	<b>FORM</b>	<b>FOR-OGITT-055</b>
	<b>FINAL REPORT OF THE RESEARCH CENTER</b>	<b>Edition No. 01</b>

## INSTRUCTIONS FOR FILLING OUT THE FOR-OGITT-055. Edition No. 01 FINAL REPORT OF THE RESEARCH CENTER

### 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. This report must be submitted within thirty (30) calendar days following the visit closing performed by the monitor.
3. To access REPEC, the sponsor or its authorized legal representative in the country must be previously registered and must have a user account and password.
4. The administrator is responsible for making sure that the information provided in this form is complete and true
5. Once the information has been entered in the form, REPEC automatically assigns a code  
Report ID: INF-XXX

### B. COMPLETING THE FORM

#### 1. NOTIFYING INSTITUTION: 1.1.

**Name of the Institution:** 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 attorney of legal representative of the institution that sends the Final Report of the research center must be identified, as well as their contact information:

to. 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.

This person is responsible for signing the form for submission to the INS OGITT.

#### 2. IDENTIFICATION OF THE CLINICAL TRIAL AND RESEARCH CENTER REASON FOR REPORT

Fields 2.1 to 2.6 are generated automatically during the electronic registration in REPEC based on the clinical trial that the administrator selects to inform.

**2.1. EC N° INS**

**2.2. Clinical trial title**

**2.3. Sponsor**


**2.4. Institution that legally represents the sponsor in the country**

**2.5. Clinical phase of the**

**study 2.6. Protocol Code 2.7.**

**Research Center:** Select from the available list of authorized centers for the clinical trial.

**2.8. Principal Investigator:** This information is generated automatically after selecting the investigation center for the report.

	<b>FORM</b>	<b>FOR-OGITT-055</b>
	<b>FINAL REPORT OF THE RESEARCH CENTER</b>	<b>Edition No. 01</b>

**2.9. Date of the report:** Corresponds to the date on which the electronic form is completed. (it is automatically generated by REPEC).

**2.10. Final situation in the research center:** It is necessary to report how the study concluded in the research center: Select one of the following conditions:

- to. The development of the protocol was fulfilled
- b. Early cancellation of study activities: Selecting this option implies submitting the procedure for Closing the research center for a clinical trial (article 82 of the REC).

**2.11. Start date of selection activities in the research center**

It corresponds to the date of the first act of selection of a possible subject for the study, in the research center. 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 dd/mm/yyyy.

If the center did not carry out any selection activity, select **Does not apply**.

**2.12. Date of the last visit of the last research subject corresponding to the center:**

Enter date in dd/mm/yy

If no research subject was enrolled, select **Not Applicable**.

**2.13. Date of the closing visit made by the monitor:** Enter date in dd/mm/yy

If not applicable, select **Does not apply**.

**3. FINAL INFORMATION FROM THE RESEARCH CENTER**

**3.1. Information in relation to the research subjects**

The information to be included in this section must correspond to the cumulative number of subjects from the start of the study to its completion at the research center.


to. **Screened subjects:** These are the subjects who were invited to participate in the CT, signed 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 outlined in the protocol and were eventually included in the study.

study. It must be recorded:

- Total number of subjects enrolled
- Number according to sex
- 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 who failed the selection (screen failure):** This number is deductible from the subtraction between the subjects who were screened and the subjects enrolled.

	<b>FORM</b>	<b>FOR-OGITT-055</b>
	<b>FINAL REPORT OF THE RESEARCH CENTER</b>	<b>Edition No. 01</b>

It should be noted that: + =

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

1st. N° of women and N° of men enrolled



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

2nd. Number of subjects who fail the selection (c)



The N° of screened subjects (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. **Number of subjects who completed treatment**: subjects who completed the treatment period according to the protocol.

F. Number of **subjects who withdrew/abandoned 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 the number and criteria considered (brief description), for example: Low Efficacy, adverse event, due to non-compliance with the protocol.
- Other cause duly specified: Indicate number and criterion considered (brief description)

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

Inform for the investigational product including the comparator(s), the following:

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

to. Total amount received at the center

	<b>FORM</b>	<b>FOR-OGITT-055</b>
	<b>FINAL REPORT OF THE RESEARCH CENTER</b>	<b>Edition No. 01</b>

- b. Amount of product administered: amount used by the research subjects of the research center
- c. Quantity of the product returned to the sponsor: corresponds to the product returned by the research center to the sponsor.
- d. Quantity of product destroyed: Includes the product destroyed in the research institution. Destruction is the responsibility of the sponsor and requires prior authorization, see article 96 of the Clinical Trials Regulation.
- and. Other destination: Enter information if a quantity of the investigational product received at the center has had another destination. Identify: - Product under investigation - Quantity - Specify destination

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**.



### Información relacionada al producto en investigación

**Agregar información relacionada al producto en investigación**

**Producto en investigación**

<b>Nombre del Producto en investigación</b>	<input style="width: 90%;" type="text"/>
<b>Forma farmacéutica</b>	<input style="width: 90%;" type="text"/>
<b>Concentración:</b>	<input style="width: 90%;" type="text"/>
<b>a. Cantidad total recibida en el centro</b>	<input style="width: 90%;" type="text"/>
<b>b. Cantidad del producto administrado</b>	<input style="width: 90%;" type="text"/>
<b>c. Cantidad del producto devuelto al patrocinador</b>	<input style="width: 90%;" type="text"/>
<b>d. Cantidad del producto destruido</b>	<input style="width: 90%;" type="text"/>
<b>e. Otro destino, según el artículo 97° del REC</b>	
- Cantidad:	<input style="width: 90%;" type="text"/>
- Especifique destino:	<input style="width: 90%;" type="text"/>

It should be noted that + + + =

By default, the system will post the amounts entered and fill in the field **Total amount received at the center (a)**


can modify



or remove the





entered information

	<b>FORM</b>	<b>FOR-OGITT-055</b>
	<b>FINAL REPORT OF THE RESEARCH CENTER</b>	Edition No. 01

### 3.2. 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 el centro	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	100mg	665	650	15	0	0		 

## 4. DEVIATIONS TO THE PROTOCOL (NEW CASES SINCE THE LAST REPORT OF ADVANCE)

### 4.1. CRITICAL OR VERY SERIOUS DEVIATIONS

### 4.2. MAJOR OR SERIOUS DEVIATIONS:

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


The notifications that will appear will be those that were made after the reporting period of the last progress report of the research center).

### 4.3. MINOR OR MINOR DEVIATIONS: The following information must be entered:

- Date of knowledge by the sponsor / OIC (dd/mm/yyyy)
- Identification code of the research subject
- Summary description of the deviation
- Measure adopted: brief description.
- Date of notification to the ethics committee (dd/mm/yyyy)

Only enter new cases that occurred after the reporting period of the last progress report of the research center). For example: If the last Progress Report presented for this center corresponded to the period 06/06/2017 to 12/06/2017, report the minor deviations that had been presented from 12/07/2017 to the date of this report. final.

To enter each minor or minor deviation to be reported, select [Add Minor or Minor Deviations](#) and complete the information requested in the pop-up window, then select **Save** and **Close**.

	<b>FORM</b>	FOR-OGITT-055
	<b>FINAL REPORT OF THE RESEARCH CENTER</b>	Edition No. 01

### Desviaciones menores o leves

**Agregar datos de la desviación**

<b>Fecha de conocimiento por el patrocinador / OIC (dd/mm/aaaa):</b>	<input type="text"/> ...
<b>Código de identificación del sujeto de investigación</b>	<input type="text"/>
<b>Descripción resumida de la desviación</b>	<input style="width: 100%; height: 40px;" type="text"/>
<b>Medida adoptada</b>	<input style="width: 100%; height: 40px;" type="text"/>
<b>Fecha de notificación al comité de ética (dd/mm/aaaa)</b>	<input type="text"/> ...

can modify



or remove the



notification entered

If the deviation is not related to a research subject, enter **NOT APPLICABLE** in the **Research Subject Identification Code** field.

#### 5. SUMMARY OF SERIOUS ADVERSE EVENTS (NEW CASES SINCE LAST PROGRESS REPORT)


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

The notifications that will appear will be those that were made after the reporting period of the last progress report of the research center.

#### 6. SUMMARY OF NON-SERIOUS ADVERSE EVENTS RELATED TO THE PRODUCT UNDER INVESTIGATION (NEW CASES SINCE LAST PROGRESS REPORT)

The following information must be entered, if non-serious adverse events related to the product under investigation have occurred:

- Identification code of the research subject
- Adverse event
- Start date (dd/mm/yy)
- Action taken: Summary description
- Outcome of the adverse event: summary description

	<b>FORM</b>	<b>FOR-OGITT-055</b>
	<b>FINAL REPORT OF THE RESEARCH CENTER</b>	Edition No. 01

Only report new cases that occurred after the reporting period of the last progress report of the research center. For example: If the last Progress Report presented for this center corresponded to the period 06/06/2017 to 12/06/2017, report the adverse events that had occurred from 12/07/2017 to the date of this report final.

To enter each related non-serious adverse event report, select [Add Non-Serious Adverse Event](#) and fill in the information requested in the pop-up window, then select **Save** and **Close**.



#### 7. ADDITIONAL COMMENTS OR OBSERVATIONS:

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

#### 8. AUTHORIZED LEGAL REPRESENTATIVE

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