AIM	Establish the requirements for the presentation of the information that the Final Technical Report of the study must contain.
RANGE	Any individual or legal entity that intends to submit a Final Technical Report of the study.
RESPONSIBILITIES	Sponsors, Contract Research Organizations, Research Centers and Principal Investigator.
DESCRIPTION OF ACTIVITIES	The report will be submitted by submitting a "Free Writing" under the homoclave "ES45".
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 Final Technical Report of the study must be submitted, therefore the following duly completed format must be presented.

FORMAT FOR ENTRY OF THE FINAL 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start date (local level): _____		**Overall study status (Phase, period or stage of the study: Early closure, Completed, Withdrawn)1 : Number of**	
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):		**subjects enrolled locally (Must coincide with the number of enrolled subjects mentioned in section 2 and with the initial protocol authorization or the respective modification amendment approving the change in sample size):**	
Date of first enrollment (locally): _____		**Date of last visit of the last subject who completed the study (locally):** _____	

1Premature termination: The study was stopped early and will not restart. Participants are no longer being tested or treated.

Completed: The study has ended normally and participants are no longer being examined or treated (i.e., the last participant's last visit has occurred).

Withdrawn: The study was stopped before enrolling its first participant.

2. Participating Research Centers.

Center *	Status from the Center of Investigation (Active/Inactive-closed)	No. Authorization/ Inclusion Letter	No. Closure Notification Letter (If still active, enter N/A)	Company Name of the Center Research (coinciding with the one registered in authorization)	Name of the Researcher Principal (matching the one registered in the authorization)	Research subjects		
						Recruited	Enrolled	Concluded
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, Version Number and Date of the Document	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	Reported period (dd/mm/aaaa to dd/mm/aaaa)

5. Materials and methods

Submit the current schedule of activities of the latest version of the research protocol approved by this H. Commission where the description and evaluation of the study procedures are referred to.

6. Summary of EA Reports identified during the development of the study (Annex I. Include a simple copy of the response letters issued by the CNFV, corresponding to the annual reports made).		
Unexpected or expected AEs and safety issues drafted under MedDRA terminology	Shipment identification number to VIGIFLOW o e-Reporting	Severity of the AE's (SEVERE / NON-SEVERE)

7. Submit the synopsis/report of the clinical study with the main results of the development of the research (efficacy, safety, tolerability, immunogenicity, etc.), attaching the corresponding analysis and interpretation.

Note: The validity and/or veracity, as well as the use of the study results recorded in this form for purposes that are convenient for the user, is the responsibility of the principal investigator and the sponsor.

8. Conclusions

(Which should be written in accordance with the hypothesis(es) of the study, as well as with the objectives set out in the research project or protocol).

Note: The validity and/or veracity, as well as the use of the results and conclusions of the study recorded in this form for purposes convenient to the user, is the responsibility of the principal investigator and the sponsor.

9. Bibliographic References

(Only those that served as a basis for planning and executing the research, as well as for the analysis of the results).

10. Annexes. The following Annexes must be submitted:	
Annex I.	Include a simple copy of the CIS Entry Form and the Final Safety Report Entry Form submitted to the National Pharmacovigilance Center (CNFV).
Annex II. Simple copy of the Technical Sheet of the National Registry of Clinical Trials (RNEC), duly completed and in its entirety.	
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.	Simple copy of the signed letters from the Research Ethics Committee, the Research Committee and the Biosafety Committee (as applicable) of each center where the study was implemented, in which it is specified that they are aware of the completion of the study.
Annex VI.	Letters signed by each principal investigator, notifying the completion of the study, the closure of the center's activities, and the conclusion and follow-up of the research subjects enrolled in their respective 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 homoclave "ES45", with its respective ticket, 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 information submitted should not be interpreted a	

as an authorization.