DIA

Latin America Annual Meeting

September 25-26 | Royal Tulip Brasília Alvorada Hotel

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Overview

DIA's 2024 Latin America Annual Meeting offers unparalleled opportunities for networking and knowledge sharing with key stakeholders to advance and implement life sciences R&D initiatives in Latin America and the Caribbean. This year, session tracks on Regulatory/Clinical, Safety and Pharmacovigilance, and Medical Affairs and Scientific Communications (MASC) expand the scope of the meeting, with cross-track sessions facilitating discussions on key connection points across these areas to promote collaboration and synergy within organizations.

Join the conversation on multi-regional cooperation, global harmonization, lessons learned, and best practices. Don't miss the chance to be part of this pivotal event, where innovation and cooperation come together to shape the future of healthcare in the region.

*The primary language is English, however translation in Spanish and Portuguese will be available during this meeting. **NOTE**: In order to utilize the translation in audio and/or written form you will need to bring your own device (cell phone, computer, tablet, etc.), headphones/ear buds and a portable charging device or cord.

Why You Can't Miss It

- Engage with a diverse range of sessions, including plenary and concurrent tracks, covering the most pressing topics in regulatory, clinical, safety, pharmacovigilance, and medical affairs
- Gain valuable insights from leading experts and key stakeholders who are driving initiatives and policies in the region
- Benefit from cross-track sessions that provide a holistic view of the interconnectedness of regulatory, clinical, safety, and medical affairs efforts
- Focused discussions on the unique challenges and opportunities in Latin America and the Caribbean, offering tailored solutions and strategies
- Build meaningful connections with peers, industry leaders, and policy makers to foster collaboration and drive innovation
- Obtain actionable knowledge and best practices that you can implement within your organization to enhance healthcare outcomes and regulatory practices
- Engage in sharing best practices with leading experts in an intimate and neutral setting
- Risk Evaluation and Mitigation Strategies (REMS)

Track Descriptions

Track A: Regulatory/Clinical

The regulatory/clinical track offers a platform for sharing information, case studies, and best practices specific to Latin America's regulatory environment, encompassing regulatory compliance, emerging trends, and innovative approaches in life sciences R&D. Furthermore, this track will delve into the intricacies of clinical research development and operations within the industry.

Track B: Safety and Pharmacovigilance

Explore the latest advancements and regulatory updates in clinical safety and pharmacovigilance for pharmaceutical products and medical devices within the dynamic landscape of Latin America. Our safety and pharmacovigilance track offer attendees a deep dive into essential topics, including best practices, case studies, and regulatory compliance strategies, ensuring a comprehensive understanding of this critical aspect of the life sciences industry.

Track C: Medical Affairs and Scientific Communications (MASC)

Dive into our Medical Affairs and Scientific Communications track, where you'll gain tangible insights into navigating this dynamic landscape. Elevate your role as a medical affairs and communication professional and stay ahead in today's rapidly evolving healthcare environment.

Who Should Attend

Professionals involved in:

- Academia
- Benefit-Risk Assessment and Communication
- Clinical Research and Development
- Clinical Operations
- CROs/Vendors
- Document Management/eSubmissions
- Drug Regulation
- Drug Safety/Pharmacovigilance
- Field Medical
- Global Submission/Project Management
- Government Affairs
- Manufacturing
- Medical and Scientific Affairs
- Medical Call Center Environment
- Medical Communications
- Medical Information
- Medical Product Safety Assessment
- Medical Writing
- Pharmacoepidemiology
- Policy and Intelligence
- Post-Market Studies
- Quality Assurance and Compliance
- Real-World Evidence
- Regulatory Agencies
- Regulatory Affairs, Operations, and Strategy
- Research and Development
- Risk Management, including Risk Evaluation and Mitigation Strategies (REMS)
- Strategic Sourcing/Planning

Learning Objectives

At the conclusion of this meeting, participants should be able to:

- Understand and distinguish key elements and strategies for strengthening regulatory systems
- Identify and analyze challenges, obstacles, and potential solutions or approaches in the implementation of Good Regulatory Practices (GRP) and the adaptation of ICH guidelines in Latin America
- Explore opportunities and strategies for collaboration among public, private, and academic sectors to advance regulatory agendas, promote regulatory harmonization, and foster knowledge and experience sharing among stakeholders
- Gain insights into the Pharmacovigilance and Technovigilance landscape in Latin America, including regulatory expectations, inspection trends, and opportunities for process alignment and improvement
- Identify and implement innovative techniques for presenting data effectively, evaluate various channels for data presentation, and explore decision-making practices necessary for the practical implementation of reliance models and risk prioritization
- Define AI and explore its practical applications in Medical Information (MI) activities, analyze real cases of AI implementation, and evaluate the digital landscape, including legal and compliance considerations related to AI and technology use
- Understand the importance of integrating the patient's perspective into pharma industry strategies
- Identify opportunities for e-labeling initiatives
- Recognize the significance of electronic Common Technical Document (eCTD) in regulatory submissions
- Discuss trends in Risk Management Plans (RMPs) and evaluate regional challenges and customization strategies for risk minimization
- Recognize international best practices in the regulation of rare diseases, including potential for evolving frameworks to facilitate access to innovative therapies

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DAY ONE | WEDNESDAY, SEPTEMBER 25		ROOM
7:30AM-6:30PM	Registration	Foyer, Outside Ballroom 1
7:30-8:15AM	Networking Breakfast	Ballroom 1 and 2
8:15-8:30AM	Welcome and Opening Remarks	Ballroom 3
8:30-9:45AM	Session 1 Plenary: **Regulatory System Strengthening: Updates on the Implementation of Good Regulatory Practices** This session will provide updates on Good Regulatory Practices in accordance with WHO guidelines, including the updates on the World Listed Authority (WLA), transitional WLAS status and the Global Benchmarking Tool (GBT) application. The objective of the session is to analyze current perceptions of key stakeholders regarding Good Regulatory Practices and their implementation in the regulatory field. The panel will include discussions regarding the challenges and obstacles identified in the implementation of Good Regulatory Practices and potential solutions or approaches to overcome them, also will identify existing opportunities for strengthening Good Regulatory Practices and improving the quality and safety of regulated products, both at the national and international levels. The discussions will facilitate the exchange of experiences and knowledge among regulators, industry, and other relevant stakeholders to promote collaboration and adoption of best regulatory practices, taking into account key elements of PAHO and WHO regulatory system strengthening.	Ballroom 3
9:45-10:30AM	Refreshments, Exhibits, and Networking Break	Ballroom 1 and 2
10:30AM-12:00PM	Session 2 Plenary: **Latin America in Perspective: Projects and Priorities from Key Stakeholders in the Region** This session will present and discuss the latest regulatory updates from national regulatory authorities from Latin America, including projects, priorities, and initiatives in the short and medium term, in the area of pharmaceutical and medical devices. It will be formatted as a panel discussion, where regulators will provide insights on some pre-defined topics of general interest, before interacting with the audience. The objective is to promote active engagement of various stakeholders involved in regulation, such as industry, healthcare professionals, and civil society organizations, to foster constructive dialogue and address regulatory challenges in the region.	Ballroom 3
12:00-1:00PM	Luncheon, Exhibits, and Networking Break	Ballroom 1 and 2
1:00-2:30PM	Session 3: Track A: **Exploring the Present and Future of Regulatory Cooperation, Collaboration and Convergence** Regulatory collaboration and cooperation are becoming increasingly important, given the growth in regulatory procedures related to innovative therapies, or with post-registration changes and limited resources. In this session, we will learn about agreements and experiences; we will also discuss harmonization efforts, plans and challenges in the Latin American region, explore issues related to regulatory harmonization, resource allocation, and overcoming regulatory disparities among countries. Examine the role and contribution of various sectors, including industry and academia, in the evolution of ICH standards. Discuss how collaboration between regulatory agencies and these sectors can enhance the development and implementation of effective regulatory frameworks. Track B: **Challenges, Practices, and Governance in Pharmacovigilance and Technovigilance: Harmonization Efforts in Safety** The session will cover various important topics related to pharmacovigilance (PV) and technovigilance. It will provide an overview of the current legislations in place for these fields, highlighting the roles of both ICH and non-ICH members. Participants will also be informed about the ongoing PV harmonization projects aimed at enhancing global safety monitoring systems. The session will include discussions on the influential role of UMC (Uppsala Monitoring Centre) and its active participation in the field. Furthermore, the session will shed light on the electronic transmission of safety information, ensuring efficient and timely exchange of data. The IMDRF framework and regional initiatives will be explored in the context of improving pharmacovigilance and technovigilance practices. Lastly, the session will emphasize the importance of reliance in pharmacovigilance and technovigilance, promoting trust and collaboration among stakeholders to ensure the safety of medicines and medical devices.	Ballroom 3 Room MN

	Track C: Communicating Science, End-to-end Messaging and Storytelling: Innovative ways to Present Data Translating data into valuable stories for internal and external customers is one of the biggest challenges in Medical Information. This session offers a comprehensive exploration of effective data communication strategies within the pharmaceutical industry. Participants will delve into diverse channels for data presentation, from traditional to digital platforms, and discover innovative data visualization techniques and storytelling methods to enhance engagement. The session also provides valuable insights into regional medical information operations, including case studies on challenges, successes, and tailored strategies. Engage in interactive discussions and leave with key takeaways to implement in your professional endeavors.	Room GH
2:30-3:15PM	Refreshments, Exhibits, and Networking Break	Ballroom 1 and 2
3:15-4:30PM	Session 4:	
	Track A: Empowering Reliance: Tools and Insights for Enhanced Regulatory Practices Attendees will gain insights on how to ensure 'product sameness' and discuss all relevant aspects to be considered, for example, same qualitative and quantitative composition, strength, pharmaceutical form, intended use, manufacturing process, suppliers of active pharmaceutical ingredients, and quality of excipients. The use of documents such as Public and Unredacted Assessment Reports and Certificates of Pharmaceutical Products (CPP) as tools to guide reliance decision-making by regulatory agencies will be discussed. Additionally, the scope of reliance beyond marketing applications, sharing how local practices related to the testing of pharmaceutical products are changing with the use of reliance will be discussed.	Ballroom 3
	Track B: Pharmacovigilance Inspections in Latin America – Current Scenario, Expectations and Trends In this session, speakers will discuss the current scenario for Pharmacovigilance Inspections in Latin America, considering the main concerns, trends and the expectations from the Regulatory Bodies for the Pharmacovigilance systems for the regulated sector.	Room MN
	Track C: Customer Engagement and Insights To make the Medical Information service available to more health professionals, not only Key Opinion Leaders (KOLs), it is essential to implement a multi-faceted approach. This can involve leveraging various channels and different professionals to act as internal ambassadors of medical information. Adapting communication styles for different stakeholders, including healthcare professionals (HCPs) and non-HCPs, is fundamental to effective medical information dissemination.	Room GH
4:35-5:50PM	Session 5:	
	Track A: Management of Product Lifecycle: Challenges and Suggested Solutions In this session, participants will gain a comprehensive understanding of the challenges and constraints caused by delays in the implementation of PACs (post-approval changes) in the pharmaceutical industry. The session will provide an in-depth analysis of the impact on the supply of medicines to patients and explore suggested solutions to develop processes for implementing changes efficiently. Participants will also have the opportunity to identify and discuss the opportunities and challenges faced by regulators and the industry in implementing reliance, particularly in the context of PACs. Additionally, the session will delve into the effect of regulations on global PACs registration strategies, allowing attendees to develop a strategic approach to navigate this complex landscape.	Ballroom 3
	Track B: New Era for Signal Detection In this session, we will Navigate the new era of pharmacovigilance, exploring innovations in signal detection across various sources and products. We will discuss the impact of innovative signal detection approaches on patient safety.	Room MN
	Track C: Innovation in Artificial Intelligence (AI) and Technology for MASC This session will dive into the realm of AI and technology applications in the medical information landscape. Participants will explore the definition and practical applications of AI in daily activities, examine real cases from Latin America, assess the trending digital landscape, and discuss how Medical Information (MI) can leverage technology advancements. Legal and compliance considerations will also be addressed to ensure ethical and regulatory adherence in the evolving technological landscape of medical information.	Room GH
5:50-6:50PM	Networking Reception	Ballroom 1 and 2

DAY TWO | THURSDAY, SEPTEMBER 26		ROOM
7:30AM-4:00PM	Registration	Foyer, Outside Ballrooms 1
7:30-8:15AM	Networking Breakfast	Ballroom 1 and 2
8:15-9:30AM	Session 6 Plenary: **Advancements in Patient Safety and Centricity in the Pharmaceutical Industry: Empowering and Engaging Better Healthcare** Effective communication strategies with patients are crucial to combat misinformation, enable stakeholders to make informed decisions, and enhance their experience with medicinal products. By providing accurate and clear information, addressing concerns, and promoting health literacy, patients can be empowered to take an active role in their healthcare.	Ballroom 3
9:30-10:15AM	Refreshments, Exhibits, and Networking Break	Ballroom 1 and 2
10:15-11:30AM	Session 7:	
	Track A: **The Future of Regulatory Submissions: CTD, eCTD, and Cloud-based Systems** In this session, speakers will discuss the future vision and potential enhancements of CTD and eCTD for regulatory submissions. The session will explore advancements in technology and best practices that can further improve the effectiveness and acceptance of these formats. Participants will also have the opportunity to recognize the importance of digital ways of work including eCTD implementation, without ignoring the different challenges and numerous advantages.	Ballroom 3
	Track B: **Risk Management and Communication as a Cornerstone of Safety Strategy** Engage in a strategic dialogue on risk management and communication as the cornerstone of safety strategy. This session focuses on driving safety initiatives through clear communications and risk management and empowering teams with effective risk communication strategies and effectiveness measures.	Room MN
	Track C: **Areas of Focus and Skills: Training, Medical Information as a Strategic Partner and Internal Communication** Placing Medical Information (MI) as a strategic partner involves recognizing its potential to contribute to organizational goals and decision-making processes. By leveraging strategic data in a highly regulated environment, MI can become a valuable tool for generating insights and driving evidence-based decision making.	Room GH
11:30AM-12:30PM	Luncheon, Exhibits, and Networking Break	Ballroom 1 and 2
12:30-1:45PM	Session 8:	
	Track A: **Regulation of Medicinal Products for Rare Disease: Challenges and Opportunities** This session will discuss the need to adopt regulatory framework, pathways, and tools to allow for timely access to medicinal products for rare diseases. Attention will be drawn to regulatory tools to prioritize or expedite the assessment and registration of treatments benefitting patients with rare diseases in Latin America. A discussion of international best practices and regional trends in the regulation of treatments for rare diseases, and how to bridge regulatory gaps through fostering discussions among regulators and industry representatives, will also be covered.	Ballroom 3
	Track B: **Technological Advancements and Data Utilization Opportunities in Pharmacovigilance** In this session, speakers will discuss the current scenario for technological advancements and how it can support pharmacovigilance operational activities. Within this scenario, data utilization opportunities and limitations will also be discussed and explored from a pharmacovigilance point of view, considering opportunities for business and regulatory submission.	Room MN
	Track A: **Outsourcing Clinical Operations, Hybrid Model Approach in Clinical Trial Execution** This session will explore the hybrid model approach to outsourcing clinical operations in clinical trial execution. Participants will gain insights into the benefits and challenges of combining in-house and outsourced resources to optimize clinical trial efficiency and effectiveness. Real-world examples and best practices will be discussed to highlight how this model can enhance flexibility, scalability, and quality in clinical operations.	Room GH
1:45-2:30PM	Refreshments, Exhibits, and Networking Break	Ballroom 1 and 2

2:30-3:45PM	Session 9 Plenary: **Fostering Regional Initiatives to Enhance Regulatory Capacity and Strengthen Health Systems** The session focuses on the rationale and importance of building regulatory capacity in the Americas to promote and protect public health. National regulatory systems play a crucial role in ensuring the quality, safety, and efficacy of health technologies. However, evolving scientific advancements, globalization, and diverse product landscapes pose challenges in effectively overseeing these technologies. One of the goals of regulatory capacity building is to improve access to safe, effective, and innovative medicines. Inefficient regulatory systems can hinder access to quality medical products. This session aims to galvanize mutual expertise and experience-sharing among regulators in the Americas, fostering a collaborative network to sustain robust regulatory agencies and for advancing regulatory practice to meet the potential of novel treatments, vaccines, diagnostics, and medical devices. The session explores strategies for enhancing regulatory capacity through collaboration, knowledge sharing, and fostering initiatives for joint work and collaboration. It discusses challenges, opportunities, and best practices in capacity building efforts, aiming to identify ways to promote collaboration and joint initiatives among regulators, universities, and industry stakeholders. By leveraging capacity building efforts, participants can enhance their ability to work together, share resources, and address common challenges in regulatory systems strengthening. Additionally, the session engages in a discussion on existing models of capacity building in regulatory systems. By analyzing and comparing these models, participants can identify best practices, lessons learned, and innovative approaches that can be applied to strengthen regulatory systems in the Americas. This discussion aims to foster collaboration and knowledge exchange among participants, promoting the adoption of effective capacity building strategies that support collaborative initiatives.	Ballroom 3
3:45-4:00PM	Closing Remarks	Ballroom 3

Translation

DIA will be offering audio and written translation in Spanish and Portuguese via Wordly Ai, our translation service.

- To access audio and written translation, using the device you wish to read/listen on, scan the QR code for the room you will be in.

BALLROOM 1
Plenaries and Track A
Regulatory/Clinical

https://attend.wordly.ai/join/ZTTD-4090

ROOM MN
Track B
Safety and Pharmacovigilance

https://attend.wordly.ai/join/TYOC-8845

ROOM GH
Track C
Medical Affairs and Scientific Communications (MASC)

https://attend.wordly.ai/join/WQQJ-0619

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