

Amgen's Policy on Sharing Our Clinical Trial Results

Amgen is committed to the timely communication of research results, whether positive or negative, from clinical trials that we sponsor.

Amgen adheres to a comprehensive policy on the public disclosure of clinical trials and trial results to ensure that our research practices are transparent, responsible, and fully compliant with regional and international laws, regulations and guidelines. This policy applies worldwide to all Amgen-sponsored phase 2, 3 and 4 clinical trials in studies designed to test safety or efficacy, or both, of an Amgen product or product candidate. To read the policy, please visit

www.amgentrials.com/medpro_policy.cfm

Amgen is a science-based company. We communicate clinical trial results in non-promotional and scientific venues that best serve the needs of the scientific, regulatory, investor, doctor and patient communities. Scientific, non-promotional summaries are made available on publicly accessible registries such as www.clinicalstudyresults.org and/or in publications that require peer review of scientific articles.

In some instances, Amgen may delay the public posting of a clinical trial summary for purposes of protecting our intellectual property, or to comply with the requirements of medical journals or medical conferences to which Amgen has submitted or plans to submit manuscripts, abstracts and/or posters for publication or presentation. **Amgen will not withhold any information that we believe has important treatment or safety implications for patients. We will always communicate such information as rapidly as possible.**

Recent Questions about Aranesp® (darbepoetin alfa) and Clinical Trial Disclosure

Amgen has consistently performed high-quality studies to evaluate the benefit/risk profile of erythropoiesis-stimulating agents (ESAs), and our data have been communicated promptly to regulatory agencies worldwide. Contrary to several recent media reports, Amgen has promptly submitted to the FDA all available data for Amgen studies discussed at the ODAC meetings, including, most recently, the primary data from the Amgen-sponsored 145 study. In addition, we have promptly provided the FDA with all data available to Amgen from the independent, investigator-led studies that are part of the Aranesp® pharmacovigilance program. In most cases, independent study groups legally own the primary study data and may not make it available to others, including Amgen.

Furthermore, **Amgen is committed to providing timely and appropriate communications to healthcare professionals whenever we become aware of significant new safety information that could affect clinical practice.**

• In November 2006, Amgen issued a "Dear Healthcare Professional" letter alerting physicians to the FDA's Public Health Advisory regarding the results of Johnson & Johnson's CHOIR trial in chronic kidney disease patients not on dialysis, even though that study explored hemoglobin targets beyond those currently recommended in all ESA labels. Amgen proactively sent copies of the advisory to all nephrologists, and our field force hand-carried the advisory into physicians' offices.



- Amgen voluntarily issued a “Dear Healthcare Professional” letter regarding the initial results of the Aranesp® 103 study and broadly communicated these initial results to investors and the media. A synopsis of Amgen’s Aranesp® 103 study results has been posted on publicly available Web sites including www.clinicaltrials.gov and www.clinicalstudyresults.org.

- Amgen has worked closely with the FDA to update ESA product labels to include new safety information. The updated label was issued by the FDA on March 9, and Amgen immediately posted the revised label on our Web sites and issued a “Dear Healthcare Professional” letter on March 12. In addition, the Amgen field sales force called on physicians to communicate this important new safety information.

Amgen will continue to serve the best interests of patients by promptly communicating new data, as they become available, to regulatory agencies, healthcare professionals and policymakers.