How does Pfizer share clinical trial data and information?

There are five ways Pfizer shares clinical trial data and information.

1) Pfizer provides important information about ongoing clinical trials, including the results of those studies, when available, on clinical trials registries including the U.S. National Institutes of Health’s publicly available clinical trials registry and database, clinicaltrials.gov.

2) Within 18 months of primary completion date, Pfizer submits for publication written results of interventional clinical studies of the use of our products in patients, whether the results are positive or negative.

3) Pfizer maintains a public online portal through which qualified researchers examining legitimate scientific questions may request patient-level data from the trials we sponsor.

4) Pfizer posts synopses on our public website of Clinical Study Reports (documents prepared for regulators) for all trials registered on clinicaltrials.gov. Many clinical study report synopses are now publicly posted, and additional clinical study report synopses will be posted during 2014.

5) Pfizer returns data to participants in our clinical studies in two ways. Starting with trials that commence in 2014, we provide lay-language summaries of the research and results to trial participants who wish to receive it and who are based in countries where the sharing of this information is allowed. We also enable U.S. patients to download their own medical data collected in our clinical trials using pilot “Blue Button” technology. Both options are available to clinical trial alumni participants through the PfizerLink website (registration required).

What Pfizer-sponsored studies have patient-level data available? Pfizer makes patient-level data available for globally conducted interventional trials in patients that complete after September 27, 2007, or initiated on or before that date and still ongoing as of December 26, 2007, as well as all such trials initiated after January 2014. Data are made available for trials of authorized medicines/indications, or terminated medicines, two years after clinical trial completion (defined as last subject last visit).

Why doesn’t Pfizer provide access to data from older trials?

The September 2007 date was chosen to align with the earliest date for data submitted to the U.S. clinicaltrials.gov database. Pfizer will evaluate requests for earlier data, but each request must be considered for feasibility. (Purely on a technical basis, retrieving older data sets and converting them to currently accepted data standards requires a substantial investment of resources.)
Who has access to Pfizer clinical data and results?
The public will have access to the synopses of clinical study reports posted on Pfizer.com and to results of Pfizer trials posted on ClinicalTrials.gov. Qualified researchers may request access to detailed patient-level data. Clinical trial participants will be offered access to their medical data collected during the trial(s), as well as summaries of the research in which they participated.

What is done to protect patient privacy?
All data provided to researchers will be anonymized to ensure that no identifiable information is provided. Patient-level data will be removed from Clinical Study Reports in the publicly posted synopses.

What happens if Pfizer declines or partially approves a request for data?
Any request not approved or only partially approved will automatically be reviewed by an external Independent Review Panel. The decisions of the Independent Review Panel will be final and binding.

How long will it take Pfizer to respond to data requests?
Pfizer endeavors to provide responses as soon as possible, but the response time varies depending on the amounts and types of data requested, the number of studies involved and the amount of work required to anonymize the patient-level data for sharing.

How were the members of the Independent Review Panel selected and what assurance does the research community have that the members are objective? Why is Pfizer using its own appointed Independent Review Panel instead of using the shared panel established by some other biopharmaceutical companies?
Pfizer selected the independent panel members based on their technical expertise and experience in biostatistics, bioethics and research policy, and expertise designing and conducting clinical trials. Pfizer chose to work with an Independent Review Panel that is dedicated to handling Pfizer data requests only in order to have the ability to assess how this solution is working given the volume and nature of requests received, number of requests escalated to the external panel, time to review, and other factors.

How do members of the Independent Review Panel make decisions?
The Panel makes decisions via consensus. Where individual Panel member recommendations differ, the Panel seeks consensus through discussion. The Panel can also request more information before making a recommendation or seek views from other non-Pfizer experts. Where consensus cannot be achieved, the decision will be by simple majority. In the event of a tie, the Chairperson makes the final decision. The process is outlined in the Independent Review Panel charter published on Pfizer’s website.
How will Pfizer provide access to data?
Pfizer will provide access to data using a secure portal designed by and hosted by SAS. This is the same technology used by other manufacturers. This portal will allow researchers to conduct their analyses, but it does not allow researchers to download or copy the data.

Why isn’t Pfizer using the centralized database, ClinicalStudyDataRequest.com?
Companies including Pfizer are committed to sharing clinical data responsibly as part of a larger and evolving effort by all who create and use such data to arrive at a transparent, harmonized access process in the best interest of patients. There are still many complexities to be resolved including establishing common data standards and identifying review processes that promote sound science and quality analyses. Many experts across the medical research community are working together to define these standards. In the meantime, Pfizer adopted an approach that could be implemented in a timely manner and that uses a platform Pfizer was already using to provide researchers with access to clinical data.