

Leaders in Clinical Trial Transparency

Providing information on clinical trials and their results serves everyone including study participants, patients and healthcare providers. For over 20 years, Novartis has supported data transparency and was one of the first to commit to publishing trial results of innovative medicines within one year of study completion, regardless of outcome. As time has passed, we only continue to strengthen our commitment to data transparency.

1999: Novartis begins registering innovative clinical trials on the public U.S. registry

Since 1999, we have registered **more than 3,600 clinical trials** on www.clinicaltrials.gov

2005: Novartis Clinical Trial Results website launched

Before it became a legal requirement, Novartis was one of the first companies to **publicly commit to disclosing clinical trial results for Phase IIb – IV trials** of our innovative medicines on www.novartisclinicaltrials.com within one year of trial completion. This included all trials, irrespective of outcome or subsequent health authority approval.

2007: Novartis registers results from controlled and uncontrolled trials on www.Clinicaltrials.gov

Since 2007, Novartis has published the results from **more than 1,600 controlled and uncontrolled trials** on www.ClinicalTrials.gov. In addition, in 2008 Novartis expanded the commitment to include results of **Phase IIa** trials on www.novartis.com/clinicaltrials

2009: Novartis posts Phase I results on company website

In 2009 Novartis expanded the commitment to include results from **Phase I** patient trials on www.novartisclinicaltrials.com in unapproved and approved innovative medicines.

2014: Novartis provides access to anonymized patient-level data and commits to expanding information about clinical trial results

Researchers can request access to patient-level data and clinical study reports from trials of innovative medicines approved in the U.S. and Europe from 2014 through www.clinicalstudydatarequest.com. Requests for trials of medicines approved in the U.S. and Europe before 2014 are also assessed on a case-by-case basis.

By the end of 2014, data interpretations were added to the Novartis clinical trial results posted on www.novartis.com/clinicaltrials

2017: Novartis commits to provide simple to understand trial summaries for patients in all languages of the trial participants. These summaries for patients are provided to the investigators for distribution to the patients and are posted publicly on www.novartis.com/clinicaltrials

2021: 2,877 technical study results and 146 trial summaries for patients are publicly available on www.novartis.com/clinicaltrials. In addition, 226 trials clinical trials are listed for secure, data sharing with qualified researchers on ClinicalStudyDataRequest.com

Phase I – Phase IV trials: The development of innovative medicines takes place in phases from I to IV. These phases all involve in-human clinical trials designed to assess the new drug in terms of safety, dosing regimen, efficacy and eventual use in the real world.

Controlled trial: A clinical trial in which one group of participants receives an experimental drug and the other receives either a placebo or a previously approved therapy.

Patient-level data: Detailed trial data from each patient that is anonymized to protect patient privacy.

Disclosure of trial information online:

- www.clinicaltrials.gov: Registry of publicly and privately supported clinical studies.
- www.novartis.com/clinicaltrials: Novartis clinical trial website, which includes ongoing trials, study results and trial summaries for patients.
- www.clinicalstudydatarequest.com: A website which qualified external researchers can access to request anonymized patient-level data and clinical study reports for research projects.