Answers That Matter.

~~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 research results of all our marketed products.

Standards for Disclosure of Lilly Clinical Trial Results:

Regardless of outcome, Lilly commits to disclose publicly the results of all trials on marketed products for which Lilly is the sponsor. This includes the results of all Phase I (early exploratory), Phase II (proof of concept), Phase III (registration), and Phase IV (post-marketing) trials conducted anywhere in the world.

?? **What we disclose:** Lilly commits to disclose the clinical trial results of the 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 which do not support the hypothesis being tested, or which are contrary to the intended outcome, will be disclosed. A listing of all phase III and phase IV trials will be posted on the registry at the initiation of each study using a unique study identifier. When the trial is completed and the drug is commercially available, the results of these trials will be appended to its identifier.

?? **When we disclose:** For phase I, II, and III clinical trials, Lilly discloses results when a drug's indication is approved and it is commercially available. Phase III trial results for secondary indications of marketed drugs that fail to achieve approval will also be posted. For phase IV clinical trials, Lilly discloses the results as soon as possible after the data analysis is completed but no later than one year after the trial has completed. For studies that are under review by peer-reviewed journals that prohibit pre-publication results disclosure, the results will be posted on the registry at the time of the publication.

?? **How we disclose:** In all cases**,** Lilly discloses clinical trial results on a publicly available clinical trial registry. Lilly also discloses clinical trial results through peer-reviewed medical journals, subject to the discretion of the journal editors. In addition, clinical trial results are disclosed through presentations and abstract submissions at professional scientific meetings. A reference will be provided in the clinical trial registry for study results disclosed in a peer-reviewed journal.

?? **Effective date:** Implementation of these standards will begin with all clinical trials of marketed products that are completed after July 1, 2004. In addition, the registry will be populated retrospectively with results of core efficacy and safety registration trials of marketed compounds with first approval after July 1, 1994.

?? **Verification of disclosure**: An independent third party will audit and verify adherence by Lilly to these standards on results disclosure.