Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	Food and Drugs Inspection and Safety Monitoring Department / Food and Drugs Import and Export Control Division	
Document Type: **Form**		Doc. No	:FDISM/FDIEC/FOM/003
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Application form for Importation of Investigational Medical Products**	Revision Number	: 0
		Revision Date:	: 22/09/2022
		Effective Date	: 23/09/2022
		Review Due Date	: 22/09/2025
		Ref Doc.	:FDISM/FDIEC/GDL/001

Date of application	
Title of the study	
Clinical Trial Approval Certificate Number	
Date of issuance	
Date of Expiration	
Sample size/Participant to be recruited	
Name of Investigational Product (IP) Proprietary Product Name (if relevant)	
International Non-proprietary Name (INN) of the Active Pharmaceutical Ingredient (API), strength, pharmaceutical form.	
Name (s) and complete address (es) of the manufacturer (s) of the Investigational product (s), including the final product release if different from the manufacturer.	
IP Therapeutic Classification	
IP Route of Administration	
Quantity needed for entire Trial	
Quantity to be imported	
Storage conditions	
Special Precautions	
Name's placebo or comparators (if applicable	
Quantity to be imported	
Storage conditions	
Other	

DECLARATION OF THE APPLICANT

I DECLARE THAT:

- ✓ *The information provided on the application is correct,*
- ✓ *The imported Investigational products will be distributed to the approved clinical trial sites approved by Rwanda FDA*
- ✓ *I confirm that the investigational products are manufactured in accordance with good manufacturing practices (GMP) and that they will be stored / distributed under appropriate conditions*
- ✓ *I will inform the Authority the quantity of investigational products and/or Placebos destroyed according to the Rwanda FDA requirements*

SIGNATURE OF APPLICANT

Applicant names	**Phone number**	**Signature**