NOVARTIS

Transparency

Research based companies are required to prove the safety and efficacy of all new medicines in clinical trials. Clinical studies in humans must comply with ethical principles, as agreed in the Declaration of Helsinki, which protect the safety and well-being of the study participants. All Novartis clinical studies are therefore designed and conducted in accordance with the ethical principles of the Declaration of Helsinki Good Clinical Practice guidelines as well as national and international regulatory requirements.

Clinical trial information disclosure at Novartis

Providing access to information about clinical research studies and their results benefits study participants, patients, healthcare providers and the wider public. This information helps people make informed decisions about potential treatment options as well as potential participation in clinical studies. Novartis therefore makes every effort to comply with national and international standards for disclosure of clinical trial information and is committed to the timely disclosure of the design and results of all interventional clinical studies for innovative treatments in patients. Results are made publicly available whatever their outcome.

Novartis clinical trial data transparency overview

Clinical trial results

Novartis has long been dedicated to informing the public about the results of its interventional trials for innovative products. Novartis launched the results website in 2005 becoming one of the first companies to provide results from our interventional trials, regardless of outcome, to the public.

Learn more about the results of Novartis-conducted trials

Trial summaries for patients

Novartis believes it is important to share what was learned from each trial with its patients and the public. In order to make the technical trial results easier to understand, the trial summary result is written in easier to understand language. These trial summaries are provided to the trial investigators to share with the trial patients in the local languages of the trial patients.

Learn more about trial summaries for patients

Clinical trial data sharing

Novartis is committed to sharing access to anonymized patient level data and clinical study reports from eligible studies with qualified external researchers. All data provided is anonymized to respect the privacy of patients who have participated in the trials in line with applicable laws and regulations.

Requests for clinical trial data from trials that completed after January 1, 2014 are made available after the medicine and indication is approved by both the FDA and EMA (or is approved by one of these agencies if submitted to only one agency), or 18 months after the trial completion, whichever is the latest. Requests for trial data from approved medicines before 2014 are reviewed on a case-by-case basis. Access to the data is

granted upon review by an external independent scientific review panel.

For more detailed information and to make a request, please view our Clinical Study Data Requests.

NARD (Novartis Anonymized Redacted Dossiers)

The Novartis Anonymized Redacted Dossiers (NARD) is a publicly accessible website for Novartis to share dossiers submitted to Health Authorities for product approval in an anonymized/redacted format. As clinical trial transparency continues to grow globally, this central location to share anonymized/redacted dossiers allows Novartis to continue our commitment to data transparency.

Learn more about NARD

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