WHO NTD Diagnostics Technical Advisory Group

A workshop with Neglected Tropical Diseases (NTD) Diagnostics manufacturers, 5-6 December 2024

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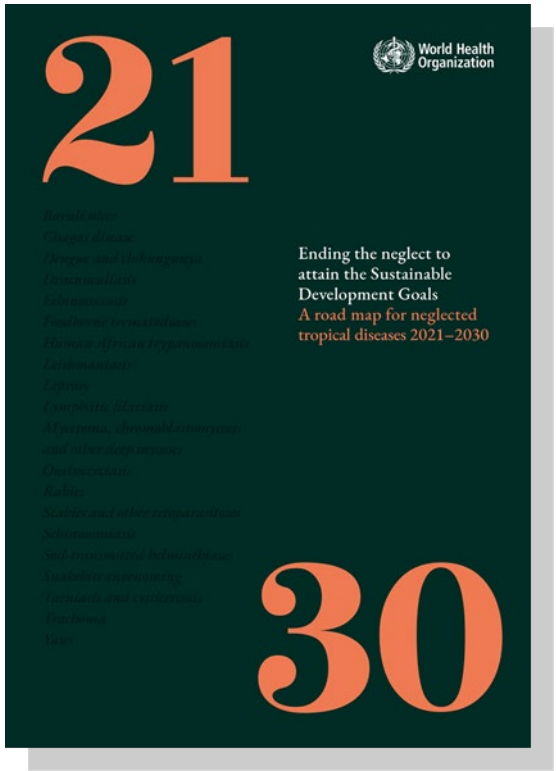
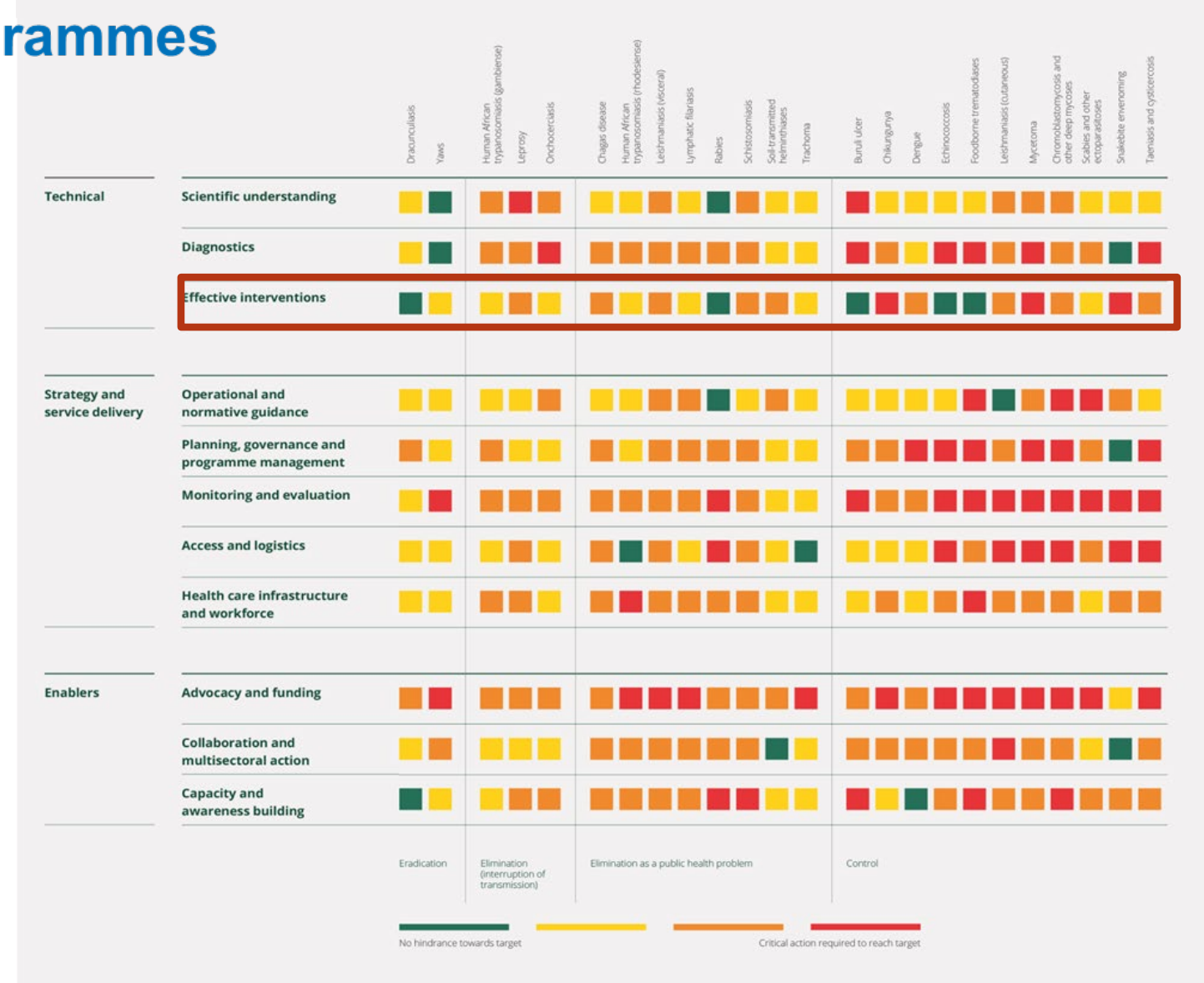
WHO Policy Strategy Framework

- WHO's road map establishes the strategies and **targets/goals** across the NTD (20)portfolio
- Defines **critical actions** needed to achieve targets
- Calls for new approaches to **accelerate progress**, enhance **cross-cutting efforts** and build country ownership



Gap Assessment for NTD Programmes

- Status of NTD programs assessed across multiple technical and programmatic dimensions
- Four interrelated priority dimensions identified:
  1. **Diagnostics**
  2. Monitoring and evaluation
  3. Access and logistics
  4. Advocacy and funding



NTD Diagnostic tests Challenges

- Our current diagnostic tools are not sufficient to meet WHO's ambitious roadmap targets, in terms of:
  - Performance
  - Quality
  - Access
- We are using 19th century tools to guide 21st century programs

Engineering Solutions

•WHO organized the DTAG in 2019 to develop a coordinated response to address diagnostic challenges for NTDs

- Made up of global experts
- Organized around subgroups focused on disease-specific and cross cutting themes through a hub and spokes model

•**The goal: to foster end-to-end solutions**

NTD DTAG and subgroups roles

DTAG

- Defines priority diagnostic gaps, coordinate development of a TPP for each priority use case, position/policy statement, strategy, access
- Establishes ad hoc use-case, disease or category specific sub-groups to deliver on a clear task, e.g., development of actual use-case and target product characteristics.

Disease, Use-Case or category specific Subgroups

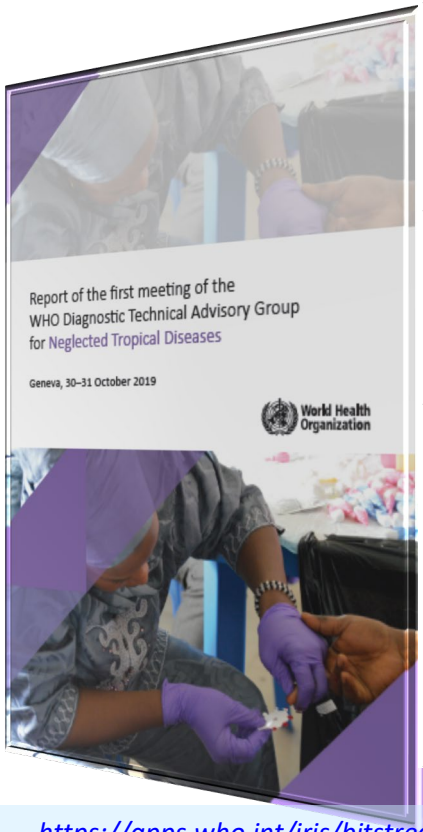
Purpose: develop draft TPPs for priority use-cases within their focus area (a specific disease or category of use case)

Approach:

- Develop and consider needed Use-Case against current Diagnostic Capabilities
- Draft TPP that passes through DTAG and a WHO process for formal approval

NTD/DTAG since 2019

- Identified the priority diagnostic needs for all NTDs
- Used an algorithmic approach to identify and prioritize urgent diagnostic needs for TPP development
- Has held 7 meetings since its establishment and development of around 23 TPP
- Initiated the ERPD process for NTD diagnostics in collaboration with PQ



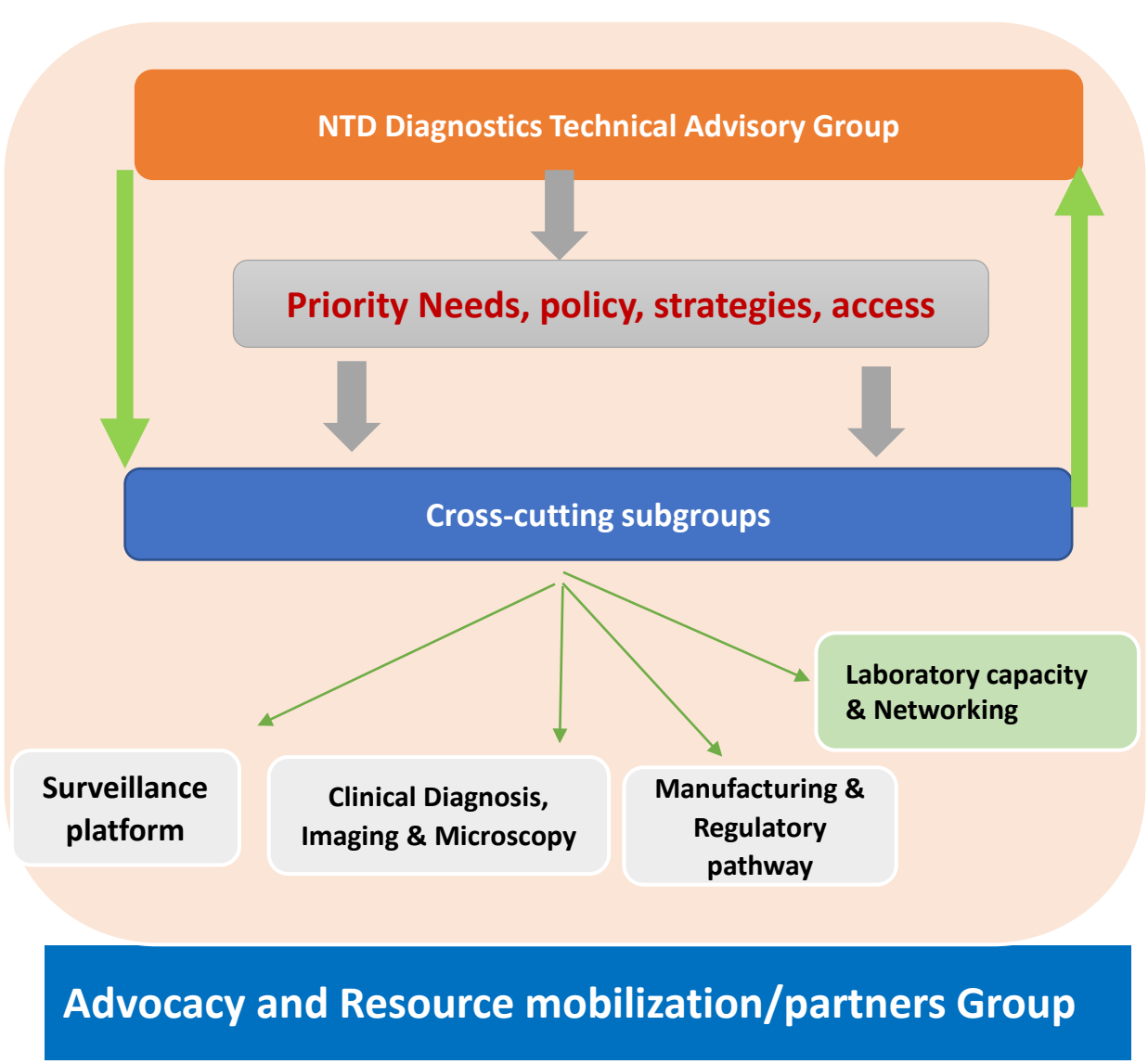
Disease	Current diagnostics	Diagnostic needs
Dracunculiasis	• Clinical with epidemiological link • Microscopy for individual clinical diagnosis • PCR test – confirmatory for individual clinical diagnosis	Serological tests to detect pre-patent Guinea worm: • to anticipate interventions to stop transmission in endemic areas; would
Yaws	• Clinical – unreliable, lesions simil… other causes • Dark field microscopy • POC test (SD Bioline) – individua… nosis and screening; very high sen… and specificity • Treponemal serological test (DPP)… diagnosis and screening • PCR – confirmation, identify subs… can be used for AZT resistance m… ing; cannot distinguish/determine… from seropositive cases	
Human African trypanosomiasis (gambiense)	• CATT (Ab serology) – screening … *gambiense*, community; low preva… during surveillance limits its use • RDT (SD Bioline HAT and Coris … Sero-K-SeT) – screening, commu… and peripheral health facility • Immune trypanolysis test (TL) – … test for surveillance, feasible on d… blood spots; cumbersome • ELISA serological test – test for su… lance (reference laboratories) • Microscopy of blood, lymph fluid … CSF – parasitological confirmatio… sensitivity • mAECT and HCT (Woo) • PCR; LAMP – to reinforce serolog… suspicion, lack of accuracy for con… tion (PCR-reference laboratories; … – district hospitals	

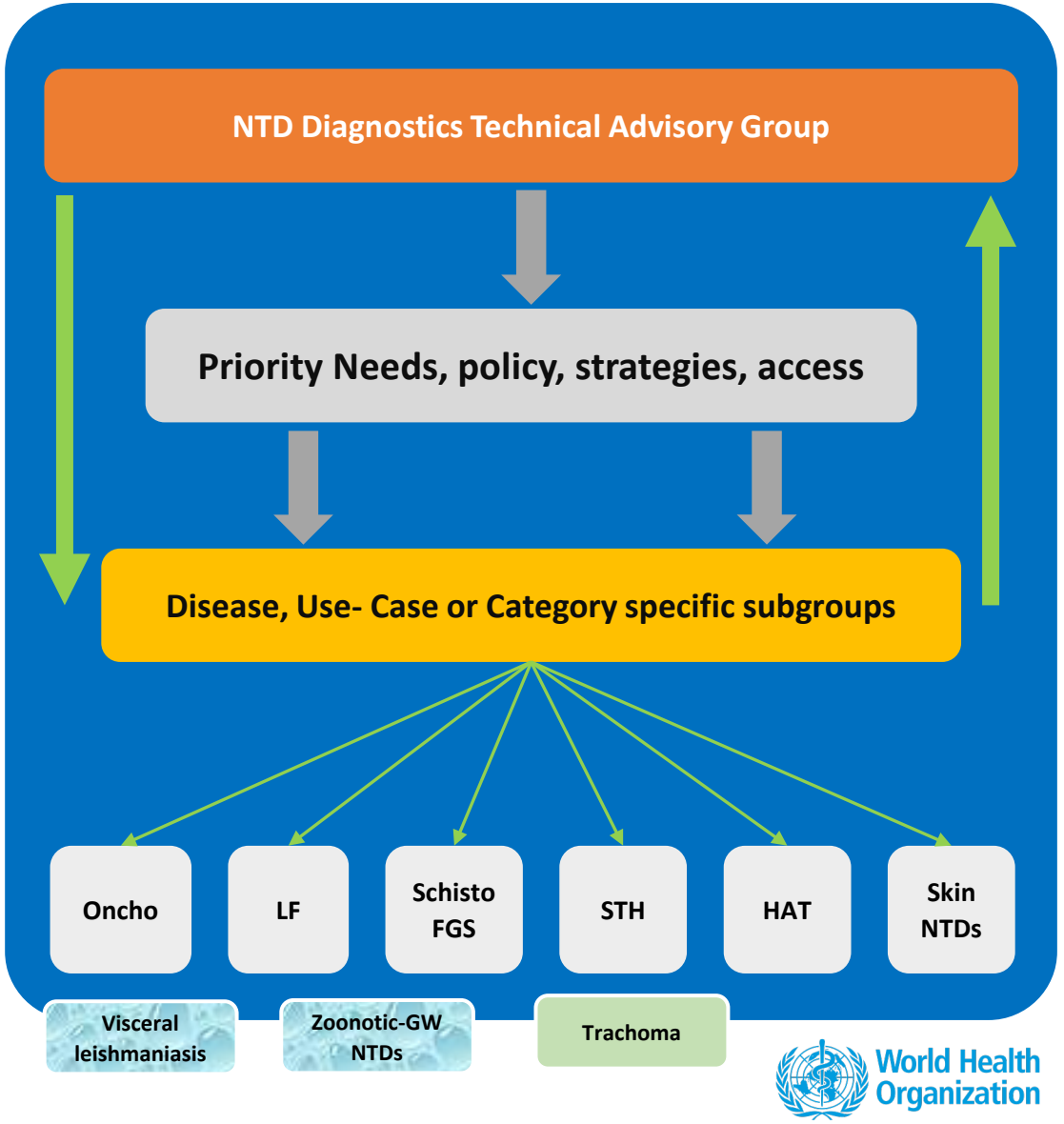
Disease	Current diagnostics	Diagnostic needs
Leprosy	• No test available for diagnosis of infection • Microscopy (demonstration of acid-fast bacilli in slit-skin smear) • Individual clinical diagnosis (some forms only); disease classification (some forms of MB leprosy); follow up and diagnosis of relapse • ELISA, lateral flow assays – individual clinical diagnosis for PB leprosy; low accuracy • PCR – individual clinical diagnosis; higher sensitivity and specificity than ELISA and lateral flow assays; lack of standardization; not commercially available; requires technical and laboratory expertise	• Diagnosis of infection – to provide prophylaxis to those most at risk • Screening for potential disease – to better identify suspected leprosy patients • Diagnosis of disease – to confirm diagnosis of all forms of leprosy (especially indeterminate and PB leprosy) • Prediction of future disease - to identify those at risk of disability • Diagnosis of nerve function loss – to recognize early nerve function loss (before it becomes irreversible)
Onchocerciasis	• Ov16 IgG4 – mapping and stopping; commonly used version: in low prevalence settings, low sensitivity and very high specificity; newer versions more sensitive but concerns about specificity • Ov16 IgG4 RDT – maybe mapping, M&E; not specific enough for stopping, issues with reading in field, much lower sensitivity in low prevalence areas; good quality assurance • O-150 PCR – entomology needed for stopping MDA and transitioning to post-treatment surveillance; being tweaked to enhance performance	• Serological test – for mapping low prevalence areas; have a bridge solution but may need new tools • Serological test – for stopping MDA; higher sensitivity • Serological test (ideally multiplex) – for post-transmission surveillance; need sensitive test of early recrudescence: possibly replace entomology long-term
Chagas disease	• Microscopy – screening and diagnosis • Blood concentration methods – screening and diagnosis • Serology (including chemiluminescence and other related tests) – screening and diagnosis • Molecular biology – Screening, diagnosis, discrete typing unit of *T. cruzi*	• Diagnostics – to detect current infection and assess treatment response • RDT – for early detection of infection in neonates (congenital transmission) • RDT – to identify the discrete typing unit of *T. cruzi*
Visceral leishmaniasis	• Clinical plus epidemiological link – individual clinical diagnosis • Microscopy – individual clinical diagnosis • RDT rK39; RDT rk28 – individual clinical diagnosis; epidemiological surveys • IFAT, ELISA – individual clinical diagnosis • Loopamp™ *Leishmania* detection kit (LAMP) • PCR – individual clinical diagnosis, species typing	• Rapid test – more sensitive and specific especially for eastern Africa and Latin America regions • Test (serological or other preferably rapid test) – to monitor treatment response or test of cure • Rapid test for PKDL – to distinguish PKDL from other skin conditions

https://apps.who.int/iris/bitstream/handle/10665/331954/9789240003590-eng.pdf?ua=1

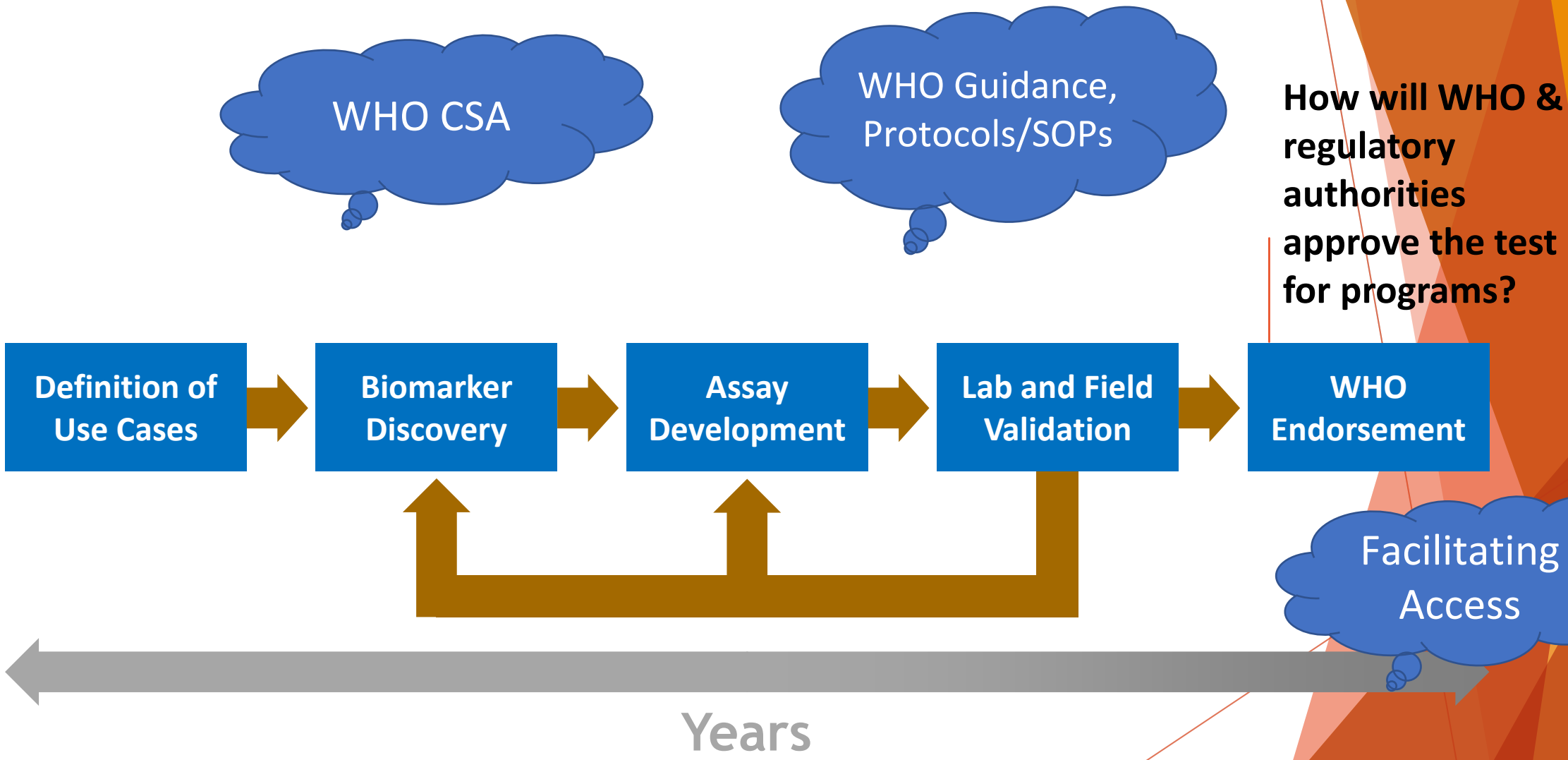
World Health Organization

NTD DTAG and subgroups





End to End Support for NTD Diagnostics



Conclusion: Diagnostics as critical tools for NTD roadmap 2030

The NTD roadmap envisages 3 paradigm shifts

- Diagnostics are critical to address especially two of the three fundamental shifts:
  - Accelerate programmatic action - *measuring impact*;
  - Intensify cross-cutting & integrated approaches
- Urgent need to develop accurate, reliable and cost-effective diagnostics that are fit for field deployment across all NTDs - different stages of the programmes.
- We need to address access, quality and local capacity are also critical issues for most of the national programmes.
- DTAG is playing a critical role to address these issues, flagging the NTD diagnostic agenda high and improve collaboration

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Kiitos

Obrigado

Gracias

Спасибо

Thank you

Merci

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