EORTC European Organisation for Research and Treatment of Cancer The future of cancer therapy	**Policy on Investigational Site Participation**		
Document owner	Clinical Operations	Version number	1.1
Effective date	2024-04-26	Identifier	D-01-POL-01

1 Purpose

This policy describes the general principles applicable for a site's participation in a clinical study from site selection to the end of patients' recruitment and in case of a substantial amendment.

2 Scope

The policy applies to all clinical studies for which EORTC is responsible for site selection, site authorization (including authorization following a substantial amendment) and patients' recruitment by sites. In case a clinical study is conducted in collaboration with other partners, only parts of the policy might apply. In such cases, EORTC informs sites on the applicable processes.

3 Policy statement

All EORTC clinical studies are conducted in compliance with applicable laws, regulations, and guidelines. EORTC ensures that clinical studies are completed in the specified schedule.

Meaningful clinical studies require timely completion of patient recruitment. Therefore, it is important that all steps that build up to the recruitment phase are done on time and sites fulfil their commitment during the recruitment phase.

EORTC informs the site of any relevant study information, applicable timelines, and supports the site to achieve this goal.

In all steps outlined in this policy, EORTC reserves the right to remove any site from participation in case the site is not responsive, not compliant to the specified timelines and deliverables, or not committing to expected patient recruitment.

All steps described in this policy are in accordance with EORTC policies, namely 'Policy on Selection, Development and Approval of EORTC Studies', 'EORTC Group and Task Force Membership' and 'Conflict of interest, Bribery and Confidentiality'.

4 Changes since last version

Process step	Changes since last version
General	Supersedes POL018: 'EORTC Principles for Investigational Site Activation' Policy name was changed to 'Policy on Investigational Site Participation'. Extension of scope: site's performance to be monitored until the end of recruitment. General Policy statement added applying to all steps. Technical details (e.g. tools, forms, timelines) replaced by general wording. Addition of a paragraph on 'Substantial amendments'.
5.1 Site selection	Typo corrected.

5 Policy

5.1 Site selection

Once EORTC HQ clearance is available, the study is offered for participation to the members of the appropriate EORTC network(s) and external network(s), if applicable.

Respondents showing interest for their site to participate can receive the relevant study information once they have agreed with the terms and conditions including confidentiality.

Investigators should provide a realistic recruitment target and assess the study feasibility at their sites. This feedback allows EORTC HQ to optimally plan the study and to assess site's ability to conduct the study.

EORTC HQ ensures a continuous communication on the selection status with the interested sites. In case a site is not selected, the reasons leading to this decision shall be provided.

5.2 Regulatory Submission

To start with the submission for regulatory approval, all selected sites are asked to confirm their study participation based upon the final released protocol version. This includes the site's final commitment regarding its contribution to patient's recruitment.

EORTC HQ organizes the preparation and collection of documents required for the submission according to the applicable laws, regulations, and guidelines.

At the same time, the role of 'national coordinator' is offered to the principal investigators suggested to take additional responsibility in their country. The 'national coordinator' supports and advises principal investigators and EORTC HQ.

5.3 Site set up and authorization

In parallel or after regulatory submission, EORTC HQ provides the site with all documents required for the start of the clinical study, including but is not limited to:

- study protocol
- study-specific guidelines and material (e.g., training),
- quality assurance procedure for radiotherapy and/or imaging, if applicable, and
- contract(s).

EORTC clearly communicates what requirements should be fulfilled prior to site authorization for patient recruitment.

Once regulatory approval is in place and the site has fulfilled all requirements:

- the site agreement is signed,
- all quality assurance procedures are successful,
- all operational requirements, including site training on study procedures and applicable software are in place,

EORTC HQ authorizes the site to start patient recruitment.

5.4 Patient recruitment

In order to achieve the study recruitment target, the site is responsible to meet accrual expectations throughout the study and to communicate rationale if expectations are not met.

The site shall register all patients that sign an informed consent form in the clinical database.

EORTC HQ monitors patient recruitment for each study and site and takes appropriate actions if sites do not comply with their commitment.

5.5 Substantial amendments

In case of any substantial amendment, EORTC HQ informs the site of the impact and necessary study requirements for the site to comply to the latest amendment (e.g., regulatory documents, updated guidelines, training).

6 Definitions

- **National Coordinator:** a selected principal investigator who has a supportive and advisory role towards all investigators within his/her country participating in the same multicenter study.
- **Principal Investigator:** An investigator who is the responsible leader of a team of investigators who conduct a clinical study at a clinical study site (as per Regulation 536/2014, article 2, definition (16))

7 Associated documents

Process step		Title	Identifier / location
3	Policy statement	Policy on Selection, Development and Approval of EORTC Studies	A-01-POL-01
3	Policy statement	EORTC Group and Task Force Membership	POL023
3	Policy statement	Conflict of interest, Bribery and Confidentiality	POL001
5.1	Site selection	Terms and Conditions	EORTC website > policies

8 References

- ICH GCP (R2) section 4.1 (investigator's qualification and agreement), 4.2 (adequate resources)
- ICH GCP (R2) section 5.6 (investigator selection), 5.11 (confirmation of review by IRB/ IEC)
- GCP ICH E6 (R2), Section 8 – (Essential Documents for the Conduct of a Clinical Trial)
- ICH GCP (R2) section 5.23 (multicentral trial, coordinating investigators)
- Clinical Trial Regulation EU No 536/2014
- European Directive 2001/20/EC on the conduct of clinical trial
- European Directive 2005/28/EC on the principles of good clinical practice
- National laws and regulations pertaining to non-IMP clinical studies

9 Signature

This document will be electronically signed.
The signatories acknowledge that electronic signature is legally binding and equivalent to a handwritten signature.

Author Liliane Henkes Senior Clinical Operations Manager	DocuSigned by: Liliane Henkes Signer Name: Liliane Henkes Signing Reason: I am the author of this document Signing Time: 22 April 2024 | 10:12:56 CEST 58EC63B09770403AB4B84E1BF65848A2
Approved & authorized by Denis Lacombe Chief executive officer *On behalf of the Board*	DocuSigned by: Denis Lacombe Signer Name: Denis Lacombe Signing Reason: I approve this document Signing Time: 22 April 2024 | 16:44:31 CEST 457339F472784605806FBD4D54FBD7A4