



AISBL International Non-Profit Association under Belgian law IVZW

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

EORTC Principles for Investigational Sites Activation

POL018

Version 1.1

ALWAYS REFER TO THE EORTC INTERNET WEBSITE TO CHECK THE VALIDITY OF THIS DOCUMENT

Author: <i>Director Headquarters</i> Denis Lacombe	Signature:	Date:
Authorized by: <i>Director General on Behalf of the Board</i> Françoise Meunier	Signature:	Date:

Table of Contents

1 PURPOSE 3

2 DEFINITIONS 3

3 POLICY..... 3

4 CALL FOR INTEREST AND SITE FEASIBILITY 3

5 INITIATION PACKAGE 4

6 SITE ACTIVATION 4

7 SUMMARY 5

8 DOCUMENT HISTORY 5

1 PURPOSE

The objective of this policy is to describe the principles for investigational site participation to EORTC studies. It defines the guidelines by which EORTC will grant authorization to sites to join a particular study and to monitor site activities until the first patient is included. Alongside these principles, it defines the level of authority and decisions which can be taken towards non performing sites early on in the process of study activation investigational sites.

The process of getting a clinical study up and running is considered to be a limiting factor for the compliance to the overall expected timelines. The steps to bring all sites on board for a clinical study are multifold and complex to be achieved simultaneously. These steps are at the corner of project management, regulatory and ethical procedures. Improvement in the efficiency of the start up of clinical studies requires the dedication of all involved parties. These steps which require optimal coordination deserve full attention and cooperation from the joining investigational sites.

2 DEFINITIONS

- ◆ **Feasibility form:** first notification and call for interest and site feasibility to the EORTC Group members
- ◆ **Confirmation of Interest form:** Trough this document the investigator will confirm the site participation to the study and give site contact details to the EORTC Headquarters.
- ◆ **Initiation package:** Package sent to all investigators who confirmed their participation. It includes all necessary documents for initial submission to the Ethics Committees by the investigators and for authorizing their site to participate in the study.

3 POLICY

Extensive regulatory work is nowadays to be performed to activate countries and sites to join a clinical study. The administrative process and compliance is now strictly regulated in EU member states since the implementation of the European directive 2001/20/EC. The complex regulatory procedures do have a direct cost to be achieved and executed but also submission costs to competent/regulatory bodies are more the rule than the exception. Insurance costs have also risen. In some countries, absence of patient entry within 1 year of study authorization will lead to authoritative closure of the study by the competent authorities. Taking all this environment into account, EORTC has implemented a specific process to control as closely as possible the activation of sites.

4 CALL FOR INTEREST AND SITE FEASIBILITY

Preliminary participation and feasibility will be done by circulation of the outline document to the relevant EORTC site network with request to complete the feasibility form.

It will capture study population / study process specific information in order to have an objective assessment of the feasibility per site. The form must be completed through the web application within 2 weeks. An extension of maximum 2 weeks will be considered.

Sites returning the form after the deadline will be logged on a waiting list. Depending on the expected and documented feasibility they might be taken on board from the start or at later stage to replace sites not fulfilling activation procedures adequately.

This first step, though preliminary is critical as it will serve for the initial budget assumption to run the study. Deviation by more than 10% should lead to budget re-evaluation.

Based on the outcome of this feasibility, the Headquarters will investigate if any quality or regulatory issue might hamper site participation.

The proposal of sites and countries participating with eventual strategies for resolving/addressing feasibility issues is discussed with the Disease Oriented Group Steering Committee and the Study Coordinator.

Final site selection will be provided to the company and/or collaborative group(s) for consideration, if applicable.

Site(s) not considered for participation will be contacted by the Headquarters.

5 INITIATION PACKAGE

The initiation package contains a number of documents and requests to be fulfilled by the sites before authorization to enter patients is given.

The Headquarters will follow-up on the local process at each institution at 2 months after initiation package distribution and will issue a reminder. If deemed necessary, an additional reminder can be issued 4 months after initiation package distribution.

Failure at 6 months after receipt of the initiation package to provide complete and thorough information or to show that the process is actively addressed will lead to site interruption and replacement by a site on the waiting list.

6 SITE ACTIVATION

Once sites are authorized, entry of the first patient is closely followed up by the EORTC Headquarters.

In absence of patient recruitment at 3 months after authorization, the Headquarters will investigate if any limiting factor can be actively addressed to overcome recruitment difficulties.

At month 6 from authorization, sites failing to prove that adequate screening procedures are in place and not documenting recruitment failure will be considered no longer interested and will be closed to patient entry and replaced by sites on the waiting list.

It is important to note that replacing sites is not only a costly process, but also creates substantial administrative burden (substantial amendment). If site replacement should exceed 25%, a complete study feasibility re-assessment and budget re-evaluation is recommended.

While the decision to close sites will always be looked at on a case by case approach jointly with the relevant EORTC network/group officers, the EORTC reserves the right not to activate a site which is the only site in a given country unless a clear motivation and past commitment data are available.

7 SUMMARY

	Aim of the process	Initial deadline	Last deadline
Feasibility form	Initial feasibility based on study outline	2 weeks	2 additional weeks
Confirmation of interest	Confirmation of participation , initial regulatory steps	3 weeks	3 additional weeks
Initiation packages	Full scientific and regulatory packages for local procedures	2 months	6 months
1 st patient included	Control study timelines	3 months	6 months

8 DOCUMENT HISTORY

Version number	Brief description of change	Author	Effective date
1.0	Initial release	Denis Lacombe	27/03/2007
1.1	Implementation of updated EORTC Headquarters procedures.	Denis Lacombe	06/04/2011