Global Campaign for Clinical Trials

Patient Access to Clinical Trials in Latin America

Patients deserve high-quality care, regardless of where they live. In Latin America, as across the globe, innovation and research can offer patients the next generation of treatments and cures.

Encouraging investment in clinical trials, therefore, is an essential part of patient care. By testing new treatments, clinical trials not only optimize development but also connect local patients with transformative medicine. And that investment is vital for low- and middle-income countries that seek cutting-edge treatments for vulnerable populations.

But some countries institute policies that, while aimed at expanding treatment, unintentionally undermine access to new innovative medicines that deliver better health outcomes. Whether it's underfunding of clinical trials, excessive red tape surrounding a new medication's approval, or compulsory licensing, poorly conceived policies can negatively impact patient care and undermine access to breakthrough treatment options.

What are the Barriers to Clinical Trials Access?

Clinical trials study new treatments to see if they are safe and effective for patients. With robust participation and investment, clinical trials can be a game-changer for patient access—improving or even saving lives and helping stop the spread of disease. The success and rapid output of COVID-19 vaccines offer one example. Investment, prioritization and timely availability to the general public prompted high levels of participation and funding of clinical trials.

But most clinical trials are woefully under enrolled. They suffer from prohibitive costs, low engagement from healthcare providers and a lack of diversity among participants. In one survey, 85% of patients were either unaware or unsure that participation in a clinical trial was an option at the time of diagnosis.[1]

Another hurdle to clinical trial access is undermining intellectual property. When countries fail to protect patent rights, they may discourage companies from conducting clinical trials. That can lead to market uncertainty, reduced innovation and, ultimately, restriction of patient's access to new treatments.

To encourage greater access to clinical trials in Latin America, sound policy is needed. Policymakers must treat clinical trials as a public health priority by supporting patient enrollment, educating providers, raising public awareness and fostering increased investment in research.

What is Compulsory Licensing?

Compulsory licensing occurs when governments allow companies to sell copies of another company's medication before the period of patent exclusivity expires. The approach was intended to provide quick, affordable medicine for a large group of patients facing dire circumstances.

But what was originally designed for medical emergencies has become a dangerous shortcut that comes at a high price. Compulsory licensing has costly unintended consequences, and its long-term use makes it increasingly impossible for patients to benefit from access to clinical trials and the next generation of innovative medicines.

Compulsory licensing can also inadvertently restrict patients' access to treatments in the long term. That's because ignoring intellectual property rights can lead to:

Reduced medical innovation.

When government policies continuously undermine intellectual property protections, manufacturers are less incentivized to bring a new treatment to that market. This disincentive inadvertently creates barriers to timely care and results in fewer treatments for patients.

Fewer clinical trial sites.

Latin America already offers fewer clinical trials, and participation rates are disproportionately lower than in European countries.[2] Compulsory licensing further exacerbates the disparity by holding developing countries back due to disincentives to new clinical research.[3] In some developing countries that implemented compulsory licensing, new treatments under development stalled and investment for clinical trial sites dried up.[4]

Delayed distribution and treatment.

Instead of democratizing treatment, compulsory licensing in certain regions led to new drug creation being delayed.[5] In India, far fewer drugs entered the market following the implementation of compulsory licensing.[6] In addition, some developing countries lack the technological capability to effectively produce foreign-created medications, forcing citizens to wait, and in some cases, even delaying distribution of a drug.[7]

The Unintended Consequences of Compulsory Licensing

Quality concerns.
Introduces quality concerns, as copies may not have been held to the highest standards of efficacy and safety

Reduced innovation.
Undermines the development of new treatments and medical innovation

Access barriers.
Hurts patient access in the long term

Market uncertainty.
Reduces manufacturers' ability to plan for future investment and to bring new medicines to the region

Fewer local trials.
Discourages companies from establishing clinical trial sites

Economic loss.
Impacts a region's long term economic vitality

A LOCAL LENS

Clinical trials and compulsory licensing in Latin America

Latin America is underrepresented in clinical research. In oncology, for example, **Latin America makes up only 5% of ongoing cancer clinical trials despite Latin Americans disproportionately suffering from high rates of diagnoses.**[8] Regulatory constraints like compulsory licensing, paired with skepticism and lack of awareness of clinical trials, hinder research and discourage funders from developing new treatments for the population's that need it most.

In Brazil, patients were forced to wait two years to receive copies of a medication following the issuing of a compulsory license.[9] The government issued a compulsory license for Efavirenz in May of 2007, but the leading government-owned pharmaceutical producer failed to deliver due to a lack of technological understanding. Brazil was instead forced to import the generic version of the drug from India before the government-manufactured version of the drug was accessible to Brazilians.

What is voluntary licensing?

Voluntary licensing is an arrangement that allows developers to partner with other companies to make, use, sell or import a patented medicine. This voluntary arrangement allows collaboration between patent holders and distributors to ensure a product's quality and consistency.

With all stakeholders in agreement, voluntary arrangements offer a more sustainable and collaborative approach to increasing patient's access to medications.

Conclusion

To offer patients the best care possible, policymakers must work to protect the access to clinical trials and the medical progress they provide.

Compared to compulsory licensing, voluntary licensing allows patent holders to work with other companies to create or sell a patented medication, offering manufacturers a solution that allows them to protect their intellectual property rights and immediately serve a larger patient population.[10]

Governments who adopt policies that encourage research stand to not only improve patient access and their population's health, but also reduce the economic cost of illness while encouraging future investment, research and innovation in their country.

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