The Standards Alliance and COVID-19 Medical Technology Regulatory Convergence (MDRC)

U.S. Government Inter-Agency Coordinating Session

November XX, 2020

STANDARDS ALLIANCE - PHASE 2

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ANSI

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

Background: Standards Alliance Phase 1 (2013-2020)

- Public-Private Partnership:
  - USAID
  - American National Standards Institute (ANSI)

- Funding Structure:

	USAID	ANSI/private sector
2013 – 2018	$2.5 million	$2.5 million
2018 – 2021*	$1.7 million	$1.7 million
TOTAL:	$4.2 million	$4.2 million

Standards and Good Regulatory Practices for Medical Devices

AdvaMed
Advanced Medical Technology Association

- Help Latin American governments (Mexico, Colombia, Costa Rica, Peru) maximize regulatory efficiency in the medical devices sector
- Two tiers to address both horizontal and vertical regulatory issues in the medical devices sector.
  - Tier 1 emphasizes regulatory coherence across government agencies benchmarked across international best practices
  - Tier 2 highlights good regulatory practices, technical regulations, standards and conformance within the medical devices sector.

Future Opportunities
Standards Alliance: Phase 2

- Public-Private Partnership:
  - USAID
  - American National Standards Institute (ANSI)
- Partner Countries:
  - Latin America, Africa, Southeast Asia
  - Programming at both national and regional levels
- Funding Structure:

	USAID	ANSI/private sector
2020 – 2024	**$5.5 million**	**$5 million**

Objectives

- Build off Phase I to support capacity of developing countries in the areas of:
  - legal and regulatory framework
  - standards development
  - conformity assessment procedures
  - private sector engagement
- Support development of national quality infrastructures aligned with international best practices
- Engage partner countries in the intersection of standards and economic development using economic development project-like approaches

Medical Devices and the COVID-19 Response

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

Context: AdvaMed and Medical Device Regulatory Convergence and Foundational GRP

Medical Device Regulatory Convergence Project (MDRC)

- AdvaMed's Global Presence and Strategy
- Governments are recognizing the highest cost-benefit regulations maximize public health/safety while stretching the impact of finite public resources
- Regulatory Convergence
- Good Regulatory Practices (GRPs)

	USAID	ANSI/private sector
2020 – 2024	$3.0 million	$3.9 million

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Global Objectives

- **International Benchmarks for EUA**
  - Primarily underpinned by global medical device regulatory convergence enabled through GRPs
- **International Center for Emergency Regulatory Response / COVID-19 Medical Device workstream**
  - Under Global Medical Technology Alliance (GMTA) and Global Diagnostics Alliance (GDA), with IMDRF
- **COVID-19 Medical Device Portal**

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Latin America Objectives

- **Project Countries:** Brazil, Colombia, Mexico, Peru
- **Tier 1: GRP Implementation (Cross-Sectoral)**
  - Phase One: Update GRP international reference and implementation guide
  - Phase Two: GRP gap analysis
  - Phase Three: GRP implementation (bilateral)
  - Phase Four: GRP implementation (multilateral)
- **Tier 2: Medical Device Sector-Specific Regulatory, Standards and Conformity Assessment Convergence**
  - Phase One: Update MD sector-specific regulatory, standards, and CA convergence International Reference and adopt a core training curriculum
  - Phase Two: MD technical regulations, standards and CA gap analysis
  - Phase Three: MD technical regulations, standards, and CA implementation (bilateral)
  - Phase Four: MD technical regulations, standards, and CA implementation (multilateral)

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Latin America Objectives

Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

- **Novel and significant component of Standards Alliance (Phase 2)**
- **Vision: One standard, one test, accepted everywhere**
- **Technical Secretariat Team (based in U.S., Mexico, and Brazil)**
- **Focus of project funding:**
  - Implement structural policy changes aligned with the project goals
  - Maximize interaction with government authorities and key stakeholders in project countries.

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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)

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Southeast Asia Objectives

- **Project Countries:** Viet Nam, Thailand, Indonesia (plus benefits to others)
- **Tier 1: GRP Implementation (Cross-Sectoral)**
  - Literature Review and Stakeholder Assessment
- **Tier 2: Medical Device Sector-Specific Regulatory, Standards and Conformity Assessment Convergence**
  - Phase One: Stakeholder assessment
  - Phase Two: COVID-19 Medical Device Regulatory Review
  - Phase Three: Implementation (local consultations and multilateral sessions)

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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**

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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.)
- **Latin America** (i.e., national industry and standards bodies, IDB, PAHO, etc.)
- **Africa** (i.e., national industry and standards bodies, PAHWP, RECs, ARSO, etc.)
- **Southeast Asia** (i.e., national industry and standards bodies, ACCSQ, AHWP, etc.)

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Performance Measures

- **Global Outputs (4)**
  - *Example: Establishment of Intl Center for Emergency Reg. Response*
- **Latin America Outputs (11)**
  - *Example: Establishment of Inter-American Coalition for Reg. Converge.*
- **Africa Outputs (10)**
  - *Example: Number of regulatory agency and private sector technical experts engaged in international standardization in project countries*
- **Southeast Asia Outputs (10)**
  - *Example: Convene COVID-19 MD regulatory review conference*

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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.*
- **Latin America, Africa, Southeast Asia 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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