

The Servier's commitments

to the EFPIA/PhRMA Data-Sharing Principles

Servier adheres to the **Principles for Responsible Clinical Trial Data-Sharing** laid out by the EFPIA (European Federation of Pharmaceutical Industries and Associations) and PhRMA (Pharmaceutical Research and Manufacturers of America). This includes the timely registration of clinical trial protocols, communication and publication of results from our clinical research programs, and sharing results with the patients who participate in our clinical trials.

Servier Transparency Policy and practices meet or exceed the five commitments of the EFPIA/PhRMA Principles for Responsible Clinical Trial Data. These principles were tackled in a manner that safeguard patient privacy, respect regulatory processes and oversight and maintain incentives to invest in biomedical research. Here is how our transparency policy meet or exceed the five EFPIA/PhRMA principles:

What are THE PHRMA/EFPIA COMMITMENTS?	HOW SERVIER MEETS OR EXCEEDS THE PHRMA/EFPIA COMMITMENTS
<p>1. Enhancing Data Sharing with Researchers “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.”</p>	<p>Researchers may submit requests for patient-level clinical trial data, study-level clinical trial data and protocols on the Servier Website. All valid research proposals will be reviewed by a qualified panel of Servier experts:</p> <ul style="list-style-type: none"> - If the request is granted, Proposals approved by the Servier panel will be transmitted for information to an Independent Review Board of external experts (IRB) - If the request is denied, the proposal will be reviewed in terms of scientific merit and value by the IRB. Decisions by the IRB are final and binding. <p>Servier strives to communicate the decision and any conditions to the researcher within 3 months. Once the research proposal has been approved, prior to providing access to data, the researcher will sign a Data-Sharing Agreement with Servier.</p>
<p>2. Enhancing Public Access to Clinical Study Information “Following approval of a new medicine or new indication for an approved medicine in the US and EU, companies will make publicly available the synopses of clinical study reports (CSRs).”</p>	<p>Servier will post CSR synopses following approval of a new medicine or new indication for an approved medicine in the US and EU on clinicaltrials.servier.com. Servier is also committed to disclose all CSR synopses for all clinical trials registered on primary public registries. Results will be posted within 1 year of completion of the trial.</p>
<p>3. Sharing Results with Patients Who Participate in Clinical Trials “Working with regulators to adopt mechanisms for providing a factual summary of clinical trial results and making the summaries available to research participants.”</p>	<p>Servier are working with EFPIA, PhRMA and regulators to adopt mechanisms through which we may provide a factual summary of clinical trial results and make this summary available to subjects who participated in a particular clinical trial.</p> <p>Servier is working hard on this commitment. In 2017, we will publish two lay summaries (pilot phase). Then, Servier will disclose on his website the summary of clinical trials results in lay language for all studies ending after the 1st January 2018.</p>
<p>4. Certifying Procedures for Sharing Clinical Trial Information “Companies will post to a publicly available website that they have established policies and procedures to implement these data sharing commitments.”</p>	<p>The Servier Transparency Policy and our procedures related to the sharing of clinical trial data are available on our website. Through established policies and procedures we certify that we are committed to EFPIA/PhRMA data sharing principles.</p>
<p>5. Reaffirming Commitments to Publish Clinical Trial Results “At a minimum, results from all Phase 3 clinical trials and any clinical trials of significant medical importance should be submitted for publication.”</p>	<p>We publish results our studies (at minimum all the phase 3) in peer-reviewed scientific conference and/or journals. We published all results regardless of study outcome. We submit articles within 18 months of the end of the study. It concerns all studies ending after the 1st January 2014.</p>