



OPEN RIMS USER MANUAL

Version # 1.0

June 2024

www.rims.dgda.gov.bd



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<https://dgda.gov.bd>

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Purpose of this guide

This guide shows DGDA Clients and Customers how to log in to and submit an application for an Export Certificate or a Product Marketing Authorization.

Overview

The main steps for the Applicant:

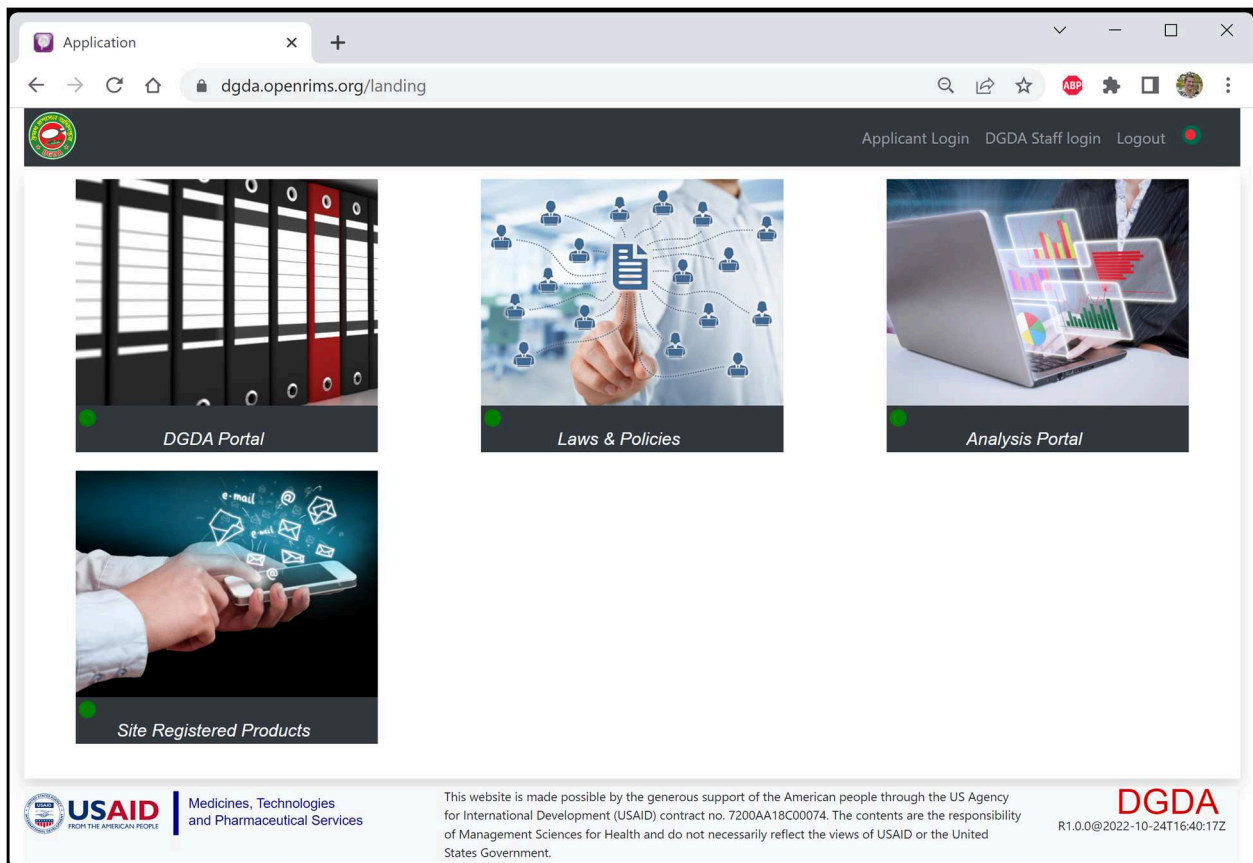
1. Go to the DGDA Application website
2. Login to the system
3. Go to Application Files and Select the needed Application type
4. Create a New Application
5. Fill out Application pages with required information
6. Fill out Application Self-Check list
7. Submit the Application to DGDA
8. Track the DGDA Status of the Application

Step 1: Go to the website <https://dgda.openrims.org>

The system is available on the following link:

<https://dgda.openrims.org>

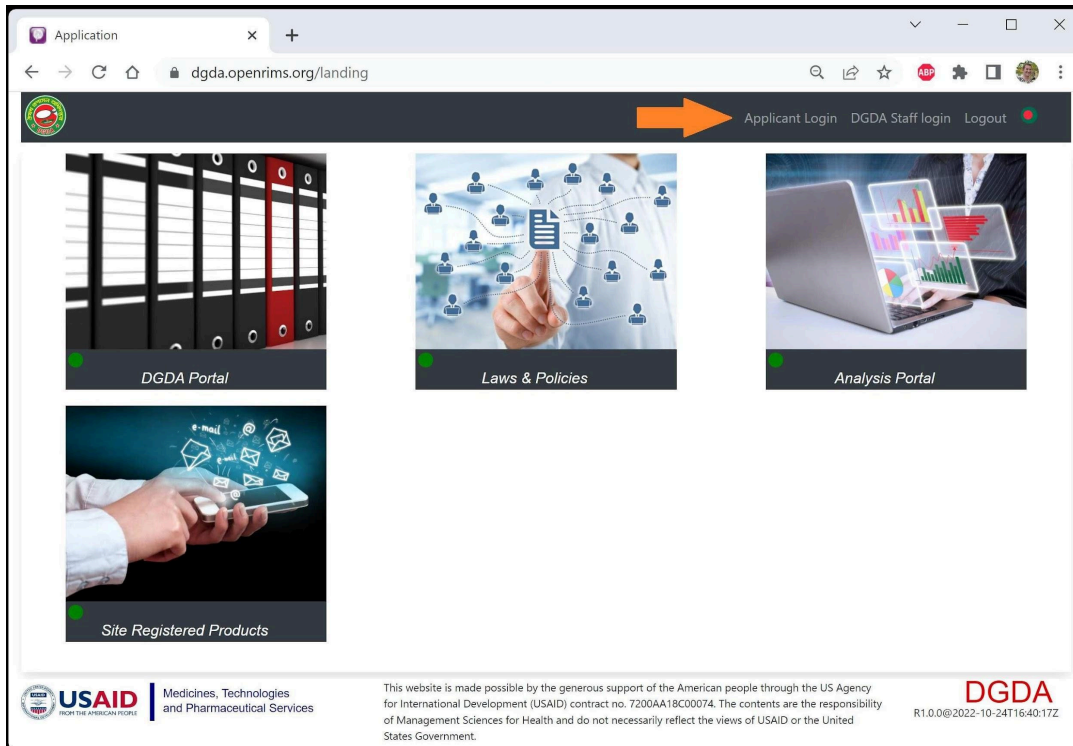
Please type the link in a browser or click the above link.



The screenshot shows a web browser window displaying the landing page of the DGDA Application website. The browser's address bar shows the URL dgda.openrims.org/landing. The page features a dark header with the USAID logo on the left and navigation links for "Applicant Login", "DGDA Staff login", and "Logout" on the right. The main content area is divided into four sections, each with a representative image and a caption: "DGDA Portal" (image of a filing cabinet), "Laws & Policies" (image of a hand pointing to a document), "Analysis Portal" (image of a laptop with charts), and "Site Registered Products" (image of a hand holding a smartphone). The footer contains the USAID logo and text: "Medicines, Technologies and Pharmaceutical Services", a disclaimer: "This website is made possible by the generous support of the American people through the US Agency for International Development (USAID) contract no. 7200AA18C00074. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.", and the DGDA logo with the text "R1.0.0@2022-10-24T16:40:17Z".

Step 2a: Login as Applicant

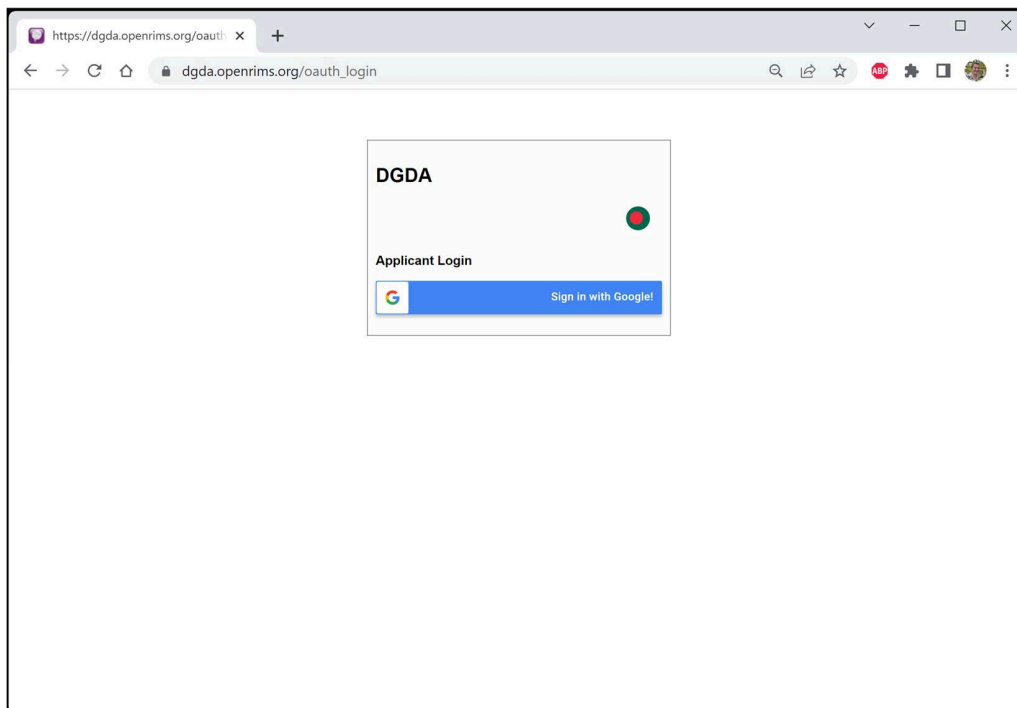
As an Applicant or Customer please click on the top right on the Applicant Login as illustrated with the orange arrow here:



NB! You do need a Google account to be able to submit any application.

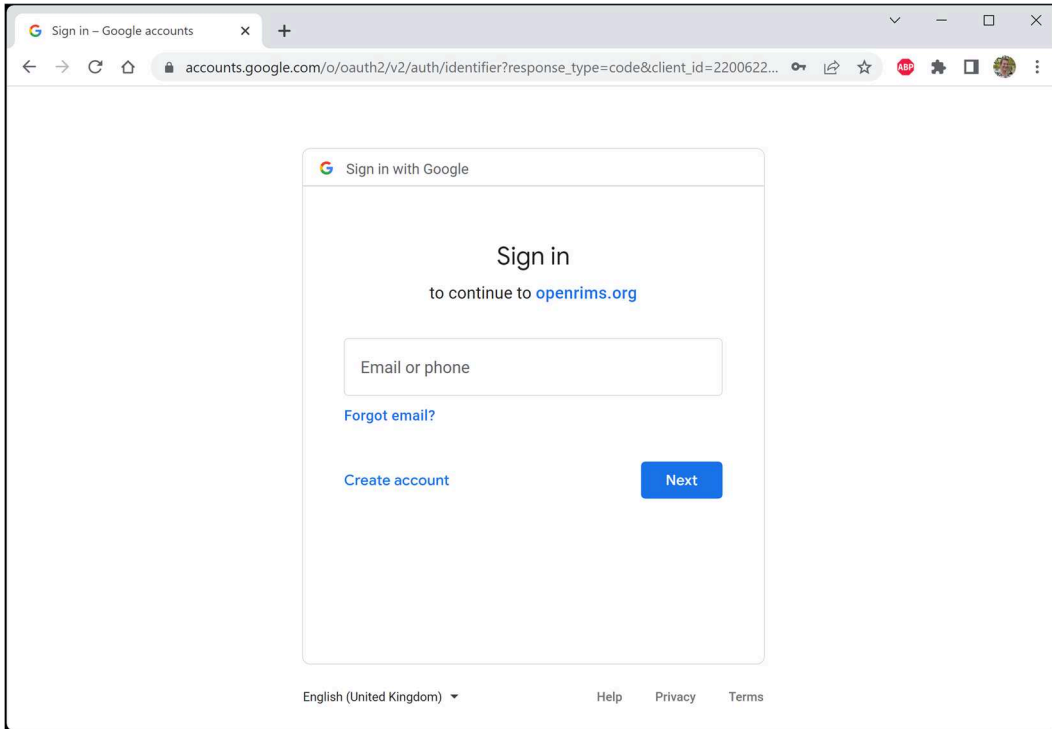
Step 2b: Select Google login

Now click the Sign in with Google button:

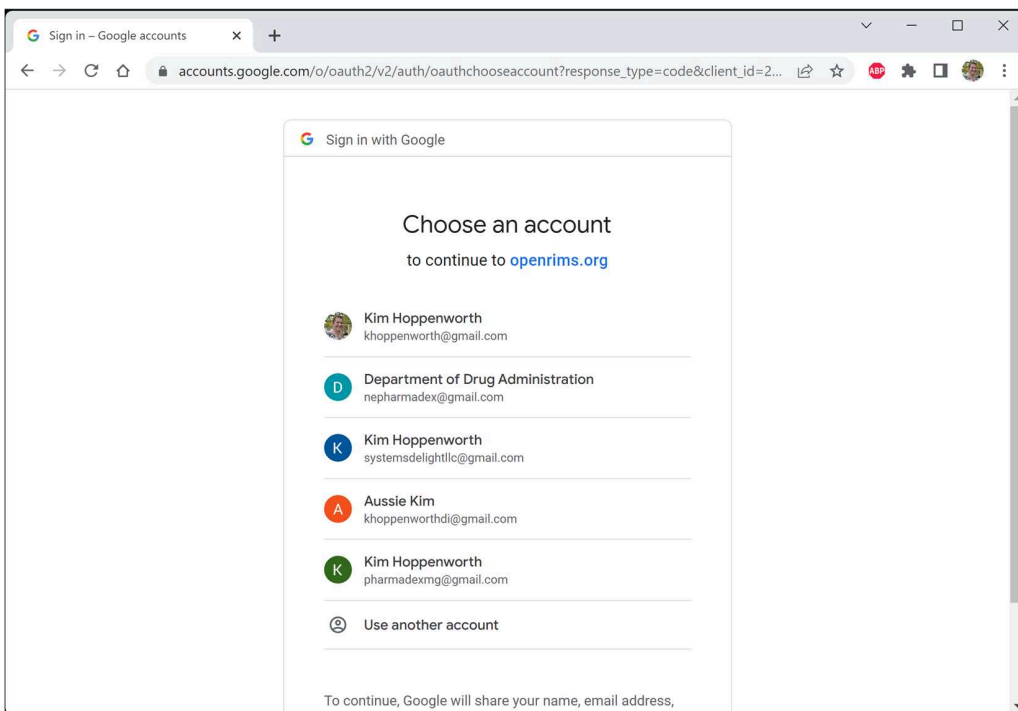


Step 2c: Choose Existing or new Google Login

Choose an Existing account. Or enter your information.



OR



Step 4: Go to Application Files

After log in please mouse over the Application tile and click the green [Start](#) button to go to Application screen.

The screenshot shows the DGDA application dashboard. The user is logged in as Kim Hoppenworth. The dashboard features a navigation menu on the left with 'Applications' selected. The main content area has three tiles: 'Start' (green button), 'To Do List' (blue background with a person pointing), and 'Monitoring' (dark background with a person holding a tablet). Below these is a 'Reports' tile with a laptop and charts. The footer includes USAID and DGDA logos and contact information.

Now click the Application Type you will apply for and then click the [Add](#) button to start (Below highlights the “Introduced Vaccine”)

The screenshot shows the DGDA application screen. The left panel shows 'Application Types Available' with a table listing various application types. The 'Registration Procedure for introduced vaccine and biosimilar products manufactured in Bangladesh' is selected. The right panel shows a table of 'Applications' with columns for Scheduled, Day, Activity, Name, and Additional information. The table lists several submitted applications, including Measles, COVID-19 mRNA Vaccine, and Vaccines No. 10, 12, and 12.

Scheduled	Day	Activity	Name	Additional information
Oct 25, 2022	4	Submitted	Measles	
Oct 25, 2022	4	Submitted	COVID-19 mRNA Vaccine called tozinameran	
Oct 25, 2022	4	Submitted	COVID-19 mRNA Vaccine called tozinameran	
Oct 25, 2022	4	Submitted	Vaccine No. 10	
Oct 26, 2022	3	Submitted	mikomycin	
Oct 28, 2022	1	Submitted	Vaccine No. 12	
Oct 29, 2022	0	Submitted	COVID-19 mRNA Vaccine called tozinameran	

Step 5: Fill out the Application pages

In our example we have 7 pages to fill out as indicated top center:

1 of 7

The screenshot shows a web browser window with the URL `dgda.openrims.org/guest#applications/applicationstart/%7B"url":"","applDictNodeid"...`. The page title is "Registration Procedure for introduced vaccine and biosimilar products manufactured in Bangladesh". The user is logged in as "Hello Kim Hoppenworth". The page is titled "New Application / Next" and "1 of 7". The form includes sections for "Product Information" (Product Type, Product Group), "ATC Code" (Search, Name, Additional information), and "Indication" (Shelf life (in Months), Pack Size, Container/Closure Type, Storage Condition). There are "Next", "Save", and "Cancel" buttons at the top right.

Input the application information as required and click the **Next** button on the top right after each page is complete. You can click the **Save** button if you need to go away and continue later.

*NB! The system also saves progress when you click **Next**.*

Step 5: Conclude Application

After the last page (7 of 7 for Introduced Vaccines) click the **Conclude** button.

The screenshot shows the final page of the application registration process, "7 of 7". The page title is "Registration Procedure for introduced vaccine and biosimilar products manufactured in Bangladesh". The user is logged in as "Hello Kim Hoppenworth". The page is titled "Module 5 - Clinical Study Reports". The form includes sections for "5.1 Module 5 Table of Contents" and "5.2 Tabular Listing of All Clinical Studies". There are "Conclude", "Show print form", "Save", and "Cancel" buttons at the top right. The footer includes the USAID logo and text: "Medicines, Technologies and Pharmaceutical Services. This website is made possible by the generous support of the American people through the US Agency for International Development (USAID) contract no. 7200AA18C00074. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government." The DGDA logo and text "R1.0.0@2022-10-24T16:40:17Z" are also present.

Step 7: Submit the Application

The Conclude button will take you to the final Self-Check of your application as seen below. You need to click through the Yes/No and add Notes if applicable at this step.

Send the Application to DGDA by clicking the **Submit** button.

The screenshot shows a web browser window with the URL `dgda.openrims.org/guest#applications/applicationstart/%7B"url":"","appDictNodeId":...`. The user is logged in as Kim Hoppenworth. The page title is "Registration Procedure for introduced vaccine and biosimilar products manufactured in Bangladesh". A modal window titled "Self Check List (Introduced vaccine and biosimilar local products)" is open, displaying a table for self-checking the application details.

Item	Yes	No	N/A	Notes
1.0 Full Module 1 included	Yes	No	N/A	Notes
1.1 Product Group Defined	Yes	No	N/A	Notes
1.2 Product Category defined	Yes	No	N/A	Notes
1.3 Brand Name included	Yes	No	N/A	Notes
1.4 Generic Name provided	Yes	No	N/A	Notes

Below the self-check list, there are buttons for "Show print form", "Save", "Cancel", and "Submit". The page also features the USAID logo and text: "Medicines, Technologies and Pharmaceutical Services" and "This website is made possible by the generous support of the American people through the US Agency for International Development (USAID) contract no. 7200AA18C00074. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government." The DGDA logo and version number "R1.0.0@2022-10-24T16:40:17Z" are also present.

NB! After Submitting the system takes you back to the Application list if you need to submit another.

The screenshot shows the "Client Applications" page in the DGDA system. It displays a table with columns for "Name" and "Additional information". The table lists several application types, each with a checkbox and a description.

Name	Additional information
<input type="checkbox"/> Export Certification	Receive a certificate to import a medicine by the standard procedure.
<input type="checkbox"/> Import Permit	Receive a permit to import a medicine by the standard procedure.
<input type="checkbox"/> Marketing Authorization	Application Form for the Registration of Drugs (which are included as monographs in BP/BPC/USP-NF/Int. Ph. or are already Introduced in Bangladesh)
<input type="checkbox"/> Marketing Authorization Certification- Applicant Section	Application Form of Vaccine registration (which are for UPA, IPA, IND & IMP in Bangladesh) under DGDA.
<input type="checkbox"/> Registration Procedure for introduced vaccine and biosimilar products manufactured in Bangladesh	Registration Procedure for introduced vaccine and biosimilar products manufactured in Bangladesh.
<input type="checkbox"/> Special Import	

At the bottom of the table, there are icons for list view and a dropdown menu set to "20". The page footer includes the USAID logo, "Medicines, Technologies and Pharmaceutical Services", and the DGDA logo with version number "R1.0.0@2022-10-24T16:40:17Z".

Step 8: Tracking the Application Status

You can easily track the status of an application by clicking the Application type.

In our example “Registration procedure for introduce vaccine”.

The screenshot shows the 'Applications' page in the DGDA OpenRIMS system. The user is logged in as Kim Hoppenworth. The page has a navigation menu with 'Applications', 'New applications', 'Modifications', 'De-registration', and 'Exit'. On the left, there is a 'Client Applications' section with a list of application types. The 'Registration Procedure for introduced vaccine and biosimilar products manufactured in Bangladesh' is selected. On the right, there is an 'Applications' table with columns for 'Scheduled', 'Day', 'Activity', 'Name', and 'Additional information'. The table shows several entries, all with a status of 'Submitted'. At the bottom, there is a footer with USAID and DGDA logos and contact information.

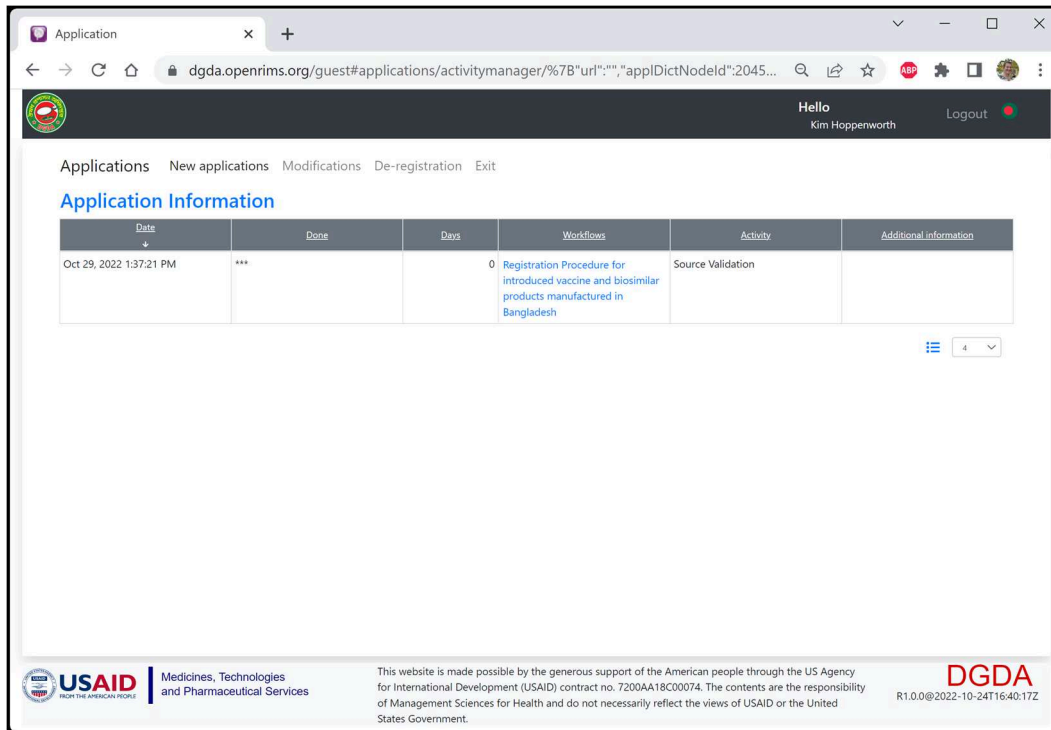
Scheduled	Day	Activity	Name	Additional information
Oct 25, 2022	4	Submitted	Measles	
Oct 25, 2022	4	Submitted	COVID-19 mRNA Vaccine called tozinameran	
Oct 25, 2022	4	Submitted	COVID-19 mRNA Vaccine called tozinameran	
Oct 25, 2022	4	Submitted	Vaccine No. 10	
Oct 26, 2022	3	Submitted	mikomycin	
Oct 28, 2022	1	Submitted	Vaccine No. 12	
Oct 29, 2022	0	Submitted	COVID-19 mRNA Vaccine called tozinameran	

Then click the Submitted link to open the Application you want to track

The screenshot shows the 'Application Information' page for a 'Registration Procedure for introduced vaccine and biosimilar products manufactured in Bangladesh'. The application name is 'COVID-19 mRNA Vaccine called tozinameran'. The page has a navigation menu with 'Applications', 'New applications', 'Modifications', 'De-registration', and 'Exit'. On the left, there is a list of application modules: 'Payment', 'Module 1', 'Module 2', 'Module 3', 'Module 4', and 'Module 5'. On the right, there is a 'Self Check List (Introduced vaccine and biosimilar local products)' table. The table has columns for 'Yes', 'No', 'N/A', and 'Notes'. The table shows several items, all with a status of 'Yes'. At the bottom, there is a footer with USAID and DGDA logos and contact information.

Self Check List (Introduced vaccine and biosimilar local products)				
	Yes	No	N/A	Notes
1.0 Full Module 1 included	Yes	No	N/A	Notes
1.1 Product Group Defined	Yes	No	N/A	Notes
1.2 Product Category defined	Yes	No	N/A	Notes
1.3 Brand Name included	Yes	No	N/A	Notes
1.4 Generic Name provided	Yes	No	N/A	Notes

Lastly click the top link [Application Information](#) to show the full history of this Application; in our case the application is now at the DGDA activity/step called **Source Validation**.



The screenshot shows a web browser window with the URL `dgda.openrims.org/guest#applications/activitymanager/%7B"url":"","applDictNodeld":2045...`. The page title is "Application" and the user is logged in as "Hello Kim Hoppenworth". The navigation menu includes "Applications", "New applications", "Modifications", "De-registration", and "Exit". The main heading is "Application Information". Below this is a table with the following data:

Date	Done	Days	Workflows	Activity	Additional Information
Oct 29, 2022 1:37:21 PM	***	0	Registration Procedure for introduced vaccine and biosimilar products manufactured in Bangladesh	Source Validation	

At the bottom of the page, there is a footer with the USAID logo and text: "Medicines, Technologies and Pharmaceutical Services". To the right, it states: "This website is made possible by the generous support of the American people through the US Agency for International Development (USAID) contract no. 7200AA18C00074. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government." On the far right, the DGDA logo and version information "R1.0.0@2022-10-24T16:40:17Z" are displayed.

This concludes the application submission and tracking process.

END OF DOCUMENT