

Regeneron Position Statement on Ethics in Clinical Studies

Regeneron is valued and trusted for the innovative medicines that we develop and for our contributions to improving the lives of people around the world. Clinical research allows scientists to study how an investigational treatment, like a potential new medicine, works in the body. No medicine can be prescribed by a doctor until its safety and effectiveness are demonstrated in a well-designed, well-controlled, and carefully monitored clinical trial in individuals who consent to participate, and these results are evaluated by a regulatory authority. Clinical trials are integral to achieving our mission to bring important new medicines to patients.

At Regeneron, we recognize the important role study participants play and are grateful to those who contribute to important medical research and are part of the process of making potential new treatment options available. This is why we ensure that the highest standards of quality, ethics and integrity inform the conduct of clinical trials, from protocol development to trial enrollment through to the release of results.

Compliant with Local Laws and International Regulatory Standards: All Regeneron-sponsored clinical studies are designed and conducted to integrate ethical and safety procedures and protocols that meet or exceed all applicable local laws and regulations as well as global guidelines, including the International Conference on Harmonization, Good Clinical Practice guidelines, and the World Medical Association Declaration of Helsinki. Doing so protects the rights and wellbeing of participants enrolled in our clinical trials while ensuring we are meeting the highest ethical, scientific, and safety standards in all our research with the ultimate goal of delivering robust and credible results at the conclusion of the study.

Internal Oversight: Our science-led, high-integrity culture is woven into the fabric of our company and by nature, our clinical research programs. We all share responsibility to conduct our clinical studies ethically, and our Corporate Governance and Compliance Board committee and senior management team is committed to ensuring our clinical research programs are based in ethical and compliant strategies. Our clinical trials are part of a framework that includes robust standard operating procedures, policies and practices that are under the oversight and coordination of several committees. These include our Protocol Review Committee, which confirms that scientific integrity, ethics and participant safety considerations are fully integrated into all of our trial protocols; our Clinical Review Committee who reviews all clinical trial recruitment material; as well as our Data Privacy Office that establishes a privacy framework to protect personal data. Further, all employees involved in clinical research are required to complete a suite of custom trainings that align with our standards, such as Good Practice (GxP) guidelines and regulations, privacy protection and quality and compliance practices.

We also have an audit program, consisting of clinical site, vendor and partner visits by our Global Development Quality Assurance team, which is designed to ensure oversight of the execution of clinical trials conducted around the world and to evaluate their associated internal systems. Should investigators, patients or the general public have any questions or comments on our research programs, they can contact our medical information team at [844-REGN-MID \(844-734-6643\)](tel:844-REGN-MID) or submit a form [here](#).

Clinical Research and Service Providers: Regeneron requires its clinical research and service providers, including investigators and contract research organizations, to adhere to the same scientifically rigorous practices. They are audited through our GxP audit program to confirm they meet our quality and safety standards and are compliant with applicable regulatory requirements, and where necessary, to identify meaningful corrective and preventive actions. In addition, a framework has been established to provide oversight of clinical research and service providers on an ongoing basis. If and when we identify issues related to contracted services or GxP standards, we manage the issues through a formal escalation pathway and triage them for appropriate action and resolution. If improvements are not made within a defined period of time, or if repeat occurrences are noted and unsatisfactorily remediated, we will limit and possibly cease future opportunities with the vendor or clinical investigators until the issues have been fully remediated.

Scientific Appropriateness of Trial Design: All Regeneron clinical trials serve to address a legitimate scientific question or need. Each research endeavor is based on a scientifically sound protocol that considers the potential risks and benefits for the participants, which is under the oversight and coordination of our Protocol Review Committee which confirms that scientific integrity, ethics and participant safety considerations are fully integrated into all of our trial protocols.

Diversity, Equity and Inclusion (DEI): Diverse populations may be impacted differently by the same disease or may have varying responses to the same treatment. A diverse group of clinical trial participants helps scientists understand these differences.

Regeneron aims to conduct clinical trials that include the intended populations for the investigational medicine. Our executive-sponsored DEI in Clinical Trials Taskforce is helping us ensure that our clinical trials represent the people who will most likely be treated with the drug being studied if it is approved. Our required curriculum for colleagues who conduct and support clinical research will also help foster awareness of DEI in clinical trials as ethical, scientific, regulatory, and business imperatives.

Our goal is to make clinical trials accessible for all. We will work with communities to increase health literacy and awareness of clinical trials. We will build trusting relationships and collaborate with partners to improve access to our clinical research and investigational treatments.

Participant Rights and Wellbeing: Regeneron has several established policies and procedures in place to ensure the rights and wellbeing of clinical trial participants are protected throughout the research process. This includes ensuring all clinical trial participant recruitment materials meets our quality standards and are easily understood and free of coercive or unduly influential language. Prior to conducting any study or collection of any data related to the study, appropriate Informed Consent Forms (ICF) must be obtained from participants (or their legal representatives) to ensure that each individual understands the nature, scope and purpose of the study, as well as the potential risks and benefits. We also continuously monitor safety and communicate findings in compliance with local regulatory reporting requirements. Additionally, study participants are provided relevant updates and information as they become available, creating an ongoing consent process throughout the trial. Lastly, Regeneron is committed to protecting the study participant's privacy by collecting minimum subject identifiers, only using the personal data provided for the purposes clearly and explicitly provided in the ICF, maintaining appropriate security controls, limiting sharing to partners that are supporting the research and implementing controls that support compliance with applicable privacy laws. A list of commonly asked questions about clinical trials, Regeneron clinical programs, how to get involved and more can be found [here](#).

Data Sharing and Transparency: We support data transparency that advances science and medicine, protects participant privacy, and is in the best interest of individuals who use our products and providers who prescribe them. Information on our clinical trial research will be shared with healthcare providers and patients to make informed treatment decisions. Clinical trial data might also be shared with researchers to promote scientific progress. More on our Clinical Trial Disclosure & Data Transparency policy can be found [here](#).

Continued Access to Investigational Medicines and Compassionate Use: Regeneron conducts clinical trials only in countries where it intends to make the investigational product available. We aim to ensure that participants of confirmatory Regeneron-sponsored studies have the opportunity for continued access to the investigational medicine from the conclusion of their participation in the study through the time that the investigational medicine receives marketing authorization or becomes otherwise available. After marketing authorization or availability by other means, responsibility for access to our medicines lies with governments as part of national healthcare programs.

In exceptional circumstances where there is a clear medical rationale, Regeneron may provide investigational medicine to non-study participants prior to availability through Compassionate Use. See [Compassionate Use policy](#).

In all cases, the main criterion considered by Regeneron when providing access to investigational products outside the context of a clinical study is that the drug candidate has sufficient data to believe that the overall risk/benefit is positive.

Regeneron will comply with all applicable local laws and regulations relating to access to investigational medicines outside of a clinical trial.