DIA

Latin America Annual Meeting

September 29 - October 1
NH Buenos Aires City, Buenos Aires, Argentina

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Overview

DIA's 2025 *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. This year, session tracks on Regulatory/Clinical and Safety and Pharmacovigilance 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 and reliance, 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

- Gain exclusive insights into current and future trends in regulatory, clinical, and pharmacovigilance (PV) across Latin America
- Hear directly from regional and global experts, including regulators, industry leaders, and key stakeholders shaping the future of drug development
- Engage with high-impact sessions, plenary and concurrent tracks covering pressing topics in regulatory affairs, clinical operations, safety and PV
- Access cross-functional discussions that highlight the interconnected nature of regulatory, clinical, and safety strategies
- Explore region-specific challenges and opportunities, with solutions tailored for Latin America's unique regulatory and public health environments
- Expand your professional network with influential voices across industry, government, and academia
- Take home actionable knowledge and best practices to strengthen compliance, streamline development, and improve healthcare outcomes
- Participate in intimate, neutral forums that encourage collaboration and honest dialogue
- Be part of the conversation shaping drug development policy and practice in Latin America and beyond

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.

Who Should Attend

Professionals involved in:

- Academia
- Benefit-Risk Assessment and Communication
- Clinical Research and Developmer
- 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 Science Liaisons
- Medical Writing
- Patient Engagement and Advocacy Groups
- Pharmacoepidemiology
- Policy and Intelligence
- Post-Market Studies
- Quality Assurance and Compliance
- Real-World Evidence Generation
- 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:

- Gain exclusive insights from Latin American regulators on evolving policies, priorities, and regional collaboration efforts
- Explore how reliance pathways are applied beyond initial marketing approvals to improve access and efficiency
- Stay ahead of the curve as digital transformation reshapes safety science, workforce development, and training needs
- Understand how Good Regulatory Practices drive better decision-making, transparency, and outcomes across regulatory systems in the region
- Develop and implement effective, patient-centered risk communication strategies by leveraging digital tools, diverse communication channels, and patient feedback to enhance safety outcomes and engagement
- Explore adaptive and decentralized trial designs that accelerate evidence generation while maintaining integrity
- Discuss the challenges and opportunities in delivering advanced therapies to patients with orphan and rare diseases
- Dive into local and regional best practices, challenges, and trends in inspections, compliance, and safety monitoring
- Examine how AI, machine learning, and NLP are reshaping pharmacovigilance and decision-making
- Understand the value of international regulatory convergence and gain insights from LATAM regulators on building capacity through global harmonization initiatives

Translation

DIA will be offering audio and written translation in English, 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.

GAUDI
Plenaries and Track A
Regulatory/Clinical

https://attend.wordly.ai/join/DLAO-2563

G. LEOPARDI
Track B
Safety and Pharmacovigilance

https://attend.wordly.ai/join/CGZP-0643

► Choose your language and click “attend.”

► Once in the session, you will need to unmute the audio. Please 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.

Schedule At-A-Glance (All times listed are ART Time)

Track A: Regulatory/Clinical Track B: Safety and Pharmacovigilance

DAY ONE | MONDAY, SEPTEMBER 29		ROOM
8:00AM-12:00PM	DIA Latin America Annual Meeting Reliance Pre-Conference Workshop *Pre-Conference Workshop requires an additional registration fee. You do not need to be registered for the meeting to attend.	Luis Alberto
11:00AM-6:00PM	Registration	Gaudi Foyer
1:00-1:15PM	Welcome and Opening Remarks	Gaudi
1:15-2:45PM	Session 1 Plenary: **Strategic Insights from Latin America Authorities** This session will provide the latest regulatory updates from national regulatory authorities from Latin America, including projects, priorities, and initiatives in the short and medium term, and delve into the priorities that dominate the regulatory agenda, shedding light on the strategic goals and objectives set forth by LATAM authorities. Attendees will gain valuable insights into the plans that are being formulated to address emerging challenges and opportunities within the regulatory framework.	Gaudi
2:45-3:15PM	Refreshments, Exhibits, and Networking Break	
3:15-4:30PM	Session 2 Track A: **Navigating Regulatory Reliance: Practical Insights and Applications Beyond Initial Marketing Authorization Application** Regulatory reliance initiatives are increasingly becoming vital in the global landscape, promoting more efficient and harmonized approaches to the approval of medicinal products. While commonly focused on medicines marketing authorization, the scope and benefits of regulatory reliance extend to essential areas such as post-approval changes, Good Manufacturing Practice (GMP) certification, clinical trials applications, medical devices authorizations and local batch release. This session will delve into how expanding reliance beyond medicines marketing authorization can streamline regulatory processes, enhance collaboration among stakeholders and support the timely availability of safe and effective medical products for patients in Latin America.	Gaudi
3:15-4:30PM	Track B: **The Future of Pharmacovigilance Professionals, Training, and Education in a Digitally Evolving World** This session will focus on the evolving role of pharmacovigilance (PV) professionals in the context of a rapidly digitizing world. As technologies such as artificial intelligence (AI), machine learning (ML), automation, and big data analytics transform the field of pharmacovigilance, there is an increasing need for PV professionals to adapt and acquire new skills. This session will explore the future of PV roles, training, and education, with an emphasis on local and regional initiatives to upskill professionals to thrive in a digital landscape.	G. Leopardi
4:40-5:55PM	Session 3 Track A: **From Principles to Impact: The Benefits of Implementing Good Regulatory Practices in Latin America** This session will explore the implementation and impact of Good Regulatory Practices (GRPs) in Latin America, highlighting institutional experiences from ANMAT and ANVISA. Through real-world examples and regional insights, speakers will examine how GRPs—such as transparency, stakeholder engagement, evidence-based decision-making, and regulatory impact assessments—are strengthening regulatory systems and advancing public health objectives. The session will also feature key findings from the Latin American Regulatory Practices Observatory, a study conducted by INNOS, offering data-driven insights into the progress and gaps in GRP adoption across the region. Finally, panelists will reflect on challenges and opportunities for embedding GRPs across the regulatory lifecycle and promoting convergence.	Gaudi
	Track B: **Unlocking Deeper Safety Insights with Real-World Evidence in Pharmacovigilance** In this session, we will explore the pivotal role that real-world data (RWD) and real-world evidence (RWE) play in enhancing pharmacovigilance (PV) practices. Integrating RWD and RWE into pharmacovigilance activities offers innovative approaches to monitoring drug safety and effectiveness, providing comprehensive insights into drug performance in diverse patient populations and real-world settings.	G. Leopardi
5:55-6:40PM	Networking Reception	

DAY TWO | TUESDAY, SEPTEMBER 30		ROOM
8:00-4:15PM	Registration	Gaudi Foyer
8:30-9:45AM	Session 4 Track A: **Innovative Trial Designs: Accelerating Access Through Smarter Evidence** This session will feature a range of perspectives—including regulators, clinical operations experts, and academic leaders—who will present case studies and experiences implementing innovative designs in the region. Topics will include how flexible methodologies have been applied to real-world clinical research in oncology and rare diseases, the evolving regulatory landscape supporting these approaches, and lessons learned in managing operational complexity and ethical oversight.	Gaudi
	Track B: **Risk Management and Communication with Patient Perspective** This session focuses on the importance of incorporating the patient perspective into risk management and communication strategies in pharmacovigilance (PV). By emphasizing patient-centric approaches and facilitating effective communication between the pharmaceutical industry, governments, and patients, we can improve drug safety and efficacy and ensure that patient needs and concerns are addressed in a comprehensive risk management framework.	G. Leopardi
9:45-10:30AM	Refreshments, Exhibits, and Networking Break	Gaudi Foyer
10:30-11:45AM	Session 5 Track A: **Orphan and Rare Disease Management: Are Patients In LatAm Getting the Advanced Therapies They Need?** As the identification of rare diseases become more sophisticated, so too do their therapies. The growing focus on advanced medicinal therapeutic products (ATMPs), biologics and specialized gene therapies for orphan diseases poses not only challenges during development but also for their regulatory assessments. This session will investigate challenges such as the use of early clinical data and decisions from other NRAs based on phase 2 or small, yet fit-for-purpose datasets. Is import testing of ATMPs being optimized or are products which are developed in precious small quantities being needlessly wasted? What do patients expect from developers and regulators to meet their unique needs?	Gaudi
10:30-11:45AM	Track B: **Challenges, Opportunities, and Best Practices in Pharmacovigilance in the LATAM (Part I)** This session will offer participants insights into the key challenges affecting Pharmacovigilance practices in the LATAM region, informed by recent global updates. We will explore opportunities for enhancement based on global regulatory changes and review the best practices from successful global PV initiatives applicable to LATAM. Participants will engage with global experts and industry representatives to foster collaboration and drive improvements in Pharmacovigilance across the region.	G. Leopardi
11:45AM-1:00PM	Luncheon, Exhibits, and Networking Break	Gaudi Foyer
1:00-2:15PM	Session 6 Track A: **Clinical Trials Operations and Management – Designing Quality into Innovative Clinical Trials** Early identification of Critical to Quality (CtQ) factors during protocol design, along with understanding the associated risks and their mitigations, plays a vital role in shaping the protocol and the operational and quality plans that direct trial conduct. This proportionate, risk-based approach ultimately leads to clinical trials that are fit for purpose—ensuring that all important trial components effectively address the research question, support the generation of reliable results, and prioritize participant safety. This presentation will delve into how publicly available tools can aid companies in navigating the implementation of ICH E6(R3), providing examples that illustrate these concepts.	Gaudi
	Track B: **Challenges, Opportunities, and Best Practices in Pharmacovigilance in the LATAM (Part II)** Continuing as Part II, this session focuses on strengthening pharmacovigilance in LATAM through Regional and local perspectives. Examine current challenges arising from diverse regulations, identify practical opportunities for regional collaboration (regulators, HCPs, industry), and learn from best practices showcased from successful LATAM initiatives to enhance local PV effectiveness.	G. Leopardi
2:15-3:00PM	Refreshments, Exhibits, and Networking Break	Gaudi Foyer

3:00-4:15PM	Session 7 Track A: **Connecting PACs, Sustainability, and Cloud Solutions for Effective Life Cycle Management** This session will highlight the recent accomplishments of the ICMRA PQKM Collaborative Pilots, illustrating how the collaborative assessment process pilot has the potential to evolve into a global regulatory programme. Regulatory authorities will share experiences as full participants or observers on the collaborative pilots. Additionally, the session will highlight the significance of sustainability in Pharmaceutical Lifecycle Management by examining the evolution of electronic product information practices.	Gaudi
	Track B: **Good Pharmacovigilance Practices – Inspections and Compliance within Pharmacovigilance in Latin America** This session will focus on the critical aspects of Good Pharmacovigilance Practice (GVP) inspections and compliance, with an emphasis on real-world case examples and a panel discussion featuring industry and regulatory experts. Understanding the requirements and best practices for GVP compliance is essential for Pharmacovigilance (PV) professionals to ensure the safety and efficacy of pharmaceuticals while maintaining regulatory adherence and compliance.	G. Leopardi

DAY THREE | WEDNESDAY, OCTOBER 1		**ROOM**
8:00AM-12:00PM	Registration	Gaudi Foyer
8:30-9:45AM	Session 8 Track A: **Advancing Global Health through Regulatory Convergence and International Collaboration** This session will explore the importance and benefits of participating in international harmonization and convergence initiatives, such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the International Medical Device Regulators Forum (IMDRF) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S). Attendees will hear firsthand from LATAM regulators about their experiences and impacts on their regulatory processes when participating in these initiatives and gain invaluable insights into how the regulators and industry can work for building capacity towards regulatory harmonization.	Gaudi
8:30-9:45AM	Session 8 Continued Track B: **Next-Gen Pharmacovigilance: AI, NLP and Beyond** Learn how the AI and NLP are revolutionizing pharmacovigilance, enhancing drug safety monitoring, streamline case processing and enable predictive analytics or more accurate adverse event detection and signal management. Gain insights into the future of PV as we push beyond the traditional methods not next generation safety surveillance.	G. Leopardi
9:45-10:30AM	Refreshments, Exhibits, and Networking Break	Gaudi Foyer
10:30-11:45AM	Session 9 Plenary: **How Advancements in AI are Revolutionizing the Pharmaceutical World** This session will present how advancements in AI are revolutionizing the regulatory submissions to streamline processes, reduce costs and time, and the crucial role of the electronic Common Technical Document (eCTD) in facilitating these advancements, ensuring that regulatory submissions are standardized and efficient. The session will also explore perspectives on AI applied for pharmacovigilance processes and the current landscape of AI regulations.	Gaudi
11:45AM-12:00PM	Closing Remarks	Gaudi

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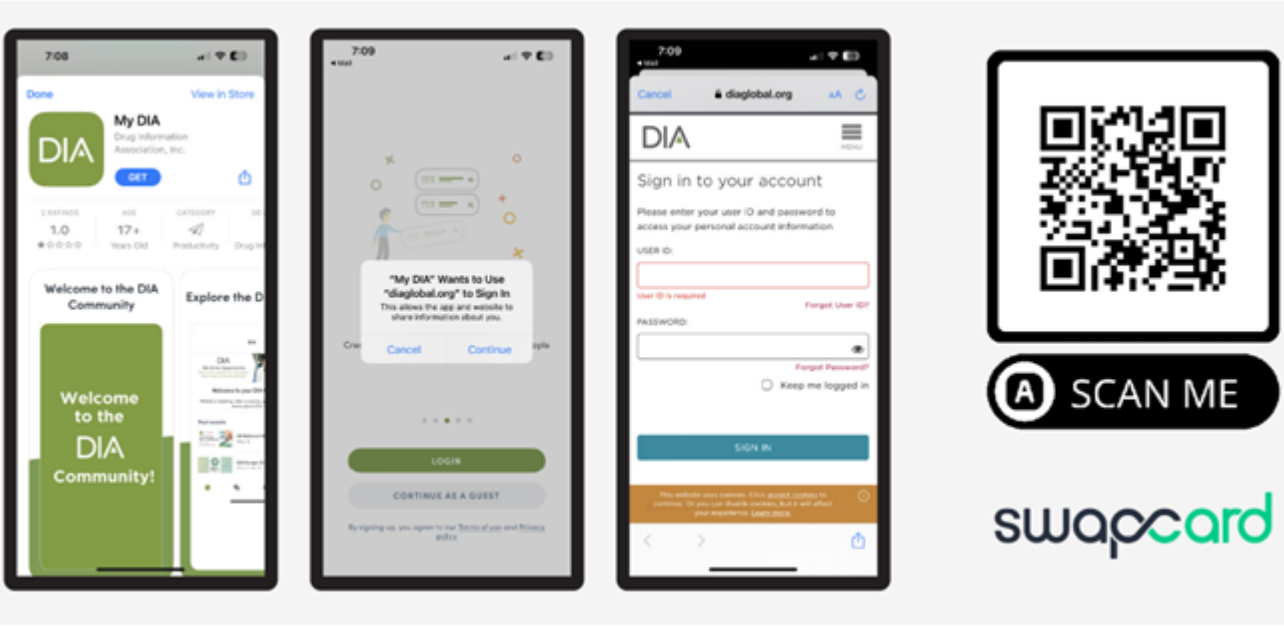

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Keep the Momentum Going in Latin America!

DIA/Sindusfarma LATAM Medical Affairs Meeting

December 4-5 | Sao Paulo, Brazil

If you're joining us at the Latin America Annual Meeting, don't miss the upcoming DIA/Sindusfarma LATAM Medical Affairs Meeting. This two-day program brings together regional experts to explore how Medical Affairs professionals are shaping the future of patient care, stakeholder engagement, and health communication across Latin America. With real-world case studies, cross-functional perspectives, and interactive discussions, the agenda highlights how MI teams, MSLs, and Medical Leads are driving innovation and aligning global strategies with local realities. Plus, you'll have plenty of opportunities to network and share best practices with peers across the region.

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EXHIBITOR DIRECTORY

LATIN AMERICA ANNUAL MEETING

SEPTEMBER 29 - OCTOBER 1, 2025

BOLÍVAR 160

C1066AAD BUENOS AIRES, ARGENTINA

DIA

BOLÍVAR 160, C1066AAD BUENOS AIRES, ARGENTINA

September 29 - October 1, 2025
NH Buenos Aires City
Bolivar, 160, C1066AAD Buenos Aires Argentina

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pga+

Website: *https://pgafarma.com.br/*
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PGA+ began its activities in 2012, just three years after the publication of the first national legislation focused on Pharmacovigilance. Since then, the Brazilian and Latin American regulatory environments have been consolidating and aligning themselves with international Pharmacovigilance standards as a precursor to activities related to Patient Safety.

PGA+ fits into this regulatory landscape. Our operations initially focused on Pharmacovigilance in the Brazilian market and gradually expanded to more than 35 countries throughout Latin America, with projects in Patient Safety, Clinical Research, Medical Information, and Customer Service (SAC).

Website: *https://www.propharmagroup.com/*
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At ProPharma, we help pharmaceutical, biotechnology, and medical device companies bring life-changing therapies to market. From early development through clinical, regulatory approval, and commercialization, we provide expert guidance to navigate complex challenges and accelerate success.

Our mission is simple: improving patient health and safety by delivering the highest-quality regulatory, compliance, clinical research, pharmacovigilance, and medical information services throughout the entire product lifecycle.

With over 20 years of expertise in regulatory sciences, clinical research solutions, quality & compliance, pharmacovigilance, medical information, and R&D technology, ProPharma partners with clients across the complete product lifecycle through an advise-build-operate model. Our end-to-end suite of consulting solutions de-risks and accelerates high-profile drug and device programs, ultimately improving patient health and safety. Discover how ProPharma can help you inspire the future of science!

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