



# **Novartis GEMS portal for Investigator Initiated Trial (IIT) submission and ongoing management**

**An introduction for external users**

Global Governance Office

# Welcome to the Novartis GEMS\* portal for Investigator Initiated Trial (IIT) submissions

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

The GEMS IIT submission portal is part of a new, global, end-to-end IIT management system, designed to make the application process and ongoing management of your 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 IIT is then managed via the portal with automated emails sent to you whenever your action is required. You can also 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.

### 1. Registration

- Begin by clicking on the link below which takes you to the welcome page. Here, you will be asked to complete a brief registration form.  
Novartis welcome page

### 2. Completing the concept submission form

- Once registered, log in to the IIT portal where you can make your initial concept submission. Go to **Start a new IIT request** at the bottom of the page to initiate a new submission. Here, you will be taken to a series of forms for completion. You can save your progress at the end of each page and to it at a later date should you need to.
- Before submitting, complete the certification section and privacy notice. Once your request is submitted, the form is locked and you will not be able to make any changes to the content.
- When the request has been assigned to a member of the Novartis Medical team, the status of your application will change to **Under Review** to show that it has started the review and approval process.
- If further information to support your request is required during the review and approval process, you will be contacted by a member of the Novartis Medical team.

### 3. Notification of decision

- If your Request is approved, the status will change to **Approved**, and you will be prompted at various points to submit further information such as the draft and final protocol, safety information, patient enrollment data and the Third-Party Study Report in the form of Impact Reports.
- If your Request is denied, you will receive an email informing you about the decision and reason why we cannot support your concept. The status will show as **Denied**.

#### 4. Submitting Impact Reports

- If your initial concept is approved, GEMS will automatically notify you immediately of the need to submit a draft protocol. You will receive this request via an automated email and it will also appear in the **Impact Reports Pending** section on your welcome page.
- To complete an Impact Report, either click on the link in the email or in the **Impact Reports Pending** section to be taken to the form, which you need to complete and submit. Upon submission, the information automatically transfers to Novartis and the workflow continues.

#### 5. Adverse Event Reporting

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

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