DYNAMIC GLOBAL EVENTS

Clinical Research in Latin America Summit

February 9-10, 2023
Online Livestream

Building a Strong Latin American Research Pipeline through Improved Collaboration Strategies, Renewed Public Outreach, and a Commitment to Diversity

IN-DEPTH ANALYSIS:

- Effectively navigating across **DIVERSE REGULATORY FRAMEWORKS**
- Overcoming the challenges to **BUILD LOCAL RESEARCH CAPACITY**
- Achieving patient centricity with **EFFECTIVE ENGAGEMENT STRATEGIES**
- Learning the optimal methods for **APPROVAL IN PROTOCOL SUBMISSIONS**
- Identifying cross-collaboration trends to **CREATE TRUST WITH STAKEHOLDERS**
- Implementing technologies that **BRIDGE PHYSICAL DISTANCE BARRIERS**

"The ONLY event exclusively devoted to the entire research landscape in Latin America beyond regulatory questions!"

FEATURED SPEAKERS

Giovanni Guzzo
Sr. Clinical Country & Site Lead, Associate Director
BIOGEN [BRAZIL]

Yaneth Giha
Executive Director
FIFARMA [COLOMBIA]

Belen Gonzalez Sutil
Associate Director, Patient Advocacy LATAM
ULTRAGENYX [ARGENTINA]

Vanessa Cohen
LATAM Head, Scientific Affairs
SANOFI [MEXICO]

Mirella Nardo
Postdoctoral Advanced Fellow in Investigational Cancer Therapeutics
MD ANDERSON CANCER CENTER [BRAZIL]

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SPEAKING FACULTY

Giovanni Guzzo
Sr. Clinical Country & Site Lead, Associate Director
BIOGEN [BRAZIL]

Yaneth Giha
Executive Director
FIFARMA [COLOMBIA]

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Mirella Nardo
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Madelyn Gutierrez
Alliances & Partnership Leader
GENENTECH [COLOMBIA]

Virginia Cozzi
LATAM Head, Clinical Operations
ROCHE [COSTA RICA]

Lawrence Liberti
Adjunct Research Professor, Regulatory Affairs & Quality Assurance
TEMPLE UNIVERSITY SCHOOL OF PHARMACY

Mario Alanis Garza
INDEPENDENT REGULATORY POLICY CONSULTANT

Belkys Ruiz
Regulatory Affairs Expert, Quality Assurance & Pharmacovigilance Management
EPROFAR [VENEZUELA]

Geoffrey Obel
National Project Director & Sr. Clinical Research Associate
UT SOUTWESTERN MEDICAL CENTER

Judy Galindo
Director of Research & Co-Owner
SUN VALLEY RESEARCH CENTER

Monica Cuitiva
Co-Founder
LATINOS IN CLINICAL RESEARCH

Ashley Margo
Co-Founder
LATINOS IN CLINICAL RESEARCH

Efrain Alarcon-Rozas
Internal Medicine, Clinical Oncology Head
HOSPITAL ALMENARA/CLINICA SAN BEATRIZ [PERU]

Mariana Abdala
Strategic Clinical Development & Clinical Research
CRYSTAL RESEARCH [PERÚ/ARGENTINA]

Mariana Ferreyra
Pediatric Intensive Care Physician & Clinical Research
HOSPITAL ITALIANO DE BUENOS AIRES [ARGENTINA]

EVENT OVERVIEW

With over 620 million people across 33 different countries, Latin America is a crucial growth zone for the future of clinical research. With over 10 distinct ethnic groups it can help with broader representation of diversity in clinical trials, and its large metro areas can provide robust population concentrations for easier patient enrollment and retention. The biggest challenges you will face concern logistics, resources, and publications. Now, at last, you can get answers to all of these questions – and more!

Join us at the **Clinical Research in Latin America Summit**, streaming online **February 9-10** for an unparalleled learning and networking experience with a diverse community of experts throughout the biopharma sector. You'll come away with new actionable strategies for study coordination, site interaction, patient enrollment, partnership design, regulatory compliance, and much more!

No other event goes into as much detail on these crucial topics your teams need!

- Gaining clarity on the current landscape and evolving growth of highly skilled HCPs
- Discovering how to effectively navigate across multiple regulatory frameworks
- Driving engagement toward regional multi-sectorial cross-collaborations
- Adopting medical education strategies to address gaps in patient knowledge
- Tackling the biggest challenges to increase the local research capacity
- Learning new ways to compensate for the low volume of publications

WHO SHOULD ATTEND

- ✓ Clinical Research
- ✓ Clinical Operations
- ✓ Research and Development
- ✓ Site Lead / Management / Monitoring
- ✓ Study Coordination / Reporting
- ✓ Regulatory Affairs
- ✓ Patient Advocacy
- ✓ Patient Support & Experience
- ✓ Patient Enrollment/ Recruitment
- ✓ Clinical Investigators/ Physicians
- ✓ Trial & Protocol Design
- ✓ Early Phase, Phase I/II
- ✓ Clinical Team Leads
- ✓ Clinical Quality
- ✓ Drug Safety
- ✓ Medical & Scientific Affairs
- ✓ Medical Education
- ✓ Global Submission / Project Management
- ✓ Strategic Sourcing & Procurement
- ✓ Government Affairs
- ✓ Clinical Trial Supply
- ✓ CROs & Clinical Suppliers

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DAY ONE | THURSDAY, FEBRUARY 9TH, 2023

ALL TIMES ARE IN EST

APPROACHING LATIN AMERICA: CURRENT LANDSCAPE & OPPPORTUNITIES

9:00 **Demystify Latin America and Better Understand the Current Landscape**

Latin America has become one of the most attractive destinations for researchers. As with any developing region, it faces many challenges. But first, many misperceptions about the region must be corrected.

- Gain clarity on the current regional landscape and recent progress
- Identify and debunk common misperceptions surrounding the region
- Examine the evolving growth of highly skilled and reliable medical professionals
- Discover often overlooked hot spots and prime areas for research

Madelyn Gutierrez, Alliances & Partnership Leader – GENENTECH [COLOMBIA]

9:45 **Review Technological Potential and Publication Reality for Preclinical and Phase-I Studies in Latin America**

All stakeholders in Latin America's emerging economies need to learn to become more competitive. Getting studies to the next level requires a clearer view of the impact of published articles and the proportion of submissions that are actually accepted by major journals. If the publication landscape isn't where researchers need it to be, what alternatives can we propose?

- Build facility relationships that emphasize innovative technology
- Map out how changes in Phase-I trials will impact phases II and III
- Aim towards better publication outcomes – and learn how to compensate

Efrain Alarcon-Rozas | Internal Medicine, Clinical Oncology Head – HOSPITAL ALMENARA/CLINICA SANTA BEATRIZ [PERU]

10:30 *BREAK*

PATIENT ENGAGEMENT, RECRUITMENT & EDUCATION

10:45 **Achieve Greater Patient Centricity with Effective Engagement Strategies**

Incorporating perspectives and the needs of patients and advocates into each stage of drug development can ensure programs meet the community's needs. Your team must be able to clearly demonstrate the value of patient input, and focus their patient engagement strategy around gathering more.

- Create open channels that offer a mix of synchronous and asynchronous engagement
- Proactively address hurdles and engage routinely and conveniently
- Segment participants to help you develop better messaging and influence their journey
- Close the loop by communicating the results back to patients and stakeholders

Belen Gonzalez Sutil | Associate Director, Patient Advocacy LATAM – ULTRAGENYX [ARGENTINA]

11:30 **Adopt Medical Education Strategies to Address Gaps in Patient Knowledge**

Lack of patient knowledge is a common reason why they don't complete clinical treatments fully or accurately. Trial training materials may be difficult for patients to understand in depth. Provide educational materials that are clear and provide transparent and accurate communication.

- Adapt to the literacy rates and preferred communication methods of your patient communities
- Understand how patients learn to best determine effective comprehension
- Work for and within communities to ensure their understanding and consent

Vanessa Cohen | LATAM Head, Scientific Affairs – SANOFI [MEXICO]

12:15 *LUNCH*

1:15 **CASE STUDY**
HIV/AIDS Infection Breakthroughs in Bogotá, Colombia

Colombia currently poses as one of the greatest hot spots for running studies and clinical trials. With an increasing GDP and greater infrastructure, it offers an ideal landscape for optimal clinical research. Hear about successful research and the process of containing HIV/AIDS infection outbreaks.

Geoffrey Obel | National Project Director & Sr. Clinical Research Associate – UT SOUTHWESTERN MEDICAL CENTER

2:00 **PANEL**
Implement Novel Community-Based Strategies to Improve Patient Engagement and Trial Recruitment

Gains in patient engagement require a deeper involvement in local communities, which is often left out of these conversations. Sponsors that lean more towards technology-centric approaches to patient engagement and recruitment often find themselves disappointed in the results.

- Reflect on successes after working at site level to recruit diverse populations
- Outline new ideas for sponsors, CROs, and other vendors when working with sites on recruitment
- Move the conversation to new areas the industry should support

Judy Galindo | Director of Research & Co-Owner – SUN VALLEY RESEARCH CENTER

Monica Cuitiva | Co-Founder – LATINOS IN CLINICAL RESEARCH

Ashley Margo | Co-Founder – LATINOS IN CLINICAL RESEARCH

2:45 *BREAK*

3:00 **Pros and Cons of Outsourcing Clinical Trials in Latin America**

Outsourcing clinical trials to developing regions has been appealing for pharma companies to reduce costs. With successful trials having been conducted for decades, Latin America is recognized for its potential and has seen the highest growth rates in clinical trials among all emerging markets. But what are the benefits and potential pitfalls of running outsourcing trials in Latin America?

- Identify the most critical challenges in outsourced trials
- Examine problems in time and costs that have previously been overlooked
- Learn from prior common setbacks

Giovanni Guzzo | Sr. Clinical Country & Site Lead, Associate Director – **BIOGEN [BRAZIL]**

3:45 *Day One Concludes*

DAY TWO | FRIDAY, FEBRUARY 10TH, 2023

ALL TIMES ARE IN EST

8:00 *Registration & Log In*

8:45 *Chairperson's Recap of Day One*

REGULATORY ADVANCES & OPPORTUNITIES

9:00 **Latest Update on Regional Regulatory Change**

National Regulatory Authorities (NRAs) have been making progress on new regulatory guidelines – but what is just proposed and what actually has a chance of passage? Gain updates on advancements made on local, regional, and global projects and priorities that will affect the Latin American regulatory landscape.

- Gain insights on current NRA projects and progress
- Pinpoint NRAs priorities for 2023 moving forward
- Discover how current projects will impact the research space

Yaneth Giha | Executive Director – **FIFARMA [COLOMBIA]**

9:45 **Highlight Opportunities for Greater Regional Convergence**

Regional and international agencies are working towards aligned and transparent interchanges, for greater regulatory and procedural efficiency. What do you need to know about the regulatory landscape to make these interchanges work?

- Identify multi-regional collaboration trends and ways to participate
- Create trust through convergence and alignment with stakeholders
- Tackle complexity and diversity in international regulatory requirements
- Prioritize data quality and integrity during regulatory preparation and submissions

Lawrence Liberti | Adjunct Research Professor, Regulatory Affairs & Quality Assurance – **TEMPLE UNIVERSITY SCHOOL OF PHARMACY**

Mario Alanis Garza | Independent Regulatory Policy Consultant

10:30 *BREAK*

10:45 **Navigate Across Multiple National Regulatory Frameworks**

Latin America and the Caribbean comprise over 665 million inhabitants throughout 33 different countries, and each country has different regulatory frameworks. Hear practical strategies on how to effectively navigate across different regulatory frameworks and key insights to consider.

- Learn why clustering countries is a must
- Discover recent efforts to ramp up local production and change the regional profile
- Identify current barriers and hurdles pressing the more developed countries
- Explore ongoing post-pandemic incentives in less developed nations

Belkys Ruiz | Regulatory Affairs Expert, Quality Assurance & Pharmacovigilance Management – **EPROFAR [VENEZUELA]**

11:30 **Target Opportunities for Oncology Clinical Trials in Latin America**

Latin America and the Caribbean have recently grown more involved in clinical cancer research, but the regional gap is still substantial – the U.S. and Europe conduct 81% of total ongoing cancer trials, whereas Latin America participates in only 5%. But due to population growth, by 2030 the majority of annual cancer diagnoses will occur in low-and-middle-income countries (LMICs) such as those in Latin America. How can you put the necessary frameworks in place now?

- Hear why now is the time to create local innovative projects and co-develop trials
- Clarify which policies will be best for improving investment and trial access
- Identify hurdles and overcome current challenges in clinical oncology trials

Mirella Nardo | Postdoctoral Advanced Fellow in Investigational Cancer Therapeutics – **MD ANDERSON CANCER CENTER [BRAZIL]**

12:15 *LUNCH*

LEADERSHIP, WORKFORCE & COLLABORATION

1:15 **Map the Best Methods for Approvals in Protocol Submissions**

Timelines for approval often result in long waiting times that may hinder entire studies. Tackle discrepancies with protocol submissions, the lack of harmonization in regulations, and the absence of knowledge of the entire regulatory framework. Understand how preparing in advance and understanding each framework before considering protocol submission can help you gain approval.

- Hold the necessary early discussions
- Build strict and consistent timelines and processes
- Create awareness among U.S. and E.U. organizations about diverse regulatory settings
- Learn how a KOL can expedite your study

Giovanni Guzzo | Sr. Clinical Country & Site Lead, Associate Director – **BIOGEN [BRAZIL]**

Virginia Cozzi | LATAM Head of Clinical Operations – **ROCHE [COSTA RICA]**

2:00 **Build A Robust Clinical Research Workforce**

Uncertainty, the lack of predictability in approvals, and delays are only a few challenges of running studies in the region. Hear how to tackle and overcome challenges by building robust and well-prepared teams ready to leverage partnerships between academia, community, government, and other industry players.

- Gain insights on site activations while dealing with delays and other common setbacks
- Incorporate legal training to interpret agreements and intellectual property for publications
- Plan ahead and prepare teams to further educate patients on how to properly use digital tools and devices when applicable

Mariana Ferreyra | Intensive Care Physician & Clinical Researcher –
HOSPITAL ITALIANO DE BUENOS AIRES [ARGENTINA]

2:45 *BREAK*

3:00 **Practical Strategies to Achieve Greater Regional Competition**

Training and continuing education are paramount to optimizing clinical trials' quality. Regulatory agencies, ethics committees, companies, and CROs are increasingly concerned with improving their processes and increasing their quality. Having qualified personnel who can act quickly and proactively, while being able to make decisions with the necessary autonomy and knowledge of each process involved can better position the region. But what can we do to achieve such excellence?

- Discuss the humanization of clinical trials
- Optimize the quality of research protocols
- Strengthen human resources to overcome challenges
- Discover new ways to source quality research

Mariana Abdala, Founder & CEO, Strategic Clinical Development,
CRYSTAL RESEARCH [PERÚ/ARGENTINA]

3:45 **Equip Sites with Technologies that Bridge Physical Distance Barriers**

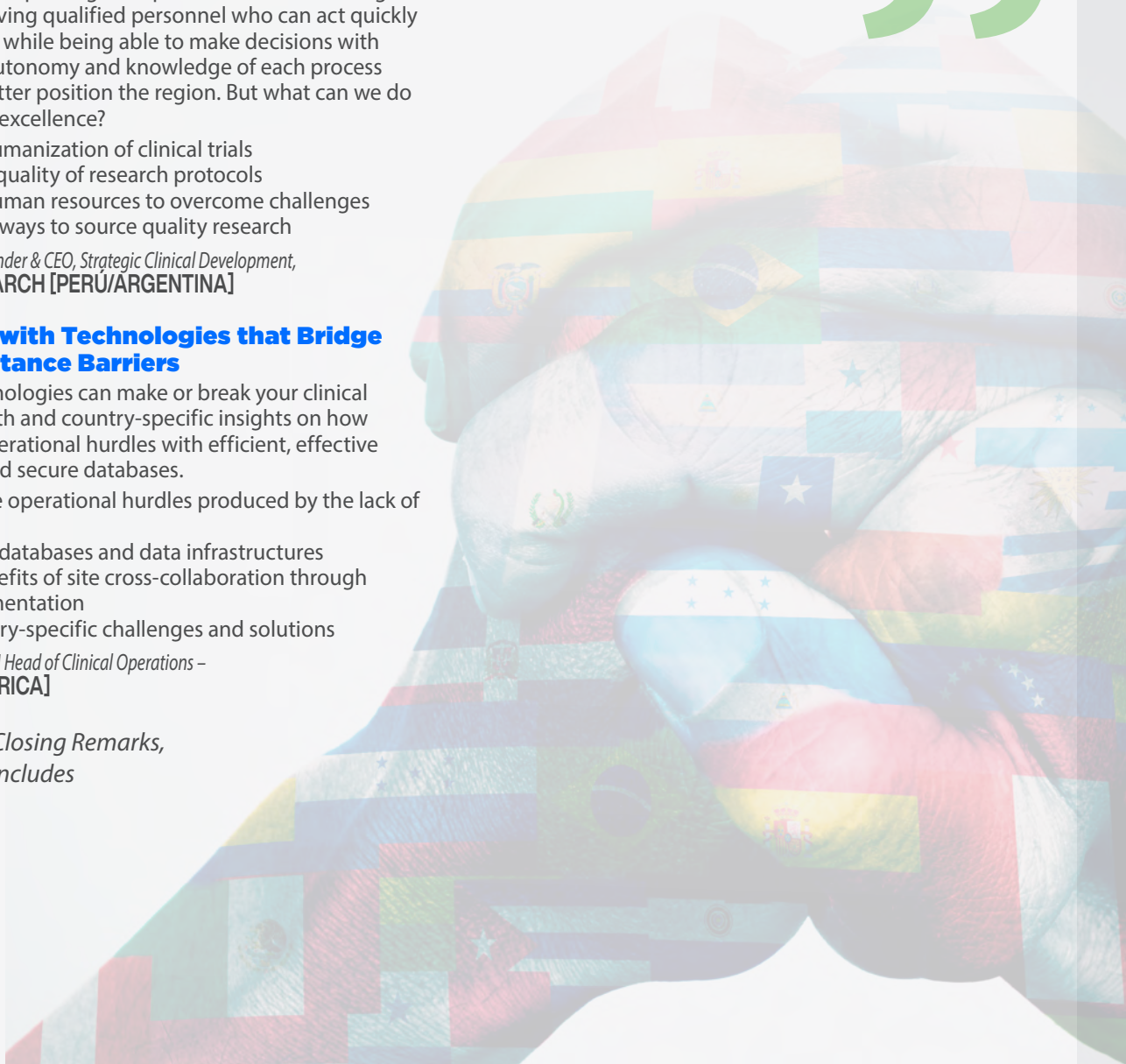
Accessible technologies can make or break your clinical trial. Get in-depth and country-specific insights on how to overcome operational hurdles with efficient, effective technologies and secure databases.

- Overcome site operational hurdles produced by the lack of data access
- Adopt secure databases and data infrastructures
- Highlight benefits of site cross-collaboration through digital implementation
- Identify country-specific challenges and solutions

Virginia Cozzi | LATAM Head of Clinical Operations –
ROCHE [COSTA RICA]

4:30 *Chairperson's Closing Remarks, Conference Concludes*

"Detailed strategies to help you gain regulatory approval, optimize patient enrollment, increase trial participation, and effectively cross-collaborate with sites within the region."



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