

Transparency in Clinical Trials

Clinical trials are crucial to helping researchers understand the safety and effectiveness of an investigational drug. Pfizer's commitment to openness and transparency includes all aspects of research and development behind our products, including clinical trials. Enhanced transparency in clinical trials fosters trust among research participants, health care professionals, and biopharmaceutical companies, while increasing knowledge of potential new treatments in development. Transparency also enables patients, physicians, and others to see the progress being made to address unmet medical needs. Pfizer's policies support clinical trial transparency to advance scientific knowledge and public health, while balancing the need to protect participant privacy and respect the regulatory process.

Background

The study of how a medicine works in people is a pivotal step in the research and development process of new treatments for diseases and medical conditions. Researchers spend years in the laboratory before conducting carefully controlled studies in research participants, known as clinical trials. Regulatory authorities issue rules regarding the conduct of clinical trials and the sharing of the results of these studies to make sure that research sponsors abide by a clearly defined set of standards. A drug is approved only when the data, collected through clinical trials, prove that the drug is both safe and effective. Clinical trials help answer questions about risks, benefits, and side effects of a potential new treatment. In addition, clinical trials are also conducted on already approved medicines to increase knowledge about their potential uses, benefits, safety, and long-term effects.

Transparency of clinical trials is an important issue to patients, the research community, and policymakers. Certain jurisdictions require registration and posting of summary results from clinical trials of regulated medical products. To facilitate these requirements and recommendations, public registries, such as ClinicalTrials.gov and EudraCT, have been created for clinical trials conducted in the U.S. and Europe, respectively.^{1,2} The World Health Organization International Clinical Trials Registry Platform is a voluntary global network that was established to provide a single point of access to multiple clinical trial databases, conforming to a set of international standards for clinical trial registries.³

An increasing call to have access to detailed clinical trial data has resulted in several additional regulations, policies, and clinical trial sponsor-led efforts. In July 2013, Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) jointly published commitments to responsible data sharing practices by biopharmaceutical companies.⁴ In 2016, the European Medicines Agency (EMA) released a policy on the requirements for publishing clinical data to support regulatory applications.⁵ The Food and Drug Administration (FDA) has explored policies designed to use and share de-identified and masked trial data from marketing applications.⁶ In 2018, FDA launched a pilot program to assess the feasibility of releasing portions of clinical study reports (CSRs) in an effort to provide usable summaries of clinical evidence.⁷ The International Committee of Medical Journal Editors (ICMJE) has a policy that medical journals require the registration of clinical trials as a condition of publication.⁸

Key Facts

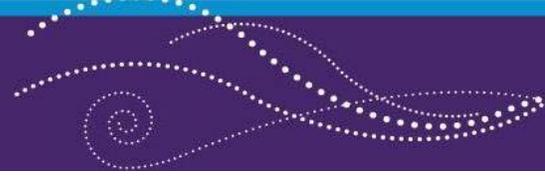
- Pfizer invested more than \$8 billion during 2018 in the research and development of new products,⁹ and as of November 30, 2019 had 96 products in its development pipeline.¹⁰
- Pfizer currently has 205 open, ongoing trials registered on www.ClinicalTrials.gov.¹¹

Pfizer Policy Positions

Pfizer believes it is important for researchers, trial participants, regulators, and others acting in the best interest of patients to have access to clinical trial information to advance medical understanding and progress. It is also important that this access protect participant privacy, preserve regulatory authority, and maintain incentives for those who generate research data.

Pfizer offers access to the clinical data gathered in company-sponsored clinical trials, in the hope and belief that greater openness may accelerate medical progress and benefit patient outcomes and public health. Pfizer publicly shares results from our clinical trials, whether the results are positive, neutral, or negative. We also share data gathered in clinical trials we sponsor with trial participants, researchers, and others. Pfizer's data access policies and practices meet or exceed the five transparency principles endorsed by PhRMA and EFPIA.⁸





Pfizer's clinical trial results and data sharing approaches include:

- **Regulatory Requirements:** Pfizer is committed to meeting or exceeding regulatory requirements for the registration of our clinical trials and provision of results upon completion.
- **Public Access to Clinical Study Information:** Pfizer publicly posts electronic synopses of Clinical Study Reports (CSRs) submitted to regulators, relating to approved products.¹² These reports include summary results for all primary and secondary endpoints with any personally identifiable information removed.
- **Sharing Results with Clinical Trial Participants:** Pfizer believes that data collected during a clinical trial should be returned to the study participants, if they wish and where permitted, so that they may better understand the research in which they participated and use the data gathered about their health. Pfizer returns clinical trial data to participants along with summaries of aggregate clinical trial results in easy-to-read, non-technical language so that they can understand why the study was done, how it was done, and the results.
- **Data Sharing with Researchers:** Pfizer provides access to de-identified patient-level data upon request from qualified scientific and medical researchers who have submitted a scientifically valid research proposal. Requests are managed through the global clinical research data sharing platform, Vivli.¹³
- **Publication of Clinical Trial Results:** Pfizer submits the primary results of all interventional clinical studies for publication in peer-reviewed biomedical journals within 18 months of study completion, regardless of the outcome.

How Patients and Health Care Systems Benefit

Clinical trials provide valuable information to help regulators ensure new medicines are safe and effective prior to being prescribed to patients. Trials also help biopharmaceutical companies, regulators, and public health officials monitor the safety and effectiveness of treatments already available to patients.

Transparency in clinical trials engenders trust between participants, health care professionals, and biopharmaceutical companies and increases patient knowledge of available medications, as well as potential new treatments in development. Pfizer's policies are designed to promote effective and ethical collaborations and build trust throughout the health care system. Finally, transparency in clinical trials enables monitoring of the progress being made to address unmet medical needs in our health care system.

¹ See: www.clinicaltrials.gov.

² See: eudract.ema.europa.eu.

³ See: www.who.int/ictrp/en.

⁴ PhRMA & EFPIA —Principles for Responsible Clinical Trial Data Sharing. See:

phrma.org/sites/default/files/pdf/PhRMAPrinciplesForResponsibleClinicalTrialDataSharing.pdf.

⁵ See: www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication.

⁶ Federal Register notice, Docket No. FDA-2013-N-0271, Availability of Masked and De-identified Non-Summary Safety and Efficacy Data; Request for Comments; June 4, 2013. Available at <http://www.gpo.gov/fdsys/pkg/FR-2013-06-04/html/2013-13083.htm>.

⁷ See: www.fda.gov/drugs/development-approval-process-drugs/clinical-data-summary-pilot-program.

⁸ ICMJE Clinical Trials Recommendations: <http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html>.

⁹ Pfizer 2018 Financial Report available at: s21.q4cdn.com/317678438/files/doc_financials/Annual/2018/2018-Financial-Report.pdf.

¹⁰ See: www.pfizer.com/science/drug-product-pipeline.

¹¹ National Institutes of Health. ClinicalTrials.gov. Available at <http://www.clinicaltrials.gov/ct2/search>, accessed November 7, 2019.

¹² See: www.pfizer.com/research/research_clinical_trials/trial_results.

¹³ See: vivli.org.

