Policy Statement | May 2026

Clinical Trial Ethics

Merck applies the same ethical standards to clinical trials in all countries, in accordance with the global standards of the International Conference on Harmonization - Good Clinical Practices (ICH-GCP), the Belmont Report, the Council for International Organizations of Medical Sciences International Ethical Guidelines for Health-Related Research Involving Humans (CIOMS, 2016), the Pharmaceutical Research and Manufacturers of America (PhRMA, 2015 and 2021) Principles on Conduct of Clinical Trials, applicable local regulatory requirements, and following the ethical principles that have their origin in the Declaration of Helsinki. Merck complies with all laws and regulations in countries where we conduct clinical trials and where we market our products and work closely with national and local authorities to provide information to demonstrate this compliance.

Background

As a global healthcare company, Merck's role is first and foremost to discover, develop and provide innovative products and services that save and improve lives around the world. Merck conducts and supports clinical trials worldwide to evaluate the safety and efficacy of our products. Clinical research is fundamental to the development of innovative medicines and vaccines that treat and prevent illness and are relevant for global human health. Merck also recognizes that the successful development and introduction of important new therapeutic and preventive products requires us to adapt to variability in national regulatory requirements, as well as to socioeconomic and cultural differences among countries.

Conducting clinical trials globally may also enable Merck to bring innovative medicines and vaccines to market more rapidly in countries with disproportionate disease burden, assess product efficacy in diverse populations, and contribute to the development of research and clinical capabilities in emerging and developing countries. Merck is committed to conducting clinical trials according to the same high ethical standards, regardless of location.

Scope

- This statement applies globally to Merck sponsored clinical trials, including clinical trials administered by contract research organizations (CROs) or academic research organizations on Merck's behalf, and clinical trials undertaken through joint ventures, acquisitions, and other partnership arrangements.

- The statement also applies to proposals reviewed by the Merck Investigator Studies Program Review Committees (recognizing that the subsequent conduct of studies funded through this program is the fundamental responsibility of the external investigator).

Ethics Committee Review and Oversight

- Merck carries out clinical trials only following approval by Ethics Review Committees with appropriate jurisdiction. Following initial approval, Merck continues to ensure subsequent oversight requirements for notifications, review and approval are met for amendments, adverse event reporting, continuing review, and study closures.

Protocol

- All clinical studies sponsored by Merck must have a written plan that describes the scientific, administrative, and regulatory aspects of the study in a manner that is consistent with currently accepted scientific methodology, Good Clinical Practices, and appropriate regulatory requirements.
- Merck conducts clinical trials based on scientifically sound protocols that take into account the potential risks to the research participant along with the possible benefit to the participant and to society. Scientific, ethical, and clinical judgments must guide and support the design of the clinical trial, particularly those aspects directly affecting the research participants.
- Merck is committed to studying our medicines and vaccines in diverse racial, sex, and ethnic populations, and to achieving this in part through broadening the diversity of the clinical investigators that we engage in our studies.
- Merck adheres to Council for International Organizations of Medical Sciences (CIOMS, 2016) Guideline 5, "Choice of control in clinical trials" when determining the intervention used with placebo-control group participants. Use of placebos must be based on ethical and scientifically sound reasoning (e.g., no established effective treatment exists, placebo is added to established effective intervention, or there is an established effective treatment, but delaying or withholding it will be no more than a minor increase above minimal risk to the participant).
- Participants in clinical trials receive appropriate medical care consistent with the applicable standard of care for their condition throughout the study, and participation in a trial does not result in the denial or delay of medically necessary treatment, with any protocol-required deviations subject to ethical justification, informed consent, and independent ethics committee approval

Informed Consent

- Merck requires that all investigational studies in human subjects be carried out in a manner respectful of the local culture and consistent with legal statutes and regulations for the

protection of human subjects. Merck requires assurances that subjects and/or their legal representatives understand the procedures, use, and any potential disclosure of personal health information, any potential use of biological samples beyond routine testing, risks/benefits involved in a study, alternatives to trial participation, and that their participation is voluntary. The subjects will be informed of the provision of planned post study care and/or product supply, if any, during the informed consent process.

- The informed consent procedures and consent form documents for any clinical study must conform to all relevant legal statutes and governmental regulations concerning research in human subjects and the privacy and security of medical information. Consent information should be communicated in a manner that ensures both compliance with local regulatory requirements and the research subject's understanding (e.g., local language).
- The consent information and its presentation must comply with all applicable regulations pertinent to where the data will be submitted and collected.
- The elements of the consent form must be consistent with those of the International Conference on Harmonization Good Clinical Practices Document.
- During the course of the trial, the subject must be made aware of any significant new information that may affect the subject's willingness to continue participation in the trial.

Training and Study Monitoring

- All personnel involved in the design, conduct, oversight, or reporting of clinical trials—including employees, investigators, and third-party partners—are required to receive appropriate and ongoing training in Good Clinical Practice (GCP), human subject protections, informed consent, and applicable ethical standards, with compliance monitored through qualification, documentation, and periodic audits.
- Clinical trials are subject to ongoing, risk-based monitoring and oversight to ensure participant safety, data integrity, and compliance with protocols, ethical standards, and applicable regulations, including routine review of safety data, site practices, and the performance of investigators and CROs. While CROs conducting Merck-sponsored trials may use their own procedures, these procedures are reviewed and approved by Merck to ensure they meet regulatory requirements and adhere to Merck's clinical trials ethical principles.

Transparency, Post-trial Obligations, and Registration

- Merck complies with laws requiring registration of clinical trials and disclosure of clinical trial results and is committed to the transparency of the clinical trials we sponsor.
- Since 2007, Merck has registered, at trial initiation, all clinical trials in patients (Phases I-V) that the company sponsors and conducts worldwide on www.ClinicalTrials.gov. We also disclose results from all registered clinical trials of marketed products – regardless of outcome – on www.ClinicalTrials.gov.

- The sponsor must determine whether an investigational agent will be made available after the clinical trial to trial participants, and determine whether other services provided during a clinical trial will continue after the trial, and under which circumstances. This also applies to investigation of new indications for licensed medicines. At minimum, healthcare services will be provided to the local standard of care where the trial is conducted and will be sufficient to ensure the clinical trial will be conducted safely.
- Merck intends for its clinical trials to be responsive to the health needs and priorities of the populations and communities in which they are carried out. This includes consideration to making any intervention or product developed, or knowledge generated as a result of clinical trial research, reasonably available for the benefit of that population or community, consistent with CIOMS Guideline 2 “Research Conducted in Low Resource Settings.”
- Merck’s intent is to pursue registration of products where the trials are conducted. Ultimately, the decision regarding registration of any product in a specific country is the decision of the Regulatory Authority in the particular country.