

## **Our Process** <sup>[1]</sup>

### **Follow the science**

Scientific research drives innovation at Novartis. Our researchers work to push the boundaries of science, broaden our understanding of diseases and develop novel products with significant benefits for patients. We are focusing on faulty molecular pathways and therapeutic areas where we see the greatest unmet medical need and believe the scientific tools to address these needs are within reach.

Research and development teams work together to bring new and better medicines to patients in the shortest possible time. This effort involves a discovery phase, during which a potential new medicine is identified. A proof of concept is established through small clinical studies in patients, after which the medicine is studied in larger numbers of patients in a clinical development phase.

By focusing on the patient and following the science, Novartis has discovered innovative treatments for disorders ranging from cancer to degenerative disease. Thanks to this approach, Novartis has one of the strongest and most productive pipelines in the industry. More than 200 research and development projects are underway.

### **Clinical Trials**

Clinical trials are research studies intended to answer scientific questions and find better ways to treat or prevent diseases. All drugs enter the clinic via proof-of-concept trials, small-scale studies designed to get an early read on a drug's safety and effectiveness, and to help find and advance the most promising drug candidates. Wherever possible, especially when molecular pathways are shared, several diseases are explored in parallel. If the proof-of-concept study is successful, a medicine typically moves into full clinical development.

The development process varies by division because of the different types of products involved.

### **Participating in a Novartis clinical trial**

Clinical studies are conducted to determine whether a new treatment is both safe and

efficacious. Such studies are possible because volunteers (healthy volunteers and patients) agree to participate and try new medicines.

[Learn More](#) <sup>[2]</sup>

## Investigator Initiated Trials

Novartis believes in the need to support ethical independent clinical research conducted by qualified third-party investigators. The value of the scientific research produced by such investigators is key to complementing Novartis-sponsored research in helping to ensure we better understand the benefit/risk profile of our therapies, as well as to explore new opportunities to address unmet medical needs.

Such clinical research must set out to address meaningful scientific and/or clinical objectives supported by valid study designs in which the privacy rights, safety, and welfare of patients is of paramount importance.

Novartis defines IITs as “studies with scientific and medical merit developed and sponsored by an independent investigator or academic sponsor. An IIT may be a clinical or non-clinical study conducted without the participation of Novartis, for which the IIT sponsor requests Novartis to provide either funding, drug product, or both.”

**If you would like to submit a proposal for a US conducted IIT, please email your proposal request to:**

[USOncology.IITsubmissions@Novartis.com](mailto:USOncology.IITsubmissions@Novartis.com) <sup>[3]</sup> (for Oncology trial proposals)

[USPharma.IITsubmissions@Novartis.com](mailto:USPharma.IITsubmissions@Novartis.com) <sup>[4]</sup> (for Non-Oncology trial proposals)

## Clinical trial results sharing

We recognize the importance of informing the public about the results of our interventional clinical trials for innovative compounds, regardless of the outcome. We make the results of our clinical trials publicly available through peer-reviewed publications and posting of results on the Novartis clinical trial results database and other online public databases.

[Learn more](#) <sup>[5]</sup>

## Clinical Pipeline

Novartis is consistently rated as having one of the industry’s most respected development pipelines, with more than 200 projects in clinical development, including 135 in the Pharmaceuticals Division, as of January 27, 2016.

[Learn More](#) <sup>[6]</sup>

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**Source URL:** <https://www.novartis.us/our-products/our-process>

**Links**

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