EORTC European Organisation for Research and Treatment of Cancer *The future of cancer therapy*	**Policy on Selection, Development and Approval of EORTC Studies**		
Document owner	HQ direction	Version number	1.0
Effective date	2023-01-31	Identifier	A-01-POL-01

1 Purpose

The present policy describes the rules to be followed for initiating, reviewing, endorsing and developing a study at or with EORTC such that it is ready to start study activation processes.

2 Scope

The policy is applicable to any prospective clinical study involving EORTC, irrespective of sponsorship or funding source.

3 Policy statement

EORTC coordinates and conducts international translational and clinical research under conditions of independence and accountability. EORTC studies are selected and developed in order to:

- align with EORTC mission, values and the EORTC strategy
- follow good clinical practice and comply with applicable regulatory framework
- comply with the quality and independency principles of EORTC as set for in this and associated policies
- comply with the transparency requirements of EORTC by publishing all study results

4 Changes since last version

Process step	**Changes since last version**
All	Version 1.0 Superseding Policy 16 v 3.3 Policy updated to align to new EORTC governance principles.

5 Policy

5.1 Study initiation

Any study starts with an idea that can come from any source. The EORTC network shall be formally involved for growing the idea into a study concept. New study concepts are debated within and endorsed by EORTC groups and task forces.

The primary group supporting the study is responsible for appointing a study coordinator amongst its members. The study coordinator is the main driver of the study on behalf of the group and takes study coordination responsibility according to ICH-GCP.

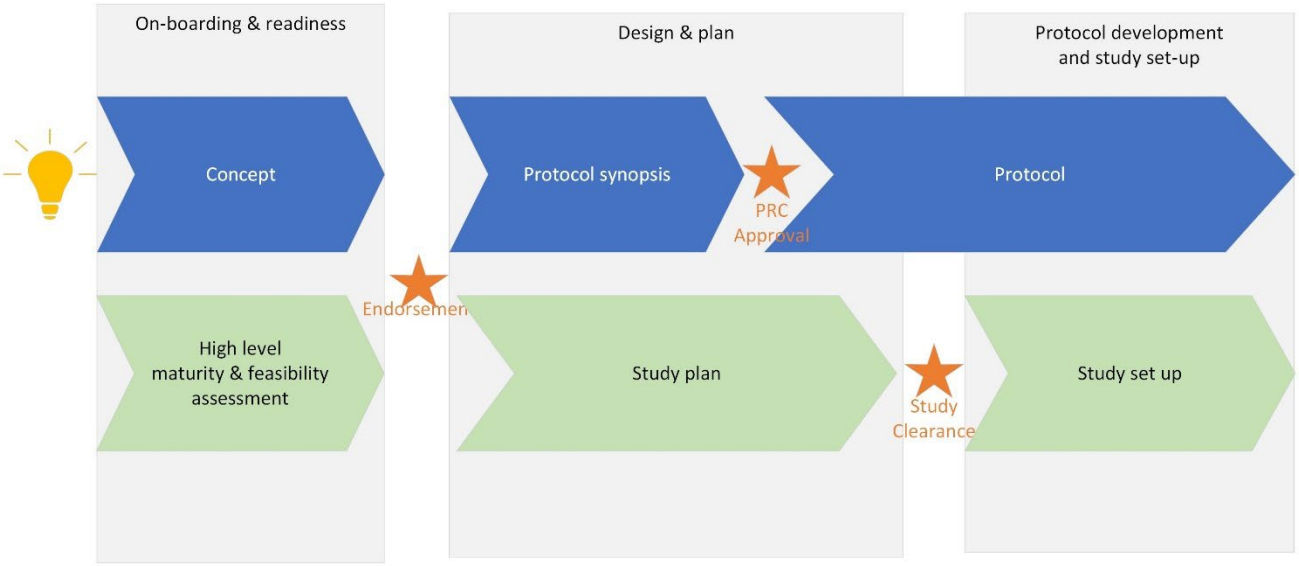
5.2 EORTC principles of independence

EORTC principles of independence are applicable to all studies:

- The study protocol synopsis is reviewed and approved by EORTC independent protocol review committee (PRC) as described in section on study design and planning.
- The clinical database of the study is controlled by EORTC or by an equivalent independent organization. For clarity, industry partners can only access efficacy data at a mutually agreed time point, close to primary endpoint maturity.
- EORTC, or an equivalent independent organization, is responsible for the final study analysis and publication.

5.3 On-boarding and developing studies

EORTC implements a phased review process to progressively evaluate new studies and support decision-making.



5.3.1 On-boarding and readiness

The study coordinator, supported by EORTC headquarters, develops the study concept that shall be channelled through the onboarding process.

The study concepts undergo successive internal maturity reviews by EORTC headquarter directors addressing key scientific and design topics, as well as operational and funding aspects. The reviews are based on preliminary study parameters, objectives and key feasibility information documented in the study concept. Study coordinator and possibly group officers are involved as needed.

Study concepts that are considered feasible and mature enough for initiation are considered as "endorsed". This gives the mandate to EORTC headquarters study team to start working on the study protocol synopsis, and on the related study execution plan. Once granted, the mandate is valid for one year. If study clearance, as defined in section 5.3.2.3., is not granted within one year, the study shall be submitted to maturity review to possibly extend the validity period for an additional year.

5.3.2 Study design and planning

5.3.2.1 Protocol synopsis and study execution plan

The study coordinator and the study team develop the protocol synopsis and the related study execution plan concurrently.

Key stakeholders are involved as early as possible to make sure that the protocol synopsis relies on a robust execution plan.

5.3.2.2 Independent review

Once ready, the protocol synopsis undergoes review by the independent protocol review committee.

The protocol review committee evaluates incoming study proposals and has decision power to

- Accept with or without comments
- Request major changes and resubmission
- Reject the study proposal normally after unsuccessful re-submission

In addition, the PRC ranks the study proposals in term of priority.

The applicant presents the study at PRC session and addresses questions that the PRC members may raise. The decisions are based on the independent review of the study protocol synopsis by several experts (members of the PRC and external reviewers). The final decision of the PRC may not be appealed.

5.3.2.3 Study clearance

EORTC headquarters grants study clearance after a feasibility assessment of the study execution plan to determine if it has the potential for successful execution.

The assessment uses a risk-based approach spanning all aspects of the study, including methodological feasibility, applicability of regulations, EORTC policies and processes, operational set-up, timelines and availability of resources, financial aspects, feasibility of successful enrolment, and execution risks.

EORTC groups are informed if significant risks are identified and involved in the identification of mitigation actions. The study execution plan is further developed or amended until the overall risk is considered as acceptable and clearance is granted to start full protocol development and study set up

Protocol review committee approval of the study protocol synopsis is a prerequisite to the study clearance.

5.3.3 Protocol development and study set-up

The study coordinator and the headquarters study team develop the study protocol and the detailed operational set-up, including collaboration with non-EORTC groups.

Study activation phase starts at the end of the study development, and once following conditions are fulfilled:

- the study protocol is reviewed and released, and
- funding is secured for the appropriate conduct of the study until planned completion

Should the study protocol differ significantly from the accepted synopsis, the modified synopsis shall be resubmitted to the protocol review committee for independent review and the amended execution plan be subject to a new clearance.

6 Definitions

- **Protocol review committee (PRC):** the PRC is an independent standing committee that reviews a selection of proposed studies based on the submitted protocol synopsis and assess their scientific value.
- **Study activation processes**: Start of operational set up and submissions to ethics committees and competent authorities.

7 Signature

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

Author Vassilis Golfinopoulos Headquarters director	
Approved & authorized by Denis Lacombe Chief executive officer on behalf of the Board	