1. INTRODUCTION

A brief summary of the status of each study in progress and each study completed during the previous year. The summary is expected to include the following information for each study.

2. RESEARCH PRODUCT

2.1. Pharmacological group and mechanism of action

2.2. Therapeutic indications

Indicate the indications of the product under investigation

23. Formulation and route of administration

2.4. Investigational dosage

Indicate the doses of the investigational product that are being studied

3. ESTIMATION OF CUMULATIVE EXPOSURE FROM CLINICAL TRIALS

Indicate the number of patients who are receiving treatment with the investigational product, during ongoing studies and all studies previously carried out.

4. MARKETING AUTHORIZATION STATUS

A brief summary of marketing developments with the drug over the past year, such as marketing approval in any country, withdrawal or discontinuation of marketing in any country.

5. GENERAL SUMMARY OF THE SECURITY ASSESSMENT

A brief summary of the risk-benefit assessment presentation should include the following information:

5.1.Adverse events: Frequent and serious

A narrative or tabular summary showing the most common and severe adverse experiences across the body system. The presentation example table is shown

Table 5.1.1 Adverse events (Classification according to MedDRA)

body system	N(Quantity) Incidence (%)	
Blood and lymphatic system disorders		
Cardiac disorders		
Hepatobiliary disorders		
Infections and infestations		

5.2. Deaths of study subjects

A list of subjects who died during participation in the research, with the cause of death for each subject, is shown in the example table:

Table 5.1.2. List of deaths during the study

Treatment group	Study Subject Cause of Death		Date

5.3. Results of subjects who withdrew or did not continue in the clinical trial due to serious adverse events or serious adverse reactions to the investigational product A list of subjects who withdrew during the course of the investigation
in association with any adverse experience, thought to be related to the product or not. in research

6. SUMMARY OF IMPORTANT RISKS

A narrative summary or tabular list of identified and potential risks, those that could lead to warnings, precautions or contraindications on labeling, detailing: ongoing and resolved risks

Table 6.1.1 Summary of important risks

Identified risks	Resolution State
	In progress
	Resolved
Potential risks	Resolution State
	In progress
	Resolved

7. ACTIONS TAKEN FOR SECURITY REASONS

A narrative or tabular summary of the measures taken for safety reasons during the reporting period, by the sponsor or OIC or regulatory authority, institutional ethics committee, etc.

7.1. Modifications to the Protocol

Description of any significant modification to the Phase 1 protocol, during the previous year and not previously reported.

7.1. Modifications to the Investigator's Manual

If the investigator's manual has been revised, a brief review of the modifications should be performed

8. **CONCLUSIONS**

Brief summary of the most relevant conclusions after the development of the executive summary

9. **Presentation of the Annual Security Report (DSUR)**

The annual security report (DSUR) is presented at the OGITT-INS offices on an optical device or similar which must be in English and Spanish.