.

8. OFFICERS OF THE EORTC GU GROUP

8.1. EXECUTIVE COMMITTEE OF THE EORTC GU GROUP

Officers will be elected by Full Members and Honorary members. The members of the Executive Committee of the EORTC GU Group are the Chairman, the Vice-chairman, the Secretary and the Treasurer.

The Chairman will occupy the post for a period of 3 years. The 3-year tenure will be preceded by 18 months as Vice-Chairman and followed by a further 18 months as Vice-Chairman. The Chairman of the EORTC GU Group shall have overall responsibility for the whole Group and will represent the Group, when necessary, to the Board or Council of the EORTC. S/He will represent the GU Group at international meetings and will chair all biannual meetings occurring during the tenure of office.

The Vice-Chairman will occupy the post for the 18 months prior to and the 18 months following Chairmanship, thus ensuring that one person is Chairman or Vice-Chairman for a total period of 6 years.

The Secretary will serve for 3 years.

The Secretary is responsible for the transmission of information to members of the Group and for assisting in organizing meetings of the EORTC GU Group, the Scientific Board and the Executive Committee of the EORTC GU group in co-operation with the Chairman.

The Treasurer will occupy the post for 3 years, and this is renewable. S/He is responsible for the management of the GU Group finances.

The ex-officio (non-voting) members of the Executive Committee are one statistician from the Data Center involved in the EORTC GU Group trials and the Coordinating Physician from the Data Center. Members of the GU Group may be invited to join the Executive Committee as non-voting members on a temporary basis in order to help or advise the members of the Executive Committee.

The Executive Committee will meet 4 to 6 times per year, 2 of these meetings immediately preceding or immediately after the biannual GU Group meetings. They are responsible for coordination between all members of the Group and between the GU Group and other EORTC Groups and the EORTC Data Center. All Officers of the GU Group of the EORTC must comply

with the various EORTC policies (available on the EORTC website). They are responsible for providing a yearly report on the activities of the Group for submission to the EORTC General Assembly.

The Executive Committee of the EORTC GU Group has all supervision and executive competences of the GU Group, except for the competences assigned to the General Assembly. The Executive Committee can delegate the executive tasks or a part of its competences to certain executive members, to members of the GU Group or to appointed members/officials.

All decisions of the Executive Committee are taken by a simple majority of votes, on condition that at least 50 percent of the members entitled to vote are present or represented.

The decisions of the Executive Committee are registered in the minutes; the Secretary will keep the records at the disposal of the members.

The Executive Committee of the EORTC GU Group shall have all powers of management and administration of the GU Group on the authority of the General Assembly.

The chairman has the mandate to sign contracts with representatives of the pharmaceutical industry regarding studies to be performed within the EORTC GU Group.

8.2. REPRESENTATION OF THE EORTC GU GROUP IN THE EORTC GENERAL ASSEMBLY

The chairman of the Group has to be approved by the EORTC Board and automatically becomes a full member of the EORTC General Assembly for the duration of his/her mandate.

9. COMMITTEES OF THE EORTC GU GROUP

9. 1. SCIENTIFIC BOARD

The Scientific Board (SB) will be responsible for the strategies, selection and supervision of the work of the EORTC GU Group and guiding the Group's clinical trials and research activities.

The Scientific Board will be composed of the members of the Executive Committee of the EORTC GU Group together with the Chairpersons of the Disease-Oriented Committees, i.e. renal, non-invasive bladder, advanced bladder, prostate and testicular cancer Committees. Chairpersons of Disease-Oriented Committees will be proposed by the Executive Committee of the EORTC GU Group and will hold office for a maximum period of 3 years, renewable. The Scientific Board meets at least twice a year, usually just before each of the two meetings during the biannual Group meetings.

The Scientific Board is responsible for determining the priorities of protocols prior to submission to the EORTC Protocol Review Committee. The final decision about the priorities and activation of studies will be taken by the Executive Committee of the EORTC GU Group.

.All members of the Scientific Board of the GU Group of the EORTC must comply with the various EORTC policies (available on the EORTC website)

9. 2. DISEASE-ORIENTED COMMITTEES

The work of the EORTC GU Group will be discussed and planned by the Disease-Oriented Committees i.e. renal, non-invasive bladder, advanced bladder, prostate and testicular cancer Committees. These Committees will be responsible for the discussion of new ideas for clinical trials and the preparation of protocols for consideration by the Executive Committee of the EORTC GU Group and Scientific Board. The Disease-Oriented Committees will consist of specialists involved in the field of research and treatment of GU tract cancer and need to include urologist(s), medical oncologist(s), a statistician, and preferably a radiation oncologist, pathologist, radiologist and basic scientist, if appropriate.

Each Committee will consist of an adequate number of members, including a Chairperson and Secretary. The officers and membership will change/rotate on a 3-year basis. If applicable,

experts from outside the EORTC GU Group from NOCI or other centres can be invited to each Committee in order to prepare new studies and translational research projects. Every EORTC GU Group member willing to be a member of the Disease-Oriented Committees has to apply directly to the Chairperson of the relevant Committee. The members will select their Secretary. The Committees will meet at the time of the GU Group meetings and once or twice per annum in addition, as necessary for the preparation of new protocols. The Disease-Oriented Committees should preferably communicate between meetings, by either holding meetings or telephone conferences.

The Chairperson or Secretary will forward to the Executive Committee the date, venue, and agenda of their meetings at least 1 month before the meeting. In order to speed up the development of new studies, the action points that have been discussed during the meeting have to be communicated to the Executive Committee within two weeks of each meeting. Regular (2-monthly) telephone conferences of the Scientific Board with the Executive Committee of the EORTC GU group will be organized to evaluate the progress of the action points discussed in the different Committees and to offer help whenever possible. The Chairpersons of the Committees will prepare a report of his/her Committee's activities for inclusion in the GU Group Newsletter and for presentation at the biannual Group meetings.

10. ELECTION OF THE EXECUTIVE COMMITTEE

The Chairman, Secretary and Treasurer are elected during the General Assembly by the attending Full Members and Honorary Members. Any Full Member can be a candidate. Written proposals for candidates for every position should be forwarded to the Executive Committee of the EORTC GU Group three months before the elections. The list of proposed candidates will be published in the Newsletter prepared before the General Assembly during which elections will be held. Candidates will make a short presentation during the General Assembly and voting will then take place.

The Secretary will prepare a list of members having the right to vote and voting forms. Each voting member will sign the list and receive a voting form. Voting forms will list the candidates' names and the position for which they have applied. A commission for counting the votes will be approved by the General Assembly and will consist of at least two members. The result of the election will be officially communicated by the Chairman at the end of the General Assembly. The Chairman Elect has to be approved by the EORTC Board.

11. STUDY COORDINATOR

Protocols are commissioned from Full Members, Associate Members and Consultants during an official meeting or on request of an officer of the Group. The member who develops a clinical trial into a full protocol and gets EORTC approval will be the Study Coordinator of that protocol. S/He will also present the data of the study at meetings and write the abstracts and papers according to the above mentioned rules, as well as the rules laid down in the EORTC Investigators' Handbook. Study coordinators of ongoing studies are encouraged to attend every group meeting. There is one Study Coordinator (and possibly one co-coordinator) for each protocol. The Study Coordinator is responsible for the protocol and should visit the Data Center to review all relevant data sheets with the Data Manager, clarify all discrepancies with responsible participants and provide such advice, guidance or direction as may be necessary to ensure the highest possible quality of the trial for which s/he is responsible. The Study Coordinator will be reimbursed for the cost of travelling to the Data Center twice (maximum) a year for this purpose.

When a protocol has been completed the Statistician is responsible for analyzing the results. The Study Coordinator discusses the outcome with the Statistician, Coordinating Physician, Data Manager and members of the relevant Disease-Oriented Committee and suggests further analysis if appropriate. The report of the outcome of that discussion should be forwarded to the Executive Committee of the EORTC GU Group. Thereafter, the Study Coordinator is responsible for presenting the results to the EORTC GU Group and, in close cooperation with the Statistician, for writing abstracts and/or draft manuscript within 3 months and the final manuscript of the results of that trial within 6 months of its completion. S/he is

also responsible for the initial presentation of the results at a suitable international meeting. Final consent concerning the presentation of the results at suitable international meetings should always be obtained prior to the presentation from the Executive Committee of the EORTC GU Group. In the event that the Study Coordinator does not comply with these rules, the Executive Committee of the EORTC GU Group will appoint a new Study Coordinator.

12. MEETINGS OF THE EORTC GU GROUP

There will be two General Assembly meetings each year. It is the duty of the Secretary to ensure that members attending the meetings receive adequate notification at least 6 weeks prior to the meeting. Members willing to organize a General Assembly should send a written request to the Executive Committee of the EORTC GU Group at least 1 year in advance, providing evidence of financial support. They must commit themselves to obtaining financial support for the meeting. A Newsletter containing a summary of the current status of the Group's trials and other relevant information will be available before the meeting.

13. FORMAT OF BI-ANNUAL MEETINGS

Meetings will last for one and a half day and will usually be held on Friday and Saturday morning. The meeting of the whole Group will be preceded by meetings of the Scientific Board. On the day prior to the EORTC GU Group meeting and at the end of the meeting, the Executive Committee of the EORTC GU Group will meet. The meetings of the various Disease-Oriented Committees should run in a sequential manner so that all members have the opportunity to attend every discussion.

14. AGENDA FOR THE MEETING OF THE EORTC GU GROUP

1. Apologies for absence
2. Minutes of previous meeting and matters arising
3. Scientific presentations
4. Reports from Disease Orientated Committees, including updates of ongoing trials and proposals for new protocols
5. Chairman's report
6. Treasurer's report
7. Vice-Chairman's report
8. Secretary's report, including review of membership status, welcome of new members, dates of future meetings
9. Report of the editor of the Newsletter, presentation of arrangements for the next meeting by the local organiser, and any other business.

All members of the EORTC GU Group and representatives of the Data Center are expected to attend the General Assembly. Experts and young (clinical) researchers from outside the EORTC GU Group can be invited to give scientific presentations, if appropriate. Representatives of other collaborative groups or scientific societies can be invited to deliver a lecture.

Representatives of pharmaceutical companies or other companies active in the field of oncological urology or in other fields considered of interest can attend the General Assembly as observers, provided that the Executive of the EORTC GU Group received notification at least two weeks prior to the meeting and has given their consent. Other investigators can attend the General Assembly by invitation.

15. NEWSLETTER OF THE EORTC GU GROUP

The Newsletter will be available on-line to all members. The issue of the Newsletter published immediately prior to the biannual EORTC GU Group meetings will contain minutes of all meetings held in the previous 6 months, the full Data Center report, one-page summaries of ideas for new protocols and all other relevant matters due to be discussed at the meeting as well as publications of EORTC GU Group studies.

16. FORMULATION OF NEW PROTOCOLS

Any Full Member, Associate Member or Consultant is entitled to write a protocol for consideration by the relevant Disease-Oriented Committee. The outline must be submitted to the Executive Committee of the EORTC GU Group by the proposer after the approval of the appropriate Committee. It will be discussed by the Scientific Board, which will judge its scientific and strategic aspects. The Executive Committee of the EORTC GU Group will select protocols to be submitted to the EORTC Protocol Review Committee after having examined the financial aspects and explored their feasibility with the Coordinating Physician and Data Center representatives. No outline should be submitted to the Protocol Review Committee until it has received the approval of the Executive Committee of the EORTC GU Group. The procedure for submission of new protocols to the EORTC Protocol Review Committee (PRC) can be found on the EORTC website www.eortc.be. In addition to a scientific review by the PRC, the trial's feasibility and priority within the EORTC as a whole will also be assessed.

17. CONDUCT OF CLINICAL TRIALS

The conduct of Phase II and Phase III trials is one of the main purposes of the EORTC GU Group. The clinical design of trials is the responsibility of the relevant Disease-Oriented Committee. The Data Center team allocated to the study will aid the Study Coordinator in protocol development. The Study Coordinator is responsible for the day-to-day supervision of the trial once it has been activated together with the review of all data collection, with the assistance of Data Center staff. The principles of trial development and conduct can be found in the Investigator's Handbook and EORTC Policies available on <http://www.eortc.be/Services/Doc/documents.htm>

18. PARTICIPATION IN AN EORTC GU GROUP TRIAL

Any member can participate in a Group trial after fulfilling the administrative procedure as described in Appendix II.

19. CLINICAL TRIAL DATA

Data will not be released from the EORTC Data Center without the permission of the study coordinator, the chair of the Group and the medical advisor/statistician. Data may not be used in oral or written form without the permission of the study coordinator.

20. RELATIONS WITH THE EORTC DATA CENTER AND WITH THE CENTRAL OFFICE

Close collaboration between the Chair, Study Coordinators, and the EORTC Data Center Group- staff and EORTC Data Center Director is essential.

All protocols to be submitted to the Protocol Review Committee and to the Translational Research Advisory Committee must be reviewed by the EORTC Data Center staff (coordinating physician, statistician, data manager, and quality of life and health economics specialists when appropriate) prior to their submission.

For sponsored trials, negotiations with pharmaceutical industries should be carried out jointly by the Chair of the Group, the Group coordinating physician, the Data Center Contract Manager and the Director of the Data Center to guarantee financial support for the management of the study, and to assure optimal services to the pharmaceutical industries. For all trials, sponsored or not, optimal communication between the Chairpersons of the Groups and the Regulatory Affairs Manager of the EORTC is also mandatory to provide adequate insurance coverage for all studies which are conducted with the EORTC label and under EORTC legal responsibility.

All applications for funding by the European Commission or by any other granting agencies on behalf of an EORTC Group, or bearing the name of the EORTC and involving EORTC, should be transmitted prior submission to the EORTC Headquarters (Director General) for appropriate coordination.

21. PUBLICATION POLICY OF THE GU GROUP

All Group publications, oral and written, will have "EORTC GU Group" in their title or authorship. The content of all reports of EORTC GU Group trials, including publications, abstracts and presentations based on patients included in an EORTC GU Group study, must

be approved by the Executive Committee of the EORTC GU Group and the Study Coordinator and be circulated to all co-authors before submission for publication/presentation.

The publication policy is to publish the results of completed protocols at the earliest opportunity in a reputable journal. Until publication, these results are not available for dissemination in any other journal or monograph. Results may not be published or presented at any national or international meeting until after the trial has reached maturity (the number of events required by the protocol has been attained). The Study Coordinator is responsible for presenting the results of the protocol to the Group, writing the first paper presenting the results of the protocol and for the initial presentation of these results at a suitable international meeting.

If the Study Coordinator is not able to finalize a draft and-or final manuscript within the desired time frame following completion of the study, the co-coordinator or a person proposed by the Executive Committee of the EORTC GU Group will write the manuscript.

The authors will consist of: the Study Coordinator and Study Co-coordinators; those members who have contributed 10% or more of the eligible patients in Phase II trials / 5% or more of the eligible patients in phase III studies; the Statistician; one other Data Center representative.

The first author of every manuscript carrying the EORTC GU Group name is responsible for obtaining the approval of the Executive Committee of the EORTC GU Group before submission to a journal. The first definitive publication of a trial will include a complete list of the participants in the reported study. All subsequent oral presentations should also list all participants (in a short oral presentation this might not be feasible if there are a very large number of participating institutions).

When a manuscript has been accepted for publication the Study Coordinator or the person in charge should send a copy to the editor of the Newsletter for publication in the next issue. By this means all participants and EORTC GU Group members will be kept informed of the final outcome of the work of the EORTC GU Group.

Following the initial presentation and publication of the results, any of the authors or any Full Member,, Associate Member, Honorary Member or Consultant of the group may present the results at suitable meetings with the agreement of the Study Coordinator and the Executive Committee of the EORTC GU Group.

Copies of slides for presentation may be obtained from the Study Coordinator or the Data Center.

The Executive Committee of the EORTC GU Group supervises publication policy. A full list of recent publications and presentations made by members is always available at the Data Center. A list of all publications in peer-reviewed journals is maintained on the GU Group website www.eortc.be/home/qugroup.

22. ALTERATION OF THE STATUTES OF THE EORTC GU GROUP

Any Full Member, Honorary Member or Consultant is at liberty to suggest alterations to these statutes. These suggestions should be submitted as written request for modification initially to the Chairman of the EORTC GU Group for consideration by the Executive Committee, preferably at their meeting 3 months before a EORTC GU Group General Assembly. The Chairman or a representative of the Executive Committee will then discuss the proposal with the proposer and will agree its submission in an appropriate form for consideration by the whole of the EORTC GU Group at its next meeting. Its discussion in the General Assembly is followed by a vote and majority of votes is necessary for its acceptance.

23. RELATIONS WITH PHARMACEUTICAL COMPANIES

Financial support from a pharmaceutical company will be negotiated by the chairman, the coordinating physician of the EORTC Data Center and the study coordinator.

Any data transfer to the pharmaceutical industry should be approved by the chair, the coordinating physician of the EORTC Data Center and the study coordinator.

APPENDIX I: POINTS REQUIRED FOR MEMBERSHIP

1. A minimum of 10 points is required for FULL MEMBERSHIP. In the event of few open trials, the Executive Committee of the EORTC GU Group may reduce this number.
2. Those with less than 10 patients will be classified as ASSOCIATE MEMBERS.
3. An institution may have one FULL MEMBER for each multiple of 10 points (with a maximum of 4 Full Members) and a maximum of one ASSOCIATE MEMBER for any fraction beyond a multiple of 10.
4. Thus an institution with 19 points would qualify for 1 FULL MEMBER and 1 ASSOCIATE MEMBER, an institution with 21 points would qualify for 2 FULL MEMBERS and 1 ASSOCIATE MEMBER whereas an institution with 65 points would qualify for 4 FULL MEMBERS and 1 ASSOCIATE MEMBER. Only 1 additional full membership may be gained as a result of points obtained for follow-up.

Any member who disagrees with the assessment of their membership status may write to the Executive Committee with supporting details.

APPENDIX II: Participation in EORTC GU GROUP TRIAL

The investigator must contact the EORTC Data Manager of the trial.
Data manager of trial no 30..., EORTC Data Center, Ave. E. Mounier 83/11, 1200 Brussels

The ICH-GCP guidelines require that all investigators participating in a trial should be qualified by education, training and experience to assume responsibility for the proper conduct of the trial.

The Data Manager will reply by a letter or e-mail, requesting the following information:

1. Curriculum vitae updated at least every three years
2. The normal laboratory ranges applicable for the Institution (minimum every two years)
3. A certificate of quality standards of the laboratory (this document is only needed for particular studies)
4. Ethics Committee approval for this specific protocol and list of Ethics Committee members
5. Commitment Statement, which includes disclosure of potential conflict of interest/acknowledgement form
6. Signature log for all delegated persons within the Institution with properly defined delegation of responsibilities (the PI is responsible for keeping the curriculum vitae of all delegated persons properly filed in his Study Master File, and providing it to EORTC upon request).

The Data Manager will put an institution on the list of authorized participants only upon receipt of the required information. This will enable the institution to enter patients into the trial. The procedure on how to enter patients into a trial is described in each trial protocol.