


Disclosure of clinical research results

A clinical trial is a research study conducted in human volunteers to determine whether a new drug or treatment is both safe and effective. Transparency on clinical trials and their outcomes is fundamental to allow healthcare professionals and patients to make the right treatment decisions. Novartis has spearheaded industry efforts to increase transparency on clinical trials and publishes results of ongoing and completed clinical trials regardless of trial outcome. The Novartis clinical trials results database, eTrials, is available online worldwide.

Novartis Position

Novartis is committed to the timely communication and/or publication of all Phase IIb, III and IV clinical trial results (except exploratory trials), whatever their outcome, because we recognize that there are important public health benefits associated with making clinical trials information more widely available to healthcare practitioners and patients.

We continuously strive to ensure the rights, the safety and the well-being and that clinical trial results are valid and credible. As such, we design and conduct all our clinical trials in accordance with ethical principles embodied in the Declaration of Helsinki, Good Clinical Practice (GCP) guidelines and national and international regulatory requirements. We furthermore believe it is in the interests of patient safety and scientific integrity to respect and defend researchers' independence and freedom to participate in and to approve all aspects of a clinical trial, including the results. All clinical investigators may have access to their own data once results have been processed and consolidated according to the agreed protocol, and all receive a summary on completion of the study and the clinical report. We also ensure that authors of a publication on a trial receive a full clinical trial report. Additionally, Novartis supports transparent communications, independent opinions and the full disclosure of any possible conflicts of interest by



investigators and authors of clinical trial publications, and in keeping with the guidelines of the International Committee of Medical Journal Editors (ICMJE), believes authorship should accurately reflect substantial contributions to the design and conduct of a clinical trial and subsequent drafting of a publication manuscript.

We strongly endorse the 2005 Joint Position on clinical trial results disclosure by the International Federation of Pharmaceutical Manufacturers and Associations, Pharmaceutical Research and Manufacturers of America, European Federation of Pharmaceutical Industries and Associations, and Japanese Pharmaceutical Manufacturers Association. As such, we commit to registering all ongoing clinical trials (Phase II-IV), except exploratory trials, on the clinicaltrials.gov website within 21 days of trial start, and registering results on both the Novartis Results database as well as the PhRMA study results database within one year of trial completion, from September 2005.