ÿ OBJECTIVE	Establish the requirements for the presentation of the information that the Partial Technical Report of the study must contain.
ÿ RANGE	Any individual or legal entity that intends to submit a Partial Technical Report.
ÿ RESPONSIBILITIES	Sponsors, Contract Research Organizations, Research Centers and Principal Investigator.
ÿ DESCRIPTION OF ACTIVITIES	The report will be submitted by submitting a "Free Writing" under the homoclave "ES45".
ÿ PRESENTATION OF THE INFORMATION	Based on NOM-012-SSA3-2012, it establishes that as part of the progress and closure of the clinical investigation, the Partial Technical Report of the study must be submitted, therefore the following duly completed format must be submitted.

FORMAT FOR ENTRY OF THE PARTIAL TECHNICAL REPORT			
1. Study data.			
Company Name/Promoter: (current before this Honorable Commission)			
Sponsor: (current before this H. Commission)			
Title of the Protocol of Investigation:			
Protocol Number:		Acronym (if applicable, Approved)	

		by this H. Commission):	
Study start date (local level): _____		General status of the study (Phase, period or stage of the study: Not yet recruiting, Recruiting, Active not recruiting, Suspended, Premature closure, Completed, Withdrawn)1 :	
Number of subjects enrolled globally (must match the number of subjects enrolled) approved in the initial driving authorization of the protocol or in the respective modification amendment that approves the change in the sample size):		Number of subjects enrolled locally (Must match the number of subjects enrolled mentioned in section 2 and the initial protocol authorization or the respective modification amendment approving the change in sample size):	
Date of first enrollment (locally): _____		Study cut-off date (locally. DD/MM/____ YYYY format): _____	

1Not yet recruiting: The study has not started recruiting subjects.

Recruitment: The study is currently recruiting participants.

Actively not recruiting: The study is ongoing and participants are receiving an intervention or being screened, but potential participants are not currently being recruited or enrolled.

Suspended: The study was stopped early, but can be started again.

Premature closure: The study was stopped early and will not restart. Participants are no longer being tested or treated.

2. Participating Research Centers.								
Center *	Status of the Center of Investigation (Active/Inactive-	No. Authorization Letter/ Inclusion	No. Closure Notification Letter (If still active, enter N/A)	Company Name Center of Research (coinciding with the registered one)	Name of the Researcher Principal (coincident with the	Research subjects		
						Recruited	Enrolled	Concluded

	closed)			(in authorization)	registered in the authorization)			
1								
2								
3								
4								
					TOTAL SUBJECTS:			

*List all research centers authorized for the clinical study.

3. Amendments and Modifications authorized during the development of the study.			
Document, Document Version Number and Date	Authorization Letter Number	Authorization Date	Date of implementation at the local level

4. Partial technical-descriptive reports (Annex I. Include letters of response to the partial/annual technical-descriptive reports prepared):		
Free Writing Number (ES45)	Date of response by this H. Commission	Reporting period (Start date DD/MM/YYYY – Cut-off date DD/MM/YYYY)

5. Materials and methods
Submit the current schedule of activities of the latest version of the research protocol approved by this H. Commission, which refers to the description and evaluation of the study procedures.

6. Summary of EA Reports identified during the development of the study (*Annex I. Include the simple copy of the response letters (or the simple copy of the CIS entry slip) of the EA Reports) issued by the CNFV, corresponding to the reports made).		
EA's and unexpected or expected security issues written under the terminology _____ MedDRA	Shipping identification number to VIGIFLOW or e-Reporting	Severity of AEs (GRAVE / NO GRAVE)

7. Bibliographic References (Only those that served as a basis for planning and executing the research)
NOTE: If there are no additional references to the protocol, only refer to the version of the protocol approved in the initial authorization to conduct the clinical study or in the respective amendment that approves the change to said document.

8. Annexes. The following Annexes must be submitted:	
*Annex I.	Include a simple copy of the CIS Entry Form for the Free Document Notification of Safety Event(s) (submitted to the National Pharmacovigilance Center (CNFV)); and a simple copy of the Authorization Letter for the respective Safety Amendment (code COFEPRIS-09-012), where applicable.
Annex II.	Simple copy of the Technical Sheet of the National Registry of Clinical Trials (RNEC), duly completed and in its entirety (except for the section referring to results, which must be presented when submitting the Final Technical Report).
Annex III.	A simple copy of the Letter of Delegation of Responsibilities signed by the Principal Investigator, which was submitted with the initial authorization process for conducting the Research Protocol and/or Inclusion of a Research Center. It should be noted that, in the event that any modification has been made to the research team, a simple copy of the amendment/modification letter (homoclave COFEPRIS-09-012) must be attached, authorizing the modifications to the study team, in accordance with the requirements established in the AGREEMENT that modifies the various agreement by which the procedures and services are made known, as well as the formats applied by the Ministry of Health, through the Federal Commission for the Protection against Sanitary Risks, registered in the Federal Registry of Procedures and Services of the Federal Commission for Regulatory Improvement, published on January 28, 2011 and its modification of July 1, 2013.
Annex IV.	Include Patient Materials (documents that do not require authorization by COFEPRIS, but which are acknowledged and are the same ones that were approved by the evaluation committees) generated from the authorization of the conduct of the protocol until the conclusion of the clinical study.
Annex V.	A simple copy of the letters signed and sent by the Research Ethics Committee, the Research Committee, and the Biosafety Committee (as applicable) of each center where the study is being conducted, including notification or acknowledgment of receipt of the annual activity report from each research center.
Others Attachments	According to section 7.4.1.6 of NOM-012, the researcher may enter any "Annexes" that he or she deems necessary to support the technical-descriptive report or those required by the institution or establishment where the research is being conducted. In this section, you must indicate which and how many annexes are being attached to this form.

ÿ INTERNAL REVIEW OF YOUR APPLICATION

Once the application has been submitted, the CIS will assign you an entry number with the homoclave "ES45", along with the corresponding slip, which you must retain for any follow-up and to collect your response ("ACKNOWLEDGMENT OF RECEIPT" OF THE INFORMATION SUBMITTED). The acknowledgment of receipt of the submitted information should not be construed as authorization.