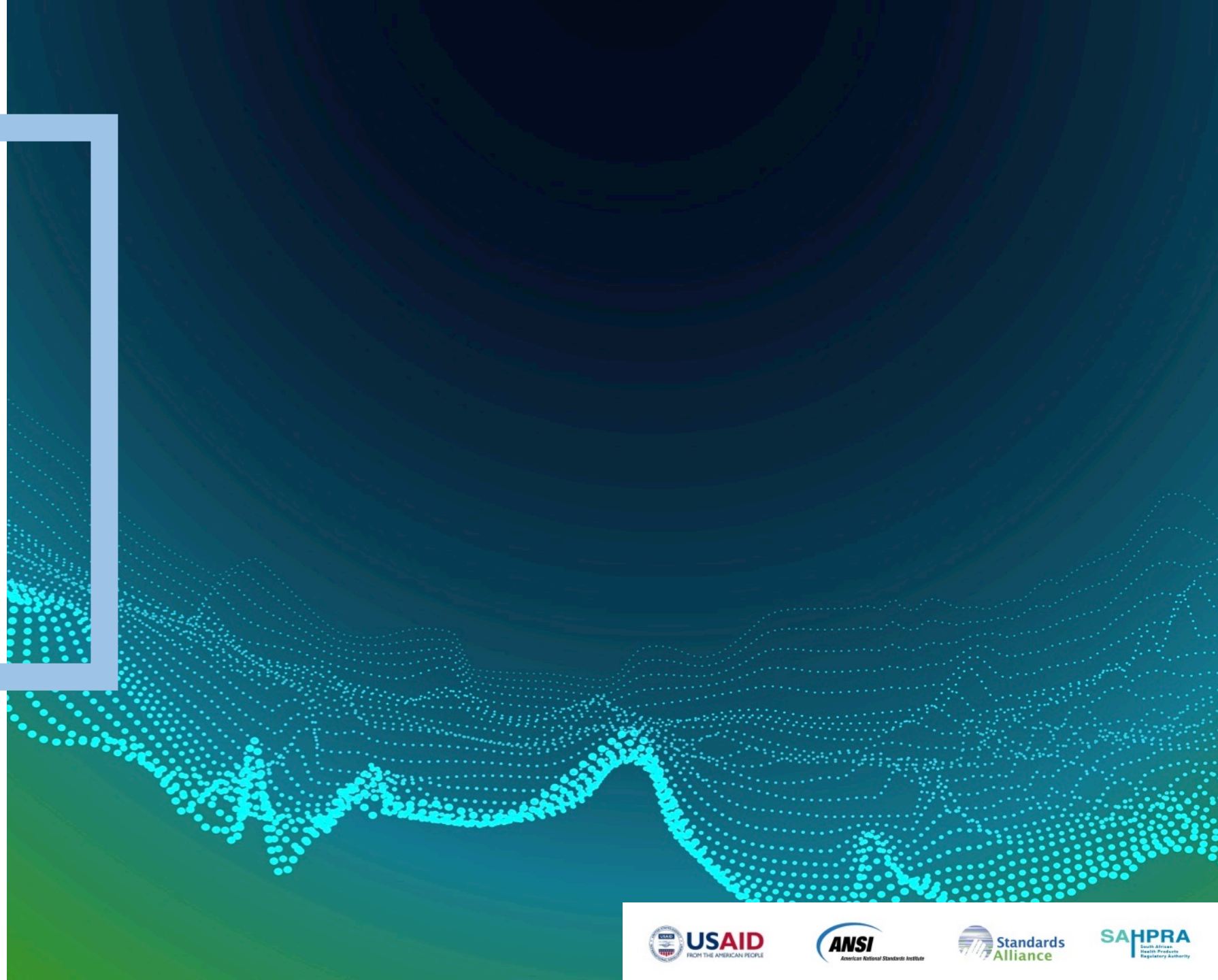
Good Regulatory Practices & Technical Competencies

14 November 2023



MDRC Project Overview

USAID FROM THE AMERICAN PEOPLE
ANSI American National Standards Institute
Standards Alliance
SAHPRA South African Health Products Regulatory Authority

Purpose & Partnerships

To advance regulatory convergence in partnership with standards developing organizations as well as national and regional health/regulatory and trade authorities

Standards Alliance - Phase 2

A public-private partnership

What does MDRC do?

- Build capacity and support implementation of:
  - Good Regulatory Practices of partner countries
  - Utilization of International Standards and References
  - Conformity assessment procedures related to medical devices
- Help identifying and removing countries' technical barriers to trade for medical devices
- Increase patients' access to needed high-quality PPE and other medical technologies to respond to and recover from COVID-19 and future global health crises

What does MDRC do? Cont.

- Advises on the adoption of international benchmarks for EUAs and related emergency regulatory frameworks and approval processes
- Support the development of institutionalized transparent, convergent, predictable, and agile regulatory frameworks so medical devices are received across and within borders at points of care in times of health crises and beyond
- Assists customs authorities in following the import criteria and policies set by the health authorities
- Foster private sector engagement in the (medtech) regulatory space

Partners & Collaborations

- World Health Organization (WHO)
- International Medical Device Regulators Forum (IMDRF)
- Global Harmonization Working Party (GHWP)
- Global Medical Technology Alliance (GMTA)
- Global Diagnostics Alliance (GDA)
- AU-NEPAD
  - Africa Centres for Disease Control and Prevention (CDC)
  - Africa Medical Devices Forum (AMDF)
  - Africa Diagnostics Advisory Committee (DAC)
- Pan American Health Organization (PAHO)
- ASEAN Medical Device Committee (AMDC)
- U.S. Food and Drug Administration (USFDA)
- Brazilian Health Regulatory Agency (ANVISA)
- Health Canada
- Australian Therapeutic Goods Administration (TGA)
- Singapore Health Sciences Authority (HSA)
- South African Health Products Health Regulatory Authority (SAPHRA)
- Kenya Pharmacy and Poisons Board (PPB)
- Ghana Food and Drug Administration (GFDA)
- World Trade Organization (WHO)
- African Free Trade Area Secretariat (AfCFTA)
- Inter-American Development Bank (IDB)
- African Regional Organization for Standardization (ARSO)
- Pan American Standards Commission (COPANT)
- Standards Developing Organizations (SDOs)
  - ISO, IEC, AAMI, ASTM, CLSI, MITA, IEEE, GMDN Agency, et al
- Ministries of Trade
- Central Regulatory Coordination Bodies
- South African Medical Technology Industry Association (SAMED)
- Southern African Laboratory Diagnostics Association (SALDA)
- Medical Device Manufacturers of South Africa (MDMSA)

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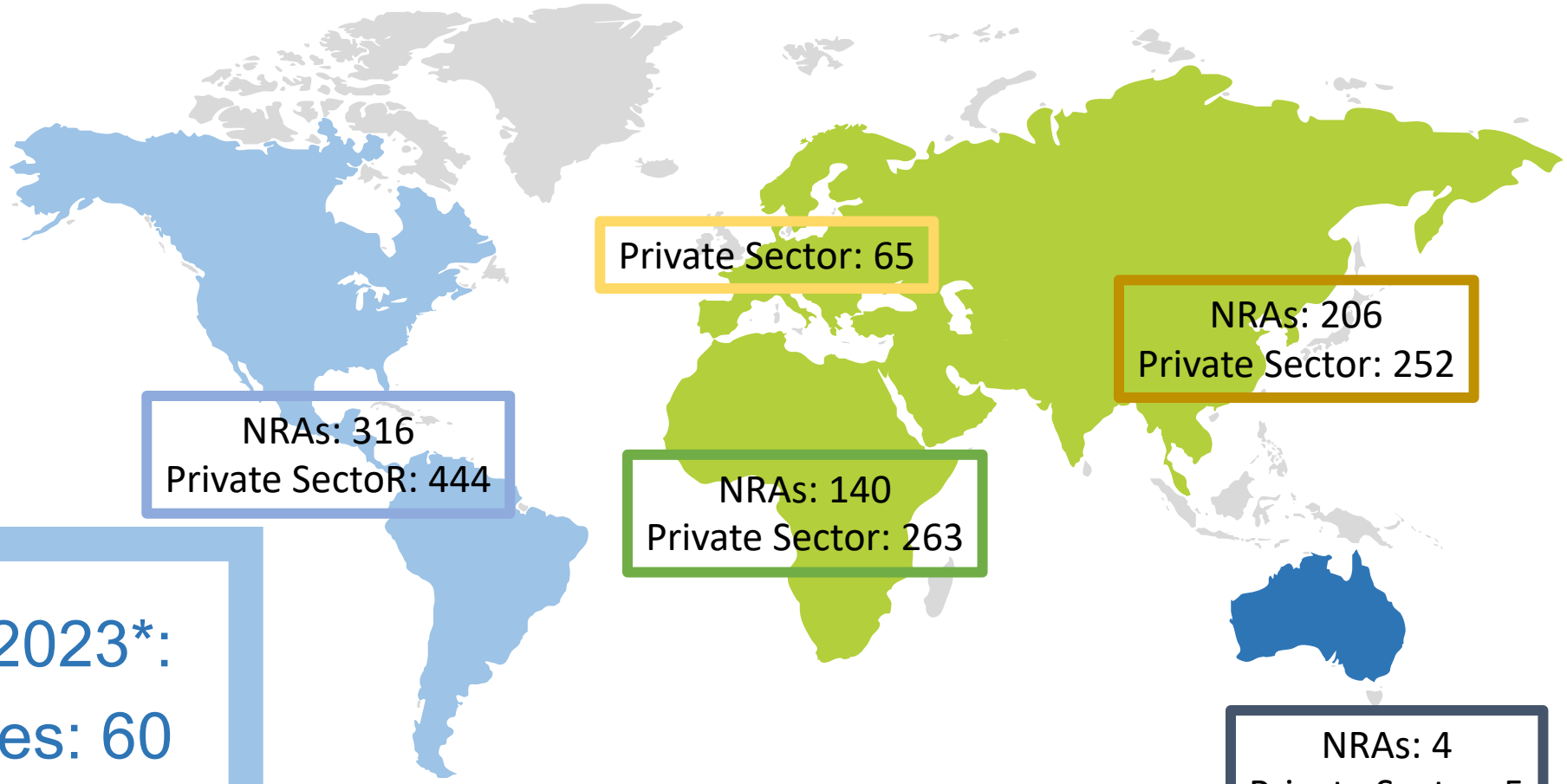


The Numbers 2023*:

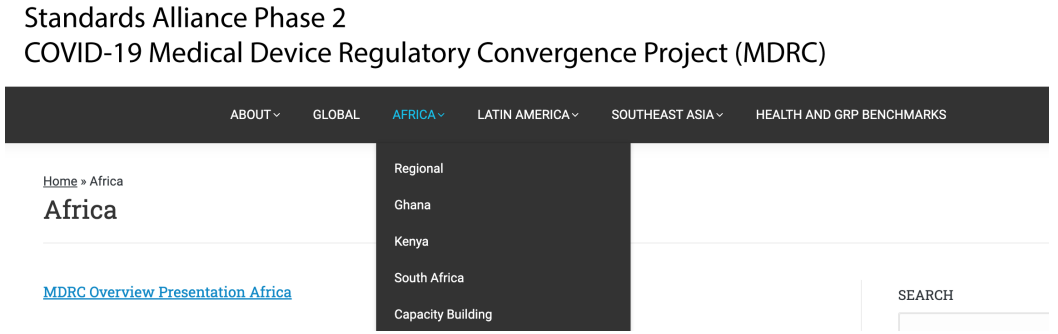
Countries: 60

NRAs: 662

Private Sector: 1029

*August 2023

MDRC Website - Resources



Home Page:

https://www.standardsalliance-mdrc.org/

Capacity Building:

https://www.standardsalliance-mdrc.org/capacity-building-category/africa/

Question & Answers

THANK YOU

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