



World Health
Organization

REGIONAL OFFICE FOR Africa



Progress Made in the Implementation of the Stepwise Laboratory Quality Improvement Process Towards Accreditation

Talkmore Maruta

ASLM2014, Cape Town

Background

ASLM is a pan-African professional body launched in 2011



Receives support from African Union, World Health Organization (WHO), United States (US) Centers for Disease Control and Prevention (CDC), Clinton Health Access Initiative (CHAI), US President's Emergency Plan for AIDS Relief (PEPFAR), Several African ministries of health and other international partners

ASLM 2020 Vision



Vision2020: Its Motivation



WHO
Resolution
AFR/RC58R2

- Strengthening Public Health Labs in Africa
-

2008
Maputo
Declaration

- Strengthening of Laboratory Systems

GOAL

2020 TARGETS

Workforce

- ✓ Curriculum review, establish professional/regulatory bodies
- ✓ Train 30,000 professionals

Accreditation

- ✓ 2500 Labs to be enrolled into SLIPTA
- ✓ 250 labs to achieve accreditation by international standards

Regulatory

- ✓ Raise regulatory standards for diagnostics products to international standards in 25 countries
- ✓ Establish harmonized regulation for new diagnostics across Africa's 8 RECs

Lab networks

- ✓ Establish African Network of Public Health Reference Laboratories, with at least 30 member countries.



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2020

Goal 2 Laboratory Accreditation: Key Mechanisms



ASLM is Implementing Partner for SLIPTA.

2020 Targets

- Enroll 2,500 labs in the WHO SLIPTA quality improvement program
- Enable 250 labs to achieve accreditation



Audit Process

Tools

WHO AFRO SLIPTA Checklist
ISO 15189:2012

Audit methods

- Review of documents and records
- Observations
- interviews

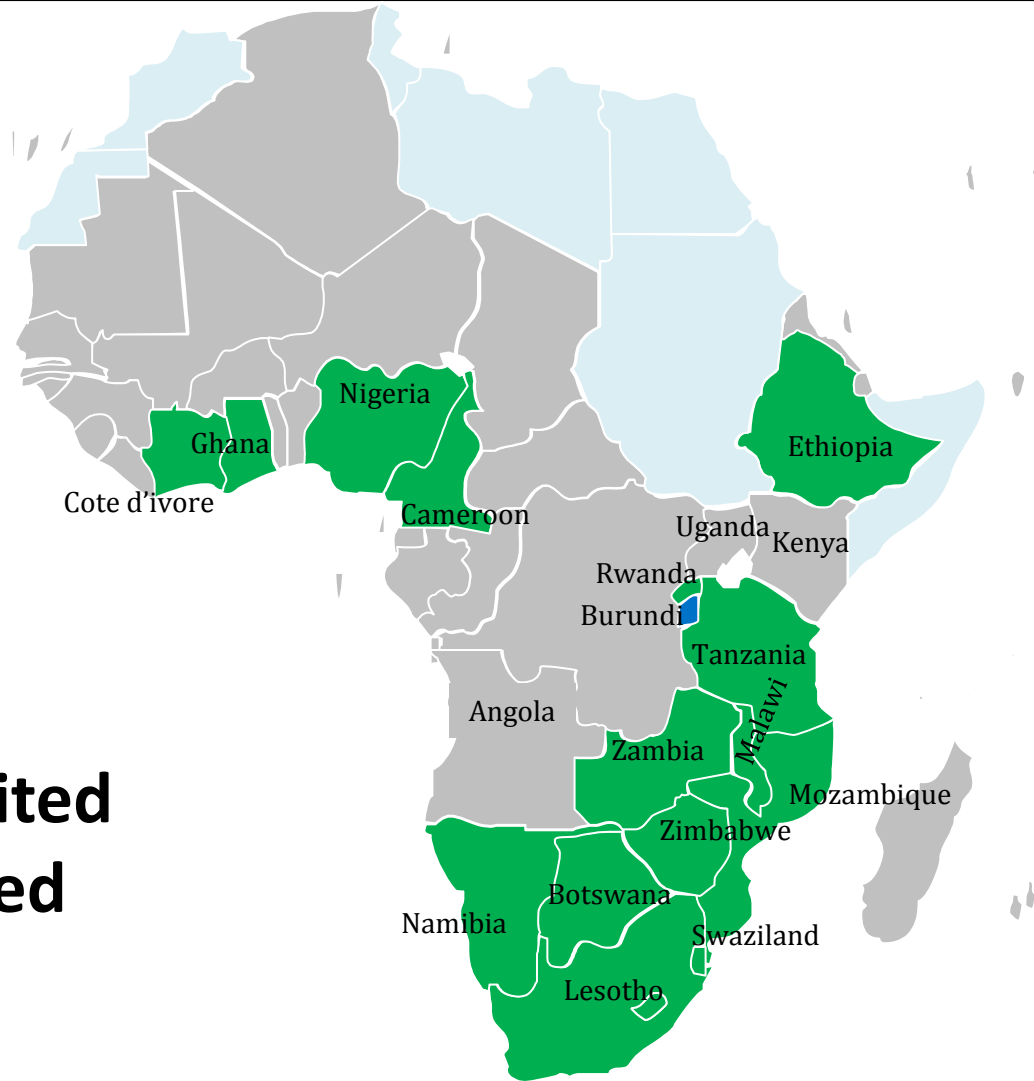
De-brief

- Lab Level
- Centrally

Report
Submission to
IAC

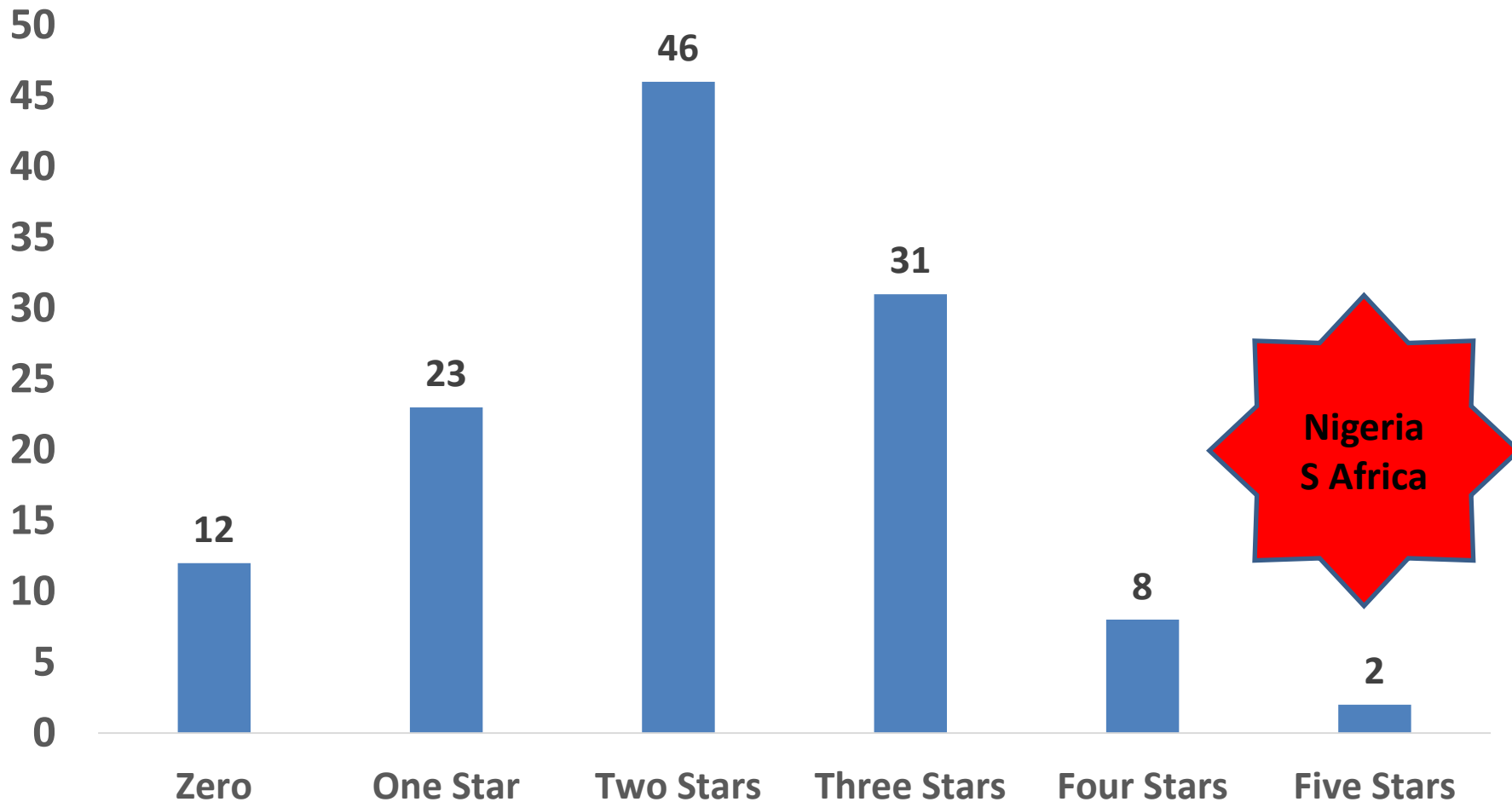
SLIPTA Progress

SLIPTA Implementation: May 2013 – Oct 2014.

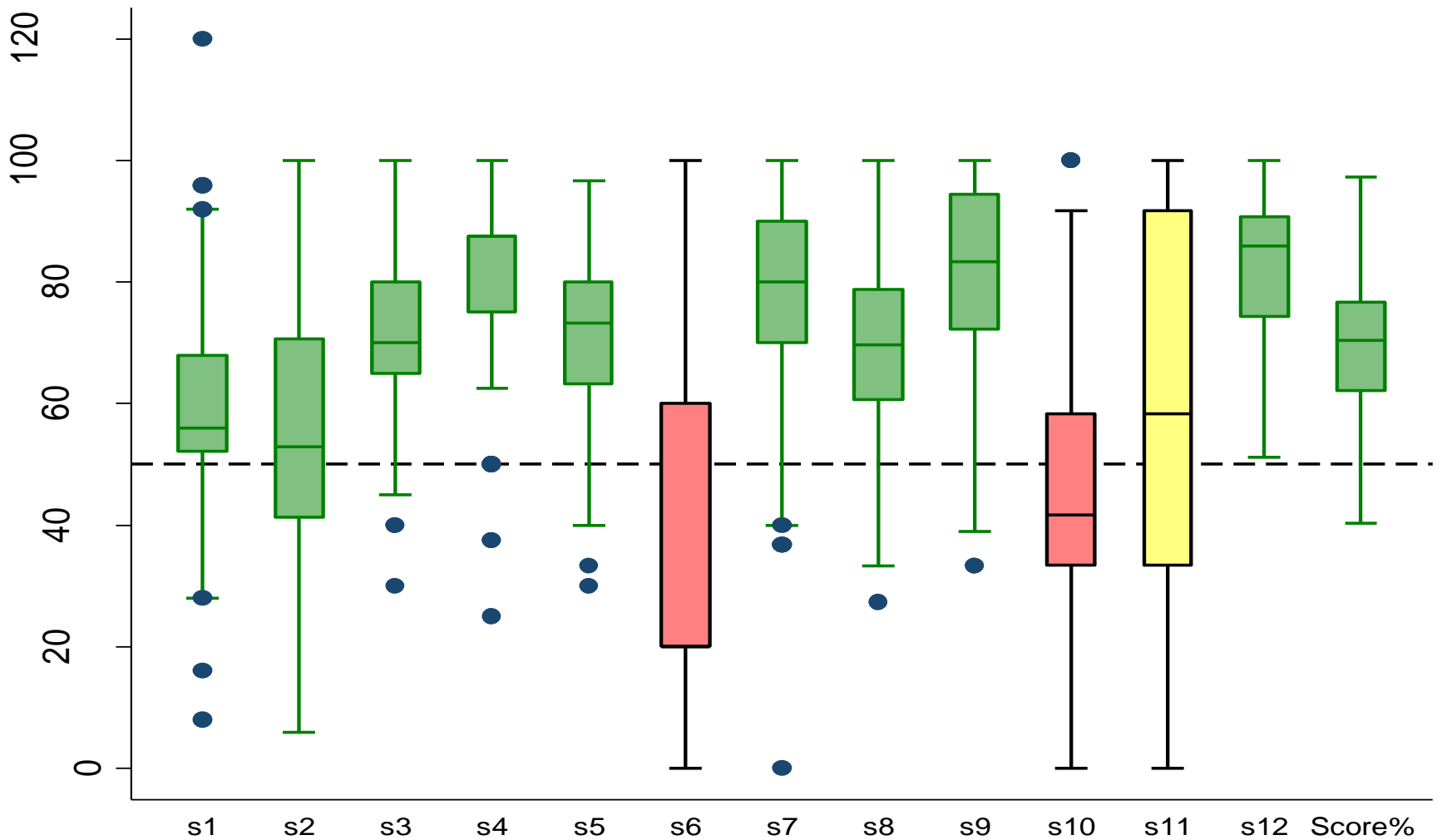


16 Countries visited
122 labs Audited

Audited Laboratories: Star Distribution (n=122)



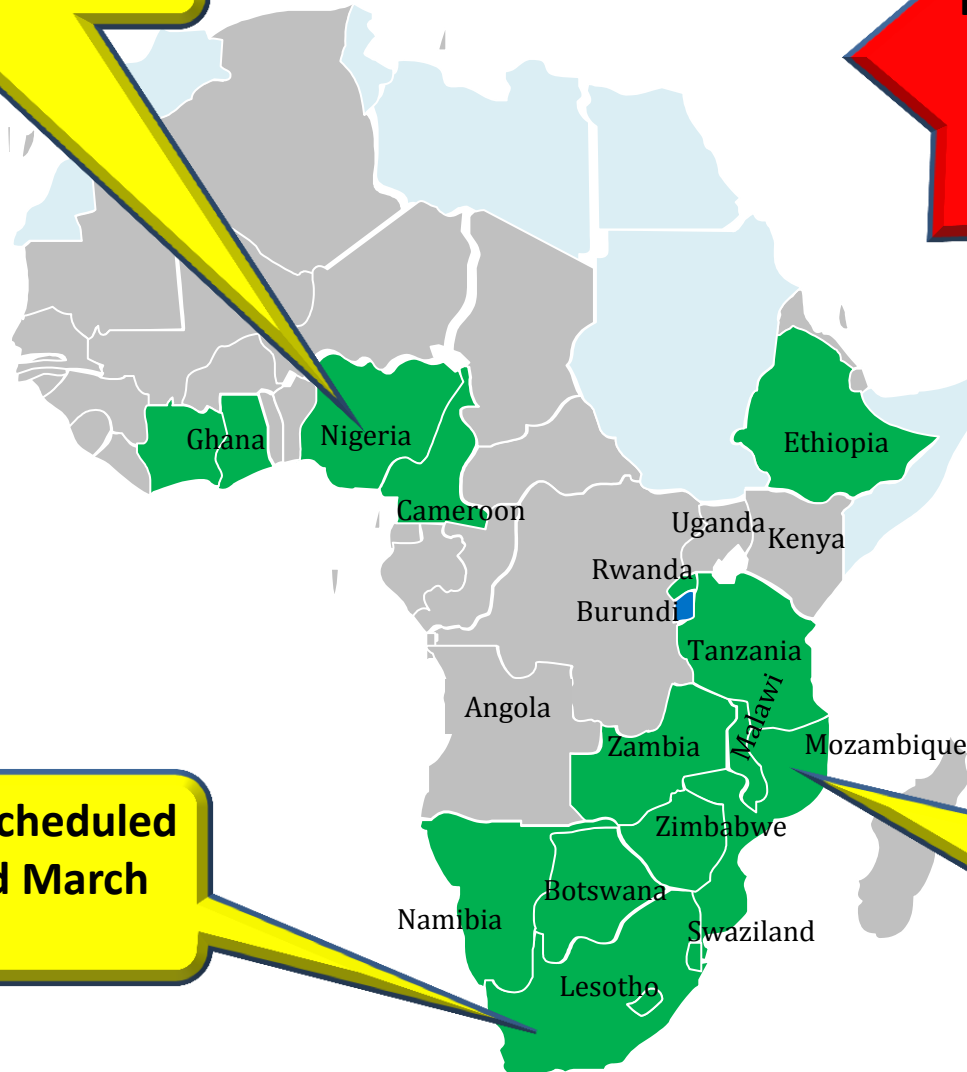
Performance of the 122 Laboratories



Progress Towards 250 Laboratories Accredited

7 Laboratories being prepared for International Accreditation

42 (34%) Labs recommended to Prepare for International Accreditation

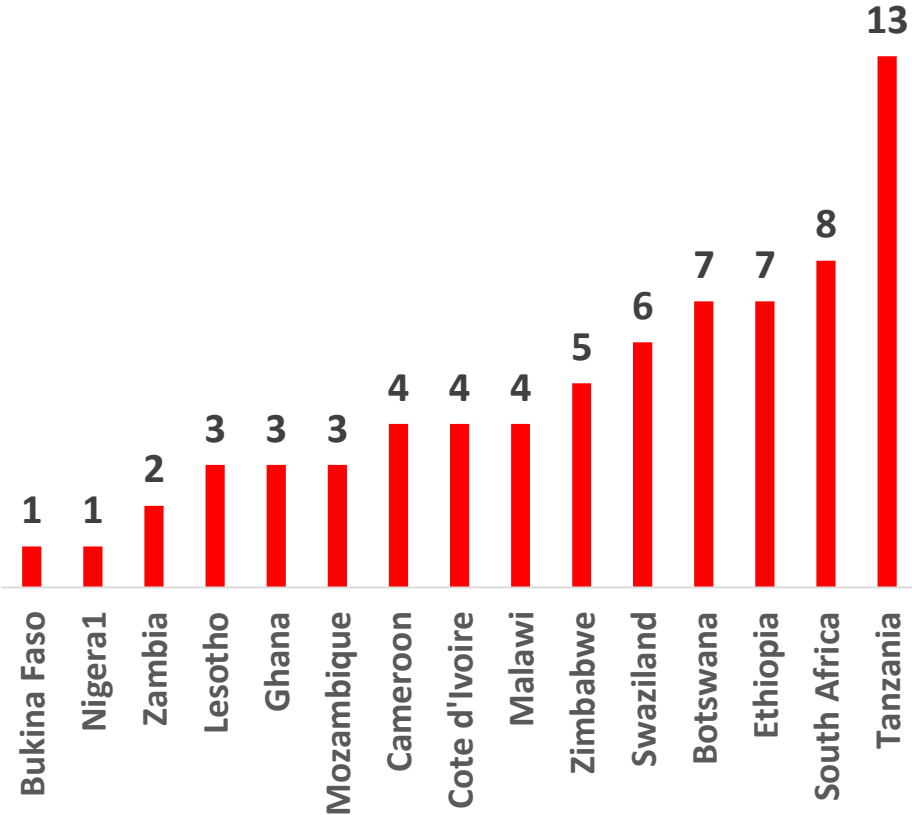
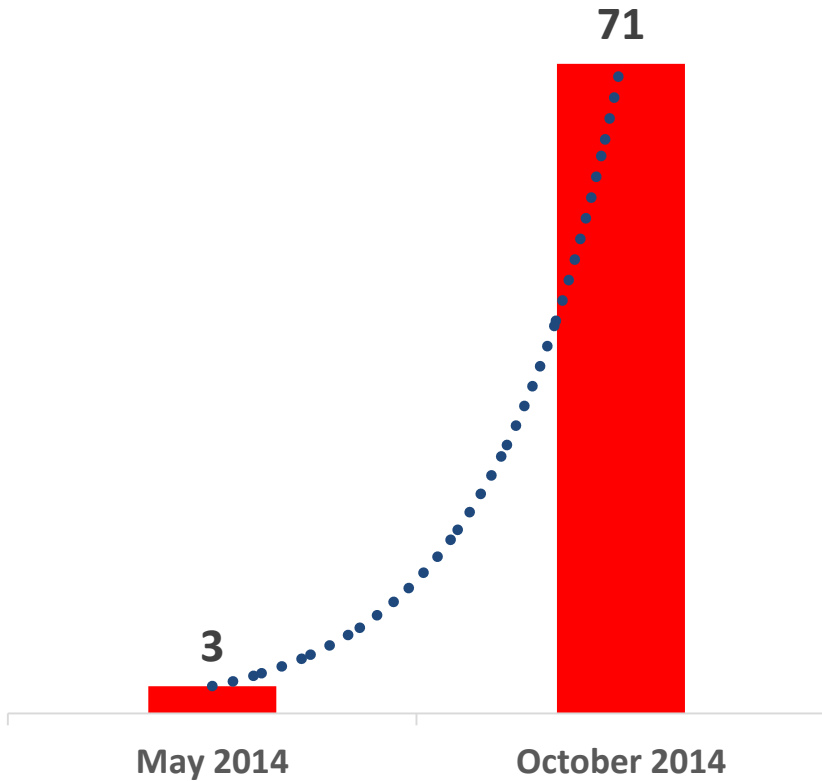


4 Pre SANAS Audits scheduled for Dec 2014 (2) and March 2015 (2)

NTRL Audited by PAC. Expect accreditation Q1 2015

Building capacity to conduct Laboratory audits

Number of certified auditors



Portuguese = 3; French = 9; English = 59

Capacity To Audit: Impact on Vision 2020 Goal



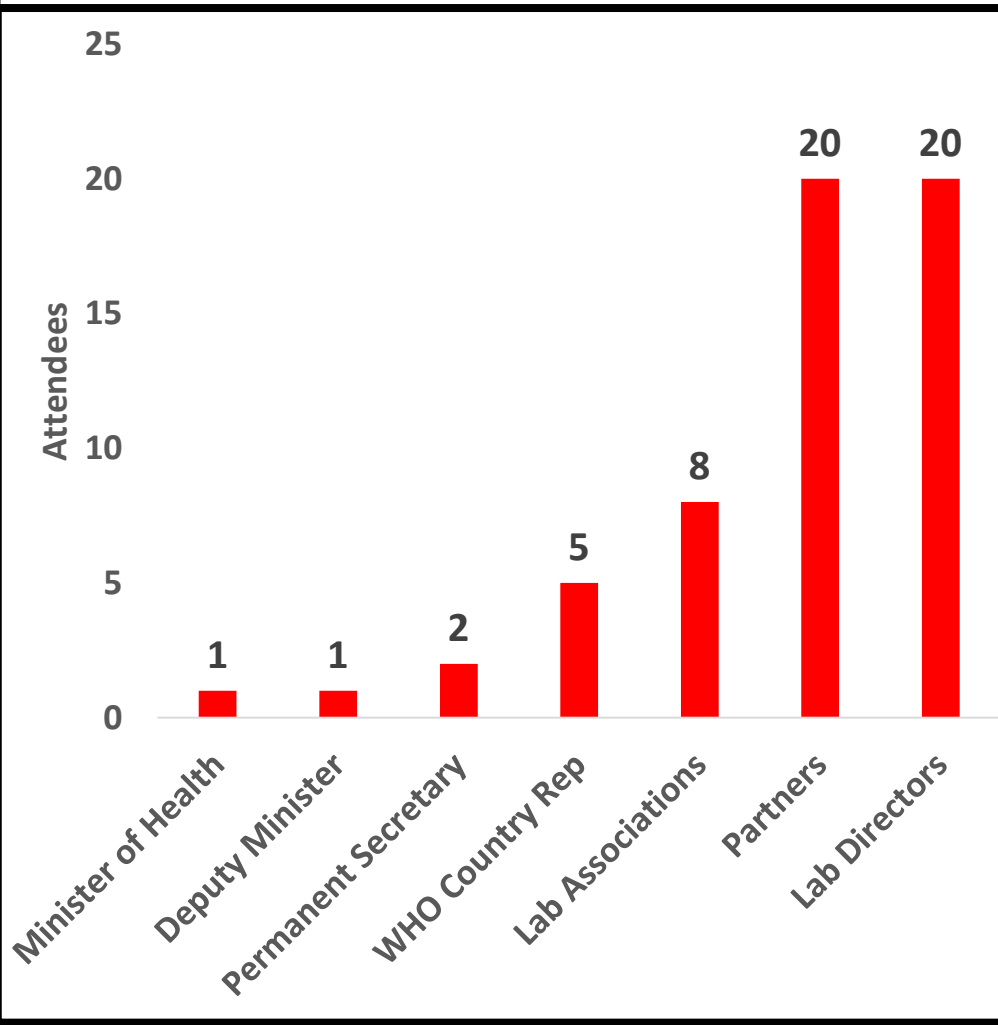
Impact of Increased Auditor Base

Framework for Engaging Other Institutions for SLIPTA Implementation

Purpose

1. In line with ASLM2020: Strategies and Vision to Strengthen Public Health Laboratory Medicine in Africa *through working collaboratively with governments, national, regional and international organizations, implementing partners, the private sector and other agencies*, this document establishes a structural role for potential partners and formalizes the modalities of their participation in supporting and implementing the WHO AFRO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA).

High Level Advocacy to build support for Laboratory System Strengthening in Africa



- Support to visit accredited labs
- Support to apply for ISO accreditation
- Commitment to support Labs for accreditation
- MOH level Implementation plans to resolve systemic issues

High Level Commitment to Support Lab System Strengthening



**14 Ministers
of Health
signed**

MINISTERIAL CALL FOR ACTION

- STRENGTHENING LABORATORY SERVICES IN AFRICA -

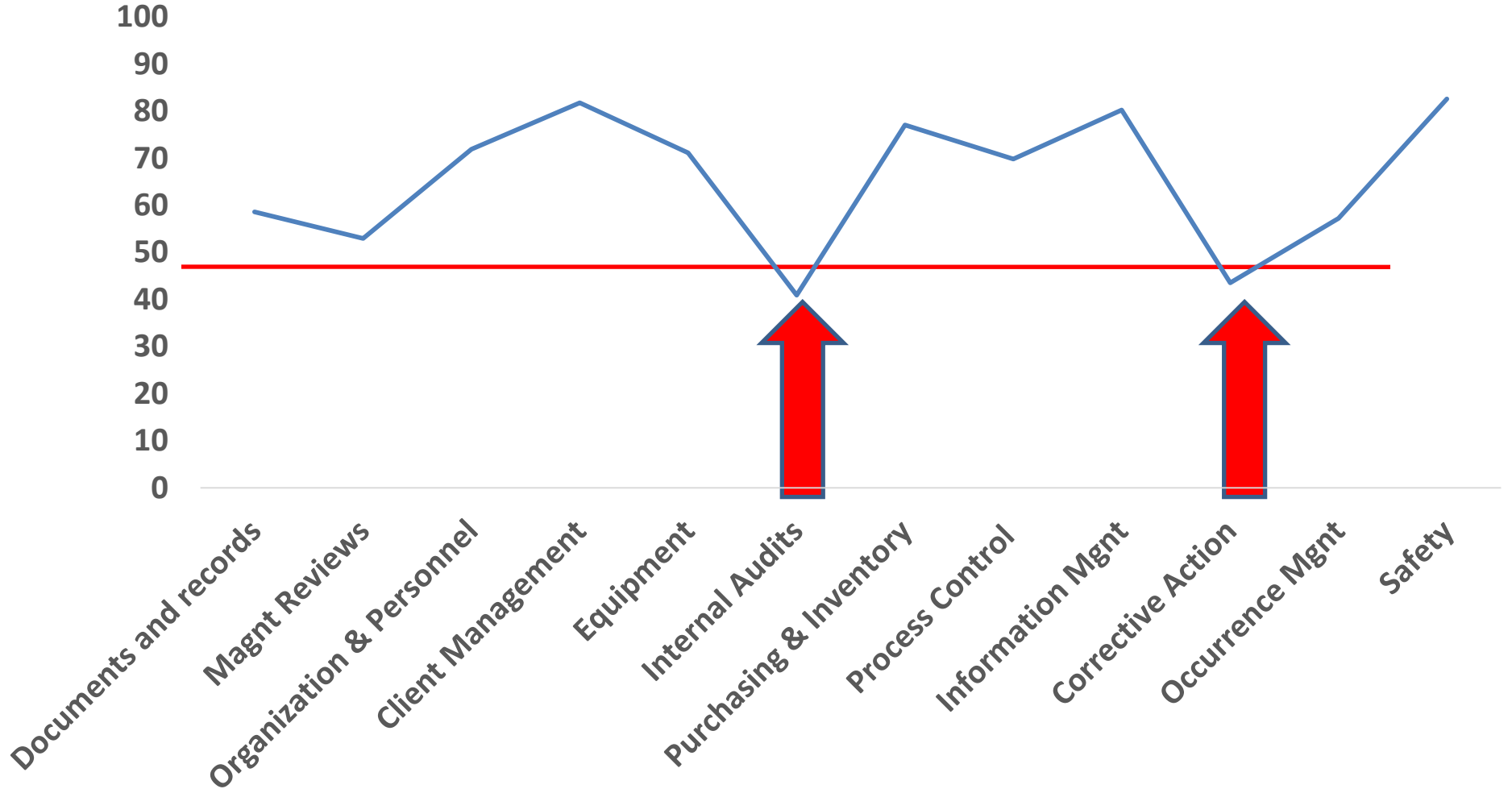
We, the undersigned Ministers of Health from African countries, attending and meeting at the 1st International Conference of the African Society for Laboratory Medicine (ASLM), Cape Town, South Africa, December 1st th, 2012 under the theme “Accurate Laboratory Diagnostics – A Pillar of Quality Health Care”

Looking Ahead

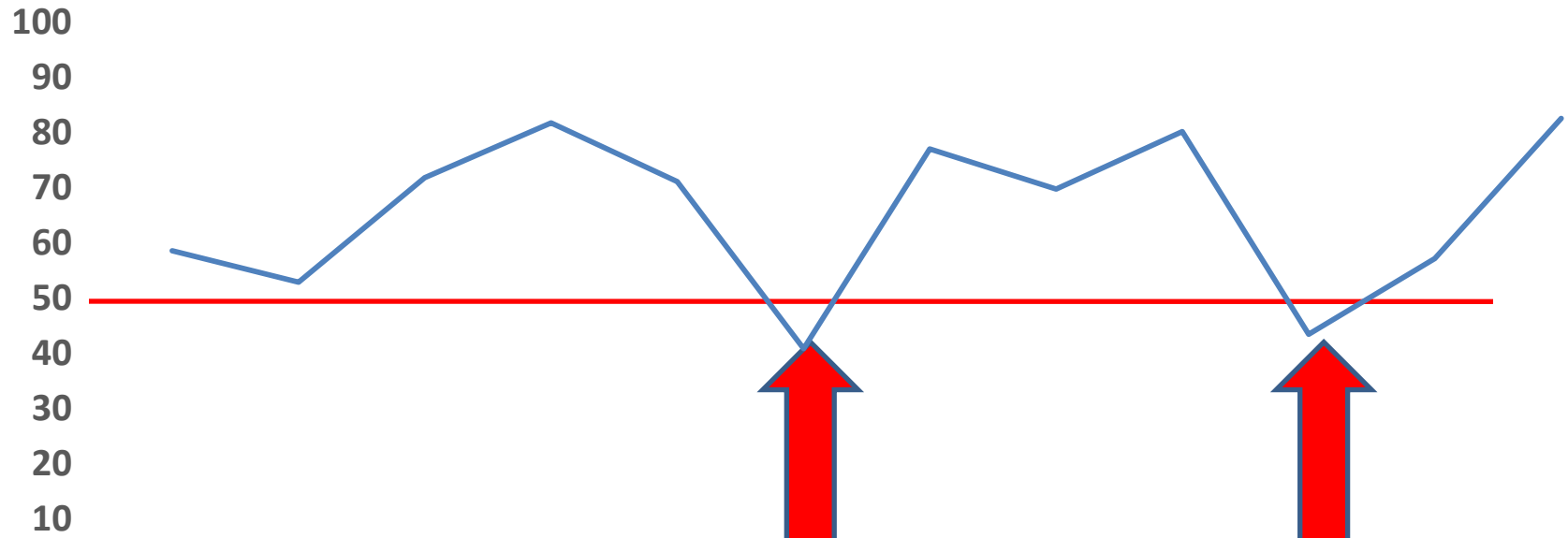


Status of QMS in Africa:
Where Are We
and
Why are We there
and
How can we move

Average performance of the 122 Laboratories in Africa



Average performance of the 122 Laboratories in Africa



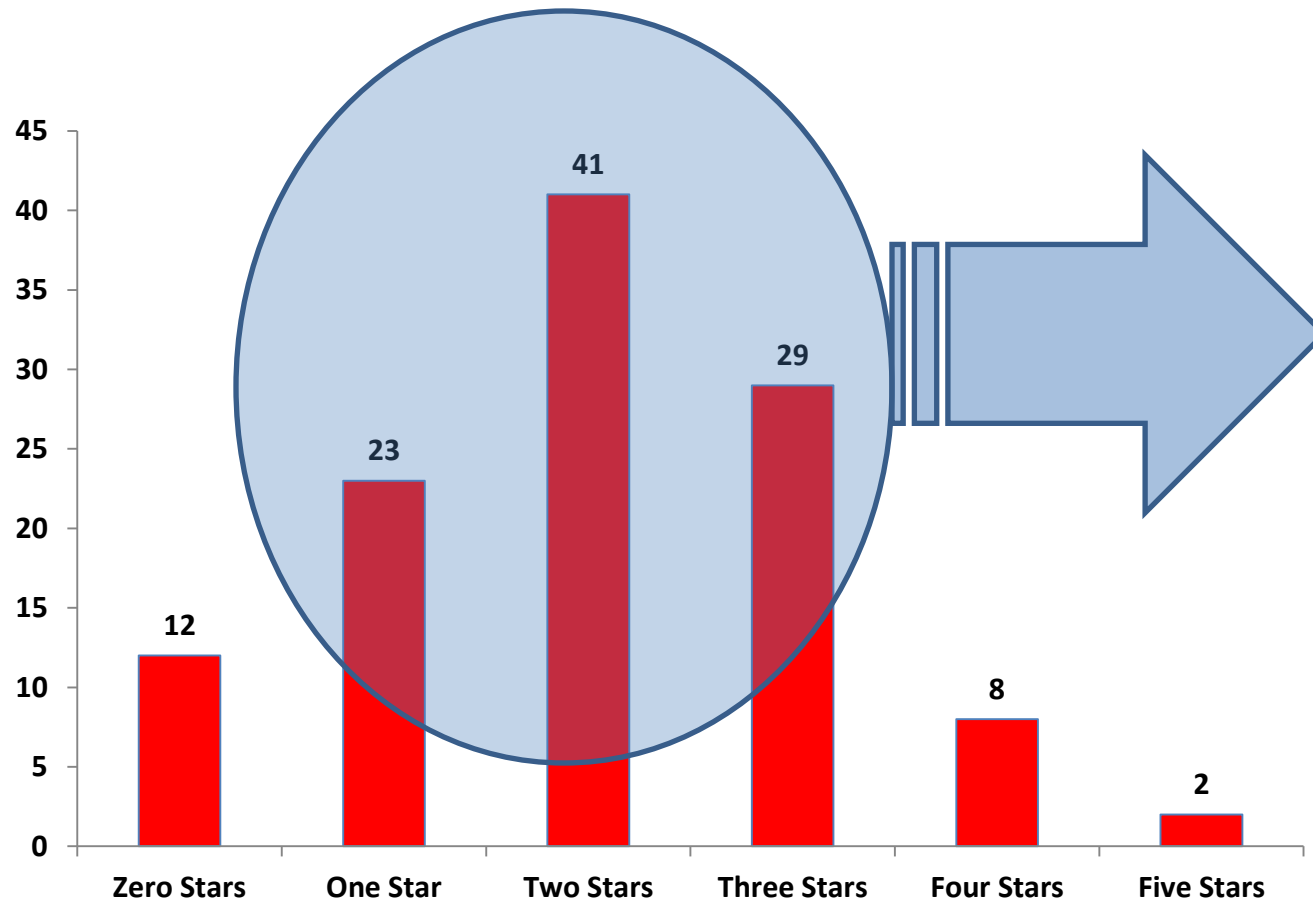
i. Review Current Training on Internal Auditing

Most programs train but do not check for competency

ii. Corrective Action and Root Cause Analysis

Most training theoretical

Barriers to Implementation of QMS Towards Accreditation



Barriers to Implementation of QMS Towards Accreditation

Infrastructure

- **Most Significant barrier (P=0001)**
 - **Size: Scope of testing**
 - **Design**

Make Available Standard Lab Plans for
different risk Levels
E.g. WHO, ASLM websites



Barriers to Implementation of QMS Towards Accreditation

Availability of a QMS

Expert (**OR: 20; p = 0.011**)

- Lab mentor
- Consultant



Training of more Lab mentors
Establish Structured Mentorship Programs
Develop local and regional Expertise

Barriers to Implementation of QMS Towards Accreditation

Staff commitment

(OR = 8.4; p = 0.013)

- *Workload to staff ratio not significant! In other words, having more staff does not necessary predict that a lab will get ≥ 3 stars*

Well defined career paths
Staff Retention Strategies
Increase Staff motivation and morale

Barriers to Implementation of QMS Towards Accreditation

**Availability of adequate
financial resources:**
(OR = 7.0; p = 0.036)



**Include Accreditation in Strategic Plans
Increase allocations for Labs
Increase involvement of the Lab in the
Budgeting Process**

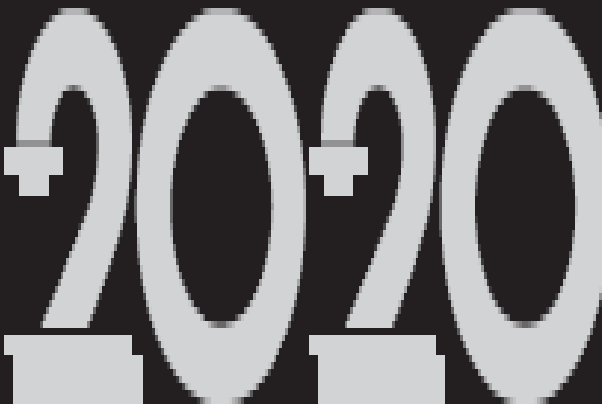
GOAL

2020 TARGETS



ASLM

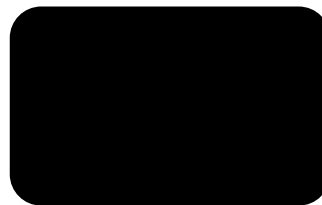
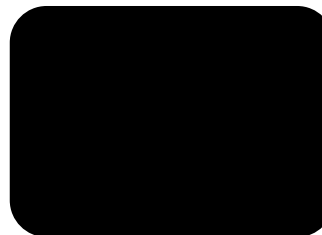
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2020



Accreditation



Acknowledgements

- ASLM
- WHO
- CDC
- Audited countries MOH and Laboratories
- SLIPTA Auditors
- Partners Supporting Laboratories