

Clinical Trial Disclosure & Data Transparency Policy Statements

Introduction

- Regeneron is committed to sharing data from our clinical research and clinical trials in a responsible manner.
- 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.
- Our pipeline of investigational medicinal products can be found at <https://www.regeneron.com/pipeline>.
- For specific inquiries regarding Regeneron's Clinical Trial Disclosure and Data Transparency commitments or practices, please contact us at clinicaltrialtransparency@regeneron.com.

Clinical Trial Registration

- Regeneron registers company-sponsored interventional clinical trials evaluating safety and/or efficacy on clinical trial registries, such as ClinicalTrials.gov and the European Clinical Trials Database (EudraCT), in compliance with applicable laws and regulations.

Summarizing the Results of Clinical Trials

- Regeneron will provide summary results of company-sponsored interventional clinical trials evaluating safety and/or efficacy, regardless of outcome, on ClinicalTrials.gov and/or the European Clinical Trials Database (EudraCT), in compliance with applicable laws and regulations.
- This also includes summary results of clinical trials evaluating safety and/or efficacy where the product has been discontinued because of safety concerns.

Publishing Clinical Trials

- Regardless of study outcome, Regeneron seeks to publish its phase 3 clinical studies and its hypothesis testing/confirming phase 1 and 2 studies; post-approval clinical studies conducted to meet a regulatory requirement; post-approval observational studies with predefined hypotheses that involve a Regeneron product; and any other clinical trial or study that provides important information on the safety and/or efficacy/effectiveness of the agent under investigation.
- Regeneron is committed to timely publication by submitting the primary findings within a year of completion of analysis of study data to a peer-reviewed journal or scientific conference.
- **Access to Data**
Authors will have access to all applicable study results supporting a publication.
- **Authorship and Acknowledgements**
Authorship of publications will be based on the criteria developed by the International Committee of Medical Journal Editors (ICMJE). Contributors who do not qualify for authorship may be listed in the Acknowledgment section of the publication. Editorial and medical writing support requested by the authors will also be acknowledged.

Sharing of Clinical Trial Data

- Regeneron is committed to sharing clinical trial data for approved products with external medical experts and scientific researchers in the interest of advancing public health.
- Qualified researchers may request access to individual patient or aggregate level data from a Regeneron sponsored study by submitting a research proposal to <https://vivli.org/>.
- Anonymized patient level data or aggregate study data will be considered for sharing when Regeneron has:
 - ensured ability to protect participant privacy
 - received marketing authorization from major health authorities (e.g., FDA, EMA, PMDA, etc) for the product and indication and has made the study results publicly available (eg, scientific publication, scientific conference, clinical trial registry)
 - the legal authority to share the data

Independent Research Request Evaluation Criteria

Administrative Evaluation:

1. Data requested is from a Regeneron sponsored trial.
2. Data is for approved medicines and indications.
3. Data is from a study in which Regeneron has already publicly disclosed the results (e.g., scientific publication, scientific conference, clinical trial registry).
4. There are no contractual, legal, or privacy limitations that would prevent sharing of the data requested (e.g., patient informed consent, Regeneron's collaborator agreements).
5. The lead researcher(s) and team are qualified to conduct this research and will follow applicable legal and regulatory requirements.
6. The lead researcher(s) and team have disclosed all financial sources, interests and affiliations, where the interests and affiliations raise concerns about potential conflicts in the analysis or reporting of results from the proposal. The leader and team will have a background and debarment check conducted.

Scientific Evaluation:

7. Data request is backed by a valid and robust research proposal.
8. Research proposal presents a novel analysis of significant scientific value that is not in conflict with additional planned and/or ongoing analysis(es) by Regeneron.
9. Proposed use of data will enhance scientific knowledge.
10. A complete, final statistical analysis plan has been provided and is judged to be rigorous and supportive of the proposed hypothesis in the data request.

11. There is a reasonable likelihood that the individual participants could not be re-identified.
12. Researchers must sign a contractual agreement listing certain obligations including, but not limited to:
 - A. publication of results;
 - B. providing Regeneron with an opportunity to review any publication and provide comments;
 - C. not to transfer shared data or information to parties not identified in the research proposal;
 - D. not to use the data for purposes not contained in the research proposal; and
 - E. not to attempt to re-identify research participants