

Accelerating Progress Towards Accreditation Through Rapid Result Initiative (RRI) - The Kenya Experience

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Outline

- **Kenya SLMTA**
- **Getting there:**
 - Creative partnerships
 - Addressing challenges—stagnation and staff turn over
 - The RRI process and results
 - Using the e-SLIPTA tool
 - Outcomes
- **Staying there:**
 - Post-accreditation support
 - Accreditation surveillance support
- **Conclusions**

Kenya SLMTA

- Kenya is one of the biggest SLMTA countries -185 laboratories enrolled into SLMTA since 2010
- By September 2017, only 15 laboratories were ISO 15189 accredited
- SLIPTA Star 3 is the tipping point
- Stagnation is a factor of 4 QSEs associated with continuous measurement and improvements:
 - Management Reviews
 - Evaluation and audits
 - Corrective and Preventive Actions
 - Occurrence/Incidence, process control
- CDC Kenya/MOH target for laboratory accreditation by end of FY2017 was 20 laboratories.

Objectives for RRI

- To accelerate the number of labs accredited
- To meet PEPFAR-Kenya lab accreditation targets of 20 labs by end of FY 2017

Rationale for Rapid Results Initiative (RRI)

What?

- A rapid but result-driven process lasting 3 months: May-July, 2017
- Rapid and targeted mentorship to laboratories that had stagnated (0-3 SLIPTA stars for more than 2 years)

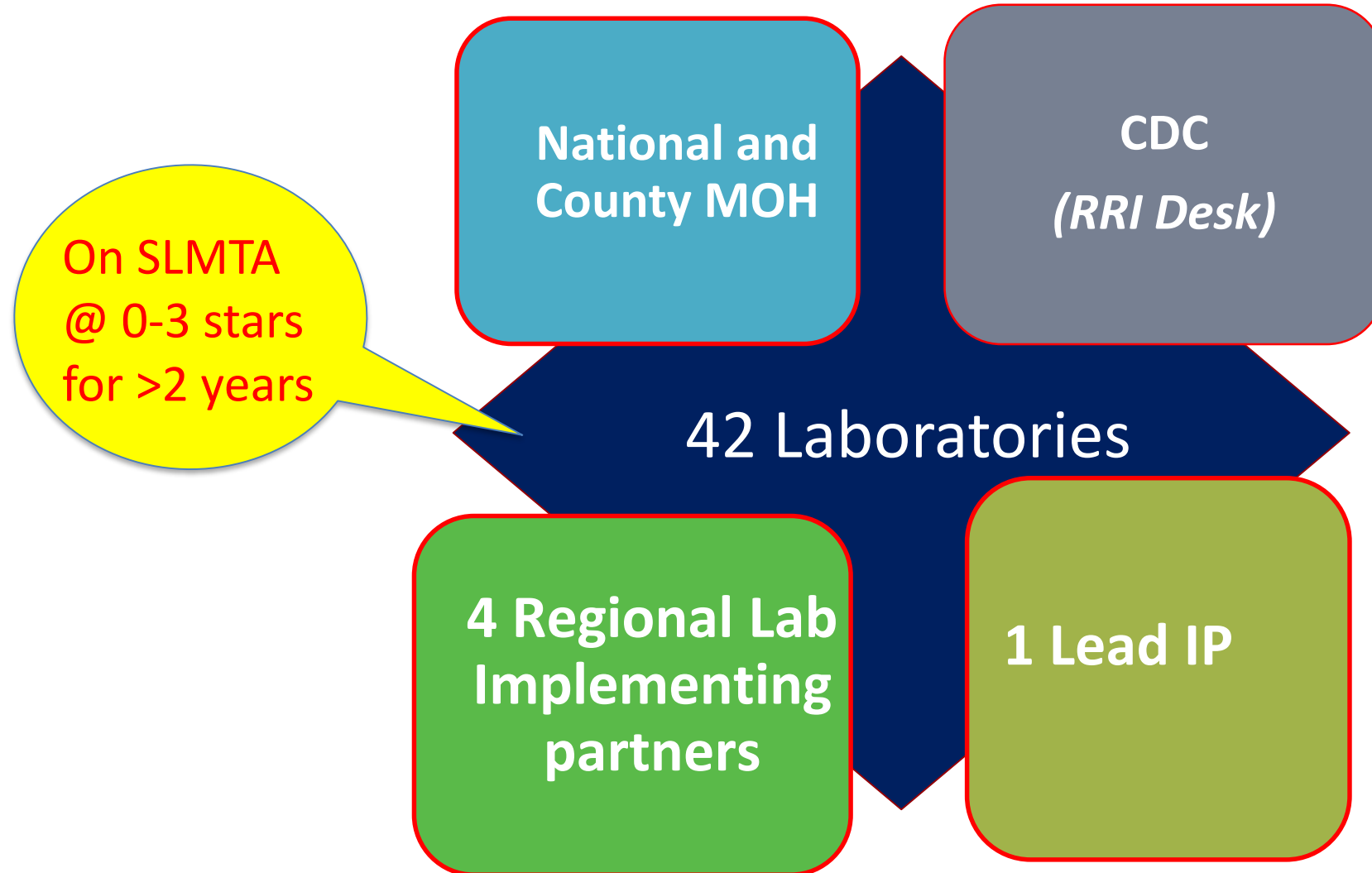
By whom?

- Coordinated by CDC/MOH
- Facilitated by 5 laboratory implementing partners
- Implemented by 42 laboratory mentors using SLIPTA e-Tool to audit and report progress

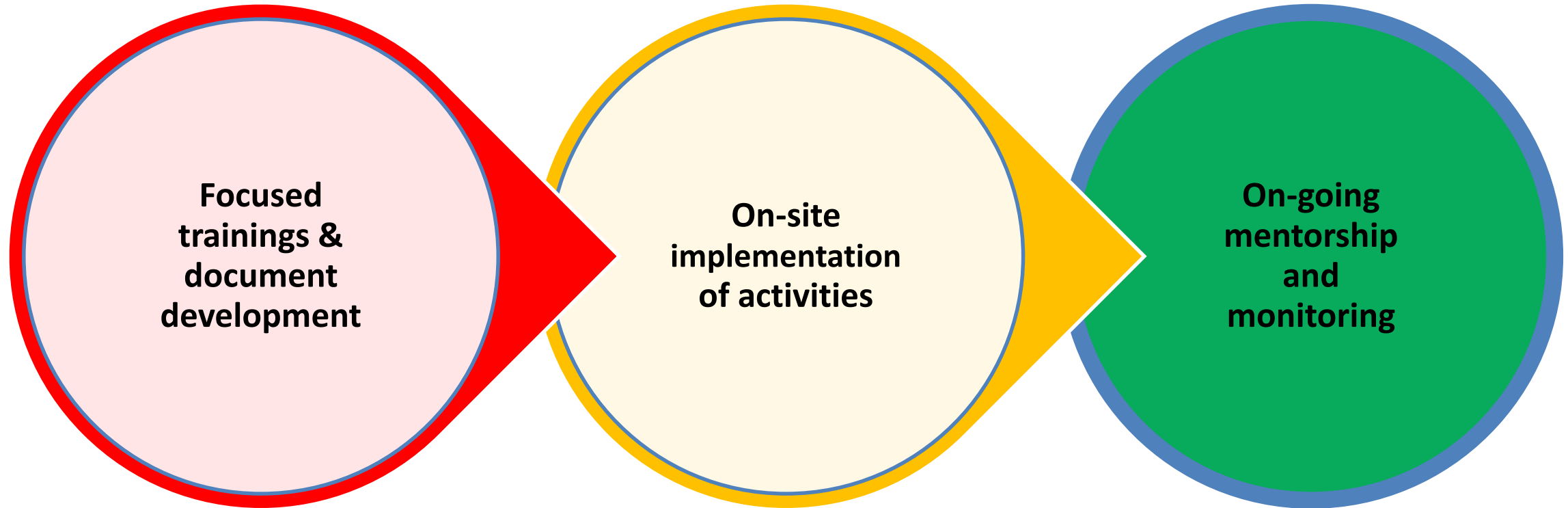
Aim:

All laboratories to achieve 5 SLIPTA Stars in 100 days

Methods – RRI Stakeholders



RRI Process: Three Months



- Stakeholder engagement
- Team Formation
- Baseline audits (BA) using e-SLIPTA Tool
- Develop and realign Lab Quality Documents

- On-site mentorship
- CDC TA visits
- Mid-term audits(MTA) using e-SLIPTA tool

- End-term audits(ETA) using e-SLIPTA Tool

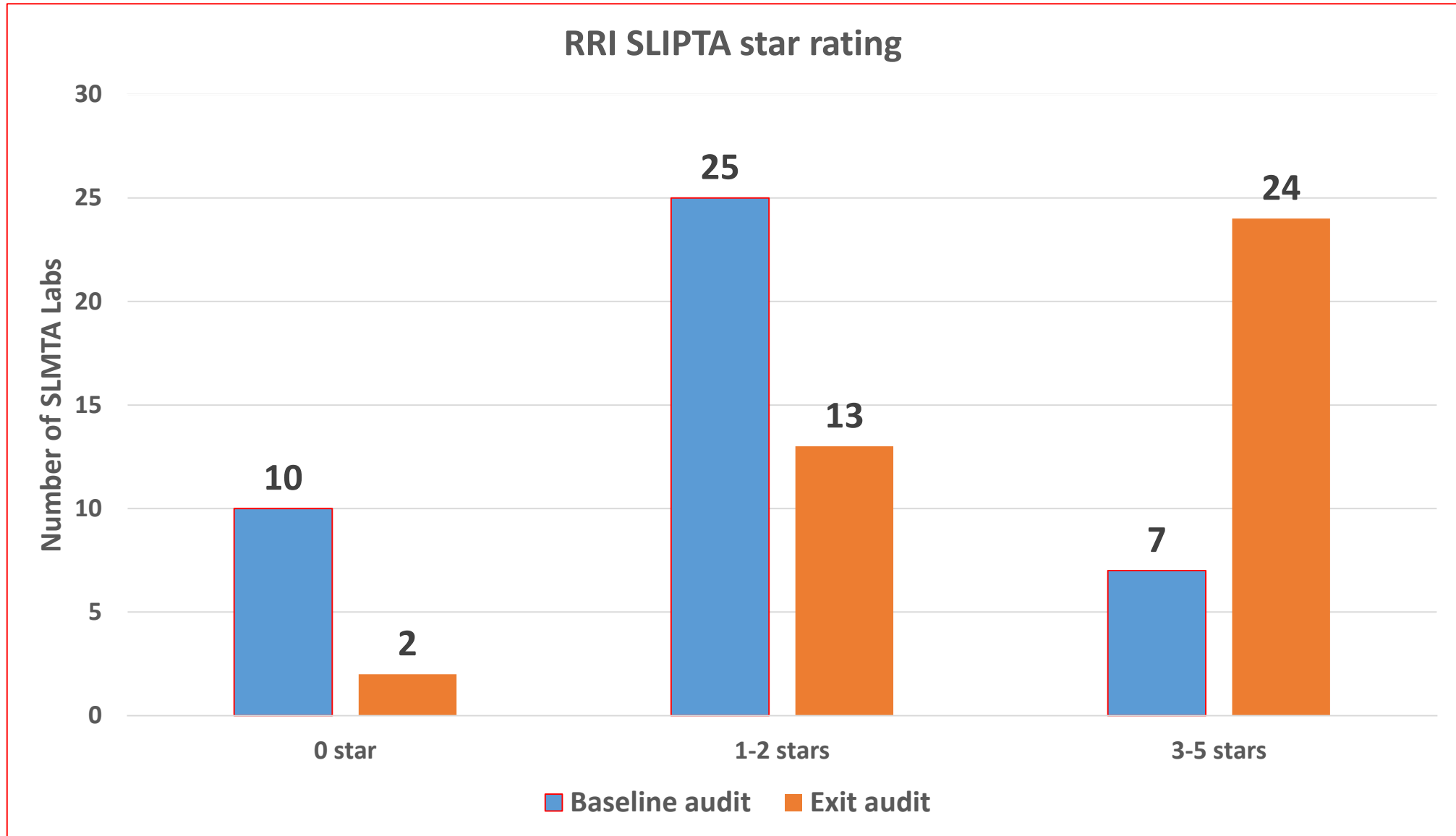
Tailored interventions by Lab Category

RRI Lab Category		
A <50% (0-1 stars)	B 56-69% (1-2 stars)	C >70% (3 stars and above)
Intensive/aggressive training across all QSEs	Targeted problematic QSEs	Addressing continuous measurement and improvement QSEs
10 labs	17 labs	15 labs

RRI Results

		RRI Exit Audit Star Rating						Total
		STAR 0	STAR 1	STAR 2	STAR 3	STAR 4	STAR 5	
RRI Baseline Audit Star Rating	STAR 0	1	1	5	1	0	0	8
	STAR 1	0	4	9	4	1	0	18
	STAR 2	0	1	2	3	1	2	9
	STAR 3	0	0	4	0	1	0	5
	STAR 4	0	1	1	0	0	0	2
	STAR 5	0	0	0	0	0	0	0
	Total	1	5	21	8	3	2	39

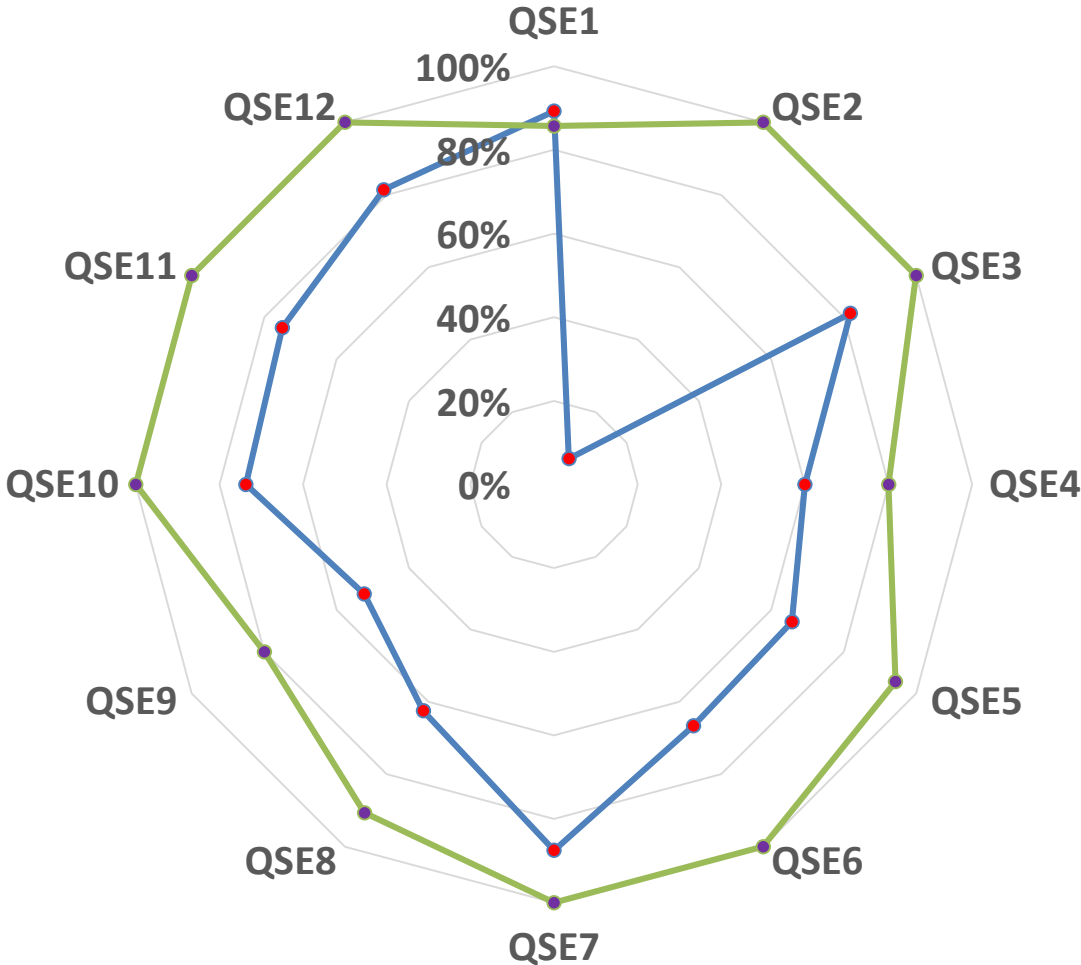
Overall RRI Gains



The Most Improved Laboratory

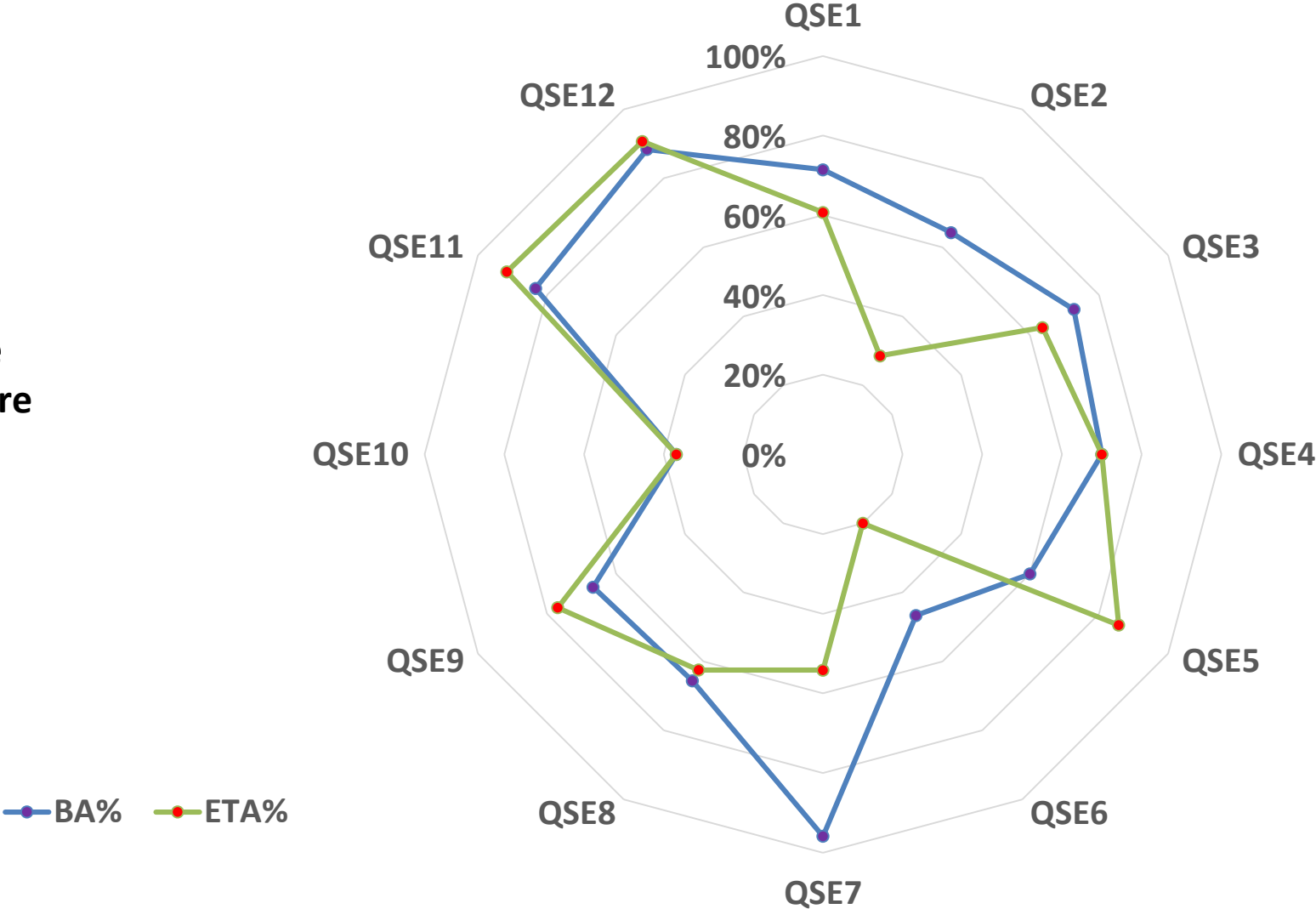
—●— BA% —●— ETA%

Key:
BA - Baseline Audit score
ETA - End term Audit score

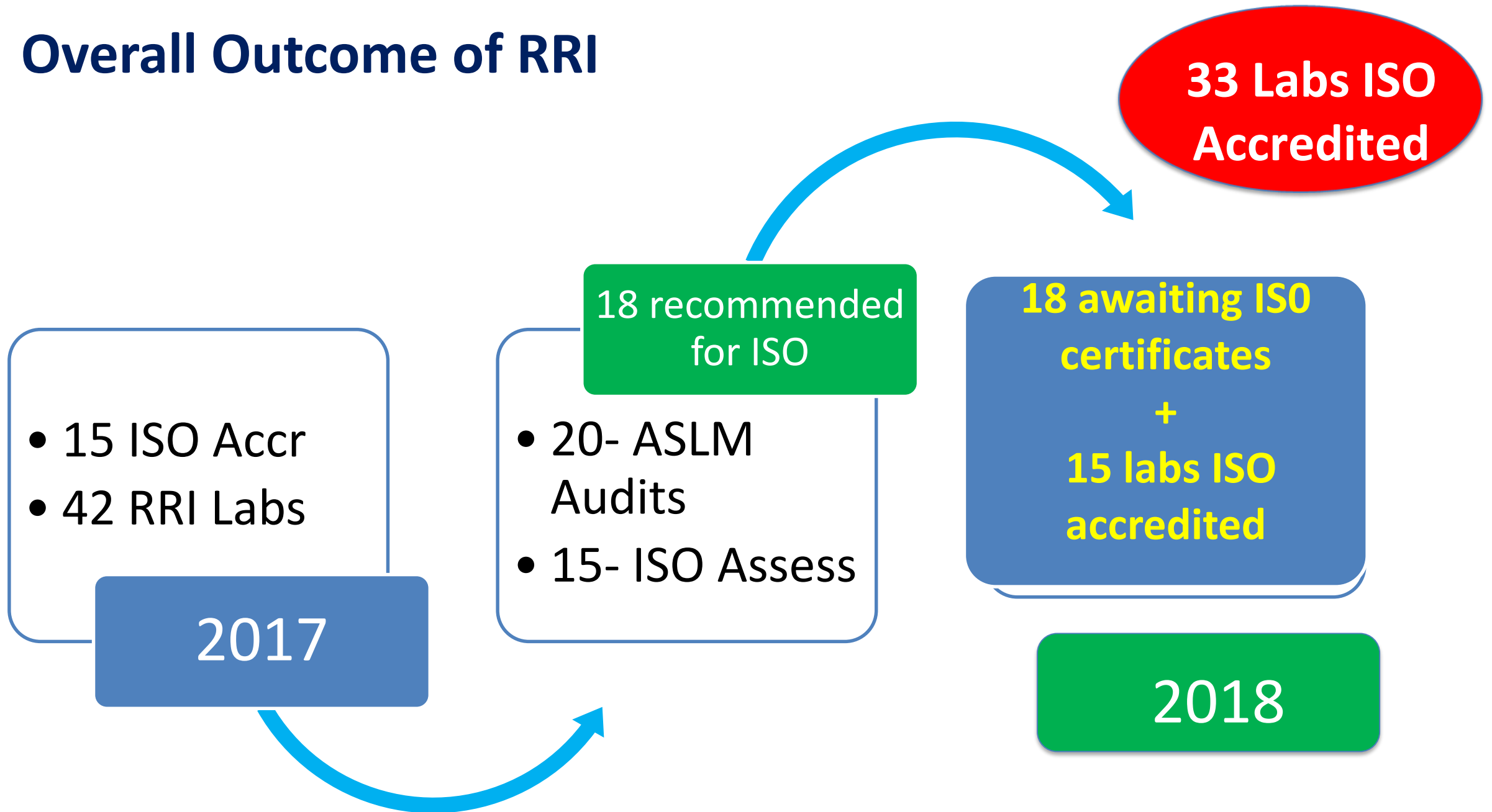


A Stagnated Laboratory

Key:
BA - Baseline Audit score
ETA - End term Audit score



Overall Outcome of RRI



The RRI

Moving from this pace to

A sprint



Lessons Learnt

- Stakeholder engagement and management support are kings
- Intense CAPA and extended mentorships period
- Well defined TORs for mentors, based on lab categories as identified at baseline audit
- Use of the e-SLIPTA Checklist to decrease TAT for audit reports, lesson learned and decision making

Staying accredited—lessons from 9 labs accredited for 4-6 Years

Lab Tier	#Enrolled	# Accredited
National	11	3
Regional/County	6	1
District/Sub-County	98	2
Faith Based/NGO	28	3
Total		9

Maintaining ISO 15189 Status

- **Cross-train all lab staff**
- **Ensure job security and conducive work environment**
- **Engage management to ensure a budget line for QMS**
- **Form quality committee and meet regularly**
- **Train lab staff on occurrence management – identification and reporting of non-conformances, root cause analysis, closure and monitoring**
- **Establish CME programs to ensure competence with job duties, internal audits, method validation, UM, CAPA/RCA**

Staying there—other strategies

- Budget allocation for laboratory commodities and fees for accreditation surveillance
- Job security and defined contract duration
- Formation of work improvement team in the lab (WITs)

Conclusions

- A well-coordinated partnership structure and lab-specific mentorship approach accelerated lab QMS improvement across most labs
- Timely review of progress and audit reports and use of SMART objectives ensured success of this RRI
- The RRI period acted as a catalyst for lab acceleration towards ISO 15189 assessment



Questions?

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.