Pfizer's Commitment to the EFPIA/PhRMA Data-Sharing Principles

Pfizer has had a longstanding commitment to ensure that data is available to those who need it, including regulators, researchers, and trial participants. Pfizer offers access to the clinical data gathered in company-sponsored clinical trials, in the hope and belief that greater openness, when managed in ways that mitigate risk, may accelerate medical progress and benefit patient outcomes and public health.

Pfizer's data access policies and practices meet or exceed the five transparency principles endorsed by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA). These principles call for broader sharing of clinical trial data in ways that safeguard patient privacy, respect regulatory processes and oversight and maintain incentives to invest in biomedical research.

Here is how Pfizer's policy aligns to the EFPIA/PhRMA principles:

EFPIA/PhRMA Principle	Pfizer's Approach
1. **Enhance Data Sharing with Researchers** by "sharing upon request from qualified scientific and medical researchers patient-level clinical trial data, study-level clinical trial data, and protocols from clinical trials in patients for medicines and indications approved in the US and the EU as necessary for conducting legitimate research."	To request access to patient-level data, researchers submit a scientifically valid research proposal via Vivli. Any request that Pfizer declines, in whole or in part, is referred to an Independent Review Panel, who makes a final, binding decision on access.
2. **Enhance Public Access to Clinical Study Information** by making publicly available, "at a minimum, the synopses of Clinical Study Reports (CSRs) for clinical trials submitted to the FDA, EMA, or national competent authorities of EU Member States" following approval of a new medicine or new indication for an approved medicine in the US and EU.	Pfizer publicly posts electronic synopses of Clinical Study Reports (CSRs) submitted to regulators, relating to approved products. These include summary results for all primary and secondary endpoints with any personally identifiable information removed.
3. **Share Results with Patients Who Participate in Clinical Trials** by working "with regulators to adopt mechanisms for providing a factual summary of clinical trial results and make the summaries available to research participants."	Pfizer makes study results summaries in plain language available to participants in Phase 2/3 clinical trials that started in 2014 or later.
4. **Certify Procedures for Sharing Clinical Trial Information** by posting to a public web site "that they have established policies and procedures to implement these data sharing commitments."	Interested members of the public may review Pfizer's full policy, including descriptions of our procedures, on Pfizer's public website Pfizer.com.
5. **Reaffirm Commitments to Publish Clinical Trial Results**. "At a minimum, results from all Phase 3 clinical trials and any clinical trial results of significant medical importance should be submitted for publication."	Pfizer submits the results of the primary end point(s) from interventional clinical studies in patients for publication in peer-reviewed journals within 18 months of study completion, regardless of outcome.

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