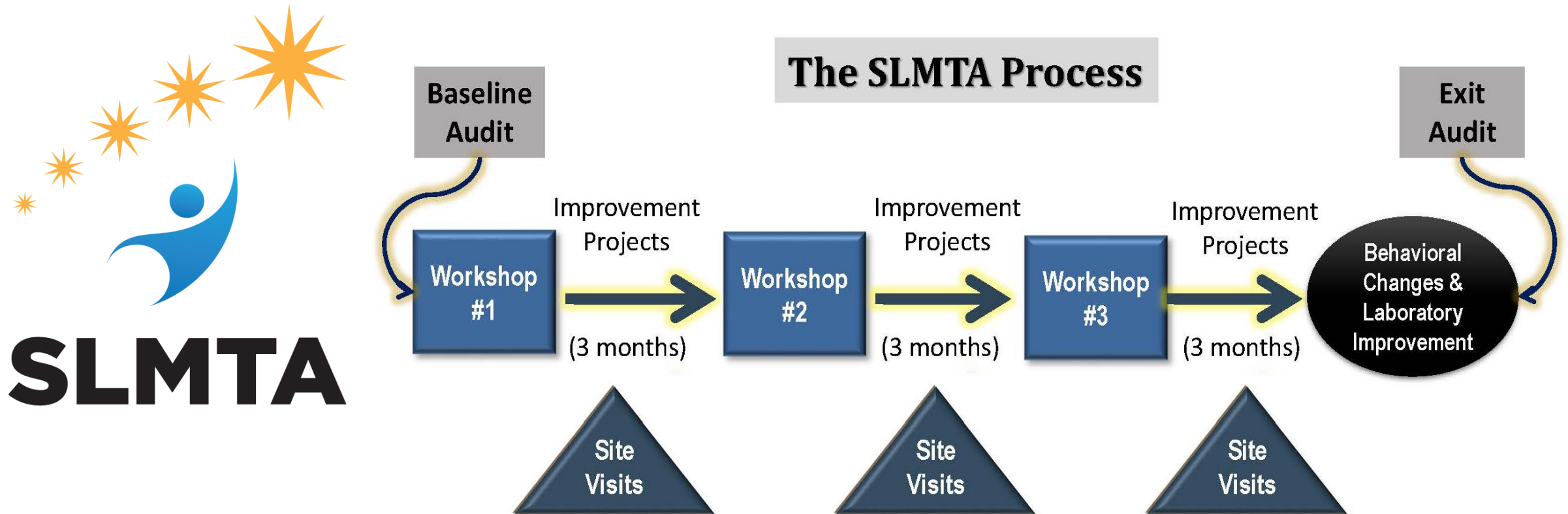


# **CRITICAL ROLE OF EFFECTIVE AUDITS IN FACILITATING ACCREDITATION READINESS**

Beatrice van der Puije, Ghana

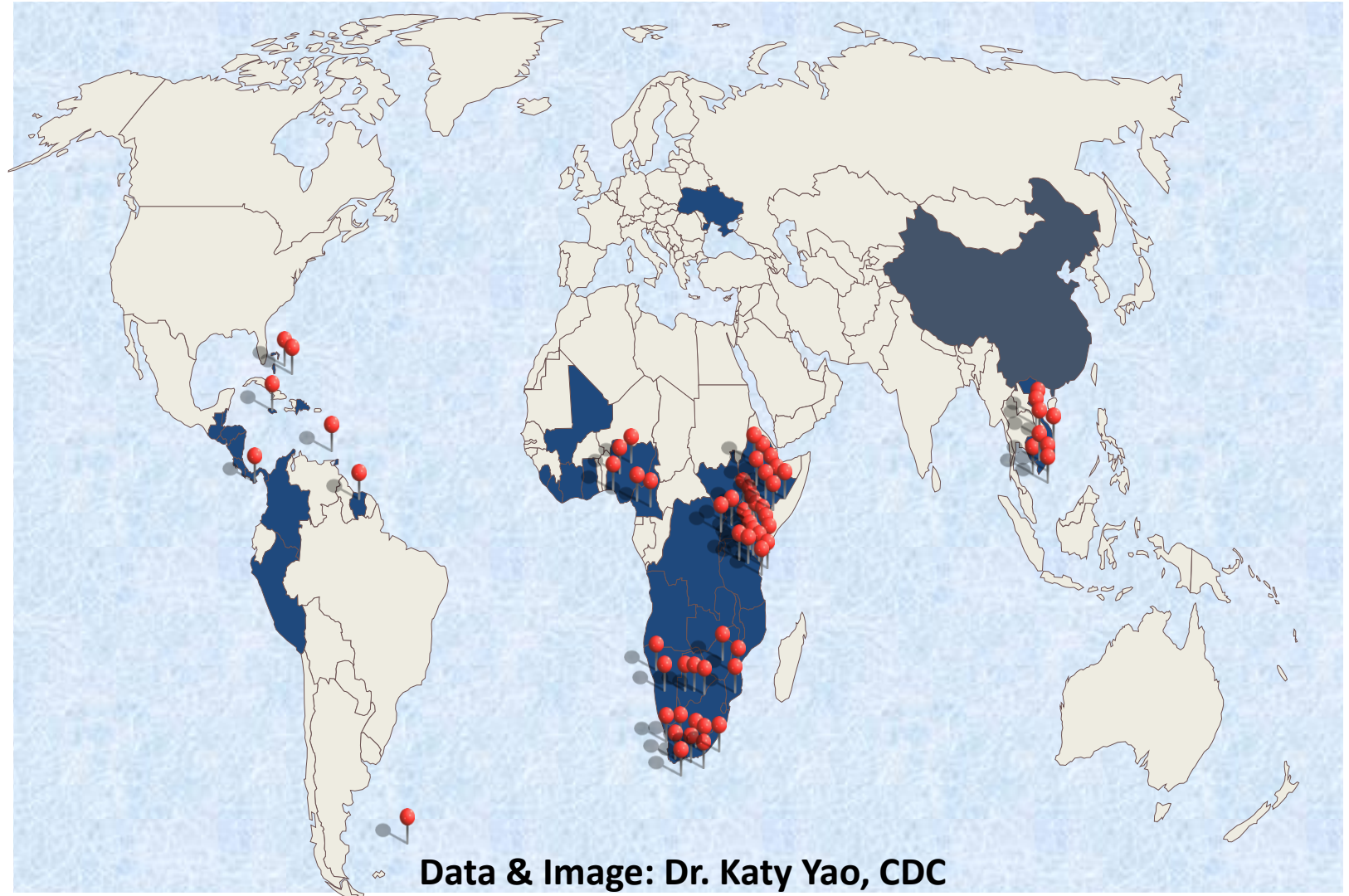
# STRENGTHENING LABORATORY MANAGEMENT TOWARD ACCREDITATION

## The revolution in LQMS implementation

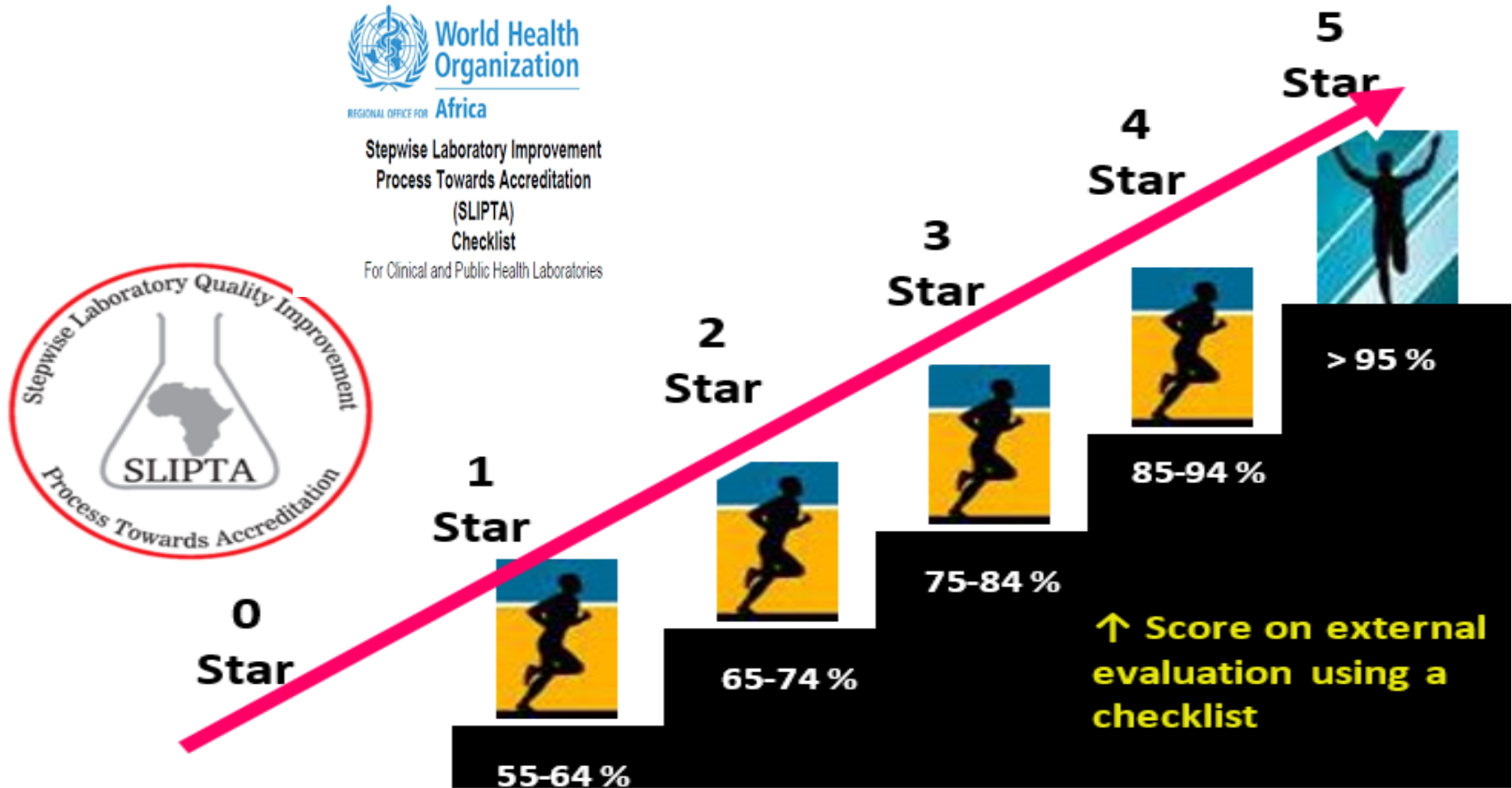


# SLMTA

- **5138** laboratory personnel trained
- **1333** laboratories enrolled
- **52** countries



# WHO-AFRO STEPWISE LABORATORY (QUALITY) IMPROVEMENT PROCESS TOWARDS ACCREDITATION (SLIPTA)



# ULTIMATE OUTCOME: **ACCREDITATION**



**92 SLMTA Laboratories  
Accredited to Date**



# WHAT DOES IT TAKE TO GET A LABORATORY ACCREDITATION READY?

- Resources
- Training/ capacity building on standards, LQMS
- Expert support & mentoring
- Commitment from management & staff
- **Strong audit program**



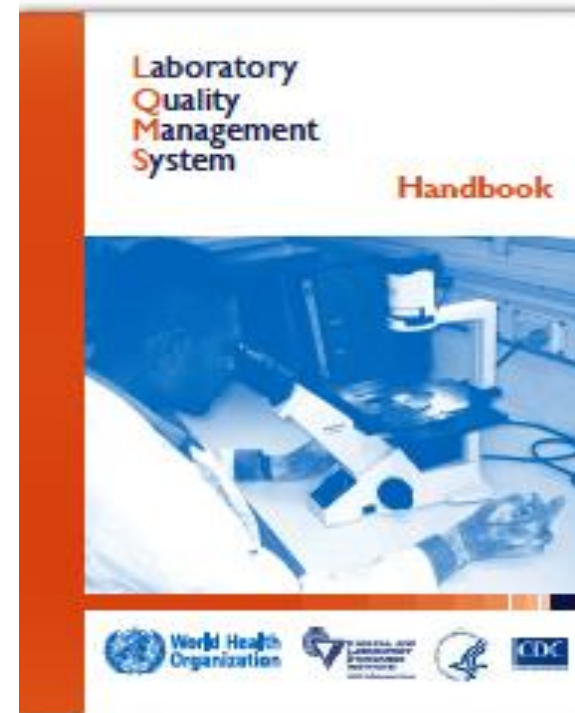
# AUDIT PROGRAMS



- Internal
- **External**

# External Audits

- Adherence to requirements (compliance to standards)
- Actual and potential areas of error and/or weakness to address
- LQMS competency
- **Verification of implementation**





# EXTERNAL AUDITS : VERIFICATION



In-House Media QC log

DATE	MEDIA AND LOT NUMBER	ORGANISM PLATED	QC PLATED DATE	QC READ DATE	QC PASSED/FAILED	INITIALS
9					Pass	MR
9					Pass	MR
9					Pass	MR
9					Pass	MR



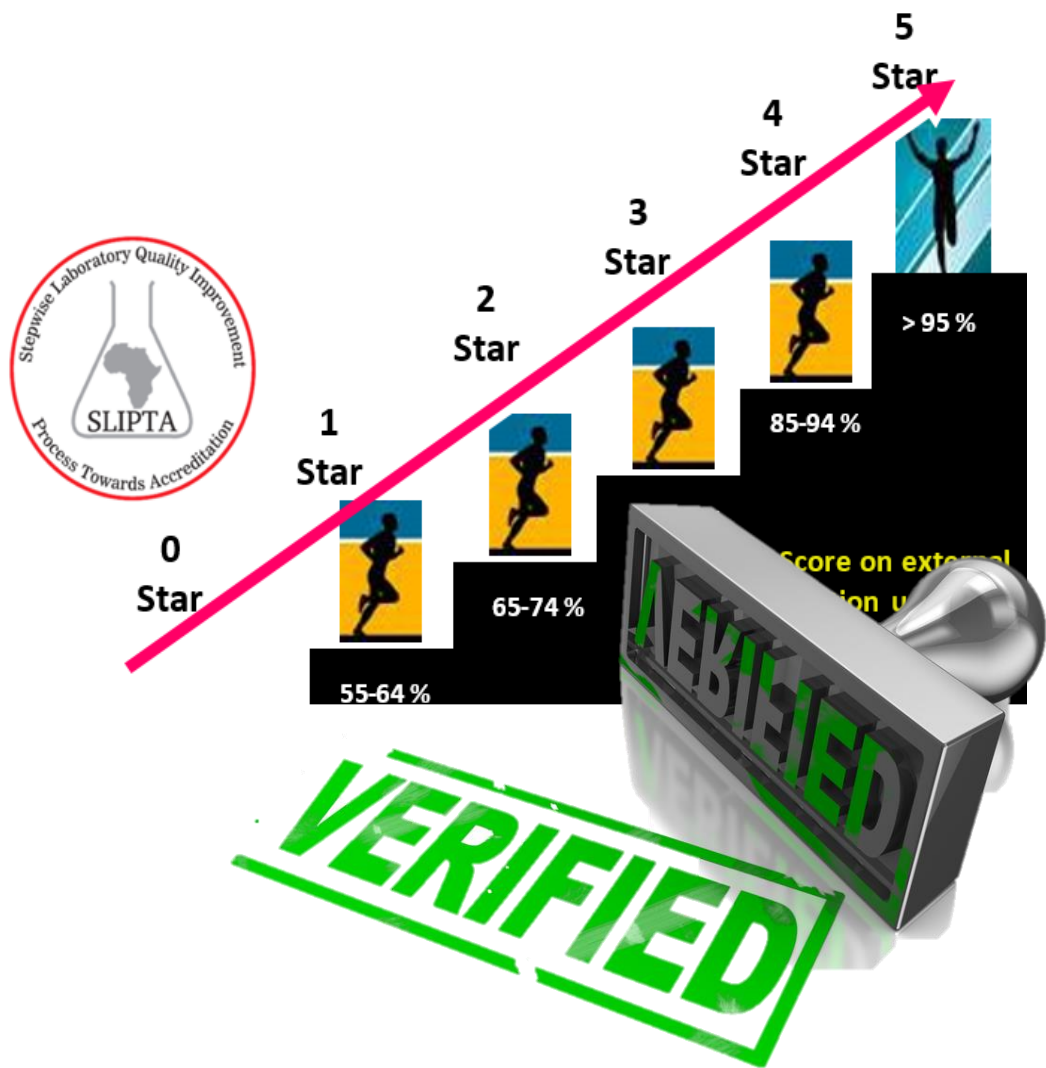
# EXTERNAL AUDITS : VERIFICATION

## ESTABLISHMENT & COMPLIANCE

- Have you implemented system as documented?
- Are you maintaining system?
- Are you complying with system?



# WHAT DO EXTERNAL AUDITS REPRESENT FOR LABS



=



Laboratory



# WHAT DO EXTERNAL AUDITS REPRESENT FOR LABS



**We've got it!**

**We know what we are  
doing!**

**We CAN get Accredited!**



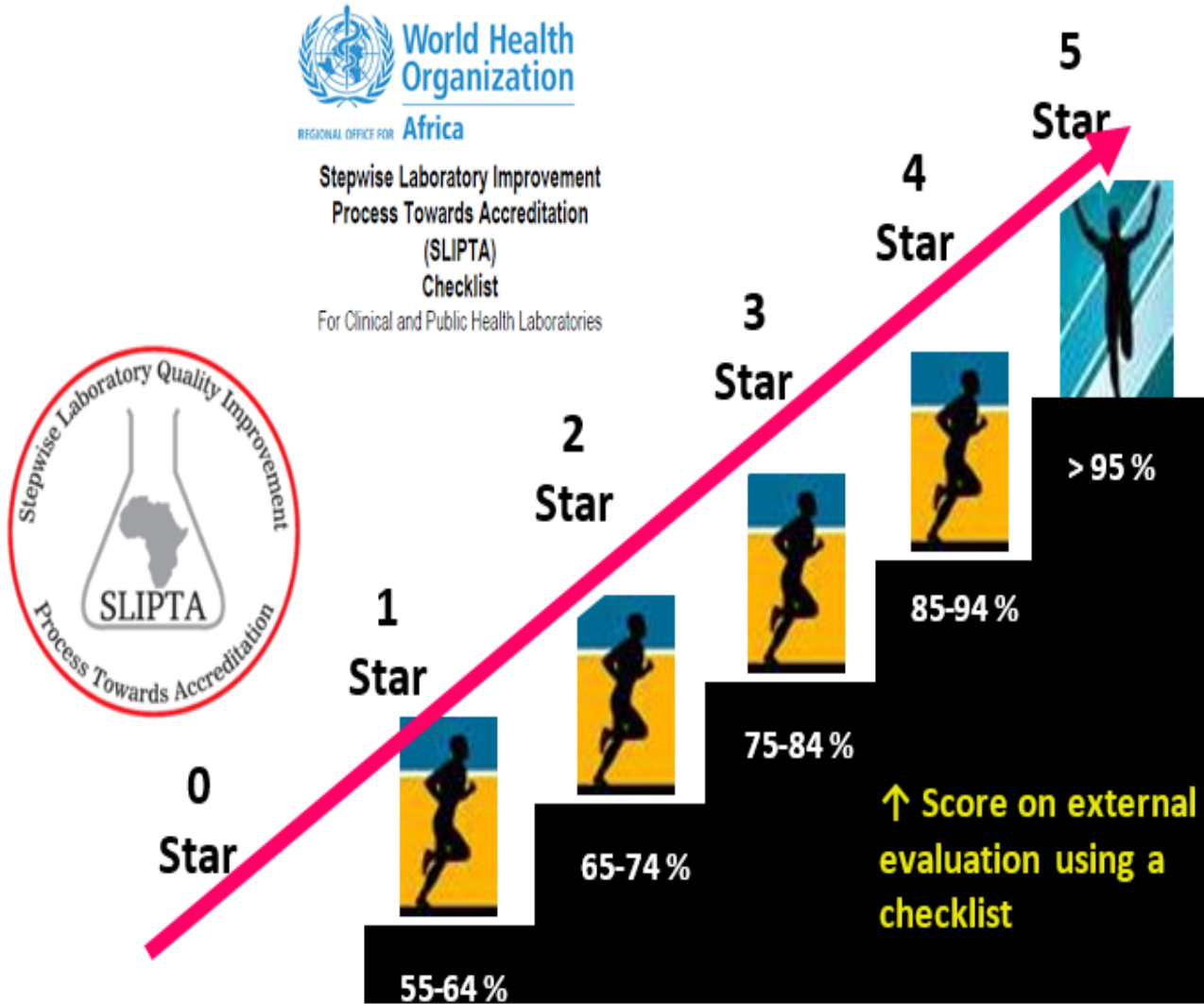
# KEY COMPONENTS TO ENSURE AUDITS DELIVER



- **Audit Process**
- **Tools**
- **Auditors**



# SLIPTA AUDITS

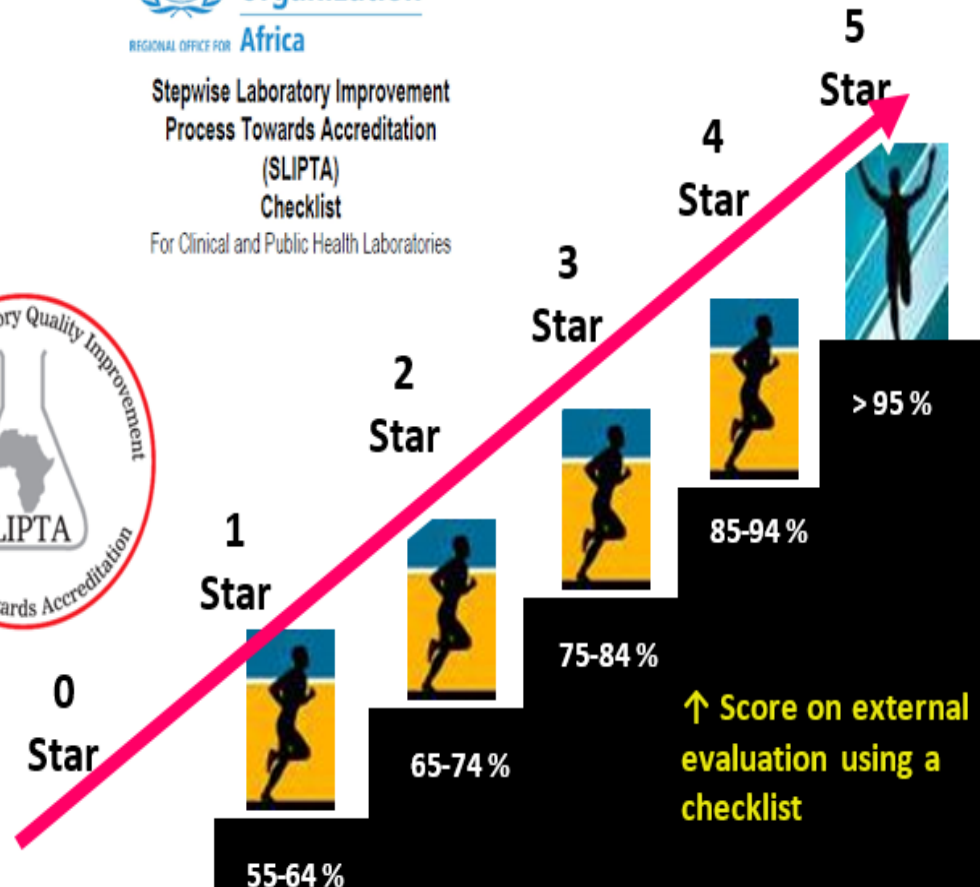


- Ultimate validation for many SLMTA Labs
- Benchmark for labs assessing accreditation readiness
- Deciding factor for moving forward to seek accreditation.

# SLIPTA AUDIT OBJECTIVES



Stepwise Laboratory Improvement  
Process Towards Accreditation  
(SLIPTA)  
Checklist  
For Clinical and Public Health Laboratories



- Evaluate and recognize the progress of QMS implementation & recommend for ISO accreditation

**TARGET: 250 accredited Labs by 2020**

- Provide feedback and guidance to address the requirements of QMS based on ISO 15189:2012 Standards
- Mentor SLIPTA Auditor trainees for certification purpose

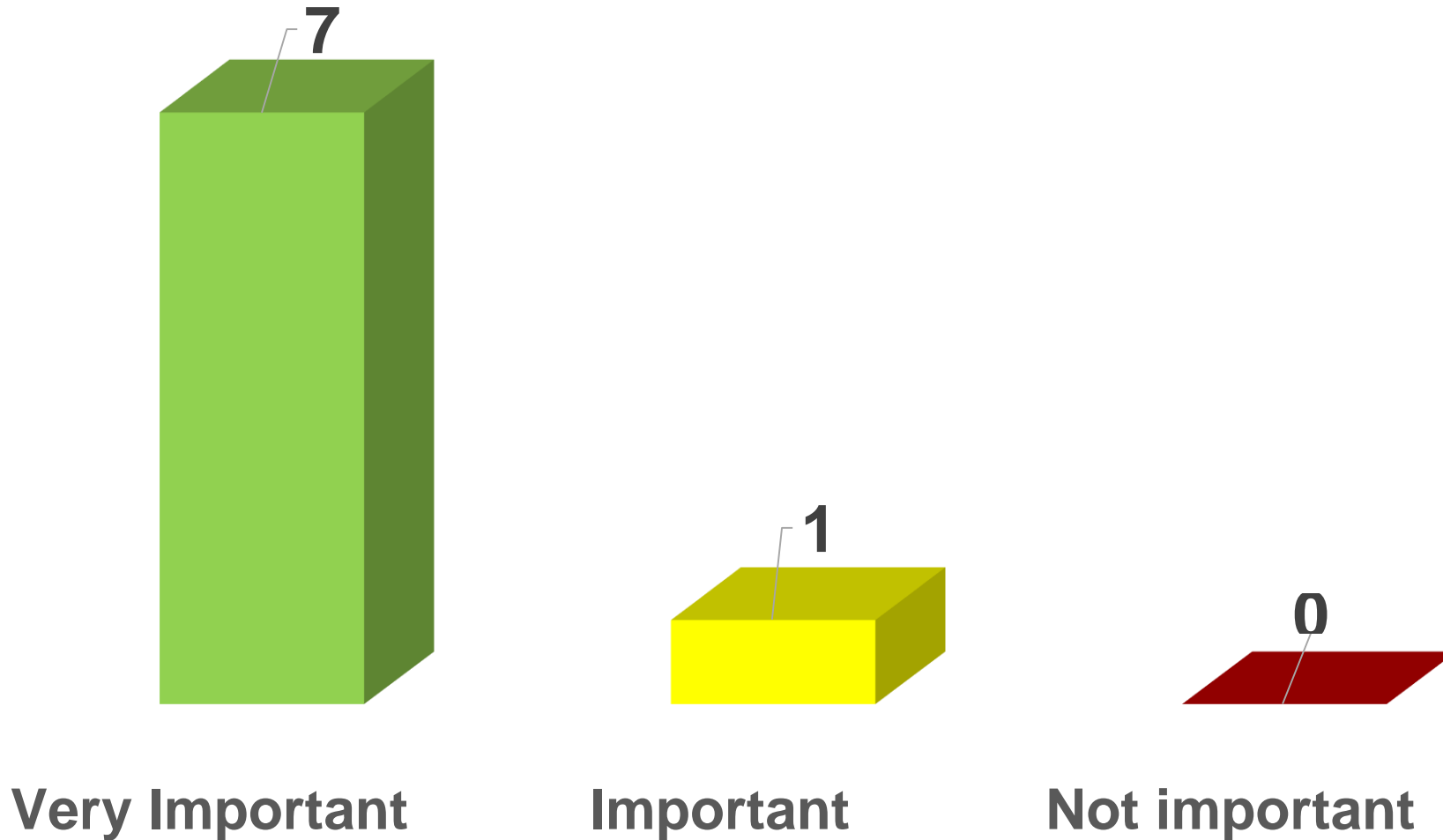
# ARE SLIPTA AUDITS DELIVERING?

Surveyed 8 Laboratories who have gone through SLMTA program, SLIPTA process and have either:

- Attained international accreditation
- Undergone assessment pre-check
- Have had more than one SLIPTA Audit



# ① How important were SLIPTA Audits in your preparation towards accreditation?

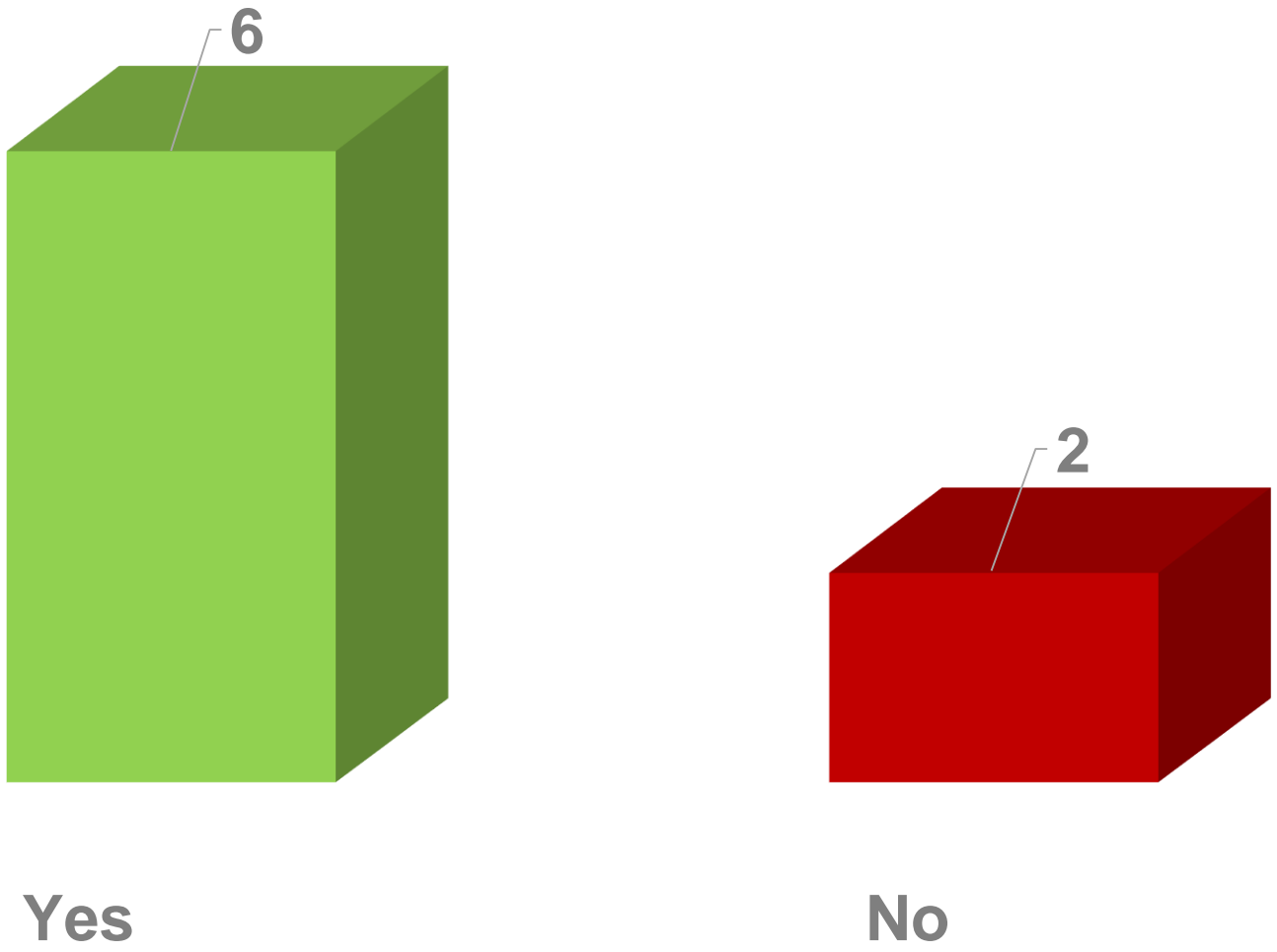


# ① **How important were SLIPTA Audits in your preparation towards accreditation?**

- Ensuring system is ISO compliant
- Independent assessment of Labs LQMS implementation process
- Check on knowledge and capacity of lab management and staff: do we know what we are doing?
- Guidance on LQMS implementation process: are we doing it right?

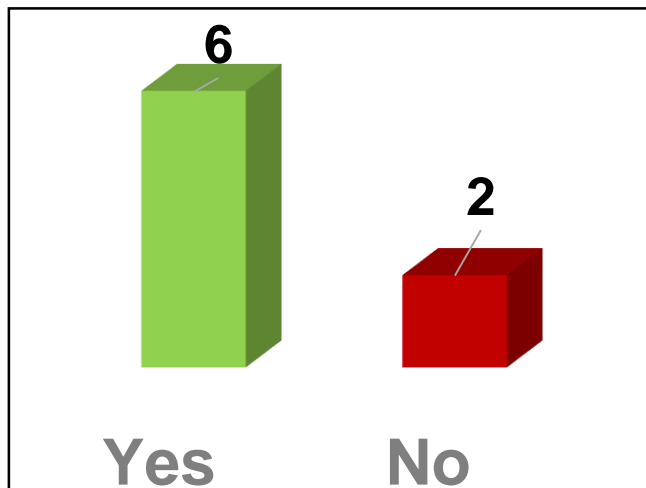


# 2 Were outcomes of SLIPTA Audits THE deciding factor in decision to seek accreditation?



2

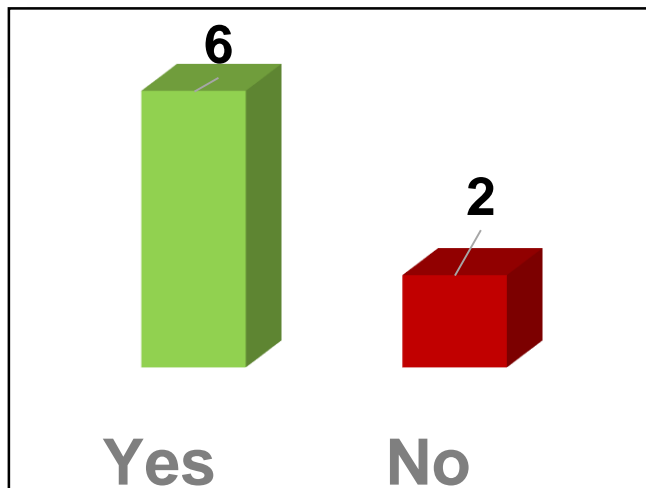
## Were outcomes of SLIPTA Audits THE deciding factor in decision to seek accreditation?



- Deciding factor for upper management support.
- Gave management and staff of Lab approval and confidence to move forward with process

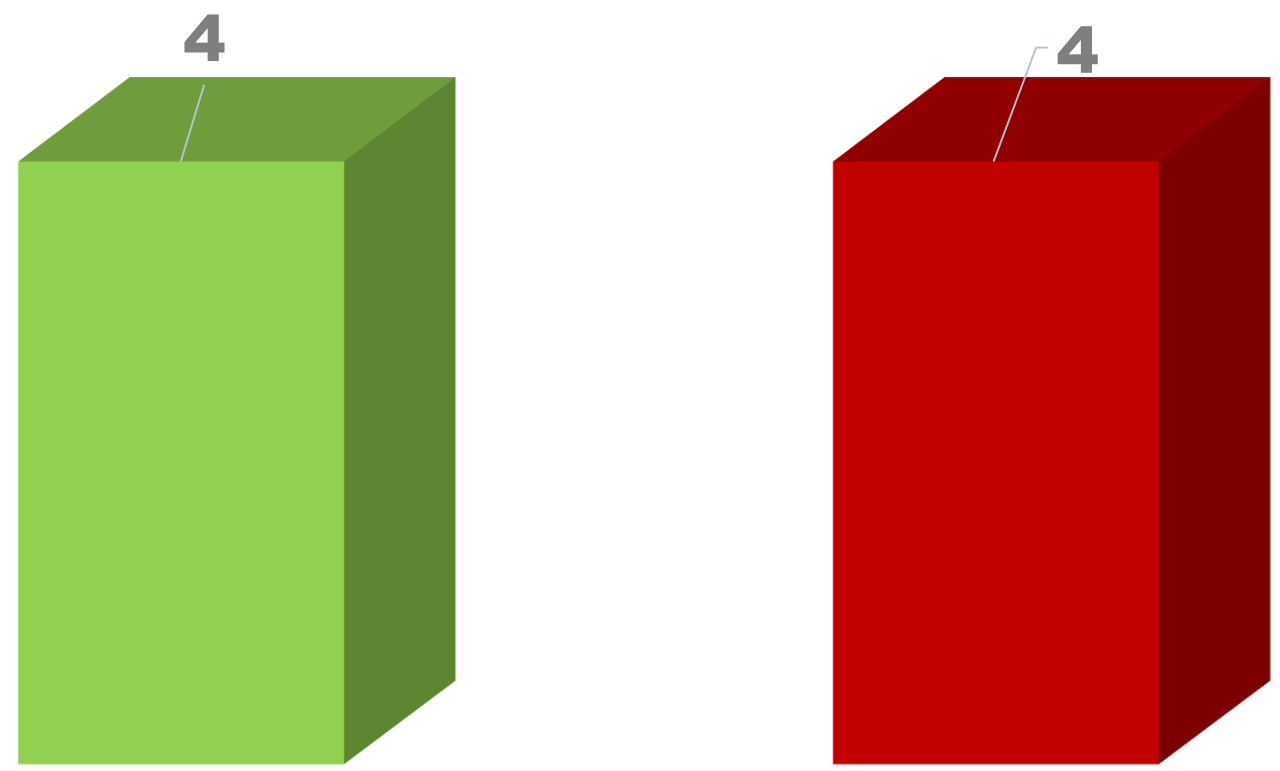
2

## Were outcomes of SLIPTA Audits THE deciding factor in decision to seek accreditation?



- Already committed to accreditation
- Proceeded despite outcomes from SLIPTA Audit

# 3 Had SLIPTA Audits been effective at assessing readiness for accreditation?



Yes

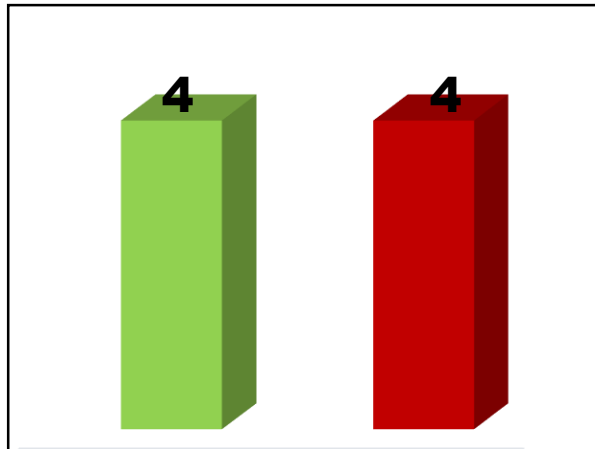
No

3

## Had SLIPTA Audits been effective at assessing readiness for accreditation?

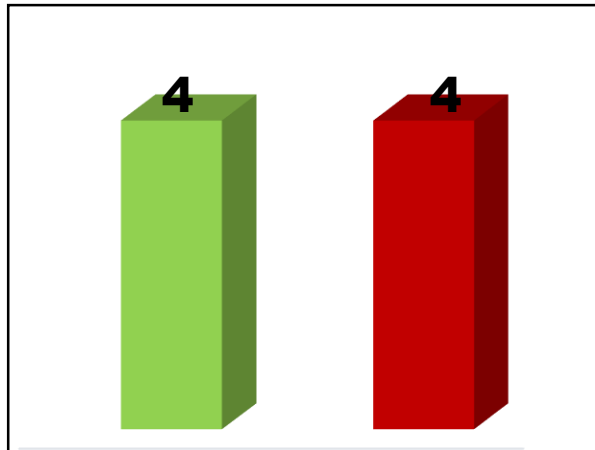


- Had accurately determined accreditation preparedness
- Addressing findings from SLIPTA assessment alone was enough to have system accreditation ready.





### 3 Had SLIPTA Audits been effective at assessing readiness for accreditation?



- Under-estimated accreditation readiness
- Over-estimated accreditation readiness
- Did not address some crucial elements for accreditation

# 4

## FEEDBACK FROM LABS: SLIPTA PROCESS



**Stepwise Laboratory Improvement  
Process Towards Accreditation  
(SLIPTA)  
Checklist**

For Clinical and Public Health Laboratories

- More time (days) to conduct Audits
- Audit team contain technical expertise for each discipline.
- Guidance/technical support for labs moving forward with accreditation process

# FEEDBACK FROM LABS: CHECKLIST



**Stepwise Laboratory Improvement  
Process Towards Accreditation  
(SLIPTA)  
Checklist**

For Clinical and Public Health Laboratories

- Checklist very documentation biased.
- Checklist does not adequately address discipline specific requirements

# FEEDBACK FROM LABS: SLIPTA AUDITORS



**Stepwise Laboratory Improvement  
Process Towards Accreditation  
(SLIPTA)  
Checklist**  
For Clinical and Public Health Laboratories

- Standardized audit practice.
- Standardized interpretation of standard
- Auditors experienced in LQMS
- Ethics and professionalism

- SLIPTA Audits are vital bridge between LQMS implementation and accreditation.
- Provide **VALIDATION** and **CONFIDENCE** to decide to move forward with accreditation process



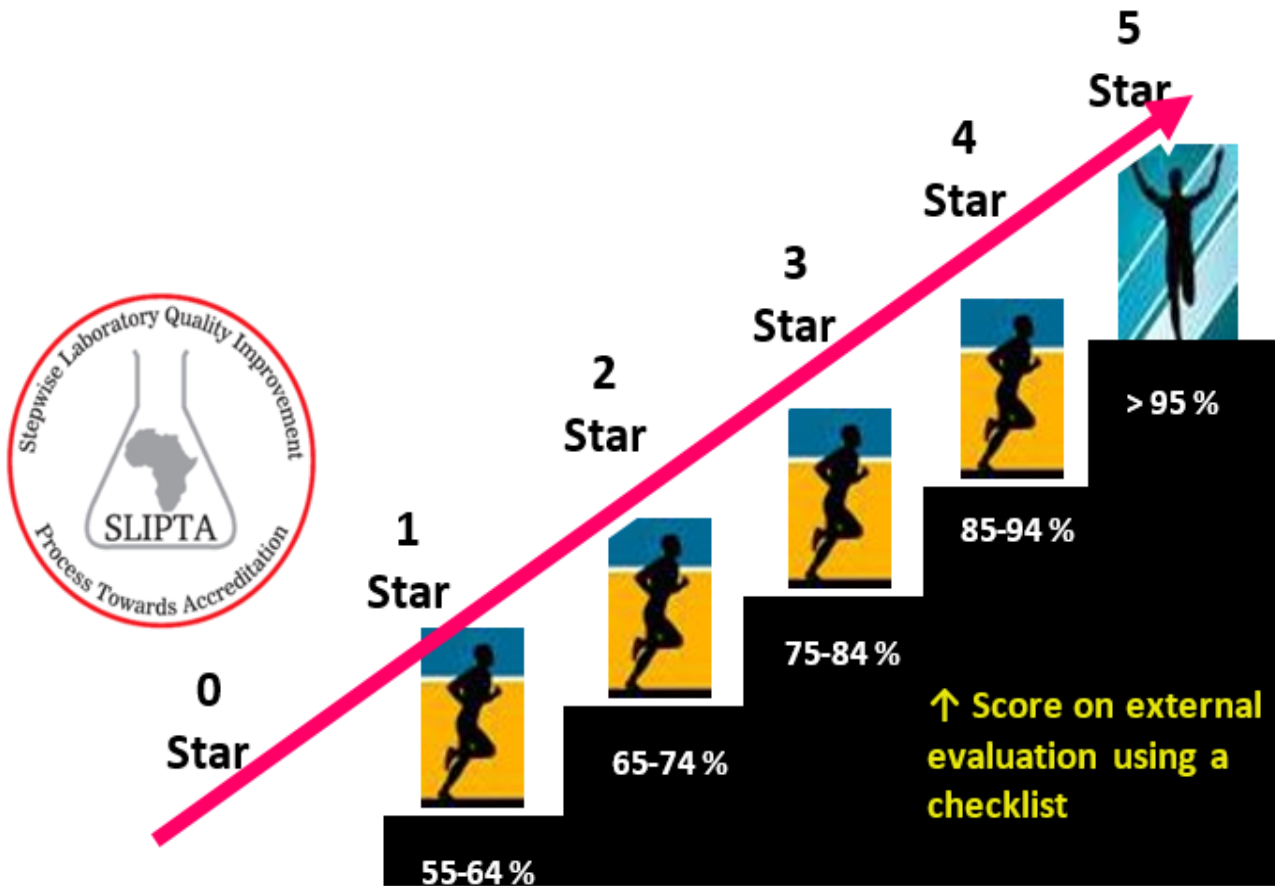
Stepwise Laboratory Improvement  
Process Towards Accreditation  
(SLIPTA)  
Checklist

For Clinical and Public Health Laboratories





- Need to review and where necessary address issues highlighted to ensure improved more effective audits that deliver on mandate.



**Stepwise Laboratory Improvement  
Process Towards Accreditation  
(SLIPTA)  
Checklist**  
For Clinical and Public Health Laboratories



- Increase in length of time audits are conducted.  
**(More time for verification, guidance & other support)**
- Addition of appendix to checklist that addresses discipline specific requirements
- Technical advice & guidance to labs moving forward to seek accreditation.



- Standardization of SLIPTA audit practice (e.g. guideline document for auditors)
- Auditor selection and certification criteria more stringently applied
- CPD & Competency program for auditors

# GUIDANCE IS ALREADY AVAILABLE

## SLMTA SYMPOSIUM 2016

Bridging the SLIPTA stars and ISO Accreditation



Published responses from discussion

<https://www.slmta.org/resources>

# EXAMPLE: CRESAC AUDITOR COMPETENCY PROGRAM



**How do you ensure competency of your auditors? What measurements are collected and analyzed?**

- 1. Systematic evaluation after each mission**
  - Review of assessment reports (50 points)
  - Consideration of complaints or observations related to the assessor's behavior and deemed to be well cohesive (20 points)
  - Professional and ethical awareness (30 points)

# EXAMPLE: CRESAC AUDITOR COMPETENCY PROGRAM



## 2. Evaluation every 3 years

- Participation in capacity building workshops for assessors organized by CRESAC once a year (40 points)
- Systematic assessment at each engagement (60 points)

## 3. Results

- Maintenance 70%;
- Warning (between 60 and 70%);
- Removal from the list <60%



# WHAT WE WANT TO ACHIEVE

**Improved  
SLIPTA Audits**



**Stepwise Laboratory Improvement  
Process Towards Accreditation  
(SLIPTA)  
Checklist**  
For Clinical and Public Health Laboratories



**MORE  
ACCREDITED  
LABS**



**Target : 250  
Accredited  
Labs by 2020**



**QUALITY  
LABORATORY &  
HEALTHCARE  
SERVICES FOR  
ALL**



**THANK YOU**