	FORM	FOR-OGIT-058
	REPORT OF RESULTS OF THE CLINICAL TRIALS TO BE PUBLISHED IN THE REPEC	Edition No. 01

Instructions: *Dear User, remember that the application must be filled out through the electronic form available in the Peruvian Registry of Clinical Trials (REPEC) at: http:// www.ensayosclinicos-repec.ins.gob.pe*

1. ADMINISTRATIVE INFORMATION

1. Name of the notifying Institution:	*(Automatically generated during electronic registration in REPEC)*		
2. Data of the person responsible for recording information.			
Last name:		**Identification document:**	
Mother's last name:		**Telephone:**	
Names:		**Email:**	

2. GENERAL INFORMATION

1. Title of the clinical trial: 2. Name	*(Automatically generated during electronic registration in the REPEC)*
of the investigational product:	
3. Indication studied:	
4. Sponsor(s):	*(Automatically generated during electronic registration in the REPEC)*
5. Protocol Code:	*(Automatically generated during electronic registration in the REPEC)*
6. Clinical phase:	*(Automatically generated during electronic registration in the REPEC)*
7. Study start date: (Global)	
8. Study completion date: (Date of the last visit of the last global participant)	
9. Primary Objective(s):	
10. Secondary Objective(s): 11. Study	
design:	
12. Number of Planned Patients: 13. Number of	
Patients Analyzed: 14. Main selection criteria:	
15. Dosage and method of administration of the Investigational Product:	
16. Duration of treatment:	
17. Primary assessment criteria(s): 18. Secondary	
assessment criteria(s): 19. Publication:	
(If it is already available, enter the DOI or URL)	DOI: URL:
20. Date of first publication in a scientific journal	
21. Report date:	

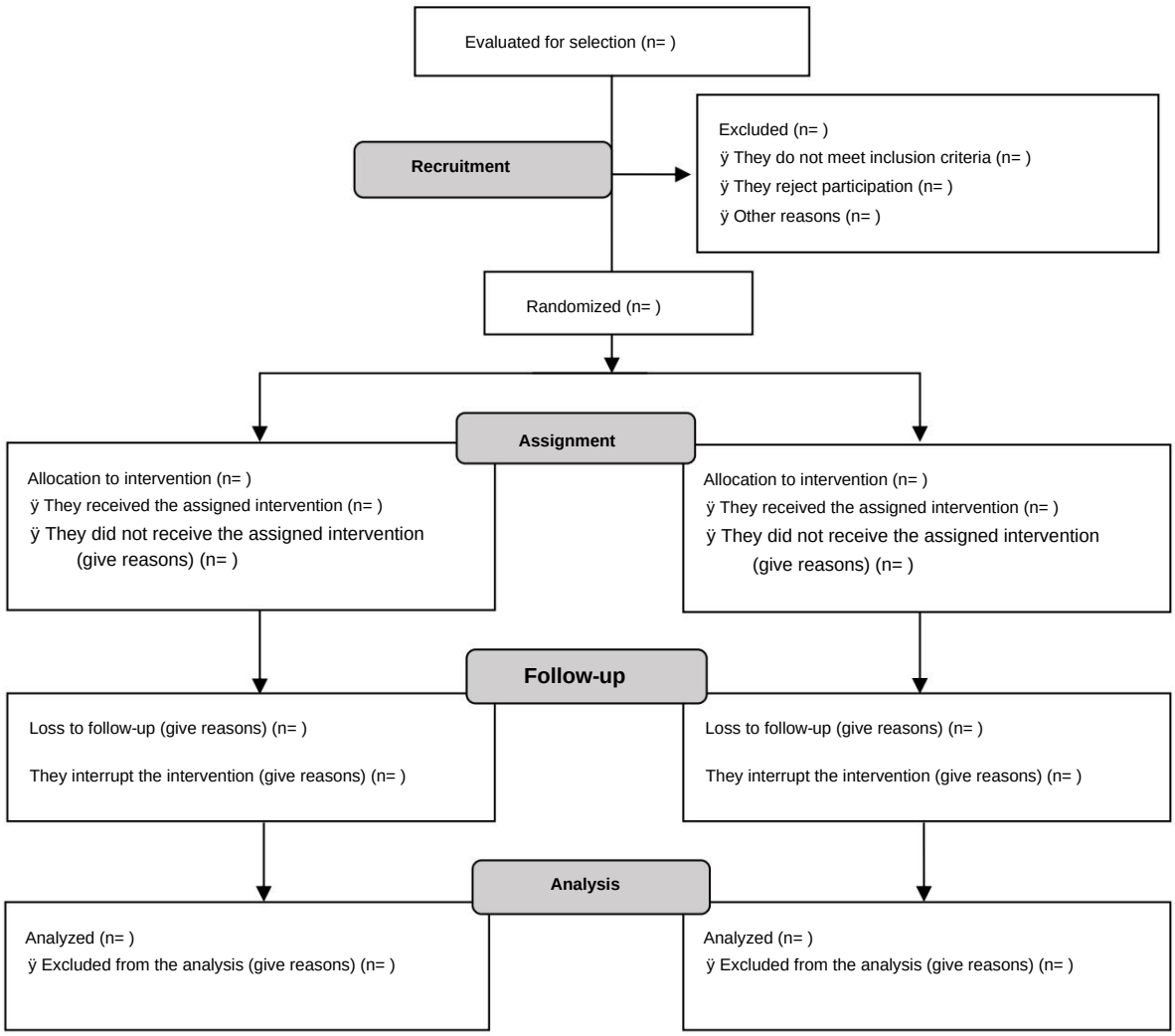
3. FLOW OF PARTICIPANTS

I. Name of the Study Period	
1. Recruitment	
1.1.Number of participants evaluated for selection	
1.2.Number of excluded participants	
ÿ Number of participants who do not meet inclusion criteria ÿ	
Number of participants who refuse participation	
ÿ Number of participants excluded for other reasons	
1.3. Detail reasons why they were excluded.	
Reason 1……	

Reason 2……			
Reason n……			
1.4.Number of participants enrolled in the study			
2. Randomization			
2.1.Number of randomized participants			
2.2.Number of arms or groups of the study			
Based on what was entered, complete the information requested below for each arm:			
	Group 1	***Group 2***	***Group n***
2.3.Name of the arm or group			
2.4.Description of the intervention *(Details about the intervention [may be, for example: dose, dosage form, frequency, duration])*			
2.5.Number of participants assigned to the intervention			
ÿ Number of participants who received the intervention			
ÿ Number of participants who did not receive the intervention			
Detail reasons:			
Reason 1……			
Reason 2……			
Reason n……			
3. Follow-up 3.1.			
Number of participants lost to follow-up			
Detail the reasons for loss to follow-up			
3.2.Number of participants interrupt the intervention			
Detail reasons for the interruption: Reason 1 ……			
Reason 2……			
Reason n……			
4. Analysis			
4.1.Number of participants analyzed			
4.2.Number of participants excluded from the analysis			
4.3.Detail reasons for exclusion			
Reason 1……			
Reason 2……			
Reason n……			

The following graph must be attached, if available:

PARTICIPANT FLOW CHART



4. BASELINE CHARACTERISTICS	
4.1. GENERAL DATA	
1. Total number of participants in the Baseline	*(Total number of units analyzed)*
2. Number of arms or groups	*(Enter number of study arms)*
3. Number of variables in the baseline	
Based on what was entered, complete the information requested below for each arm:	
4.2. AGE VARIABLE	
4. Variable name	**Age**

5. Description of the analysis population in the Baseline *(If necessary, for example whether or not the pediatric population was included, age ranges for the study, etc.)*					
6. Total number of participants corresponding to the group (Baseline)		***Group 1***	***Group 2***	***Group n***	***Total***
AGE AS A CATEGORICAL VARIABLE					
7. Number of participants per category corresponding to the group	**ÿ 18 years**				
	18 – 65 years				
	ÿ 65 years				
8. Unit of measurement	Participants				
AGE AS A CONTINUOUS VARIABLE					
Item		***Group 1***	***Group 2***	***Group n***	***Total***
9. Summary measure *(Select summary measure to be used:* ☐ *Mean* ☒ *Median* ☐ *Least Squares Mean* ☐ *Geometric mean*					
10. Dispersion measurement *Select dispersion measure to be used:* ☐ *Standard deviation* ☒ *Interquartile range* ☐ *Total range*					
11. Unit of measurement					
AGE, ANOTHER CATEGORIZATION					
Item		***Group 1***	***Group 2***	***Group n***	***Total***
12. Number of participants per category corresponding to the group	**Category 1 title**				
	Category 2 title				
	Category title n				
13. Unit of measurement					
4.3. VARIABLE SEX					
14. Variable name		**Sex**			
15. Description of the analysis population in the Baseline		*(Complete tables only when the study included both sexes, otherwise indicate it in the description)*			
Item		***Group 1***	***Group 2***	***Group n***	***Total***
16. Number of participants per category corresponding to the group (Baseline)	Female				
	Masculine				
17. Unit of measurement	Participants				
4.4. OTHER CONTINUOUS VARIABLES *Enter information for each additional continuous variable*					
18. Variable name					
19. Description of the analysis population in the Baseline					
Item		***Group 1***	***Group 2***	***Group n***	***Total***
20. Summary measure *(Select summary measure to be used:* ☐ *Mean* ☒ *Median* ☐ *Least Squares Mean*					

☐ *Geometric mean*					
21. Dispersion measurement *Select dispersion measure to be used:* ☐ *Standard deviation* ☐ *Interquartile range* ☐ *Total range*					
22. Unit of measurement					

4.5. OTHER CATEGORICAL VARIABLES

Enter information for each additional continuous variable

23. Variable name					
24. Description of the analysis population in the Baseline					
Item		***Group 1***	***Group 2***	***Group n***	***Total***
25. Number of participants per category corresponding to the group.	**Category 1 title**				
	Category 2 title				
	Category title n				
26. Unit of measurement					

5. MEASUREMENT OF RESULTS

5.1. ASSESSMENT CRITERIA(S)

27. Type of evaluation criterion	☐ Primary ☐ Secondary Other: ……☐……..
A table must be generated for each assessment criterion and complete the following information:	
28. Name of the evaluation criterion *According to evaluation criteria indicated in the protocol (outcomes)*	
29. Description of the endpoint *(Brief description of outcome measure)*	
30. Period of time in which the measurement was carried out *As stated in the protocol*	
31. Description of the analyzed population *(Type of analysis population)*	
32. Number of arms or groups considered for analysis	

Enter information for each arm or group according to the following table (a table must be generated for each arm or group and according to each endpoint

33. Name of primary endpoint			
34. Description of the endpoint *(Brief description of outcome measure)*			
35. Period of time in which the measurement was carried out *As stated in the protocol*			
36. Description of the analyzed population (Type of analysis population)			
37. Number of groups considered for analysis			
38. Title of the arm or group	***Group 1***	***Group 2***	***Group n***
39. Description of the arm or group *(Details about the intervention [may be, for example: dose, dosage form, frequency, duration])*			
40. Total number of participants analyzed in the arm or group			
41. Summary measure type *Select measure:*	☐ *Mean* ☐ *Median* ☐ *Least squares mean* ☐ *Geometric mean*		

		☐ Number Percent ☐					
42. Dispersion/precision measurement *Select measure:*		☐ Does not apply ☐ Standard deviation ☐ Standard error ☐ Interquartile range Total range ☐ Confidence interval: ……% ☐ Geometric variation coefficient)					
		Group 1		***Group 2***		***Group n***	
43. Measurement value summary	**44. Value of dispersion/precision**						
45. Apply categories	Category 1 title						
	Category 2 title						
	Category title n						
46. Unit of measurement							

5.2. STATISTIC ANALYSIS

1. Description of the statistical analysis		
2. Comparison groups		
3. Type of statistical test	☐ *Superiority* ☐ *Non-inferiority* ☐ *Equivalence*	☐ *Other (for example, single group or other descriptive analysis)*
In case of selecting Non-inferiority or Equivalence:	*Power calculation or other key information:*	
	Definition of the non-inferiority margin/ equivalence margin	
4. Hypothesis Testing	*p value:*	
	Statistical test used:	
5. Estimation method	*Measurement of effect:*	*For example Hazard ratio, Mean difference, Odds Ratio, Relative risk, etc.*
	Estimated value:	
	Confidence interval:	*It must include the level expressed as a percentage: Eg 95%, 99%* *Number of queues: 1 or 2 queues . Lower limit . Upper limit*
	Dispersion type	☐ *Standard deviation* ☐ *standard error of the mean*
	Dispersion value	
6. Other type of statistical analysis:		*Provide a description and results if statistical analysis cannot be presented using the above items.*

6. ADVERSE EVENTS

1. Time period			
2. Description of the report of adverse events	*Additional pertinent information about the collection of adverse events or how the analysis population was determined.*		
3. Arm/Group Title	***Group 1***	***Group 2***	***Group n***
4. Description of the Arm/Group			

6.1. SERIOUS ADVERSE EVENTS

	Group 1			***Group 2***			***Group n***		
1. Total according to group	*No. affected*	*No. at risk*	*Number of events*	*No. affected*	*No. at risk*	*Number of events*	*No. affected*	*No. at risk*	*Number of events*

2. Term of the EAS									

6.2. MORTALITY FROM ALL CAUSES

	Group 1		***Group 2***		***Group n***	
1. Total according to group	*No. affected*	*No. at risk*	*No. affected*	*No. at risk*	*No. affected*	*No. at risk*

6.3. OTHER ADVERSE EVENTS (NOT SERIOUS)

1. Time period 2. Description	*Complete if it is different from what was previously indicated*								
of the adverse event report	*Complete if it is different from what was previously indicated*								
3. Arm/Group Title	***Group 1***			***Group 2***			***Group n***		
4. Description of the Arm/Group									
5. Frequency of occurrence threshold (0-5%) **....%**	***Group 1***			***Group 2***			***Group n***		
	No. affected	*No. at risk*	*Number of events*	*No. affected*	*No. at risk*	*Number of events*	*No. affected*	*No. at risk*	*Number of events*
6. Total									
7. End of the adverse event									

7. PERSON RESPONSIBLE FOR THE INFORMATION REGISTRATION.

☐ On behalf of the study sponsor, I confirm that this report accurately describes the conduct and results of the study. I also certify that the information contained herein is true and accurate.