	FORM	FOR-DIIS-058
	SUMMARY REPORT RESULTS	Edition No. 01

INF No: (Automatically generated during registration) electronic in the REPEC)
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I. SPONSOR'S DATA	Foreign: <input type="checkbox"/>	National: <input type="checkbox"/>
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1. NATURAL PERSON <input type="checkbox"/>
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Father's Surname:		Mother's Surname:	
Names:		DNI/ CE/ PAS:	
Email:		Telephone and extension:	
Legal Address: (District, Province and Department)			

2. LEGAL ENTITY <input type="checkbox"/>
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2.1. FOREIGN SPONSOR (Previously registered in the INS REPEC)
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Registered Name: (According to the Certificate of Incorporation of the company, business or organization or instrument equivalent in the country of origin).		Registered Trade Names: (From the company or organization).	
Commercial registration number:		Names and surnames of the legal representative: (Duly empowered to act as representative of this and grant powers in your name).	
Identity Document Number of the legal representative: (The document equivalent to the country of origin).		Position held in the organization:	
Email:		Telephone and extension:	
Legal address:		Zip code:	

2.1.1. REPRESENTATIVE OF THE FOREIGN SPONSOR IN PERU (Check one of the options)


<input type="checkbox"/> SUBSIDIARY:	<input type="checkbox"/> BRANCH:	<input type="checkbox"/> OIC:	<input type="checkbox"/> OTHER:
RUC:		Company Name: (Data of your legal representative add them in numeral 1.2.1 and 1.2.2)	
Trade Name:		Telephone and extension:	

2.2. NATIONAL SPONSOR (Previously registered in the INS REPEC)

RUC:		Company Name: (Data of your legal representative added in numerals 2.3 and 2.4)	
Trade Name:		Telephone and extension:	
Email:			

2.3. LEGAL REPRESENTATIVE (For a company, accredited in the validity of the power / for a public entity, accredited in the Resolution that designates): (If there is a person other than the legal representative as an attorney, he/she must have the special power which must expressly indicate the act(s) to be performed. which was conferred)


Father's Surname:		Mother's Surname:	
Names:		DNI/ CE/ PAS:	
Power of attorney registered at the Office Registry - SUNARP: (Complete if you are from Lima or province)		Post:	

	FORM		FOR-DIIS-058
	SUMMARY REPORT RESULTS		Edition No. 01

Electronic record No.:		Seat No.:	
Resolution number that designates him: <i>(Complete this item only if you are an entity public and detail the full name of the resolution)</i>		Date: <i>(Day, month and year)</i>	
Email:		Telephone and extension:	
2.4. ADDRESS OF THE LEGAL REPRESENTATIVE: <i>If you consider any additional information important, add it.</i>			
Address:		District:	
Province:		Department:	
2.5. OTHERS: <i>If you consider any additional information important, add it.</i>			
TYPE OF INSTITUTION:			

II. GENERAL INFORMATION ABOUT THE CLINICAL TRIAL			
Scientific Title (Spanish):		Scientific Title (English):	
Title for the Public (Spanish):		Title for the Public (English):	
Protocol Code:		Indication Studied:	
Publication: <i>(If this were already available, enter the DOI or URL)</i>	<input type="checkbox"/> Yes. DOI: _____ URL: _____ <input type="checkbox"/> No. <i>(Attach a summary of the results, addressed to the participant, taking the CONSORT 2022 declaration as a reference).</i>		


2.1. FLOW OF PARTICIPANTS		
2.1.1. Number of participants enrolled in the study:		
2.1.2. Number of study arms or groups:		
	Group 1	Group 2
2.1.3. Name of the arm or group		
Description of the intervention <i>(Details about the intervention [which may be by example: dose, dosage form, frequency, duration])</i>		
2.1.4. Number of participants who received the intervention		
2.1.5. Number of participants with loss of follow-up		
2.1.6. Number of participants who interrupt the intervention		
2.1.7. Number of participants analyzed		
2.1.8. Number of participants excluded from the analysis		
2.2. RESULTS MEASUREMENT		
2.2.1. EVALUATION CRITERIA(S)		
CRITERION 1		
1. Type of assessment criterion	<input type="checkbox"/> Primary <input type="checkbox"/> Secondary <input type="checkbox"/> Other:	
2. Name of the evaluation criterion <i>According to the assessment criteria indicated in the protocol (outcomes)</i>		
3. Description of the assessment criteria <i>(Brief description of the outcome measure)</i>		
4. Period of time in which the measurement was made <i>As stated in the protocol</i>		

	FORM	FOR-DIIS-058
	SUMMARY REPORT RESULTS	Edition No. 01

5. Description of the population analyzed (Type of analysis population)		
6. Summary Measure Type	<input type="checkbox"/> Average <input type="checkbox"/> Median <input type="checkbox"/> Least squares mean <input type="checkbox"/> Geometric mean <input type="checkbox"/> Number <input type="checkbox"/> Percentage	
7. Measure of dispersion/precision	<input type="checkbox"/> Not applicable <input type="checkbox"/> Standard deviation <input type="checkbox"/> Interquartile range <input type="checkbox"/> Total range <input type="checkbox"/> Coefficient of geometric variation <input type="checkbox"/> Standard error <input type="checkbox"/> Confidence interval: % <input type="checkbox"/> Coefficient of geometric variation	
8. Unit of measurement		
9. Number of groups considered for the analysis		
		Group n
10. Title of the arm or group		
11. Total number of participants analyzed from the arm or group		
12. Summary measure value		
13. To apply categories		

CRITERION 2

1. Type of assessment criterion	<input type="checkbox"/> Primary <input type="checkbox"/> Secondary <input type="checkbox"/> Other:
2. Name of the evaluation criterion <i>According to the assessment criteria indicated in the protocol (outcomes)</i>	
3. Description of the assessment criterion (Brief description of the outcome measure)	
4. Period of time in which the measurement was performed As stated in the protocol	
5. Description of the population analyzed (Type of analysis population)	
6. Summary Measure Type	<input type="checkbox"/> Average <input type="checkbox"/> Median <input type="checkbox"/> Least squares mean <input type="checkbox"/> Geometric mean <input type="checkbox"/> Number <input type="checkbox"/> Percentage
7. Measure of dispersion/precision	<input type="checkbox"/> Not applicable <input type="checkbox"/> Standard deviation <input type="checkbox"/> Interquartile range <input type="checkbox"/> Total range <input type="checkbox"/> Coefficient of geometric variation <input type="checkbox"/> Standard error <input type="checkbox"/> Confidence interval: % <input type="checkbox"/> Coefficient of geometric variation
8. Unit of measurement	
9. Number of groups considered for the analysis	
Group n	

	FORM		FOR-DIIS-058
	SUMMARY REPORT RESULTS		Edition No. 01


10. Title of the arm or group			
11. Total number of participants analyzed from the arm or group			
12. Summary measure value			
13. To apply categories			

CRITERION 3

1. Type of assessment criterion	<input type="checkbox"/> Primary <input type="checkbox"/> Secondary <input type="checkbox"/> Other:
2. Name of the evaluation criterion <i>According to the assessment criteria indicated in the protocol (outcomes)</i>	
3. Description of the assessment criterion (Brief description of the outcome measure)	
4. Period of time in which the measurement was performed As stated in the protocol	
5. Description of the population analyzed (Type of analysis population)	
6. Summary Measure Type	<input type="checkbox"/> Average <input type="checkbox"/> Median <input type="checkbox"/> Least squares mean <input type="checkbox"/> Geometric mean <input type="checkbox"/> Number <input type="checkbox"/> Percentage
7. Measure of dispersion/precision	<input type="checkbox"/> Not applicable <input type="checkbox"/> Standard deviation <input type="checkbox"/> Interquartile range <input type="checkbox"/> Total range <input type="checkbox"/> Coefficient of geometric variation <input type="checkbox"/> Standard error <input type="checkbox"/> Confidence interval: % <input type="checkbox"/> Coefficient of geometric variation
8. Unit of measurement	
9. Number of groups considered for the analysis	
	Group n
10. Title of the arm or group	
11. Total number of participants analyzed from the arm or group	
12. Summary measure value	
13. To apply categories	

CRITERION 4


1. Type of assessment criterion	<input type="checkbox"/> Primary <input type="checkbox"/> Secondary <input type="checkbox"/> Other:
2. Name of the assessment criterion <i>According to the assessment criteria indicated in the protocol (outcomes)</i>	
3. Description of the assessment criterion (Brief description of the outcome measure)	
4. Period of time in which the measurement was performed As stated in the protocol	
5. Description of the population analyzed (Type of analysis population)	

	FORM	FOR-DIIS-058
	SUMMARY REPORT RESULTS	Edition No. 01

6. Summary Measure Type	<input type="checkbox"/> Average <input type="checkbox"/> Median <input type="checkbox"/> Least squares mean <input type="checkbox"/> Geometric mean <input type="checkbox"/> Number <input type="checkbox"/> Percentage
7. Measure of dispersion/precision	<input type="checkbox"/> Not applicable <input type="checkbox"/> Standard deviation <input type="checkbox"/> Interquartile range <input type="checkbox"/> Total range <input type="checkbox"/> Coefficient of geometric variation <input type="checkbox"/> Standard error <input type="checkbox"/> Confidence interval: % <input type="checkbox"/> Coefficient of geometric variation
8. Unit of measurement	
9. Number of groups considered for the analysis	
	Group n
10. Title of the arm or group	
11. Total number of participants analyzed from the arm or group	
12. Summary measure value	

CRITERION 5	
1. Type of assessment criterion	<input type="checkbox"/> Primary <input type="checkbox"/> Secondary <input type="checkbox"/> Other:
2. Name of the evaluation criterion <i>According to the assessment criteria indicated in the protocol (outcomes)</i>	
3. Description of the assessment criterion <i>(Brief description of the outcome measure)</i>	
4. Period of time in which the measurement was performed <i>As stated in the protocol</i>	
5. Description of the population analyzed <i>(Type of analysis population)</i>	
6. Summary Measure Type	<input type="checkbox"/> Average <input type="checkbox"/> Median <input type="checkbox"/> Least squares mean <input type="checkbox"/> Geometric mean <input type="checkbox"/> Number <input type="checkbox"/> Percentage
7. Measure of dispersion/precision	<input type="checkbox"/> Not applicable <input type="checkbox"/> Standard deviation <input type="checkbox"/> Interquartile range <input type="checkbox"/> Total range <input type="checkbox"/> Coefficient of geometric variation <input type="checkbox"/> Standard error <input type="checkbox"/> Confidence interval: % <input type="checkbox"/> Coefficient of geometric variation
8. Unit of measurement	
9. Number of groups considered for the analysis	
	Group n
10. Title of the arm or group	
11. Total number of participants analyzed from the arm or group	
12. Summary measure value	

2.2.2. STATISTICAL ANALYSIS	
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	FORM	FOR-DIIS-058
	SUMMARY REPORT RESULTS	Edition No. 01

1. Description of the statistical analysis		
2. Comparison Groups		GROUP 2 GROUP 1
3. Type of statistical test		<input type="checkbox"/> Superiority <input type="checkbox"/> No Inferiority <input type="checkbox"/> Equivalence <input type="checkbox"/> Others (e.g., a single group or other descriptive analysis)
If you select No Inferiority or Equivalence:	Power calculation or other Key information:	
	Definition of the margin of no inferiority/margin of equivalence	
4. Hypothesis Testing	p-value:	
	Statistical test used:	
	Comments:	
5. Estimation method	Measure of effect:	
	Estimated value:	
	Confidence interval:	
	Dispersion type:	<input type="checkbox"/> Standard deviation <input type="checkbox"/> Standard error of the mean
	Dispersion value:	
	Comments:	
6. Other types of statistical analysis		

V. ADVERSE EVENTS			
Group n			
1. Total by group	Number of people affected	No. at risk	Number of events (%)
5.1. MORTALITY FROM ALL CAUSES			
Group 1			
1. Total by group	Number of people affected	No. at risk	Group 2
VI. CONCLUSIONS			
6.1. Effectiveness Conclusions			
6.2. Security Conclusions			

VI. PERSON RESPONSIBLE FOR RECORDING INFORMATION	
<input type="checkbox"/> On behalf of the study sponsor, he confirmed that this report accurately describes the conduct and results of the study. I certify that the information contained herein is true and accurate	

Date: dd/mm/year. time	
<div></div> <div>Name and signature of the Legal Representative (section 2.3)</div>	