MEDICAL DEVICE REGULATORY CONVERGENCE (MDRC) PROJECT

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.

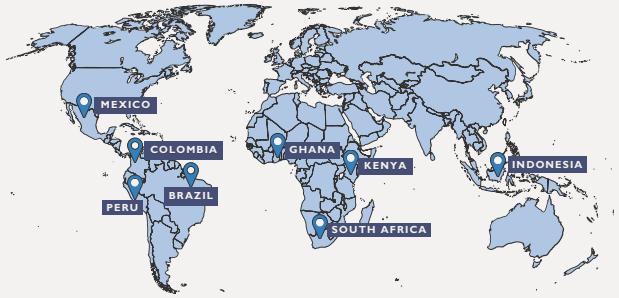
PROJECT COUNTRIES

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**

MDRC ECONOMIC OUTCOME

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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