INSTRUCTIONS FOR FILLING OUT THE FOR-OGITT-028. Edition No. 03 REQUEST FOR AUTHORIZATION OF THE CLINICAL TRIAL

A. GENERAL CONSIDERATIONS

1. The form must be filled out in its electronic version available in the Peruvian Registry of Trials Clinical – REPEC and in both Spanish and English, as requested.
2. To access REPEC, the sponsor or its authorized legal representative in the country must be previously registered in REPEC and must have a user account and password.
3. Information requested in this form that does not apply or does not correspond to your Institution or clinical trial, must be filled out with the acronym NA (Not applicable)
4. The information requested collects the items from the WHO Trial Registry Data Set (TRDS), that is, the minimum amount of information that must appear in a registry for a given trial to be considered fully registered.
5. The administrator is responsible for ensuring that the data provided in this form is complete and truthful.

B. MAIN MODIFICATIONS REGARDING THE PREVIOUS VERSION:

1. Additions to the content for the item Evaluation criteria (Page 07)
2. Additions to the Note shown for the item: Sponsor (Page 08)
3. Table No. 01 is incorporated: Study intervention - Example of entry in FOR-OGITT-028 (Page 11) and Table N°02 Primary / secondary valuation criteria. Examples of entry in the FOR-OGITT-028 (Page 12)

C. FILLING OUT THE FORM

I. REQUESTING INSTITUTION:

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.

2. Legal Representative: The person with current power of legal representative of the institution requesting authorization of the clinical trial before the OGITT of the INS must be identified, as well as their contact information:

to. First Names, Paternal Surname and Maternal Surname:
b. Identity Document: 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.

II. GENERAL INFORMATION OF THE CLINICAL TRIAL

1. IDENTIFICATION OF THE CLINICAL TRIAL

1.1. Scientific Title: Title of the study as it appears in the research protocol submitted for ethical review and request for authorization by the INS. It must be entered in Spanish and English.

1.2. Title for the public: Title intended for the general public, in easy-to-use language. understanding Must be entered in Spanish and English.

1.3. Protocol Code: Unique identifier of the EC protocol assigned by the sponsor.

1.4. Secondary ID(s): Other identifiers of the EC in addition to the identification number granted by the REPEC (primary ID). Enter, any of the following as applicable:

a) WHO UTN: The Universal Trial Number (UTN) is a unique number that aims to facilitate the unequivocal identification of CEs registered in the WHO Primary Registry Network (ICRTP). A UTN can be obtained at: http://apps.who.int/trialsearch/utn.aspx b) ClinicalTrials.gov from US National Institutes of Health. c) The European Union Clinical Trials Register, whose ID is the EudraCT Number

For example:
Protocol code: CQVM149B2302
REPEC identifier: EC 24-16 (generated by REPEC)
Secondary identifiers:
- WHO UTN: NA
- ClinicalTrials.gov ID: NCT02571777
- EudraCT Number: 2015-002899-25

1.5. Total national budget of the clinical trial (S/): Total amount in soles of the cost involved in executing the CE in Peru. This amount must match what was declared in FOR-OGITT-032.

1.6. Insurance Policy Expiration Date: Indicate the expiration date of the policy acquired. It must match the documentation sent from the insurance policy.

1.7. Clinical phase of the study: Research phase (I, II, III or IV), as appropriate, in accordance with what is indicated in section 18 of Article 2. Operational definitions and abbreviations of the REC.

1.8. Total duration of the Clinical Trial: Time (in months) planned for the execution of the clinical trial in Peru once authorization is obtained from the INS. It should not be confused with the duration of the research subject's participation in the clinical trial.

1.9. Worldwide enrollment start date: (dd/mm/yyyy): Actual or expected date of enrollment of the first research subject worldwide.

1.10. Estimated date of start of enrollment in Peru (dd/mm/yyyy): Expected date of enrollment of the first research subject in the country. The actual date of the start of enrollment in the country will be entered by the administrator through another form.

1.11. Recruitment status in Peru

a) Without starting recruitment: Recruitment of participants in the country has not yet begun. none of the authorized research centers in the country. This option must be selected for the EC Authorization Request process.

b) In recruitment: The study is recruiting participants. This information will not be entered by the administrator during the EC Authorization Request process.

c) Recruitment paused: there is a suspension in recruitment, but it will potentially resume. This information will be entered by the administrator/ OGITT through another procedure.

d) Closed recruitment: The trial is ongoing but participants are no longer being recruited. This information will not be entered by the administrator during the EC Authorization Request process.

1.12. Other characteristics of the EC: Select YES or NO, as appropriate to the EC

- Superiority
- Bioequivalencia
- Non-inferiority
- Dose response

2. OBJECTIVES AND DESIGN OF THE CLINICAL TRIAL

2.1. Allocation method: Indicate if the clinical trial is:

- Randomized: It means that the assignment of subjects to the different comparison groups (for example, intervention and control) was random or using a method based on chance.
- Non-randomized: It means that the assignment of subjects to the different comparison groups is done in an expressly deliberate manner, and not by chance.
- Does not apply

Note: Clinical trials with quasi-random allocation procedures such as: allocation by medical record number, date of birth, alternate days of the week, allocation by physician discretion, based on participant preference; based on the results of a laboratory test or series of tests or based on the availability of the intervention do not qualify as a randomized trial and should be classified as Non-randomized.

2.2. Assignment: Select if the assignment is:

- Single arm: All research subjects receive the same intervention throughout the entire study.
- Parallel: Research subjects are randomly assigned to two or more different study arms. Each arm receives a different treatment and the treatments are received during the same time period of the study. Each group receives only one type of treatment.
- Crossover: Research subjects receive two or more interventions in a particular order or in a specific sequence during the study. They act as their own control.
- Factorial: Research subjects were randomly assigned to receive no intervention, one or some interventions, or all interventions combined.
- Other: None of the previous options provide an adequate description of the study assignment. If "Other" is selected you must provide a brief description of the study assignment, in Spanish and English.

23. Type of blinding: Indicate the type of blinding used:

- Single blind: Generally applied if the research subject does not know his/her assignment.

- Double blind: If the research subject and the researcher(s) are unaware of their assignment.
- Triple blind: If in addition to the research subject and researchers, the professional who analyzes the data also does not know the assignment
- Open: Absence of blinding. Everyone involved in the study knows the intervention assignment.

2.4. Detailed description of the design: Corresponds to the textual description of:

a) Type of study/phase

b) Allocation method: indicate whether the CS is randomized or non-randomized

c) Blinding. Indicate the type of blinding used and, if so, who is blinded: The research subject, the researcher who administers the treatment or the one who provides medical care, The researcher who evaluates the endpoints, the professional who analyzes the data .

d) Assignment: Select whether it corresponds to single-arm, parallel, crossed or factorial assignment, other.

e) Purpose: short description of the primary purpose of the study, for example prevention, diagnosis or treatment.

Note that the text entered in this section brings together the items: a, b, c, d and e. Other design features that are considered important can be incorporated in this field. Information must be entered in Spanish and English.

Example:

This is a phase 3, multicenter, randomized, double-blind, parallel-group trial to evaluate the efficacy and safety of Drug A compared to vancomycin in patients ÿ 18 years of age, of both sexes, with ABSSSI whose suspected cause or confirmed to be gram-positive pathogens. The investigators, clinical study staff, sponsor, and patients will be unaware of treatment assignment with the study medication.

2.5. Purpose/Primary Objective: It must indicate the purpose (Prevention, Treatment, Diagnosis) and the primary objective of the clinical trial. Information must be entered in Spanish and English.

3. STUDY INTERVENTION

The information requested in this section must be entered independently for both the study intervention and the comparator(s).

3.1. Type of product under investigation: Indicate if the product is being developed as:

- Medicine
- Organic product
- Herbal medicine
- Dietary product
- Medical device - Others: If selected, you must give a brief description in Spanish and English.

3.2. Identification of the product under investigation: You must enter the information corresponding to:

- Type of product: Based on the options indicated in “a”.
- ATC code
- Generic name
- Product name

More than one product can be registered in this section.

3.3. Description of the Intervention(s): Must include the following information:

a) Group name: name that identifies the study intervention. If there are multiple study arms, label (e.g. arm 1, arm 2, etc.) The name of the intervention should be consistent throughout the form.

b) Type of group: Select if the group entered is experimental or control.

c) No. of subjects: No. of research subjects to be assigned to the group according to the research protocol.

d) Description: It must be detailed enough for each arm. Enter in Spanish and English.

Yo. For drug trials, specify the dosage form, dose and frequency of administration (e.g., 5 mg once daily), duration of administration (e.g., 4 weeks), and route of administration (e.g., route oral, intravenous infusion).

Provide the International Nonproprietary Name (INN) of each drug (not brand or commercial names). For an unregistered drug, the generic name, chemical name, or a manufacturer's code is acceptable.

ii. For trials with other types of interventions, please specify as appropriate:

- Material or device that will be used in the intervention.
- Each of the procedures, activities and/or processes used that make up the intervention, including, if applicable, who will provide the intervention.

The number of times the intervention will be delivered and over what time period including the number of sessions, schedule and their duration, intensity or dose (e.g. 8 one-hour sessions, once/week for 8 weeks, then once/week). month for 4 months).

The context in which the intervention occurs (for example, hospital, the research subject's home, other)

iii. The identification of the comparator group must be clear. It is/are the intervention(s) against which the study intervention is being evaluated (e.g., placebo, no treatment, active control). If an active comparator is used, be sure to enter the name(s) or label "placebo" or "no treatment" as appropriate.

Example:

This is a phase 3, multicenter, randomized, double-blind, parallel-group trial to evaluate the efficacy and safety of Drug A compared to vancomycin in patients ÿ 18 years of age, of both sexes, with ABSSSI whose suspected cause or confirmed to be gram-positive pathogens. The investigators, clinical study staff, sponsor, and patients will be unaware of treatment assignment with the study medication.

See Table N° 01 STUDY INTERVENTION - EXAMPLE OF ENTRY IN THE FOR-OGITT-028 (P.11)

e) Treatment time of the subjects

f) Subject monitoring time

4. STUDY POPULATION

4.1. Key Inclusion Criteria: Must include a summary of the key inclusion criteria that determine the subject's eligibility to participate in the study. Enter in Spanish and English.

4.2. Key Exclusion Criteria: Must include a summary of key exclusion criteria for patient characteristics that determine eligibility to participate in the study. These should not simply be the opposite of the inclusion criteria. Enter in Spanish and English.

4.3. Disease or medical condition studied

4.4. Classification of the disease studied (ICD-10): select the ICD-10 code from the condition under study in the clinical trial.

4.5. Medical Specialty: You must choose the medical specialty from the breakdown list. It is in relation to the condition or disease under study.

4.6. Countries in which recruitment takes place: Select from the available list, the country(ies) where recruitment for this EC takes place/is planned.

4.7. Number of subjects to include worldwide: Write the amount in Arabic numerals of subjects planned to enroll worldwide, including Peru.

4.8. Estimated number of subjects to be included in Peru: Write in Arabic numerals the number of subjects expected to be enrolled in Peru. This information will be filled out during the registration of the clinical trial by the institution responsible for registering the trial.

4.9. Population to be included according to sex: Select whether only women, only men, or subjects of both sexes will be included in the CS.+

4.10. Type of population to be included: Indicate by selecting YES or NO if the population of study will include some of the indicated groups.

4.11. Age range of subjects to be included: Select by checking YES or NO in the group(s) age of the research subjects expected to be included in the CS.

5. ASSESSMENT CRITERIA

5.1. Primary Endpoints: Also called primary outcome variable or primary endpoint. It corresponds to the variable capable of providing the most relevant and convincing clinical evidence directly related to the primary objective of the trial.
The primary outcome should be the variable used in sample size calculations, or the main outcome used to determine the effect of the intervention.
If there is more than one primary endpoint, record them individually.
Enter in Spanish and English.

In this section you must provide:

a) Name of the assessment criterion: It constitutes the specific measurement variable. Do not use abbreviations

b) Measurement method used to measure the assessment criterion, its operationalization, instrument or method to be used for its evaluation/measurement.
Answers the question: How will the primary endpoint be evaluated?

c) Time in which the measurement will be carried out: and which will allow obtaining the criterion of primary assessment.

5.2. Key Secondary Endpoints: Secondary endpoints are variables used to measure the effect of the study intervention. It may involve the same event or variable as the primary endpoint, but measured at different time points than the primary endpoint.

All key secondary endpoints should be recorded individually in this field. Those designated as keys correspond to "endpoints" more clinically relevant side effects.

Enter the following in Spanish and English for each key secondary endpoint:

a) Name of the assessment criterion: It constitutes the specific measurement variable. Do not use abbreviations

b) Measurement method used to measure the assessment criterion, its operationalization, instrument or method to be used for its evaluation/measurement.
Answers the question: How will the secondary endpoint be evaluated?

c) Time in which the measurement will be carried out: and which will allow obtaining the secondary endpoint.

See TABLE N° 02: PRIMARY / SECONDARY ASSESSMENT CRITERIA. EXAMPLES OF ENTRY IN THE FOR-OGITT-028 (P.12)

6. DATA MONITORING

6.1. Interim Analysis: Select Yes or No, as appropriate.

6.2. Existence of a Data Monitoring Committee: Select YES or NO as appropriate.

III. SPONSOR INFORMATION AND SOURCE OF FINANCING

1. INFORMATION OF THE SPONSOR(S)

1.1. Main Sponsor:

Individual person, group of people, company, institution or organization, including academic ones, with legal representation in the country duly registered in the corresponding public registries, who assumes responsibility for the initiation, maintenance, conclusion and financing of a trial clinical. Additionally, you are responsible for ensuring that the trial is recorded correctly. It must be selected from the list of previously registered sponsors, also entering the type of sponsor. This item must be consistent with the name or company name indicated in the clinical trial documents.

1.2. Secondary Sponsors: Individual person, group of people, company, institution or organization, including academic ones, who have agreed to form a group with the primary sponsor in such a way that sponsorship responsibilities are distributed among the members of the group. It must be selected from the list of previously registered sponsors, also entering the type of sponsor. This item must be consistent with the name or company name indicated in the clinical trial documents.

USE:

- In the case of a clinical trial with more than one sponsoring institution, it must be identified which one will assume the role of main sponsor and which one as secondary sponsor, depending on the level of responsibilities for the initiation, execution of the clinical trial and the communication of research results. This level of responsibilities must be documented and presented as information attached to the authorization file.

- The main and secondary sponsors must not be the same.
- It is essential that the sponsor(s) be indicated in the research protocol and in all documents relating to the clinical trial.

2. INFORMATION ON THE SOURCE OF FINANCING

Enter the name of all organizations (academic, government, or private) that are funding the study. If there is more than one source of financing, they must be included in the form.

3. RESPONSIBILITIES

3.1. The listed responsibilities must be assigned as provided by the sponsor and documented through a Delegation of Duties Document.
3.2. For each activity indicated in the form, enter the delegated Institution and add any additional observation or precision that may apply.
3.3. Include the name of the document by which the sponsor has delegated functions or tasks for the EC and its subscription date.

IV. RESEARCH CENTER, PRINCIPAL INVESTIGATOR and ETHICS COMMITTEE

1. RESEARCH CENTERS WHERE THE CLINICAL TRIAL WILL BE EXECUTED

Correctly identify, from the available list, the proposed research center and the research institution to which it belongs. Verify that the chosen center does not appear as:

RCI canceled or RCI inactive. Likewise, that it is not found with observations resulting from an inspection.

Enter your data correctly; since this is how they will be recorded in the resolution.

2. CHIEF INVESTIGATOR OF THE RESEARCH CENTER WHERE IT WILL BE EXECUTED THE CLINICAL TRIAL

The information to be entered corresponds to the principal investigator for each research center included in the application:

- Surnames and First Names: -
Identity Document Number:
- Address - District / Province / Department: Enter institutional contact information.
- Telephone: Enter institutional contact information.
- Email: Enter institutional contact information.

You can export the data if the Investigator has previously been registered in previous ECs, register the information for a new researcher or update the registered information.
Enter the data correctly, as it appears on the identity documents.

3. COINVESTIGADORES

Enter information in the same way as for the Principal Investigator.

4. INSTITUTIONAL RESEARCH ETHICS COMMITTEE (CIEI) THAT APPROVED THE TEST FOR THE CENTER

Correctly assign the Institutional Research Ethics Committee. Verify that the accreditation of said committee is current.

V. CLINICAL TRIAL DOCUMENTS UNDER WHICH THE APPLICATION IS SUBMITTED

Enter correctly since this is how they will be recorded in the resolution. They must be consistent with the name, version and date of the document presented, as well as what is indicated in the approvals of the CIEI and the corresponding research institutions.

1. PROTOCOL: Enter the name of the document, version and date, with which the authorization request is being submitted.

2. INFORMED CONSENT FORMATS: List the names of the documents, version and date, with which the authorization request is being submitted. If there is a difference in the version number or date for the included research centers, clearly indicate which version corresponds to a certain RCI.

SAW. SHARING OF CLINICAL TRIALS DATA (ANIMIZED INDIVIDUAL DATA)

1. PLAN TO SHARE ANONYMOUS INDIVIDUAL DATA OF SUBJECTS OF INVESTIGATION:

1.1. Answer yes *Is there a plan to make anonymized individual data from research subjects, including data dictionaries, available to other researchers?*

1.2. If the answer is YES, briefly describe which subject data sets will be shared, when these data will be available and how the data can be obtained (by what mechanism) and for what types of analysis.

2. ADDITIONAL INFORMATION THAT WILL BE SHARED:

2.1. Select all that apply from the available list. If Others are indicated, describe in Spanish and English.

2.2. If you have selected at least one option, briefly describe when it will be available. information available and how it can be obtained.

3. URL: Provide the website address where you can find additional information regarding data sharing plans, if available. Otherwise, place NOT AVAILABLE

VII. EC REGISTRATION DATE: Automatically generated during electronic registration in the REPEC.

VIII. INFORMATION OF CONTACT PERSONS OF THE CLINICAL TRIAL

1. INFORMATION OF THE CONTACT PERSON(S) FOR INQUIRIES ABOUT THE CLINICAL TRIAL

The contact must be specified for each type of consultation: for the general public, administrative or scientific. Provide names and surnames, sex, email and telephone number of the institution where you work.

2. DATA OF THE PERSON WHO CARRIED OUT THE TRANSLATION OF THE DATA SHEET

Complete the data of the person who translated the information fields into English required for registration. Provide the names and surnames, gender, email and telephone number of the institution where you work.

3. DATA OF THE PERSON RESPONSIBLE FOR THE INFORMATION REGISTRATION

Complete the data of the person responsible for recording the information in the fields requested in the form. Provide the names and surnames, gender, email and telephone number of the institution where you work.

IX. REQUIREMENTS CHECKLIST

It corresponds to a checklist to help when submitting the EC Authorization file.

THIS FIELD IS FOR EXCLUSIVE USE BY THE HEAD OF THE DOCUMENTARY PROCESSING AREA OF THE INS.

X. AUTHORIZED LEGAL REPRESENTATIVE

It corresponds to the section for the signature and date of signature of the legal representative of the Institution that presents this application on behalf of the Sponsor, according to the data recorded in section I.

TABLE N° 01: STUDY INTERVENTION - EXAMPLE OF ENTRY INTO THE FOR-OGITT-028

EC with 03 arms, the allocation is 1:1:1 and the number of subjects to enroll worldwide is 669

Arm 1		
	Español	**English**
Group Name:	Fevipiprant (QAW039) 150 mg	Fevipiprant (QAW039) 150 mg
Group type:	☒ Experimental ☐ Control	
Number of subjects:	223	
Description of the intervention: Name of the Intervention. Pharmaceutical form, dose and frequency, duration of treatment, route of administration.	One QAW039 150 mg tablet + one QAW039 450 mg placebo tablet to be administered orally once daily for 52 weeks of treatment added to standard of care therapy.	One tablet of QAW039 at 150 mg + one tablet placebo to QAW039 450 mg daily to be given orally during 52 weeks of treatment in addition to the standard of care treatment.
Arm 2		
	Español	**English**
Group Name: Type of	Fevipiprant (QAW039) 450 mg	Fevipiprant (QAW039) 450 mg
group: Number of	☒ Experimental ☐ Control	
subjects:	223	
Description of the intervention: Name of the Intervention. Pharmaceutical form, dose and frequency, duration of treatment, route of administration.	One QAW039 450 mg tablet + one QAW039 150 mg placebo tablet to be administered orally once daily for 52 weeks of treatment added to standard of care therapy.	One tablet of QAW039 at 450 mg + one tablet placebo to QAW039 150 mg daily to be given orally during 52 weeks of treatment in addition to the standard of care treatment.
Arm 3		
	Spanish	**English**
Group Name:	Fevipiprant (QAW039) Placebo	Fevipiprant (QAW039) Placebo
Group type:	☐ Experimental ☒ Control	
Number of subjects:	223	
Description of the intervention: Name of the Intervention. Pharmaceutical form, dose and frequency, duration of treatment, route of administration.	One QAW039 450 mg placebo tablet + one QAW039 150 mg placebo tablet to be administered orally once daily for 52 weeks of treatment added to standard of care therapy.	One tablet placebo to QAW039 at 450 mg + one tablet placebo to QAW039 150 mg daily to be given orally during 52 weeks of treatment in addition to the standard of care treatment.

TABLE N° 02: PRIMARY / SECONDARY ASSESSMENT CRITERIA. EXAMPLES OF ENTRY IN THE FOR-OGITT-028

EXAMPLE N°01:	Spanish	English
Endpoint name *What is the variable?* *What is the data directly collected from the subject?*	**Use of systemic corticosteroids** Total dose of systemic corticosteroids in mg of prednisone/ prednisolone, or its equivalent, during 52 weeks of treatment.	Systemic corticosteriods use Total systemic corticosteroid dose in mg prednisone/prednisolone (or equivalent) over 52 weeks of treatment.
Measurement method used: *How will the primary endpoint be evaluated?*	The patient will record daily Oral Corticosteroids (number of tablets taken in the previous 12 hours) in the morning and evening, on the electronic diary device.	The total amount of daily oral corticosteroids (number of tablets taken in the previous 12 hours) will be recorded morning and evening by the patient, in the eDiary device.
Time in which the measurement will be carried out:	52 weeks	52 weeks
EXAMPLE N°02:	**Spanish**	**English**
Name of the evaluation criterion *What is the variable?* *What is the data directly collected from the subject?*	Change from Baseline in Daytime and Nighttime Symptom Scores	Change from baseline in daytime and nighttime symptom scores
Measurement method used: *How will the primary endpoint be evaluated?*	Symptom diary scale, completed by patients via electronic diary device. Daytime asthma symptoms (04 questions) will be classified on a scale from 0 to 6, and nocturnal asthma symptoms (01 question) will be classified on a scale from 0 to 3.	Symptom diary scale, recorded by patients in the eDiary device. Daytime asthma symptoms (04 questions) will be rated on a 0 to 6 scale and nocturnal asthma symptoms (01 question) will be rated on a 0 to 3 scale.
Time in which the measurement will be carried out:	52 weeks	52 weeks
EXAMPLE N°03:	**Spanish**	**English**
Name of the evaluation criterion *What is the variable?* *What is the data directly collected from the subject?*	Adverse events, vital signs, ECG and laboratory tests	Adverse events, ECG, vital signs and laboratory analysis
Measurement method used: *How will the primary endpoint be evaluated?*	Medical history and physical examination - Asthmatic exacerbations, according to the definitions of mild, moderate or severe exacerbations - Vital signs Height and weight	- Medical history and physical examination - Asthma Exacerbations, according to definitions of mild, moderate or severe exacerbations Vital signs - Height and weight - Electrocardiogram

	- Laboratory evaluations (hematology, clinical biochemistry includes HbA1C and urinalysis) - Pregnancy test	- Laboratory evaluations (Hematology, Blood chemistry including HbA1c, Urinalysis) - Pregnancy testing
Time in which the measurement will be carried out: EXAMPLE	52 weeks	52 weeks
EXAMPLE	**Spanish**	**English**
Name of the evaluation criterion *What is the variable?* *What is the data directly collected from the subject?*	- Progression-free survival (PFS) - General supervision (OS)	- Progression-free survival (PFS) - Overall survival (OS)
Measurement method used: *How will the primary endpoint be evaluated?*	- PFS: Time from the date of randomization to the date of disease progression or death (from any cause, in the absence of progression). - OS: Time from the date of randomization until death due to any cause It will be measured through Blinded Independent Central Review (BICR) assessments according to Response Evaluation Criteria in Solid Tumors, version 1.1 (RECIST 1.1).	- PFS: Time from the date of randomization until the date of objective disease progression or death (by any cause in the absence of progression). - OS: time from the date of randomization until death due to any cause. Using Blinded Independent Central Review (BICR) assessments according to Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST 1.1)
Time in which the measurement will be carried out:	- PFS: 25 months from the admission of the first patient - OS: 46 months duration from first patient admission	- PFS: 25 months from First patient in (FPI) - OS: 46 months from FPI
EXAMPLE N°05:	**Spanish**	**English**
Name of the evaluation criterion *What is the variable?* *What is the data directly collected from the subject?*	Early clinical response (ECR)	Early clinical response (ECR)
Measurement method used: *How will the primary endpoint be evaluated?*	Proportion of patients with response (RCT) in the analysis set by intention to treat (IT) It is considered RCT if it meets the following 4 criteria:	Proportion of patients with response (ECR) in the analysis set by intention to treat (ITT) RCT is considered if the following 4 criteria are met:

	- Is alive - Improvement in at least 2 of the 4 cardinal symptoms of community-acquired pneumonia (CAP) - No worsening of any of the 4 cardinal symptoms of CAP. - Did not receive a concomitant antibiotic for the treatment of CAP.	Patient alive - Improvement in at least 2 of the 4 cardinal symptoms of community-acquired bacterial pneumonia (CAP) - No worsening of any of the 4 cardinal symptoms of CAP. Patient did not receive a concomitant antibiotic for the treatment of CAP.
Time in which the measurement will be carried out:	96 ± 24 hours after the first dose of study medication.	96 ± 24 hours after first dose of study drug