	FORM	FOR-OGIT-047
	NOTIFICATION OF THE PREGNANT WOMAN AND THE NEWBORN BORN IN CLINICAL TRIALS	Edition No. 01

I. GENERAL INFORMATION OF THE CLINICAL TRIAL

Clinical trial title:

Sponsor:		**Company/Institution/Other Executor:**	
Clinical phase of the study		**Protocol code**	
		Test code Clinical (INS)	

II. REPORT IDENTIFICATION

Notification of the INS	(autogenerated)	**Notification of the Sponsor**	(autogenerated)

2.1. Type of Report of the Pregnant Woman

First Trimester	Second Trimester		third trimester		Part		

2.2. Type of Newborn Report

First Trimester of life of the Second trimester of the newborn life		of the newborn		First year of life	

III. PREGNANT INFORMATION

3.1 Information about the Pregnant Woman

Patient Identification Code		Age:
Sex:		Talla:
Occupation:		Weight:
Education Level:		
Continued in Clinical Trial **3.2 Obstetric History**	•No •Si	Justification:

3.2.1. Number of previous pregnancies and outcome

3.2.2. Previous pregnancy complications

3.2.3. Neonatal/fetal abnormalities previously and type

3.2.4. History of subfertility

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3.2.5. Medical history of the pregnant woman			
3.3 Pregnancy information			
3.3.1. Date of last menstruation period			
3.3.2. Gestational age when contacting the principal investigator (specify if it is based on ultrasound, HBCG blood tests, among others.			
3.3.3. Due date estimate	(dd/mm/aaaa)	3.3.4. Multiple pregnancy	•No •Yes, detail the number: _____
3.3.5. Treatment for infertility (specify) •No •Yes			
3.3.6. Illnesses during current pregnancy and other complications			
3.3.7. Prenatal Control (specify dates and results of ultrasound, blood tests, serological tests, clinical examination, among others)			
3.3.8. Consumption of tobacco, alcohol, among others. (specify frequency and quantity)			

IV. INFORMATION ON THE PRODUCT UNDER INVESTIGATION.

4.1 Description of the Product under investigation						
Name of Lot Number	Dose and Frequency and Administration			Duration of therapy	Therapy start date	Date of last feeding
4.2. The cecum opened due to pregnancy						
•No	•Yes, Blind opening date:					
4.3. Measurements taken with the research subject						

Medication therapy was given	Supportive therapy was given:
No action was taken	

4.4. This item applies **IF** the research subject is the pregnant woman (*):

Measurements taken with the	What is the type of measurement taken with the product in Investigational Product investigation?
•Suspended •Temporarily suspended	•It was definitively suspended
•It was not suspended	•Justification: _____ •Specify Other Measure(s) Taken: _____

V. Concomitant medication information

List the concomitant medications you were taking at the time of pregnancy diagnosis

Tradename	Dosage and concentration	Frequency and route	Duration of therapy	Therapy start date	Date of last feeding	Reason for prescription

SAW. FETAL INFORMATION IN CASE OF: SPONTANEOUS ABORTION AND DEATH LATE FETAL

Source of information:	Date of receipt of information:	Gestational age of pregnancy term:
Reasons for termination of pregnancy		
Results of physical examinations (gender, external abnormalities) and pathologies		
Birthdate:	Neonate sex:	Gestational age •F •M of the fetus:
Physical exam:		
Weight:	Head circumference:	Talla:
Clinical examination:		
Laboratory tests (anatomo-pathological):		

VII. Neonate information

Source of information:		Date of receipt of information
Pregnancy outcome (alive at birth, spontaneous abortion, late fetal death, ectopic pregnancy, molar pregnancy, etc.)		
Birthdate:	Neonate sex: •F •M	Gestational age at birth:
Premature: •No •Yes, specify age:		
Neonatal physical examination results including:		
Birth weight:	Head circumference:	Talla:
Malformations/anomalies diagnosed at birth: •No •Yes		
Conditions at birth (including 1-5 minute APGAR test, need for resuscitation, intensive care admissions)		
Neonatal illness, hospitalization and medications		
Developmental Evaluation (describe the pediatric controls in the reports in section 2.2)		

VIII. Infant information (Applies to reports for the first trimester, second trimester and first year of life)

Source of information:		Date of receipt of information
Birthdate:	Neonate sex: •F •M	Current age:
Premature: •No •Yes, specify age:		
Neonatal physical examination results including:		
Weight:	Talla:	
Malformations/anomalies diagnosed at the time: • No	• Yes	
Developmental Evaluation (describe pediatric controls according to the reports in section 2.2)		
Infant illness, hospitalizations, medications, breastfeeding		

IX. Research Center Source.

Research Center:			
Principal investigator (names and surnames)		**Telephone**	
Email			
Date of notification of the surrogate mother	**Dd/mm/aaaa**		
Legal representative of the sponsor or OIC (names and surnames)		**Job that performs**	
Address			
Email		**Telephone**	
Signature of the legal representative of the sponsor / OIC:			
INS notification date (autogenerated)			