REGENERON®

# Clinical Trial Disclosure & Data Transparency Policy Statements

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## 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-sponsored interventional trials are registered on clinical trial registries such as ClinicalTrials.gov and/or the EU Clinical Trials Information System (CTIS). Studies are registered in compliance with applicable laws and regulations.

## Summarizing the Results of Clinical Trials

- Summary results (e.g., technical and Plain Language Summaries, when required) of Regeneron-sponsored interventional trials are reported on registries such as ClinicalTrials.gov, European Clinical Trials Database (EudraCT), and/or the EU CTIS. Results are reported in compliance with applicable laws and regulations.

## 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 or has globally discontinued development of the product for all indications on or after April 2020 and has no plans for future development
    - made the study results publicly available (e.g., 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 or a product for which development has been discontinued globally on or after April 2020 and Regeneron has no plans for future development.

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 robust research proposal that:
    A. has a clearly articulated scientific purpose
    B. will materially enhance scientific knowledge and inform science and public health
    C. is not in conflict with additional planned and/or ongoing analysis(es) by Regeneron
    D. has a high probability that the requested data can address the research objective
    E. is not a re-evaluation of safety and/or efficacy issues that REGN has already published, are under peer review, or are being or has been reviewed by regulators
8. 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.
9. There is a reasonable likelihood that the individual participants could not be re-identified.
10. 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
    E. not to attempt to re-identify research participants