	FORM	FOR-OGIT-059
	OTHER RELEVANT NOTIFICATIONS	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

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

2.2. Clinical Trial Title:

(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. Progress Report Frequency

according to RD:

As established in the authorization resolution of the EC

Quarterly
 II Semester

2.8. Report date:

(Automatically generated during electronic registration in REPEC)

3. NOTIFICATION RELATED TO THE CLINICAL TRIAL

Type of notification to be made

- Enrollment in the country.
- Publication in scientific journal
- Report resulting from the evaluation of the EC Data Monitoring Committee
- Update of the Investigator's Manual
- Destruction of the product under investigation.

Enter the information requested in the section corresponding to the type of notification you wish to make:

3.1. Enrollment in the country


to. Enrollment date of the first research subject in the
country b. End date of enrollment

(dd/mm/aaaa)

in the

country

(dd/mm/aaaa)

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c. Recruitment status in Peru	<input type="checkbox"/> Without starting recruitment <input type="checkbox"/> In recruitment <input type="checkbox"/> Recruitment stopped <input type="checkbox"/> Closed recruitment
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3.2. Submission of publication in a scientific journal

to. Publication date:	
b. URL o DOI:	

3.3. Report resulting from the evaluation of the EC Data Monitoring Committee

a.	
b.	
c.	

3.4. Update of the Investigator's Manual

to. New version/Date:	
b. The update applies to other active ECs:	<input type="checkbox"/> And <input type="checkbox"/> NO

If yes, enter the requested information:

N°	N° EC INS	Protocol code	EC Title
1.			
2.			

4. 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.