	FORM	FOR-OGIT-054
	CLINICAL TRIAL PROGRESS 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 No.:** *(Generated automatically during the electronic registration in REPEC)*

1. NOTIFIING INSTITUTION

1.1. Name of the Institution:	*(Automatically generated during the electronic registration in REPEC)*		
1.2. Legal representative:			
Names:		**document of 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 the electronic registration in the REPEC)*

2.2. Clinical Trial Title: *(Automatically generated during the 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. Periodicity of Progress Report according to RD:	*As established in the authorization resolution of the CE* ☐ Quarterly ☐ II Semester
2.8. Research Center:	
2.9. Principal investigator	
2.10. Report date:	*(Automatically generated during electronic registration at the REPEC)*
2.11. Report No. for the center:	*(Automatically generated during electronic registration at the REPEC)*
2.12. Reporting period:	**Del : ……. / ……. / …… (dd/mm/aaaa)** **Al: ……. / …… / …… (dd/mm/aaaa)**

3. PROGRESS IN THE RESEARCH CENTER

3.1. Execution status of the clinical trial

a.Selection *(Screening):*	☐ AND ☐ NO	Start date:	Date of term: Continue to date: ☐

b. enrollment:	☐ AND ☐ NO	Start date:	Date of term: Continue to date: ☐
c.Treatment:	☐ AND ☐ NO	Start date:	Date of term: Continue to date: ☐
d. Tracing:	☐ AND ☐ NO	Start date:	Date of term: Continue to date: ☐

3.2. Information regarding the research subjects

a. No. subjects screened		**b. No. of subjects enrolled:**		
		ÿ No. Women ÿ		
		No. Men		
		- Minimum age		
		- Maximum age		
		cN° subjects that fail in the selection *(Screen failure)* e.		
d. No. of subjects who continue in the study		**Number of subjects in treatment**		
		f. No. of subjects in follow-up without treatment		
g. No. subjects that withdraw/drop out of study		**reasons**	**By withdrawal of consent**	
			By decision of the investigator and/or sponsor	To specify:
			Another cause:	To specify:
h. No. of subjects who completed the study:		**Yo. Number of subjects missing to enroll:**		

3.3. Information related to the monitoring of the CE by the sponsor during the period of report

Number of monitoring activities carried out	
Execution dates	**Date:** **Method:** ☐ in the research center ☐ Centralized
	Date: **Method:** ☐ in the research center ☐ centralized

4. DEVIATIONS FROM THE PROTOCOL OCCURRING DURING THE REPORTING PERIOD:	
4.1. CRITICAL OR VERY SERIOUS DEVIATIONS	*(Automatically generated during the electronic registration in REPEC)*
4.2. MAJOR OR SERIOUS DEVIATIONS	*(Automatically generated during the electronic registration in REPEC)*
4.3. MINOR OR SLIGHT DEVIATIONS	☐ AND ☐ NO If you check YES, complete the following information for each minor or slight deviation:

Date of knowledge by sponsor / OIC (dd/mm/aaaa)	Research subject identification code	Summary description of the deviation	Measure adopted:	Date of notification to the ethics committee (dd/mm/aaaa)

5. SUMMARY OF SERIOUS ADVERSE EVENTS REPORTED DURING THE REPORTING PERIOD
The reported serious adverse event data is automatically generated based on the information recorded in the REAS-NET Serious Adverse Event Reporting System.

6. SUMMARY OF NON-SERIOUS ADVERSE EVENTS RELATED TO THE PRODUCT IN INVESTIGATION OCCURRING DURING THE REPORTING PERIOD.				
Subject identification code	adverse event	Start date (dd/mm/yy)	Action taken	outcome of the event

7. ADDITIONAL COMMENTS OR OBSERVATIONS:
Add 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.

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Signature of Authorized Legal Representative
SURNAMES AND NAMES:

Date: , ,

The information contained in this document has the character of an Affidavit. The General Office for 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 will be taken.