EORTC
European Organisation for Research and Treatment of Cancer
The future of cancer therapy

Avenue E. Mounier 83/11
1200 Brussels
Belgium
Tel: +32 2 774 1611
Email: eortc@eortc.org
www.eortc.org

Scientific Audit Committee

POL007
Version 3.5

ALWAYS REFER TO THE INTRANET
TO CHECK THE VALIDITY OF THIS DOCUMENT

Author *Director General* Denis Lacombe	Signature:	Date: *(DD-MMM-YYYY)*
Authorized by: *Director General* *on Behalf of the Board* Denis Lacombe	Signature:	Date: *(DD-MMM-YYYY)*

Table of Contents

1 PURPOSE

The EORTC Scientific Audit Committee (SAC) was created to provide independent advice to the EORTC Board regarding the activities of the EORTC Groups and Task Forces.

2 POLICY

SAC reviews are the method by which the EORTC evaluates the effectiveness of the research programs conducted by its Groups and Task Forces (hereinafter referred to as 'Groups').

The SAC is an independent body of experts assembled to review and discuss both the Group's work since the last SAC review and also its future research strategy proposals for the next period. The SAC provides a scientific assessment of each Group's achievements (including publications), ongoing activities and future plans. The SAC can advise the EORTC Board on scientific quality and suggest changes (if any) that would be appropriate to strengthen the Groups and therefore the overall functioning of the EORTC.

The EORTC Board aims to ensure that the financial management of the Groups is handled according to EORTC policies and strategies. SAC reviews should ensure that the structure and management of the Groups are compliant with EORTC policies.

3 RESPONSIBILITIES

- **Group Chair:** Prepare reports to the SAC for the SAC meetings, reply to the recommendations made by the SAC, if applicable. Attend the SAC meeting.
- **EORTC Headquarters Disease / Treatment Oriented Group teams:** Prepare reports with the status of ongoing studies, recently closed studies and studies which are expected to be opened for the SAC meetings.
- **EORTC Director General's Office:** support the organization of the SAC review and meeting throughout the whole process according to this policy.
- **EORTC Compliance & Audits (C&A):** provides assessment concerning the quality of the Groups through means of information on audits, data timeliness or any other relevant information.
- **EORTC Protocol Development Department:** Provide assessment concerning the synopsis and protocols submitted by the Groups.

4 SAC COMPOSITION

SAC consists of up to 15 members, including the SAC Chair and Secretary, plus up to four ex-officio members, i.e., the EORTC Director General, EORTC Headquarters Director and EORTC Scientific Director. The SAC Chair can also decide to invite guests according to needs.

A few Board members are invited to attend the discussion to ensure cohesion and implementation of the EORTC strategy.

Members are committed for a three-year term which is renewable once. Members of the SAC should represent a cross section of opinion and expertise. It is somewhat difficult for oncologists who are not familiar with EORTC policies to perceive conformity or non-conformity with EORTC structure,

policies and strategies. About 50% of members should not be involved in current EORTC activities (e.g. officer of a Group). The choice of EORTC and non-EORTC members must be approved by the EORTC Board upon consultation of the EORTC Headquarters.

The Chair of SAC reviews the composition of the SAC after his/her appointment and proposes new members to the EORTC Board. A turnover of two to three members is recommended to maintain continuity in SAC reviews, i.e. not all members should be renewed at the time of change of Chair.

5 PROCESS FOR EORTC GROUP REVIEW

5.1 Prior to the SAC meeting

All EORTC Groups should be reviewed on a three-year basis unless specific problems require more frequent reviews at the request of the EORTC Board or Headquarters.

The Groups to be reviewed are chosen by the SAC from a list produced by the Director General's Office, indicating the time of previous review of all Groups.

A primary and a secondary rapporteur are designated among SAC members for each Group. The rapporteurs prepare a report based on his/her review of a particular Group and forwards it to all SAC members via the Director General's Office at least two weeks prior to the SAC meeting.

An external review and report may be organized if the designated rapporteurs do not have relevant expertise in the field. The SAC Chair proposes one or more (up to three) external expert(s) in the specific field of the Group to be reviewed (if such expertise is not available within SAC) to provide written comments for the review.

Selection of an external reviewer:

Two important criteria should be taken into account when selecting an external reviewer:

- *Is the proposed person too close to the Group to be reviewed?*
- *Is the individual concerned in conflict with the Group to be reviewed?*

The Groups' review schedule and dates for the SAC meeting are planned about one year in advance by the SAC and the Director General's Office.

The EORTC Director General's Office also informs the EORTC Director General, Compliance & Audits and Protocol Development about the Groups to be reviewed and the schedule at least six months in advance.

The Director General's Office coordinates the preparation of the EORTC Headquarters report in collaboration with the Compliance & Audits, the Clinical Research Physician or the appointed person at the Medical Department, Clinical Operations Manager assigned to the Disease / Treatment Oriented Group and the relevant teams. The report contains the status of ongoing studies, recently closed studies and studies which are expected to be opened; feedback about collaboration with the Group, information about the compliance of participating sites through means of information on audits, data timeliness or any other relevant information.

The EORTC Headquarters reports are reviewed and approved by the EORTC Director General and the Headquarters Director.

Protocol Development prepares a separate report in which the protocol synopsis and protocols submitted by the reviewed Groups are described.

The EORTC Director General's Office circulates the questionnaire designed by SAC, "EORTC SAC: questionnaire to Chairs of EORTC Groups", to the Group Chair at least six months prior to the review and requests a reply to the questionnaire.

The Group should ensure that the completed SAC questionnaire is received by the EORTC Director General's Office at least 8 weeks before the review.

The Director General's Office distributes to the SAC rapporteur (and external experts if any) at least six weeks prior to the review:

- The completed questionnaires;
- The reports coordinated by the relevant departments of the EORTC Headquarters;
- Documentation from the previous review (letter of the EORTC President, SAC recommendations, feedback from the group chair).

The SAC rapporteurs for each group send their reviews to the Director General's office at least two weeks prior to the review. The Director General's office circulates the report to all SAC members.

The documents to be circulated at least two weeks prior to the meeting to all SAC members include:

- Conclusions and SAC recommendations of the previous review for each Group;
- Letter sent by the EORTC President to the Chairs of Groups and response from the Chairs;
- The Rapporteurs' comments;
- The reports prepared by the relevant EORTC Headquarters Departments.

5.2 During the SAC meeting

A separate discussion is organized between the SAC members and the EORTC staff (Clinical Research Physicians or the appointed person at the Medical Department, Statisticians) collaborating with the groups.

The Group's Chair is asked to withdraw following his/her presentation and discussion with SAC members.

Closed discussion among members of the SAC occurs and recommendations are formulated. The Group Chair is then invited back to hear these recommendations and any serious concerns or errors of interpretation or facts can be provided.

5.3 Following the SAC meeting

The SAC Secretary prepares the draft minutes within 14 days, proofread by the SAC Chair as appropriate, and these are circulated among all SAC members. The SAC members, including the SAC Chair, have seven days to review the draft and submit their comments and suggestions to the SAC Secretary. If no comments are received within this period of time, the SAC membership agrees with the contents of the minutes and the Secretary submits the final version to the EORTC Director General's Office.

The EORTC Director General's Office sends SAC members, the EORTC President the final version of the minutes. The SAC Chair also produces a short executive summary of the minutes for circulation to the Board.

This executive summary is discussed at a Board meeting following the SAC meeting. The final SAC minutes/recommendations are then sent by the Director General's Office on behalf of the EORTC President to the reviewed Group's Chair. The Group Chair is requested to respond to the EORTC President regarding the SAC minutes/recommendations within three months after having received them.

The EORTC Director General's Office circulates the Group Chair's response to the SAC members and to the EORTC Board Members.

The SAC Chair presents and discusses his/her report including review, recommendations and feedback from the Group's Chair at the following EORTC Board meeting.

The SAC members receive a final copy of the extract of the minutes of the EORTC Board meeting related to the reviewed Groups.

6 FLOW CHART

Planned timelines	Responsible	Action
- 1 year	Director General's Office	Prepare Group's review list, schedule and meetings
- 1 year	SAC	Agreement on list of Groups to review Designation of the Rapporteur Propose an external review (if applicable)
- 8 months	Director General's Office	Send letter to the Group's Chair to inform on SAC meeting date
- 6 months	Director General's Office	Inform EORTC Director Headquarters, Compliance & Audits and Protocol Development of SAC meeting date and Groups to be reviewed Send questionnaire to Group's Chair
- 2 months	Group's Chair	Send the completed questionnaire to EORTC Director General's Office
- 6 weeks	Director General's Office	Send Group's completed questionnaire, Headquarters reports and documentation to the Rapporteur
- 4 weeks	Director General's Office	Prepare draft program for SAC meeting
- 2 weeks	Rapporteur	Send report on Group review
- 2 weeks	Director General's Office	Send final information package to SAC members
SAC MEETING		
+ 2 weeks	SAC Secretary	Prepare and circulate minutes to SAC members
+ 3 weeks	SAC members	Send comments on minutes to SAC Secretary
+ 5 weeks	Director General's Office	Send final version of minutes to SAC members and EORTC President+ EORTC Board Members
-	Board	Discuss minutes at next EORTC Board meeting

Planned timelines	Responsible	Action
-	Director General's Office	Send final minutes to Group's Chair
-	Group's Chair	Send feedback (to Director General's Office) within three months of receipt of the minutes and recommendations
-	Director General's Office	Circulate Chair's response to SAC and Board members
-	SAC Chair	Present and discuss report, recommendations and feedback at the next EORTC Board meeting.
-	Director General's Office	Send extract of the minutes of the EORTC Board to SAC members

7 DOCUMENT HISTORY

Version N°	Brief description of change	Author	Effective date
1.0	Initial release	Françoise Meunier	08 Sept 1999
2.1		Françoise Meunier	November 1999
3.0		Françoise Meunier	July 2001
3.1	Minor changes, new template, new co-author	Françoise Meunier	29 Aug 2006
3.2	Clarification and update of process	Françoise Meunier	14 Sept 2010
3.3	Update Executive Committee to Board. Update of functions according to current organization chart. Group review on a 3-year basis. Involvement of Clinical Research Physician and Statistician. Clarification of the process.	Françoise Meunier	13 Sept 2013
3.4	Review of timelines and various clarifications Update of responsibilities	Denis Lacombe	15 Dec 2016
3.5	Adaptation to the new organigram	Denis Lacombe	23 Jan 2020