

Merck Perspective

Clinical Trial Registration and the Publication of Clinical Trial Results

THE ISSUE

Merck conducts clinical trials worldwide to evaluate the safety and efficacy of our products. These trials are fundamental to the development of innovative medicines and vaccines that treat and prevent illness in both humans and animals.

Merck has long been committed to publishing the results of our clinical trials – regardless of outcome – in a timely manner. In conjunction with other pharmaceutical companies and as outlined in a Joint Position issued by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), European Federation of Pharmaceutical Industries and Associations (EFPIA), Japan Pharmaceutical Manufacturers Association (JPMA), and Pharmaceutical Research and Manufacturers of America (PhRMA), we are taking important steps to ensure that information on clinical trials and results is made public in a timely and balanced manner, while protecting essential proprietary information.

WHAT MERCK BELIEVES

Merck believes that clinical trial registries serve an important function for patients and their health care providers to learn about and gain access to relevant clinical trials of experimental treatments or preventative agents.

A clinical trial registry also serves those that analyze, report, or publish the results of clinical trials by providing information on trials in progress and the ability to track such trials over the course of development.

In keeping with our publication guidelines, Merck is committed to disclosing balanced, complete, and accurate information about our registered clinical trials of marketed products, regardless of outcome.

WHAT WE DO

It is the policy of Merck to comply with applicable laws and regulations associated with registration of clinical trials and posting trial results. Merck has put into place the processes necessary for compliance with The Food and Drug Administration Amendments Act of 2007, including those related to clinical trial registration and posting results.

Registration of Clinical Trials

Merck is registering clinical trials in patients of investigational and marketed products in which treatment is assigned that it sponsors and conducts anywhere in the world on www.clinicaltrials.gov at trial initiation.

Merck continues to comply with The Food and Drug Administration Modernization Act (FDAMA) requirement to post information on www.clinicaltrials.gov about clinical trials designed to treat life-threatening or otherwise serious illnesses, regardless of phase. Information posted by Merck allows patients to identify potentially appropriate trials for their disease conditions and to pursue participation by calling a central contact number for further information.

In addition to the compound identification number, each individual clinical trial registered has a unique trial identification number, a [clinicaltrials.gov](http://www.clinicaltrials.gov) identifier ("NCT#") and a Merck identifier ("Study ID number"). The NCT number will aid in tracking an

individual trial through to completion and will be included in manuscripts submitted for publication or in summaries posted on www.clinicaltrials.gov.

Publication of Clinical Trial Results

Merck is committed to disclosing balanced and accurate information regarding our registered clinical trials of our marketed products. We stand firmly behind this commitment, regardless of trial outcome. Clinical trial results of marketed products will be disclosed by submitting a synopsis to www.clinicaltrials.gov within 30 days after the product is marketed in the United States or within 12 months after the last patient's last visit for the primary outcome occurs, whichever is later.

Merck's commitment to publishing results of hypothesis-testing trials has existed for many years. This has been expanded to include disclosure of results from registered trials of marketed products, as noted above, including extensions of these clinical trials. Merck formally developed and implemented our Guidelines for Publication of Clinical Trials and Related Works in 2003 and posted them publicly online in January 2004. The guidelines contain additional information about how and when we disclose trial results.

In addition to publishing our clinical trial results, Merck has provided clinical trial results for our marketed products at the free public PhRMA clinical trial results database, www.clinicalstudyresults.org, along with citations of published trials entered concurrently in clinicaltrials.gov¹. Starting in October 2008, trial results are now provided to the www.clinicaltrials.gov database.

If a clinical trial of a marketed product is terminated early for safety reasons, Merck will promptly disclose medically important information to regulatory authorities and the public, update the status on clinicaltrials.gov within 30 days, and submit a manuscript to a journal (or post a summary online) within 12 months after the last patient's last visit occurs. If terminated for efficacy reasons, the results will be disclosed within 12 months after the last patient's visit occurs. Summaries of terminated trials will provide information about patient disposition, safety and adverse experiences, as well as an explanation for why the trial was terminated early.

What are "hypothesis-testing" trials?

Hypothesis-testing clinical trials are well-controlled trials designed to provide meaningful results by examining pre-stated questions (hypotheses) using predefined statistically valid plans for data analysis, allowing solid conclusions to be drawn to support specific product claims. Such trials are often called "confirmatory" or "clinically directive" and are generally considered to be phase III trials. Merck designs its phase II studies to test hypotheses, but these earlier phase studies are generally not pivotal confirmatory trials and typically do not have clinically directive outcomes.²

¹ Effective December 2011, the study results maintained in the PhRMA database will be transferred to www.merck.com because of PhRMA's announcement that the database will be removed by the end of 2011.

² Adapted from the ICH Harmonised Tripartite Guideline. Statistical Principles of Clinical Trials. Stats Med (1999) 18:1904-42.

WHERE TO GO FOR MORE INFORMATION

If you or someone you know needs more information on participating in clinical trials, go to <http://www.clinicaltrials.gov/>.

For more information on Merck's publications practices, view the *Merck Guidelines for Publication of Clinical Trials and Related Works* at <http://www.merck.com/research/discovery-and-development/clinical-development/Merck-Guidelines-for-Publication-of-Clinical-Trials-and-Related-Works.pdf>

FORWARD LOOKING STATEMENT

This website includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined company’s plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck’s management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period, due to, among other things, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry; the risk that the businesses will not be integrated successfully; disruption from the merger making it more difficult to maintain business and operational relationships; Merck’s ability to accurately predict future market conditions; dependence on the effectiveness of Merck’s patents and other protections for innovative products; the risk of new and changing regulation and health policies in the U.S. and internationally and the exposure to litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck’s 2010 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).

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