Novartis Public Affairs

Novartis Position on Clinical Study[1] Transparency – Clinical Study Registration, Results Reporting and Data Sharing

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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: pharmaceuticals, eye care, generic medicines and biosimilars.

Clinical studies are an essential part of the development and registration of new innovative medicines, biosimilars, devices and generics. These studies are possible only because participants and patients volunteer to participate and test new medicines.

Information on clinical studies and their results serve patients and their healthcare providers 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. Researchers have the ability 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 subjects are laid down in the Declaration of Helsinki. For clinical study registration and results reporting, there are a number of national requirements that vary between countries and are continuously evolving.

In May 2005 Novartis became one of the first pharmaceutical companies to publish clinical trial results of innovative medicines[2] within one year of trial completion, regardless of outcome, on a publicly accessible website, www.novartisclinicaltrials.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 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 individual privacy of study participants and investigators as well as the intellectual property of the knowledge generated.

- 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 of clinical study data that is relevant to patient care, regardless of a positive or negative outcome.
- While protecting the data privacy of clinical study participants and investigators, Novartis policy is not to withhold or suppress scientific data obtained during clinical studies.

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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, Chapter 1, Article 2-Definitions http://ec.europa.eu/health/human-use/clinical-trials/regulation/index_en.htm

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

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 on publicly accessible clinical study registries and reported on results websites as required by applicable industry codes, laws and regulations in the 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 and biosimilars as well as trials conducted with eye care consumer products 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 no later than 1 year after trial completion for trials in adults and 6 months for pediatrics, regardless of product approval status.
  - Report results of trials conducted with eye care consumer products 1 year after completion.
  - Report results of trials conducted with US-approved medical devices and biosimilars 1 year after completion
- provide a clinical trial search tool on www.novartisclinicaltrials.com to identify Novartis sponsored ongoing worldwide interventional clinical trials with innovative medicines in patients.
- post results from all Novartis sponsored Phase I-IV interventional clinical trials conducted in patients with innovative medicines as well as approved medical devices, approved biosimilars and eye care consumer products on the Novartis public website www.novartisclinicaltrials.com within 1 year after trial completion for trials in adults and 6 months for pediatrics, independent of trial outcome.

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

- In 2016 Novartis began to provide patient lay summaries to patients participating in Phase I/IIa interventional general medicines clinical trials.
- Starting with Phase IIb and III interventional innovative medicine trials initiating in 2017, Novartis will provide patient lay summaries to trial investigators to share with their patients and will make these lay summaries publically available on www.novartisclinicaltrials.com.

Novartis supports scientific exchange and research through:

- facilitating interpretation and publication of data from Novartis-sponsored studies by ensuring that authors of the study publication have access to the study results and analyses for planned publications[4].
- providing the participating clinical investigators with a summary of the clinical trial results and the individual patient 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 and provides a website through which external scientific and medical researchers can request access to anonymized patient level clinical trial data and supporting clinical trial documents at http://www.clinicalstudydatarequest.com. Through this website, researchers can request trial data on innovative medicines and indications approved by regulators in the US and European Union as of 2014 and after the relevant clinical trial results have been accepted for publication in scientific journals. 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. Novartis will take the necessary steps to ensure that the patient's privacy is safeguarded.

Last updated on November 2016

[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.

[4] https://prod.novartis.com/sites/www.novartis.com/files/novartis_publication_guidelines_posting.pdf