A Guide to Requesting Pfizer Patient-Level Clinical Data

Overview 2
Eligibility 2
Application Process 2
Review Process 3
Review Criteria 3
Engagement with Pfizer 4
Scope of Data Available 4
Data Access Agreement 4
Anonymization of Data 4
Data Access 5
Updates to Pfizer policy 5
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 provides 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)
Review Process

Only complete requests will be reviewed by Pfizer. Researchers will receive an acknowledgment 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 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 approved, and the number declined.

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. Has the applicant certified that they will not attempt to identify the study subjects to which the data in the Data Set(s) relates and will implement appropriate internal policies, procedures, or protocols to minimize the risk of any such identification?
7. 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?
8. 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 if necessary. Interactions will be limited to providing clarifying information.

Scope of Data Available

Pfizer will provide access to anonymized patient-level data in response to scientifically valid research proposals.

Data from Pfizer-sponsored global interventional clinical studies are available from:

- Trials conducted for medicines, vaccines and medical devices for indications that have been approved in the US and/or EU.
- Trials conducted for medicines, vaccines and medical devices that have been terminated (i.e. development for all indications has been discontinued)

Data from these trials will be made available 24 months after study completion. Pfizer will make reasonable efforts to fulfill all data requests for legitimate research purposes, but there may be instances in which retrieval or delivery of data is not feasible (for example, if Pfizer does not have legal authority to provide the data, if costs of retrieval of older or pre-electronic data are prohibitive, etc. – see details below*).

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 line with the Safe Harbor method by:

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

The basic data sets researchers will access 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.

Copyright © 2017 Pfizer
All Rights Reserved
Data Access

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

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

Updates to Pfizer policy

Pfizer will review and, if appropriate, update its clinical data access 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.

*Circumstances under which it may not be possible for Pfizer to fulfill data requests may involve:

- Clinical data for which anonymization is difficult, there is a reasonable likelihood of re-identification (e.g. small studies, single-center studies, studies terminated early for lack of enrollment, clinical studies of rare diseases, or studies for which data does not exist in a format that can be readily anonymised), or there is a reasonable likelihood of otherwise violating the privacy rights of individuals;
- Clinical data that have been collected subject to legal, contractual or consent provisions that prohibit transfer to third parties;
- Locally administered studies in which data and results are only available in languages other than English;
- Case narratives, documentation for adjudication, imaging data (e.g. x-rays, MRI scans, etc.), genetic data and exploratory biomarker data;
- Or substantial practical constraints to providing technical data access (e.g. older, pre-electronic data for which files cannot be located).

Where Pfizer has a co-research, co-development or co-marketing/co-promotion agreement or where the product has been out-licensed, it is recognized that the responsibility for disclosure may be dependent on the agreement between parties. Under these circumstances, Pfizer will endeavor to gain agreement to share data in response to requests.