	FORM	FOR-DIIS-053
	NOTIFICATION OF DEVIATIONS TO THE PROTOCOL	Edition No. 01

Instructions:

- *Dear User, remember that the application must be completed through the electronic form available in the Peruvian Registry of Clinical Trials (REPEC) at: http:// ensayosclinicos-repec.ins.gob.pe.*
- *The administrator is responsible for verifying that the data entered in this form is complete and accurate.*
- *If during the notification you do not have all the data, you must complete the information through the Actions/ Measures Report form. adopted.*
- *If the deviation affects several patients, you must submit one form per patient.*

Notification ☐	**Clarification/Ratification**

If you select "Notification", the System assigns the "Deviation Registration Code – INS": DESV-0000 **and the DG-DIIS secretary during the procedure For activation, enter the Registration Number (SITRADOC)**

INS Diversion Registration Code:	**Registration No. (SITRADOC):**

If you select "Clarification/Rectification", the System must automatically assign "Follow-up" **followed by the "Deviation Registration Code – INS": "Clarification/Rectification - DESV-0000" and the SITRADOC Registration Number of the Notification previously submitted to the INS.**

Clarification/Rectification:	**Registry No. (SITRADOC)**

1. NOTIFYING ENTITY

1.1. Sponsor

1.1.1 Name of the Clinical Trial Sponsor:

1.1.2. National ☐	**1.1.3. Foreigner** ☐

1.2. Legal representative of the sponsor in Peru *(if the sponsor is a foreigner):*

1.3. OIC *(with delegation of responsibilities for reporting deviations from the protocol)*

1.3.1. National ☐	**1.3.2. Name of the Contract Research Organization (CRO):**

2. GENERAL INFORMATION ABOUT THE CLINICAL TRIAL

2.1. EC INS No.:		**2.2. Protocol Code:**	
2.3. Version:		**2.4. Date:**	
2.5 Title of the clinical trial:			
2.6. Clinical Phase of the study:			

3. DEVIATION CODE (a)

0000-24(0)

Assigned by the sponsor to ensure traceability with the registration code assigned by the INS.

4. IDENTIFICATION OF THE RESEARCH INSTITUTION AND RESEARCH CENTER

4.1. Name of the Research Institution

4.2. Name of the Research Center

4.3. RCI No.:

4.4. Principal Investigator:

5. DEVIATIONS FROM THE PROTOCOL

5.1. Date of occurrence of the deviation:		**5.2. Date of taking knowledge by the IP:**	

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	NOTIFICATION OF DEVIATIONS TO THE PROTOCOL	Edition No. 01

5.3. Date of acknowledgment by the sponsor/OIC:		**5.4. Date of notification to the Ethics Committee:**	

5.5. Description of the deviation:

5.5.1. Clinical trial subject code: N/A. *If the deviation from the protocol does not or may not have an impact on the rights, safety of the subject in the trial and scientific value/ data integrity, "Not Applicable" must be indicated.*

5.5.2. Background related to the deviation:

5.5.3. Detailed description of the deviation:

5.5.4. Did the deviation result in a serious adverse event? Yeah ☐ No

5.5.5. If the answer is YES, indicate:

5.5.5.1. Date of notification of the EAS:	**5.5.5.2. EAS No. (According to REAS-Net):**

5.5.6. Is the subject continuing in the study? Yeah ☐ No

5.5.7. Explain the reasons why the subject continues or does not continue in the study:

5.5.8. Did the deviation result in a modification of the protocol? ☐ Yeah No ☐

6. IMPACT OF DEVIATIONS (NON-COMPLIANCE) WITH THE PROTOCOL	HAS	CAN HAVE
1. Informed Consent (IC) / Re-informed consent, for non-compliance with:		
1.1. Inform and take the IC before subjecting the subject to any clinical trial procedure.		
1.2. Inform and obtain re-consent in the event of new information and/or modifications to the clinical trial.		
1.3. Procedures for completing and filing the CI.		
2. Confidentiality, due to non-compliance with:		
2.1. Procedures for the protection and maintenance of the confidentiality of the subject's information and identity data in the clinical trial.		
3. Subject safety in the clinical trial, due to non-compliance with:		
3.1. Procedures or periodicity for the evaluation of selection criteria (Inclusion/Exclusion).		
3.2. Procedures to confirm a woman's fertility and/or to perform pregnancy tests on women of reproductive capacity during the screening period.		
3.3. Procedures to confirm the presence of disease or stage of disease during the screening period.		
3.4. Scheduling visits during the selection period.		
3.5. Procedures for permitted and/or disallowed treatment during the selection period.		
3.6. Randomization and treatment allocation procedures.		
3.7. Procedure for the washing period.		
3.8. Treatment regimen (Dose of the investigational product, route of administration, frequency of the dose(s) or interval between each dose.		
3.9. Laboratory analysis procedures, examinations, frequency of these, and subject evaluation prior to the administration of the clinical trial products during the treatment period.		
3.10. Procedures to ensure and verify that the subject complies with taking the clinical trial products during the treatment period.		
3.11. Procedures to ensure that the subject correctly follows instructions regarding not taking other treatments during the clinical trial treatment period.		
3.12. Administration of treatment to a subject who meets Inclusion/Exclusion criteria.		
3.13. Procedures for permitted and/or disallowed treatment during the treatment period.		
3.14. Procedure for concomitant treatment during the treatment period.		

	FORM	FOR-DIIS-053
	NOTIFICATION OF DEVIATIONS TO THE PROTOCOL	Edition No. 01

3.15. Scheduling visits during the treatment period.		
3.16. Scheduling visits during the follow-up period.		
3.17. Include if not included in the above:		
4. Scientific value / data integrity, due to non-compliance with:		
4.1. Procedures or periodicity for the evaluation of selection criteria (Inclusion/Exclusion)		
4.2. Procedures to confirm a woman's fertility and/or to perform a pregnancy test on a woman capable of conceiving during the screening period.		
4.3. Procedures to confirm the presence of disease and/or stage of disease during the screening period.		
4.4. Scheduling visits during the selection period.		
4.5. Procedures for permitted and/or disallowed treatment during the selection period.		
4.6. Randomization and treatment allocation procedures.		
4.7. Procedure for the washing period.		
4.8. Treatment regimen (Dose of the investigational product, route of administration, frequency of the dose(s) or interval between each dose.		
4.9. Administer treatment to a subject who meets Inclusion/Exclusion criteria.		
4.10. Laboratory analysis procedures, examinations, frequency of these, and subject evaluation prior to the administration of the clinical trial products during the treatment period.		
4.11. Procedures to ensure and verify that the subject complies with taking the clinical trial products during the treatment period.		
4.12. Procedures to ensure that the subject correctly follows instructions regarding not taking other treatments during the clinical trial treatment period.		
4.13. Procedures for permitted and/or disallowed treatment during the treatment period.		
4.14. Procedure for concomitant treatment during the treatment period.		
4.15. Scheduling visits during the treatment period.		
4.16. Scheduling visits during the follow-up period.		
4.17. Include if not included in the above:		
5. Research product, due to non-compliance with:		
5.1. Storage conditions		
5.1.1. Facilities, lighting, temperature and relative humidity suitable to ensure the maintenance of the conditions and characteristics of the products during the development of the clinical trial.		
5.2. Storage conditions		
5.2.1. Controlled room temperature (temperature and humidity according to the manufacturer's conditions)		
5.2.2. Special storage temperatures		
5.3. Procedures to ensure the cold chain of clinical trial products		
5.4. Import authorization conditions (labeling, quantity)		
6. Others:		
6.1. Failure to notify (EAS-REAS-SUSAR and Deviations to the protocol) within the regulatory period (No more than 7 calendar days from the Sponsor/OIC becoming aware of it (Art. 40 and Art. 110 REC))		

7. SEVERITY OF THE DEVIATION Critica o muy grave ☐ Mayor o grave ☐

8. CAUSE ANALYSIS

9. ACTIONS/MEASURES ADOPTED

9.1. Corrective Actions

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#	Description of the activity		Implementation		Follow-up
		Responsible	Start Date	Responsible End Date	Date of Follow-up
9.2. Preventive Actions					
#	Description of the activity		Implementation		Follow-up
		Responsible	Start Date	Responsible End Date	Date of Follow-up

10. LEGAL REPRESENTATIVE

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

Name and signature
Legal Representative

REPEC Notification Date: