



# PEPFAR

U.S. President's Emergency Plan for AIDS Relief

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## The Impact of the Strengthening Laboratory Management Toward Accreditation (SLMTA) Training Program on Improving Laboratory Quality Systems in the Caribbean Region

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**The Bahamas**

North  
Atlantic  
Ocean

**Jamaica**

**St. Kitts & Nevis Antigua & Barbuda**

**Belize**

**Dominica**

**St. Lucia**

**St. Vincent & the Grenadines Barbados**

**Grenada**

**Trinidad & Tobago**

**Suriname**

Caribbean Sea

of Mexico

Bank

ICO

Belize City

HONDURAS

NICARAGUA

COSTA RICA

PANAMA

600,000

UNITED STATES

THE BAHAMAS

Freeport

Grand Abaco

Eleuthera

Nassau

Car Island

San Salvador

Run Cay

Long Island

Samana Cay

Crooked Island

Moyigua

Schiffel Island

Great Inagua

Grand Turk

Turks and Caicos Islands (U.K.)

Grand Cayman

Andros Island

Guinches Cay (THE BAHAMAS)

Cay Lobos (THE BAHAMAS)

RAGGED ISLAND RANGE (THE BAHAMAS)

Great Exuma

City Sal Bank (THE BAHAMAS)

Key West

Key West

Key West

Key West

Key West

Key West

Key West

Key West

Key West

Key West

Key West

Key West

Key West

Key West

Havana

Pinar del Rio

Matanzas

Santa Clara

Ciego de Avila

Camaguey

Holguin

Manzanillo

Santiago de Cuba

Granma

U.S. Naval Base Guantanamo Bay

Montego Bay

Kingston

Nassau Island (U.S.)

George Town

Cayman Islands (U.K.)

SWAN ISLANDS (HONDURAS)

Isle of the Pines (CUBA)

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Port-au-Prince

Cap-Haitien

Santiago

Santo Domingo

San Juan

Puerto Rico (U.S.)

St. Croix

Basseterre

ST. KITTS AND NEVIS

Plymouth

Montserrat (U.K.)

Guadeloupe (FRANCE)

Marie-Galante

DOMINICA

Roseau

Martinique (FRANCE)

Fort-de-France

Castries

ST. LUCIA

Kingstown

THE GRENADINES

St. George's

GRENADA

Tobago

TRINIDAD AND TOBAGO

Port-of-Spain

Colonia

Maracaibo

Maturin

San Fernando

Ciudad Bolivar

Ciudad Guayana

**St. Vincent & the Grenadines**

**Grenada**

**Trinidad & Tobago**

**Suriname**

VENEZUELA

ORIENTAL

GUYANA

600,000



# Background



- CARICOM region has 15 countries.
  - Population sizes range from 50,000 (St. Kitts & Nevis) up to 2.8 million (Jamaica)
- Small island states; heavily dependent on tourism; high level of mobility; and fragile economies
- Estimated 250,000 People Living with HIV/AIDS (PLHIV)
- Adult HIV prevalence of 1% [0.9% -1.1%]. Highest known HIV prevalence rates are among MSM and female sex workers. Decline in new infections from 22,000 (2001) to 13,000 (2011)
- Slow rate of Laboratory Accreditation. In 2009 only 3 government owned Medical laboratories across the region Accredited





# Methodology





- Five national reference labs from four (4) countries
- Lab Mentors assigned to guide trainees on their improvement projects and to assist in development of the QMS
- Mentor visits were from 1–3 weeks depending on stage of implementation
- Audits conducted at baseline, 6 months, exit (12 months) and post-SLMTA (18 months) using the SLIPTA checklist, to measure implementation changes
- At the end of each audit a comprehensive implementation plan was developed to address gaps
- Data collected included scores in each QSE, number of non conformances, SOPs produced, overall improvement.



# Caribbean Implementation model



<b>BASELINE</b>	<b>Month 1-2</b>	<b>Baseline Audit (Gap Analysis)</b>	<b>Quality System Implementation plan development</b>	
	<b>Month 3</b>	<b>Initiation of Mentorship</b>		
	<b>Month 3</b>	<b>1<sup>st</sup> SLMTA workshop</b>		
	<b>Months 3-6</b>	<b>Monthly Mentor visits</b>		
	<b>Month 6</b>	<b>2<sup>nd</sup> SLMTA workshop</b>		
<b>IMPLEMENTATION</b>	<b>Month 6-9</b>	<b>Improvement projects</b>	<b>Monthly Mentor visits</b>	
		<b>6 month lab mid-term audit</b>		
	<b>Month 9</b>	<b>3<sup>rd</sup> SLMTA Workshop</b>		
	<b>Months 10-12</b>	<b>Improvement projects</b>	<b>Monthly mentor visits</b>	
	<b>Month 12</b>	<b>Lab Exit audit</b>		
<b>PROGRAM EVALUATION</b>	<b>Months 13-18</b>	<b>Monthly Mentorship visits</b>		
	<b>Month 18</b>	<b>Lab follow up audit</b>		



# Six week lab implementation plan

<i>Week</i>	<i>Routine activities</i>	<i>SLMTA Follow up Activity</i>
<b>1</b>	Using the ISO 15189 meet Quality Manager to ensure policies and procedures are revised or created; review findings with supervisors	Facilitate SLMTA activities to support equipment management
<b>2</b>	Develop schedule for internal reviews with the Quality Manager or department directors  Conduct training on root cause analysis Review the document archival system and revise accordingly	Facilitate SLMTA activities to support procurement and inventory
<b>3</b>	Introduce quality objectives, indicators and improvement projects  Develop a schedule for internal audits, and conduct training on internal auditing with Quality Manager	Facilitate SLMTA activities to support process control
<b>4</b>	Develop checklist(s) to guide the review and authorization of documents  Review data on quality indicators and work with department heads to develop quality improvement activities	Review checklist items 5.0; 7.0; 8.0 and 12.0 in all departments
<b>5</b>	Review the Safety Manual against the requirements of ISO 15190  Revise schedule for staff meetings; Perform desktop review of procedures developed/revised in week 1	Facilitate SLMTA activities to support safety
<b>6</b>	Discuss with Quality Manager annual management reviews (planning and follow up)	Conduct audits against ISO 15189 for process control, equipment, safety, procurement and inventory

**Activities cutting across the six weeks:**

Conduct training on revised procedures from week one. With the Quality Manager and section heads develop action plans following all internal reviews

Practice using root cause analysis techniques and completion of corrective and preventive action forms



# Number of Standard Operating Procedures per lab



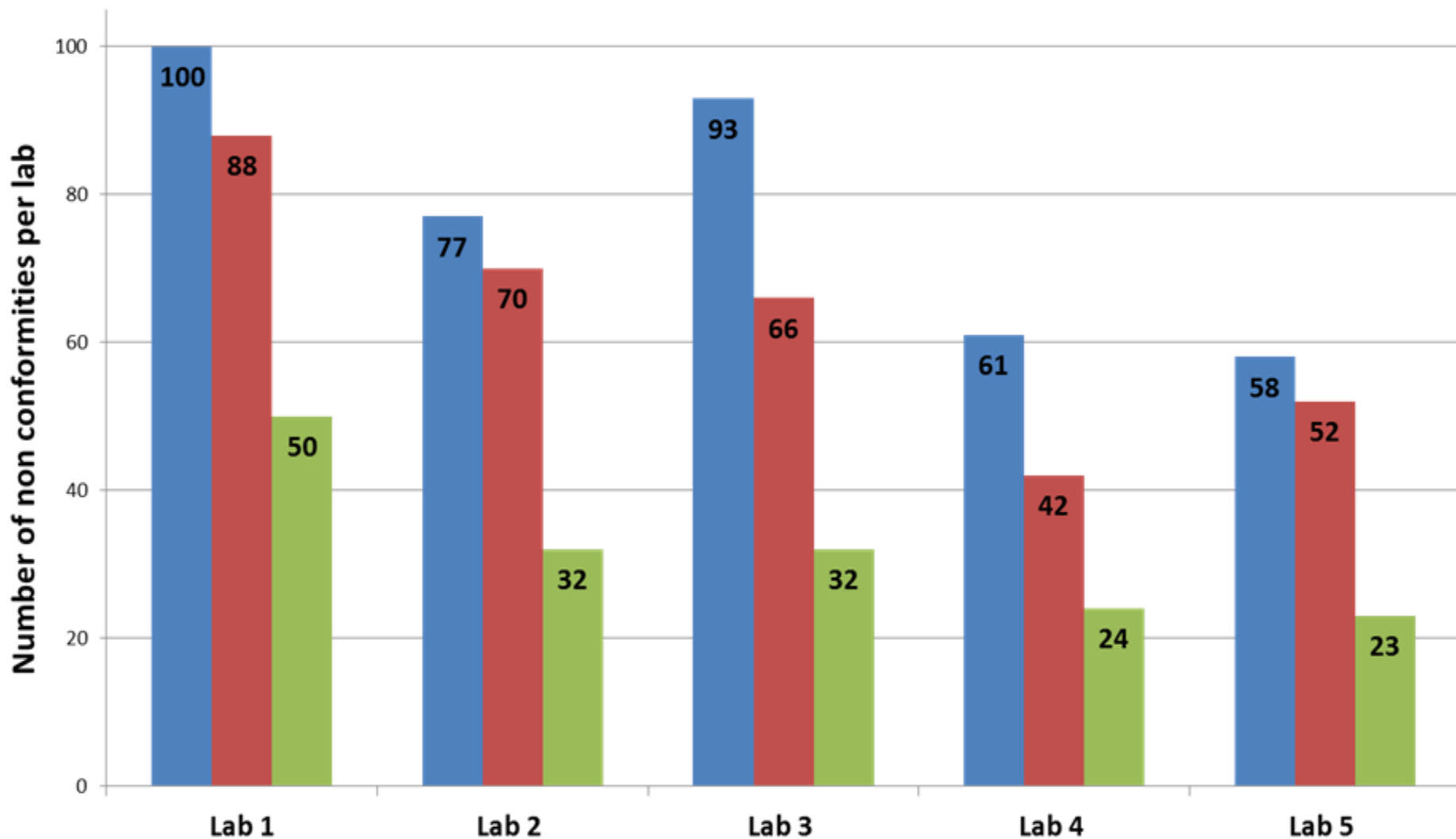
Laboratory	Size of Lab (staff)	Management SOPs	Technical SOPs	Total SOPs produced
1	Large (>50)	29	176	205
2	Large (>70)	60	396	456
3	Medium (20-30)	169	123	292
4	Large (>70)	303	432	735
5	Small (<10)	53	88	141



# Decrease in non conformities



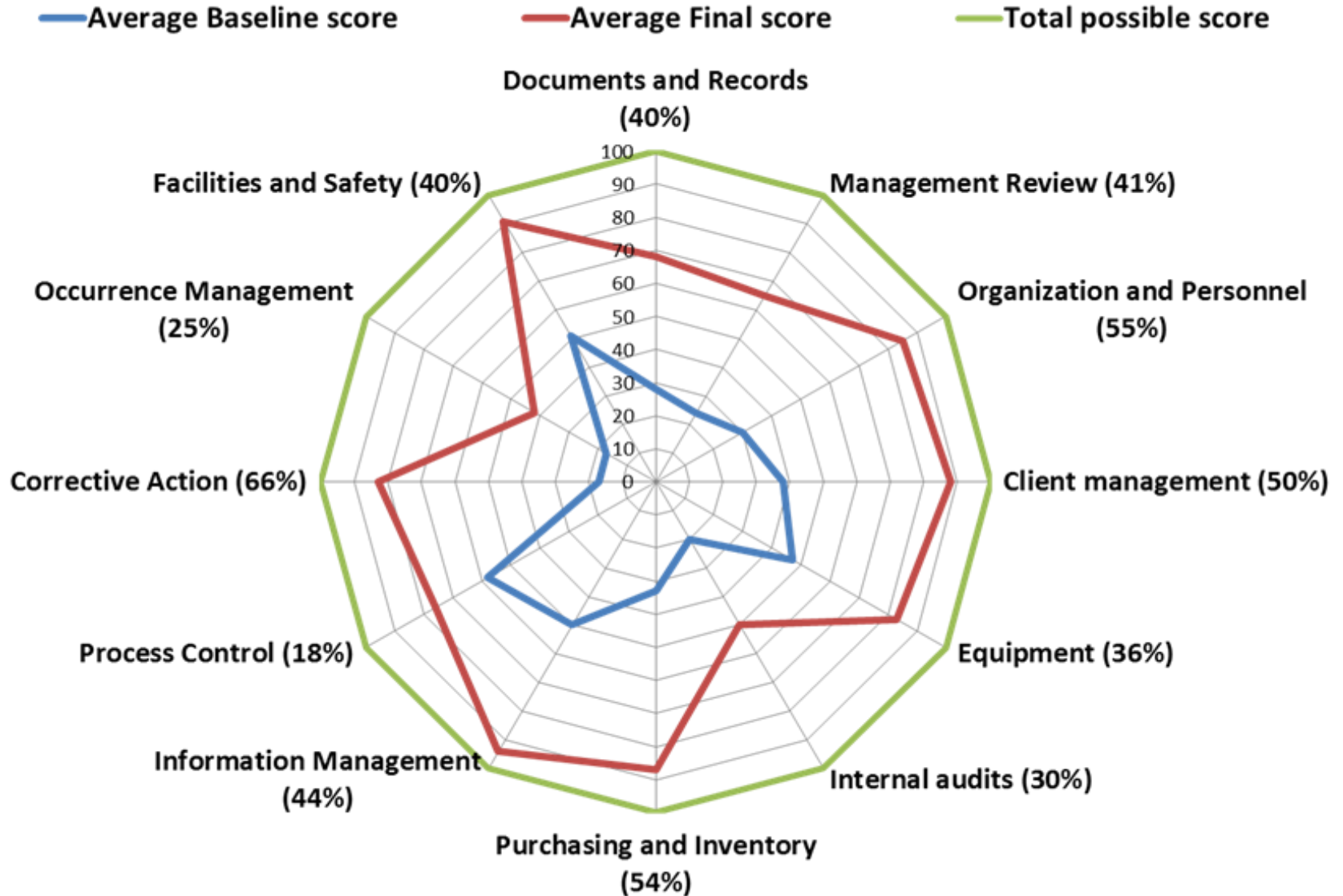
■ Baseline Nonconformities    ■ Exit Audit Nonconformities    ■ Current Nonconformities







# Average performance over QMS areas in the 5 labs

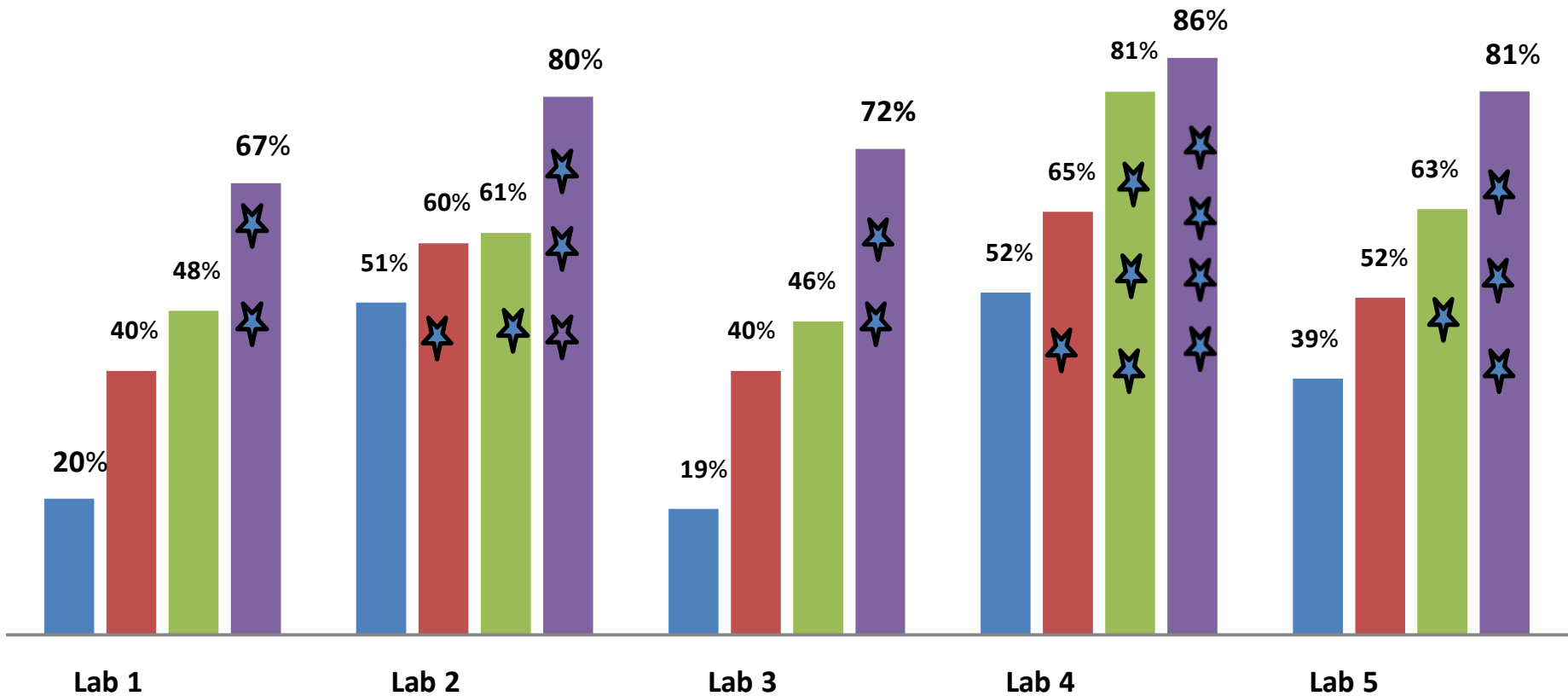




# Impact of Technical Assistance



■ Baseline score ■ 6 month assessment ■ 12 month Assessment ■ 18 month Assessment







### The Bahamas

1 Accredited, 1 assessed in Sept

Assessed in Nov

Jamaica

St. Kitts & Nevis Antigua & Barbuda

Awaiting date

St. Vincent & the Grenadines Barbados

Awaiting date

Trinidad & Tobago

Suriname



# Summary: Challenges



- Human Resource
  - High turnover and attrition of trained staff, Overworked staff
  - Shortage of qualified and experienced mentors
- Solution
  - Governments to prioritise health system strengthening leading to staff development
- Geography
  - Islands separated by ocean, high cost of travel for mentors
- Solution
  - Establish a cadre of local mentors
- Funding
  - Reliance on external funding
- Solution
  - Transition to local governments and partners to facilitate expansion and ensure sustainability



# Summary: Success Strategies



- Early engagement of key stakeholders
  - Full involvement of decision makers and technical staff
- An Implementation Roadmap
  - Stepwise improvement process, detailed quality implementation plan, review of progress periodically
- Structured Improvement approach
  - SLMTA Training, improvement projects, user friendly tools and templates, process approach (input-process-output)
- Mentorship
  - Technical assistance partners, “champion”, follow up and accountability
- Tangible Evidence
  - Regular Progress reports, visible proof of changes within lab





# Conclusion

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Encourage labs to apply for Accreditation when they have 80% implementation. The deadline motivates the last of the effort and eliminates complacency.

The quality improvement seen in these 5 Caribbean national reference laboratories illustrates that SLMTA coupled with mentorship appears to be an effective, user-friendly, flexible, and customizable approach to implementation of laboratory QMS.

Other laboratories in the Caribbean region are considering using the SLMTA training program as they engage in quality systems improvement and preparation for accreditation.



# THANK YOU



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