STANDARDS ALLIANCE PHASE 2 COVID-19 MEDICAL DEVICE REGULATORY CONVERGENCE (MDRC) PROJECT

FINAL PROJECT REPORT – EXECUTIVE SUMMARY

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Executive Summary

The Standards Alliance Phase 2 (SA2) COVID-19 Medical Device Regulatory Convergence Project (MDRC) is a partnership between the U.S. Agency for International Development (USAID) and the American National Standards Institute (ANSI) in collaboration with the Advanced Medical Technology Association (AdvaMed) to advance medical technology (medtech) regulatory convergence and reliance, working together with the global medtech industry, standards developing organizations (SDOs), as well as with national, regional and international health, trade, and regulatory authorities.

The overarching MDRC project objective is to accelerate coordinated medtech sector, supply chain, trade, and regulatory efforts to coherently combat and recover from the COVID-19 pandemic in alignment with foundational Good Regulatory Practices (GRPs) that support regulatory convergence, reliance and use of international standards to improve access to life-saving technology. Under the Standards Alliance Initiative, the MDRC provides capacity building assistance specifically related to implementation of the World Trade Organization Technical Barriers to Trade Agreement (WTO/TBT), which is one of the strongest GRPs. By building capacities for improved medical technology regulatory procedures and removing technical barriers to trade, the MDRC will lower unnecessary market authorization costs by about $235 million annually and improve patient access to life-saving medical technologies, including high-quality personal protective equipment (PPE) and other medical devices that assist in the recovery from the COVID-19 pandemic and prepare for future global health emergencies. While the project focused on specific countries, the impact will be global, as other countries adopt similar globally aligned regulatory practices and discourage use of country-unique systems. **In partnership with eight project countries in Africa, Latin America, and Southeast Asia, the MDRC aims to:**

01. Build capacity of partner countries for international standards and conformity assessment procedures for medical devices;

02. Remove countries' technical barriers to trade for medical devices;

03. Increase access to needed high-quality personal protective equipment (PPE) and other medical technologies to respond to and recover from COVID-19 and future global health crises; and

04. Foster private sector engagement and co-responsibilities in public consultations and WTO notifications of draft technical regulations and standards regarding medical technologies.

PROJECT COUNTRIES

The MDRC project countries include:

Africa: Ghana, Kenya, South Africa

Latin America: Brazil, Colombia, Mexico, Peru

Southeast Asia: Indonesia

STRUCTURE

MDRC Structure under SA2 (2020-2023)

$3,000,000 from USAID + **$4,000,000** from AdvaMed = **$7,000,000**

$3,500,000 via AdvaMed In-Kind Contributions of Staff Time
$500,000 via Direct Contributions from AdvaMed LatAm budget

- USAID funding was allocated to expenses such as foreign government delegation travel and training costs and support of the MDRC programmatic and administrative team.
- AdvaMed funding was allocated to staff time toward MDRC deliverables, technical expert participation and core MDRC functions such as online resources.

CAPACITY BUILDING & PROJECT IMPLEMENTATION

After establishing workstreams in each project country and developing a workplan, the MDRC focused on implementation during the final project years. Recognizing the importance of both public and the private sector engagement, the MDRC convened NRAs and other stakeholders to foster a collaborative approach toward capacity building and regulatory reliance. These activities laid the foundation for sustainable improvements in regulatory processes, focusing on the use of international standards and conformity assessment, ensuring that public and private stakeholders are better prepared for future global health crises.

Year	Workshops	Participants	Person Hours
2021	24	4,746	11,692
2022	26	3,587	12,195
2023	23	3,507	16,520
Total	**73**	**11,840**	**40,407**

Project Country/ Region	Capacity Building Activities	Total Participants
Latin America	**13**	**1,316**
Brazil	**11**	**1,846**
Colombia	**5**	**391**
Mexico	**19**	**4,720**
Peru	**2**	**553**
Africa	**4**	**586**
Kenya	**4**	**363**
South Africa	**7**	**1,165**
Southeast Asia	**2**	**414**
Indonesia	**7**	**486**

In order to build resilient health systems, the MDRC led capacity building activities advancing regulatory reliance, encouraging health and trade authorities – with support from industry – to:

01.

Implement globally aligned regulatory practices as established by the WTO, World Health Organization (WHO) for health products, and implement globally harmonized reference documents of the International Medical Device Regulators Forum (IMDRF)

02.

Base national medtech technical regulations, standards and conformity assessment procedures upon relevant international standards with the objective of aligning with international best practices

03.

Leverage reliance pathways to streamline market authorization processes and reduce the duplication of regulatory efforts, ultimately increasing efficiency and patient access to medical technologies

MDRC ECONOMIC OUTCOME

The MDRC generated the following estimates of the costs of medical device market authorization bottlenecks deriving from regulatory, standards and conformity non-alignments in the MDRC countries. These values are estimates only based on aggregated information from MDRC-supporting medical device manufacturers.

Non-Aligned Medical Device Technical Regulatory Requirements and Delays (World)	**50B**
Non-Aligned Medical Device Technical Regulatory Requirements and Delays (MDRC Countries)	**2.35B**
MDRC Policy Change Economization (if Colombia GRP model extended to all MDRC countries)	**1.75B**
MDRC Policy Change Economization (policies implemented to date)	**235M**

numbers in USD

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