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From Pilot to scale: KNCV Nigeria experience in TB LAMP implementation in Nigeria

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Presentation Outline

- Introduction of KNCV projects
- Rationale for TB LAMP Introduction
- Strategic Expansion
- Achievements recorded with TB LAMP
- Key to success
- Challenges and areas of improvement
- Conclusion
- Acknowledgement



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KNCV Nigeria – projects till date

2004-2020

KNCV Global

USAID funding mechanisms (**TBCTA**, **TBCAP**, **TBCARE I**, **Challenge TB**)



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2016-2020

Transition period to
National entity

Capacity transfer
Technical & Managerial as part
of Challenge TB
& transitioning projects-
WASP Project
through **SHOPS** funded by
USAID

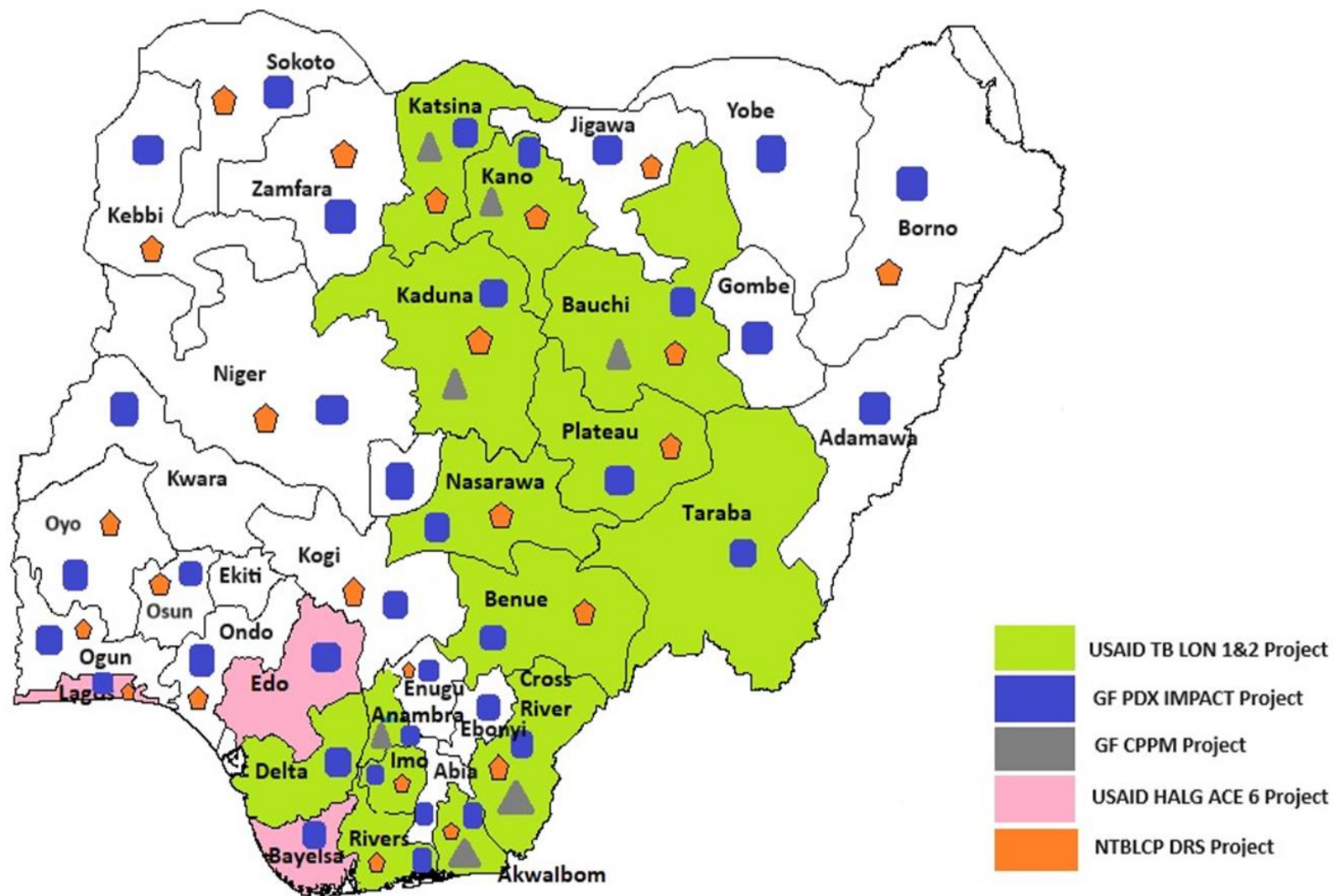
2020- to date

KNCV Nigeria-
National legal entity

- ☐ **TB-LON 1 & 2**
- ☐ **GFTB PPM**
- ☐ GloVax
- ☐ ACE 6
- ☐ DATS
- ☐ TB Connectivity
- ☐ TIFA – STOM & SOFT
- ☐ **GF IMPACT**
- ☐ NTBLCP DRS



KNCV NIGERIA PROJECT MAP – Spread across 36 states and FCT



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Rationale for TB LAMP Introduction

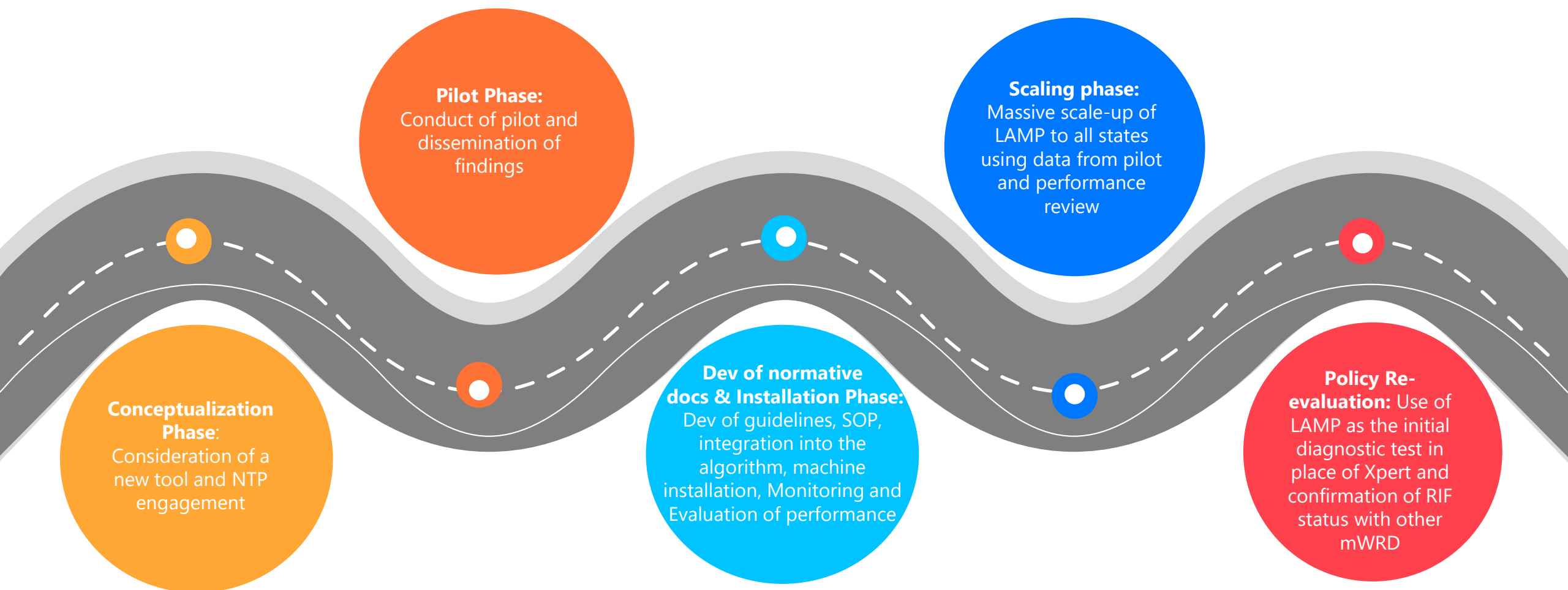
- The limitations of culture and direct microscopy, necessitated recommendation of molecular tests (GeneXpert and TB-LAMP) as the initial diagnostic test by WHO
- Given the vast population , endemic nature of TB and the power challenges in the rural areas in Nigeria, it was unrealistic to use Xpert as the sole diagnostic test for TB
- TB LAMP was introduced by KNCV Nigeria in collaboration with NTBLCP through USAID funding to close testing gap and complement Xpert in power challenged locations



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Strategic Expansion: From start-up to scale-up



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CONCEPTUALIZATION PHASE

- The poor TB case notification and low utilization rate of Xpert machines were great concerns to KNCV and NTP at the onset of the LON project.
- This was primarily due to the infrastructural challenges and low throughput of the 4-module Xpert machines being used at the time
- We needed a tool that
 - Can withstand our **high temperature** and **dusty environment**
 - Can operate **uninterruptedly** at the rural health facilities with pervasive power issues
 - Can test **multiple samples** in a run
 - It is **rugged** enough to withstand **frequent tear** and wear from **frequent transportation** of instruments to communities for ACF



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CONCEPTUALIZATION PHASE

Reasons for choosing TB LAMP

- It does not require an air conditioner to function optimally
- Instruments are simple and user-friendly: (Human Loop T and centrifuge)
- Uses solar system, hence no interruption during testing in areas with power challenges
- TAT is <2hrs, ability to test 70 samples in a day
- Good sensitivity and specificity

Unsophisticated equipment that is easily transportable for community ACF



TB LAMP solar system that addresses power issues even in rural areas



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PILOT PHASE

A pilot study was conducted in 2 states across 5 sites to investigate the diagnostic accuracy of TB-LAMP in routine laboratories

It was an operational research and cross-sectional in design

Summary of findings

	XPERT	LAMP	MICROSCOPY
Sensitivity	84.50%	76.7%	54.30%
Specificity	99.10%	99.30%	99.80%
Kappa Score	0.83 (0.79 - 0.87)	0.8(0.76 - 0.84)	0.67 (0.64 - 0.71)

Findings was disseminated widely among key TB stakeholders and in Greener Journal of Medical Sciences

<https://www.gjournals.org/2021/10/11/092921097-odume-et-al/>



Pilot Study team in 2020 during the COVID-19 Pandemic

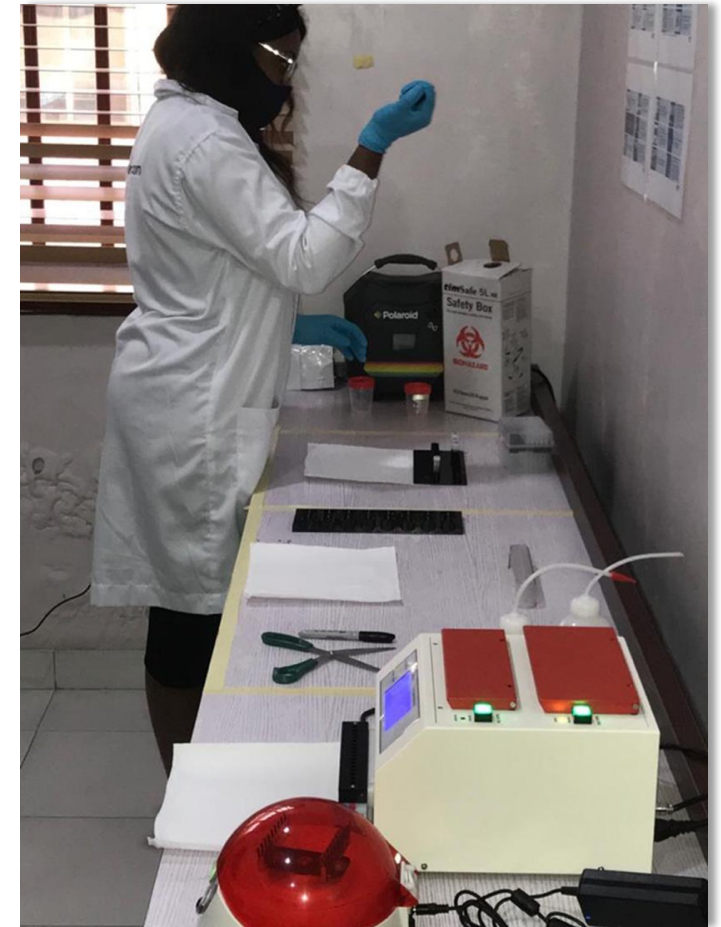


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INSTALLATION AND TRAINING PHASE

- KNCV Nigeria commenced TB LAMP implementation with 5 pilot machines installed in 2 states in 2021
- Additional instruments were procured with USAID funds and added to the pool of 5 instruments
- Gift donations of TB LAMP machines and reagents were received from partners Agbami, Human, and the BUA group
- A local service provider Mcpage was engaged for maintenance of machines
- A strong monitoring and evaluation system was instituted to monitor the quality and performance of the assay
- The National TB LAMP implementation guideline and SOP were developed
- The assay was also integrated in the national diagnostic algorithm in preparation for scale up



Machine installation and training

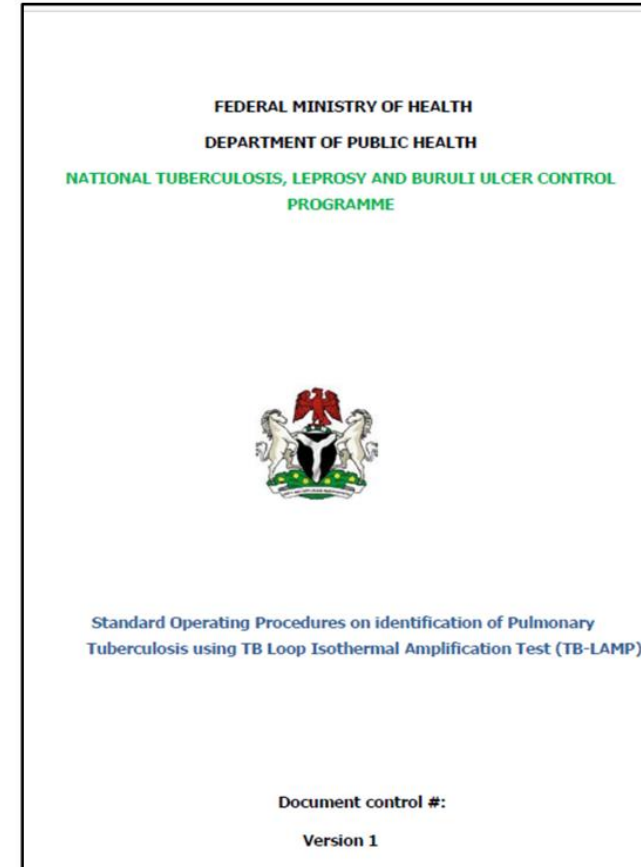
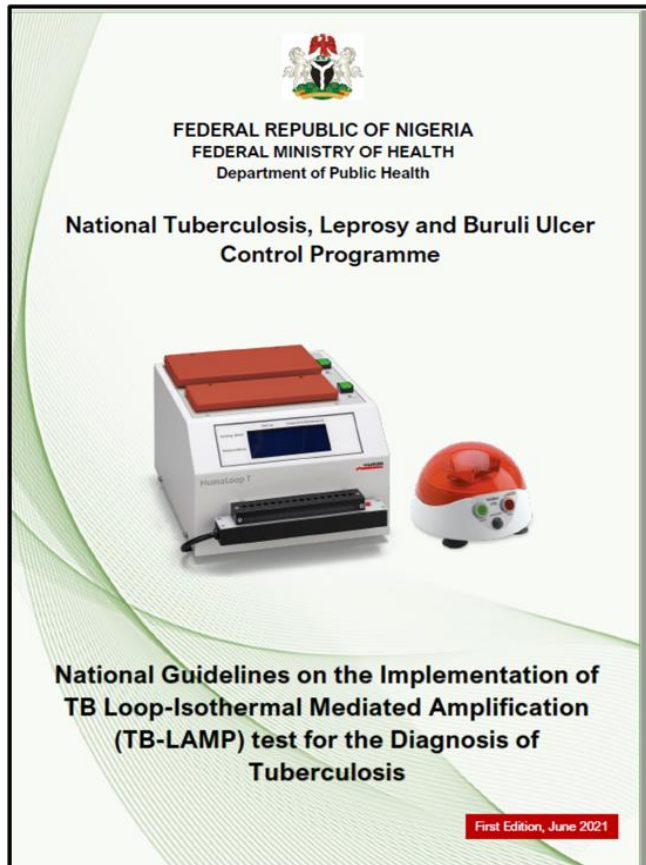


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INSTALLATION AND TRAINING PHASE

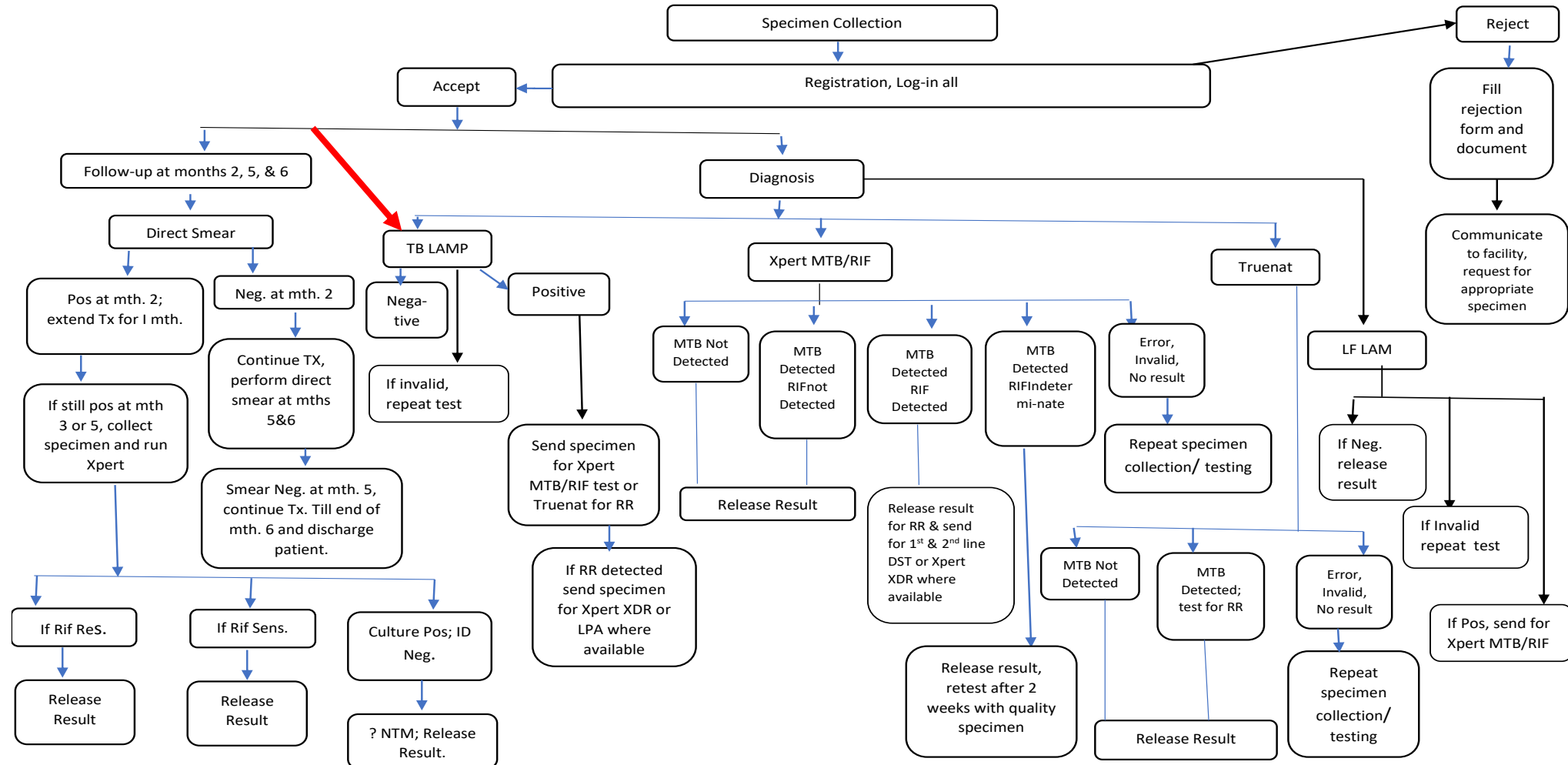
National TB LAMP Implementation guideline and SOP



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INSTALLATION AND TRAINING PHASE - TB LAMP integrated into the National TB Laboratory Diagnostic Algorithm



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SCALE-UP PHASE

- The comprehensive database from the pilot study and weekly performance data tracking from the M&E unit made adoption and scale up of TB LAMP seamless
- It was easy to convince funders to procure more machines with the proof of concept from pilot study and the scientific evidences from the performance review data
- In 2024, one hundred TB LAMP machines were procured and installed in all states with GF funding
- Laboratory staff were trained and retrained on TB LAMP assay.
- Massive sensitization of health care workers was done in all states to create demand for the assay



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Implementation models adopted for expansion in the Scale-Up Phase

- **Model 1:**

Use in power challenged hard-to-reach communities lacking a molecular diagnostic tool for facility active case search

- **Model 2**

Use in high burden facilities to complement GeneXpert or Truenat tool

- **Model 3**

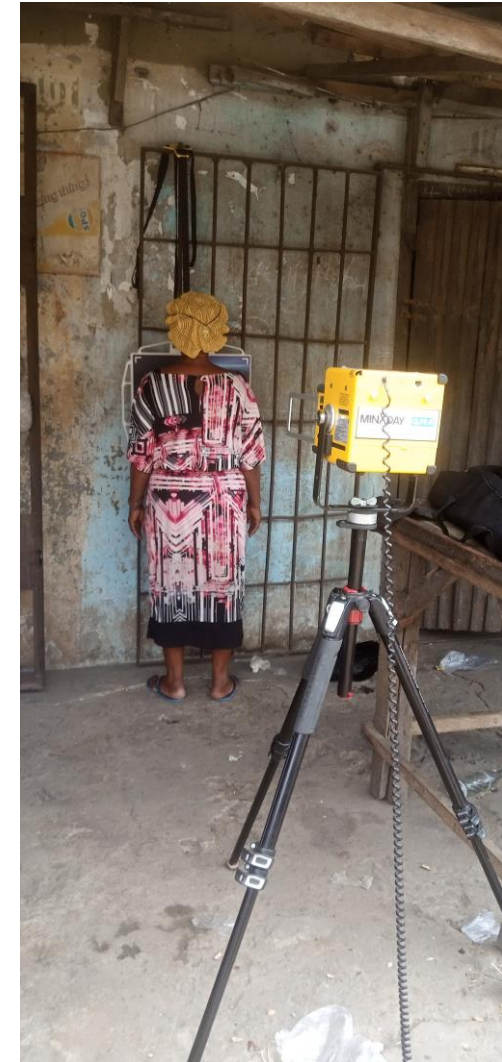
Use in a mobile fashion with wellness on Keke (WoK) for active case search in community (One-stop-shop)



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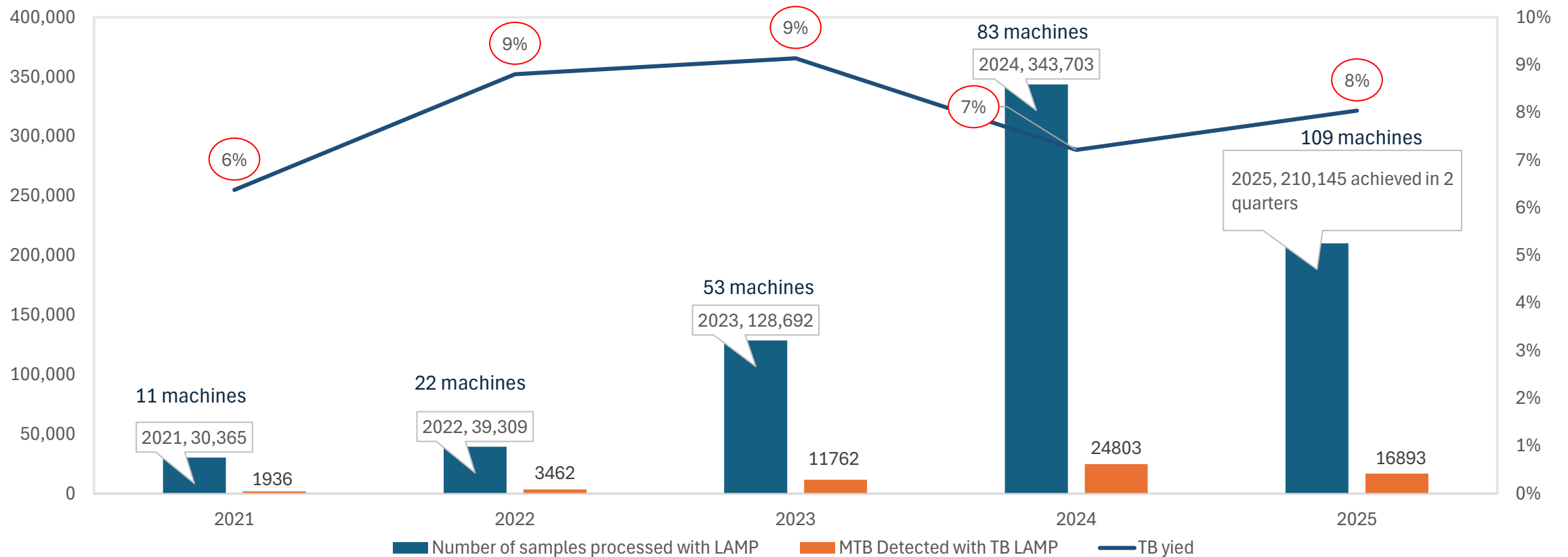
Model 3: Use of TB LAMP in a mobile fashion with wellness on Keke (WoK)



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IMPACT OF SCALE-UP ON TESTING CAPACITY AND CASE FINDING



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POLICY RE-EVALUATION PHASE

- Prior to 2024, TB LAMP, Xpert, and Truenat were all used as initial TB tests where available; positive TB LAMP samples were processed with Xpert and Truenat platforms for RIF confirmation
- As the country got better with implementation strategies, the number of samples for laboratory tests steadily increased
- Laboratories with low-throughput instruments were increasingly overwhelmed with high workload and widening evaluation gap
- This informed a change in policy to a more efficient approach- Use of TB LAMP, not Xpert for initial testing
- Positive samples still processed with Xpert or Truenat for confirmation of the RIF status
- The approach facilitated high-volume testing and the gradual closing of the evaluation gap

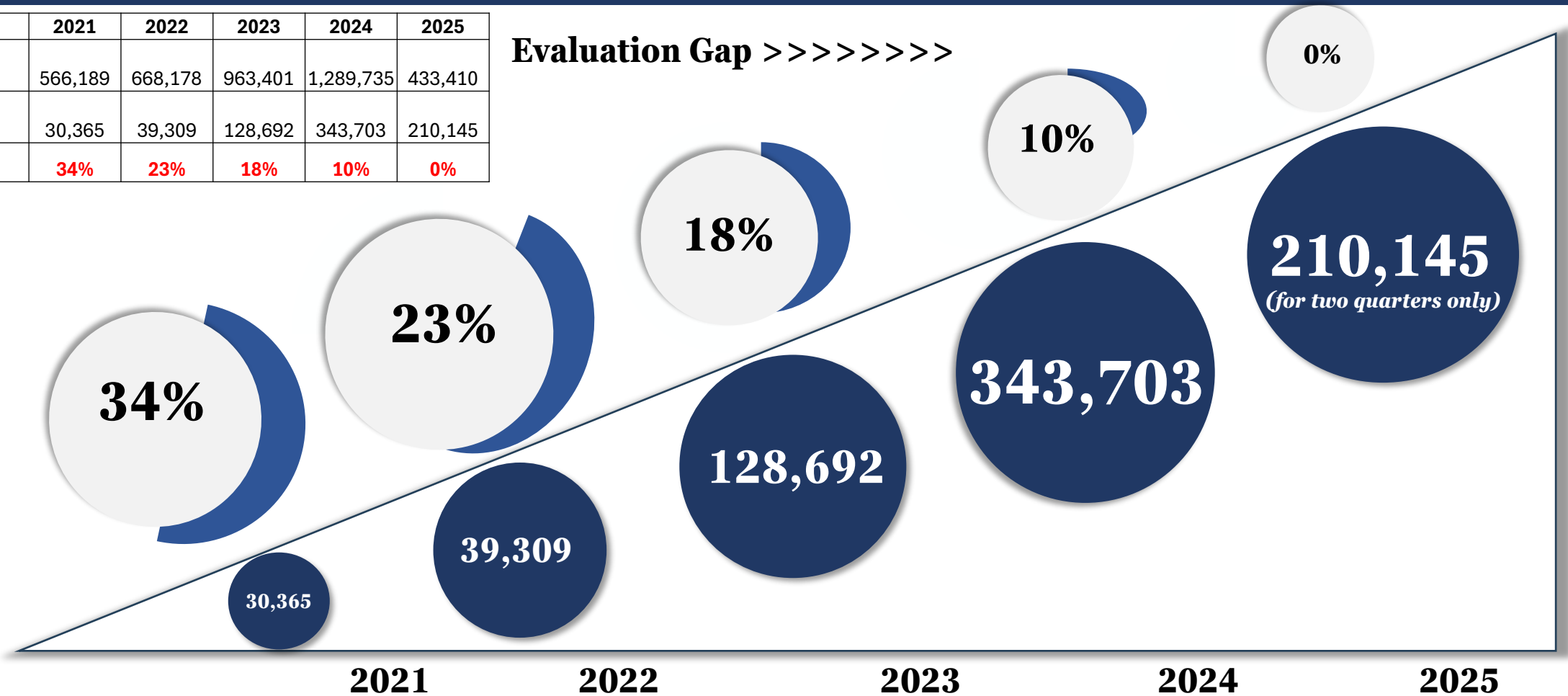


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Significant increase in the proportion of tests conducted and reduction in evaluation gap during the policy re-evaluation phase (2025)

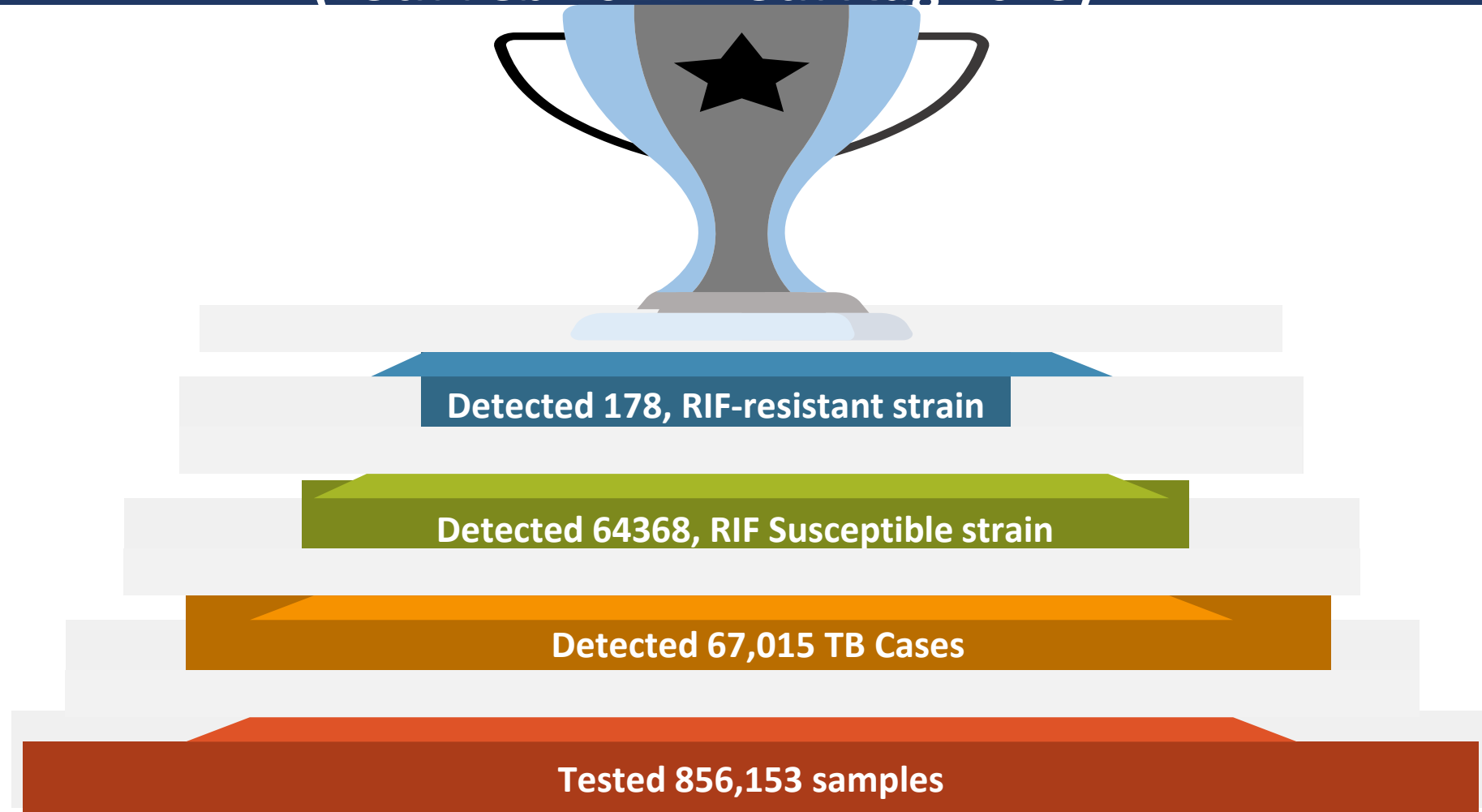
Year	2021	2022	2023	2024	2025
Total Tested (All Diagnostics)	566,189	668,178	963,401	1,289,735	433,410
# Tested with TB LAMP	30,365	39,309	128,692	343,703	210,145
Evaluation gap	34%	23%	18%	10%	0%



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Overall achievement recorded with TB LAMP across 14 KNCV-supported states (13th Feb 2021 – 8th Aug 2025)



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Keys to Success

02- Stakeholder's engagement

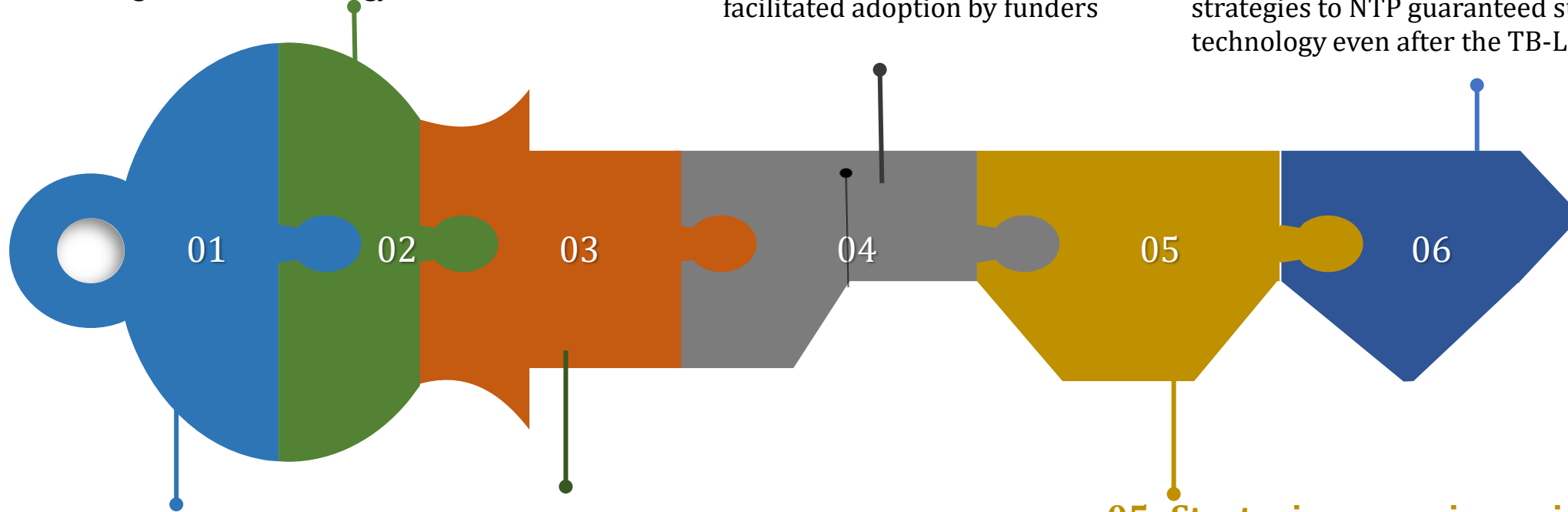
Getting NTBLCP buy-in was very critical to introducing the new technology

04-Robust database

The availability of scientific evidence facilitated adoption by funders

06- Well-articulated Transition plan

Seamless transition of machines and implementation strategies to NTP guaranteed sustainability of TB LAMP technology even after the TB-LON project closeout



01-Proof of concept

Demonstrated practical implementation of TB LAMP through a pilot study

03 -TB LAMP strategic placement

Strategic placement of machines in selected sites increased test accessibility

05- Strategic expansion guided by well-defined implementation models

The deployment of the implementation models increased machine utilization rate and TB notification



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Challenges and areas of improvement

- Sample other than sputum cannot be processed using TB LAMP
- No digital connectivity interface for real time data upload
- Test results are not stored on the platform for future reference and process validation



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Conclusion

- TB-LAMP is an alternative test for sputum smear microscopy
- It is valuable in settings where resources and infrastructure requirements for other molecular tests such as Xpert technology are inadequate
- It is suitable for community ACF owing to its portable nature and use of solar system and has improved diagnostic services to underserved communities
- TB LAMP diagnostic tool has significantly bridged diagnostic gaps and ultimately increased TB case notification in Nigeria



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Acknowledgement

- National Tuberculosis Leprosy and Buruli Ulcer Control (NTBLCP) – and the state Teams
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- The Global Fund
- KNCV Nigeria, staff members
- Mcpage Investment – TB LAMP local partner



TB LAMP focal persons

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THANK YOU

