

# **Novartis GEMS portal for Investigator Initiated Trials (IITs) / Investigator Initiated Research (IIR) submission and ongoing management**

**An introduction for external users**

**Effective date: 18 April 2023**

# Welcome to the Novartis GEMS\* portal for Investigator Initiated Trials (IITs) and Investigator Initiated Research (IIRs) submissions

## \*Grants, External Studies and Managed Access System

The GEMS portal is part of a, global, end-to-end management system, designed to make the application process and ongoing management of your IIT or IIR study faster and easier.

It is built around an easy-to-complete initial concept submission form, which automatically transfers all content to Novartis ensuring faster processing time. All workflow associated with your study is then managed via the portal, with emails sent to you whenever your action is required. You can access GEMS through any desktop or mobile device.

GEMS is largely intuitive. However, should you require any technical assistance, just click on the link at the bottom of any page in GEMS to raise a query with our support team who will either answer your query directly or redirect it to the correct team for a response.

If you require any other form of assistance related to your request, please email us at [gemsit.office@novartis.com](mailto:gemsit.office@novartis.com). Below is some guidance for using the portal.

## Registration

1. Click the 'submit your concept here' link found in the Investigator Initiated Trials page on [novartis.com](http://novartis.com) or click [here](#) to view. Prior to undertaking any activity within the GEMS portal, you will need to answer the YES/NO questions presented on the screen. This will help your submission to be directed accurately.
2. If this is your first time visiting the site, you need to create a password. To do this, click on 'Create a Password' at the top of the screen. Once you have followed the instructions around the creation of a password and logged in, you will be asked to complete a brief registration form.
3. After registration, an email is sent to the address you provided. Confirm the registration by clicking on the link provided. Once registered, you have access to your own Welcome Page.

## Concept submission

1. Select whether you wish to start a new IIT request or a new IIR request at the bottom of the page to initiate a new submission.
2. Next, you will be taken to a series of forms for completion. You can save your progress at the end of each page and add to it at a later date should you need to.
3. Before submitting, complete the Attestation. Once your request is submitted, the form is locked, and you will not be able to make any further changes to the content.
4. If further information to support your request is required during the review and approval process, you will be contacted by a member of the relevant Novartis Medical team.

### **Notification of decision**

1. If your Request is approved, you will be prompted at various points to submit further information in the form of Impact Reports.
2. If your Request is denied, you will receive an email informing you about the decision and reason why we cannot support your concept.

### **Submitting Impact Reports**

1. If your concept is approved, then from time to time you will be asked to complete Impact Reports at significant milestone points. They will be sent to your registered email address and links will also appear on your Welcome Page in the Impact Reports Action Required section.
2. Please complete and submit the relevant Impact Report. Upon submission, the workflow continues.

### **Adverse Event Reporting (for IITs only)**

Please report Adverse Events (AEs) relevant to Novartis products from IITs as per the agreement.

You can access the GEMS online portal by clicking [here](#)