

	Policy on Quality		
Document owner	Quality	Version number	1.0
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1 Purpose

This policy describes the quality principles that govern design, conduct, oversight, recording and reporting of clinical research.

This policy communicates the quality commitments and expectations of EORTC as study or local sponsor of clinical studies to EORTC HQ staff and study stakeholders performing activities on behalf of EORTC or under EORTC oversight.

2 Scope

This policy applies to EORTC HQ staff, contractors, consultants, participating investigators, service providers and downstream partners to the extent that they perform activities on behalf of EORTC or under EORTC oversight.

This policy applies to all clinical studies activities where EORTC acts as study sponsor or local sponsor. It is recommended to work in the spirit of this policy for any other research activities managed by the EORTC headquarters.

Compliance in this policy refers to adherence to study protocol documents including study plans, related contracts, procedure documentation, EORTC code of ethical conduct, EORTC work regulations and applicable regulations and guidelines.

3 Policy statement

EORTC commits to

- prioritize participant safety and wellbeing throughout all stages of any research, in compliance with applicable ethical and regulatory standards, including good clinical practice,
- deliver high-quality, ethical, and scientifically sound clinical research, ensuring the generation of robust, reliable, and reproducible datasets that support meaningful clinical outcomes, and
- implement quality by design and appropriate quality management.

4 Changes since last version

Initial version

5 Policy

5.1 Governance

This policy is endorsed by the EORTC board and is revised periodically, and updated as needed to reflect changes in regulations, standards and objectives.

5.2 Responsibilities

Role	Responsibility
EORTC board	Accountable for organizational quality commitments Ensure EORTC has the means to develop and apply high-quality standards Support open dialogue
Chief officers and directors	Foresee adequate resources (qualified and competent) Ensure quality is embedded in study design and leadership decisions
Independent quality assurance	Develop, manage and monitor quality management system Coordinate audit program Report on quality performance to EORTC management Provide guidance on good clinical practice requirements
Operational and study management staff	Quality planning Day-to-day study oversight Manage deviations and CAPA
EORTC HQ staff and study stakeholders	Perform activities in accordance with applicable agreements, this policy and relevant quality management system documents Raise quality concerns through established channels

5.3 Quality culture

EORTC implements proactive quality management by

- Striving for continuous improvement of the quality management system and the study quality through learning (plan-do-check-act) and by promoting innovation and efficiency.
- Systematically evaluating lessons learned from audits, inspections, quality events, deviations, CAPAs and study conduct activities and applying them to improve processes and future studies.

- Applying critical thinking through open, proactive dialogue, evaluating information from observation, reasoning and experience with focus on what matters.
- Fostering accountability by taking ownership for the full activity and organization, encouraging open and transparent communication, including sharing documentation as required, and establishing a culture of collaboration and shared responsibilities.
- Promoting a speak-up culture in which quality, participant safety, compliance, ethical conduct and research integrity concerns can be raised without fear of retaliation. Concerns shall be appropriately investigated and addressed.

5.4 Participant protection as first principle

Study participant's rights, safety, dignity, and well-being shall always prevail over the interests of science and society. EORTC studies are initiated and continued only where anticipated benefits justify known and anticipated risks.

EORTC, investigator sites and study stakeholders implement processes and controls to

- safeguard adequate collection of informed consent from and communication with the study participant,
- safeguard adequate safety monitoring and reporting, and
- avoid loss of data at end of participation.

5.5 Regulatory compliance

Studies shall be conducted in accordance with applicable regulations and guidance.

EORTC staff and study stakeholders shall comply with these standards and EORTC policies on data protection and the EORTC code of ethical conduct. Compliance is ensured by implementation of fit-for-purpose procedures and legal and regulatory watch to ensure a current state of knowledge.

EORTC and co-sponsors collect authorisation by regulatory bodies before initiation of study activities and adhere to regulatory reporting requirements during study lifecycle.

5.6 Qualified staff

EORTC works with qualified experts in oncology research including EORTC HQ expertise and input from a network of prominent leading investigators. Qualification for membership of the EORTC network is described in the policy on 'EORTC group membership'.

All staff and individuals involved in study design, conduct, or oversight shall be qualified by education, training and experience to perform their respective tasks.

EORTC implements and documents appropriate, continuous training through annual planning, role-based training curricula and study-specific training requirements.

5.7 Quality by design

Quality shall be integrated in the study from concept development. EORTC studies must be scientifically sound and based on current scientific knowledge, contain clear and explicit scientific objectives, be fit for purpose, feasible and ethical, focus on what is critical to quality, and implement appropriate controls to avoid non-compliances.

The principles for study selection and approval are described in the EORTC policy on 'Study selection and approval'.

Protocol documents and study plans must be clear, concise and feasible which is controlled through approved templates and peer review.

5.8 Non-compliance management

EORTC and study stakeholders have systems in place to identify, document and manage non-compliances with focus on participant's safety and study integrity.

In case of serious breaches and/or critical quality events EORTC and study stakeholders commit to

- perform a thorough investigation assessing the root cause
- implement corrective and preventive measures to avoid recurrence and support continuous improvement
- report appropriately to study stakeholders and authorities

Any suspicion of research misconduct shall be handled as per EORTC policy on 'Research misconduct'.

5.9 Risk-based quality-management

EORTC adopts a proportionate and risk-based approach to quality management:

- including proactive risk management and planning, prior to study initiation and throughout conduct with focus on critical systems, processes and data, and
- avoiding unnecessary burden and complexity.

EORTC shall monitor quality through metrics and key performance indicators, reviewed by leadership at planned intervals. EORTC plans routine audits per risk-based annual audit program to ensure continuous improvement.

EORTC plans and manages risk-based quality control with sufficient focus on data review and monitoring activities. The extent and nature of monitoring is based on identified risks and considers study complexity.

EORTC oversees quality control and quality assurance activities delegated to study stakeholders.

5.10 Data integrity

5.10.1 Record management

Any essential record generated under EORTC sponsorship shall be recorded, processed, stored and reported in a way that ensures accuracy, completeness, legibility, timeliness and traceability. This ensures EORTC studies to be inspection ready, as it allows verification and reproducibility of research activities.

EORTC, investigator sites and study stakeholders shall

- ensure data integrity by having the data attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available (i.e. ALCOA+ principles),
- define the appropriate level of review, approval and release with rationale as per regulatory requirements, good practices or purpose,
- define the appropriate signature rules,
- apply appropriate document control throughout the clinical study life cycle, and
- ensure all essential records are available in English.

5.10.2 Data collection and processing

EORTC shall apply following principles qua data collection and processing to safeguard data integrity:

- apply the data minimisation principle: collect and process minimum amount of data for the research purpose,
- use standard data collection elements, aligned with international standards,
- focus on data critical for the research purpose,
- predefine statistical analysis for all EORTC studies and research projects, and
- apply standard operating procedures cover all steps of data lifecycle, safeguard essential elements of the clinical trial, support key decision making.

Preplanned and ad-hoc review by an interim data monitoring committee is described in the policy on 'Independent Data Monitoring Committee'.

The principles for collection or acquisition, processing, and storage of human biological material are described in the policy on 'Human Biological Material collection and use'.

5.10.3 Computerised systems

EORTC shall

- apply risk-based validation, prior to use and throughout system lifecycle, including study specific data collection configuration,
- ensure systems are fit for purpose and thus conform requirements,

- oversee the computerised systems under EORTC responsibility and as appropriate the use of other computerised system relevant to the study, and
- apply procedures for computerised systems usage, maintenance and change control.

5.10.4 Retention of essential records

EORTC shall

- implement information security controls for computerised systems to ensure data integrity and protection of rights of study participant.
- oversee records held by study stakeholders, and
- archive essential records per determined retention period ensuring retrieval, readability and security throughout this period.

5.10.5 Transparency

The policy on 'Transparency in clinical trials' describes how EORTC promotes transparency and sharing of knowledge about the proceedings and findings of EORTC clinical trials.

5.11 Oversight

EORTC clearly defines the roles, activities and responsibilities for the clinical study in respective agreements. EORTC may transfer of regulatory sponsorship in accordance with applicable arrangements, while clearly defining the resulting responsibilities, but retains overall responsibility as study sponsor. Delegated activities are subject to the same quality standards as activities conducted by EORTC.

EORTC commits to qualify study stakeholders for conducting delegated and transferred activities and keep appropriate oversight of delegated responsibilities.

EORTC provides adequate support to investigator sites who are responsible for medical care, safety reporting and compliance.

The Audit and Finance Committee of the EORTC board oversees

- audit planning and timely management of audit outcomes, and
- all findings that adversely affect or are likely to affect to a significant degree the safety and rights of the subjects and/or the reliability and robustness of the data generated in the clinical study.

Regarding investigational medicinal product management, EORTC does not act as marketing authorisation holder. EORTC organizes the drug supply chain from manufacturer to administration and ensures appropriate oversight.

6 Quality management system structure

1. The quality policy stating the quality commitments of the organization.

2. Standard operating procedures describing how responsibilities are executed across study and support activities.
3. Work instructions providing practical guidance.
4. Records and forms providing evidence that processes have met requirements and have been conducted as described in procedures and work instructions.

The quality management system is subject to periodic review, internal audit and revision in response to regulatory developments.

Leadership periodically reviews the performance and effectiveness of the quality management system, including objectives, key performance indicators, significant quality events, audit and inspection outcomes, quality risks, and opportunities for improvement. The outcomes of these reviews support continual improvement and the allocation of appropriate resources.

7 Definitions

- **Data integrity:** Data integrity includes the degree to which data fulfil key criteria of being attributable, legible, contemporaneous, original, accurate, complete, secure and reliable such that data are fit for purpose. (ICH GCP E6 (R3))
- **Essential record:** Essential records are the documents and data (and relevant metadata), in any format, associated with a clinical trial that facilitate the ongoing management of the trial and collectively allow the evaluation of the methods used, the factors affecting a trial and the actions taken during the trial conduct to determine the reliability of the trial results produced and the verification that the trial was conducted in accordance with GCP and applicable regulatory requirements. (ICH GCP E6 (R3))
- **Informed consent:** A process by which a participant or their legally acceptable representative voluntarily confirms their willingness to participate in a trial after having been informed and been provided with the opportunity to discuss all aspects of the trial that are relevant to the participant's decision to participate. Varied approaches to the provision of information and the discussion about the trial can be used. This may include, for example, providing text in different formats, images and videos and using telephone or video conferencing with investigator site staff. Informed consent is documented by means of a written (paper or electronic), signed and dated informed consent form. Obtaining consent remotely may be considered when appropriate. (ICH GCP E6 (R3))
- **Monitoring:** The act of overseeing the progress of a clinical trial and of ensuring that the clinical trial is conducted, recorded and reported in accordance with the protocol, standard operating procedures, GCP and the applicable regulatory requirement(s). (ICH GCP E6 (R3))
- **Quality assurance:** All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded) and reported in compliance with GCP and the applicable regulatory requirement(s). (ICH GCP E6 (R3))

- **Quality control:** The operational techniques and activities undertaken to verify that the requirements for quality of the trial-related activities have been fulfilled. (ICH GCP E6 (R3))

8 References

- Clinical Trials Regulation (EU) 536/2014
- ICH E6(R3) Guideline for Good Clinical Practice
- EMA/INS/GCP/112288/2023: Guideline on computerised systems and electronic data in clinical trials
- ICH E8(R1) General Considerations for Clinical Studies
- Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (WMA, as amended)
- EU General Data Protection Regulation (GDPR) 2016/679 and applicable national data protection legislation
- EMA/698382/2021 Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol
- ICH Q9(R1) Guideline on Quality Risk Management
ICH E9 and E9(R1) Guideline on statistical principles for clinical trials

9 Signature

This document will be electronically signed.

The signatories acknowledge that electronic signature is legally binding and equivalent to a handwritten signature.

Author Liv Meert Head of Quality	Signed by: <i>Liv Meert</i>  Signer Name: Liv Meert Signing Reason: I am the author of this document Signing Time: 05 October 2026 09:30:39 CEST 1F58156FE4B4471BA16CE9F2D1C6D77A
Approved & authorized by Denis Lacombe Chief executive officer <i>on behalf of the Board</i>	Signed by: <i>Denis Lacombe</i>  Signer Name: Denis Lacombe Signing Reason: I approve this document Signing Time: 05 October 2026 15:03:06 CEST 457339F472784605806FBD4D54FBD7A4