Standards Alliance Phase 2 COVID-19 Medical Technology Regulatory Convergence (MDRC) Project

Africa

STANDARDS ALLIANCE - PHASE 2

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Overview

- Background – Standards Alliance
- Activity Focus: Standards and good regulatory practices for medical devices
- Standards Alliance Phase 2, Medical Devices and the COVID-19 Response

Standards Alliance: Phase 2

- Leading Organizations:
  - USAID
  - American National Standards Institute (ANSI)
- Funding Structure:

2019 - 2024	USAID	ANSI/private sector

COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Recovery from the pandemic, and strengthening resilience for future global health crises, will require a concerted effort to:

- Strengthen collaboration to rapidly implement medical device sector-specific regulatory convergence and cross-sectoral GRPs.
- Invest in global medical device regulatory infrastructure

COVID-19 has demonstrated the dire need to build up the soft infrastructure of medical device regulatory agencies:

- Implementing foundational 'whole-of-government' GRPs using international standards and conformity assessment (institutional/consistent)
- Implement GRP policies within the regulatory processes of the agencies
- Implementing a Standards and Conformity Assessment program

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Standards Alliance: Phase 2
Medical Device Regulatory Convergence Project (MDRC)

Africa Objectives

Project Countries: Kenya, Ghana, and South Africa (plus benefits to others)

Tier 1: GRP Implementation (Cross-Sectoral)

Phase One: Gap Analysis (GRP policies and stakeholders responsible for implementation)

Phase Two: Implementation (local consultations and multilateral sessions)

Tier 2: Medical Device Sector-Specific Regulatory, Standards and Conformity Assessment Convergence

Phase One: Stakeholder assessment

Phase Two: Implementation (local consultations and multilateral sessions)

COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Key Methodologies

- International Dimension / Leveraging Global Institutions, Alliance and Benchmarks
- Good Regulatory Practices and MD Regulatory Convergence
- Recognizing the Difference b/w MedTech and Pharmaceuticals
- Addressing Customs-Related Barriers though Health and Regulatory Authorities
- Diagnostics Elements
- Development Context and Gender Balance

COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Government Engagement and Partner Orgs

- Medical Device Regulatory Authorities
- Ministries of Health / Centers for Disease Control
- Central Regulatory Coordination Bodies
- Ministries of Trade / Foreign Affairs
- National Standards Bodies
- Customs and Border Authorities

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Partner Organizations

- **Global Collaboration** (i.e., GMTA, ISO, etc.)
- **USAID Project Collaboration** (i.e., PQM+, MTaPS, etc.)
- **Diagnostics Collaboration** (i.e., GDA, LSHTM-IDC, etc.)
- **Africa** (i.e., national industry and standards bodies, PAHWP, RECs, ARSO, etc.)

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COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Performance Measures

- **Global Outcomes:**
  - *Establishment at the global level by medical regulators, taking medical device industry recommendations into consideration, of the international benchmarks for Emergency Use Authorizations and related emergency regulatory frameworks, based on international standards, providing a transparent, convergent, predictable and agile international mechanism to most readily bring medical technology to points of care and patients in times of health crises.*

- **Africa Outcomes:**
  - The alignment of medical device regulatory frameworks, technical regulations, standards, and conformity assessment requirements across a core set of countries in each region
  - Increased regulatory efficiency, improved patient access to innovative healthcare technologies and lowered barriers to trade across a core set of countries in each region
  - Lowered regulatory, customs and technical barriers to MDs required to combat COVID-19
  - Improved medical device regulatory agency efficiency to increase bandwidth for COVID-19 as well as for non COVID-19 health matters in the road to recovery post pandemic

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