Novartis Public Affairs

Novartis Position on Responsible Clinical Trials

Novartis' mission is to discover new ways to improve and extend the lives of all people – inclusive of race, ethnicity, gender, age, sexual orientation, disability, location, and socioeconomic status. Using science-based innovation, Novartis strives to deliver better outcomes for patients and to address the evolving healthcare needs of society.

Clinical trials[i] are required to demonstrate the benefits and risks of new medicines in patients and to enable their approval by health authorities.

Clinical trials may carry benefits for the individual participants (e.g. early access to novel investigational therapies), although participation may also carry potential risks for individual trial participants (e.g. side effects or that the medication will not work)[ii].

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).

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

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Novartis Position

To fulfill our purpose to reimagine medicine and our mission to discover new ways to improve and extend people's lives, Novartis conducts Clinical Trials responsibly:

- We aim for the highest scientific integrity of our trials.
- We have mechanisms in place to ensure the accuracy 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.
- 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 continuously strengthen our clinical trial transparency processes, to ensure timely disclosure of results regardless of the trial outcome and to ensure the autonomy of the external authors.

Novartis-sponsored clinical trials[vii] are designed and operationalized under a framework of strict internal policies and procedures developed 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[viii] and Code of Ethics[ix], 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 have valid scientific merit and are conducted responsibly.

- We aim for the highest scientific integrity in our trials. We have mechanisms in place to ensure the accuracy and security of the data that our trials generate.
  - We ensure that our trials are designed to answer appropriate research questions that will ultimately benefit patients.
  - 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 confirmatory[x] clinical trials in countries where we intend to make the product available to patients[xi].
  - We make every effort to ensure that the trials we conduct are diverse, equitable and inclusive. Conducting our trials in diverse populations ensures that the trials address possible heterogeneity of patient responses in the populations that suffer from the disease.
  - We focus on improving the patient experience in clinical trials through innovative solutions, such as Decentralized Technologies (DCT) and Novartis Digital Recruitment (NDR) capabilities, as well as fostering partnerships with community and patient organisations. This will facilitate greater retention and recruitment of trial populations and help us to become more efficient bringing innovative medicines to patients.

- We have mechanisms in place to protect all trial participants.
  - We only start testing new compounds in clinical trials when there is sufficient data to support the benefit-risk for trial participants, as well as working with sites and investigators that have the capabilities to conduct the research.

  - We constantly assess the benefit-risk balance throughout the drug development process by continuously evaluating 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 discontinue from the trial at any time and, where applicable, the right to withdraw consent for the collection of the trial participants' personal data in accordance with local applicable laws and regulations.
  - We strive to alleviate any financial burdens resulting directly from participation in our trials, by reimbursing trial participants expenses as permitted by local law[xii]. We may compensate for time spent on trial activities if deemed fair and necessary[xiii].
  - We offer continuity of treatment for patients who completed a confirmatory Novartis- sponsored clinical trial and are still deriving benefit from that treatment[xiv].
  - We ensure protection of vulnerable patients such as children or patients unable to provide consent, for instance because they have a cognitive impairment, or patients in low- and middle-income settings.

- Transparency in our clinical trials fosters trust with society. Our clinical trial transparency processes demonstrate our commitment to patients and healthcare professionals by ensuring our trials are registered and results are published in publicly accessible registries and on Novartis's website, www.novctrd.com. We commit to help investigators inform patients about the clinical trials in which they participate by publishing plain language trial summaries publicly on www.novctrd.com, and we support scientific exchange and research by facilitating access to qualified researchers to anonymized clinical trial data for approved medicines while protecting patient privacy[xv].

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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] www.novartisclinicaltrials.com/TrialConnectWeb/benefits.nov
[iii] Declaration of Helsinki (World Medical Association) (2013) and the United States (US) Belmont Report (1979)
[iv] International Council for Harmonisation (ICH) E6: Guideline for Good Clinical Practice (GCP) (1996)
[v] International Ethical Guidelines for Biomedical Research Involving Human Subjects issued by the Council for International Organizations of Medical Sciences (CIOMS 2016)
[vi] The Universal Declaration on Bioethics and Human Rights adopted by the United Nations Educational, Scientific, and Cultural Organisation (UNESCO) (2005)
[vii] The terms study and trial 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
[viii] Novartis Commitment to Patients & Caregivers (2023)
[ix] Novartis Code of Ethics (2020)
[x] 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 trials have provided an early signal of efficacy and are large enough to quantify the size of the beneficial and adverse effects. Data from confirmatory trials are generally used for registration
[xi] 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

[xii] Reimbursement is used when the Participant or Caregiver is repaid expenses incurred during the trial. Novartis offers reimbursement for out-of-pocket expenses (e.g., travel, meals, accommodation, and other expenses incurred directly from trial participation)

[xiii] Compensation is "payment" for or acknowledgment of the time the Participant or Caregiver spent participating in the clinical trial. We may offer compensation in proportion to the time spent on average on trial activities (e.g., time spent will vary depending on the number and length of trial visits and procedures, as described in the protocol). Compensation to Patients and Caregivers is not common practice in Novartis outside the scope of Healthy Volunteer trials. However, in the unusual case where compensation is considered, there are considerations to be applied when offering compensation, especially to minimize the risk of coercion and undue influence on patients

[xiv] Novartis Position on Post-Trial Access

[xiv] Novartis Position on Clinical Study Transparency