AbbVie's Approach to Implementing the
PhRMA-EFPIA Principles for Responsible Clinical Trial Data Sharing

Description of the PhRMA-EFPIA Principle	Description of Approach (as of Jan 22, 2014)
1. Enhancing Data Sharing with Researchers "*Sharing by 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*."	Researchers may submit requests for access to clinical research information in support of legitimate scientific research by completing AbbVie's Access to Data and Information Privacy Agreement and the Research Proposal Form and emailing both to accesstodata@abbvie.com. Requests will be reviewed by the company and may either be granted or denied. In cases where a request is rejected based on scientific merit, the request will be reviewed by the Access to Clinical Research Information Board (ATCRIB). The ATCRIB will include as members, scientists and/or healthcare professionals who are not AbbVie employees. Decisions by the ATCRIB are final and binding.
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)*."	Beginning in January 2014, AbbVie will post CSR synopses following approval of a new medicine or new indication for an approved medicine in the US and EU on AbbVie.com. AbbVie is also committed to posting CSR synopses for historical approvals dating back to May 2004 via a phased approach. To locate the CSR synopsis for a particular clinical trial supporting a new medicine or new indication for an approved medicine in the US and EU, click on the name of the product on our webpage and select the clinical trial of interest by number and title.
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*."	AbbVie and our industry peers are working with 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.
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.*"	Descriptions of AbbVie's policies and procedures related to the sharing of clinical trial data and information appear on our AbbVie.com web pages under the Research and Innovation header, Clinical Trial Data and Information Sharing tab. We will post the metrics regarding our company's data sharing activities on a semi-annual basis. AbbVie has certified that we have established policies and procedures to implement our data sharing commitments with PhRMA and EFPIA.
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*."	For AbbVie-sponsored interventional clinical trials conducted in patients using AbbVie marketed products or investigational compounds (including compounds for an indication whose development program has been discontinued), AbbVie submits a manuscript, that at a minimum, reports the results of the primary endpoint, to a peer-reviewed scientific/medical journal within 12 months, and no later than 18 months, of: • Last patient last visit (LPLV) for already marketed AbbVie products (marketed anywhere in the world); **OR** • The first regulatory approval of the AbbVie investigational compound; **OR** • The date of AbbVie's decision to discontinue development of an investigational compound for an indication, unless an out licensing plan exists.