Pfizer’s Approach to Providing Access to Patient Level Data
Pfizer believes that giving qualified scientific researchers access to patient-level data collected in clinical trials provides additional opportunities for them to conduct research that can improve patient care and help advance medical science.

Pfizer provides access to patient-level data to qualified researchers with a scientifically valid research proposal (including statistical analysis plan) for 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) or terminated medicines, two years after clinical trial completion.

Since respect for patient privacy is a paramount concern, all necessary measures are taken to ensure that privacy is safeguarded.

Researchers receiving access to patient-level data or other information such as clinical study reports are required to enter into a Data Access Agreement committing the applicant to use the data only for the stated research purposes and not to disclose the data to third parties.

Purpose of Independent Review Panel
An internal Pfizer Review Committee conducts the initial review of in scope requests. Any request approved by Pfizer will not require a secondary review by the Independent Review Panel.

Pfizer is piloting the use of an Independent Review Panel during 2014. The Panel will review any proposal declined, or partially approved, by Pfizer. The role of the Panel is to review the application, the rationale for Pfizer’s response, and to make a final decision. The decision of the Panel will be binding.

This Charter describes the responsibilities and decision-making process of the Panel. Panel members review research proposals in a personal capacity, not as representatives of their respective organizations or institutions.

Pfizer pays members of the Panel fair market value fees for their time and expertise.

Scope
Panel members review all requests that are only partially approved/approved with limitations or declined by Pfizer.

Review
If Pfizer does not approve the application or approves it partially or with limitations, the proposal is sent to the Independent Review Panel. Then Panel conducts a high level review of the Internal Review Committee’s decisions, 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?

Based on this review, each Panel member makes one of the following recommendations:

1. Confirm
2. Overturn

Decision Making Process
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 Chairperson informs Pfizer in writing of the Panel's decision, including the rationale, and any conditions, where applicable. Pfizer communicates the decision, and any conditions to the applicants.

An Evolving Policy
There are many initiatives currently ongoing to define global standards for data sharing. Pfizer policies and procedures will evolve accordingly.