

Principles of Medical Research Clinical Trial Registry

Eli Lilly and Company is committed to principles of medical research that define the ethical conduct, funding, and communication of clinical research. Lilly conducts clinical research with the highest standards of scientific integrity and respect for patients. Lilly discloses publicly all medical research results that are significant to patients, health care providers or payers – whether favorable or unfavorable to a Lilly product - in an accurate, objective and balanced manner in order for our customers to make more informed decisions about our products. The standards described below represent our commitment to serve patients through transparent and comprehensive disclosure of clinical trial data.

Standards for Disclosure of Lilly Clinical Trial Data:

Clinical Trial Initiation: All Phase II, III and IV trials will be registered at initiation on the Lilly Clinical Trial Registry www.LillyTrials.com, and an independent public registry such as www.ClinicalTrials.gov. These registrations will be done in compliance with the following laws and organization standards: Section 113 of the [FDA Modernization Act](#) of 1997 (FDAMA), [World Health Organization](#) (WHO) Technical Consultation on Clinical Trials Registration Standards, 25-27 April, 2005, [Joint Global Pharmaceutical Industry Position](#) and the [Pharmaceutical Research and Manufacturers of America](#) (PhRMA). In all cases, consistent with the above guidelines, the following information will be provided: unique trial number, trial registration date, secondary identifiers, funding source(s), primary and secondary sponsors, responsible contact person, research contact person, brief title, research ethics review, condition, key inclusion and exclusion criteria, study type, anticipated trial start date, and recruitment status. For some studies, additional information will also be disclosed at study initiation. For each study registered at initiation, Lilly will also publicly disclose the results of that study as described below.

Clinical Trial Results: The results of all Phase I, II, and III trials conducted in support of a product's initial registration will be disclosed on the publicly accessible websites www.LillyTrials.com and www.ClinicalStudyResults.org, regardless of outcome, no later than when the first indication is approved and the drug is commercially available for patient use anywhere in the world. The results of all subsequent Phase II, III, and IV trials conducted after initial approval will be similarly disclosed within one year of trial completion. A trial's results, irrespective of study phase, will be disclosed as soon as possible if there are any significant safety findings. The registry will also be populated with the results of core efficacy and safety registration trials for products first approved after July 1, 1994.

Consistent with ICH E3 guidelines, Lilly will disclose the results of primary and secondary outcome measures that are specified in the study protocol, as well as additional safety and efficacy results that impact patient care and the use of our products. Also, Lilly discloses a comprehensive description of the trial design and methodology for each study. Results will be disclosed regardless of whether they support the hypothesis being tested or are contrary to the predicted outcome. Clinical trial results will be publicly disclosed as stated above, unless posting would compromise publication in a peer-reviewed medical journal or contravene national laws or regulations. Results of studies that are under review by peer-reviewed medical journals that prohibit pre-publication disclosure will be posted on the registry at the time of publication. Clinical trial results are also disclosed through presentations and abstract submissions at professional scientific meetings.

Effective Date: Lilly will comply with these standards for disclosing results for all clinical trials completed after July 1, 2004. Lilly will comply with these standards for disclosing trial initiation for all new studies beginning after July 1, 2005 and for all ongoing trials by September 13, 2005. Results of core efficacy and safety registration trials for products first approved after July 1, 1994 will be disclosed by July 1, 2005.

Verification of Disclosure:

An independent third party will audit and verify Lilly's adherence to these standards of disclosure.