

Novartis Position on Post-Trial Access

The purpose of Novartis is to reimagine medicine to improve and extend people's lives. We use innovative science and technology to address society's most challenging healthcare issues.

Clinical trials are an important part of the development and registration of innovative products, enabling the collection of robust safety and efficacy data to support regulatory approval. This is only possible thanks to the patients who participate in our clinical trials.

By participating in a clinical trial, patients may receive innovative treatments. When a patient has completed their participation in an in-scope¹ Novartis sponsored clinical trial, there is usually a time lag between the patient completing their clinical trial participation and the product availability on the market (local patient access²). We offer post-trial access to all patients who participated in an in-scope clinical trial and who are deriving clinical benefit as assessed by the study doctor. This ensures that the patients can continue to be treated, uninterrupted, from the time they finish their participation in a clinical trial until the time that the product is launched or reimbursed, when applicable. This is what we call "Post-Trial Access" (PTA).

Novartis Position

At Novartis, we consider it ethical to provide post-trial access, wherever possible, free-of charge to all patients who participate in, and complete an in-scope clinical trial³ until the product is commercially available⁴ and accessible locally if:

- The clinical trial is designed to demonstrate superiority of a Novartis investigational product over other treatment options.
- There is evidence of continued clinical benefit for the patient, and the patient consents to continue with the treatment.

Such provision of post-trial access is only granted where permitted by local laws and regulations.

As already affirmed in the Novartis Commitment to Patients and Caregivers[ref], and in our Code of Ethics[ref], our PTA principles are aligned with international ethical frameworks including the Declaration of Helsinki⁵, the ICH Good Clinical Practice⁶, and other international guidelines such as CIOMS⁷ and UNESCO's Universal Declaration on Bioethics and Human Rights⁸.

We describe the post-trial access provision in all our clinical trial protocols and the related patient informed consent, so patients are fully aware prior to agreeing participation in a clinical trial.

The complex and variable nature of clinical trials and considerations for post-trial access means that we cannot anticipate and plan for all situations⁹. To address the post-trial treatment needs of patients who have participated in Novartis-sponsored clinical trials as efficiently as possible, Novartis ensures a process is in place to support prompt, fair and consistent approach to the provision of post-trial access across all countries in compliance with applicable local laws and regulations.

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¹ In-scope clinical trials are clinical trials at any stage of clinical development in serious and life threatening conditions, and also confirmatory clinical trials. Confirmatory clinical trials are defined in ICH guideline E9 as "adequately controlled trials in which the hypotheses are stated in advance and evaluated." Confirmatory clinical trials are generally done after preliminary clinical trials have provided an early signal of efficacy and are large enough to quantify the size of the beneficial and adverse effects

² "Accessible to patient" means pay or coverage or reimbursement in place, or a local access mechanism available (especially for self-paying markets).

³ For conditions which are serious and/or life threatening, PTA may be provided earlier in the development lifecycle e.g. post proof of concept (post-POC) or following early exploratory clinical trials, even without a fully elucidated safety and efficacy profile. Novartis will determine with the investigator evidence of benefit on a case-by-case basis for those clinical trial participants with serious/life threatening conditions.

⁴ "Commercially available" means local health authority approval and product launched.

⁵ Declaration of Helsinki (World Medical Association) (2013) and the United States (US) Belmont Report (1979).

⁶ International Council for Harmonisation (ICH) E6: Guideline for Good Clinical Practice (GCP) (1996).

⁷ International Ethical Guidelines for Biomedical Research Involving Human Subjects issued by the Council for International Organizations of Medical Sciences (CIOMS 2016).

⁸ The Universal Declaration on Bioethics and Human Rights adopted by the United Nations Educational, Scientific, and Cultural Organisation (UNESCO) (2005).

⁹ The provision by Novartis may be discontinued in certain instances e.g. if the program is terminated and the product is no longer manufactured, or if product is divested.