

Accrual accounting in the Intergroup Trials

POL010

Version 1.2

(Always refer to the Intranet to check the validity of this document)

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1. Objectives

The EORTC is an international network of institutions/investigators collaborating with other national/international groups. Consequently, some of the EORTC investigators are also members of other international or national groups.

The EORTC generally considers group membership as an authorization to an institution/investigator to participate in EORTC clinical trials. For non-EORTC groups, their group statutes and procedures ensure this condition.

The contribution of the investigators to clinical trials in terms of accrual for his/her institution is an important factor for membership. Therefore, the EORTC issues a yearly report detailing the contribution of each institution to each group. In addition, patient accrual plays a major role in the certification of an EORTC affiliated institution/department.

This policy describes how the patient accrual within the intergroup trials involving an EORTC clinical group will be counted for the EORTC membership.

For more information on intergroup trials see Policy 005 (“Intergroup trials”, ref.: POL005) and Policy 012 (“EORTC support to Intergroup trials”, ref.: POL012).

2. Responsibilities

EORTC Data Center is responsible to provide the EORTC clinical groups with the accrual figures that will be used for the EORTC affiliation/membership, using internal and external information.

EORTC Data Center Team will forward the accrual information from non-EORTC groups to the person at the Data Center responsible for the accrual statistics.

Principal Investigator's responsibility is to help the EORTC Data Center to collect the accrual information, if necessary.

3. Definitions

Group: national/international network of investigators and/or institutions and/or groups or structure/agency working for a group of investigators and/or institutions and/or groups.

Principal investigator: the investigator within the institution who signed the commitment statement for the particular trial

Intergroup trial: a trial conducted by several groups (i.e. between several EORTC clinical/laboratory groups or an EORTC clinical/laboratory group and non-EORTC group).

Coordinating group: group responsible for the scientific content of the protocol and contribute to the conduct of the trial or coordinates it.

Cooperating group: the group that participates in the intergroup trial, coordinated by another group

Group membership, affiliation: the right to belong to the group (under certain group-specific conditions)

Clinical Trial Office (CTO): administrative office responsible for the management of the trial

Data Center (DC): CTO that includes the data management and statistical office.

Sponsor: an individual, company, institution or organization which takes responsibility for the initiation, management of a clinical trial and/or financing of a clinical trial

4. Procedures

Whereas the accrual accounting in single EORTC groups is very straightforward, the accounting in intergroup trials is more complex.

The EORTC is a Sponsor for all members of EORTC clinical/laboratory groups in the EORTC trials. In case of intergroup collaboration, the collaborating groups are frequently Sponsors of their members.

Within a given EORTC-intergroup protocol, participants might be members of the EORTC group and of the other collaborating national/international group(s). In this case, members have to choose their main group for a particular trial ("primary affiliation" group). This "primary affiliation" group will be in the most of time their Sponsor. Consequently, the EORTC investigators will participate either on behalf of the EORTC or on behalf of another collaborating group, depending on the trial.

In the Intergroup trials, EORTC investigators participating on behalf of the EORTC (idem. "primary affiliation group") will have their accrual accounted for the EORTC affiliation, even if they are also members of other collaborating group(s).

The patients accrual of the EORTC investigators who participate on behalf of another collaborating group is also, under certain conditions, accounted for the EORTC affiliation. The following chapters describe these conditions.

4.1. Intergroup trials concerned by this procedure

Several EORTC clinical groups or (an) EORTC clinical group(s) and non-EORTC national/international group(s) can conduct intergroup trials following the basic principles described in the EORTC policy 005 ("Intergroup trials", ref.: POL005).

4.1.1. EORTC & non-EORTC collaboration.

When participating on behalf of a non-EORTC group ("primary affiliation"), the EORTC investigator **can use** the accrual also for his EORTC group affiliation ("secondary affiliation"), if both, EORTC group and non-EORTC group collaborate in the same intergroup trial and where either one is the coordinating group.

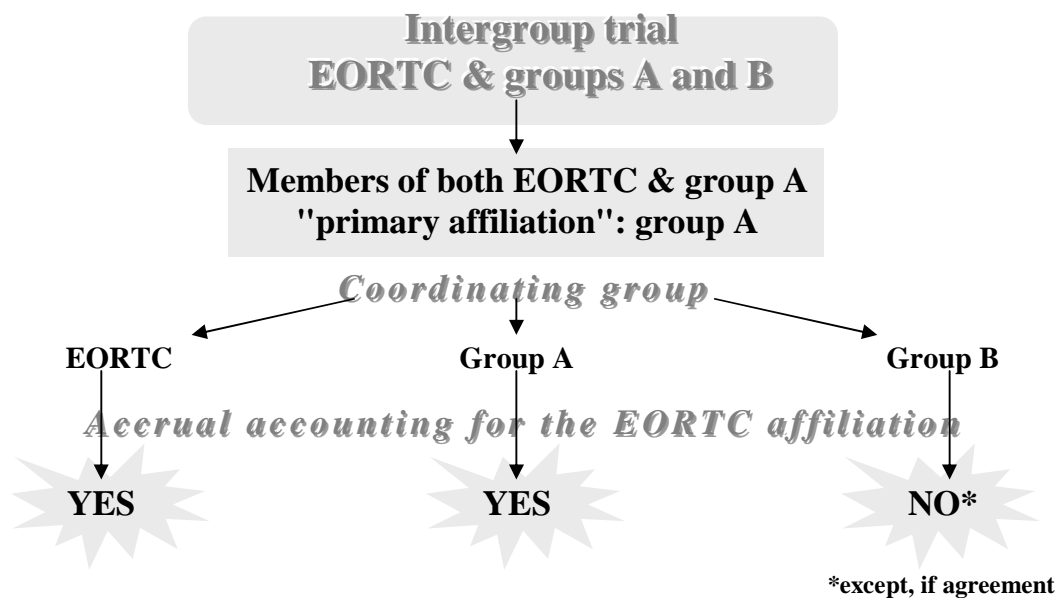
The same rule is applicable to the EORTC affiliated institutions/departments.

This means that the accrual of the EORTC investigators entering patients on behalf of a non-EORTC group in a given trial **cannot be** used for the EORTC group affiliation:

- ◇ if the EORTC group does not participate in the trial (which implies that patients entered before the trial has been approved by the EORTC PRC will not be accounted).
- ◇ if both EORTC and non-EORTC groups participate in the intergroup trial, but the trial is coordinated by a third party.

If the member of the EORTC clinical/laboratory group does not have the possibility to register his/her patients on behalf of the EORTC or of the coordinating group (because of a special agreement between groups) these rules will be adapted to this particular situation.

The following scheme illustrates these rules:



4.1.2. EORTC-EORTC collaboration

When two EORTC clinical groups are collaborating in a trial, the patient accrual of an investigator member of both groups is counted for both groups (once for each group). For the affiliated institutions/departments the patient accrual is accounted once for their institution.

In this case, the "primary affiliation group" and the "secondary affiliation group" do not have any importance for the accrual accounting.

4.2. Source of information

4.2.1. Randomizing at the EORTC Data Center

At the EORTC Data Center, the primary and the secondary affiliation are automatically collected through the ORTA system at the time of randomization. The rules describing to which group every particular investigator will give the primary and secondary affiliation will be described in the protocol (chapter on the randomization).

Each affiliation is compared with the EORTC Addressograph: the investigator should belong to an institution having an active or probationary member of the selected group involved in this trial. Both primary and secondary group affiliations will be taken in account for the EORTC membership.

If another group wishes to be informed about the accrual of their members to EORTC Intergroup trials, the EORTC Data Center can provide this information upon request.

4.2.2. Randomizing outside the EORTC Data Center

If the patients are randomized outside the EORTC Data Center (i.e. the Data Center of the coordinating and/or collaboration group), the precise procedure to inform the EORTC data center about the accrual of the EORTC institutions should be discussed prospectively with the concerned non-EORTC group's Data Center and the EORTC members should be informed.

In case such procedure can not be organized between the EORTC and non-EORTC Data Centers, the principal investigator of the interested institution should provide the EORTC Data Center with the requested information (providing evidence).

Although the EORTC strongly recommends adhering to the described framework, slight modifications may be required on an individual basis as the procedure also implicates non-EORTC groups.

5. List of abbreviations

Abbreviation	Full name
EORTC:	European Organisation for Research and Treatment of Cancer

6. Appendices and references

Document title	Reference (file name)
Intergroup trials	POL005
EORTC support to Intergroup trials	POL012