	FORM	FOR-OGIT-054
	CLINICAL TRIAL PROGRESS REPORT	Edition No. 01

INSTRUCTIONS FOR FILLING OUT THE FOR-OGITT-054. Edition No. 01 CLINICAL TRIAL PROGRESS 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 Document Processing Office.
2. 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.
3. The administrator is responsible for ensuring that the data provided in this form is **complete and truthful**.
4. Once the information is entered in the form, REPEC automatically assigns a report identification code: INF-XXX
5. These reports must be sent by the sponsor or its legal representative in the country on a **quarterly or semiannual basis**, counting from **the date of authorization of the clinical trial in Peru**. The maximum submission period is **up to seven (07) calendar days after the end of the** quarterly or semiannual period.
6. The report is sent **to each of the authorized research centers**, regardless of their **enrollment status**.

B. FILLING OUT THE FORM

1. NOTIFYING 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 Progress 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 INS OGITT.

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

Fields **2.1 to 2.6** are generated automatically during electronic registration in the REPEC based on the clinical trial (CT) that the administrator selects to report.


2.1. N° EC 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

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2.6. Protocol Code 2.7. Periodicity

of Progress Report: Select periodicity in the presentation of the Progress Report, based on what is established in the Authorization Resolution of the EC.

2.8. Research center: Select from the available list of centers authorized for the clinical trial.

2.9. Principal Investigator: This information is generated automatically after selecting the research center for the report.

2.10. Report date: Corresponds to the date on which the electronic form is completed.
(It is generated automatically by REPEC)

2.11. Report No. for the center: Corresponds to the correlative number of the report presented for the research center. This information is generated automatically by REPEC.

2.12. Reporting period: Corresponds to the time period to which the information included in this report corresponds. The start and end dates must cover a time period of 03 months or 06 months, according to what was selected in item 2.7.

3. PROGRESS IN THE RESEARCH CENTER**3.1. Clinical trial execution status.**

to. **Selection:** Period also called *screening* or screening. Select *YES* when selection or selection activities have begun in the research center.
evaluation of potential research subjects for possible inclusion in the study. Must include:


- Start date: Corresponds to the date of the first act of selection of a possible subject for the study, at 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.
- End date: the date on which the selection activities were concluded. If as of the date of the report, these have not been completed, leave them blank and select *Continue as of date*.

b. **Enrollment:** Select *YES* when the research center has enrolled research subjects. Enrolled research subjects are those who meet the selection criteria indicated in the protocol. Must include:

- Start date: Date on which the first research subject is enrolled in center.
- End date: Corresponds to the date on which the last subject was enrolled in the research center. If selection activities continue as of the report date, leave blank and select *Continues as of date*.

c. **Treatment:** Select *YES* when the treatment or administration period of the investigational product has begun in the research center. Must include:

- Start date: Date on which the product is administered for the first time in research to a research subject.
- End date corresponds to the date on which the investigational product was last administered to a research subject. If treatment continues as of the report date, leave blank and select *Continued as of date*.

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- d. **Follow-up:** Select YES when the research center has started the follow-up period for at least one of the enrolled research subjects, after the completion of treatment with the investigational product. Indicate start and end date. If the tracking period continues as of the report date, leave blank and select Continues as of date.

For example:

3.1. Estado de Ejecución del ensayo clínico			
a. Selección (Screening):	<input checked="" type="radio"/> Si <input type="radio"/> No	Fecha de inicio: 01/02/2018 ...	Fecha de término: ... (*) Continúa a la fecha <input checked="" type="checkbox"/> (*) Si a la fecha del Informe, la selección no han finalizado, dejar en blanco y seleccionar <i>Continúa a la fecha</i>
b. Enrolamiento:	<input checked="" type="radio"/> Si <input type="radio"/> No	Fecha de inicio: 05/03/2018 ...	Fecha de término: ... (*) Continúa a la fecha <input checked="" type="checkbox"/> (*) Si a la fecha del Informe, el enrolamiento no han finalizado, dejar en blanco y seleccionar <i>Continúa a la fecha</i>
c. Tratamiento:	<input type="radio"/> Si <input checked="" type="radio"/> No	Fecha de inicio:	Fecha de término: ... (*) Continúa a la fecha <input type="checkbox"/> (*) Si a la fecha del Informe, el tratamiento no han finalizado, dejar en blanco y seleccionar <i>Continúa a la fecha</i>
d. Seguimiento:	<input type="radio"/> Si <input checked="" type="radio"/> No	Fecha de inicio: 25/02/2018 ...	Fecha de término: ... (*) Continúa a la fecha <input type="checkbox"/> (*) Si a la fecha del Informe, el seguimiento no han finalizado, dejar en blanco y seleccionar <i>Continúa a la fecha</i>

3.2. Information regarding research subjects


The information to be included in this section must correspond to the accumulated number of subjects from the beginning of the study at the research center until the final date considered in item 2.12 Reporting period.

to. Screened subjects: These are the subjects invited to participate in the CT who signed the Informed Consent and underwent a series of analyzes and/or visits to determine if they meet the selection criteria and who will not necessarily be enrolled. Enter the total number.

b. Enrolled subjects: Screened research subjects who meet the selection criteria indicated in the protocol and are finally included in the study. It must be recorded:

- Total number of subjects enrolled
- Number according to sex
- Minimum age: record the years of age of the youngest research subject enrolled to date. If applicable, the number of months completed will be included instead (Example: EC with the participation of infants and preschoolers). The age at the time of enrollment must be considered.
- Maximum age: record the years (or months if applicable) of the oldest research subject enrolled to date. The age at the time of enrollment must be considered.

c. Number of subjects who fail selection (*screen failure*): This number is deductible from the subtraction between the screened subjects and the enrolled subjects.

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It should be noted that: + =

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

1st. No. of women and No. of men enrolled



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

2nd. No. of subjects who fail in the selection (c)



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

Complete the data regarding minimum age and maximum age.

3.2. Información en relación a los sujetos de investigación			
a. N° sujetos tamizados	8	b. N° de sujetos enrolados	6
		N° de Mujeres:	02
		N° de Hombres:	04
		Edad Mínima:	45
		Edad Máxima:	58
		c. N° sujetos que fallan en la selección (screen failure):	2

d. No. of subjects continuing in the study: Indicate the number of subjects enrolled who are participating in the clinical trial to date.

and. No. of subjects under treatment: Indicate the number of subjects receiving treatment with the investigational product.

F. No. of subjects in follow-up without treatment: Indicate the number of subjects who are during the follow-up period of the study and who no longer receive the investigational product.

For this block (d, e and f) enter the information in the following order:


1st. No. of subjects in treatment (e)



The number of subjects continuing in the study (d) will appear by default

2nd. No. of subjects in follow-up without treatment (f)

d. N° sujetos que continúan en el estudio:	4	e. N° sujetos en tratamiento:	3
		f. N° sujetos en seguimiento sin tratamiento:	1

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g. Number of subjects who withdrew/abandoned the study: Indicate the total number of enrolled subjects who did not complete the study, and must also specify the reason for withdrawal and

- abandonment: - Due to withdrawal of subject consent: Indicate number of subjects.
 - By decision of the researcher and/or sponsor: Indicate number of subjects and criteria considered (brief description), such as: Low Efficacy, adverse event, due to non-compliance with the protocol.
 - Another duly specified cause: Indicate number of subjects and criterion considered (brief description)

g. N° sujetos que se retiran / abandonan el estudio:	2	Por retiro de consentimiento:	2
	Motivo:	Por decisión del investigador y/o patrocinador:	0
		Otra causa:	0
		Especificar:	
		Especificar:	

h. No. of Subjects who completed the study: Indicate the number of subjects who have completed the study, complying with all scheduled visits.

Yo. Number of subjects missing to enroll: Indicate number of subjects missing to enroll as previously estimated. For example, if it was estimated that the center would enroll 10 research subjects, and if at the time of the progress report it has only enrolled 6, the subjects that remain to be enrolled would be 4 for the center in question.

It should be taken into account that: () + () + () = ()

No. of subjects continuing in the study (d) + No. of subjects who withdrew/abandoned the study (g) + No. of Subjects who completed the study (h)
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= Number of subjects enrolled (b)

3.3. Information related to the monitoring of the EC by the sponsor during the reporting period

In this section you must report the number of monitoring activities executed in the research center during the period included in this Report (section 2.12).

Likewise, report for each recorded activity:

- Execution date: start date of the activity
- Method: Select if the monitoring was:
 - o At the research center (in person, visit to the research center)
 - o Centralized (remote monitoring)

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If during the reporting period (section 2.12) no monitoring activities have been carried out, mark **No activity**. By default, the **No. of monitoring activities executed** box will show 0 (Zero)

3.3. Información relacionada a la monitorización del EC por parte del patrocinador durante el periodo de informe

N° de actividades de monitoreo ejecutadas Ninguna actividad

[Agregar Actividades de monitoreo ejecutadas](#)

To enter each monitoring activity that was executed during the reporting period, select **Add Executed Monitoring Activities** and complete the information requested in the pop-up window, then select **Save** and **Close**.

Actividades de monitoreo

Agregar datos para actividad de monitoreo

Fechas de ejecución

Fecha: ...

Método :

En el centro de investigación

Centralizado



By default, the system will count the activities entered and complete the field **No. of monitoring activities executed**


You can modify  or delete the  activity entered

3.3. Información relacionada a la monitorización del EC por parte del patrocinador durante el periodo de informe

N° de actividades de monitoreo ejecutadas Ninguna actividad

[Agregar Actividades de monitoreo ejecutadas](#)

N° Actividad	Fechas de ejecución		Opciones
	Fecha	Método:	
1.	30/05/2018	<input checked="" type="radio"/> En el centro de investigación <input type="radio"/> Centralizado	 

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4. DEVIATIONS TO THE PROTOCOL OCCURRED DURING THE REPORTING PERIOD:

4.1. CRITICAL OR VERY SERIOUS DEVIATIONS

4.2. MAJOR OR SERIOUS DEVIATIONS

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

The notifications that will appear will be those that were made during the report reporting period (section 2.12), through the form available in REPEC.

4.3. MINOR OR MINOR DEVIATIONS: The following information must be entered, for each deviation that occurred during the reporting period (section 2.12)

- Date of knowledge by the sponsor / OIC (dd/mm/aaaa)
- 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)

To enter each minor or slight 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**.

Desviaciones menores o leves

Agregar datos de la desviación

Fecha de conocimiento por el patrocinador / OIC (dd/mm/aaaa):	<input style="width: 80%;" type="text"/> ...
Código de identificación del sujeto de investigación	<input style="width: 80%;" type="text"/>
Descripción resumida de la desviación	<div style="border: 1px solid #ccc; height: 40px;"></div>
Medida adoptada	<div style="border: 1px solid #ccc; height: 40px;"></div>
Fecha de notificación al comité de ética (dd/mm/aaaa)	<input style="width: 80%;" type="text"/> ...

You can modify




or delete the



notification entered

Remember that information must be entered for each deviation to be reported.

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

5. SUMMARY OF SERIOUS ADVERSE EVENTS REPORTED DURING THE PERIOD OF REPORT

The list of serious adverse events is generated automatically based on the notifications made through 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 during the reporting period of the report (section 2.12).

6. SUMMARY OF NON-SERIOUS ADVERSE EVENTS RELATED TO THE PRODUCT UNDER INVESTIGATION OCCURRING DURING THE REPORTING PERIOD.

The following information must be entered for each non-serious adverse event related to _____ occurred during the reporting period (section 2.12)


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

To enter each notification of a related non-serious adverse event, select [Add Non-Serious Adverse Events](#) and complete the information requested in the pop-up window, then select **Record** and **Close**.

Eventos Adversos No Serios

Agregar datos del evento adverso no serio

Código de identificación del sujeto	<input type="text"/>
Evento adverso	<input style="width: 100%; height: 40px;" type="text"/>
Fecha de inicio (dd/mm/aa)	<input type="text"/> <input type="button" value="..."/>
Acción tomada	<input style="width: 100%; height: 40px;" type="text"/>
Desenlace del evento	<input style="width: 100%; height: 40px;" type="text"/>

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7. ADDITIONAL COMMENTS OR OBSERVATIONS:

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

8. AUTHORIZED LEGAL REPRESENTATIVE

It 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 recorded in section 1.