

### 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:	(Automatio	ally g	enerated during the electronic registr	ation in REPEC)	
1.2. Legal representative:					
Names:		document of Identity:			
Last name:		Telephone:			
Mother's last name:		Email:			
2. IDENTIFICATION OF THE	CLINICAL TRIA	L AN	ID RESEARCH CENTER REA	ASON FOR THE REPORT	
2.1. EC INS N°: (Generated automa	tically during the ele	ctronic	c registration in the REPEC)		
2.2. Clinical Trial Title:	(Auton	(Automatically generated during the electronic registration in REPEC)			
2.3. Sponsor:			2.4. Institution that legally represents the		
2.5. Clinical phase of the study:			sponsor in the country:		
III III Does not apply			2.6. Protocol Code:		
2.7. Periodicity of Progress Report			As established in the authorization resolution of the CE		
according to RD:			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	Sta	urt date:	Date of term:	
NO NO				Continue to date:	



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b. enrollment:	AND NO	Start date:		Date of term:			
				Continue to date:			
c.Treatment:	AND NO	Start date:		Date of term:			
				Continue to date:			
	AND NO	Start date:		Date of term:			
d. Tracing:				Continue to date:			
3.2. Information regarding the	3.2. Information regarding the research subjects						
		b. No. of s	ubjects enrolled:				
		ÿ No. Wome	en ÿ				
a. No. subjects screened		No. Men - Minimum age - Maximum age  CN° subjects that fail in the					
a. No. subjects screened							
			n (Screen failure) e.				
d. No. of subjects		Number of	subjects in treatment				
who continue in the study			ubjects in follow-up treatment				
		reasons	By withdrawal of consent				
			By decision of				
g. No. subjects that			the investigator	To specify:			
withdraw/drop out of study			and/or sponsor				
			Another cause:	To specify:			
h. No. of subjects who completed the study:			er of subjects g 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							
	Date: Method: in the research center Centralized						
Execution dates	Date: Method: in the research center						
	centralized						

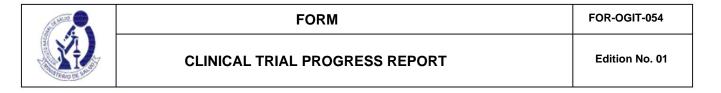


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4. DEVIATIONS FROM THE PROTOCOL OCCURRING DURING THE REPORTING PERIOD:								
4.1. CRITICAL OF SERIOUS D 4.2. MAJOR	EVIATIONS	(Automatically generated during the electronic registration in REPEC)						
SERIOUS DEVIA	TIONS	(Automatically generated during the electronic registration in REPEC)						
4.3. MINOR OR S DEVIATION	_	NO  If you check YES, complete the following information for each minor or slight deviation:						
Date of knowledge by su sponsor / OIC (dd/mm/aaaa) id		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 AE	OVERSE EVENTS F	REPORTED	DURING THE REPOR	RTING 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 e		art date (dd/mm/	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.								



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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 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.