Novartis Corporate Affairs
Public Affairs Policy

Novartis Position on Responsible Clinical Trials

Novartis' mission is to discover new ways to improve and extend people's lives. Using science-based innovation, Novartis strives to deliver better outcomes for patients and to address the evolving healthcare needs of society.

Clinical trials[i] involving human beings are needed to demonstrate the benefits and risks of new medicines and to enable their approval by health authorities. They may carry benefits for the individual participants (e.g. early access to treatments not yet available). In addition, clinical trials may bring benefits to the wider patient population (e.g. enhancing disease knowledge), to the research community and healthcare (HC) systems (e.g. improved efficacy and investments into HC infrastructure), and to the wider economy (e.g. creation of highly-skilled jobs). While having many potential benefits, they may also carry potential risks for individual trial participants.

To protect trial participants, various national and international regulations and ethical guidelines have been issued, such as the Declaration of Helsinki[ii], the ICH Good Clinical Practice (GCP) Guidelines[iii], CIOMS [iv] and UNESCO's Universal Declaration on Bioethics and Human Rights[v].

Novartis Position

To fulfill our mission to discover new ways to improve and extend people's lives, Novartis commits to conduct Clinical Trials responsibly:

- We aim for the highest scientific integrity of our trials. We have mechanisms in place to ensure the accuracy, trustworthiness and security of the data that our trials generate.
- We have a framework of strict policies and procedures that we apply in all our clinical trials, regardless of the indication, population or country where the trial is being conducted.
- We have mechanisms in place to protect all trial participants, when consenting to the research, during the conduct of the trial and after completion. We have additional processes in place to protect vulnerable patients.
- We continuously strengthen clinical study transparency processes. We have processes in place to ensure timely disclosure of results regardless of the study outcome and to ensure the autonomy of the external authors.

Novartis sponsored clinical trials are designed and operationalized under a framework of strict policies and procedures in accordance with the above international guidelines and all applicable laws and regulations. This framework reflects our commitment to conduct clinical trials responsibly, in line with our Commitment to Patients & Caregivers[vi], and is sustained by three pillars: scientific integrity of our trials, protection of all trial participants, and transparency of research. In addition, we only support third party trials that adhere to a set of principles to ensure that those clinical trials are conducted responsibly.

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- We aim for the highest scientific integrity of our trials. We have mechanisms in place to ensure the accuracy, trustworthiness and security of the data that our trials generate.
  - We ensure that our trials are designed to answer appropriate research questions;
  - We select countries and sites to implement clinical trials based on the medical need in those areas and the capabilities of the sites. We only initiate clinical trials in countries where we intend to make the product available to patients[vii];
  - We make efforts to understand the diversity and unmet needs of patients with the diseases we study and we aim at reflecting this diversity in our study populations;
  - We focus on improving the patient experience in clinical trials through innovative solutions. This will help us to become more efficient bringing innovative medicines to patients and also to widen diversity in enrolment, expand to new areas of unmet need and engage new trial populations.

- We have mechanisms in place to protect all trial participants. We are grateful for the involvement of individuals who voluntarily decide to participate in our research.
  - We only start testing new compounds in humans when there is sufficient data to support the benefit-risk for trial participants, as well as sites and investigators with the capabilities to conduct the research.
  - We optimize the benefit-risk balance throughout development through continuous assessment of accumulated and emerging data. If the benefit-risk balance changes, we ensure appropriate measures to protect trial participants are taken promptly.
  - We ensure voluntary informed consent to the research, including the right to withdraw from the trial at any time and the right to withdraw consent for the collection and use of their personal data.
  - We strive to provide fair compensation for participants' expenses, any additional risks and time incurred, as permitted by local law, so that a decision to participate or not in the trial is not made for financial reasons.
  - We offer continuity of treatment for patients who completed a confirmatory Novartis-sponsored clinical trial and still benefit from that treatment[viii].
  - We pay special attention to protecting vulnerable patients such as children and older people, those who have a cognitive impairment or those in developing countries[ix].

- We continuously strengthen clinical study transparency processes, harmonizing standards, reporting our clinical trials in publically accessible databases and publishing our clinical trial results. We also commit to help inform patients about the clinical trials in which they participate; and we support scientific exchange and research by facilitating access to anonymized data from our clinical trials for approved medicines and biologics[x].

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[i] For the purpose of this document, clinical trials are the same as interventional clinical studies, defined as per Regulation (EU) No 536/2014, Chapter 1, Article 2-Definitions
[ii] Declaration of Helsinki (World Medical Association) (2013) and the United States (US) Belmont Report (1979)
[iii] International Council for Harmonisation (ICH) E6: Guideline for Good Clinical Practice (GCP) (1996)
[iv] International Ethical Guidelines for Biomedical Research Involving Human Subjects issued by the Council for International Organizations of Medical Sciences (CIOMS 2016)
[v] The Universal Declaration on Bioethics and Human Rights adopted by the United Nations Educational, Scientific, and Cultural Organisation (UNESCO) (2005)
[vi] Novartis Commitment to Patients & Caregivers (2018)
[vii] In this context, making the product available includes registering and commercially launching the product. Exceptional circumstances (e.g. a different indication proposed), may limit our ability to launch the product in all countries. In those situations, we have provisions in place to ensure continuity of access to innovative treatments – see Novartis Position on Post-Trial Access to Investigational Medicines
[viii] Novartis Position on Post-Trial Access to Investigational Medicines (coming soon)
[ix] Novartis Position on Ethical Principles for Transplantation Studies
[x] Novartis Position on Clinical Study Transparency