	FORM	FOR-OGIT-056
	NATIONAL FINAL REPORT	Edition No. 01

INSTRUCTIONS FOR FILLING OUT THE FOR-OGITT-056. Edition N° 01 NATIONAL FINAL REPORT

A. GENERAL CONSIDERATIONS

1. The form must be filled out in its electronic version available in the Peruvian Registry of Clinical Trials - REPEC. Then it must be printed, signed and presented at the INS Documentary Processing Office.
2. To access REPEC, the sponsor or their authorized legal representative in the country must be previously registered and must have a user account and password.
3. Once the information is entered, REPEC automatically assigns a report identification code: INF-XXX 4. The administrator is responsible for making sure that the data provided in this form is complete and true 5. The Final National Report must be submitted within sixty (60) calendar days following the date of submission of the final report from the last research center.
6. In the case of clinical trials carried out only in Peru, in addition to the data on this form, the final national report includes the results and conclusions of the study. The maximum period of presentation of the results of the study is six (6) months after the end of the clinical trial. The guidelines for the presentation, structure and content of the information to be presented are indicated in *Annex 02 of the Clinical Trial Procedures Manual: Guide for reporting the results and conclusions of the clinical trial.*

B. FILLING OUT THE FORM

1. NOTIFIING INSTITUTION: 1.1.

Institution Name: Field generated automatically when entering the form, based on the recognition of the user account and password that was assigned to the institution.

1.2. Legal Representative: The person with current power of legal representative of the institution that sends the Final Report of the research center must be identified, as well as their contact information:

- a. Names, Paternal Surname and Maternal Surname: Enter as it appears on the identity document
- b. Identity Document: (Number)
- c. Telephone: Enter institutional contact information, not personal.
- d. Email: Enter institutional contact information, not personal.

It is up to this person to sign the form for submission to the OGITT of the INS.


2. IDENTIFICATION OF THE CLINICAL TRIAL

Fields 2.1 to 2.7 are generated automatically during the electronic registration in REPEC based on the clinical trial that the administrator selects to report.

2.1. EC INS No.

2.2. Title of the clinical trial

2.3. Sponsor

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2.4. Institution that legally represents the sponsor in the country 2.5. Clinical phase of the study 2.6. Protocol Code 2.7. Report date:

Corresponds to the date the electronic form is completed

(It is automatically generated by REPEC).

2.8. Final situation in the country: Inform how the study concluded in the country. select one of the following conditions: a.

The development of the protocol was fulfilled

b. Cancellation of the EC (definitive interruption of activities, early or premature termination). Selecting this option implies that the clinical trial cancellation process is submitted (article 81 of the REC).

2.9. Start date of selection activities in the country

It corresponds to the date of the first act of selection of a possible subject for the study, in Peru. The first act of selection corresponds to the date of initial contact with a potential research subject, unless another definition is expressly and clearly stated in the clinical trial protocol submitted to the OGITT.

Enter date in mm/dd/yyyy.

If no selection activity was carried out in Peru, select **Does not apply**.

2.10. Enrollment date of the first research subject in the country: Generated automatically if the registration was previously made in REPEC. If the registration has not been made, enter the corresponding date in mm/dd/yyyy.

If no research subject was enrolled in Peru, select **Does not apply**.

2.11. End date of enrollment in the country: Generated automatically if the registration in REPEC has been previously carried out. If the registration has not been made, select the corresponding date.

If it does not apply, select **Does not apply**.

2.12. Date of last visit of the last research subject in the country: Enter date not dd/mm/yy.

If no research subject was enrolled in Peru, select **Does not apply**.


3. FINAL INFORMATION ON THE CLINICAL TRIAL

3.1. Information regarding the research subjects:

Complete with respect to the number of **subjects participating in Peru**.

a. Screened subjects: These are the subjects who were invited to participate in the CT, signed the informed consent and underwent a series of tests and/or visits to determine if they met the selection criteria and were not necessarily enrolled. Enter the total number.

b. Enrolled subjects: Screened research subjects who met the selection criteria indicated in the protocol and were finally included in the study. The following must be recorded: - Total number of subjects enrolled - Number according to sex

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- Maximum age: record the completed years (or months if applicable) of the oldest research subject enrolled. (Age at the time of enrollment is considered).

- Minimum age: record the completed years (or months if applicable) of the youngest research subject enrolled. (Age at the time of enrollment is considered)

c. Number of subjects that failed in the selection (*screen failure*): This number is deductible from the subtraction between the subjects that were screened and the enrolled subjects.

It should be noted that: + =

For this block (**a, b and c**), enter the information in the following order:

1st. Number of women and number of men enrolled



The number of subjects enrolled (**b**) will appear by default

2nd. Number of subjects that fail in the selection (**c**)



The number of subjects screened (**a**) will appear by default

Complete the data regarding minimum age and maximum age.


3.1. Información en relación a los sujetos de investigación			
a. N° sujetos tamizados	55	b. N° de sujetos enrolados	50
		N° de Mujeres:	25
		N° de Hombres:	25
		Edad Mínima:	18
		Edad Máxima:	50
		c. N° sujetos que fallaron en la selección (screen failure):	5

d. Number of subjects who completed the study: Indicate the number of subjects who have completed the study, complying with all scheduled visits.

and. No. of subjects who completed treatment: subjects who completed the treatment period according to the protocol.

F. Number of subjects who withdrew/withdrew from the study: Indicate the number of enrolled subjects who did not complete the study, and must also specify the reason for withdrawal and abandonment: - Due to withdrawal of the subject's consent: Indicate number.

- By decision of the investigator and/or sponsor: Indicate number and criteria considered (brief description) for example: Low Efficacy, adverse event, due to non-compliance with the protocol.

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- Other duly specified cause: Indicate number and criteria considered (brief description)

3.2. Information related to the monitoring of the CE by the sponsor

In this section, you must report the number of monitoring activities carried out since the beginning of the CT for each authorized research center. You must record:

- Number of activities carried out
- Method: Select if the monitoring was:
 - o At a research center (face-to-face, visit to the research center) o Centralized (remote monitoring)

REPEC will display the list of authorized research centers. If no activity has been carried out, complete with 0 (Zero) in the box corresponding to the research center.


3.2. Información relacionada a la monitorización del EC por parte del patrocinador Informe respecto de las actividades ejecutadas desde el inicio del EC			
	Centro de Investigación	Monitoreo en el centro (N°)	Monitoreo centralizado (N°)
N° de actividades de monitoreo ejecutadas según centro de investigación	RCI 1115 - Centro Médico Monte Carmelo	<input type="text"/>	<input type="text"/>
	RCI 58 - DEPARTAMENTO DE INVESTIGACIÓN	<input type="text"/>	<input type="text"/>
	RCI 73 - Servicio de Oncología Médica	<input type="text"/>	<input type="text"/>
	RCI 163 - CENTRO DE INVESTIGACION DEL INSTITUTO REGIONAL DE ENFERMEDADES NEOPLASICAS DEL NORTE - IREN NORTE	<input type="text"/>	<input type="text"/>
	RCI 1205 - Centro Especializado de Enfermedades Neoplásicas SRL - CEEN SRL	<input type="text"/>	<input type="text"/>

3.3. Information related to the investigational product used (including the comparators)

Report for the product under investigation, including the comparator(s), the following:

Product under investigation: Identify the product. For pharmaceutical products, enter Name, pharmaceutical form and concentration.

- a. Total amount received at the research centers
- b. Amount of product administered: amount used by the country's research subjects.
- c. Quantity of Product Returned to Sponsor: Enter information if product has been returned to the country of origin (or to a sponsor located outside the country).
- d. Quantity of destroyed product: Quantity of research product destroyed in Peru. Destruction is the responsibility of the sponsor and requires prior authorization, see article 96 of the Clinical Trials Regulations.
- and. Other destination: Enter information in the event that a quantity of the product under investigation received in the country has had another destination. Identify: - Product under investigation - Quantity - Specify destination

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To enter the information requested for the investigational product (including comparators), select [Add Information Related to the Investigational Product](#) and complete the information requested in the pop-up window, then select **Save** and **Close**.

By default, the system will post the quantities entered and fill in the field **Total quantity received at the centers (a)**

Información relacionada al producto en investigación utilizado (Incluyendo los comparadores)

Agregar información relacionada al producto en investigación utilizado (Incluyendo los comparadores)

Producto en investigación

Nombre del Producto en investigación (incluye comparador)

Forma farmacéutica

Concentración:

a. Cantidad total recibida en los centros de investigación

b. Cantidad del producto administrado

c. Cantidad del producto devuelto al patrocinador

d. Cantidad del producto destruido

e. Otro destino, según el artículo 97° del REC

- Cantidad:

- Especifique destino:

It should be noted that + +
+ =

can modify





or delete




the information entered

3.3. Información relacionada al producto en investigación utilizado (Incluyendo los comparadores)

Agregar información relacionada al producto en investigación

Producto en Investigación			a. Cantidad total recibida en los centros de investigación	b. Cantidad del producto administrado	c. Cantidad del producto devuelto al patrocinador	d. Cantidad del producto destruido	e. Otro destino según el artículo 97° del REC		Opciones
Nombre	Forma farmacéutica	Concentración					Cantidad	Especifique destino	
AAAA	tabletas	100 mg	670	550	120	0	0		 

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3.4. Information related to post-study access: Report regarding the actions planned for post-study access, if applicable.

4. DEVIATIONS FROM THE PROTOCOL

4.1. CRITICAL OR VERY SERIOUS DEVIATIONS

4.2. MAJOR OR SERIOUS DEVIATIONS

The list for both numerals is automatically generated since these deviations are notified to REPEC through *FOR-OGITT-053: Notification of clinical trial deviations*.

REPEC will display the list of all notifications made for the clinical trial.

4.3. MINOR OR SLIGHT DEVIATIONS: REPEC will show the list of all the Notifications made for the clinical trial.

5. SUMMARY OF SERIOUS ADVERSE EVENTS:

The list of serious adverse events is generated automatically based on the notifications made through *FOR-OGITT-046: Serious Adverse Events Report* available in the Serious Adverse Events Reporting System - REAS-NET.

6. SUMMARY OF NON-SERIOUS ADVERSE EVENTS RELATED TO THE INVESTIGATIONAL PRODUCT The data on reported non-serious adverse events are automatically generated based on information previously recorded in REPEC.

7. ADDITIONAL COMMENTS OR OBSERVATIONS:

Any additional information that is considered important for the purposes of the National Final Report, that has not been requested in this form, can be entered in this section.

8. REGARDING THE RESULTS AND CONCLUSIONS OF THE CLINICAL TRIAL


First of all, it is necessary to identify if the CE is executed only in the country, for this, select as appropriate:

- The EC is multinational**
- The EC runs only in Peru**

In the case of CE executed only in Peru: _____

Attach to the printed form, the final results and the conclusions of the EC. A guide regarding the structure and content to present them is available in **Annex 02 of the Manual of Clinical Trial Procedures: *Guide for the Report of results and conclusions of the clinical trial***.

- If at the time of submitting the **FOR-OGITT-056: Final national report** the results and conclusions of the study will be attached, select the option:

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Results and conclusions are presented

If, on the date of submission of **FOR-OGITT-056: Final national report**, the results and conclusions of the clinical trial are not yet available, select and complete:

Shipping pending

Estimated shipping date:/...../..... (dd/mm/yyyy)

The maximum period for sending the results and conclusions is six (6) months after the end of the EC.

9. AUTHORIZED LEGAL REPRESENTATIVE

Corresponds to the section for the signature and date of signature of the legal representative of the Institution that presents the Report on behalf of the Sponsor, according to the data registered in section 1.