	FORM	FOR-OGIT-055
	FINAL REPORT OF THE RESEARCH CENTER	Edition No. 01

Instructions: *Dear User, remember that the application must be filled out 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 in REPEC)

1. NOTIFYING INSTITUTION

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

2. IDENTIFICATION OF THE CLINICAL TRIAL AND RESEARCH CENTER REASON FOR THE REPORT

2.1. EC INS N°: *(Generated automatically during electronic registration in REPEC)*	
2.2. Clinical Trial Title:	
2.3. 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. Research Center:	
2.8. Principal investigator	
2.9. Report date:	*(Automatically generated during electronic registration in the REPEC)*
2.10. Final situation in the center of investigation:	Select one of the following conditions: ☐ The *development of the protocol* was complied with ☐ Early cancellation of study activities.
2.11. Start date of selection activities at the research center	**……. / ……. / …… (dd/mm/aaaa)**
2.12. Date of the last visit of the last research subject corresponding to the center.	**……. / …… / …… (dd/mm/aaaa)**
2.13. Date of closing visit carried out by monitor:	**……. / …… / …… (dd/mm/aaaa)**

	FORM	FOR-OGIT-055
	FINAL REPORT OF THE RESEARCH CENTER	Edition No. 01

3. FINAL INFORMATION FROM THE RESEARCH CENTER

3.1. Information regarding research subjects

to. No. subjects screened:		b. Number of subjects enrolled:		
		ÿ No. Women		
		ÿ No. Men		
		- Minimum age		
		- Maximum age		
		c. No. subjects who failed in the selection *(Screen failure)*		
d. No. subjects who completed the study:		And. No Subjects who completed treatment:		
F. No. subjects who withdrew/ abandoned the study:		Reasons	For withdrawal of consent	
			By decision of the researcher and/or sponsor	
				To specify:
			Another cause:	
				To specify:

3.2. Information related to the investigational product used (Including comparators)

a.Total amount received at the center	b. Amount of product administered	c. Quantity of product returned to sponsor	d. Quantity of destroyed product
Item 1			
Item 2			

and. Other destination, according to article 97 of the REC:	Inform: ÿ Product under investigation: ÿ Quantity: ÿ Specify destination:

4. DEVIATIONS TO THE PROTOCOL (NEW CASES SINCE THE LAST PROGRESS REPORT)

4.1. CRITICAL OR VERY SERIOUS DEVIATIONS	*(Automatically generated during electronic registration in REPEC)*
4.2. MAJOR OR SERIOUS DEVIATIONS	*(Automatically generated during electronic registration in REPEC)*

4.3. MINOR OR MINOR DEVIATIONS	☐ AND ☐ NO If you check YES, complete the following information for each minor or slight deviation:			
Date of knowledge by the sponsor / OIC (dd/mm/aaaa)	**Research subject identification code**	**Summary description of the deviation**	**Measure taken:**	**Date of notification to the ethics committee (dd/mm/yyyy)**

5. SUMMARY OF SERIOUS ADVERSE EVENTS (NEW CASES SINCE THE LAST REPORT OF ADVANCE)

Data on reported serious adverse events are generated automatically based on information recorded in the REAS-NET Serious Adverse Event Reporting System.

6. SUMMARY OF NON-SERIOUS ADVERSE EVENTS RELATED TO THE PRODUCT IN INVESTIGATION (NEW CASES SINCE THE LAST PROGRESS REPORT)

Subject identification code	Adverse event	Start date (dd/ mm/yy)	Action taken	Outcome of the event

7. ADDITIONAL COMMENTS OR OBSERVATIONS:

Add any additional information that you consider important and has not been requested in this form.

8. AUTHORIZED LEGAL REPRESENTATIVE

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

_____

Signature of Authorized Legal Representative
SURNAMES AND NAMES:

Date: / /

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