Merck Perspective

Clinical Trial Registries 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 humans.

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, 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[1]. Merck has put into place the processes necessary for compliance with The Food and Drug Administration Amendments Act of 2007 and the European Medicines Agency (EMA) clinical trial Directive 2001/20/EC, 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 on www.clinicaltrials.gov, www.clinicaltrialsregister.eu or www.encepp.eu/ at trial initiation.

Publication of Clinical Trial Results

[1] Prior to March, 2007, Merck registered phase II and later trials in which treatment was assigned. Merck's phase II studies are designed to be hypothesis-testing, but they are generally not pivotal confirmatory trials.

Merck is committed to disclosing balanced and accurate information regarding our registered clinical trials. We stand firmly behind this commitment, regardless of trial outcome. Clinical trial results will be disclosed by posting synopsis on the following publicly accessible websites: www.clinicaltrials.gov, www.clinicaltrialsregister.eu or www.encepp.eu/. Merck also posts trial synopses on www.merck.com.

Merck accepts the obligation to facilitate publication of medically important clinical data in a timely, objective, accurate, and balanced manner, regardless of the outcome of a trial. Merck formally developed and implemented our publication guidelines in 2003 and recently revised them to reaffirm our commitment to the principles of the Joint Statement to submit for publication in the scientific literature the results of its Phase 3 interventional clinical trials involving a Merck product, and any interventional clinical trial results in patients (or preventive interventional trial results in healthy subjects) of significant medical importance, according to the pre-specified plans for data analysis. The latest version of Merck's Guidelines for Publication of Clinical Trials in the Scientific Literature is posted on www.merck.com.

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 last 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.

WHERE TO GO FOR MORE INFORMATION

If you or someone you know needs more information on participating in clinical trials, go to clinicaltrials.gov; clinicaltrialsregister.eu; www.merck.com

For more information on Merck's publications practices, view the *Merck Guidelines for Publication of Clinical Trials in the Scientific Literature at* http://www.merck.com/clinical-trials/policies-perspectives.html

FORWARD LOOKING STATEMENT

This statement includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include, but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and healthcare legislation in the United States and internationally; global trends toward healthcare cost containment; technological advances, new products and patents

attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to litigation, including patent 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 2013 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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