INFORME EJECUTIVO DE REALIZACIÓN DE VIAJES AL EXTERIOR

1- Datos del Evento		
1	Denominación	Estudios Post aprobación de fase IV en el contexto de vacunas aprobadas mediante procedimientos acelerados: Estudio de caso, Vacuna Chikungunya
2	Organización	CEPI - ANVISA
3	Objetivo	Presentar y actualizar a los reguladores sobre los recientes desarrollos y procesos regulatorios en el otorgamiento de licencias de vacunas contra el Chikungunya, y abordar el diseño, viabilidad y realización de estudios posteriores a la aprobación para que las Autoridades Reguladoras estén preparadas en caso de solicitudes de autorización de comercialización por parte de los desarrolladores de vacunas contra el Chikungunya.
4	Fecha de realización	19 y 20 de marzo
5	Lugar (ciudad/país)	San Pablo/Brasil
6	Lugar de hospedaje	A confirmar
2- Datos de la persona autorizada		
1	Nombres y Apellidos	Leticia Marlene Ortiz Díaz
2	Cédula de Identidad Civil N°	4.668.029
3	Cargo	Evaluador Técnico de Departamento de Biológicos
4	Entidad/Dependencia donde presta servicios (Dirección/Departamento)	DINAVISA – Dirección General de Evaluación y Registros Sanitarios/Dirección de Medicamentos
3- Costos		
1	Fecha de salida y Fecha de retorno	18/03/2025 21/03/2025
2	Costo de Pasaje	Por cuenta de la organización
	Costo de Viático	Por cuenta de la organización
4	Costo de refuerzo de viático	1.319.552 Gs.
5	Costo total del viaje	A determinar por cuenta de la organización
4- Pertinencia		
1	Correspondencia entre el objetivo del evento y las funciones desempeñadas por el solicitante	Si, debido a las funciones realizadas para la aprobación del registro sanitario de vacunas en el país.
2	Carácter de la participación (p. ej.: expositor)	Participante
3	Resolución que autoriza el viaje	Resolución DINAVISA N°76/2025
5- Información Complementaria		
	Se adjunta Programa.	

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CEPI

ANVISA
Agência Nacional de Vigilância Sanitária

Phase IV post-approval studies in the context of vaccines approved through accelerated procedures: Case study, CHIKUNGUNYA vaccines.

Purpose of the meeting:

Present and update regulators with the recent developments and regulatory processes in the licensing of chikungunya vaccines, and to address the design, feasibility and conduct of post-approval studies for the NRAs to be prepared in the event of requests for market authorization by chikungunya developers.

Draft Agenda

Day 1		
8:00-8:30	Registration of participants	30'
9:00-9:30	Opening remarks and general introduction of participants	30'
Introduction of chikungunya disease and epidemiology (1:15 hours)		
Purpose: Set the scene for chikungunya disease globally and regionally. Present the symptoms, disease, and treatment, case definition of chikungunya and diagnosis, and recent developments.		
9:30-10:45	Chikungunya disease: clinical and diagnosis	15'
	Epidemiology of Chikungunya disease: Global, Regional, country. (WHO, PAHO, Asia, Colombia, India, Kenya, Thailand) ()	45'
	Modelling of chikungunya disease (Henrik, Paraguay)	15'
10:45-11:00	Coffee break	15'
Immune correlates/surrogates (1:30 hour)		
Purpose: Conducting Phase 3 randomized clinical trials with disease outcomes is challenging with some vaccines, either because trials require very large sample sizes, or because of the unpredictability of outbreaks. This session will discuss generalities of the use of correlates of protection in the assessment of vaccine efficacy, how they can be applied, and how to identify a suitable model. While two national regulatory authorities will present how they have used the correlates (surrogate) of protection for the licensing of chikungunya vaccine, a panel of NRAs will discuss if this alternative is considered in their current regulations.		
11:00-11:20	Use of correlate of protection to assess vaccines (MHRA)	20'
11:20-11:50	Presentations of FDA and EMA on their use of correlates for Chik vaccine.	30'
11:50-12:30	Panel discussion of NRAs. (Selected NRAs to comment on validity of concept in their legal framework) (Colombia, Ghana, South Africa, Malaysia, Singapore)	40'
12:45-13:45	**Lunch**	60'

Outbreak protocols		
Purpose: Large outbreaks of Chikungunya may present an opportunity to generate evidence on efficacy / effectiveness of CHIKV vaccines. However, such outbreaks are unpredictable and may not provide sufficient time for trial set-up & implementation. This emphasizes the importance of advanced planning for an outbreak clinical trial. The session would focus on the development and feasibility for conducting outbreak studies and the various aspects involved in planning for such a study (e.g. pre-approved clinical trial protocols and other clinical trial documents, infrastructure and logistics)		
11:45-12:15	Design of an outbreak protocol	30'
12:15-13:00	Developing infrastructure for conducting outbreak study	45'
13:00-14:00	**Lunch**	60'
Use of chikungunya vaccines		
Purpose: A session will be held with potential users of the vaccine, representatives from NITAGs and RITAGs, where it is expected some of their concerns may be raised regarding properties of the vaccines, risk-benefit and country and regional priorities.		
14:00-15:00	Panel of RITAG and NITAG representatives to discuss probability of recommending use of chikungunya vaccines with data available (AMRO, AFRO, SEARO)	60'
Recommendations and conclusion (30 minutes)		
15:00-15:30	Recommendations and conclusion	30'