

CLINICAL TRIAL DATA SHARING



What is clinical trial data sharing?

Developing new therapies to treat disease and to improve quality of life is a long, complex and costly process. A critical part is the utilization of clinical trials — the study of biopharmaceutical products in human subjects. Clinical trials generate incredible amounts of data which are used by the sponsor to answer a specific set of questions; however, these data also have the potential to answer questions beyond the specific trial as well. To this end, our member companies make original datasets and other detailed clinical trial information available to qualified researchers in an effort known as **data sharing**.



Why do we share clinical trial data?

The biopharmaceutical industry believes that disclosure of clinical trial results and responsible sharing of clinical trial data is in the best interests of patients, clinicians and medical research.

PhRMA member companies participate in a variety of clinical trial data sharing initiatives in order to make data available to qualified researchers. Researchers then use these data in order to perform confirmatory analyses, but more often they use the data to explore answers to new questions in efforts to improve patient care and accelerate the development of new treatments.



How do we responsibly share clinical trial data?

The biopharmaceutical industry is at the forefront of initiatives to improve access to clinical trial data. Industry's commitments to data sharing are reflected in the joint **EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing**, adopted by the boards of both associations in July 2013. These Principles were designed to support detailed data sharing with qualified researchers on request while addressing the key challenges of safeguarding patient privacy, respecting the integrity of national regulatory systems and maintaining incentives for investment in biomedical research by protecting commercially confidential information.

Under these Principles, biopharmaceutical companies commit to enhance data sharing with qualified researchers, work with regulators to adopt mechanisms for providing summary results to clinical trial participants, enhance public access to clinical study information, as well as reaffirm their commitment to consider all company-sponsored trials for publication and submit all phase 3 and other clinical trials of significant medical importance for publication.