	FORM	FOR-OGIT-057
	FINAL INTERNATIONAL REPORT	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)*		
Legal representative:			
1.2. Names:		**document Identity:**	
Last name:		**Telephone:**	
Mother's last name:		**Email:**	

2. IDENTIFICATION OF THE CLINICAL TRIAL

2.1. EC INS N°: *(Generated automatically during electronic registration in REPEC)*

2.2. Title of the Clinical Trial: *(Automatically generated during electronic registration in REPEC)*

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. Report date:	*(Automatically generated during electronic registration in the REPEC)*
2.8. Final situation worldwide	Select one of the following conditions: ☐ The *development of the protocol* was complied with . ☐ *Cancellation of the EC (Definitive interruption of activities)*
2.9. Start date of activities worldwide selection	……. / ……. / …… (dd/mm/aaaa)
2.10. Enrollment date of the first subject worldwide	……. / ……. / …… (dd/mm/aaaa)
2.11. End date of enrollment world level:	……. / ……. / …… (dd/mm/aaaa)
2.12.Date of the last visit of the last research subject worldwide	……. / …… / …… (dd/mm/aaaa)

3. FINAL INFORMATION FROM THE CLINICAL TRIAL

3.1. Information regarding research subjects

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

4. ADDITIONAL COMMENTS OR OBSERVATIONS

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

5. REGARDING THE RESULTS AND CONCLUSIONS OF THE CLINICAL TRIAL

Attach to this report the final results and conclusions of the EC.
See ***Guide for the Report of results and conclusions of the clinical trial.***

If you do not have this information as of the date of this report, select:

Shipping pending ☐ Estimated shipping date: ……./……/…… (dd/mm/yyyy)

Justification for delay in submission:

6. 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.