Chief Medical Office
Managed Access Center
of Excellence

Novartis GEMS portal for Managed Access Program (MAP) Requests

Version 2.0

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NOVARTIS

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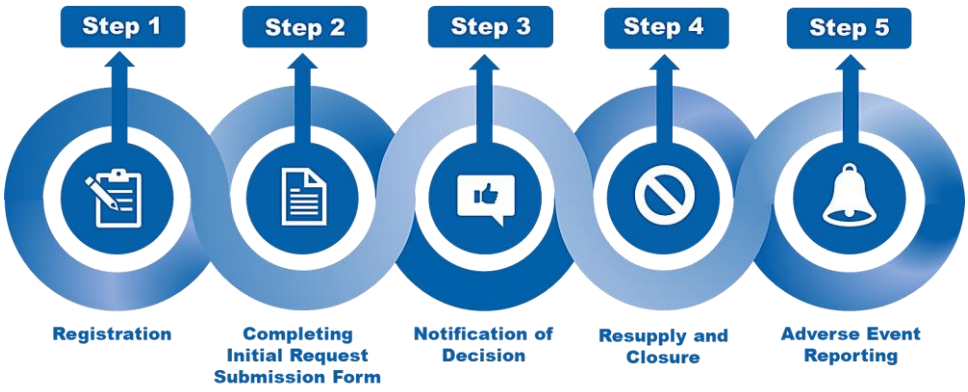
1. Welcome to the Novartis Grants, External Studies and Managed Access System (GEMS) portal for Managed Access Program (MAP) requests!

GEMS is a global cloud-based system for the submission and ongoing management of all Managed Access Program (MAP) requests. All initial and resupply requests must be submitted via the GEMS online portal accessed from www.novartis.com. GEMS makes it easy for you (the physician) to submit and manage your request and for Novartis to speedily review and make a decision.

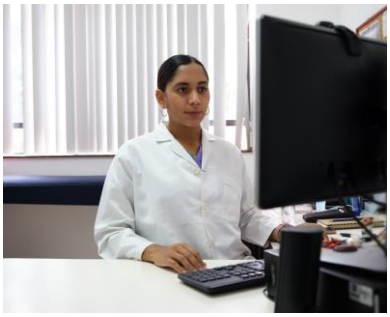
The system is largely intuitive. However, should you require any technical assistance, just click on the link at the bottom of any page in GEMS to raise a query with the technical support team. If you require any other form of assistance related to your request, please email us at managed.access@novartis.com.

Here you can find the information needed about GEMS and its use.



1.1. Registration

- Begin by clicking on this link, which takes you to the welcome page. Here, under **'Create your password'** you will be asked to complete a brief registration form.
  The system will generate an automated email with a confirmation link to activate your account. If you did not receive the email, please make sure to check your spam folder as the email may have been triaged there.



1.2. Completing the Initial Request Submission Form

- Once registered, log in to the Managed Access portal where you can submit your request. Go to **Submit New Request** at the bottom of the page to initiate a new application. You will be asked to complete further details, including information about your organization, your request and shipping requirements.

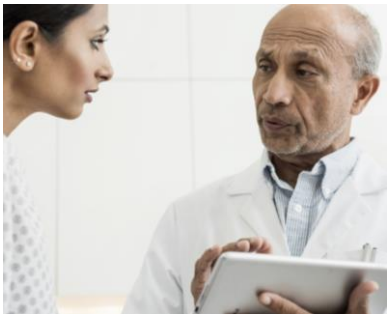
- Depending on the product, you may be asked to complete additional questions.

- Finally, once you agree to the confidentiality section and privacy notice, you will be able to submit your request. Please note that after your request is submitted the form is locked and you will not be able to make any changes to the content. Your request is now in status **External**.

- Once the request has been assigned to a member of the Novartis Medical team, the status of your application will change to **Pending** to show that the review process has started.

  If further information to support your request is required during the review process, a member of the Novartis Medical team will return your request for further information or contact you.

1.3. Notification of decision



- If your request is *approve*d, you will be asked to sign either Terms & Conditions (T&C), or a Letter of Agreement in line with your country regulation. Upon execution of the Terms & Conditions / Letter of Agreement, shipment is executed. You will be prompted by the system to submit further information at various points like first treatment date or last treatment date.
  Submitting accurate information on time is key to ensuring correct data is reflected in our system. This information is important because it may be requested by Health Authorities, enables accurate reporting of patient exposure to our products and can support regulatory submissions. Finally, and equally important, your information helps us to better understand benefits patients are deriving from our product.

- If your request is *denied*, you will receive an email informing you about the decision and reason why we cannot support your request.

1.4. Resupply and closure

- Once the shipment has been executed, you will be given the option to initiate a resupply in the system if your patient is deriving benefit from our product. We expect you to share with us the first treatment date of your patient upon treatment initiation.

- After your patient discontinues the treatment, you are required to notify us of the last treatment date of your patient. The request will be closed once you provide this date.

1.5. Adverse Event Reporting

- Please report Adverse Events (AEs) relevant to Novartis products as per the Terms & Conditions/ Letter of Agreement and safety brochure. When the online tool should be used click here.

You can access the GEMS online portal by clicking here. We welcome any feedback on our system and remain open for any suggestions for improving your user experience.

We appreciate your collaboration and thank you for utilizing this guide!

2. Change History of this Document

Version:	Description of Change
Version 2	New template used. Minor editorial changes done. Section 2.3. Terms & Conditions added as newly introduced in GEMS.