Novartis Public Affairs

Clinical Study[1] Transparency: Clinical Study Registration, Results Reporting and Data Sharing

Novartis' mission is to discover new ways to improve and extend people's lives. Using science-based innovation, Novartis delivers better outcomes for patients and addresses the evolving healthcare needs of society. It focuses on growing areas of healthcare where innovation plays an important role: innovative medicines[2], medical devices, generic medicines and biosimilars.

Clinical studies are an essential part of the development and registration of new innovative medicines, generics, biosimilars and medical devices. The studies are possible only because healthy participants and patients agree to participate and test these products.

Information on clinical studies and their results serve patients and healthcare professionals directly as well as the public at large. Such information can help interested individuals make informed decisions about their potential participation in a clinical study and describes the outcome of clinical trials for the purposes of increased transparency of clinical research. Researchers are encouraged to publish the results of clinical studies in biomedical journals, not only to enable the scientific community to assess and further use this information, such as in the design of future studies, but also to receive credit for their scientific work.

The ethical principles that protect the safety and wellbeing of the clinical study healthy participants and patients are set forth in the Declaration of Helsinki. For clinical study registration and results reporting, there are a number of national requirements that vary between regions/countries and are continuously evolving.

In May 2005 Novartis became one of the first pharmaceutical companies to publish clinical trial results of innovative medicines in patients within one year of trial completion, regardless of outcome, on a publicly accessible website, www.novctrd.com.

Novartis Position

Novartis conducts clinical studies worldwide for a wide range of products. We strongly support the concepts of clinical study transparency and are continuously strengthening

[1]The terms studies and trials are often used interchangeably. However, for the purpose of this document, studies and trials are defined as per Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, Chapter 1, Article 2-Definitions https://ec.europa.eu/health/human-use/clinical-trials/regulation_en

[2] Innovative medicines are defined as novel patentable compounds, excluding generic small molecules, biosimilars and medical devices

clinical study transparency processes enterprise-wide. We adjust our processes and practices to the varying and evolving statutory requirements in a timely manner. At the same time, we have practices in place to ensure protection of the data privacy of study participants and investigators as well as the intellectual property of the knowledge generated through clinical studies.

- We respect and defend investigators' independence and freedom to participate in, and to agree to all aspects of, a clinical study.
- Novartis encourages and supports the publication utilizing clinical study data, regardless of a positive or negative outcome.
- While protecting the data privacy rights of clinical study participants and investigators, Novartis' policy is not to withhold or suppress scientific data obtained during clinical studies.

Novartis' commitment to clinical study data transparency is the foundation of its framework of clinical trial data sharing.

Novartis ensures clinical study transparency

Novartis-sponsored clinical studies are registered in publicly accessible clinical study registries and results are reported on publicly available websites as required by applicable industry codes, laws and regulations in the region, country or countries in which the research is performed.

To promote overall transparency, Novartis commits to a globally harmonized minimum standard, independent of country requirements. Novartis commits to:

- register and report interventional clinical trials in patients, independent of trial location in the world, on the US ClinicalTrials.gov website as follows:
  - Register all Phase I-IV clinical trials conducted in patients with innovative medicines, biosimilars, generics and medical devices[3] in advance of the first subject visit.
  - Report results of all Phase II-IV clinical trials in patients conducted with innovative medicines, generics and biosimilars no later than 1 year after trial completion for trials in adults and 6 months for pediatric trials, subject to EU regulatory requirements, regardless of product approval status.
  - Report results of clinical trials conducted with US-approved medical devices no later than 1 year after trial completion.
- provide a clinical trial search tool on www.novartis.com/clinicaltrials to identify Novartis-sponsored clinical trials which are currently recruiting trial participants.
- post results from all Novartis sponsored Phase I-IV interventional clinical trials conducted in patients with innovative medicines, generics and biosimilars regardless of approval status as well as approved medical devices on the Novartis public website www.novctrd.com no later than 1 year after trial completion for trials in adults and no later than 6 months for pediatric trials with an EU nexus, independent of trial outcome.

Novartis commits to help inform patients about the clinical trials in which they participated by providing an easy-to-understand summary of the clinical trial results:

- In 2016 Novartis began to provide plain language trial summaries to the trial investigators to share with their patients participating in Phase I/IIa interventional clinical trials with non-oncology innovative medicines. This policy was expanded in

[3] Trials conducted with unapproved devices (by FDA) are registered but will not be publicly displayed until after approval, per US Law. Small feasibility and proof of concept device trials are not registered on Clinicaltrials.gov.

2017 to include new Phase I through III interventional medicine clinical trials and expanded again in September 2018 to include new Phase IV interventional clinical trials.
- These plain language trial summaries are also publicly available in the English language and translated to local languages of trial participants as applicable and are available on www.novctrd.com.

Novartis supports the sharing of New Drug Application decisions through NARD

- The Novartis Anonymized Redacted Dossiers (NARD) is a publicly accessible website for Novartis to share dossiers submitted to European Medicines Agency (EMA), Health Canada and Swissmedic 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. www.www.novartis.com/clinicaltrials.

Novartis supports scientific exchange and research through:
- facilitating interpretation and publication of data from Novartis-sponsored clinical studies by ensuring that authors of the clinical study publication have access to the clinical study results and analyses for planned publications[4].
- providing the participating clinical investigators with a summary of the clinical trial results and the patient-level data from the investigational site upon completion of the clinical trial and analysis of the results.
- enabling access to interventional clinical trial data from innovative medicines through the website www.clinicalstudydatarequest.com, where external scientific and medical researchers can request access to anonymized patient-level clinical trial data and supporting clinical trial documents[5]. Novartis will take the necessary steps to ensure that the patient's privacy is safeguarded.

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[4] https://www.novartis.com/sites/novartis_com/files/novartis-publication-guidelines-posting.pdf
[5] Requests for clinical trial data from trials that completed after January 1, 2014 will be 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 with no plans to submit to the other agency), or 18 months after 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 independent scientific review panel.