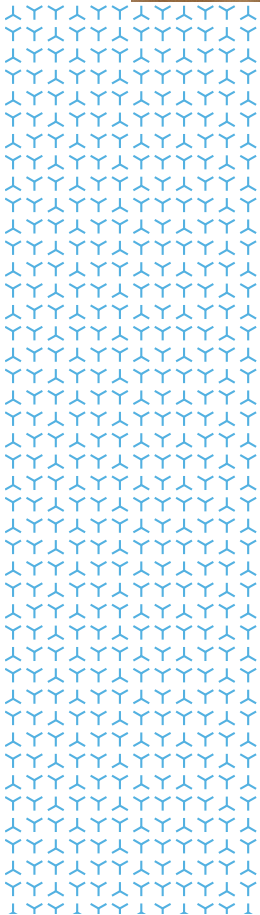




Chief Medical Office



# **Research Collaborations: A simple guide for our partners**

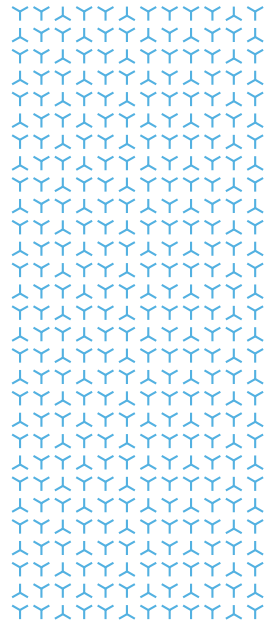




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# We embrace pioneering collaborations to advance specific shared scientific research objectives

## Introduction

Our purpose at Novartis is to reimagine medicine to extend and improve people's lives. To reflect this, we embrace pioneering collaborations to advance specific shared scientific research objectives.

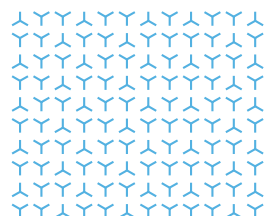
By partnering with external scientific experts, we can mutually benefit from ideas, knowledge, capabilities and the complementary competencies that will enable us to innovate together.

In this regard, we strongly value collaborations that will push scientific boundaries.

Novartis is willing to support projects with scientific merit by providing meaningful intellectual contribution, that is both acknowledged and documented, and may also provide financial support, drugs, or resources.

This document provides interested parties with an overview of how we manage our Research Collaborations at Novartis.

We look forward to hearing from you!





## How we define and manage Research Collaborations at Novartis

### First, how do we define a Research Collaboration?

We define Research Collaborations as activities in which Novartis collaborates with one or more external organizations to advance specific, shared scientific research objectives.

Research Collaborations can be initiated by the partner, by Novartis, or by both parties.

Research partners may include, but are not limited to:

- One or more institutions or organizations (e.g. academic, governmental or co-operative groups)
- One or more pharmaceutical or non-pharmaceutical industry partners.

Please be aware that Novartis will not accept proposals for Research Collaborations from individual healthcare professionals.

Levels of involvement for both the partner and Novartis will vary depending on the research proposal. The scope and frame of such collaboration will be documented in a signed agreement before any work is initiated.

### **What are the minimum criteria our partners need to fulfill?**

Our partners must bring the relevant skills, knowledge and capabilities to enable the project to be effectively and efficiently conducted.

At a minimum, the partner must meet the following criteria:

- Prior research experience relevant to the project proposal
- Relevant GxP training, e.g. Good Clinical Practice (GCP), Good Pharmacoepidemiology Practice (GPP), as applicable
- Knowledge and ability to comply with other applicable regulatory requirements such as those associated with safety reporting.

As part of the evaluation process, a risk management assessment will be carried out to ensure our partners are qualified to fulfill their responsibilities.

### **The research proposal**

The research proposal must:

- Have clearly defined and tangible scientific objectives and deliverables
- Focus on an area of research that is of mutual interest to Novartis and the partner.

### **Resources**

As a partner, you must have the appropriate infrastructure in place and the capabilities to conduct the research in an ethical and compliant manner as outlined in the agreement executed between the parties.



## How we work closely with our partners throughout the process

### Initiation and planning

Following submission of the Research Collaboration proposal, a concept sheet is prepared by both parties, with all necessary supporting documentation. This includes:

- A summary of the project rationale, design and plan of analysis
- Clear definition of who will act as the Regulatory Sponsor of the project
- Specification of expected safety reporting requirements
- An itemized budget and / or drug forecast, if required
- Proof of qualification and CV of the assigned Principal Investigator or researcher.

During this period, it will be required to sign a confidentiality agreement.

### Review and evaluation

The final concept is then reviewed by Novartis, taking into consideration scientific merit and strategic fit.

Novartis also carries out assessment of the budget (if required) in line with Fair Market Value, along with third-party risk management and other risk assessments.

### Research Collaboration agreement

If the project is approved, the agreement will be drafted and agreed upon by the parties. The agreement will outline key details including, but not limited to:

- Roles and responsibilities of each party regardless of the regulatory sponsorship structure adopted
- The joint Governance structure (as needed)
- Timelines, costs and payment milestones
- Intellectual Property (IP) and data ownership rights
- Safety reporting obligations
- Publication and Data Disclosure plan
- Data Privacy
- The use of third-party sub-contractors.

Research activities as well as the funding of such activities, will not occur before the agreement is fully executed.





## **Safety reporting**

Patient safety and product quality are key priorities.

One of the most important requirements of a Research Collaboration is the responsibility to monitor and report safety data in a timely and accurate manner. The Partner shall abide by all local laws for Regulatory Safety reporting to Health Authorities, and also report Safety information to Novartis as defined in the executed agreement.

Together, we must comply with Regulatory Safety reporting requirements where the project is being conducted, as well as other regulatory requirements, as defined in the executed agreement.

## **Project close-out and publication**

Novartis is committed to transparency and therefore requires that project data be reported in the form of a study report, and publication. Requirements and timelines will be agreed upon as part of the contractual agreement.

We encourage the co-authoring of publications, in order to reflect the truly collaborative nature of the research activities.

## Overview of our Research Collaboration process

We look forward to hearing from you!

Click [here](#) to locate your local Novartis contact.



In addition to the requirements set forth within this guidance document, each request will be assessed subject to applicable local laws and regulations

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