

## Novartis Position on Investigator Initiated Trials (IITs) and Investigator Initiated Research (IIRs)

### Introduction

As part of our commitment to delivering innovative therapies to patients worldwide, Novartis believes in the need to support ethical independent clinical and non-clinical research conducted by qualified third-party investigators. The value of the scientific research that is produced by such investigators is key to complementing Novartis-sponsored research. It helps us to better understand the benefit/risk profile of our therapies as well as explore new opportunities to enhance patient care.

Novartis defines an Investigator-Initiated Trial (IIT) as a clinical study with scientific and/or medical merit developed and sponsored by an independent third-party sponsor being conducted without the participation of Novartis, for which the IIT sponsor requests Novartis to provide either funding, drug product or both.

Novartis defines Investigator-Initiated Research (IIR) as non-clinical research by an independent third-party sponsor to evaluate the effects, properties or profile of a Novartis drug that is conducted in animals or in vitro assays or utilizes previously collected human tissue.

### Overarching principles

The overarching principles governing the evaluation of IITs include that:

- The IIT proposal received is unsolicited and aligned with Novartis Strategic Areas of Interest.
- A valid scientific question is being addressed and data generated by the IIT will complement the existing body of evidence.
- The IIT to be conducted is of robust and ethical design.

### Commitments

Novartis commits to the below for the evaluation and oversight of third-party sponsored IITs worldwide:

- We ensure the investigator or affiliated study sponsor is responsible for the overall conduct of the study including conception, design, operational execution, data handling, data analysis/interpretation, subsequent reporting/publication, and ensuring compliance with all local laws and regulations.
- We apply rigorous ethical and scientific standards when reviewing study proposals from third-party sponsors, including investigator qualifications and the institutional site's ability to carry out a trial (please refer to *IIT: Guide for*

*Prospective Investigators* for more details).

- We only support proposals where there is a commitment by the investigator/sponsor to disclose and disseminate the findings in an appropriate, transparent, and timely manner in accordance with Novartis and local regulatory requirements and timelines.
- We execute a contractual agreement with the institution and/or investigator prior to the study initiation, detailing the roles and responsibilities of all parties, the support provided and the approved research protocol.
- We evaluate all funding requests against Fair Market Value benchmarks.
- We put in place robust medical and scientific governance systems at all levels of the Novartis organization (globally, regionally, locally) with no commercial funding or undue influence on any aspect of the IIT process. Under no circumstances will Novartis permit the involvement of sales and marketing associates in any aspect of IIT design, review and approval, operational execution, funding, or transfer of value to a sponsor/investigator undertaking an IIT.
- We provide worldwide training of Novartis associates on the policies and practices required for successful IIT support, including the rules of independence of the third-party investigators/sponsor and no undue influence from Novartis when engaging in all aspects of the IIT process.

We track and monitor in an ongoing and transparent manner our IIT-contracted obligations and practices.

### **Qualification of Investigators/Sponsors of IITs and IIRs**

Novartis will only undertake IITs with third-party sponsors/investigators that are suitably qualified, and able to demonstrate sufficient experience and clear evidence of high ethical and scientific standards as it relates to clinical research in human subjects as stipulated by the applicable regulations and international standards. Please refer to *IIT: Guide for Prospective Investigators* for more details.

Investigators undertaking IIRs will have to provide evidence of ethical standards and/or Good Laboratory Practices (GLP).

In both types of research, the investigator must have adequate resources including staff and facilities to conduct the proposed study.

### **Scientific and Medical Engagement**

Unsolicited IIT requests may be derived following a scientific discussion or meeting with the Novartis medical organization. Novartis medical colleagues may respond to investigator-expressed interests with a science-based discussion intended to:

- Rationalize the scientific interest of Novartis in specific novel pathways for which Novartis has specific therapies or development programs, and
- Avoid unintended duplication in areas where there is known ongoing

work with other collaborators.

Such interactions must not interfere with the independence of the Investigator's decision making in the care of their patients.

### **Tracking and Monitoring Systems**

To hold ourselves accountable to high ethical standards, Novartis will monitor and audit its associates' adherence to our policies, standards, and effectiveness of training on IITs as part of our global risk assurance program and compliance framework. In addition, Novartis will monitor the IIT investigators' compliance and adherence to their contractual obligations related to disclosure of IIT findings, agreed upon milestones, and safety information reporting.

### **References**

Please refer to the below for additional information.

- For IIT-related questions, please contact the medical team in your Novartis local country office.
- A request for support for an IIT must be submitted via [GEMS](#).
- Novartis Code of Ethics and other policies / guidelines available [here](#)

*Last updated December 2021*