	FORM	FOR-OGIT-033
	LIST OF PRODUCTS AND SUPPLIES TO IMPORT IN THE CLINICAL TRIAL	Edition No. 03

I. REPRESENTATIVE OF THE SPONSOR OR OIC

RUC:	Business name:
Legal Domicile:	

1.1. DATA OF THE LEGAL REPRESENTATIVE OR ATTORNEY

Surnames:	Names:
DNI / CE / PAS:	Cargo:
Power registered in SUNARP: *(Electronic Item No.)*	Telephone and annex:
Email:	

II. GENERAL INFORMATION OF THE CLINICAL TRIAL

Clinical trial title:		
Sponsor:		
Clinical Phase of the study: I • II • III• IV • Post-study	Protocol code:	Clinical trial code (INS):

III. RESEARCH CENTERS WHERE RESEARCH PRODUCTS AND SUPPLIES WILL BE USED

N°	Name	Product quantity in investigation (*)	Number of patients involved (*)

Only Research Centers that have been previously authorized by INS should be entered.
(*) The data will be completed when the clinical trial is running or being developed.

IV. PRODUCTS UNDER INVESTIGATION (Include placebo and/or active comparator)

• Authorization of the clinical trial *Attach quality documentation according to ANNEX 5 of the REC*	
• Modification of the List	***a) Change of batch number:*** *Certificates of analysis and labeling project* ***b) Change of manufacturer or country:*** *Certificates of analysis, labeling project and GMP certificate*

• Expansion of the List

N°	Name of Product or Corresponding code	Active Pharmaceutical Ingredient Name (API)	pharmaceutical form and route of administration	Concentration	Name of Manufacturer and country	Amount	Batch number o Coding system*

**If you consider the coding system, it is essential to mention the respective description here:*

Form approved by RD No. 303 - 2021 - OGITT/INS Date: 07/26/2021

If any of the products under investigation have authorization for use in research on human beings in other countries with high health surveillance (USA, European Community, Japan, Canada, Australia, etc.), indicate:

N°	Name or Code	Country	Form Pharmaceutical and route of administration	Concentration	Authorization number	Authorization date	Indications

If any of the products under investigation have marketing authorization in another country, indicate:

N°	Name Commercial	Country	Form Pharmaceutical and route of administration	Concentration	Indications	Name of marketing authorization holder

If the product under investigation has a health registration in our country, indicate:

N°	Name Commercial	Form Pharmaceutical and route of administration	Concentration	Registration number healthcare	Indications	Name of the legal representative

Check all categories to which the investigational products that will be used in the clinical trial belong.	
	Product under investigation of chemical origin
	Research product of biological origin
	Blood product
	Vaccine
	Gene therapy
	cell therapy
	genetically modified organism
	Radiopharmaceutical
	Allergen
	Natural therapeutic resources
	homeopathic product
	Narcotic, psychotropic, precursors for medical use
	Gas medicinal
	Others)

V. COMPLEMENTARY PRODUCTS (Pharmaceutical products, medical devices and health products)

The definitions and requirements of pharmaceutical products, medical devices and health products are included in Law No. 29459, DS No. 016-2011 and its respective amendments.

5.1. PHARMACEUTICAL PRODUCTS

No.	Name	Name of pharmaceutical ingredient(s) Asset(s)	Pharmaceutical form and route of administration	Concentration	Batch	Name of Supplier	Country of origin	Amount

5.2. MEDICAL DEVICES

N°	Name	Usage (*)	Model and brand	Name of Supplier	Country of origin	Amount

If the medical device is a laboratory kit, the actual components of the kit must be specified and recorded in the corresponding row. (*) If the medical device is a diagnostic or biomedical device, it is essential to briefly indicate its use within the study.

5.3. MEDICAL DEVICES

N°	Name	Use	Presentation	Concentration	Name of Supplier	Country of origin	Amount

SAW. LABORATORY MATERIALS FOR THE EXECUTION OF THE CLINICAL TRIALS

N°	Name	Use	Presentation	Name of Supplier	Country of origin	Amount

Only those materials that are essential for carrying out the study and that are directly related to the patient will be recorded.

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The investigational products, complementary products and registered laboratory materials will be used exclusively in the clinical trial protocol declared in section II of this FOR-OGITT-033.

I declare that the information provided is true and I authorize the verification of what was declared in accordance with the “Principle of Presumption of Truth” of numeral 1.7 of article IV of the Preliminary Title of the Single Ordered Text of Law No. 27444 - Law of General Administrative Procedure, approved with Supreme Decree 004-2019-JUS.

City,…….of……..of 20…

_____

Name and signature
DNI / CE

ANNEX 3

INSTRUCTIONS FOR FILLING OUT THE FOR-OGITT-033: LIST OF PRODUCTS AND SUPPLIES TO IMPORT IN THE CLINICAL TRIAL

A. GENERAL CONSIDERATIONS

ÿ To request the import of investigational products and other supplies, you must use FOR-OGITT-033, which is available on the Peruvian Registry of Clinical Trials (REPEC) website in the forms, guides and annexes section.

ÿ The information on investigational products, complementary products and laboratory materials that are registered in FOR-OGITT-033 must be what is required to be imported for the development of the study protocol authorized by the OGITT/INS. ÿ FOR-OGITT-033
should not be submitted prior to a request for Authorization of Report for Amendment to the protocol or the Informed Consent Form (FCI) that is directly related to criteria that vary the quantity or need to modify or expand products. in research and other supplies. ÿ FOR-OGITT-033 must be accompanied by a report that justifies the need to import the product under
investigation and other supplies **(ANNEX 2 or** 3).

ÿ All data in FOR-OGITT-033 must be completed correctly.
ÿ FOR-OGITT-033 will not include stationery, desk material, packaging or everyday electronic devices such as: cell phones, laptops, tablets, televisions, printers, among others.
ÿ All information must be recorded in Spanish and if the products have a label or description in English, it must be accompanied by a duly understandable translation into Spanish in parentheses.
ÿ The form must not have blank or unrecorded rows. If it is not necessary to fill out all the spaces in the form tables, it must be completed with *"Not Applicable (NA)"* or the excess rows must be eliminated.

B. FILLING OUT THE FORM

Carefully follow the instructions for recording data.

I. REPRESENTATIVE OF THE SPONSOR OR OIC

Adequately complete each space or requirement in this section. There must be coherence of the information that is recorded with the data on the REPEC website and the documentation that is presented to the OGITT/INS.

II. GENERAL INFORMATION OF THE CLINICAL TRIAL

ÿ **Title of the clinical trial:** the name of the title of the clinical trial must be the one registered on the REPEC website.
ÿ **Sponsor:** the sponsor's name must be the one found registered on the REPEC website.
ÿ **Clinical Trial Phase:** mark the corresponding clinical trial phase that has been authorized by the OGITT/INS.

ÿ **Protocol code:** it must be the one registered on the REPEC website and appears in the Directorial Resolution authorizing the clinical trial by the OGITT of the INS. ÿ **Clinical trial code (INS):** it must be the one registered on the REPEC website and appears in the Directorial Resolution authorizing the clinical trial by the OGITT of the INS

NOTE: The documentation must be consistent between the information recorded in the FOR-OGITT-033, the study protocol, FCI and that shown in the REPEC summary sheet.

III. RESEARCH CENTERS WHERE THE PRODUCTS WILL BE USED IN RESEARCH AND SUPPLIES

ÿ **Name of the research centers:** include only the research centers that are authorized by Directorial Resolution of the OGITT/INS.

ÿ **Quantity of research product:** when requesting an extension or modification, the quantity of research product available in each research center at the time of the request must be entered. ÿ **Number of patients enrolled:** when requesting an extension or modification, the number of patients enrolled for each research center must be entered.

IV. PRODUCTS UNDER RESEARCH

ÿ **Authorization of the clinical trial:** this option is checked when you are in the process of requesting authorization of the clinical trial, the complete FOR-OGITT-033 is attached with the research products, complementary products and laboratory materials necessary for the development of the clinical trial and detailed documentation in Annex 5 of the Clinical Trials Regulation approved with DS 021-2017-SA.

The quantities must be calculated based on the number of patients to be enrolled in the country and the consumption of the product under investigation. Consumption is understood as the doses administered to a research subject within an established time. Furthermore, in the calculation, it is feasible to include an additional percentage of product for shrinkage. The first version of FOR-OGITT-033 must contain the total quantities of the investigational products, complementary products and laboratory materials to be imported for the development of the clinical trial.

ÿ **Expansion of the List of products and supplies:** this option is checked when for reasons of expansion of the research center or increase in the number of subjects to be enrolled in the country or any amendment to the protocol or FCI, a greater quantity of investigational products, complementary products or laboratory materials to be imported for the study is required. Likewise, when the batch number or manufacturer or supplier of the ***complementary products (pharmaceutical product or medical device) has also changed.***

By selecting this option, **the batch number, manufacturing, country of origin and quality parameters** (certificates of analysis, stability, labeling and GMP) **of the product under investigation have not been modified.**

It is essential to attach a report that supports the reasons for the extension request, the FOR-OGITT 033 and the change control **(ANNEX 2).**

NOTE: The quantities to be registered in the FOR-OGITT-033 in case of expansion are those that remain to be imported to complete the clinical trial authorized by the OGITT/INS.

ÿ **Modification of the supply list:** this option is checked when the batch number, manufacturer or country of import has been modified ***in the research product .*** If the *batch number* is modified , the batch number release analysis certificate and the labeling project must be attached, and if *the manufacturer or country of origin is modified,* the Good Manufacturing Practices certificate must also be attached. Stability studies. The documentation presented is sent to the ANM (National Authority for Pharmaceutical Products, Medical Devices and Health Products) for its respective evaluation and issuance of a technical quality opinion.

In the event that in the request to modify the list of products and Supplies, if a larger quantity of complementary products (pharmaceutical products or medical devices) or laboratory materials are also required, can be completed on the form. Therefore, the option to expand the supply list should not be checked.

It is essential to attach a report that supports the reasons for the modification request, the FOR-OGITT 033 and the change control **(ANNEX 3).**

NOTE: The quantities to be registered in the FOR-OGITT-033 in case of modification are those that remain to be imported to complete the clinical trial authorized by the OGITT/INS.

V. COMPLEMENTARY PRODUCTS

ÿ Complementary products include pharmaceutical products, medical devices and health products.

ÿ Complementary products registered in FOR-OGITT-033 must have a health registration in Peru or High Health Surveillance countries.

ÿ If the medical device is a laboratory kit, it must be specify the actual components of the kit and they should be located in the appropriate row. In addition, the quantities of the kit in general and not by component of the kit must be recorded.

ÿ If the medical device is a diagnostic device or a biomedical device, it is essential to briefly specify its use according to the protocol approved by the OGITT/INS.

ÿ For the ***authorization of the clinical trial,*** the quantities of complementary products that are registered must reflect the calculation based on the number of patients (plus an additional percentage for shrinkage) to be enrolled in the country and quantities that reflect standardized or automated numbers should not be estimated. .

ÿ If you request ***an extension or modification*** of complementary products, the remaining balances or quantities that remain to be imported of each product must be recorded in the quantities.

SAW. LABORATORY MATERIALS FOR EXECUTION OF THE TEST CLINICAL

ÿ All materials (including laboratory equipment or laboratory reagents) whose use is essential for the execution of the clinical trial and which are directly related to the patient will be recorded.

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ÿ The signature of the legal representative can be physical or virtual. It is important that the date on the form is always updated after changes are made to FOR-OGITT-033.