

AGENDA



DIRECCIÓN NACIONAL
DE VIGILANCIA SANITARIA

XX ENCUENTRO INTERNACIONAL DE
FARMACOVIGILANCIA
DE LA REGIÓN DE LAS AMÉRICAS

"Security without borders: The patient, our regional commitment"

23rd to 26th
september
2025



DIRECCIÓN NACIONAL DE
**VIGILANCIA
SANITARIA**
PARAGUAY

PAHO



Pan American
Health
Organization



World Health
Organization
Americas Region

AGENDA - XX INTERNATIONAL MEETING ON PHARMACOVIGILANCE OF THE AMERICAS.

Tuesday, September 23

National Meeting: Hotel Dazzler: Dazzler Hotel: Jacarandá Plenary Hall.

Uppsala Monitoring Centre workshop: Hotel Dazzler: Tajy A and Tajy B rooms.

TIME (GMT-3)	ACTIVITY	SPEAKERS
08:30 – 09:00	Participant Registration	
09:00 – 09:30	Opening of the II National Meeting on Pharmacovigilance and Technovigilance and XX International Meeting on Pharmacovigilance of the Americas. – Welcoming Address.	Ministry of Health Dr. Jorge Iliou Silvero DINAVisA Haydee Padilla PAHO/PY Robin Rojas PAHO/WDC
09:30 – 09:50	National Meeting National Surveillance System of Paraguay.	Oscar Allende DINAVisA - Paraguay
09:50 – 10:20	National Meeting Pharmacovigilance in Paraguay – Collaboration with the Pharmacovigilance Focal Points Network of the Americas	Cinthia Ojeda DINAVisA - Paraguay
10:20 – 10:50	National Meeting Use of Antimicrobials and Surveillance of Antimicrobial Resistance	Francisco Ovando General Directorate of Health Surveillance Hernán Rodríguez DINAVisA - Paraguay
10:50 a 11:15	Coffee break	
11:15 – 11:45	National Meeting Vaccine Pharmacovigilance: Management of Adverse Events Following Immunization (AEFI)	Iván Salas National Immunization Program Ministry of Public Health and Social Welfare – Paraguay
11:45 – 12:30	National Meeting Patient Safety at the “Niños de Acosta Ñu” General Pediatric Hospital	Héctor Castro “Niños de Acosta Ñu” General Pediatric Hospital Ministry of Public Health and Social Welfare – Paraguay
12:30 – 14:00	Lunch	
14:00 – 15:30	VigiLyze workshop. Part 1	UMC team: • Carlos Melgarejo • Elki Sollenbring • Mónica Tarapué • Jose Antonio Maza Larrea • Michele Fusaroli
15:30 – 15:45	Coffee break	
15:45 – 17:15	VigiLyze workshop. Part 2	UMC team
17:15 – 17:30	Closing remarks.	PAHO and Country Representatives

Wednesday, September 24:

International Meeting: Hotel La Misión. Main room.

TIME (GMT-3)	ACTIVITY	SPEAKERS
08:30 – 09:00	Participant registration.	
09:00 – 09:30	Welcoming Address and Start of activities of the XX International meeting of Pharmacovigilance of the Americas	Ninfa Ayala DINAVIS - PARAGUAY
09:30 – 10:00	“Connecting the Americas: Collaborative networks for medicine safety.”	Robin Rojas PAHO
10:00 – 10:30	Pharmacovigilance in Paraguay: New Regulations and Advances	Cinthia Ojeda DINAVIS - Paraguay
10:30 – 11:00	CIMLAC Network: Medicines Information Centers of Latin America and the Caribbean allied in the monitoring of safety and rational use.	Francisca Aldunate. ISP - Chile CIMLAC Network
11:00 – 11:30	Coffee break	
11:30 – 13:00	International cooperation in active surveillance: - Yellow fever. Protocol National Strategy for Active Surveillance of Adverse Events of Vaccines against FMD in Colombia. - Active surveillance of TB-Malaria. - Updates on vaccine safety in pregnant women Q&A	Coordinator: Diego Macías - PAHO William Saza Londoño INVIMA - Colombia Kelly Serrano DIGEMID - Perú Diego Macías PAHO
13:00 – 14:00	Lunch	
14:00 – 15:30	Roundtable: Passive surveillance of vaccine safety: - Technical strengthening in vaccination against yellow fever. - Operational interaction between pharmacovigilance and epidemiological surveillance for vaccine safety monitoring: The yellow fever case. - The role of the regulator in the preparedness and response of pharmacovigilance systems for health emergencies. Dengue and yellow fever experience - Detection and monitoring of vaccine safety signals in the context of a mass vaccination campaign. The example of mpox and dengue. - Need for data generation and use in epidemiological surveillance for vaccine safety surveillance: The case of the risk of EPAV due to the dengue vaccine.	Coordinator: Carolina Rancano - PAHO William Saza Londoño INVIMA - Colombia Katherine Rengifo Secretary of Health Tolima, Colombia (virtual) Flavia Alves ANVISA-Brasil Jadher Percio NIP- MOH Brazil Analía Cáceres CIM/PAHO
15:30 – 16:10	Coffee Break	

16:10-18:00	New challenges in interoperability and coding of ICSRs: • PAHO-IMT intro • AI Monitor: Artificial Intelligence Platform to Support ANVISA's Pharmacovigilance • National catalogs for the identification of vaccines in vaccination information systems using international standards in Latin America. • Interoperability and coding of ICSR. • SMART Guides for the Development of Digital Tools for ESAVI Surveillance. • Results of support to countries for sending reports to Vigibase. (10 minutes). • Country videos: Brazil, Chile, El Salvador, Guyana, Paraguay, Uruguay. Q&A Closing day.	Coordinator: Ana María Reyes - PAHO Flavia Neves ANVISA - Brasil Angie Arévalo PAHO-CIM (virtual). Salvador Alvarado Oficial Regional de Farmacovigilancia. UMC Daniel Rizzato. International Expert - Argentina (virtual) Ana María Reyes PAHO Participating Countries
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Thursday, September 25

International Meeting: La Misión Hotel. Main room.

TIME (GMT-3)	ACTIVITY	SPEAKERS
8:30 – 09:00	Participant registration.	
09:00 – 09:25	Global Strategy for Smart Pharmacovigilance.	Shanti Pal OMS (virtual)
09:25 – 09:45	Pharmacovigilance based on Artificial Intelligence.	Michele Fusaroli - UMC
09:45 – 10:45	Benefit-Risk Balance for Medicinal Products.	Claudia Ana Ianos CIOMS – WG Representative (virtual)
	Pharmacovigilance of potential drug abuse.	Maryse Lapeyre-Mestre Faculte de Medecine Universite de Toulouse (virtual)
	“Protocol presentation on estimation of Guillain-Barré syndrome background rates in the general population in low- and middle-income countries.”	Noha Iessa WHO (virtual)
10:45 – 11:00	Coffee break	
11:00 – 11:45	Route of the regulatory systems of the Region to levels 3 and 4 of maturity of the GBT and WLA. WLA processes. Good regulatory practices. Challenges for our Region. Country experiences: • ISP – Chile • ANVISA – Brasil • COFEPRIS – México • CECMED - Cuba	Robin Rojas PAHO Verónica Vergara ISP, Chile Flavia Alves ANVISA, Brasil Rogelio Ríos COFEPRIS, México Ismayr Alfonso CECMED, Cuba

11:45 - 12:15	Regulatory reliance and collaborative work in pharmacovigilance. Regional examples: Chile and Paraguay.	Gloria Giraldo Health Canada Verónica Vergara ISP - Chile Cinthia Ojeda DINAVISIA - Paraguay
12:15 - 13:15	Strategic partnership between NRAs and NIPs to strengthen vaccine safety. - Guidelines for the effective coordination of functions and roles between the national regulatory authority, the national immunization program, and other stakeholders involved in AEFI surveillance. (10 min). - Comprehensive management of ESAVI from research to regulatory action. WG presentations: Costa Rica, Cuba, El Salvador, Brazil, Mexico, Chile. (10 min). - Strategy for a vaccine safety surveillance network in Argentina. Próximos pasos (coordinador GT)	Coordinator: Carolina Rancano - PAHO Paola González COFEPRIS – México (WG Coordinator) (virtual) Xiomara Vega Ministerio de Salud-Costa Rica Ismary Alfonso CECMED, Cuba Flavia Alves ANVISA, Brasil Mariela Torres y Julia Gómez SRS, El Salvador (virtual) Gandi Rayon COFEPRIS, México (virtual) Alejandra Rodríguez ISP, Chile (virtual) Analía Cacérés CIM-PAHO Paola González COFEPRIS – México (WG Coordinator) (virtual)
13:30 – 14:30	Lunch	
14:00 - 15:45	Presentations on good pharmacovigilance inspection practices - El Salvador - Ecuador - Costa Rica - Bahamas - Belice - Guyana - Jamaica (virtual) Q&A	Coordinator: Gabriela Carrasco, PAHO Representantes de países: Marilyn Deleón SRS - El Salvador María José Zambrano ARCSA - Ecuador Xiomara Vega MOH - Costa Rica Gina Archer MOH -Bahamas Kristen Waight MOH - Belice Fayon Duncan GDD/FDA-Guyana Julie Anne Jemmot MOH -Jamaica (virtual).
15:45 - 16:00	Coffee break	
16:00 - 16:15	Notification of foreign regulatory action in signal detection and validation.	Gloria Giraldo Health Canada - Canadá

16:15 - 16:30	New Vaccine Pharmacovigilance Dashboard.	Diego Macías PAHO
16:30 - 17:00	Closing of the XX International Meeting on Pharmacovigilance of the Americas.	Robin Rojas - PAHO Representative PAHO - Paraguay Representative DINAVISA
17:00-18:00	Subregional meetings: English - Caribbean and Central America countries.	PAHO – Countries

Friday, September 26

Closed Meeting of the Pharmacovigilance Network.

La Misión Hotel. Main room

HORARIO	ACTIVIDAD	DISERTANTES
09:00 – 10:30	Closed Network Meeting – Review of ongoing projects. Review of ongoing projects: 1) NIP-NRA Coordination 2) GPFV Inspections 3) Signal management	Robin Rojas PAHO GT representantes: Rogelio Ríos COFEPRIS, México Marilyn DeLeón SRS-El Salvador Gloria Giraldo Health Canada
10:30 – 11:00	Coffee break	
11:00 – 12:00	Proposal of new projects and initiatives: • IT bridges • Active surveillance	PAHO consultants
12:00 – 12:30	Review of first year of coordination.	Cinthia Ojeda DINAVISA, Paraguay
12:30 – 13:30	Almuerzo	
13:30 – 15:30	Workshop: Risk Management Plans	Gloria Giraldo Health Canada Giset Jiménez López Expert-PAHO (virtual)
15:30 – 16:00	Coffee break	
16:00 – 17:00	UMC Workshop VigiLyze	UMC Team
17:00 – 17:15	Closing of the Pharmacovigilance Focal Points Meeting.	PAHO-DINAVISA