



Latin America towards Global Convergence

Strategic Overview

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Abstract

- As communication and knowledge increase, the need to involve diverse active stakeholders arises, so they may provide valuable insight.
- Latin America and the Hispanic community will have an increasing participation in international forums, clinical studies and in corporate strategies.
- The effective creation and implementation of plans to expand into the Latin American markets requires knowledge, capabilities and skills that might exceed the internal resources of an organization.

Content

Challenges and opportunities in Latin America

- ① Convergence and Harmonization
- ② Disruptive technologies
- ③ Inclusion of Communities
- ④ Growth and Expansion

Conclusion

① Convergence and Harmonization

Good practices worldwide

Which direction will Convergence take?



Various initiatives have helped the harmonization/convergence of regulations

CAN - Comunidad Andina de Naciones	1969
Caricom - Comunidad del Caribe	1973
Mercosur - Mercado Común del Sur	1991
SICA / SIECA - Sistema de la Integración Centroamericana	1991
NAFTA - North American Free Trade Agreement	1994
ALBA - Alianza Bolivariana para los pueblos de nuestra America	2004
CAFTA-DR - Central American-Dominican Republic Free Trade Agreement	2007
CELAC - Comunidad de Estados Latinoamericanos y Caribeños	2010
UNASUR - Unión de Naciones Suramerican. 12 South American Countries	2011
OEA - Organización de los Estados Americanos	1948
Bilateral free trade agreements with other Nations and Economic Alliances	--

After years of debates there is some convergence of Global & LATAM regulations

But there are still several differences between Latin American countries and the rest of the world, thus creating an ambiguous environment for companies that want to enter or expand their business in the region.



The role of Latin America in the Globalization of Regulations

From follower to participant

Public, Private and Patient Organizations will be more active at international forums

Government



Industry / Service

NGO

② Disruptive technologies 21st Century Medicine

- Biotechnology
- Next-generation sequencing-based genome diagnostics
- Single cell diagnosis
- Nanotechnology
- Prediction, detection before diagnosis
- Precision medicine
- Pharmacogenomics
- Bioinformatics
- Devices and smart phones
- New paradigms in the treatment of diseases

Genomics and Healthcare Conference


Funmi Olopade, M.D.






Sept 28, 2015 - New York Academy of Medicine

BRCA1 and *BRCA2* Founder/Recurrent Mutations throughout the World


Population	<i>BRCA1</i> mutation(s)	<i>BRCA2</i> mutation(s)
Ashkenazi Jewish	185delAG, 188del11, 5382insC	6174delT
Austrians	2795delA, C61G, 5382insC, Q1806stop	-
Bahamas	<i>BRCA1</i> IVS13+1G>A	-
Belgians	2804delAA, IVS5+3A>G	-
Dutch	Ex2 deletion, ex13 deletion, 2804delAA	5579insA
Finns	3745delT, IVS11-2A>G	8555T>G, 999del5, IVS23-2A>G
French	3600del11, G1710X	-
French Canadians	C4446T	8765delAG
Hungarians	300T>G, 5382insC, 185delAG	9326insA
Icelandics	-	999del5
Italians	5083del19	8765delAG
Japanese	L63X, Q934X	-
Mexico	185delAG, ex9-12del	-
Nigerian	Y101X, 1742insG, 4241delTG, 4359insC	2630del11, 9045delGAAA
Northern Irish	2800delAA	6503delTT
Norwegians	816delGT, 1135insA, 1675delA, 3347delAG	-
Pakistanis	2080insA, 3889delAG, 4184del4, 4284delAG3337C>T	-
Polish	300T>G, 5382insC, C61G, 4153delA	-
Russians	5382insC, 4153delA	-
Scottish	2800delAA	6503delTT
Slovenians	-	IVS16-2A>G
South Africans	E881X	-
Spanish	R71G	3034delAAAC, 9254del5
Swedish	Q563X, 3171ins5, 1201del11, 2594delC	4486delG

Introducing and adopting technologies 21st century medicine


 The Nobel Prize in Physiology or Medicine 1984
Niels K. Jerne, Georges J.F. Köhler, César Milstein

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The Nobel Prize in Physiology or Medicine 1984



Niels K. Jerne
Prize share: 1/3



Georges J.F. Köhler
Prize share: 1/3



César Milstein
Prize share: 1/3

The Nobel Prize in Physiology or Medicine 1984 was awarded jointly to Niels K. Jerne, Georges J.F. Köhler and César Milstein *"for theories concerning the specificity in development and control of the immune system and the discovery of the principle for production of monoclonal antibodies"*.

Photos: Copyright © The Nobel Foundation

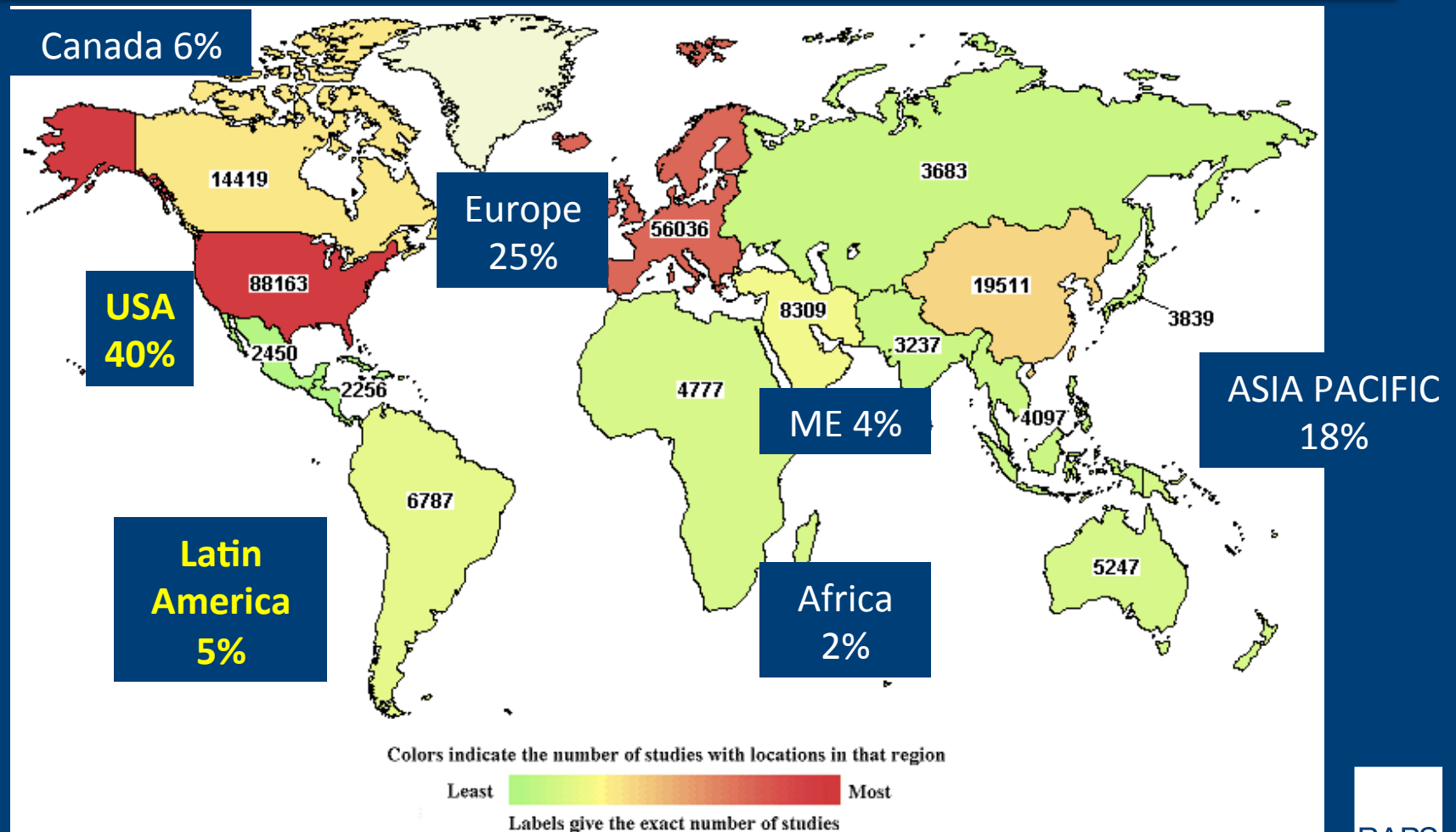
- There is a real and immediate opportunity to incorporate medical advances in Latin America
- 650 million people in the region with the need and the right to access scientific advances
- It is critical to understand each country in its various dimensions -its people, its culture, its health systems- to create a viable strategy.

③ Inclusion of communities and minorities

- The selection and inclusion of patients in clinical studies will continue evolving to encompass a greater number of what are now considered minorities
 - Latin American and Hispanic communities will have the opportunity to actively participate in more clinical trials

Overview - Clinical Trials: ClinicalTrials.gov

World = 222,811





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Consumer Updates

Clinical Trials Shed Light on Minority Health

"Potential racial, ethnic and other differences in response to drugs are important to FDA's efforts to help ensure that the safety and effectiveness of drugs are studied in all people who will use the products once they are approved," she says.

But historically, both women and minorities have been under-represented in clinical trials. For example, according to a 2011 report from the conference "Dialogues on Diversifying Clinical Trials," sponsored by FDA's Office of Women's Health and the Society for Women's Health Research and supported by OMH:

- African Americans represent 12% of the U.S. population but only 5% of clinical trial participants;
- Hispanics make up 16% of the population but only 1% of clinical trial participants; and
- Men make up more than two-thirds of the participants in clinical tests of cardiovascular (heart and blood vessel) devices.

At the conference, more than 200 representatives from government and industry came together with patient advocates and the scientific community to discuss strategies for increasing the participation of women and minorities in clinical trials.

Hispanic Accrual on Randomized Cancer Clinical Trials: A Call to Arms

Alberto Parra, Anand B. Karnad, and Ian M. Thompson, *University of Texas Health Science Center at San Antonio, San Antonio, TX*

The Hispanic population is the fastest growing demographic group in the United States and is expected to triple from 46.7 million to 132.8 million by 2050.¹ Hispanics suffer from major health disparities, and they have low participation in cancer screening and prevention programs and higher incidence rates for cancers of the cervix, stomach, liver, and gall bladder compared with non-Hispanic whites.^{1,2} Despite the compelling impact of cancer on Hispanics as evident from the death of 17,400 Hispanic men and 15,800 Hispanic women as a result of a malignancy in 2012 alone, the data on Hispanic enrollment onto practice-changing cancer clinical trials are negligible.

South Texas is the largest geographic region in Texas, about the size of Pennsylvania, and the population in this region is predominantly of Hispanic ethnicity. Of note, 58% of the population of San Antonio—the largest city in South Texas—is Hispanic, although the upward trend (approaching 90%) of Hispanic population is evident in

With a view to Hispanic patients in the year of 2012 by investigators in the *Medicine, Journal of*

Table 1. Cancer Clinical Trials With Reports of Minority Accrual in 2012

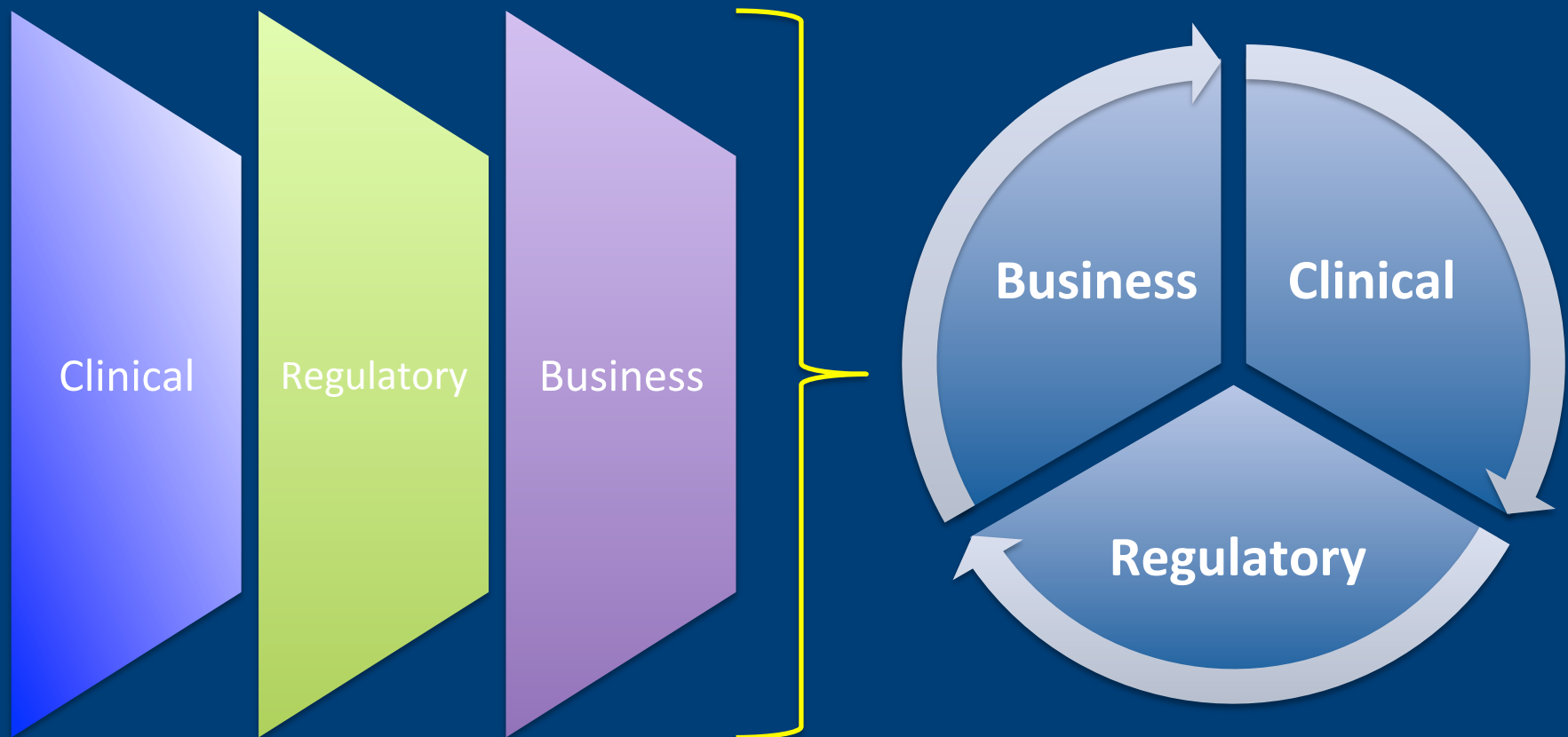
Reference	Trial Phase	Total Accrual	Hispanic Accrual	
			No.	%
O'Brien et al ⁴	II	65	17	26
Levine et al ⁵	II	40	10	25
Kindler et al ⁶	II	115	6	5.22
Lynch et al ⁷	II	204	1	0.5
Tap et al ⁸	II	38	6	16
Uldrick et al ⁹	II	17	3	17.64
Sosman et al ¹⁰	II	132	2	2
Karlan et al ¹¹	II	161	5	3.10
Cruciani et al ¹²	III	376	5	1.32
Paz-Ares et al ¹³	III	772	16	2.07
Scagliotti et al ¹⁴	III	1,090	66	6.05
Levenback et al ¹⁵	III	452	9	2
Socinski et al ¹⁶	III	1,052	16	2
Total		4,154	162	3.9

Despite Hispanics being a growing proportion of the US population, most recently reported cancer clinical trials either do not report the proportion of accrued Hispanic patients or they report rates that are far lower than the proportion of this ethnic group in the US population. Steps must be taken at this time to improve the accrual and reporting of Hispanics in clinical trials to be able to best monitor and treat neoplastic disease in this ethnic group.

④ Growth and Expansion

- Latin America is a growing market and a high-demand market
- Latin America has shown a continuous Compound Annual Growth Rate (CAGR) of over 2 digits for many years (almost double that of the Global Market)
- Latin American countries can help life-science companies to
 - achieve both their vision and mission statements, and reach those patients for whom they have developed their products
 - boost their returns on invested resources, add revenue by entering major international markets, and increase their global reach and total value

Create and implement an integrated Latin American expansion strategy at early stages

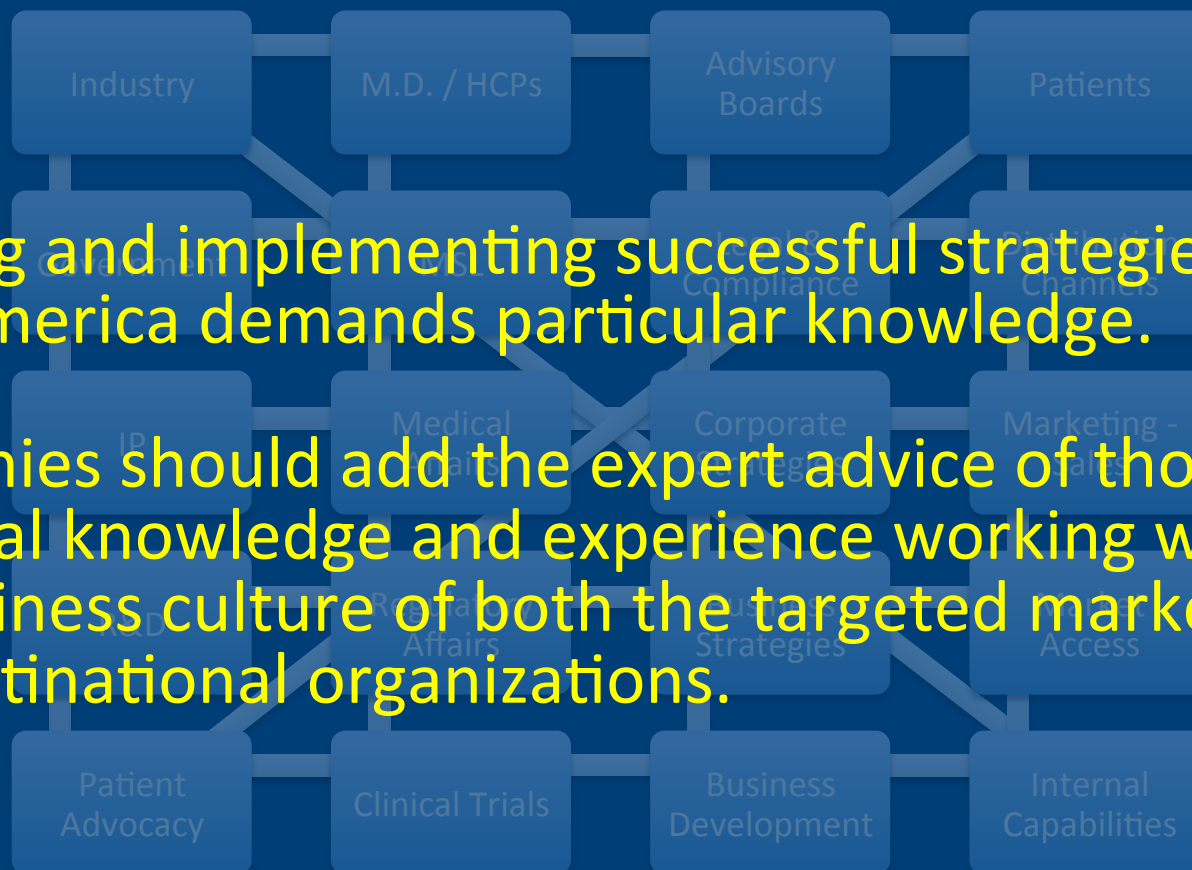


Maximize opportunities by integrating corporate strategies

Connect the edges, integrate the pieces with global mindset and local knowledge

Planning and implementing successful strategies in Latin America demands particular knowledge.

Companies should add the expert advice of those who have real knowledge and experience working within the business culture of both the targeted markets and the multinational organizations.



Conclusions

- ① Latin American Governmental Agencies, Industry/Services and NGOs will have an increasing role in the development of global regulations
 - ↳ all these stakeholders shall be invited and will be represented in international forums
 - ↳ they will be responsible for a fast internalization of those regulations / decisions in which they have participated
- ② The Medicine of the 21st Century will penetrate Latin America by leaps and bounds
 - ↳ industry, regulatory agencies and healthcare/reimbursement systems shall speed up the approval and inclusion process of new services and products
 - ↳ medical practices will adopt new techniques and use more clinical geneticists, bioinformatic experts, and diagnosis tools; training will be critical

Conclusions

③ Communities will be better represented in clinical trials

- ↳ government, industry/services, HCPs and patients/ patient organizations should be prepared to respond appropriately
- ↳ the senior management of life science organizations should consider this trend in making their corporate decisions

④ Growth and Expansion

- ↳ Latin America will continue growing above the Global Pharmaceutical market
- ↳ Life science companies should implement a multidisciplinary team of experts to develop and execute efficient and effective advanced strategies to capture new opportunities in Latin America

Thank you
Muchas Gracias
Muito Obrigado

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