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Review Article

Regulatory Intelligence in Emerging Pharma Markets: Bridging Innovation with Compliance

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ABSTRACT

The delayed access to innovative medicinal products such as orphan drugs and biologics and mRNA vaccines and advanced therapy medicinal products ATMPs occurs in numerous developing nations because of disjointed regulatory frameworks and inadequate infrastructure and minimal harmonization efforts. The strategic process of Regulatory Intelligence (RI) which entails real-time collection and analysis of global regulatory insights functions now as a bridge to speed up market entry. This analysis evaluates the developing significance of RI as a tool for enhancing rapid and secure regulatory procedures which maintain transparency within Low- and Middle-Income Countries (LMICs) that experience substantial neglect diseases and new health challenges. We detail worldwide RI strategy approaches through an examination of their implementation towards delivering therapeutic treatment for high priority areas. Through a study of regulatory structures and capacity-building methods and asset-based pharmaceutical systems we establish major obstacles and facilitators to Integration of Regulatory Innovation. The paper provides detailed insights regarding how RI affects the development of expedited pathways together with Real-World Evidence (RWE) methods and adaptive licensing practices and collaborative review procedures. Multiple real-world examples from Asian, African and Latin American regions demonstrate how RI drives enhancements in both regulatory speed and public health service delivery. A step-by-step guide is provided to resolve infrastructural and human capital challenges and policy inconsistencies so LMICs can properly implement RI in their regulatory framework. The document provides specific policy suggestions that combine regulatory convergence with digital development and stakeholder relations and openness. The findings from this review demonstrate that RI operates beyond being a practical mechanism by establishing the core element needed in resilient regulatory frameworks which also include inclusivity and future-readiness. Investment in RI by LMICs enables them to boost regulatory performance and establishes their stronger strategic positions within the global pharmaceutical sphere which ensures fair access of innovative healthcare to all populations.

Keywords: Regulatory Intelligence (RI), Accelerated access, Orphan drugs, Biologics, mRNA vaccines, Advanced Therapy Medicinal Products (ATMPs), Developing countries, Regulatory harmonization.

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INTRODUCTION

The pharmaceutical industry experienced an immense technological revolution in the twenty-first century by developing revolutionary treatments which science previously believed to be impossible. A complete range of innovative medicinal products now exists in the scientific pipeline including orphan drugs for rare diseases as well as biologics which offer advanced potency effects alongside mRNA vaccines that enabled successful pandemic responses and Advanced Therapy Medicinal Products (ATMPs) such as cell and gene therapies. The delivery of innovative therapies faces substantial difficulties in areas that include Asia and Latin America together with Africa because of equitable distribution challenges. Many developing nations face challenges matching their regulatory frameworks for approval with innovative research because high-income countries already have established these frameworks but they lack the resources to implement them. The pharmaceutical regulatory ecosystem allows Regulatory Intelligence (RI) to function as a vital strategic discipline which connects between different regulatory areas. The methodical acquisition of regulatory information through analysis leads to beneficial outcomes for life sciences entities and regulatory experts since they can predict and take well-informed choices during product lifecycle activities. RI serves a mandate that extends beyond regulatory adherence since it enables healthcare agencies to presentially adapt to changing

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regulatory environments while simplifying the approval process and streamlining documentation submission for improved relationship management with medical authorities. ITanium therapies require such complex benefit-risk assessments and post-market commitments and cold-chain requirements that RI exceeds its helpfulness to serve as an essential regulatory framework. RI continues to prove its vital role in delivering transformative medicines to markets early on through various recent global health crises particularly the ongoing COVID-19 pandemic. All regulatory authorities worldwide including Global South institutions were compelled to change their traditional models by implementing emergency approvals and continuous assessment methods and source authority reviews and real-world evidence evaluation. The regulatory change opened up an exceptional chance for developing countries to test and make RI tools permanent alongside digital framework advancements. The successful adaptation to changes depended on the strength of regulatory frameworks and digital systems as well as technical knowledge between different countries (Calamia and Abraham, 2023).

The requirement for regulatory discussions becomes most crucial during the evaluation of innovative therapeutic products because each follows its own distinct set of regulatory challenges. Orphan drugs face difficulties with obtaining market viability because their trial populations remain small which makes statistical validation difficult to achieve. Biologic drugs demand extensive studies about immune responses because their complex molecular structure combined with strict requirements about bio similarity testing and cold-storage distribution. MRNA-based vaccines require advanced research concerning their particle-lipid behavior and super frost storage protocols and variable acceptance from regional regulatory bodies. The delivery of individualized patient treatment with gene and cell therapies necessitates customized regulatory oversight together with adaptable production clearance protocols and present-time quality evaluation and long-term safety management systems that find ongoing development in many emerging regulatory structures (Chopra and Lopes, 2017). This review analyzes how RI functions to enable therapeutic accessibility throughout emerging markets through predictions of regulatory standards while developing proper submission solutions and exploitation of reliance connections and global regulatory alignment. The structure of this review presents multiple viewpoints about the topic. First, we define innovative therapies then explain the special regulatory challenges they bring to the table. Next, we examine basic RI principles with a focus on its extensive area of application together with its central role for accelerating both development process and market penetration of new products. Subsequent sections will analyze Asia and Latin America and Africa through dedicated research and realities from the field regarding RI implementation in these regions. A review conducts analysis of RI strategic components which include gap identification as well as adaptive regulatory approaches and real-time data collection and global governance mechanisms. The practical implementation of RI will be explained through different real-life examples which include India's orphan drug procedures and Brazil's biologics regulatory practices and South Africa's swift mRNA vaccine approval process. The article evaluates the obstacles that impede efficient RI implementation across the regions including information fragmentation and language differences and worker shortages alongside technical system deficits. The conclusion anticipates future changes in RI through examinations of artificial intelligence capabilities and blockchain-based submission systems and real-world evidence implementation and free regulatory database accessibility for improving RI during the next decade. RI plays an essential role beyond competitive industry conditions because it directly influences global healthcare fair distribution standards. Revolutionary novel treatments provide no benefit when regulatory hurdles result in their complete inaccessibility for billions of people worldwide. Emerging markets participate actively in pharmaceutical development as they conduct tests for pharmaceutical products while fabricating key Active Pharmaceutical Ingredients (APIs) along with demonstrating homegrown pharmaceutical innovation. The achievement of Universal Health Coverage (UHC) together with UN Sustainable Development Goals (SDGs) especially SDG 3 demands market empowerment through essential regulatory capacity and intelligence tools for cutting-edge therapy adoption (Detiček, Locatelli, and Kos, 2018).

ORPHAN DRUGS AND THE CRITICAL ROLE OF REGULATORY INTELLIGENCE IN BRIDGING ACCESS GAPS IN DEVELOPING NATIONS

Orphan drug research and development has been an extremely tough but indispensable aspect of global innovation in pharmaceuticals for populations that suffer from the ravages of rare diseases. These therapies often administer life-saving but are often made difficult for countries in low-and-middle income states to develop and get approved. Introducing Regulatory Intelligence into the lifecycle of orphan drug regulation has marked a major change in the systemic disparities that exist in specific regions. Defined as a systematic collection, analysis, and application of regulatory information in decision-making guidance, RI holds the key for LMICs to align themselves with changing global standards while hastening access to the niche-high-impact therapies. A review of the multidimensional barriers to orphan drugs in LMICs and the strategic application of an RI framework in dismantling these barriers towards creating an avenue for equitable health access is articulated in this section. The absence of rare disease policy and dedicated regulatory pathways in most LMICs has been recognized as an important deterrent to orphan drug access. Western regulations such as those developed by the United States Food and Drug Administration (FDA) or the European Medicines Agency (EMA) include detailed

orphan drug legislation like the U.S. Orphan Drug Act of 1983; however, many LMICs do not even recognize rare diseases as a regulatory priority. This absence results in an uncoordinated approach towards evaluation of therapies intended for small patient populations. There are no defined incentives like market exclusivity, fee waivers, or protocol assistance that can encourage manufacturers to register orphan products in those markets. This is where RI becomes critical: monitoring global legislative trends and analyzing how orphan-specific incentives have worked in different jurisdictions will help LMIC regulators design and advocate for locally adapted orphan drug policies that are both pragmatic and responsive to public health needs (Driscoll *et al*., 2021). Moreover, RI enables such countries to adopt regulatory reliance models for orphan drugs, especially when national resources for product evaluation are limited. Abridged reviews based on trusted reference authorities, such as the FDA and the EMA or Swissmedic, can materialize into dramatic shortening of time to market combined with safety and efficacy measures. RI supports this mechanism through structured comparative assessment of regulatory decisions, dossiers, risk management plans, and post-marketing surveillance data across jurisdictions. Thus, RI fosters evidence-informed reliance to reduce the duplication of regulatory effort and leverage scientific rigor from established agencies around the world. For example, with little technical input guided by regulation intelligence teams, Colombia and South Africa are moving towards embracing such models to use in orphan drug approvals.

In parallel, the RI process provides scientific advice and early conversations that are essential for LMIC decision-making about the development pathway of orphan drugs. Once orphan drug development begins, there are usually not many attempts made to standardize against precedents in the common disease areas because of the rarity and heterogeneous nature of the diseases. This makes it imperative to have an early set of consultations with regulators so that the developers and regulators are aligned with each other's expectations regarding trial design, biomarker validation, and Real-World Evidence (RWE). Here, RI plays a crucial role in picking up best practices from various parts of the world-for example, from Japan with Sakigake designation or Australia with its Priority Review Pathway-and supporting their accommodation for LMICs. These lessons create a local ecosystem that nurtures innovation without too much regulatory ambiguity. RI is also being called on more and more to inform pricing, reimbursement, and HTA decisions concerning orphan drugs. Because of their high unit costs and uncertain cost-effectiveness corresponding to small patient populations, orphan therapies put serious fiscal pressure on national health systems. Whenever RI complements horizon scanning and cross-border data sharing, it allows LMICs to get advance warnings concerning high-cost therapies, then RM can proactively engage with manufacturers, collaborate in joint procurement, or seek multilateral funding assistance. Thus, regional regulatory networks in Latin America and Africa have begun looking into pooled HTA approaches, promisingly informed by international cooperation platforms, such as the International Network of Agencies for HTA (INAHTA) and EUnetHTA. Such developments indicate the role of RI not only in the assessment of regulation but also in aiding strategic resource allocation and equitable coverage policies. One major contribution of RI when considered from the view of orphan drugs is its ability to drive regional regulatory harmonization and information exchange. Given the tiny and often dispersed target populations for rare diseases, regional cooperation will be vital for generating meaningful clinical data, minimizing redundant trials, and ensuring timely regulatory processing. This coordination is supported by formal RI systems that provide shared databases, regulatory convergence maps, dossier templates, and frameworks for common terminology. The African Medicines Regulatory Harmonization (AMRH) and ASEAN Joint Assessment Program illustrate that centralized intelligence platforms can facilitate orphan drug approvals across different jurisdictions and give pharmaceutical companies a wider window to enter the international market while ensuring the timely delivery of novel therapies for patients. All in all, the success of RI in enhancing the availability of orphan drugs in reality will depend on also the human resource capacity-building. Regulatory authorities in LMICs are also often plagued by human-resource constraint, limited pharmacovigilance, and lack of specific training. As given in tables given in Table 1.

On top of that, RI gives valuable information concerning safety monitoring after approval, a very sensitive issue regarding orphan drugs and many ending with conditional or accelerated approvals. RI helps LMICs better monitor adverse events and provide timely safety communications through international pharmacovigilance database mining (VigiBase at Uppsala Monitoring Centre) comparing risk mitigation strategies between regulators. By protecting patient populations and maintaining public trust in the new therapeutic technologies, this is especially important in markets where skepticism about innovation may slow uptake. RI deals with ethical and societal issues arising from the introduction of orphan drugs in LMICs. Questions surrounding fairness in access, the opportunity cost of funding expensive therapies for few patients, and the risk of creating two-tier systems of care must be navigated with great care. RI provides intelligence-monitoring civil society dialogues, policy discussions, and trends of patient advocacy-so regulators and policymakers understand what is expected from them and are prepared for reactions from society. This intelligence could then be translated into regulatory strategies that are more inclusive of balancing incentives to innovate with the imperative of distributive justice. For example, "Ruta de Atención Integral para Enfermedades Huérfanas" in Colombia emerged as a result of patient advocacy, and was further nourished by the intelligence inputs from the Latin American counterparts (European Medicines Agency, 2023).

Particularly, the aspect of the digital transformation of RI for the maximization of the access impact onto orphan drugs would be the increasing embedding of advanced data mining, natural language processing, and machine learning tools towards RI platforms so that regulators can process the huge amounts of unstructured regulatory and scientific information at speeds that have never been attained before. For LMICs, it provides the promise of scale and sustainability but only if there is adequate investment in IT infrastructure and cybersecurity to complement these digital tools. Such RI cloud systems permit a region to have a shared service mode for managing multiple national authorities, all saving costs and promoting cross-border intelligence sharing. Some pilot projects are exploring this model under the WHO Global Benchmarking Tool framework in Africa and Southeast Asia. Finally, RI empowers LMICs to engage in global regulatory diplomacy with even greater confidence. Advances in orphan drugs, particularly gene therapies, cell therapies, and mRNA platforms, push the frontiers of medical science, meaning that regulatory positions taken by LMICs will increasingly inform the global debate on harmonization, access, and safety. A well-designed RI system assures that these countries will not be merely recipients of international norms; they will also be players in discourses around them. To cite an example, the Indian Central Drugs Standard Control Organization recently initiated position papers and guidances on orphan drug regulations according to RI based on European and US footprints as an indicator of the path toward strategic engagement (Gieber *et al*., 2023).

REGULATORY INTELLIGENCE: CONCEPT, SCOPE, AND STRATEGIC ROLE IN PHARMA INNOVATION

Regulatory Intelligence (RI) has metamorphosed into a mission-critical discipline with a role superior to pure compliance functions, particularly with the emerging pharmaceutical and biotechnological frontiers-in any part of the world, especially with that of emerging markets. RI, in short, is the process of gathering, analyzing, and applying regulatory information and insights to make a more optimal decision in the life cycle of the product-from preclinical planning and clinical trial design through marketing authorization, post-marketing surveillance, and lifecycle extension. It thus provides the requisite means for all stakeholders-multinational pharmaceutical firms, local startups, and everything in between-to safely navigate the complex, evolving, and most often fragmented regulatory ecosystems they encounter as they bring their interventions to practice in Low- and Middle-Income Countries (LMIC). For progressive innovations such as orphan drugs, biologics, mRNA vaccines, and cell/gene therapies, RI offers a competitive edge by expediting regulatory timelines, mitigating risks, and increasing access to patients. Unlike traditional regulatory affairs that are mainly concerned with preparation of submissions and engagement with agencies, RI is an outward-looking discipline. Proactive rather than reactive, it requires not only knowing existing regulations but also foreseeing regulatory changes, cognizant of global precedence, and adapting immediately development programs to the changing international environment. As an example, as new regulatory frameworks emerge for mRNA platforms or CAR-T cell therapies, RI assists stakeholders to rapidly interpret these frameworks and apply them in LMIC contexts, even where local legislation may be silent or ambiguous. Thus, RI becomes an enabler of innovation, translating global scientific innovation into local and acceptable regulatory strategies. To really feel the might of RI, however, it is necessary to understand the five core pillars upon which RI is built. The first of these pillars is regulatory monitoring and surveillance. In a globalized world, new decrees from agencies such as the U.S. FDA, EMA, PMDA (Japan), ANVISA (Brazil), CDSCO (India), or SAHPRA (South Africa) can considerably change regulatory routes in other parts of the world. An RI system must therefore track these functional changes in real-time coalitions through new guidances, advisory committee decisions, trends in inspection, and scientific publications-instead of collecting raw data points for analysis. Contextual analysis, which is the second pillar of RI, takes the raw data points and transforms them into insights. For instance, a refusal-to-file decision by the FDA on an oncology gene therapy may highlight problems related to dossier quality and prompt developers to amend their submission strategies in parallel jurisdictions. The third core pillar is strategic planning, where RI bridges the gap between intelligence and execution. This includes identifying the most efficient regulatory pathways-response through reliance procedures, conditional approvals, or orphan drug fast tracks, depending on a country's regulatory maturity and existing precedents. A company can thus be an excellent fit for the market while using the system established by that regulatory authority.

The site that was selected for the present study is Amity University's celebration of 10 years of its establishment. This site was chosen because it would likely serve as a venue for a future Industrial and Academic Interaction Workshop, which the SASTRA University has proposed for this year. The way things are progressing during the Democratic Republic of Congo elections shows that there is much to be refined in future polls." The technical building process should progress with time. This process will soon show its scope regarding how the electorate can vote without the ink." It should be temporary before permanent arrangements could be handled (Government of Singapore, 2005). The great populations are surely waiting with bated breath to see a true demonstration of this technology," Hiss said. It is important to have appropriate pictures showing how brilliant the screen can be put when people are covering the windows. Put up beautiful decorations when Christmas comes so that Nairobi residents can be able to see the straight heavens lighting this capital city more in the spirit of Christmas. As the electrifying event unfolded, the students flexed their muscles in the dance choreography competition. The

students outweighed one another, as there were too many teams vying for the prizes, glory, and fame in the annual event. When asked for their reasons, some claimed it was just for leisure, while others expressed their love for the music and dance styles. As given in Figure 1.

When implemented correctly, RI can serve as an effective accelerator for the regulatory process-one that critically needs to respond to life-saving, time-sensitive therapies. Every week of delay in any innovative product category catering to rare diseases, cancers, or pandemics means a potential loss in clinical benefit and diminished quality of life. RI smartly maps regulatory bottlenecks, process redundancies, and reviewer capacity limitations to enable sponsors to optimally time their regulatory submissions, minimizing the chances of non-acceptance of the dossier and thus contributing to shortening time-to-market. Case-studies showed RI usage in identifying orphan drug review exemptions in India or conditional approval policies in Brazil that enabled companies to gain faster market access than their competitors. Besides these, RI plays an important role in managing risks, particularly relevant for advanced therapeutics such as gene therapies or RNA-based platforms, where regulatory uncertainties are high. Appropriate use of historical regulatory precedents helps in diminishing the risk of non-approval due to safety data insufficiency, manufacturing validation inadequacy, or ambiguity in the evaluation of benefit-risk ratio. Suppose for example, the EMA grants approval for CAR-T therapy under conditional marketing authorization, with a promise of long-term follow-up. In that case, RI can allow the applicant to replicate that model in submissions to LMICs. Also, if an mRNA vaccine obtained emergency use based on its surrogate endpoints, RI may assist the developers to advocate for the same in developing locations still undergoing the development of vaccine regulations. In those emerging markets where often regulatory frameworks are fragmented or in flux, RI equally supports regulatory harmonization and localization. It allows companies to reconcile their core Common Technical Document (CTD) with localized divergences required in particular countries-be it translations, region-specific clinical data, or ethical committee formats. More importantly, RI helps align local product labels, packaging insert content, and risk management plans with global best practices, which effectively prevents any possible compliance issues during the post-approval phase. This is even more critical for therapies that have special handling requirements (e.g., cell therapies requiring cryogenic) or novel delivery systems (e.g., use of lipid nanoparticles in mRNA vaccines), which need region-specific labeling and instructions. Beyond single companies, RI also has a major role at the regulation system level. Governments and health authorities have adopted RI approaches to inform policymaking, build capacity, and adopt reliance models. Regulatory reliance permits NRAs in LMICs to base their decisions on evaluations performed by more mature agencies (like FDA or EMA), greatly enhancing review times. Through RI, these authorities can observe global trends, highlight loopholes in national legislation, and chalk out streamlined procedures. A good instance is the continental RI platform being built by the African Medicines Agency (AMA).

REGIONAL LANDSCAPE OF REGULATORY INTELLIGENCE AND INNOVATIVE THERAPY REGULATION IN ASIA, LATIN AMERICA, AND AFRICA

The developing world is witnessing changes in the regulatory environment for novel therapies at an unprecedented pace. However, the speed and level of sophistication pertinent to change vary widely across Asia, Latin America, and Africa, each region representing its own constellation of opportunities and challenges. For orphan drugs, mRNA vaccines, biologics, and advanced therapies- such as gene therapies and cell-based treatments- the success of regulatory strategy depends on not only scientific hurdle navigation but on the regional agility of regulations and the readiness of intelligence. The development and implementation of Regulatory Intelligence (RI) frameworks remain highly fragmented in these parts of the world. Yet increasing recognition that RI is a strategic enabler of innovation drives change, influences local policy, and reshapes access to life-saving technologies (Guillen *et al.*, 2023).

Asia: A Rising Powerhouse with Diverse Regulatory Maturity

In general, Asia, with its highest regulations such as Japan and emerging markets such as India, Indonesia, and the Philippines, is an immense market in terms of pharmaceuticals, with varied climes of regulatory maturities. A country such as Japan and South Korea is operating under global harmonized frameworks, hence closer to the ICH (International Council for Harmonisation) and OECD principles. Others are still modernizing their post-market surveillance, pharmacovigilance infrastructure, and fast-track pathways. Thus, Asia is an opportunity as well as a challenge for

Table 1: Incentives for Orphan Drug Development-Comparative Overview.

Incentive	USA (FDA)	EU (EMA)	India	South Africa
Market exclusivity	7 years	10 years	5 years	Under discussion
Fee waivers	Yes	Yes	Partial	Limited
Scientific advice	Yes	Yes	Case-by-case	No
Orphan designation	Established	Established	Yes (since 2019)	No formal process

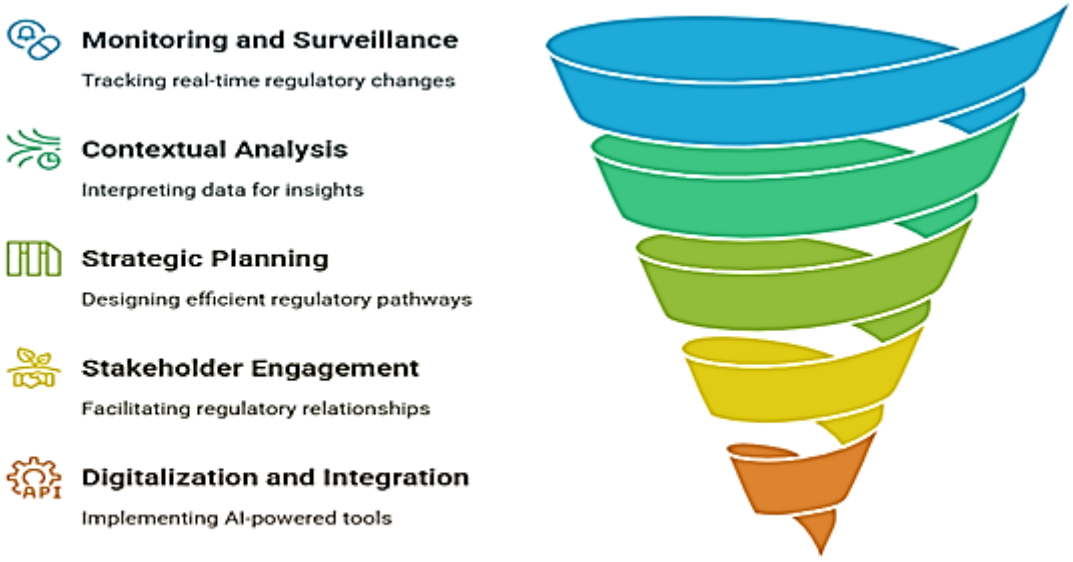

Figure 1: Optimizing Regulatory Intelligence.

sponsors developing innovative therapies. In the case of India, the New Drugs and Clinical Trials Rules (NDCTR) enacted in 2019 are a turning point in its evolution, especially considering orphan drug provisions-waiver of local clinical trial requirements, shorter review timelines, and fee exemptions. But here again, the implementation of these provisions in practice would depend on whether the sponsors are well versed in the new changes and could take such facts into account in their submission strategies. Regulatory Intelligence plays a very important role in this context especially for multinational companies who want to follow the same global development milestones along with the Indian conditional approval pathways. Furthermore, CDSCO is increasingly becoming digital with draft guidelines being published on mRNA vaccines and biosimilars. Without strong RI systems, however, any local developer will lose crucial opportunity windows in early access pathways or regulatory discussions. The other part is that the regulatory ecosystem rapidly changes under the aegis of the National Medical Products Administration, NMPA, in China. More than 50 drug-related laws and guidelines were developed or updated, while it has introduced a prioritization review process and conditional approval for urgent and otherwise unavailable therapies, which include those for rare diseases and cell therapies. The NMPA Center for Drug Evaluation has also launched public dashboards for review timelines and scientific advice-potential-rich data sources for RI platforms but suffers from language barriers, unclear enforcement practices, and shifting timelines. Sophisticated RI systems with localized analytic abilities will be needed to help decode and trace the rapid regulatory shifts. The sponsors will need to rely heavily on RI in the navigation of classification disputes, deal with their CMC requirements, and understand the standards regarding data acceptability since China is expanding its cell and gene therapy pipeline, especially for rare pediatric cancers. A more complex fragmented scenario is presented by Southeast Asian countries. Indonesia, Vietnam, Malaysia, and the Philippines are at various stages of regulatory modernization. Though all have established drug approval processes, none have solid, well-defined processes for biologics or for mRNA-based products, and ATMPs (Harris *et al.*, 2017).

Latin America: Progress through Reliance and Collaborative Networks

Latin America is undergoing unprecedented regulatory change, largely due to initiatives at regional harmonization, increased participation in the Pan American Network for Drug Regulatory Harmonization, and authority referenced from such external resources. Some of the most proactive countries in terms of updating their regulatory systems to facilitate the registration of biosimilars, vaccines, and oncology products are Brazil, Mexico, Colombia, and Argentina. ANVISA has emerged as one of the most exciting and proactive regulatory agencies in the area, with innovations that include conditional approval based on unmet medical needs, acceptance of foreign clinical data, and alignment with WHO Collaborative Procedures, a hallmark of an RI-sensitive agency. For COVID-19 vaccines, ANVISA was amongst the first in Latin America to acknowledge the emergency use authorizations granted by other reference authorities, thereby working under an RI-driven strategy to fast-track access. However, for complex therapies like gene editing or RNA therapeutics, local regulatory pathways remain uncertain. There is an urgent need to support RI stakeholders with full knowledge of what requirements may be expected in the future, especially given, with updates planned for ATMP classification and pharmacovigilance within the next two years. COFEPRIS is evolving, as Mexico seeks to regain WHO Level 3 maturity status,

to modernize its internal processes, and increase transparency in its reviews. Implementing consistency, especially concerning novel products manufactured locally, continues to be a challenge. Regulations for novel therapy products are often poorly defined; hence the resulting unpredictable regulatory decisions. Here, not only does RI form a bridge back into COFEPRIS with respect to information-gathering, but it also provides a lens on the regulatory precedents of the U.S., Canada, and Europe so that local developers can refine their dossiers and foresee scientific queries. For RI, in particular, that means sponsors to mRNA-based oncological candidates can relate acceptability of past clinical endpoints judged within the FDA or EMA with more credibility towards the value proposition presented to COFEPRIS reviewers. The digital regulatory platforms that have been initiated and the regional reliance mechanisms have boosted the influence of RI in both Colombia and Argentina. Columbia's establishment of pathways for abbreviated review based on PAHO or EMA approvals has reduced regulatory timelines by almost 40% for certain monoclonal antibody products. Smart application of RI will, therefore, enable easier planning for sponsors struggling with staggered launches across LATAM to achieve the best resource deployment while still ensuring quick patient access. Argentina's participation in the regional pharmacovigilance harmonization also allows RI systems to forecast post-approval safety expectations and reporting rigors, which is particularly relevant for developers of cell therapies.

Africa: The Frontier of Regulatory Convergence and Capacity Building

Africa presents a distinct set of regulatory challenges, largely due to limited infrastructure, workforce shortages, and historically fragmented governance. However, this is rapidly changing with the operationalization of the African Medicines Agency (AMA) and growing investment in local regulatory capacity. As given in Figure 2 Sub-Saharan Africa, in particular, is undergoing a paradigm shift where Regulatory Intelligence can play a transformative role in bridging innovation and access. South Africa, via its regulatory agency SAHPRA, is one of the few African nations with defined pathways for innovative therapies. SAHPRA has introduced fast-track mechanisms for high-priority products, is piloting digital submission portals, and participates in the WHO Collaborative Procedure for accelerated reviews. Nevertheless, capacity constraints and workload surges can delay processing. RI can help sponsors pre-position dossiers for optimal timing, anticipate data expectations based on WHO precedent, and navigate submission through both centralized and decentralized processes. Additionally, RI is instrumental in identifying opportunities to engage with SAHPRA during early-stage product development, facilitating smoother acceptance of novel technologies like CAR-T or nucleic acid therapeutics. Elsewhere in Africa, Nigeria, Kenya, Ghana, and Egypt are advancing their regulatory systems through regional partnerships, technical assistance programs, and digital modernization. Nigeria's NAFDAC, for example, has partnered with the U.S. FDA and WHO to build capacity in vaccine evaluation and biosimilar regulation. For innovative products, however, most African NRAs still lack dedicated guidelines. In such cases, Regulatory Intelligence offers a powerful workaround-by leveraging data from stringent authorities, sponsors can build strong scientific justifications for regulatory reliance or waiver-based approvals. This has already facilitated early market entry of WHO-prequalified products in Kenya and Ghana, often within months of global authorization. Perhaps most transformative is the AMA's long-term vision: to create a pan-African regulatory authority capable of conducting

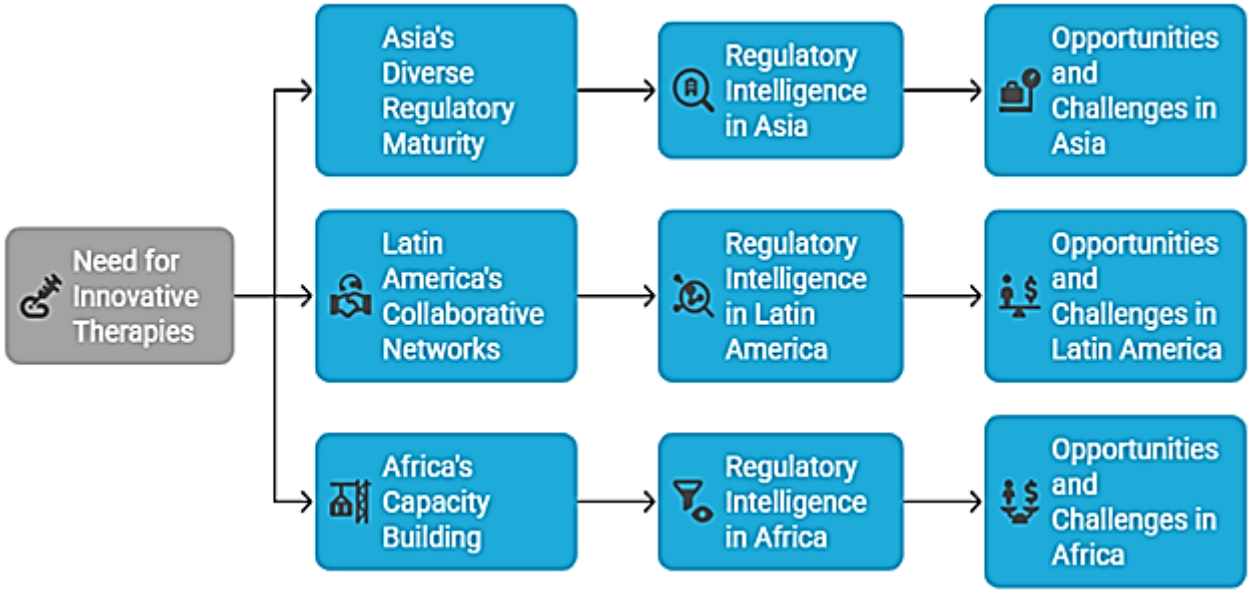

Figure 2: Evolving Regulatory Landscape in Developing Region.

joint assessments, issuing centralized recommendations, and harmonizing requirements for complex products. As AMA matures, RI systems that track its operational rollouts, pilot programs, and procedural templates will become invaluable. Developers of mRNA-based vaccines for diseases like malaria or Ebola, as well as gene therapies for sickle cell disease, can use RI to map agency readiness, dossier expectations, and alignment strategies across participating countries. In doing so, RI not only supports regulatory efficiency but also equity and sovereignty, enabling African countries to define their innovation agenda without overreliance on foreign agencies (Health Promotion Administration, 2000).

REGULATORY INTELLIGENCE FOR SPECIFIC MODALITIES: MRNA VACCINES, ORPHAN DRUGS, BIOLOGICS, AND ATMPS

The rise of innovative therapeutics-especially mRNA vaccines, orphan drugs, biologics, and Advanced Therapy Medicinal Products (ATMPs)-has dramatically transformed the pharmaceutical landscape, offering novel mechanisms to tackle previously untreatable diseases. However, the complex nature of these modalities, their high development costs, and often limited clinical precedent make regulatory approval especially challenging in developing nations. In this context, Regulatory Intelligence (RI) becomes not just a facilitator but a critical determinant of success, enabling sponsors to understand, adapt to, and even shape evolving regulatory expectations in Low- and Middle-Income Countries (LMICs). This section unpacks how RI can be strategically leveraged for each of these modalities to accelerate access, ensure compliance, and bridge the innovation gap across diverse regulatory ecosystems as given in Table 2.

mRNA Vaccines: A New Paradigm Requiring New Regulatory Thinking

The success of mRNA-based COVID-19 vaccines catalyzed global interest in mRNA as a versatile and rapid-response platform. However, the regulatory science surrounding mRNA remains underdeveloped, especially in regions outside of the U.S., EU, and Japan. (ICH Harmonisation for Better Health, 2023) Unlike traditional vaccines, mRNA-based products rely on Lipid Nanoparticle (LNP) delivery systems, novel excipients, and cold-chain infrastructure that challenge existing guidelines. Many LMIC regulators have no formal frameworks to assess mRNA vaccines, making Regulatory Intelligence essential. Through RI, developers can monitor real-time shifts in global regulatory stances-such as the FDA's guidance on mRNA CMC data or the EMA's adaptive licensing approach. These insights allow sponsors to structure their dossiers based on global precedence and proactively address issues that are likely to emerge during local review, even when country-specific guidelines are absent. For example, understanding that the EMA accepts surrogate immunogenicity markers for pandemic-response mRNA vaccines allows sponsors to build bridging strategies for LMICs, where conducting full-scale efficacy trials may be infeasible. RI also enables engagement with Emergency Use Authorization (EUA) frameworks, many of which emerged during COVID-19 and have since remained in place or been codified. Countries such as India, South Africa, and Brazil implemented expedited review processes based on WHO listings or foreign reference approvals. Monitoring changes in these EUA policies and their scope (e.g., are they limited to pandemics, or can they be applied to other mRNA-based infectious disease vaccines?) is a key RI task. Furthermore, tracking public health priorities across countries helps sponsors align product development with national needs-such as an mRNA vaccine for tuberculosis in India or Ebola in parts of Africa-thereby increasing the likelihood of accelerated regulatory support (International Bar Association, 2023).

Orphan Drugs: Regulatory Leverage for Rare Disease Treatments

Orphan drugs represent a therapeutic class where regulatory flexibility is both necessary and achievable. These drugs target rare conditions with limited treatment options, and as such, traditional expectations for large-scale randomized trials or long-term safety data may not be feasible. While major agencies like the FDA and EMA have robust orphan drug frameworks, most LMICs are still developing or refining their definitions, incentives, and pathways. In this environment, RI becomes indispensable for identifying where opportunities for regulatory innovation exist. For instance, India's NDCTR provides expedited review and fee waivers for orphan products, but there's no unified registry or clear-cut criteria for designation. RI can assist sponsors in navigating this ambiguity, drawing from definitions used in other countries and comparing disease prevalence thresholds. Similarly, Brazil offers reduced clinical requirements and tax incentives for orphan drugs, but only when local data confirm the rarity status-a condition that can be fulfilled by leveraging epidemiological intelligence through RI. Moreover, RI plays a vital role in aligning regulatory incentives with health system capabilities. Many LMIC regulators face the dilemma of whether to approve a rare disease therapy with limited domestic demand and high cost. By tracking international Health Technology Assessments (HTAs) and reimbursement models, RI allows sponsors to build a compelling narrative for affordability, outcomes-based pricing, or inclusion in special access programs. For example, an orphan drug for spinal muscular atrophy approved by the FDA with post-marketing surveillance commitments can be proposed in Africa or Southeast Asia using reliance pathways, supported by RI data showing real-world effectiveness in similar populations.

In parallel, RI tools can help local health authorities assess international post-marketing safety data, enabling them to accept foreign benefit-risk assessments rather than conducting independent evaluations from scratch. This drastically shortens

review timelines and opens the door for orphan drugs to reach populations that historically waited years post-approval in high-income countries. Case in point: Colombia has recently adopted risk-based review for rare disease drugs based on EMA approval, a shift documented and tracked by RI systems.

Biologics: From Biosimilars to Next-Gen Antibodies

Biologics, including monoclonal antibodies, recombinant proteins, and cytokines, represent some of the most important tools in modern medicine-yet access remains deeply unequal, particularly in LMICs. Unlike small molecules, biologics require complex manufacturing validation, cold-chain distribution, and extensive characterization. Regulatory pathways for both originator biologics and biosimilars are uneven across emerging markets, ranging from highly developed (e.g., Brazil, South Africa) to rudimentary (e.g., parts of sub-Saharan Africa). RI enables developers to track evolving biologics guidelines, particularly as more countries begin to adopt WHO's guidelines on biosimilarity. For example, Malaysia and Kenya recently published draft guidances on biosimilars referencing WHO's framework; RI allows sponsors to detect these changes early, engage in public consultations, and adapt CMC and clinical documentation accordingly. Similarly, China's CDE has been issuing increasingly specific requirements for Fc-function assays and immunogenicity studies-critical updates for developers of therapeutic antibodies. RI also assists in managing the challenge of global-local regulatory alignment. A biologic approved in the EU under a hybrid pathway (e.g., extrapolated indications or streamlined comparability studies) may require full datasets in countries like Mexico or Thailand unless a clear scientific bridge is built. Regulatory Intelligence informs these bridging strategies by identifying precedents-such as previously accepted extrapolations, local comparator approvals, and foreign clinical site data acceptability. This minimizes unnecessary repetition and speeds up market entry. Another critical RI role is in the management of post-approval variations. Biologics are sensitive to manufacturing changes, and in emerging markets, local regulators may require notification or re-approval for even minor modifications. Through RI, sponsors can compare global variation classification systems (Type IA, IB, II) and map them against local requirements, ensuring proactive compliance. Moreover, safety signal tracking through RI systems enables companies to stay ahead of changing pharmacovigilance mandates, particularly in jurisdictions adopting ICH E2E or EU GVP modules.

Advanced Therapy Medicinal Products (ATMPs): Navigating the Frontier of Regulation

ATMPs-including gene therapies, somatic cell therapies, and tissue-engineered products-represent the cutting edge of therapeutic innovation. However, their regulatory approval is among the most complex in any drug class, and in LMICs, the path is often non-existent or extremely unclear. Many National Regulatory Authorities (NRAs) lack dedicated ATMP frameworks, experienced reviewers, or even classification systems to distinguish between ATMPs and biologics. In this vacuum, RI becomes essential for regulatory roadmap construction. In jurisdictions without formal ATMP guidelines, sponsors can use RI to propose regulatory models borrowed from EMA's ATMP Regulation (EC No. 1394/2007) or Japan's SAKIGAKE designation. For example, developers of autologous cell therapies in South Africa or Indonesia can use RI to justify regulatory fast-tracking based on unmet need, referencing global risk-benefit analyses. Additionally, RI can support the use of compassionate use or hospital exemption schemes-often underutilized due to poor awareness but legally viable in many LMICs. Manufacturing and quality control pose another major challenge for ATMPs. Many therapies require decentralized production, sterile compounding, or patient-specific manipulation. Through RI, companies can identify technical standards accepted internationally, such as FDA's CMC guidances for AAV vectors, and advocate for their local adaptation. Moreover, RI can be used to inform regulators about evolving standards-such as digital twins in cell culture process validation or next-generation sequencing in identity testing-ensuring dossier alignment with cutting-edge expectations. RI also plays a pivotal role in post-market monitoring for ATMPs, which often require lifelong follow-up due to risks of insertional mutagenesis or immune complications. Many LMICs lack such infrastructure. By drawing on global post-marketing surveillance models, RI can help sponsors co-develop pharmacovigilance plans that regulators can realistically implement. This not only facilitates approval but also builds institutional trust-essential for future submissions.

Table 2: Examples of Regulatory Intelligence Tools Used in Developing Nations.

RI Tool/Source	Use Case	Example Region
WHO Global Benchmarking Tool	Regulatory capacity self-assessment.	Africa, Southeast Asia.
Reliance review procedures	Speeding approvals via reference authorities.	Colombia, Philippines
Horizon scanning platforms	Anticipating upcoming therapies for HTA planning.	Brazil, India
EUnetHTA network resources	Cross-national HTA comparisons.	Latin America (via PAHO).
VigiBase (UMC)	Monitoring post-market drug safety.	Global

REAL-WORLD CASE STUDIES OF RI-DRIVEN APPROVALS AND FAILURES IN LMICS

The true power of Regulatory Intelligence (RI) is best illustrated not by theoretical constructs but through practical, real-world examples of success and failure. Across Low- and Middle-Income Countries (LMICs), the integration-or absence-of RI into regulatory planning has had tangible consequences on access to life-saving innovative therapies. In this section, we delve into a series of case studies spanning Asia, Latin America, and Africa, analyzing how RI has either accelerated approvals or contributed to market failure. These examples not only validate the impact of RI on product lifecycle strategy but also provide critical learning points for future regulatory efforts, particularly for orphan drugs, biologics, mRNA vaccines, and Advanced Therapy Medicinal Products (ATMPs).

The Case of Pfizer-BioNTech's mRNA Vaccine in Latin America: RI in Action

A landmark example of RI in action is the rollout of the Pfizer-BioNTech COVID-19 mRNA vaccine (BNT162b2) across Latin America. In early 2021, countries like Chile, Mexico, and Brazil were among the first in the region to authorize mRNA vaccines under emergency use protocols. This rapid uptake was not merely the result of high-level diplomacy or urgency due to the pandemic, but also a masterclass in regulatory foresight and intelligence. Pfizer's regulatory teams employed real-time RI tools that monitored Emergency Use Authorization (EUA) frameworks across more than 30 countries, focusing on WHO policies and regional reliance mechanisms. By tracking regulatory changes daily-including temporary guideline releases, legal waivers, and reference agency alignment policies-Pfizer was able to sequence its submissions strategically, starting with jurisdictions that allowed reliance on FDA or EMA approvals. In Chile, for instance, the Public Health Institute of Chile (ISP) leveraged the UK's MHRA approval to expedite the local authorization within days. Similarly, in Brazil, ANVISA's policy to consider conditional approvals from mature agencies was exploited effectively using RI data streams that showed which regulatory precedents would trigger automatic fast-tracking. Moreover, RI played a vital role in cold chain logistics and site preparedness. By mapping country-specific storage mandates and customs clearance timelines, Pfizer adjusted its formulation and packaging strategy. In Mexico, where regulatory inspectors were known to delay novel excipient imports due to lack of prior exposure, Pfizer pre-emptively included detailed US pharmacopoeial data and cross-referenced Brazilian import precedents. This averted months of delay that other vaccine manufacturers faced. The end result was a dramatic acceleration in access: by March 2021, Mexico had administered over 2 million doses of BNT162b2, compared to other LMICs that were still navigating approval. This case underscores the transformative role of proactive, localized Regulatory Intelligence, which went beyond tracking laws to anticipating procedural bottlenecks, preemptively building regulatory trust, and adapting technical dossiers accordingly.

Zolgensma in India and South Africa: The Cost of RI Failure

In contrast, the high-profile gene therapy Zolgensma (onasemnogene abeparvovec) for Spinal Muscular Atrophy (SMA) serves as a cautionary tale of RI failure in LMICs. Approved in the U.S. and Europe as the world's most expensive drug (priced at over $2 million per dose), Zolgensma quickly garnered global attention. However, its launch strategy in India and South Africa was marked by significant delays, missteps, and public backlash, largely due to poor regulatory intelligence integration. In India, Novartis underestimated the policy complexity surrounding high-cost, low-volume drugs. (IQVIA, 2023) While the New Drugs and Clinical Trials Rules (NDCTR) of 2019 had introduced provisions for accelerated approval of orphan drugs, there was no harmonized guideline on pricing, reimbursement, or compassionate access. Novartis filed under an import license pathway, but failed to anticipate CDSCO's requirement for local pharmacovigilance readiness and real-world monitoring infrastructure, even for an orphan indication. Compounding this was the public outcry over unequal access, as several families resorted to crowdfunding for the therapy. The lack of a clear RI-driven plan to align with Indian patient advocacy groups, rare disease consortia, or CDSCO's orphan drug registry led to reputational damage and indefinite delays. A similar scenario unfolded in South Africa, where Zolgensma's application to SAHPRA was met with technical queries that could have been anticipated through robust RI. Regulatory Intelligence could have revealed that SAHPRA was closely monitoring ATMP frameworks in the EU, particularly around vector shedding studies and long-term safety monitoring. By neglecting to adapt its dossier accordingly and failing to build local medical infrastructure partnerships in advance, Novartis missed the opportunity to capitalize on South Africa's existing fast-track program for "medicines addressing public health need." In both nations, Zolgensma's rollout was impaired by the absence of anticipatory intelligence around ethical approval processes, insurance scheme alignment, and public perception management-areas where RI could have guided strategic adaptation. These failures illustrate how even scientifically revolutionary therapies can be blocked without grounded, jurisdiction-specific regulatory insights.

Biosimilar Trastuzumab in Egypt: RI Enables a Domestic Breakthrough

One of the most markedly positive RI-led initiatives has been the successful development and local marketing authorization of the biosimilar trastuzumab in Egypt for HER2-positive breast cancer. Egypt had traditionally depended upon expensive imported biologics until 2019 when they set out a draft guideline for the

evaluation of biosimilars by the Egyptian Drug Authority, built upon principles defined by the WHO and EMA. By employing an astute RI strategy, EVA Pharma, a local player, was able to align their clinical and analytical comparability studies with the guidelines accepted by EDA and PAHO, while at the same time engaging neighboring regulatory authorities in Jordan and Algeria. Having scrutinized the regulatory journeys of EMA-approved trastuzumab biosimilars, EVA Pharma had foreseen key dossier requirements of the EDA: acceptance of foreign comparator data, a shorter duration of immunogenicity studies, and acceptance of PK/PD surrogate endpoints. They kept a close watch on updates to EDA inspection checklists by their RI team, while compliance with GMP regulations was assured from the very outset to satisfy audit requirements. Significantly, RI intelligence was also utilized to plan for post-approval variations. EVA Pharma integrated modules for future variations in fill volume of the vials and batch release testing into their submission, proactively anticipating that the EDA would soon apply EMA's variation classification system. Such an anticipatory RI move ensured that any future adjustments to manufacturing would not entail re-evaluation, thereby securing continuous supply as a primary benefit. The success of this biosimilar has enabled national access to breast cancer treatment at nearly half the cost and, importantly, provided a precedent for the approval of biologics going forward from the region. This showcases how homegrown regulatory intelligence, when benchmarked against international practices, evens out the playing field for developers situated in LMIC contexts. (Kockaya *et al.*, 2014)

Orphan Drug Nitisinone in Colombia: RI Bridges Regulatory Gaps

Nitisinone has been found effective in treating Hereditary Tyrosinemia type 1 (HT-1) and yet is another compelling example of RI-enabled success in Colombia. When in 2016 the Ministry of Health brought HT-1 onto its list of priority rare diseases, there were very few local regulatory precedents. An RI strategy was hence employed by the sponsor, a Scandinavian biotech firm, to leverage PAHO reliance mechanisms as well as real-world data from Canada and Sweden to support efficacy and safety in rare metabolic diseases. RI tools helped the firm tailor its submission to INVIMA (Colombian FDA equivalent), specifically highlighting past reliance-based approvals and precedent data acceptance (Lloyd-Williams and Hughes, 2021). Most importantly, the company engaged early with Colombia's National Health Institute (INS), based on intelligence suggesting increased scrutiny in the context of pediatric metabolic conditions. This foresight enabled alignment of safety monitoring and early access program protocols with national priorities. The use of real-world evidence and patient registries from European cohorts-all combined and justified using global RI benchmarks-was key to expediting approval within just eight months-a record for an orphan product in Colombia. This example offers a case that defines the strategic depth that RI brings to product launches for rare diseases, especially where local data may not be strong, yet international precedents can be very persuasive. By demonstrating a necessity and not a luxury, these case studies convey that the need for Regulatory Intelligence is absolutely there for sponsors navigating complex, fragmented, and evolving regulatory environments in LMICs. In fact, whether fast-tracked success, homegrown innovation, or painful delays, RI seals the outcome. Henceforth, RI will empower developers to accelerate approvals, optimize compliance, and most importantly, improve patient access to innovative therapies across resource-constrained settings, as it integrates jurisdiction-specific insights, procedural foresight, scientific benchmarking, and stakeholder mapping.

STRATEGIC FRAMEWORKS FOR IMPLEMENTING REGULATORY INTELLIGENCE IN LMIC REGULATORY PATHWAYS

Integrating Regulatory Intelligence (RI) within the Low-and Middle-Income Countries' (LMICs') regulatory systems is by far a strategic imperative rather than just an operational enhancement. For LMICs that are also constrained due to limited infrastructure, workforce shortages, and antiquated legal frameworks, RI offers a transformative instrument for both regulatory authorities and pharmaceutical sponsors. The section provides comprehensive, realistic, and actionable framework with regards to RI's implementations for developing regulatory environments. Considering global best practices and multilateral cooperatives with the addition of digital innovations, it actually proposes scalable strategies that entrench RI to systematize the overall fabric into National Regulatory Authorities (NRAs), academic stakeholders, and industry actors operating in LMICs (Macdonald, Hartman, and Jacobs, 2015).

The Pillars of RI Implementation in LMICs

Implementation of RI in LMICs must be sustained on four interdependent bases: (1) legal-structural enablement, (2) digital

Table 3: Types of Innovative Therapies and Their Regulatory Bottlenecks.

Therapy Type	Main Barrier in LMICs	How RI Helps
Orphan Drugs	No dedicated legislation or pathway.	Policy benchmarking, reliance strategies.
Biologics	Complex manufacturing and high cost.	CMC dossier comparisons, biosimilar RI.
mRNA Vaccines	Cold chain, limited manufacturing know-how.	Tech transfer analysis, trial mapping.
Gene/Cell Therapies	Ethical/legal uncertainties, lack of review guidelines.	Global regulation synthesis, training.

RI infrastructure, (3) workforce and knowledge capacity, and (4) mechanisms for cross-border cooperation. Such pillars set the agenda to upscale regulatory capabilities while ensuring consistent attachment with the scientific and public health goals of individual LMICs. Legal-structural enablement is the conceptualization of policy environments that recognize and institutionalize the value of intelligence-based regulatory operations. Regulatory actions in many LMICs are inflexible or outdated and are hampered by strictly statutory requirements, which leads to delays in the evaluation of novel therapies for commercialization. For instance, some jurisdictions still do not have formal pathways for conditional approvals, fast-track reviews, or reliance mechanisms - all of which are prerequisites for leveraging global RI insights. Hence, flexible review pathways must be codified in legislative reforms along acceptance of foreign data as well as formal usage of Real-World Evidence (RWE) - this is the necessary substrate for RI to function meaningfully. Digital RI infrastructure is the second pillar and encompasses national databases, AI-assisted surveillance systems, regulatory benchmarking platforms, and policy monitoring tools. These ecosystems of digital information will be built according to local contexts, but they must allow interoperability with global standards. Countries such as Rwanda and Nigeria have launched pilot RI databases to collect and cross-link datasets from FDA, EMA, TGA, and PMDA through partnerships with WHO and the African Medicines Agency (AMA). These systems will not only reduce manual burden but also democratize intelligence, making regulatory data accessible to small firms, NGOs, and academia. Eventually, building APIs into these tools will allow automating horizon scanning; flagging guideline changes; and providing real-time alerts on product classification updates or expedited pathways available in comparator nations. This last pillar refers to capacity-building and knowledge development in workforce. Perhaps most important of all is that a digitally advanced system is a barren wasteland if properly trained personnel are not able to interpret, contextualize, and act on intelligence. Establish regulatory intelligence fellowships, share international secondments, and integrate RI modules to pharmacy, regulatory affairs, and biomedical science curricula in LMICs. For instance, the Central Drugs Standard Control Organization (CDSCO) of India is starting to fund regulatory training modules with embedded RI components at certain public universities. In addition, regional regulatory networks such as ASEAN's PPWG and PAHO's RCC will provide shared training frameworks for workforce RI development at lower cost and enhanced scalability. Cross-border cooperation mechanism is the fourth pillar, which addresses the disjointedness of regulatory jurisdictions in LMICs. Efforts in RI therefore become silos and inefficient, being done independently, without much cross-country harmonization. To this end, as part of its pilot projects for the AMA, African regulators are piloting joint regional assessments (Morrison, 2021).

RI Integration Strategies for Local Regulators

For national regulatory authorities in low- and middle-income countries, the incorporation of regulatory intelligence into daily operations requires both a top-down and bottom-up approach. A top-down approach would include establishing specific RI units within NRAs responsible for conducting surveillance on policy developments, assessing the relevance of guidance from other countries for external reviews, and holding refresher meetings for reviewers. These should be multidisciplinary teams of pharmacists, clinicians, data scientists, and legal experts for interpretation of change from a contextual perspective. The government task force has internally established RI task force reporting of work every second week with a guideline tracking function based on 12 of the major global authorities in the Ugandan National Drug Authority, for example. The bottom approach empowers self-service RI dashboards and training on critical appraisal of regulatory precedents for frontline reviewers or inspectors and pharmacovigilance officers. They have a clear in-field contextual understanding of local barriers and are the ones in the best position to identify misalignments with foreign intelligence versus domestic feasibility. Such embedded RI tools into daily reviews systems like Integrated Regulatory Management Systems (IRMS) help local regulators flag gaps more effectively and request clarifications on an international level. Integration become RI multi-stakeholder engagement models. Public facing RI portals should be maintained by regulators to allow industry stakeholders to anticipate changes and submit technical questions and to co-develop solutions. Examples include open regulatory insight bulletins and regular meetings that stakeholder agencies have held below Brazil's ANVISA and Indonesia's BPOM in consonance with stakeholder expectations on strategic initiatives from RI. This builds credibility, transparency, trust, and compliance, all important currencies in low-resource settings.

Strategic Models for Pharma Companies Operating in LMICs

Pharmaceutical sponsors must integrate RI into their LMIC strategies through a multi-level approach. For example, building region-specific regulatory intelligence maps-facing visual overlays of guidance documents, procedural timelines, dossier structure preferences, and decision-making precedents including all these things into a map helps companies choose the right filing order, proactively align documentation, and identify optimal reliance or abridged review strategies. Sandoz built a step-wise reliance narrative-referencing EMA approval and WHO PQ status-to use RI-driven model for gaining consecutive approvals across Jordan, Egypt, and Kenya concerning the filgrastim biosimilar. Second, pharma companies need a country-specific advocacy plan towards RI evidence. It needs identifying knowledge gaps or policy grey zones in a target market and submitting white papers, expert consultations, or co-hosted trainings with regulators. Through the demonstration of RI-supported comparisons on cold chain

requirements in Japan and Canada, Moderna aided acceptance of mRNA-specific stability protocols in Thailand. This not only familiarized regulators with the product class but shortened approval timelines, avoiding superfluous stability studies. Thirdly, companies must integrate RI in pharmacovigilance and post-market compliance. LMICs now demand an increasing local safety data, periodic benefit-risk reassessments, and indigenous signal detection systems. The RI systems will be able to track which countries adopt E2E, GVP modules, or local PV legislation, which will allow tailoring a company's safety strategy proactively. Most importantly, RI helps sponsors link their PV systems with emerging digital health infrastructures such as Africa CDC surveillance platform, India PvPI, etc., ensuring compliance and partnership in health systems strengthening. Lastly, it must be integrated into corporate access and pricing strategies. Understanding how countries use HTA data, cost-effectiveness thresholds, or international reference pricing models will allow companies to construct differentiated value dossiers for LMICs. Take Roche, for example, which altered its pricing model for Herceptin SC in Malaysia incorporating RI-driven data on breast cancer burden, healthcare spending, and comparator availability; resulted in inclusion within a national formulary without a fully blown cost-effectiveness trial (Muhsen *et al.*, 2020).

Global and Regional RI Harmonization Models: Lessons for LMICs

Beyond national strategies, regional and global harmonization models offer scalable RI architectures for LMICs. Perhaps the best example is the African Vaccine Regulatory Forum (AVAREF), which has built a common RI ecosystem for 19 African countries. This includes common templates, shared reviewer pools, and a pooled intelligence database that has cut the approval of vaccines during Ebola and now during COVID-19 crises. AVAREF's design-federated yet unified-is ideomics for regions like Southeast Asia or Central America. Similarly, the ASEAN Pharmaceutical Product Working Group (PPWG) and the Caribbean Regulatory System (CRS) have facilitated pooled efforts by standardizing CTD formats, timelines for reviews, and frameworks for reliance between these countries. These groups also issue joint statements on emerging issues in regulatory science, allowing countries in the bloc to respond collectively. These mechanisms particularly address the paralysis of "regulatory fragmentation," where disunifying efforts slow access, impose burdens on industry, and subvert public health. Global AI-enabled regulatory platforms, like WHO's RegInsight, ICH's CIRS database, and FDA's Data Modernization Initiative, are additional resources for RI strategies in LMICs. As given in Table 3 By interfacing with these systems through regional hubs or public-private partnerships, LMICs would have access to advanced prediction analytics, risk-based classification systems, and real-time guidance shifts. Such models integrated into local infrastructure ensure that even the smallest regulator has access to world-class intelligence (Organisation for Economic Co-operation and Development, 2018).

CHALLENGES AND FUTURE DIRECTIONS FOR REGULATORY INTELLIGENCE IN DEVELOPING COUNTRIES

Low- and middle-income countries are increasingly seeking to put regulatory intelligence to better use for improving drug access and regulatory agility, but they must deal with a set of unique structural, systemic, and strategic challenges. While RI would be fundamentally a loophole to accelerate access to orphan drugs, biologics, mRNA vaccines, and ATMPs, structural barriers to effective RI adoption, implementation, and scale-up remain deeply entrenched within various LMICs. It is essential to identify these hurdles and begin imagining strategic resolutions as road mapping for resilient, responsive, and intelligent regulatory ecosystem setups that would deal with 21st-century health challenges (Rahalkar *et al.*, 2021).

Infrastructure and Data Ecosystem Gaps

The most serious obstacle in the implementation of RI in LMIC countries is a lack of reliable, interoperable digital infrastructure. Regulatory authorities in the majority of LMICs still use paper documentation, have minimal IT systems, and fragmented data repositories. Without foundational digital systems to house and analyze regulatory trends in an easily retrievable way, RI cannot scale. Most often, LMICs do not have integrated regulatory databases for product listings, review timelines, precedent decisions, adverse event databases, or post-market surveillance outcomes. This deprives them of the infrastructure that could enable horizon scanning and forces regulators to resort to informal networks or outdated information, increasing the chances of inconsistent or delayed decisions. There is also constrained access to global intelligence databases-for instance, what the European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA), or World Health Organization (WHO) has-on top of already limited access. Most of these are denied access because of licensing fees, barriers of language, and mismatches in data standards. For example, countries with mostly Spanish or French regulations face difficulties in understanding English-only regulatory bulletins. This language break is a barrier to the timely assessment of regulatory changes for specific regions, especially Francophone Africa and parts of Latin America. Another side of the infrastructural gap is that of data standardization. The majority of LMICs lack regulatory maturity for accepting harmonized CTD formats or electronic submissions, which would be conditions for the automated RI processes. Thus, filing nonexistent harmonized data for a comparative analysis of the dossiers across jurisdictions becomes impossible, hampering any prospects of reliance or recognition-shaped models. These dysfunctional metadata around types of submissions, outcome timelines, or clinical requirements are additional barriers to

enabling regulators to benchmark their performance against global standards, one of the main benefits of RI systems (Rägo *et al.*, 2018).

The RI implementation most essential problem for LMICs is improvident consideration: digital infrastructure may be reliable and interoperable. Cebu of regulatory authority per many LMICs continues to use paper-based documentation, minimal IT systems, and fragmented repositories of data. Without the foundational digital systems to house, analyze, and track regulatory trends, RI cannot operate on a large scale. Most often, LMICs lack consolidated regulatory databases with product classifications, timescales for review, precedent decisions, adverse event databases, and outcomes of post-market surveillance. This would provide the infrastructure that would enable horizon scanning and compel regulators to rely on informal channels or obsolete information, increasing the likelihood of inconsistent or delayed decisions. Moreover, the access to global intelligence databases, such as the databases maintained by EMA, FDA, or WHO, is limited. Many of these go beyond denial of access through licensing fees, barriers of language, and mismatches of data standards. For example, counties that have mainly Spanish or French regulation face difficulty understanding completely English-only regulatory bulletins. This language break is a barrier to the timely assessment of regulatory changes for specific regions, especially Francophone Africa and parts of Latin America. Another aspect of the infrastructural gap revolves around data standardization. Most simple LMICs are quite immature in terms of regulation for adopting even harmonized CTD formats or completely electronic submissions, which are both prerequisites for automatic RI processes. As a result, it becomes virtually impossible to have harmonized data on which comparative analysis could be done across jurisdictions, thus impeding any promising reliance or recognition-shaped models. The absence of structured metadata around types of submissions, outcome timelines, or clinical requirements prevents regulators from benchmarking their performance against global norms-one of the central advantages of RI systems (Riviere, 2020).

Human Capital and Expertise Deficiencies

Even though they have proper infrastructure, a large number of LMICs struggle and face a serious shortage of trained professionals who are able to operate and interpret any incoming RI system. The requirement for Regulatory Intelligence involves many interdisciplinary knowledge inputs such as regulatory policy, data analytics, clinical science and public health, as well as legal interpretation. Unfortunately, most regulatory bodies of LMICs do not meet relevant staffing requirements and even if they could provide a better condition, resource-limited training in regulatory science or policy surveillance has tended to abate such hope. When a reviewer within such countries has to work on files ranging from biologics, small molecules, to diagnostics; the time spent on important intelligence-gathering or comparative global policy is all too short. Furthermore, large lacunae exist with regard to local academic and professional training initiatives that include RI as a comprehensive element of regulatory affairs learning. Unlike high-income countries that offer graduate programs or fellowships in regulatory intelligence, orientation and other structured pathways have not yet been established in LMICs for building this expertise. Foreign consultancy or multilateral agency dependency has been entrenched in this training gap as this limits long-term sustainability and ownership by local people of RI tools. In countries with relatively well-advanced regulatory authorities, such as India, Brazil or South Africa, the compartmentalization of regulatory authorities leads to silos in which the knowledge so painstakingly acquired is not shared across departments. Institutionalization of all functions, starting from clinical trial authorization to marketing application review and post-market surveillance, is what would make RI thrive. The absence of culture-sharing of knowledge hampers the supposed flow of insights that are to be incorporated into RI systems (Sharma *et al.*, 2021).

Policy Misalignment and Legal Ambiguity

Another major challenge lies in the misalignment of RI systems with existing legal and policy frameworks. In many LMICs, the regulatory landscape is still evolving, often based on colonial-era drug laws or fragmented regional statutes. As a result, there is limited legal recognition of regulatory innovation models such as expedited pathways, rolling submissions, conditional approvals, and reliance mechanisms-all of which are foundational to RI-based strategy. This legal ambiguity can render intelligence useless in practice. For instance, while RI may highlight a global trend toward Real-World Evidence (RWE) in biologics evaluation, the absence of legal provisions to accept such data in local jurisdictions can block its implementation. Similarly, intelligence on reference country decisions may not be usable if local laws require independent data review or prohibit reliance on foreign regulatory judgments. Moreover, regulatory decisions in many LMICs are not routinely published, peer-reviewed, or justified in public documents. The lack of transparency prevents companies, civil society, and academics from conducting comparative intelligence or building predictive models based on past decisions. This limits the ability of stakeholders to use RI proactively to align submissions, anticipate regulatory risks, or lobby for evidence-based reforms (Vogler *et al.*, 2018).

Fragmented Regional Harmonization and Geopolitical Barriers

Even though several LMIC regions are trying to establish regulatory harmonization frameworks-AVAREF in Africa, the PPWG of ASEAN, and the Zazibona initiative in Southern Africa-most of the initiatives are either still in their infancy or without mechanisms of enforceability. These regional bodies often operate without funding, clearly defined jurisdiction, or

legal recognition from one another-a recipe for fragmentation and inconsistency of execution. Therefore, the utility of shared RI platforms, which hinge upon the synchronization of policies, timelines, and data standards across member states, is compromised. Geopolitical tensions, protectionism, and pharmaceutical sovereignty issues also come into play. Some LMICs see dependence on foreign regulatory decisions as a challenge to national sovereignty, particularly when expedited or otherwise politically close decisions are rendered by foreign regulators. The idea that RIs project Western regulatory norms may further spur resistance, especially in instances where they clash with national health priorities or traditions of medical practice.8.5 Financial and Sustainability Constraints. Costs continue to be the greatest barrier for developing and running RI systems in LMICs. The regulatory authorities typically operate on a shoestring budget and prioritize crucial routine functions such as inspections and approvals, as well as pharmacovigilance, leaving no resources for intelligence-building. Sometimes the donor agencies and development partners would come in to fund pilot projects to initiate RI implementation, but invariably the long-term sustainability of such systems flickers without any domestic investment. Most importantly, the private sector, especially the local or regional pharmaceutical companies, would not have enough financial bandwidth to build full-fledged RI departments. Unlike multinationals that have global regulatory intelligence teams, the majority of domestic firms in the LMICs depend on anecdotal knowledge, informal networks, or consultant-driven strategies. This situation limits their ability to engage proactively with regulators, anticipate changes, or co-create innovative access pathways (Wolff-Holz and Weise, 2020).

Cost remained one of the primary constraints to the development and maintenance of RI systems in LMICs. Regulatory authorities usually operate on small budgets; thus, issues of routine nature, such as inspections and approvals, along with pharmacovigilance, receive all the attention and intelligence-building is completely overlooked. Rarely do donor agencies and development partners see anything beyond household-specific pilot projects they may fund for the purpose of RI implementation relating to a long-term sustainable future of this system in a domestic setting. More often than not, the private sector, especially local or regional pharmaceutical companies, would not have sufficient financial leeway to develop full-fledged RI departments. In contrast to multinationals that have global regulatory intelligence teams, most domestic firms in the LMICs rely on anecdotal knowledge or informal networks or consultant-driven strategies. This situation constrains proactivity in engaging with regulators, anticipating changes, or effectively co-creating innovative access pathways (World Economic Forum, 2022).

Costs remain a critical limitation on developing and maintaining RI systems in LMICs. Regulatory authorities usually run on a shoestring budget, with priority given to critical everyday necessities such as inspections and approvals along with pharmacovigilance, leaving intelligence-building completely neglected. While most donor agencies and development partners will be jump-starting RI implementation through funding pilot projects, the extension of those efforts is seldom before much long-term permeable sustainability of such systems via domestic investments. Oftentimes, it may well be the private sector, particularly the local or regional pharmaceutical companies, that lacks adequate financial bandwidth to establish full-fledged RI departments. Unlike multinational corporations that have dedicated global regulatory intelligence teams, most domestic firms in LMICs rely on anecdotal knowledge, informal networks, or consultant-driven strategies. This limits their ability to engage proactively with regulators, anticipate changes, or co-create innovative access pathways (World Health Organization, 2022).

Future Directions: Toward Sustainable, Sovereign, and Smart RI Systems

They have to produce a multi-layered future vision for a sustainable, sovereign and smart RI system. One fundamental priority must be strengthening the regulatory system as a key component of national health and innovation policy. Funding digital tools, training programs, and legal reforms that embed intelligence into regulatory mandates in national health and innovation policy includes regulation systems strengthening (Yousefi-Nooraie *et al.*, 2006). An example of such future direction is RI centers of excellence developed within regional blocs, e.g. the African Medicines Agency, the Caribbean Public Health Agency, or ASEAN's Health Division. Such centers can pool data, harmonize standards, offer shared analytical tools, and support member states with limited individual capacity. Integration of artificial intelligence and machine learning into RI platforms-signal detection, policy forecasting, and dossier benchmarking-could improve efficiency dramatically. Open-source pro- RI tools and collaborative knowledge bases are a priority. These dashboards, toolkits modular, and resources multilingual can provide much for LMICs considering dependency reduction on proprietary databases and enhanced local access. That has been the promise of WHO, UNCTAD, and the ICH in expanding investment in digital public goods that provide for regulatory transparency and decision-making. Above all, LMICs must also nurture a new generation of RI leaders using their national education systems. In doing so, they will create a talent pipeline equipped to lead national and regional RI transformation, while embedding RI concepts across pharmacy, law, public health, and engineering curricula, developing regulatory internships or fellowships. People's futures in RI for LMICs lie in building approaches that will be inclusive and people centered. Not only regulators and industry should be served; also, patient groups, civil society, and local innovators should be served. Through participatory policymaking, open data, and inclusive consultation, LMICs can

build RI systems that are transparent, trusted and responsive to their unique developmental needs.

CONCLUSION

In low- and middle-income countries, Regulatory Intelligence (RI) for enhanced innovative therapy access-including orphan medicine, biologics, mRNA, and Advanced Therapy Medicinal Products (ATMPs)-is no longer a theoretical benefit, but a strategic necessity. Such an indication was not conceived at this time when the global pharmaceutical environment would so much become defined by therapies increasingly complex, short timeframes for developing, and the science of regulation in flux; RI became a mobilizing force. Regulators and industry actors can steer through the uncertainties, mitigate the duplicity, and align regulatory actions with public health priorities. Through this approach, for LMICs where systemic barriers have historically delayed or made impossible the availability of cutting-edge treatments, RI could serve as a bridge within which innovation meets compliance, speed meets safety, and sovereignty converges with global convergence. One of the main conclusions of this review is that it has to be institutionalized and not only operationalized in LMIC regulatory systems. This means embedding RI into legal mandates, organizational structures, national development strategies, and cross-sectoral governance. It can no longer remain the subject of ad hoc task forces or pilot projects. Each National Regulatory Authority (NRA) should indeed have a dedicated RI unit set up with the mandate, the digital applications, and the multidisciplinary personnel to systematically scan, analyze, and use intelligence from international and domestic sources. In addition, regulators within LMICs should proceed from reactive decision-making models to predictive models. Through AI-enhanced horizon scanning, trend analytics, and structured decision tree mapping, RI systems could foresee global shifts and pre-empt local regulatory responses. This shift from passive adaptation to strategic foresight can enable LMICs to be co-creators of global regulatory norms, rather than perpetual rule-takers.

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ABBREVIATIONS

WHO: World Health Organization; **EMA:** European Medicines Agency; **ICH:** International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; **LMICs:** Low- and Middle-Income Countries; **RWE:** Real-World Evidence; **HCPs:** Healthcare Professionals; **GDP:** Good Distribution Practice; **GMP:** Good Manufacturing Practice; **GCP:** Good Clinical Practice; **NRA:** National Regulatory Authority; **RIA:** Regulatory Impact Assessment; **R&D:** Research and Development; **ATMPs:** Advanced Therapy Medicinal Products; **HTA:** Health Technology Assessment; **BRICS-TM:** Brazil, Russia, India, China, South Africa, Turkey, Mexico; **FDA:** Food and Drug Administration (U.S.); **mAbs:** Monoclonal Antibodies; **API:** Active Pharmaceutical Ingredient; **PQ:** Prequalification (WHO); **NLEM:** National List of Essential Medicines; **QMS:** Quality Management System; **BMT:** Blood and Marrow Transplantation; **Orphan Drugs:** Drugs developed for rare diseases; **TGA:** Therapeutic Goods Administration (Australia).

CONFLICT OF INTEREST

The authors declare no conflicts of interest, financial or otherwise.

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AUTHORS CONTRIBUTIONS

Isha A. Mirzapure conceptualised and finalised the review, supervised the literature analysis and acted as the corresponding author. Mayur R. Dandekar and Yash M. Salve conducted literature searches, analyzed the data, and drafted key sections of the manuscript. Dr. Manish P. Deshmukh and Dr. Manjusha Bhange contributed to the methodology, validated the data, and drafted the technical sections, ensuring scientific accuracy.

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