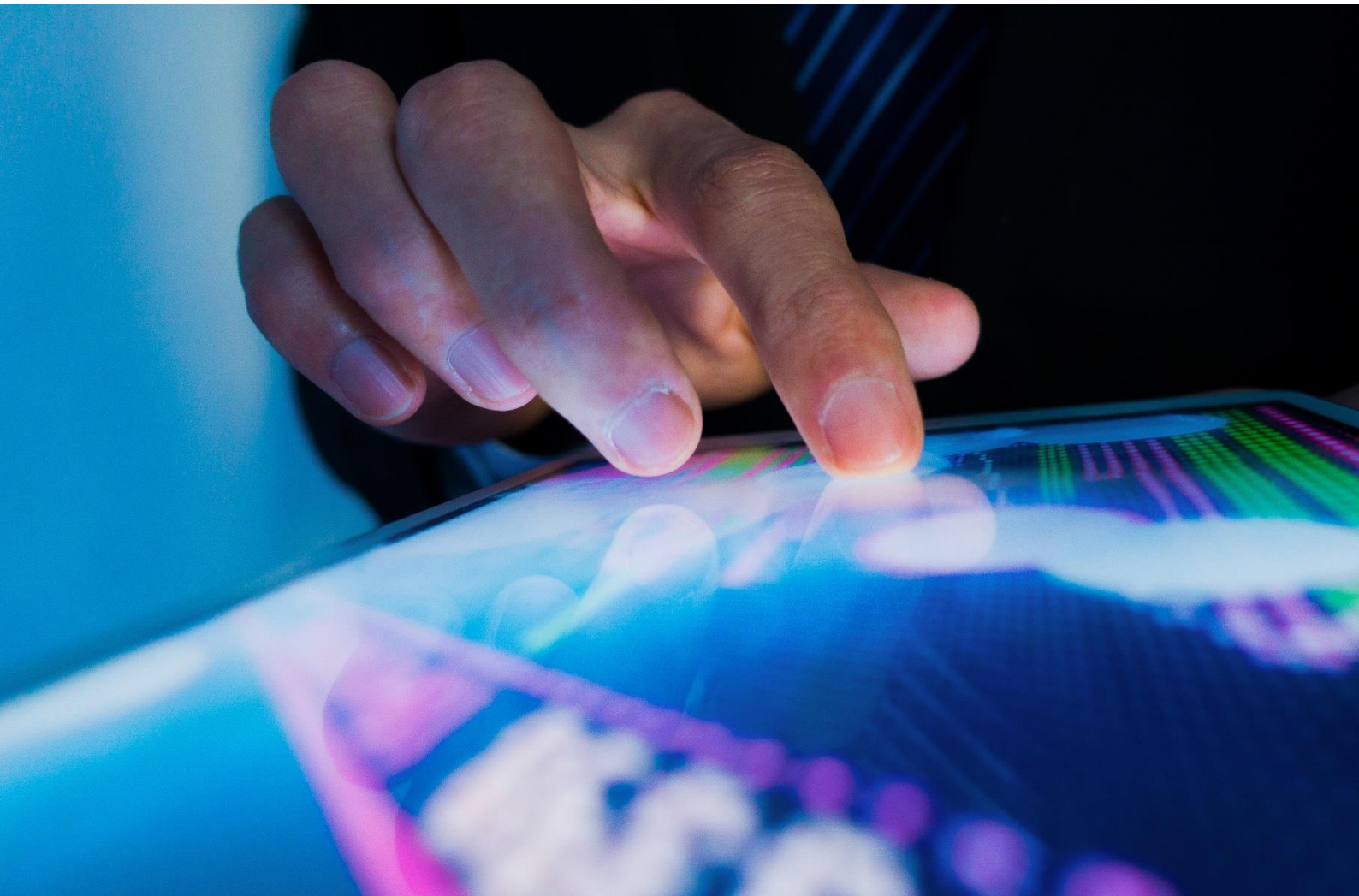
Clarivate™

Whitepaper

LATAM Summit: Navigating market and innovation opportunities



Contents

Introduction

The LATAM pharmaceutical market has undergone significant development in recent years. Valued at $98 billion dollars, and with an expected growth of 10.1%, the LATAM market increase will outperform the expected growth of developed markets such as North America (3.1%) and Europe (3.9%). With a greater focus on innovation and expansion of local manufacturing, the LATAM market offers an attractive destination for domestic and international pharmaceutical companies, for clinical trials and for investment in local manufacturing sites.

Barriers remain, including technology gaps, supply chain constraints, and a high dependence on API imports. Overcoming these challenges will provide potential for even more aggressive growth in the region. To do so, the correct articulation between the main bases of the innovation environment (industry and startups, government, academia) is more critical than ever.

Illustration 1. Some numbers that are representative of the current reality in Latin America[i]

Clarivate has been operating in the region for more than two decades, providing solutions for market development and public policy in LATAM markets. In addition, through events like this, Clarivate contributes to dialogue-building in the sector. Throughout this document, we will present the highlights of the LATAM Summit as discussed in our Barcelona office, prior to CPhI 2023, by some of the most experienced representatives from the private and public sector in the region, presenting the current main challenges and opportunities for the continent. Below we highlight Clarivate's vision for the region:

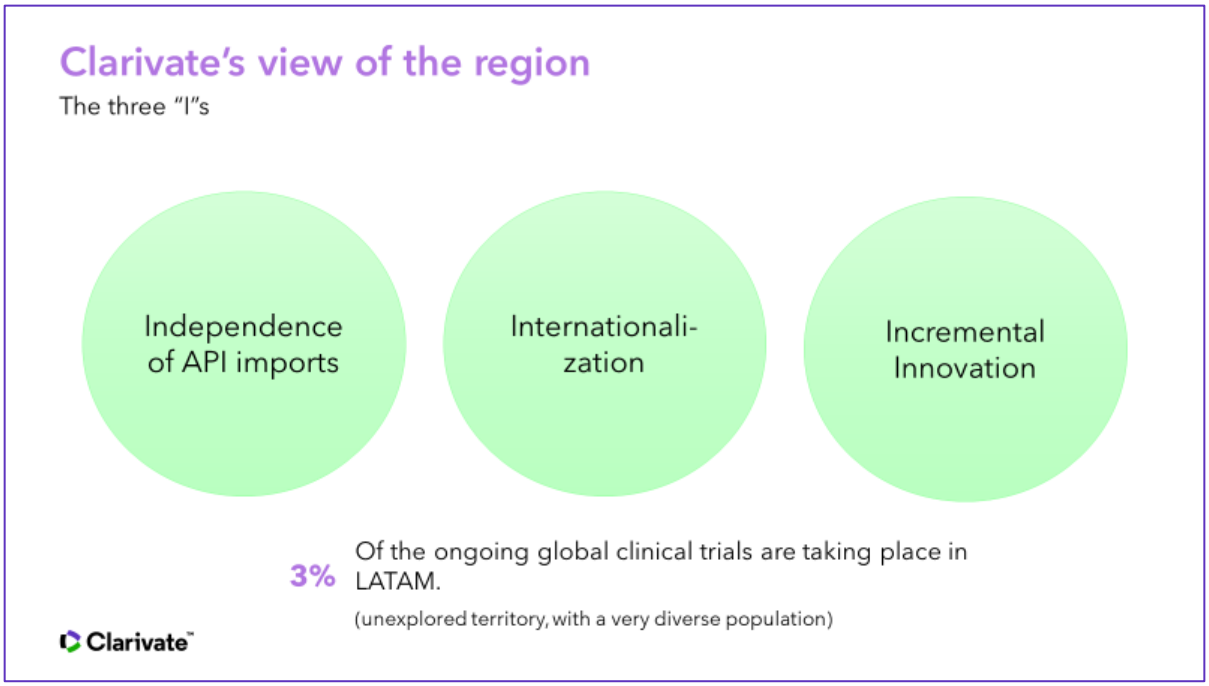


Illustration 2. Vision of the pillars of development in the region that we have at Clarivate

Objectives

The main objective of the LATAM Summit was to build a platform to support discussion and accelerate solution-development processes to expand opportunities and innovation in the region. This forum is a bridge for meeting and debate between different stakeholders in the health sector, between public and private bodies, industry, and regulatory agencies.

The discussion aimed to identify obstacles, uncover opportunities, and discuss solutions and paths to accelerate the development processes in the region. In addition, the goal was to come up with practical solutions and key steps that could be applied to guide the transformation in the region and shape the future.

Clarivate roundtable

Ahead of the opening of CPHI 2023 in Barcelona, Clarivate organized the LATAM Summit in the Clarivate office in Barcelona on October 23rd, together with ABIQUIFI (*Associação Brasileira da Indústria de Insumos Farmacêuticos* [Brazilian Association of the Pharmaceutical Products Industry]) and InTrials. Sixty people from more than 30 government-related institutions in the area of health and innovation, development institutions and representatives of the pharmaceutical industry of various Latin American countries (Brazil, Argentina, Colombia, Chile, Peru, Mexico, Uruguay) were present to discuss market opportunities and innovation in Latin America, creating a discussion forum on these topics among the different stakeholders of the region.

The group has called on Latin American organizations to do the following:

- Change and/or create a culture of innovation, promoting it from the academic and university worlds
- Create stimuli to aid and accelerate innovation (e.g., with public/private investments, building partnerships for productive development, etc.)
- Accelerate regulatory processes to accelerate the potential for clinical studies
- Develop a regional action plan for production of APIs in the region.

The Discussion

LATAM Market Dynamics

It all started with a panel on market dynamics in LATAM. Leaving a pandemic context, where there has been marked revenue growth in the global pharmaceutical industry, companies now face declining growth. However, by most measures, this correction represents a reversion to pre-pandemic growth, and Latin America is one of the fastest growing regions in sales compared the global pharmaceutical market.

Regarding regional performance: a clear tendency to optimize the production capacity and market growth of large national companies was mentioned, which has led to the expansion of the activity at the regional level. Whether through the establishment of strategic partnerships or the formation of large groups operating primarily in LATAM, regionalization has been identified as the first step to penetrating the most regulated international markets, such as the United States. This strategy, successful in the medicines market, has also served as a mirror for the pharmaceutical ingredient industry, which is subject to strong Asian competition. Offshoring of active pharmaceutical ingredient (API) production was presented as a risk element for the regional production chain. Resumption of regional production of APIs is expected to increase the resilience of the sector and contribute to projects for innovation between pharmaceutical ingredients and pharmaceutical products. On the other hand, this regional market growth has undergone a major transition, not only focused solely on generics but also based on incremental innovation initiatives and original product licenses from partners with a very limited regional presence.

The unanimous understanding that the biologicals and biosimilar market not only represents a clear horizon for growth but also translates into an essential horizon with great potential to explore was mentioned and discussed. In countries like Brazil where access to such drugs is highly dependent on public purchasing power, resumption of product development partnerships (PDPs) may be critical stimuli for the development of new products and incorporation of new technologies. One of the current challenges to further stimulate market growth and access to new therapies for patients in the region lies in greater orchestration among the sectors involved: industry, government, academia and startups or biotechnology companies. “From my understanding, the best way to promote a positive agenda in terms of innovation in the Latin American countries, and specially in Brazil, is to develop something similar to the grants provided by the main research institutes in the U.S.,” explains **Stephani Saverio, VP of Business Development at Knight Therapeutics. “**where the private sector, academic institutions, and the government can align themselves on a common agenda and establish areas or technologies that tend to access resources. Startups, private companies and research institutes tend to carry out research and development within the selected parameters to access subsidies. These mechanisms, where the main institutions and governments dictate whether companies and researchers can access resources and finance, have the power to consistently promote a specific innovation agenda.”

Optimizing regulatory times and processes for both clinical study approval and new product registration can have a major impact on market dynamics. As a major learning experience during the last pandemic, international representative agencies such as ANVISA (Agência Nacional de Vigilância Sanitária [Brazilian Health Surveillance Agency]), have dealt with emerging projects from the outset, contributing to the industry’s best evolution. In that regard, Saverio says, “There are relevant differences in terms of current status and type of problems that the different regulatory agencies in each country are facing in Latin America. It is important to find points of common interest to develop a common agenda and understanding to promote regulatory synergies in the LATAM region. Working towards mutual recognition and common Contract Research Organizations (same CRO approved by different regulatory agencies from different countries) throughout the region may help to find such synergies.”

Advanced technologies face great difficulty in implementation and, above all, in paying the costs they entail. This is a clear limitation when it comes to being able to more rapidly expand the major technological advances we see in the world today. Some of the emerging technologies and their impact in recent years on publications, clinical studies, etc. can be seen in the graph below.

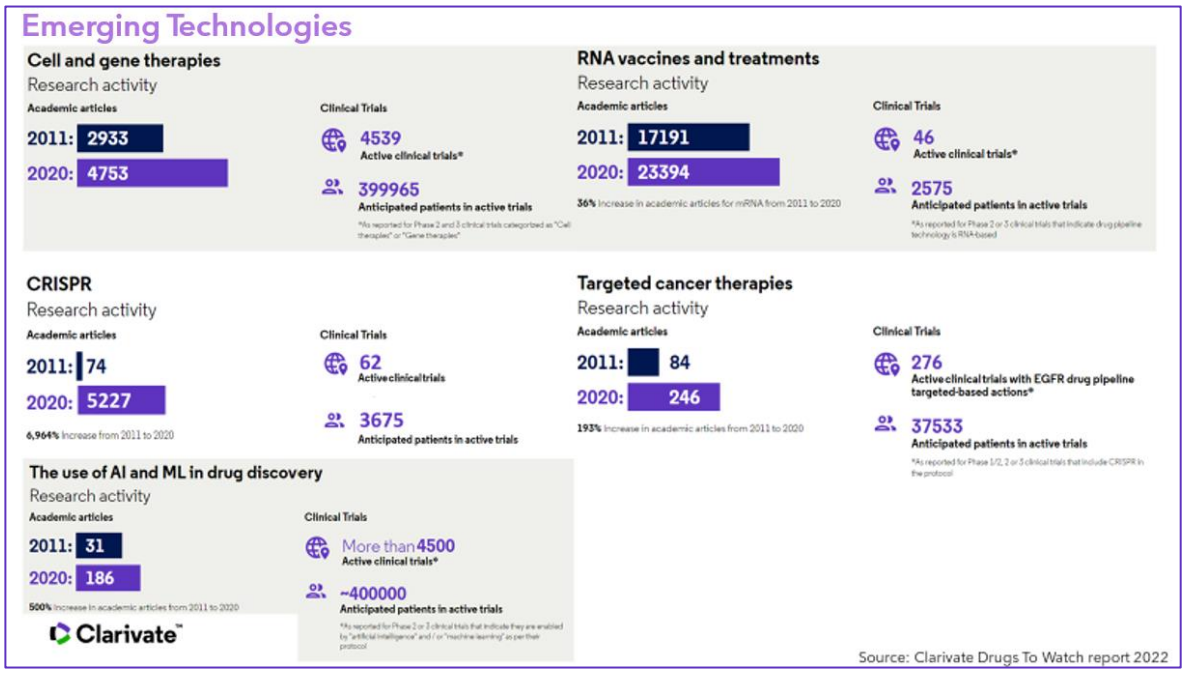


Illustration 3. Emerging technologies applied to pharmaceutical innovation, identified through the Drugs to Watch 2022 report, by Clarivate [ii]

One of the most discussed aspects of market dynamics was the development of APIs. Independence from or less dependence on regions such as China and India for APIs would appear to be key if we could envision a change in the mid-term situation but, by all indications, this will not be easy. Brazil will not be likely to solve the problem alone; the approach should be more successful if taken as a regional priority. A study could be conducted to identify the most important APIs for each of the countries, as well as those of common interest. Brazil could manufacture the most important ones themselves and also export to the region APIs that are of interest to other countries, while importing other APIs manufactured in the region from Argentina, Mexico, etc., for the same purpose. "The importance of prioritizing actions that strengthen the production of LATAM APIs is critical," said **Norberto Prestes, Chair of ABIQUIFI.** "This will only be possible if there is a careful analysis of the production capacity and knowledge and understanding of the technology horizon. The time of nearshoring is a reality to which due importance must be given. We are undergoing considerable geopolitical changes that pose a threat to the block, but at the same time a unique opportunity."

The panel concluded by discussing the great unexplored potential in the Latin American market, where the most mentioned topic was innovation, prompting the start of the second panel that discussed precisely the innovation ecosystem in Latin America.

LATAM Innovation Ecosystem

The discussion began with comments on the need to innovate and exactly how this sparks the interest of the different Latin American companies. This need stems from the existing imperative to remain competitive and differentiate from others operating in the same space. Historically, the Latin American region has always been prominent in terms of incremental innovation (which is not unimportant and is interesting when searching for new business opportunities), which involves making incremental improvements or changes to existing medicines or drug-related processes rather than developing entirely new medicines. However, as discussed by the panel, a greater interest arises in driving and stimulating radical innovation in the region, but the complexity, long wait times and need for substantial investments lead to insecurity in the decision to continue in that direction.

"A big challenge in our region is the weak radical innovation culture we have, because we live in a successful pharmaceutical industry and that has never needed to innovate," said **Peter Andersen, CEO of Grupo Centroflora.** "The challenge is to think about the next 10-20 years, where this model will no longer make sense." This concern was raised on several occasions, and the panel agreed that, in fact, one of the main barriers to the advancement of this activity would be a lack of a culture of innovation in this region. Most local companies focus on activities of lower risk and rapid return, while most basic science, discovery and initial development of new products takes place in research institutes and the academic world. These researchers also do not have the experience and vision of the late stages of this development, doing science for knowledge and publishing their results in scientific papers rather than partnering with the industry and patenting. Part of the rationale for this also comes from a certain bias of the scientific community and funders regarding activities in translational research and involved with commercial activities. This aspect was discussed by different participants, thereby demonstrating that it is a regional reality. "We need more global cases of Brazilian innovation to provide visibility and strengthen the ecosystem in Brazil," added **Miller Freitas, CEO and founder of NINTX.**

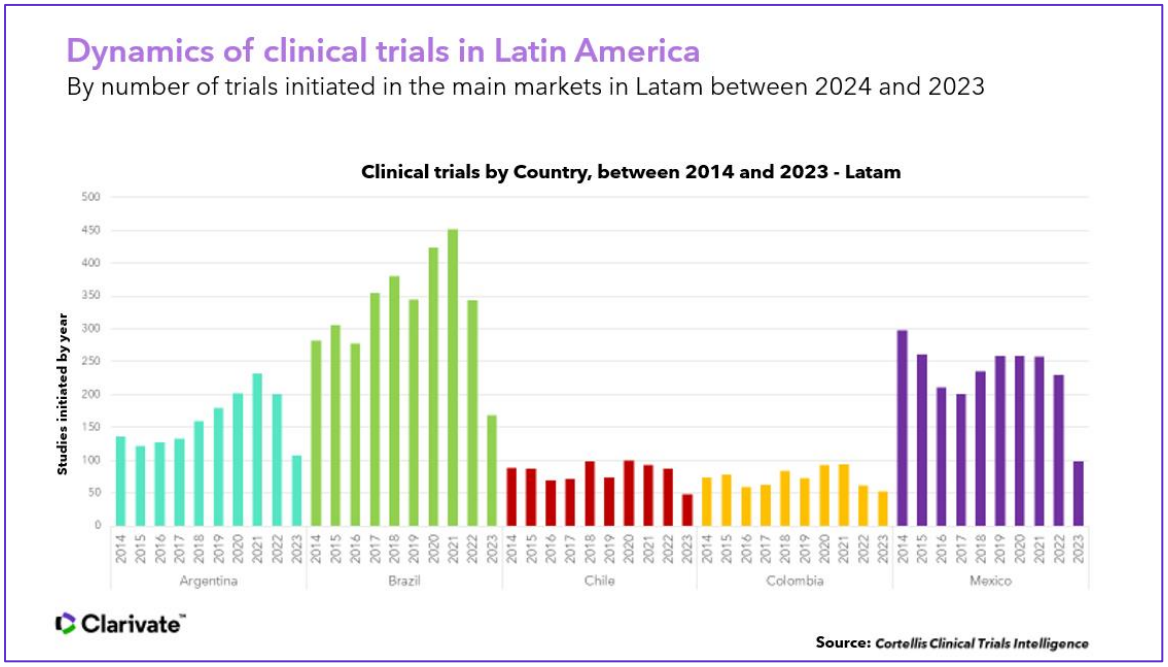
In terms of the current way of innovating, one of the most discussed points was the need for startups in the region for generating this radical innovation. Miller Freitas and Peter Andersen report that there are several small biotechnology companies with interesting products. "We have another window of opportunity to invest and advance radical innovation with the current decentralized R&D model globally, where big pharma is looking for biotechnology and research institutes to license new molecules/technologies," Miller explains, further exploring the great advantage of the vast biodiversity available in the region: "Brazilian biodiversity associated with advanced analytical characterization technologies (OMICS), next-generation DNA sequencing (metagenomics) and fourth generation X-ray (synchrotron) in an environment that is legally structured through the biodiversity law, which offers security for access to genetic heritage and clear rules of value-sharing, provides a unique context of opportunity for the country to excel globally."

It would be important to create stimuli to aid and accelerate this transformation. There are new government programs in Brazil that are implemented to help fund this type of activity, as noted by the **Secretary of Strategic Policies and Programs of the Ministry of Science, Technology and Innovation (*Ministério da Ciência, Tecnologia e Inovações*,** MCTI), Marcia Barbosa, but there is a need for pressure on various government institutions to create more and new initiatives that drive radical innovation activities in the country. "The Brazilian State has the enormous challenge of providing drugs for the population," explained Secretary Barbosa, particularly for the Unified Health System, and it is up to the MCTI to seek scientific strategies to meet the challenges in pharmaceutical inputs, production of new molecules, feasibility of clinical trials, among other issues." Peter Andersen commented: "it is clear to me that the way out lies in startups, which should be supported by companies that are looking for innovative assets. Brazil can take the first steps to develop innovation, but I don't think we have the financial strength (or knowledge) to take innovation from academia to the point of use. Abroad, this resource originating from governments is enormous, which is even the subject of debate, because a lot of innovation is subsidized by public money, and then patents protect companies and not the patient." On this topic, Miller Freitas concluded: The complexity and high tax burden on small businesses that need to invest large amounts in high-risk projects to carry out radical innovation act in the opposite way, discouraging this type of venture in the country."

Daniela Blum de Oliveira, Product Development Lead at SAIL for Health, commented on the existence of organizations in other countries, specialized in supporting innovation activities for small businesses and guiding the next steps in the successive clinical stages. The results of the implementation of this organization are impressive, where the majority of projects have had a prior analysis and those that moved forward, a higher rate of successful results. “Taking into account the success of the SME Office of the European Medicines Agency (EMA) in supporting micro, small and medium-sized businesses, the opportunity arises to implement a similar initiative in Brazil, especially focused on startups,” commented de Olivera. “This proposal aims to establish a mechanism that provides scientific and regulatory guidance to startup projects, simplifying the development of innovative medicines in the national context and the procedures to obtain marketing authorization. A collaborative approach, with the aim of satisfying the specific needs of startups and also streamlining regulatory processes. When considering clinical research in Brazil, we highlight the great diversity of the population, allowing for broader representation in studies. This not only enriches, but can also accelerate patient recruitment, directly benefiting the development and successful completion of clinical studies. Furthermore, conducting clinical research in Brazil can have a positive economic impact, drive innovation, generate jobs and strengthen the country's position in the global research and development scene. Therefore, integrating startup support initiatives with specific advantages of clinical research in Brazil can create an environment conducive to significant progress in medical innovation." There is general agreement that there is unexplored potential in the region, which is a territory of less competitiveness, greater access to patients and wide diversity, but it faces bottlenecks -- for example, around approval times to carry out clinical studies by regulatory bodies.

The graphs below present an analysis of the dynamics of clinical studies by comparing the main markets in Latin America in a temporal model and, subsequently, the ratio in the countries of the former BRICS group.

A



B

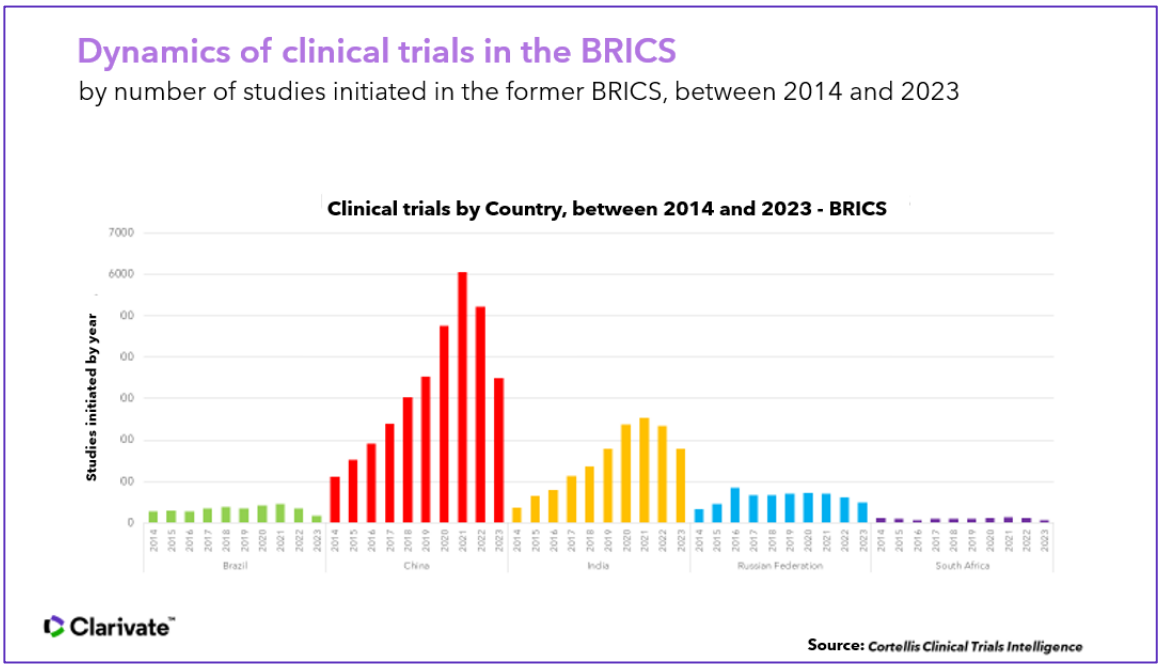


Illustration 4. Dynamics of clinical studies started in the respective countries, in the last decade, in two contexts: A - Latin America; B - former BRICS[iii]

"Dialogue with the private sector is essential to pave the way towards building an Industrial Health Complex that is not simply an expression of effect" commented Barbosa. "We understand some of the regulatory problems, some elements such as the existence of few CMOs and CDMOs, which are structures that need to be promoted by the state." "We need to make the agendas converge in a single direction by bringing together businesses, government, the academic world and class entities so that the ecosystem of research/startups/business in the country is more favorable," Miller added.

Regarding the end of the conversation, it is clear that there is a great need to work with data science, combined with the use of analytical tools and artificial intelligence, to shorten some processes. This seems to be the only model so that each of the different groups involved can contribute to accelerating innovation activity in Latin America.

At the end of the Summit, Andersen commented "events like this one from Clarivate/ABIQUIFI should be repeated often, because it is the only way to consolidate the topic and, in fact, build partnerships with startups, universities and companies, walking together." "The event was one of several conversations necessary to build a disruptive industrial policy for health", concluded Barbosa. This was the first forum for discussion on market and innovation for Latin America – but it will not be the last – in a model that will be repeated across the region.

Barriers and Opportunities

Main barriers identified by the panel:

1. A lack of culture of innovation
    a. Local companies that are always successful in low-risk, short and mid-term developments
    b. Academic researchers (where initial innovation is made) without knowledge of how to do translational research
    c. Bias of the scientific community and funders regarding translational research activities
2. Few orchestrations among the sectors involved: industry, government, academia and startups or biotechnology companies
3. Low government incentives (neither investments nor less tax burden) for innovative developments, as in other parts of the world
4. Little contact between agencies in LATAM to find regulatory synergies in the region
5. Long timelines for approval of clinical studies
6. Few global clinical studies are conducted in LATAM
7. Asian competition for the regional pharmaceutical ingredient industry
8. Lack of communication between countries about each other's API needs
9. No regional work in the production of critical APIs for each country and the region as a whole
10. Presence of few CMOs and CDMOs in the region
11. Advanced technologies with a major implementation issue due to costs

Key opportunities identified by the panel:

1. Latin America continues to be a region with significant growth;
2. The region already has very well-structured industrial parks and is able to address the better part of local demand;
3. Regional growth is not only based on generics but also on incremental innovation models and innovative product licenses;
4. The PDP model implemented in Brazil is a good example of an opportunity for the development of complex products such as biologicals or biosimilars;
5. Optimization of wait times and processes can have a major impact when approving clinical studies or new product registrations;
6. Regulatory synergies in the region, that if promoted, could present a way of accelerating wait times and decrease costs;
7. Biodiversity in Brazil and other countries in the region is a great opportunity for innovation. Development and investment in this segment is key;
8. Diversity and size of the population in Latin America is a strong point in the development of clinical studies;
9. Strong academic expertise regionally, for certain medical areas with serious unmet needs – graph below, like Brazil. For example:

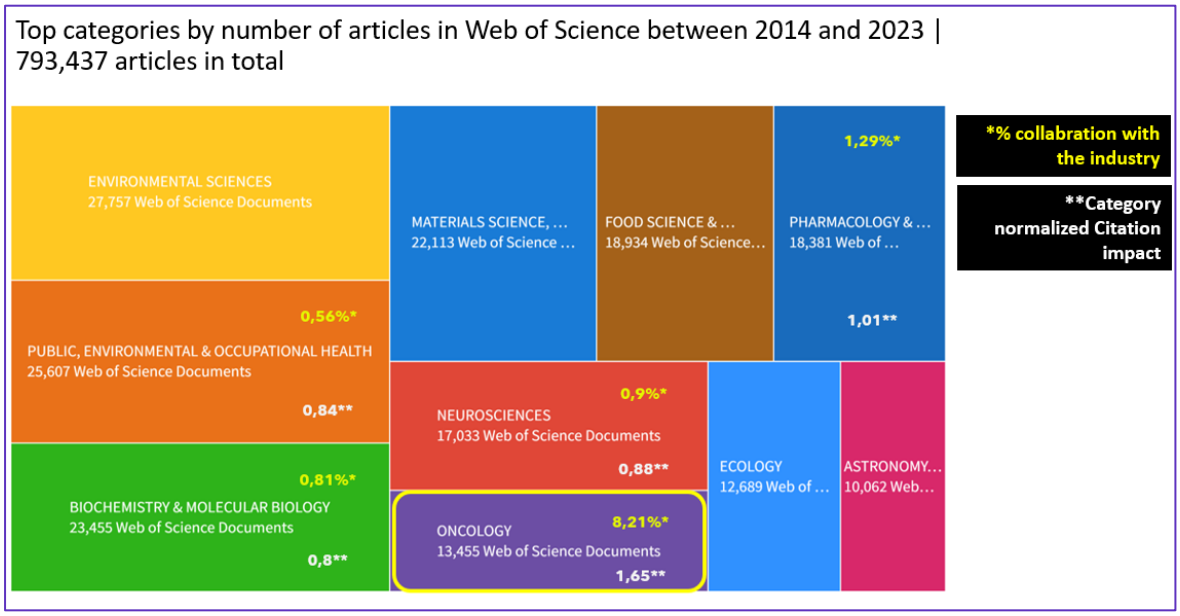


Illustration 5. *Main areas of scientific research in Brazil, between 2014 and 2023, according to the number of articles published by national institutions indexed on the Web of Science (793,437 articles in total). Percentile of publications in collaboration with the industry and the scientific impact standardized by the global mean are represented*[iv]

Proposed Actions

The creation of a culture of innovation, as widely discussed by the panels, would allow for a greater interest in innovating without bias and with better support to carry out that activity. Likewise, as already discussed, investments are not small, and it is a higher-risk activity that the regional industry is not used to. In other regions, there are government grants for this activity; in a region like Latin America, where the radical innovation that exists is done in academia and research institutes, which are generally public, it should not be any different. Public-private alliances for product development, tax incentives or government investments would have a positive impact on the development of radical innovation in Latin America.

Promoting meetings and forums with agendas in this regard in the different countries of the region will aid closer work among the different sectors involved.

Decreased wait times for clinical trial review for its approval in the region would also be likely to have a significant impact on innovation in these countries, not only for products developed in those countries but also for external studies to be executed in the region. As presented, only 3% of the studies conducted globally are also conducted in Latin America, and the increase in that percentage, in addition to being a benefit for the population, would also bring external investments to the region. As a comparison, data published by the Brazilian Association of Representative Clinical Research Organizations (ABRACRO, *Associação Brasileira das Organizações Representativas de Pesquisa Clínica*) show that Brazil is very slow in these reviews. The ethical and health evaluation of clinical studies takes, on average, eight months and may take more than one year-- not to mention the many outstanding issues and requirements for changes to research protocols during their development. In the U.S., this timeline is 45 days; in Europe it is 60 days.

Work with regional regulatory agencies to seek optimization of review times and processes.

The development of APIs for key products regionally is very important. There are not many companies developing active ingredients in Latin America, and the countries are widely dependent on China and India, in addition to other countries, for importing these materials and subsequent production of the medicines. There are molecules that have a regional interest, and these products can be developed by different countries and exported to others in the region in a joint activity to decrease the external dependence on the most relevant molecules.

Regional work with the different boards, associations and government institutions, from a collaborative aspect, can lead to incredible benefits in the mid-term.

Generate an ecosystem in LATAM, where all players involved (companies, governments, regulatory agencies, academia and startups) participate in search of a common agenda and collaborative interests. Hold systematic meetings and draft documents that demonstrate advances in pillars of innovation, clinical studies and API production.

Conclusions

As can be concluded, the potential of Latin America in terms of market opportunities and ability to develop innovations is gigantic. However, there are challenges and barriers that must be overcome so that the great untapped potential can be met. Local joint actions between countries and different players, such as industry, governments, etc., can contribute significantly to an acceleration in innovation activities in the region.

The meeting held in Barcelona was the first forum of the type, but it will not be the last. The main action items identified at that meeting for better development of the Latin American region were:

1. Help develop a wider culture of innovation in the region
2. Work on models that promote a decrease in review times by regulatory agencies
3. Promote, through analysis and studies, improved local production performance for APIs of interest to LATAM countries
4. Stimulate an ecosystem in the region with the involvement of different stakeholders in the health sector

Participants

Panelists

Stephani Saverio	VP Business Development	Knight Therapeutics
Norberto Prestes	Chair	ABIQUIFI
Marco Antonio Fernandes	Business Development	Bionovis
Romison Mota	Director of the Third Board	Brazilian Health Surveillance Agency (ANVISA)
Peter Andersen	CEO	Centroflora Group
Daniela Blum de Oliveira	Product Development Lead	SAIL for Health
Marcia Barbosa	Secretary of Strategic Policies and Programs	Brazilian Ministry of Science, Technology and Innovation (MCTI)
Miller Freitas	CEO and Founder	Nintx
Henry Levy	President of Life Sciences & Healthcare	Clarivate
Cristian Madoery	Director Latin America	Clarivate
Leticia Ferreira Terra	Senior Consultant Americas	Clarivate
Antero Macedo	Senior Account Manager Brazil	Clarivate

Attendees

ABIQUIFI	Brazil
Aché	Brazil
Adeste	Brazil
Althaia	Brazil
ANVISA	Brazil
Bionovis	Brazil
Biosano	Chile
Blanver	Brazil
Centroflora	Brazil
Brazilian Consulate in Barcelona	Brazil
Cristalia	Brazil
Ease Labs	Brazil
EMS	Brazil
Globo	Brazil
FINEP (*Financiadora de Estudos e Projetos* [Funding Authority for Studies and Projects])	Brazil
Hypera	Brazil
INPI (Instituto Nacional da Propriedade Industrial [Brazilian Institute of Industrial Property])	Brazil
InTrials	Brazil
Knight Therapeutics	Canada
Libbs	Brazil
Lukoll	Peru
MCTI	Brazil
Mega Labs	Uruguay
Nintx	Brazil
Pharmatique	Colombia
Prati Donaduzzi	Brazil
Promediol	Brazil
Qalycare	Brazil
Rossmore	Brazil
SAIL for Health	Brazil
Siegfried SAS	Colombia
Tecnologia Innovativa	Argentina
Tuteur	Argentina

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iii. Data analyzed from Cortellis Clinical Trials Intelligence, a Clarivate Analytics solution (https://clarivate.com/products/biopharma/research-development/clinical-trials-intelligence-analytics/)
iv. Data analyzed from InCites, a Clarivate Analytics solution (https://clarivate.com/products/scientific-and-academic-research/research-analytics-evaluation-and-management-solutions/incites-benchmarking-analytics/)

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