ÿ OBJECTIVE	Establish the requirements for the presentation of the information that the Partial Technical Report of the study must contain.
ÿ SCOPE	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 code "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 research, the Partial Technical Report of the study must be presented, therefore the following duly completed format must be presented.

FORMAT FOR SUBMITTING THE PARTIAL TECHNICAL REPORT			
1. Study data.			
Company Name/Proponent: (valid before this H. Commission)			
Sponsor: (current before this H. Commission)			
Title of the Protocol 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or stage of the study: Not yet recruiting, Recruiting, Active not recruiting, Suspended, Premature closure, Completed, Withdrawn)1 :	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 authorization to conduct the protocol or in the respective amendment that approves the change in sample size):		Number of subjects enrolled locally (This must match the number of subjects enrolled mentioned in section 2 and the initial protocol authorization or the respective amendment approving the change in sample size):	
Date of first enrollment (at the local level):		Study cut-off date (at the local level. Format DD/MM/YYYY):	

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

Recruitment: The study is currently recruiting participants.

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

Suspended: the study was stopped early, but can start again.

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

2. Participating Research Centers.

Center *	Status of the Center Investigation (Active/Inactive-	No. Authorization Letter/ Inclusion	No. Closure Notification Letter (If still active, enter N/A)	Company Name of Center Investigation (coinciding with the recorded	Name of the Researcher Major (coinciding with the	Research subjects		
						Recruited	Enrolled	Completed

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

*List all authorized research centers for the clinical study.

3. Amendments and modifications authorized during the development of the study.			
Document, Version Number and Document Date	Authorization Letter Number	Authorization Date	Local implementation date

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

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

6. Summary of EA Reports identified during the development of the study (*Annex I. Include a simple copy of the response letters (or a 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 problems written under the terminology MedDRA	VIGIFLOW shipment identification number or e-Reporting	Severity of the EA's (SERIOUS / NOT SERIOUS)

7. Bibliographic References (Only those that served as the basis for the planning and execution of 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 Slip of the Free Letter of Notification of Security Event(s) (submitted to the National Center for Pharmacovigilance (CNFV)); and a simple copy of the Authorization Letter of the respective Security Amendment (COFEPRIS-09-012 code), when applicable.
Annex II.	A simple copy of the Technical Data 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 in the submission of the Final Technical Report).
Annex III.	Simple copy of the Letter of Delegation of Responsibilities signed by the Principal Investigator, which was submitted with the initial authorization process for the Research Protocol and/or Inclusion of Research Center. It should be noted that, in case any modification has been made to the research team, a simple copy of the amendment/modification letter (COFEPRIS-09-012) authorizing the modifications to the study team must be attached, in accordance with the requirements established in the AGREEMENT that modifies the one that makes known the procedures and services, as well as the formats applied by the Ministry of Health, through the Federal Commission for 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 as those approved by the evaluation committees) generated from the authorization of the protocol's execution 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 implemented; in which the notification or acknowledgment of receipt of the annual activity report of each research center is referred to.
Others Annexes	According to section 7.4.1.6 of NOM-012, the researcher may include any "Annexes" they deem necessary to support the technical-descriptive report, or those required by the institution or establishment where the research is conducted. In this section, you must indicate which annexes and how many 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 code "ES45", along with a corresponding slip, which you must keep 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 interpreted as authorization.