

Disclosure of Clinical Research Information

Any new medication that is developed has to prove in clinical trials that it is safe and effective. Clinical studies in humans have to comply with ethical principles that protect the safety and well-being of the study subjects, as laid down in the Declaration of Helsinki¹ (DoH). Providing access to information about clinical research studies and their results serves study participants, patients and their healthcare providers as well as the public at large. Such information can help people to make informed decisions about their potential participation in a clinical study.

Publication of results in biomedical journals allows researchers to receive credit for their scientific work and enables the scientific community to assess, correct and further develop these results.

Novartis Position

Novartis is committed to timely disclosure of designs and results of all interventional Phase II-IV clinical studies² for innovative treatments as well as pediatric Phase I-IV trials³. Results are made publicly available, whatever their outcome.

We commit to registering these studies on a publicly accessible database⁴ within 21 days of the trial commencing⁵. Novartis will disclose all information requested by regulators as well as the minimum data set defined by the World Health Organization (WHO)⁶.

Results of all registered studies are made available on a publicly accessible database⁴ within one year after the end of the trial⁵. Where commitments (scope or timing) go beyond legal requirements disclosure of information of a competitive nature may be delayed.

Novartis makes all efforts to comply with evolving national and international statutory requirements regarding disclosure of clinical studies and to do so in a timely manner.

We continuously strive to ensure that clinical study results are valid and credible. We design and conduct all our clinical studies in accordance with ethical principles embodied in the DoH¹, Good Clinical Practice (GCP) guidelines as well as national and international regulatory requirements.

We respect and defend researchers' independence and freedom to participate in and to approve all aspects of a clinical study, including the results. Clinical investigators may have access to their own data once results have been processed and consolidated according to the agreed protocol, and they receive a summary on completion of the study and the clinical report.

Novartis supports transparent communication, independent opinions and the disclosure of any possible conflicts of interest by investigators and authors of clinical study publications. We ensure that authors of a publication on a trial receive a full clinical study report. We believe authorship should accurately reflect contributions to the design and conduct of a clinical study and subsequent drafting of a publication manuscript.

¹ The Declaration of Helsinki (DoH) forms the foundation of all significant international documents on ethical conduct in biomedical research. It establishes guiding principles and recommendations for physicians regarding ethics, human rights and medical norms in clinical research, and has been incorporated in the regulations, guidelines and laws of many countries as well as into international guidelines.

² Clinical Study/Clinical Trial and Intervention (WHO explanation): A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.

³ This refers to pediatric trials conducted in an EU member state or trials mentioned in a Pediatric Investigation Plan (PIP).

⁴ Novartis currently uses the following databases: www.ClinicalTrials.gov for registering ongoing interventional clinical studies and the Novartis Clinical Trials Result Database at www.novctrd.com for posting results of clinical studies. In case of any changes, e.g. legal requirements to post information on more than one registry, addresses will be updated accordingly.

⁵ Trial start is defined here as First Patient First Visit (FPFV). Trial end is defined here as Last Patient Last Visit (LPLV).

⁶ "Minimum data set" as defined by the report of the WHO Technical Consultation on Clinical Trial Registration Standards:

1. Unique trial number
2. Trial registration date
3. Secondary IDs
4. Funding source(s)
5. Primary sponsor
6. Secondary sponsor(s)
7. Responsible contact person (Public contact)
8. Research contact person (Principal investigator)
9. Title of the study
10. Official scientific title of the study (intervention for condition on outcome)
11. Research ethics review (Yes / No)
12. Condition
13. Intervention(s) (Including intervention duration)
14. Key inclusion and exclusion criteria
15. Study type (Select from list (currently available in the clinicaltrials.gov register))
16. Anticipated trial start date (estimated enrolment of the first participant)
17. Target sample size
18. Recruitment status (Is this information available yes/no. If yes, link to information)
19. Primary outcome (Include time of measurement or time to completion)
20. Key secondary outcomes