

Elevating Diagnostic Accessibility

(Overcoming Challenges, Shaping Solutions, and Forging Ahead)

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1. The Value of Diagnostics
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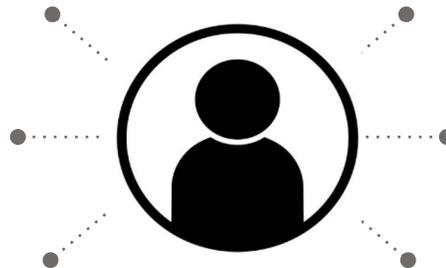
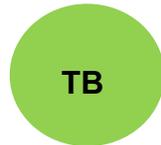
Time to Diagnosis and Treatments Matters.....

More than 9 of every 10 cases of cervical cancer are caused by HPV and can be **prevented**¹ with early detection



Early detection and [breast cancer] treatment has proven successful in high-income countries and should be applied in countries with limited resources where some of the standard tools are available⁴

The spread of TB is **preventable** when diagnosed early and, in most cases, treatable²



Early detection of cardiovascular disease can **be the difference between life and death**⁵

Earlier diagnosis **improves Covid-19 prognosis**³



An **early diagnosis can improve the quality of care and quality of life** and may reduce the financial and emotional impact of the disease⁶

1. <https://www.cdc.gov/hpv/parents/cancer.html>. Accessed March 27, 2023.
2. <https://www.cdc.gov/niosh/topics/tb/default.html#:~:text=TB%20is%20preventable%20and%2C%20in%20by%20available%20anti%20DTB%20drugs>. Accessed March 27, 2023.
3. [Earlier diagnosis improves COVID-19 prognosis: a nationwide retrospective cohort analysis](https://www.who.int/news-room/fact-sheets/detail/breast-cancer), June 9, 2021
4. <https://www.who.int/news-room/fact-sheets/detail/breast-cancer>. Accessed April 2023.
5. <https://www.cardiophoenix.com/news/the-importance-of-the-early-detection-of-cardiovascular-disease>. Accessed April 2023.
6. <https://www.alz.org/professionals/public-health/public-health-topics/early-detection-diagnosis>. Accessed April 2023.

The 76th World Health Assembly

(Diagnostics Resolution Highlight)



- ❑ **On 26 May** Member States endorsed a resolution to **strengthen diagnostics capacity** in countries and to **improve access to diagnostic services**.
- ❑ The broad ranging resolution **recognizes** that diagnostic services are **vital** for the precise identification of diseases, and therefore the **timely initiation** of the correct treatments for better health outcomes.
- ❑ The resolution considers the **full spectrum** of “diagnostics”, including both “in vitro” laboratory tests and “non in vitro” diagnostics. It covers actions for research and development, manufacturing, regulation, selection and procurement, awareness, advocacy and addressing access barriers in general.

The Global Diagnostics Gap

The Challenge:

- 47% of the global population lacks access to basic diagnostics.
- 60% of "Blueprint" pathogens lack diagnostic tests.
- 50% of the top 20 diseases have no appropriate tests.
- Access is worse for remote, rural, low-income, and marginalized communities.

Impact and Potential:

- Reducing the diagnostic gap to 10% could save 1.1 million lives annually.
- Diagnostics are crucial for outbreak surveillance and pandemic preparedness.

Advancing Diagnostics for Global Health

Benefit:Cost Ratios:

- Diagnostics for **HIV, TB, hepatitis B, syphilis, and hypertension** have benefit:cost ratios from **3:1 to 24:1**.

Global Initiatives:

- WHO's Essential Diagnostics List urges member states to prioritize investments.
- G20 Health Ministers emphasize diagnostics for universal health coverage.

Innovation and Collaboration:

- Science and innovation, including digitalization, point-of-care testing, and genomics, enhance diagnostics.

Africa's Endeavors



African Medical Device Forum (AMDF)

- Serves as a **vital resource** in **fostering** technical expertise in Medical Device & IVDs, developing international standard documentation, and offering technical advices within the **African Medicine Agency (AMA)**.
- It aim to advance and **promote** the **harmonization, mutual recognition, and reliance** on medical device regulations across the **African** continent.
- **AMDF** recently provided positive feedback to partner with **MEDAK**, this collaboration aim to enhance access to life- saving MDs/ VIDs.



Africa Center for Disease Control and Prevention

- ❖ On 20 August 2023, Africa CDC and AUDA-NEPAD Established Diagnostic Advisory Committee (DAC) to **Harmonize** regulatory processes for **In-vitro Diagnostics** (IVDs) and to **accelerate** access to diagnostics for the health security of the continent.
- ❖ launched the **Africa Collaborative Initiative to Advance Diagnostics** (AFCAD).
- ❖ The establishment of the **DAC** is an important **milestone** in the implementation of comprehensive strategies outlined under the AFCAD initiative
- ❖ Africa **CDC** is supporting **AMDF** to close the gap between the laboratory and regulatory work streams for IVDs.



Challenges in African Nations & Recommendations



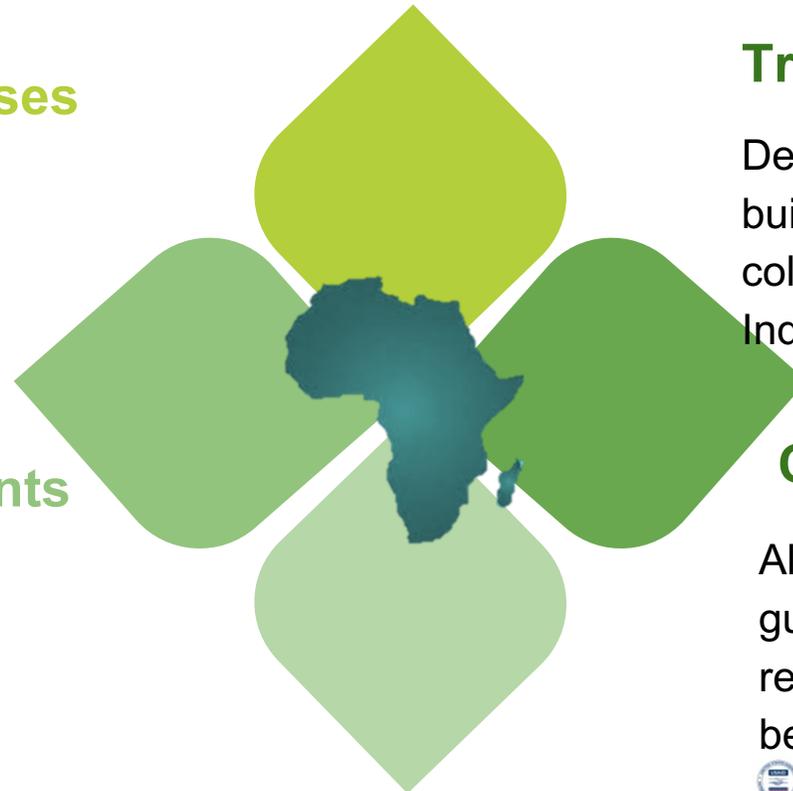
IVD Accessibility Regulatory Roadblocks, and Recommendation

Challenges

Limited Resource & Expertises

Country-Specific Requirements

For instant Country specific
Labeling requirements



Recommendations

Training & Capacity Building

Develop a comprehensive training and capacity-building program for regulatory staff, with collaboration from international agencies, and Industry

Convergence and harmonization

Aligning national regulations with international guidelines and standards, and avoid requirements that lack patient safety and benefits

IVD Accessibility Regulatory Roadblocks, and Recommendation

Challenges

In-Country Lot verification testing

In -Country Clinical Trial



Recommendations

Recognize the international recommendation

As per the WHO, “Countries may implement a system of risk-based lot verification of high-risk IVDs (class D)”

Acceptance of Global Clinical Trials

NRA May consider the acceptance of data from clinical investigations conducted outside its jurisdiction, if global and national standards are



IVD Accessibility Regulatory Roadblocks, and Recommendation

Challenges

GMP Inspection

Counterfeit Medical Devices



Recommendations

Reliance / Work-Sharing

Promote the use of reliance and work-sharing pathways for Inspection, and other regulatory processes, to avoid redundant work, and optimize the use of available resources.

Traceability, Penalties and Enforcement

Implement UDI for tracking & tracing medical devices. Impose penalties

IVD Accessibility Roadblocks, and Recommendation

Challenges

Residual Shelf Life



Recommendations

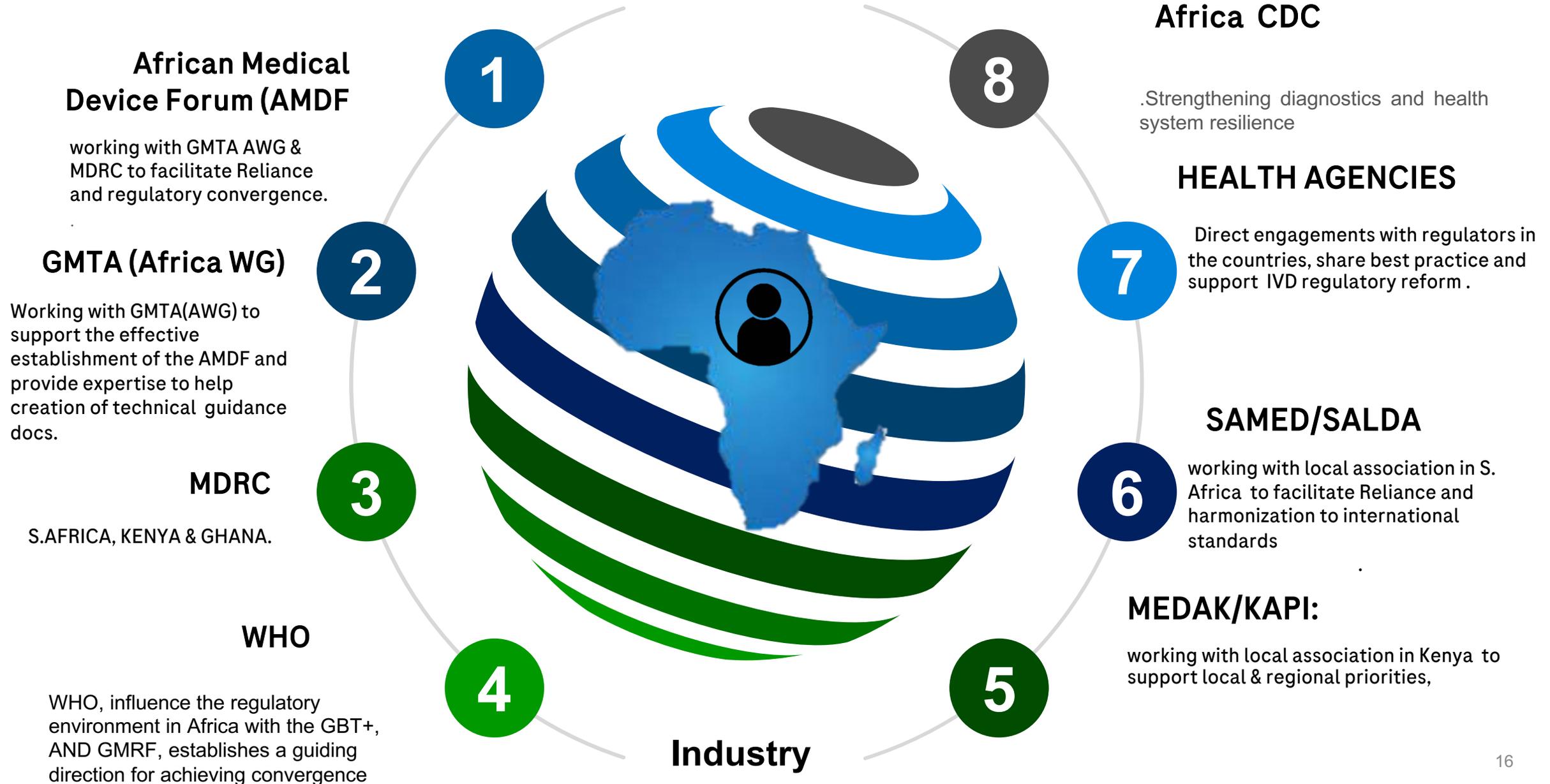
Recognize the international recommendation

Non of the IMDRF countries requires a minimum shelf life, and Adhering to WHO guidance and requesting the remaining shelf life in months ensures consistency across various products and aligns with commodities.

Key stakeholders



Africa: Key Stakeholders



Industry and Manufacturer Commitments

- ❖ Collaborate with different stakeholders (local and international) for harmonized standards to ensure equitable access to quality assured, safe and effective IVDs.
- ❖ Investing in the development of IVDs tailored to the specific healthcare needs of the African population is crucial.
- ❖ Support training programs and capacity building initiatives to enhance local expertise in using IVDs effectively.
- ❖ Advocate for the importance of IVDs in healthcare and raise awareness among governments, healthcare providers, and the public.

Ultimate goals of modern, flexible regulation

A system is optimal when it leads to improved patient access to new products and high standards for patient health and safety





Question & Answers



THANK YOU

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