	FORM	FOR-OGIT-046
	REPORTING SERIOUS ADVERSE EVENTS	Edition No. 02

I. INSTITUCION NOTIFICANTE					
II. GENERAL INFORMATION OF THE CLINICAL TRIAL					
Clinical Trial Title					
Sponsor(s)		**Company/Institution/Other, executor**			
Test Phase Protocol Code clinical					
		Clinical Trial Code (INS)			
II. IDENTIFICATION OF THE ADVERSE EVENT REPORT					
1. **INS** auto-generated notification **number .**		**2. Sponsor notification number**	autogenerated		
3. Type of report	○ Home ○ Initial/Final ○ Final Follow-up				
III. INFORMATION ABOUT THE PATIENT					
4. Patient identification code				**5. Age**	Years/months
6. Sex:	○ Female ○ Masculine	**7. Weight (Kg)**		**8. Size (cm)**	
IV. INFORMATION ABOUT THE SERIOUS ADVERSE EVENT					
9. Seriousness criteria: Check all that apply.		**10. Serious Adverse Event (Medical Diagnosis) Use MedDRA terminology.**		**11. The serious adverse event in relation to the Research Product is:**	
☐ Death ☐ It put the patient's life at risk ☐ Required hospitalization ☐ I prolong hospitalization ☐ Produced disability or permanent disability ☐ Produced congenital anomaly or malformation. ☐ Other: important medical event. To specify:_____				○ Expected ○ Unexpected	
12. EAS start date	dd/mm/aaaa	**13. EAS end date**	dd/mm/aaaa		
14. Detailed description of the EAS (with the data obtained to date):					

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15. Outcome of the EAS (as of the date of the report)			
◯ Completely recovered	Recovery date:		
◯ Recovered with sequel	Recovery date:	Specify sequel type:	
◯ Improved condition	◯ Deteriorated condition	◯ Condition still present and unchanged	
◯ Death	Death date:	Basic cause of death:	Autopsy: ◯ Yeah ◯ No
There is no information, explain why:			

16. Causality Assessment (relationship of the Serious Adverse Event with the investigational product)		
Serious Adverse Event	**Relationship According to Researcher** (breakdown)	**Relationship According to Sponsor** (breakdown)
	◯ Related ◯ Probable ◯ Possible ◯ Improbable ◯ Not related	◯ Related ◯ Probable ◯ Possible ◯ Improbable ◯ Not related

17. If the EAS is not related to the research product, indicate if it is associated with:	
◯ Study procedure ◯ Progression of underlying disease ◯ Another condition or illness.	◯ Other medication (Specify in Information on concomitant medication, Item 24) ◯ Another cause different from the previous ones:…….. ……

V. INFORMATION ON THE INVESTIGATIONAL PRODUCT.

18. List the product(s) under investigation. Indicate the product that the patient receives

Names) EAS? product in research from the	Code ATC	Number of lot	Dosage/ frequency cia	Way of adminis traction	Indication for use	Therapy start date	Date of last dose before EAS.	Duration of therapy in days.	Is he suspected of
									◯ AND ◯ NO
									◯ AND ◯ NO

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19. Due to the EAS, was the cecum opened by the EAS?		
◯ Yeah, Cecum opening date: dd/mm/yyyy Describe the rationale: …….. ……..	◯ No	◯ There is no information-

20. Measures taken with the research subject in relation to the EAS	
☐ Supportive therapy was given To specify:	☐ Medication therapy was given To specify:
☐ No action was taken	

21. Measurements taken with the investigational product	22. What is the type of measurement with the product under investigation?	23. Evolution of the case.
◯ It was suspended	◯ It was temporarily suspended	If there was temporary suspension, does the Serious Adverse Event reappear when the investigational product is administered again? ◯ Yeah ◯ No
	◯ It was permanently suspended	If there was permanent suspension, what happens with the Serious Adverse Event? ◯ EAS Improvement ◯ EAS Does not improve
◯ It was not suspended	◯ No change, continue ◯ Another measure taken To specify:_____	What happens to the research subject? ◯ Improvement due to tolerance ◯ Improvement by treatment

SAW. INFORMATION ON CONCOMITANT MEDICATION

24. List the concomitant medications you were taking on the date of the EAS, (Do not include medications used to treat the EAS)

Did you receive concomitant medication? ◯ Yeah ◯ No

Medicine then it came to pass in view of	Dosage, frequency cia	Via de admin ation	Lot Number	Indication for use	Date Of start	Final date	Duration of administration ation (days)	Mark if continued	Is he a suspect of EAS?
									◯ BUT ◯
									◯ BUT ◯

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VII. OTHER RELEVANT DATA FROM THE CLINICAL HISTORY

List relevant medical history, diagnoses or pre-existing medical conditions, for example: allergies, kidney or liver failure, etc.

25. Do you have any relevant medical history, diagnoses or pre-existing medical conditions?

◯ Yeah ◯ No

Illness/medical condition	Start date	End date (year)

VIII. LABORATORY EXAMS OR OTHER DIAGNOSTIC TESTS

List all laboratory examinations or other diagnostic tests performed to establish or rule out causality of SAE

26. Were laboratory tests or other diagnostic tests performed?

◯ Yeah ◯ No

Laboratory examination io or diagnostic test that	Date prior to occur company of EAS	Result Normal value range	Test results upon occurrence of EAS	EAS Occurrence Date	Are they related to the EAS?	Observations
					◯ But ◯	
					◯ But ◯	

(*) Fill out in case of laboratory exam

IX. EAS INFORMATION SOURCE

Research Center			
Principal Investigator (names and surnames)			
Telephone		Email	
Date of receipt of the EAS Report by the sponsor/OIC	(dd/mm/aaaa)		
Legal representative of the sponsor/OIC (names and surnames)		Job that performs	
Signature of the Legal Representative of the Sponsor/OIC			
Address		Email	
Telephone			
INS Notification Date: dd/mm/yyyy			