



## Clinical Trial Data Access

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## Overview

Pfizer believes that giving qualified scientific researchers access to patient-level data collected in clinical trials provides additional opportunities to conduct research that can improve patient care and help advance medical science. Pfizer will attempt to honor all bona fide research requests.

- ⊕ Pfizer provides secure access to patient-level data for the purposes of 'bona fide scientific research' that will contribute to the scientific understanding of the disease, target, or compound class including but not limited to:
  - Identification of trends and associations to develop hypotheses for further research.
  - Review of results from individual trials to validate results [in-line with some journal publication policies].
  - Review baseline data/placebo arm to assess the natural progression of disease.

## Eligibility

Requests will be considered from qualified researchers with the appropriate competencies to perform the proposed analysis. Research teams must include a bio-statistician.

- ⊕ Data will not be released to applicants with significant conflicts of interest, including individuals requesting access for commercial/competitive or legal purposes.
- ⊕ Funding requests along with requests for clinical trial data will not be supported. Only clinical trial data will be provided.

## Application Process

Applications (proposals) must be made through the INSPIIRE Portal and conform to the submission process. The following core information will be required:

- ⊕ Research Proposal detailing:
  - Background
  - Scientific Rationale
  - Objectives
  - Methods, including the identifiers of requested clinical studies
  - Statistical Analysis Plan
  - Publication plan
- ⊕ Curriculum Vitae (of all researchers)
- ⊕ IRB\IEC Initial and any Annual Renewal (if applicable)

Detailed instructions and a sample analysis plan are available on [www\(pfizer.com/IIR](http://www(pfizer.com/IIR).

## Review Process

Only complete requests will be reviewed by Pfizer. Researchers will receive an acknowledgement of receipt and the request will proceed for evaluation by a Pfizer review committee.

A primary review will be conducted by an internal Pfizer Review Committee (the review committee will include a clinician and a statistician). The internal committee will review each in scope request and make a recommendation to approve or decline the request.

Requests that are declined or partially approved/approved with limitations at the primary review stage will undergo Secondary Review by the Independent Review Panel (see Independent Review Panel Charter for more information).

A formal notification of the approval status is provided to the researcher through the INSPIIRE portal.

Pfizer will publish metrics on its website on an annual basis capturing the number of requests received, the number declined and the number approved.

## Review Criteria

The review process is based on the following criteria:

1. Is the research question clearly defined with a scientifically valid rationale?
2. Is there a well-documented and rigorous Statistical Analysis Plan?
3. If the proposal includes combining data across different Pfizer trials, is there a clear plan to standardize data sets to ensure they are comparable?
4. Is there an adequate publication plan to disseminate findings in a peer reviewed journal or scientific meeting?
5. Has the applicant certified that the stated research purpose has been declared fully and openly and that the research as described will be conducted and reported in good faith?
6. Is the applicant willing to declare all professional interests, affiliations, possible conflicts of interest and all sources of support for the research as part of the dissemination of their results?
7. Does the research team have sufficient expertise and qualifications to perform the proposed investigation?

## **Engagement with Pfizer**

For approved proposals, Pfizer will provide a medical and statistical point of contact for the principal investigator. Interactions will be limited to providing clarifying information.

## **Scope of Data Available**

Pfizer will provide access to patient level data from clinical trials for which Basic Results are posted in the clinicaltrials.gov registry (dating back to September 2007).

Data will be made available for patient level data from studies conducted for authorized (approved indications in the US and/or EU) or terminated medicines two years after clinical trial completion.

## **Data Access Agreement**

The requestor will need to enter into a standard Data Access Agreement with Pfizer prior to Pfizer's provision of access to clinical trial data.

## **Anonymization of Data**

Data will be anonymized in accordance with applicable privacy laws and regulations.

- Removing personally identifiable information (PII) from the dataset including all verbatim text.
- Recoding participant (patient) identifiers and investigator identifiers.
- Destroying the link (code key) between the dataset that is provided and the original dataset.

The basic data sets researchers will have access to in the SAS portal may look different from those submitted to regulators or used in publication(s) due to anonymization. As such, in some cases, researchers may not be able to completely duplicate the results of Pfizer analyses.

## **Data Access**

Pfizer will provide researchers access to the anonymized data sets via a secure portal administered by SAS.

Pfizer will provide relevant raw and derived data, with the data handling rules, derivation algorithms, inclusion indicators, the SAP, and the protocol.

## **Updating this policy**

Pfizer will review and, if appropriate, update this policy to include feedback regarding this process as well as information from other members of industry, academic institutions, public research funders, regulators and academic publishers.