REGENERON®

Position Statement on Ethics in Clinical Studies

Regeneron is a leading science-based biopharmaceutical company that discovers, invents, develops, manufactures and commercializes medicines for the treatment of serious medical conditions.

Clinical research allows physician scientists to study how an investigational treatment 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 people with serious diseases.

At Regeneron, we recognize the important role study participants play and are grateful to those who contribute to 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.

All Regeneron-sponsored clinical studies are designed and conducted to 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 meet 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 principles 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 Safety Oversight Committee that reviews any data trends potentially affecting the safety of participants; our Clinical Review Committee who reviews all clinical trial recruitment materials; 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 trainings that align with regulatory standards, such as Good Practice (GxP) guidelines and regulations, privacy protection and quality and compliance practices.

Last Updated: April 2025

Regeneron is committed to conducting high-quality clinical trials around the world. Vendors, clinical study sites, and collaborators involved in the execution of clinical trials are overseen by various functions within Regeneron including our Global Development Quality team, to ensure quality of work and compliance with laws, regulations and standards. Should investigators, participants 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)*** 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 service provider or clinical investigators until the issues have been fully remediated.

Representative Enrollment Into Our Clinical Trials

People and populations may be impacted differently by the same disease or have varying responses to the same treatment. Having a representative group of clinical trial participants helps scientists understand how treatments might impact a wider range of people.

When conducting clinical trials, we aim to reflect the investigational medicine's intended population. We strive to ensure our clinical trial processes, procedures and outreach methods support patient enrollment that reflects the disease epidemiology. We also seek feedback from external communities and insights from patients to raise awareness and buid trust among patient communities.

Epidemiological and real-world data inform the protocol strategy and design of clinical trials. Artificial Intelligence (AI) and machine learning also help us understand how diseases may progress in certain populations, which could help us design more representative trials while reducing the number of patients required

Participant Rights and Wellbeing

Regeneron has several 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, an

appropriate Informed Consent Form (ICF) is 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. 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 Product Candidates and Managed Access Program

Regeneron conducts clinical trials only in countries where it intends to make the product candidate available. We aim to ensure that participants of confirmatory Regeneron-sponsored studies have the opportunity for continued access to the product candidate 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 the product candidate to non-study participants prior to marketing authorization and product availability through our Managed Access Program. For more information see our Managed Access Program Policy.

In all cases, the main criterion considered by Regeneron when providing access to product candidates outside the context of a clinical study is that the product 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 product candidates outside of a clinical trial.