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### Pharmacovigilance Systems in Latin America for COVID-19 Vaccines Brazil, Chile, Costa Rica and Mexico

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One of the greatest challenges to pharmacovigilance in Latin America has been the sensitivity and willingness of the population, healthcare professionals and patients, to report adverse events. As vaccination has been one of the key instruments in combatting the COVID-19 pandemic, are these pharmacovigilance systems positively influencing this sensitivity and willingness to be an active part of the surveillance of these vaccines in this public health emergency.

The pharmacovigilance field in Latin-American works through four steps to examine whether the information obtained through these “real-life” (or real-world) reports is in accord with previous knowledge of these vaccines or if they present new relevant safety information that demands action: Analyze risk, understand risk, communicate risk, and mitigate risk. This article overviews the state of COVID-19 vaccinations and the systems established to analyze, understand, communicate, and mitigate their risk in Brazil Chile, Costa Rica and Mexico. e.g. Brazil.

As of the end of November 2021, an estimated 300 million doses of four available vaccines had been administered in Brazil. The National Drug Monitoring Center, which was established as part of the Brazilian regulatory agency ANVISA in 2001, conducts safety surveillance of these vaccines based on five operational pillars:

- Daily evaluation
- Signal detection

- Risk management plan
- Monthly executive summary of AEs
- Periodic quarterly benefit-risk assessment reports

Through these and other paths of action, Brazil, Chile, Costa Rica and Mexico have adapted current structures and created new ones to communicate relevant safety information to their respective populations with transparency and robustness to ensure that the benefits of COVID-19 vaccines continue to outweigh their risks. Therefore, thanks to these innovations and updates of pharmacovigilance systems, significant improvements have been achieved that transcend in building confidence in these tools that drug science has provided us to be able to deal with a pandemic such as COVID-19.

#### Speaker Biography

Josue Bautista Arteaga is a Pharmacist, his experience is mainly related with the Pharmacovigilance field: ICSRs, PSURs-PRBERs, Signal Management, Risk Management and Risk Minimization, Audits, Inspections, Legislations, Vendor and CRO management, Interaction with Independent PV Organizations, Regulatory Agencies as well as Pharmaceutical Chambers. As part of his PV career, he worked at GlaxoSmithKline, Merck Sharp & Dohme, and Pfizer. Founder of the Global Pharmacovigilance Society (GPS) as well Chairman for the AMERICAS region, in addition he is also member of the International Society of Pharmacovigilance (ISoP). Founder of “JBA Farmacovigilancia”, entity aims to build innovative scenarios to learn, share, apply and build knowledge in Pharmacovigilance across the LATAM region. Former president of the Mexican Drug Safety Society.

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