

## Scaling Reproductive and Maternal Health Technologies in Diverse Global Contexts Part 2: Navigating Regulatory Pathways and Clinical Trials

This document is a companion guide to the webinar “Scaling Reproductive and Maternal Health Technologies in Diverse Global Contexts Part 2: Navigating Regulatory Pathways and Clinical Trials”, hosted by [Rhia Ventures](#), [Propelevate](#), and [Catalyst Global](#) (June 2023). The recorded webinar is available on our [website](#). For a detailed discussion of reproductive and maternal health equity in global contexts, please reference our Part 1 recording and companion guide (available on <https://rhiaventures.org/ecosystem-building/>).

### This guide will:

- Highlight important considerations for clinical and acceptability trials in diverse global settings, with a focus on the ethical concerns and setting requirements of these markets.
- Share best practices for conducting clinical trials to bring innovative reproductive and maternal health products or services to diverse global contexts.
- Discuss the development of an effective regulatory strategy (e.g., regulatory requirements, timelines, and potential regulatory pathways).
- Provide an insight into the product registration process, including WHO pre-registration.

### Overview of Clinical Trials in Diverse Global Contexts

- In the global reproductive and maternal health space, ‘equity’ usually focuses on access to care.
  - There little emphasis on ensuring all voices have a say in what solutions are prioritized, or what solutions are acceptable within a given context.
- Clinical research is rarely conducted in countries with a high burden of disease
  - Asymmetry in clinical trial representation leads to concerns about equity, data ownership, limited external validity, and post-trial accessibility in underrepresented global settings.
  - Diversity in clinical trial representation promotes health equity, safety, efficacy, and consumer tolerance of new products and services.
- Globally, access to essential vaccines, diagnostics and health services is limited.
  - 70% of internationally defined research and development priorities remain unaddressed (e.g., hypertensive disorders during pregnancy)

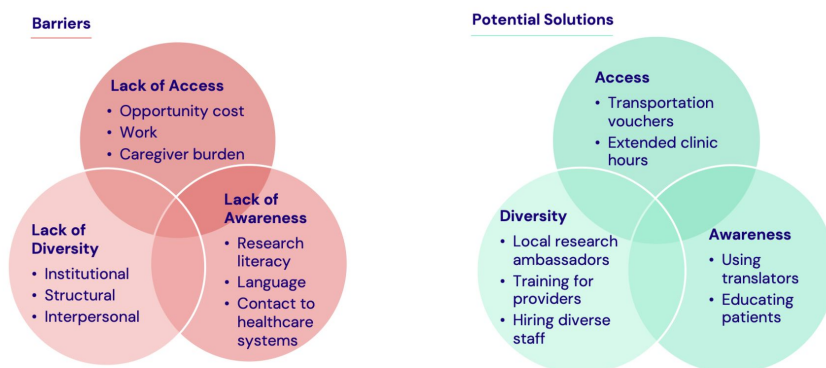


Figure. Barriers and Solutions to Clinical Trial Participation

## Ethical Considerations of Clinical Trials in Diverse Global Contexts

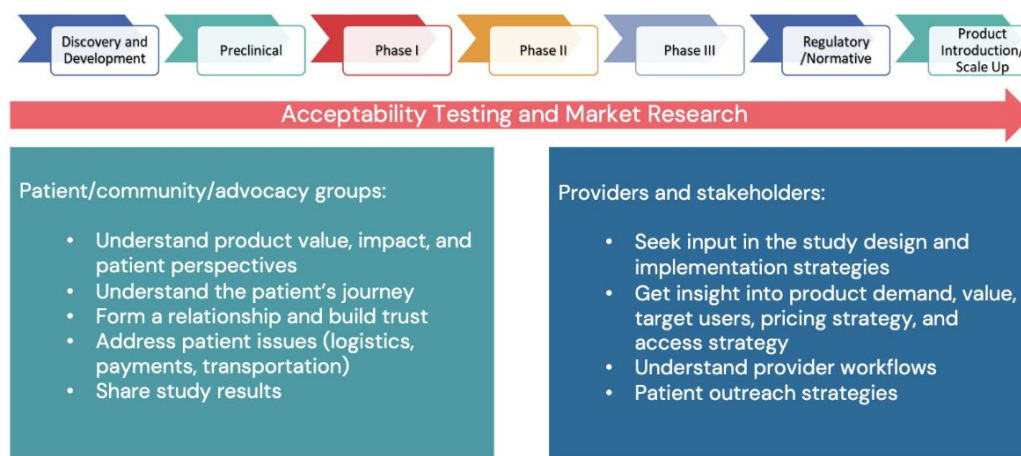
- Different global settings have variation in needs, preferences, and utilization requirements, so clinical trial data may not extrapolate across geographic regions.
- Level of literacy, poverty and lack of access to medications and services increases patient vulnerability
- International ethical principles must guide research.
- Researchers should engage local stakeholders, foster community partnerships, and subject their protocols to comprehensive scientific and ethics reviews to ensure that products are relevant to differing global contexts.
- Companies should co-design a solution / product with the target market in mind, as opposed to adapting a finished product to a target market.
- Companies should improve access strategies, including voluntary licensing, equitable pricing strategies, and improve manufacturing capacity building.

## Linking Trials to Market Opportunities

Consumers in diverse global markets must be involved in the design of products to ensure that it reflects their needs.

## Engaging Patients and Providers

Market Research / Acceptability studies



## Product Development Process Shifts

- There has been a paradigm shift in product development:
  - Country-level focus → Global, multi-national focus
  - Retrospective data analysis → National Regulatory Authority consultations on prospective data collection
  - Dependence on clinical trial results → Real world data
  - Regulatory intelligence and intuitive global regulatory strategy are very important.

## Developing an Effective Regulatory Strategy

- Global markets have various policies and regulatory requirements for medicines and medical devices.
- A global regulatory strategy is the roadmap for obtaining product regulatory approvals in desired markets.
- Global regulatory strategies should:
  - Include global regulatory authority requirements, the patient's interests in the drug development process.
  - Ensure that the company's strategic goals align with medical community opinions.
  - Consider and anticipate change(s) in drug regulatory authority policies; company positions/business strategy.
  - Leverage international harmonization and reliance regulatory procedures.

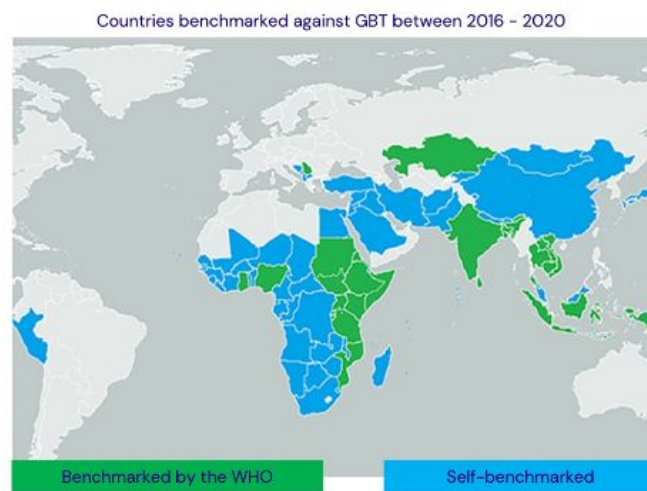


Figure. Components of an Effective Regulatory Strategy

*\*Note: Medical device regulatory processes in diverse markets are not well-defined. Many countries rely on clearance from the European Medicines Agency or the U.S. Food and Drug Administration (FDA).*

## WHO Global Benchmarking Tool

- WHO estimates a prevalence of poor-quality medicines is about 10% in low and middle income countries
- Partly due to limited oversight by under-resourced national regulatory authorities
  - 40% of countries in African region have no regulations for medical devices, 32% have some regulations and 28% have no available data.
  - Some software or mobile apps are gradually being regulated.
- WHO developed a Global Benchmarking Tool (GBT) as part of its capacity-building program to assist under-resourced National Regulatory Authorities.
- The GBT is comprehensive across the entire product life cycle and allows benchmarking to be customized to the needs of National Regulatory Authorities.



Source: WHO Regulatory Systems Strengthening Program

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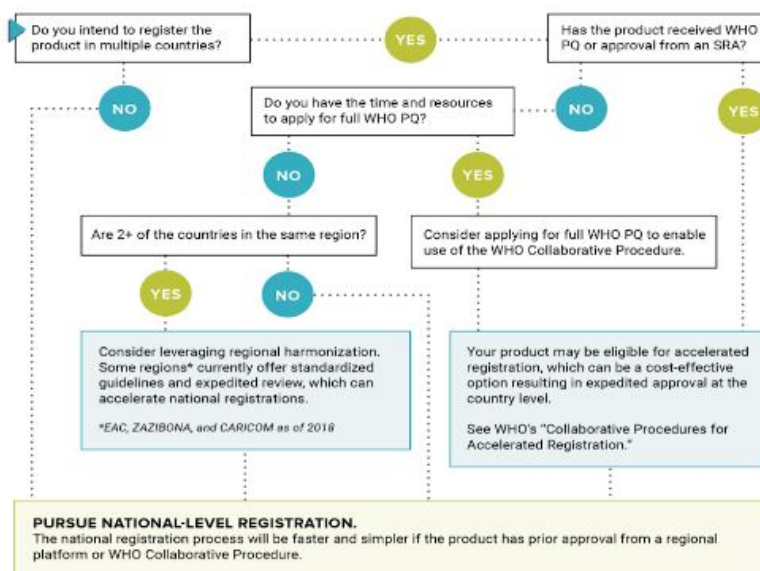
## Traditional Regulatory Pathways

- Country-by-country registrations are the traditional way to register your product.
  - Some countries offer expedited review if a higher fee is paid.
  - This is the only pathway available for medical devices where they are regulated.
- It can be less efficient if your regulatory strategy requires registrations in multiple countries or regions.
- Close contact with each National Regulatory Authority ensures the process keeps moving.
- Registration timelines can range from 3-6 months to a couple of years and fees range from a few hundred dollars to several thousands.

## Regional Harmonization Pathways

- Standardized guidelines and expedited review of priority conditions, including reproductive and maternal health products
- Work-sharing, joint dossier assessments, and joint inspections
- Product registration decisions made by individual National Regulatory Authorities
  - No mutual recognition across standardized regions, so companies who want to register in multiple countries still need to follow country specific guidelines and submission processes
- Process usually takes less than one year to complete and costs could be less than \$10,000 (US)

## Choosing a Registration Pathway



## Regulatory Assessment Landscape Checklist

- Identify the country's regulatory authority and website and establish points of contact.
- Confirm product classification (e.g., pharmaceutical, medical device, combination, innovator, or generic).
- Confirm trademark requirements (e.g., country of origin, local, classification).
- Define requirements for Marketing Authorization Holder and/or Local Technical Representative.
- Confirm submission process.
- Confirm fees (application, registration, and Goods Manufacturing Practice submission) and any additional costs.
- Confirm dossier evaluation process and timeline.
- Confirm if samples are required for registration including the quantity, condition, and when / to whom they should be shipped.

Propelevate is a boutique consulting firm that supports changemakers working at the intersection of the private sector and social impact in diverse global contexts, with a strong focus on sexual and reproductive health and rights. They support investors and NGOs to identify and scope market and impact opportunities, and create and iterate strategy and business models.

Catalyst Global is a US-based 501(c)(3) committed to increasing access to critical sexual and reproductive health products and services in diverse global contexts. Catalyst works with a range of value-matched partners across the system – from laboratories and manufacturing plants to national authorities and service delivery partners – to bring innovations to the girls and women around the world who need them.

Rhia Ventures is a women-led nonprofit seeking to advance reproductive and maternal health equity by intentionally leveraging capital to center the needs, experiences, and perspectives of historically marginalized people in decision-making. The Rhia Ventures Ecosystem Building program supports early-stage reproductive and maternal health entrepreneurs and investors with building and growing in a way that incorporates a health equity lens and a culture of impact management and measurement.