



AISBL International Non-Profit Association under Belgian law IVZW

EORTC  
Avenue E. Mounierlaan 83 / 11  
Brussel 1200 Bruxelles  
België - Belgique  
Tel : +32 2 774 16 11  
Fax : +32 2 772 35 45  
E-mail : eortc@eortc.be  
Web : <http://www.eortc.be>

## Scientific Audit Committee

POL007

Version 3.2

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|   |            |       |
|---|------------|-------|
| Author:<br><i>Director General</i><br>Françoise Meunier                                   | Signature: | Date: |
| Authorized by:<br><i>Director General<br/>on Behalf of the Board</i><br>Françoise Meunier | Signature: | Date: |

**Table of Contents**

1 PURPOSE ..... 3

2 POLICY..... 3

3 RESPONSIBILITIES ..... 3

4 SAC COMPOSITION ..... 3

5 PROCESS OF EORTC GROUP REVIEW ..... 4

    5.1 Prior to the SAC meeting ..... 4

    5.2 During the SAC meeting..... 5

    5.3 Following the SAC meeting..... 5

6 FLOW CHART ..... 6

7 APPROVAL ..... 7

8 DOCUMENT HISTORY ..... 7

## 1 PURPOSE

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

## 2 POLICY

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

The SAC acts as 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 quinquennium. The SAC provides a scientific assessment of each Group's achievements (including publications), ongoing activities and future plans. The SAC also proposes on a set of recommendations with regards to the strategy of the Group. The SAC can advise the EORTC Board on scientific quality and make suggestions about changes (if any) that would be appropriate to strengthen the Groups and therefore the overall functioning of the EORTC.

The EORTC Board wishes 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 financial 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.
- ◆ **Disease / Treatment Oriented Group teams at EORTC Headquarters:** Prepare reports to the SAC for the SAC meetings, detailing the status of ongoing studies, recently closed studies and studies which are expected to be opened.
- ◆ **Director General's Office:** support the organization of the SAC review and meeting throughout the whole process according to this policy.
- ◆ **Quality Systems & Compliance and Quality Control Units at EORTC Headquarters:** Providing feedback about the quality of the different Groups through means of information on audits, data timeliness or any other relevant information.
- ◆ **Protocol Development Unit at EORTC Headquarters:** Providing feedback about the outlines and protocols submitted by the different Groups.

## 4 SAC COMPOSITION

SAC consists of 10 members, including the SAC Chair and Secretary, plus two ex-officio members i.e. the EORTC Director General and the Scientific Director of the EORTC Headquarters.

Members are committed for a three-year term which is renewable. 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 extensive EORTC activities (officer of a Group for example). The choice of EORTC and non-EORTC members must be approved by the Board.

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 OF EORTC GROUP REVIEW**

### **5.1 Prior to the SAC meeting**

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

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

A Rapporteur is designated among SAC members for each Group. The Rapporteur prepares 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.

When necessary, an external review and report are organized if the designated Rapporteur feels that he/she does 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:

There are two important issues to take 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 HQ's Scientific Director, the Quality Systems & Compliance (QS&C) Unit and the Protocol Development Unit about the Groups to be reviewed and the schedule at least six months in advance.

The QS&C Unit coordinates the preparation of the EORTC Headquarters report in collaboration with the Quality Control Unit, the Clinical Research Physician, and the Project Manager(s) of the Disease / Treatment Oriented Group. 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 Protocol Development Unit will prepare a separate report in which the outlines 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 completed SAC questionnaire should be sent by the Group to arrive at the EORTC Director General's Office at least three months before the review (the EORTC Director General's Office sends the necessary reminders).

The Director General's Office distributes:

- ◆ the completed questionnaires to the SAC members (and external experts if any) at least eight to 10 weeks prior to the review;
- ◆ the reports coordinated by the relevant units of the EORTC Headquarters;
- ◆ papers sent out to external referees along with two copies of a confidentiality agreement at least eight weeks before the SAC meeting.

SAC members provide questions/suggestions to be transmitted to the SAC or Group's Chair by the Director General's Office at least four weeks prior to the review.

The Director General's Office sends reminders for referees' comments if not received three weeks prior to the meeting.

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 Units of the EORTC Headquarters.

## **5.2 During the SAC meeting**

There will be sufficient time for feedback of the previous meeting and, subsequently, up to seven Groups could be reviewed. If needed and if problems are anticipated, fewer Groups are reviewed to guarantee in depth discussions.

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, which are circulated among all SAC members asking for comments. The members of the SAC, 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 and the EORTC President (and the Executive Committee) the final version of the minutes within 14 days.

These final minutes are discussed at an Executive Committee 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 Chair, asking for feedback to be sent to the President.

This feedback is sought from Group Chair (with a timetable of actions) within one month after having received the minutes and SAC recommendations.

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

The SAC Chair presents and discusses his/her report including review, recommendations and feedback from the Group Chair at the following EORTC Board meeting. In case of major problems or emergencies, the SAC Chair is invited by the EORTC President to the Executive Committee 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

| 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   |
| - 1 year        | SAC                       | Designation of the Rapporteur   |
| - 1 year        | SAC                       | Propose an external review (if applicable)  |
| - 8 months      | Director General's Office | Send letter to the Group's Chair to schedule SAC meeting date   |
| -6 months       | Director General's Office | Inform Scientific Director of SAC meeting date and Groups to be reviewed                                  |
| -6 months       | Director General's Office | Inform EORTC QS&C Unit and Protocol Development Unit of SAC meeting date and Groups to be reviewed.       |
| - 6 months      | Director General's Office | Send questionnaire to Group's Chair   |
| - 3 months      | Director General's Office | Send schedule of events to Group's Chair  |
| - 3 months      | Group's Chair             | Send the completed questionnaire to Director General's Office   |
| - 8 to 10 weeks | Director General's Office | Send Group's completed questionnaire and Headquarters reports to the SAC members                          |
| - 8 weeks       | Director General's Office | Send documents sent out to external referees (+ 2 copies of confidentiality agreement) to the SAC members |
| - 4 weeks       | SAC members               | Provide questions/suggestions to Group's Chair via Director General's Office                              |
| -4 weeks        | SAC Secretary             | Prepare draft programme for SAC meeting   |

| Timelines          | Responsible               | Action  |
|--------------------|---------------------------|---|
| -4 weeks           | Director General's Office | Send draft programme to Group's Chair   |
| - 3 weeks          | Director General's Office | Send reminders for referees' comments (if applicable)   |
| - 2 weeks          | Director General's Office | Send final information package to SAC members   |
| - 2 weeks          | Rapporteur                | Prepare report on Group review  |
| <b>SAC MEETING</b> |                           |   |
| + 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+ Executive Committee                       |
| NA                 | Executive Committee       | Discuss minutes at next Executive Committee meeting   |
| NA                 | Director General's Office | Send final minutes to Group's Chair   |
| NA                 | Group's Chair             | Send feedback (to Director General's Office) within one month of receipt of the minutes and recommendations |
| NA                 | Director General's Office | Circulate Chair's response to SAC members and Executive Committee   |
| NA                 | SAC Chair                 | Present and discuss report, recommendations and feedback at the next EORTC Board meeting.                   |
| NA                 | Director General's Office | Send extract of the minutes of the EORTC Board to SAC members   |

## 7 APPROVAL

| Version number | Board approval date |
|----------------|---------------------|
| 3.2            | Not applicable      |

## 8 DOCUMENT HISTORY

| Version number | Brief description of change                | Author            | Date           |
|----------------|--|-------------------|----------------|
| 1.0            | Initial release                            | Françoise Meunier | 08/09/1999     |
| 2.1            |  | Françoise Meunier | 11/1999        |
| 3.0            |  | Françoise Meunier | 07/2001        |
| 3.1            | Minor changes, new template, new co-author | Françoise Meunier | 29/08/2006     |
| Version number | Brief description of change                | Author            | Effective date |
| 3.2            | Clarification and update of process        | Françoise Meunier | 14/09/2010     |