	FORM	FOR-OGITT-056
	NATIONAL FINAL REPORT	Edition No. 01

Instructions: *Dear User, remember that the request must be completed through the electronic form available in the Peruvian Registry of Clinical Trials (REPEC) at: http://www.ensayosclinicos-repec.ins.gob.pe*

INF number:

(Automatically generated during electronic registration at REPEC)

1. NOTIFYING INSTITUTION

1.1. Name of the Institution:	*(Automatically generated during electronic registration at REPEC)*		
1.2. Legal representative:			
Names:		**Document from Identity:**	
Last name:		**Telephone:**	
Mother's last name:		**Email:**	

2. IDENTIFICATION OF THE CLINICAL TRIAL

2.1. EC INS N°: *(Automatically generated during electronic registration at REPEC)*

2.2. Clinical Trial Title:

23. **Sponsor:**	**2.4. Institution that legally represents the sponsor in the country:**
2.5. Clinical phase of the study: ☐ I ☐ II ☐ III ☐ IV ☐ Does not apply	**2.6. Protocol Code:**
2.7. Report date:	*(Automatically generated during electronic registration at REPEC)*
2.8. Final situation in the country:	Select one of the following conditions: ☐ The *development of the protocol* was fulfilled . ☐ *Cancellation of the EC (Definitive interruption of activities)*
2.9. Start date of activities selection in the country:	……. / ……. / …… (dd/mm/yyyy)
2.10. Enrollment date of the first research subject in the country:	*(Automatically generated if you have previously registered with REPEC)*
2.11. End date of enrollment in the country:	*(Automatically generated if you have previously registered with REPEC)*
2.12. Date of the last visit of the last research subject in the country.	……. / ……. / …… (dd/mm/yyyy)

Form approved by RD N° 585-2017-OGITT-OPE/INS **Date: 04 - 10 - 2017**

3. FINAL INFORMATION ON THE CLINICAL TRIAL

3.1. Information in relation to the research subjects

aN° subjects screened:		**b. N of subjects enrolled:**		
		No. of men enrolled:		
		Number of women enrolled		
		Maximum age:		
		Minimum age:		
		cN° subjects who failed in the selection *(screen failure):*		
d. Number of subjects who completed the study:		**and. No. of subjects who completed treatment:**		
F. No. of subjects who withdrew / left the study:		**Reasons**	**By withdrawal of consent**	
			By decision of the investigator and/or sponsor	
				Specify:
			Another cause:	
				Specify:

3.2. Information related to the monitoring of the EC by the sponsor Report regarding the activities carried out since the beginning of the EC.

	Research Center Monitoring in the center (N°)		Centralized monitoring (N°)
No. of monitoring activities carried out by research center	RCI		
	RCI		
	RCI		

3.3. Information related to the investigational product used (including comparators)

a.Total amount received in research centers	b. Quantity of product administered	c. Amount of product returned to sponsor	d. Quantity of product destroyed
Item 1			
Item 2			
and. another destination	Inform if its use is contemplated for post-study access or as a donation: ÿ Research product: ÿ Quantity: ÿ Destination:		

3.4. Information related to post-study access

Report regarding the actions planned for post-study access, if applicable:

4. DEVIATIONS TO THE PROTOCOL	
DEVIATIONS CRITICAL OR VERY SERIOUS	*(Automatically generated based on previous registration in REPEC)*
DEVIATIONS MAJOR OR SERIOUS	*(Automatically generated based on previous registration in REPEC)*
DEVIATIONS MINOR OR MINOR	*(Automatically generated based on previous registration in REPEC)*

5. SUMMARY OF SERIOUS ADVERSE EVENTS
The data of reported serious adverse events are automatically generated based on the information registered in the REAS-NET Serious Adverse Event Reporting System.

6. SUMMARY OF NON-SERIOUS ADVERSE EVENTS RELATED TO THE PRODUCT IN RESEARCH
The data of the non-serious adverse events reported are automatically generated based on the information previously registered in the REPEC.

7. ADDITIONAL COMMENTS OR OBSERVATIONS:
Add the additional information that you consider important and has not been requested in this form.

8. REGARDING THE RESULTS AND CONCLUSIONS OF THE CLINICAL TRIAL	
Select as appropriate: - The EC is multinational ☐ ÿ The EC is executed only in Peru ☐	In the case of EC executed only in Peru, attach to this report, the final results and the conclusions of the EC. See ***Guide for the Report of results and conclusions of the clinical trial.*** If this information is not available as of the date of this report, select: Pending shipment Estimated date of shipment: ……./……./…… (dd/mm/yyyy) ☐ Remember that the maximum term for sending the results and conclusions of the CT is six (6) months after the end of the study.

9. AUTHORIZED LEGAL REPRESENTATIVE

By signing this application, I certify that the information contained herein is current, true and accurate.

_____

Signature of the Authorized Legal Representative
SURNAMES AND NAMES:

Date: / /

The information contained in this document has the character of an affidavit. The General Office of Research and Technology Transfer -OGITT will take into account the information consigned therein, reserving the right to carry out the corresponding verifications; as well as request the accreditation of the same. If it is detected that false information has been omitted, concealed or recorded, the corresponding administrative and criminal actions would be taken.