7th ANNUAL MEETING OF NTD PROGRAMME MANAGERS IN AFRICA

Leveraging innovative tools & sustainable financing to advance NTD elimination in Africa

13-16 April 2026

Lilongwe, Malawi

African Union

World Health Organization
African Region

ESPEN
EXPANDED SPECIAL PROJECT FOR ELIMINATION OF NEGLECTED TROPICAL DISEASES

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Attendance – Day 2

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Welcome, objectives of the day, and link to overall PMM themes

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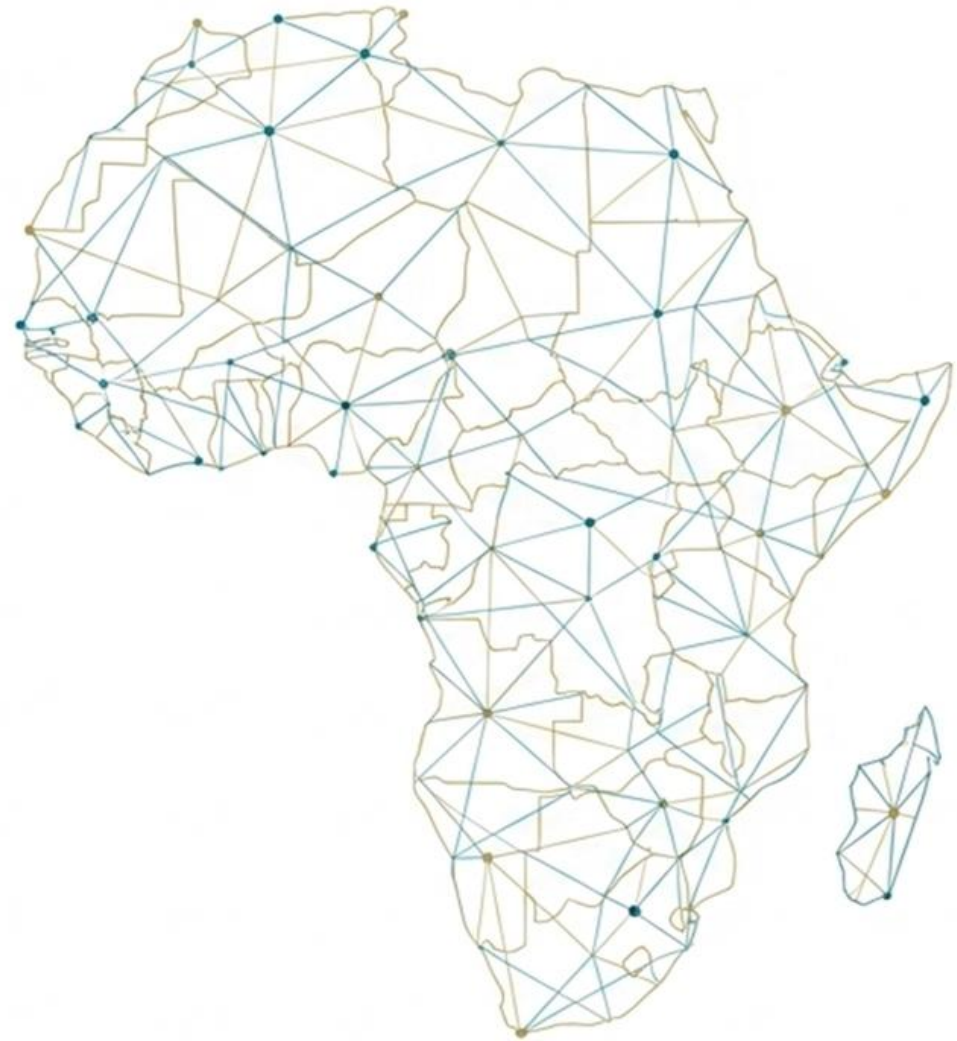
Day 2: Data, Digital Innovation, and Regional Collaboration

7th Annual Meeting of NTD Programme Managers in Africa



The Strategic Context

The Shift: As we transition from large-scale preventive chemotherapy to targeted elimination, precision is paramount.

The Challenge: Transmission respects no borders. Fragmented data limits our ability to see the complete regional picture.

The Imperative: We must build interoperable systems, leverage AI, and formalize transboundary collaboration to sustain our elimination gains.

Our Shared Objectives for Today

Strengthening regional coordination through evidence-based decision-making and accountability.

Cross-Border Coordination

Establish operational frameworks for joint surveillance and synchronized interventions in transmission hotspots.

Digital Integration

Enhance engagement with regional digital platforms (ESPEN Portal, Campaign Health Hub) to reduce duplicative reporting.

Advanced Analytics & AI

Define practical, country-owned use cases for AI-enabled forecasting, data validation, and diagnostics.

Harmonized Accountability

Align indicators and reporting processes across national, regional, and global levels to improve efficiency and data quality.

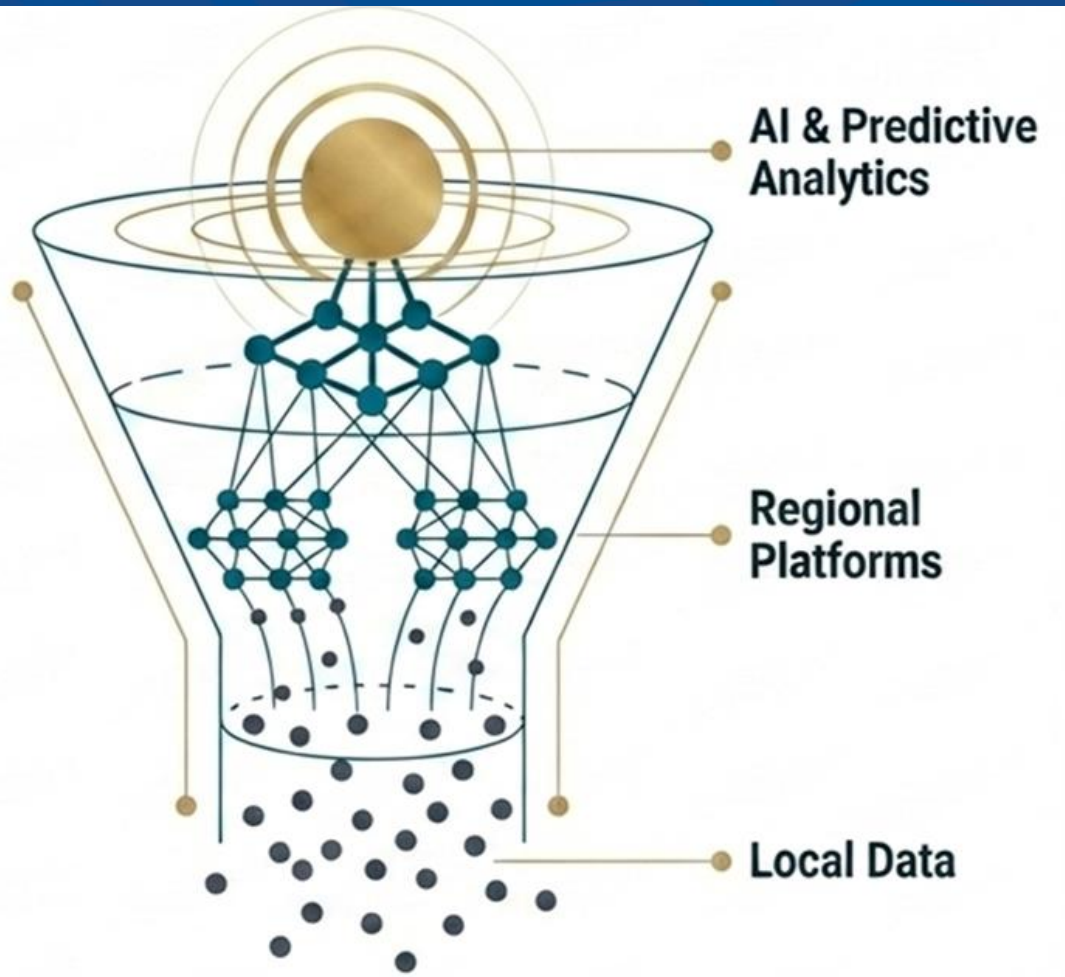
Accelerating Digital Transformation to build coherent regional picture

Session Synthesis (08:45 – 11:15)

Data & Analytics (Session 6): Framing the strategic role of digital public health and interoperability in sustaining elimination.

Regional Platforms (Session 7): Practical integration of the Campaign Health Hub and ESPEN/WHO-AFRO Data Portals for campaign coordination and microplanning.

The AI Frontier (Session 8): A moderated panel exploring the responsible, country-owned application of AI driving innovation across surveillance, diagnostics, and delivery.



Upward Conceptual Funnel

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Addressing transboundary risk through shared governance and operational alignment

Session Synthesis (11:15 – 15:30)

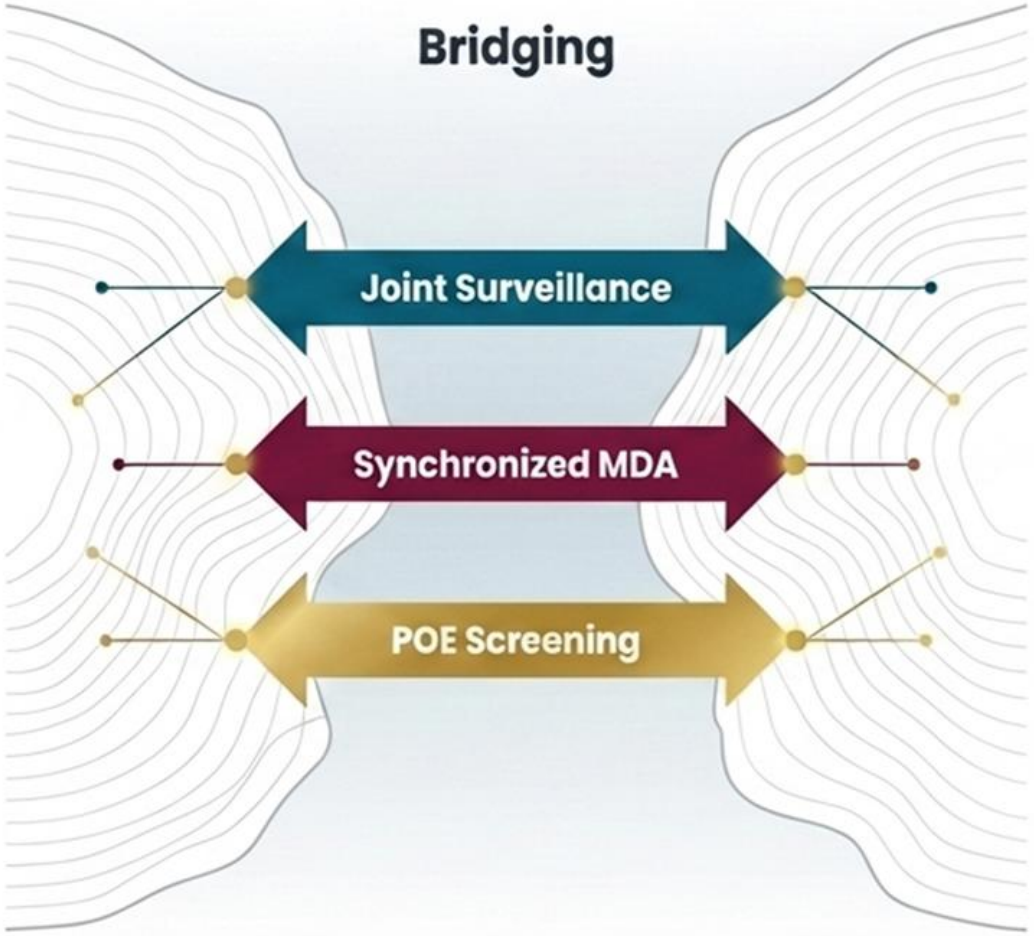
Operationalizing the Borders (Session 9): Country experiences (Kenya, Sudan, Ethiopia, Togo) in synchronized Mass Drug Administration (MDA), point-of-entry screening, and joint surveillance.

Formalizing Cooperation (Session 10): Discussing the institutional dimensions of the Memorandum of Understanding (MoU) on cross-border collaboration.

Targeted Mapping & Innovation (Session 11 Parallel Tracks):

Track 1: Epidemiological mapping of Visceral Leishmaniasis (VL) in East Africa.

Track 2: Country perspectives on operationalizing the new fixed-dose co-formulation of IVM-ALB for STH control.



Reducing the reporting burden while increasing accountability

AUC Data Collection Tool (Session 12): Direct feedback from Member States on implementing new regional reporting mechanisms to better support country needs.

Where We End the Day (Expected Outcomes)

1. Operational Consensus

A clear understanding of **cross-border collaboration** tactics.

2. Platform Awareness

Practical familiarity with available regional **digital platforms** and AI tools.

3. Reduced Friction

Greater clarity on **harmonized reporting standards** to reduce national reporting burdens.

4. Actionable Directives

A generated list of prioritized recommendations to improve data interoperability across the continent.

SESSION 6

Advances in data and analytics for sustaining NTD elimination in Africa

8:45 - 9:30

Progress on Digital Public Health

Charles Sandy, AUDA NEPAD

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Presentation Overview

- Introduction
- Current NTD data systems status- Progress, Challenges and Opportunities
- DHIS-2 and NTD Programmes
- AUDA-NEPAD support approach
- Next Steps

Introduction

- Neglected tropical diseases (NTDs) continue to exert a profound public health and economic burden disproportionately affecting Africa's vulnerable and underserved populations.
- The African Union (AU) established the Continental Framework on the Control and Elimination of NTDs in Africa, which set ambitious goals for 2030,
  - a framework to coordinate continental strategies, harmonize efforts among member states, and mobilize resources to drive NTD elimination.
- Progress to achieve this vision is currently constrained by two challenges.
  - Low domestic financing of NTD control programmes, with many national NTD programmes heavily reliant on external funding, which leaves them vulnerable to fluctuations in donor priorities, as highlighted by recent funding cuts.
  - Persistent deficit in the foundational tools of public health: reliable data and integrated surveillance systems.
  - The data deficit is undermining the continent's capacity to grow NTD programme country ownership and compromises efficient allocation of limited resources.
- Lack of high quality, comprehensive NTD data limits :
  - programmes capacities to prioritize interventions,
  - targeting of high-risk populations
  - monitoring progress toward elimination goals

Box 2. Best practices in NTD data processes

Data collection	• **Integrated and standardized** disease-specific and cross-cutting indicators and data collection tools • **Mainstreamed** into health management information system/integrated disease surveillance and response • Disaggregated by **age, gender and location** • Recorded and reviewed on the **same day** that collected • Reported to the next level in a timely manner • **Supervised** collection of data • **Digital health platform** used for collection
Data storage and aggregation	• **Mainstreamed** into health management information system/integrated disease surveillance and response • **Secured** with defined users and access • **Updated** at regular intervals
Data validation	• Validated at **multiple levels** with **feedback** on data quality • **Triangulated** from various sources • Checked for internal and external **consistency** • **Routine** (e.g. during supportive supervision) and **periodic exercises** (e.g. coverage evaluation surveys, data quality audits) conducted
Data analysis	• Viewed through the lens of **person, time, place** to answer **4/5 Ws: "what, where, when, why and how?"** • Analysed at **multiple levels** (community, health facility, district, national, regional, global) • **Advanced analyses** used to fill public health data gaps
Monitoring progress towards targets	• Progress measured with attention to geographical areas, population groups and trends over time • Progress analysed as to how and why targets are being achieved or not achieved to inform decisions

Situational Overview

Roles and Current Systems in use

Function	*Main system*
Routine facility surveillance	**DHIS2**
MDA & treatment reporting	**DHIS2 + Excel (transitioning)**
Sub-national PC-NTD data	**ESPEN Portal**
Surveys & mapping	**ESPEN Collect + GIS**
Official international reporting	**GNARF / GHO**
Planning & financing (emerging)	**Africa CDC Micro-planning Platform**

DHIS2 (District Health Information Software 2) is an open-source, web-based platform used by over 75 countries as a national health information system.

- *DHIS2 NTD Toolkit integrates NTD data into a harmonized system, facilitating reporting on various diseases to meet WHO targets.*
- *Data Collection & Reporting: It supports mobile (Android) apps for field workers to collect data on cases (e.g., Lymphatic Filariasis, Soil-transmitted helminths) and report them, reducing reliance on paper systems.*
- *Mapping and Surveillance: DHIS2 allows for mapping, enabling teams to visualize hotspots for diseases like Schistosomiasis to guide, for example, mass drug administration (MDA) campaigns.*
- *Stock Management: The system connects with logistics platforms to manage the, for example, delivery of medications, reducing shortages.*
- *Data Visualization and Analysis: It provides dashboards to analyze trends over time, helping decision-makers monitor progress towards elimination.*

DHIS2 strengthens national systems by allowing for the integration of data from multiple programs, ensuring sustainability and better decision-making

How are you using DHSI2? Green/Red Exercise

- Surveillance at health facility level - cases (suspected, probable, confirmed), rumors, deaths, and treatments.
- NTD - Human Resources
- LMIS NTD-related medical items.
- Does your DHIS-2 cover the five key priority PC-NTDs targeted for elimination by 2030 :
  - *Lymphatic filariasis (often called elephantiasis)*
  - *Onchocerciasis (river blindness)*
  - *Schistosomiasis (bilharziasis)*
  - *Soil-transmitted helminthiases (intestinal worms)*
  - *Trachoma (blinding infection)*

Food for thought

Background

The District Health Information Software (DHIS2), adopted as national health information system by the ministry of public health in Cameroon, did not integrate neglected tropical diseases (NTD) program data. Integrating NTD program data into the national DHIS2 might require more than technical skills. Our study aimed to explore the factors that affect acceptability and use of DHIS2 by NTD stakeholders for successful integration of NTD program data into the national DHIS2.

Challenges in using DHIS2

The most critical challenges in using DHIS2 were related to facilitating conditions. Issues in facilitating conditions were internet connection (geographical coverage, cost, quality), electricity (coverage, stability), and availability of smartphones/computers to work on DHIS2.

Suggestions to tackle challenges reported by stakeholders

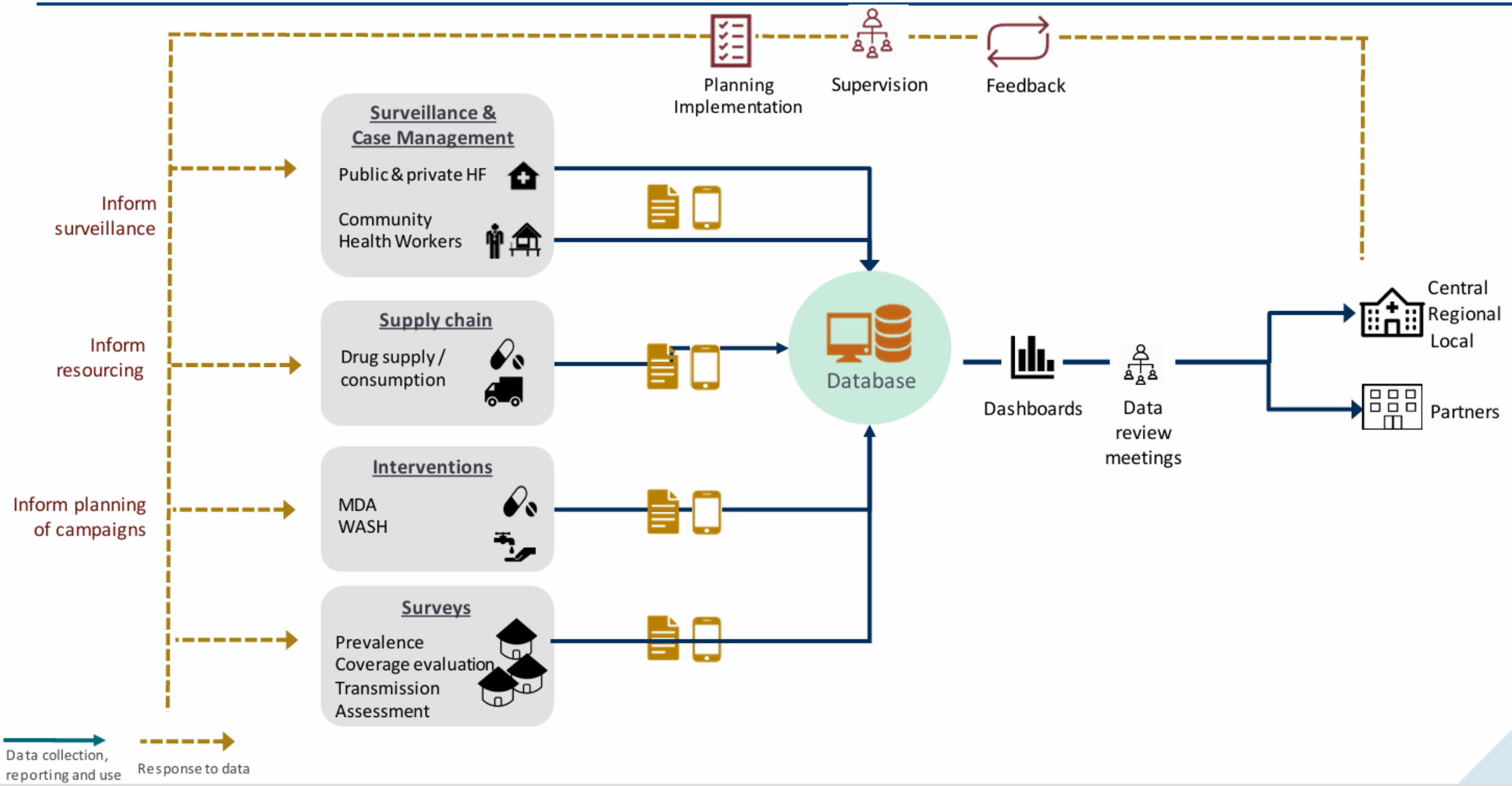
The most reported suggestion to tackle the above-mentioned issues was related to improvements in facilitating conditions. Participants suggested providing wifi modems and/or lump sums to afford internet data bundle, solar panels in rural health facilities to make electricity available and computers/smartphones. It was suggested to provide not only basic training on data entry but also in-depth training on data analysis including data cleaning. In addition, participants suggested looking for ways to work offline with DHIS2

Study revealed that NTD stakeholders in Cameroon are ready to accept DHIS2 for NTD program in Cameroon. However, to ensure its successful implementation, we recommend that NTD program managers plan adequate support in providing proper training, non-vendor specific 2G-3G-4G internet modems with data bundle and smartphones/laptops to ease the use of DHIS2 by NTD stakeholders.

Journal of Global Health Reports

Moungui HC, Nana-Djeunga HC, Nko'Ayissi GB, Sanou A, Kamgno J. Mixed-methods evaluation of acceptability of the District Health Information Software (DHIS2) for neglected tropical diseases program data in Cameroon. Journal of Global Health Reports. 2021;5:e2021071. doi:10.29392/001c.25973

The ideal NTD surveillance system reflects collection of high-quality data, its integration, and visualization for optimal program planning and implementation

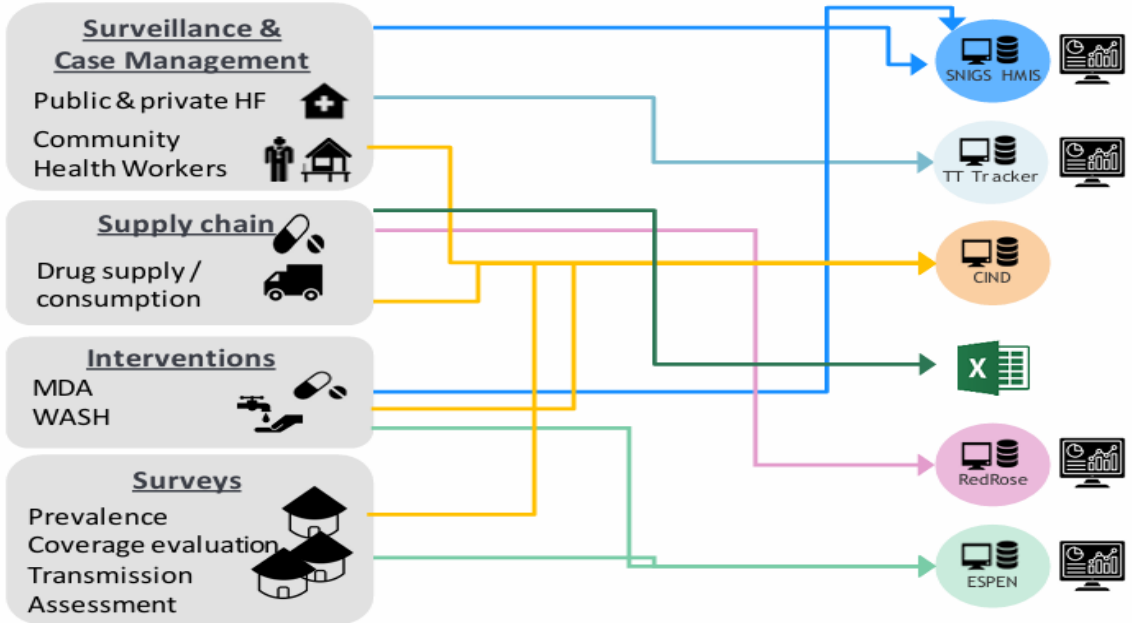


Data Fragmentation

2022 Kenya example

Database name	CIND (Access database)	ASCEND	Tropical data	REVEAL	Google sheet	ESPEN portal
Author	WHO	ASCEND	ITI-GET 2020	AKROS	MOH + partner	ESPEN
Platform		dhis2		Reveal		
NTDs covered	PC-NTDs	SCH, Trachoma &LF	Trachoma	SCH (Vihiga county, 2021)	PC-NTDs	PC - NTDs and WASH
Data included	Prevalence MDA; Drug supply Morbidity NTD programmatic data	MDA Case Management; Morbidity management and disability prevention	Prevalence	MDA	MDA	Prevalence MDA WASH indicators

2022 Benin example



This data fragmentation hinders data use - programs spend more time compiling, cleaning, mapping, and calculating data than they do reviewing and responding to data

- Widespread redundancies in data collection and reporting tools
- NTD programs do not have timely access to data and must solicit it from partners, creating major delays in access
- Data dictionaries vary considerably, making joint analysis and cross-comparison difficult. Using NTD data therefore requires extensive technical capacity due to the messiness and inconsistencies within the varying data sets
- Lack of automated outputs

- No strategic vision or roadmap for digitization/data systems
- Uncoordinated system design and development efforts
- Limited collaboration between MoH programs and digital health/IT units
- Disjointed funding sources
- Ad hoc tool proliferation to fill in the many gaps left behind

- Need to shift from investment in tools but towards systems
- Systems developed from an overarching vision and not just *ad hoc*
- co-design these systems with stakeholders and end users to align with in-country workflows

The digital health landscape in Burundi is fragmented, according to the Ministry of Public Health.
Tools such as DHIS2, SIDAInfo and OpenClinic operate in silos, leading to duplication, inconsistencies and a heavier workload for health workers.

Participants mapped existing tools, identified priority data exchange flows and defined common technical standards, including the international HL7 FHIR standard.

Middleware solutions were also explored to facilitate system integration.

The initiative is part of the National Health Information Development Plan (PNDIS II, 2026–2028), supported by Belgian Development Cooperation.

It is also part of a broader continental trend, as telemedicine, electronic patient records and artificial intelligence expand rapidly across Africa to address infrastructure gaps.

The interoperability effort is expected to improve data quality, strengthen decision-making and reduce the administrative burden on health professionals. No timeline or budget has been made public.

Burundi Moves to Make Fragmented Health Data Systems Interoperable

Monday, 13 April 2026 14:57

AI in Health: High-level Recommendation for AI Adoption in the Health Sector in Africa

- Promote the widespread adoption of AI in the health sector in Africa through the exchange of experience and by deploying AI use cases in the health sector.
- Designate a centre of excellence to conduct research and build a knowledge base on use cases in the health sector on the continent, facilitating the sharing of experiences and solutions.

AI Insights allows users to analyze DHIS2 health data using natural language queries.

- Healthcare professionals, data analysts, and decision-makers can ask questions in plain language to **identify trends, compare performance across organization units, and generate actionable** insights from their data.
- The app works by connecting to external AI services to interpret questions and **analyze aggregate, event, and tracker data.**
- AI Insights is generic and works with any DHIS2 instance and metadata structure.
- The app requires an internet connection to communicate with AI services and may need API keys for OpenAI or local Ollama setup.
- All analysis happens through conversational interfaces that produce visualizations and downloadable reports.

Regional Programme for Health Systems Strengthening and NTD Elimination

NTD Data Systems Strengthening

- Data systems are a strategic investment, not a technical afterthought
- Digital integration offers high returns for both public health and health-system strengthening
- AUDA-NEPAD can play a convening and standard-setting role, ensuring coherence across partners
- Strong NTD data systems directly support Agenda 2063, universal health coverage, and equity

Integration of NTD indicators into DHIS2 & interoperability

- 7 Country focus: Kenya, Uganda, Burundi, URT, DRC, STP, Ethiopia
- Varying levels of DHIS-2 optimization by country
- Project aiming to optimize DHIS2 by
  - Needs analysis
  - System modifications
  - Training
  - IT equipment
  - Mentoring
  - Cross-country sharing of best practices facilitated by REC

Next Steps

Countries primarily rely on a mix of regional, national, and global digital platforms for Neglected Tropical Diseases (NTDs) data management and surveillance.

- Mainstream PC-NTD indicators into national DHIS2/HMIS. Integrate routine data (MDA coverage, cases) using the WHO NTD Overarching Module and link with LMIS for commodities.
- Enhance interoperability, seamless data flow between ESPEN Collect/Portal and national DHIS2/HMIS (via APIs or automated exports) .
- Leverage AI and digital tools
- Data strengthening addendum in 2026–2030 NTD Master Plans: Include clear targets for data governance, quality, capacity building, and integration into primary health care.
- Build capacity and promote data analysis and use for planning and decision making

Strategic role of AI and Advanced Analytics

Aida Dodo, Dimagi

The Global Landscape: AI in Public Health

Evolution

Predictive AI
(outbreak modeling)

Generative/Agentic AI
(real-time assistants)

Transitioning from "Predictive AI" to "Generative/Agentic AI".

The Shift

Static Data Dashboards

Conversational Intelligence
(Understands Context)

Moving away from static data dashboards toward conversational intelligence that understands context.

Current Use Cases

- Automated medical scribing

- Supply chain forecasting

- Personalized clinician training

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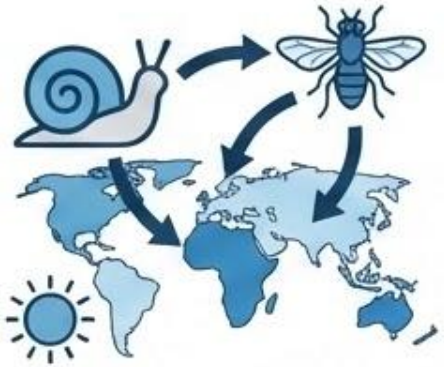
The Broader AI Frontier for the 2030 Roadmap

Drug Discovery & R&D: AI identifies new molecules and candid for NTD medicines years faster than traditional labs.

Advanced Diagnostics: Machine Learning and computer vision are **identifying pathogens in the field** with smartphone-based microscopic analysis.



Vector Control: AI-driven ecological modeling predicts the movement of snails or flies based on climate shifts.

The Missing Link: While these innovations are vital, they all rely on one thing: The ability to access and act on data.

Closing the “Roadmap Gap”

- Context: The 2021–2030 NTD Roadmap was conceived before the current AI revolution.

- The Problem: “Data Friction"—the hours lost sifting through hundreds of manuals and fragmented spreadsheets.

- The Opportunity: AI acts as the “Intelligence Layer" that allows managers to spend less time finding data and more time acting on it.

Practical AI Applications Across the NTD Cycle

Data Quality: Moving from "Is this cell empty?" to "Does this number make sense in context?"

Analysis: Instant natural-language trend visualizations (e.g., 'Show me MDA coverage vs. prevalence over 5 years').

Decision Support: Real-time integration guidance (e.g., 'What are the WHO safety protocols for co-administering drugs X and Y?').

Project Background

Current Central Data Hub (ESPEN Portal)

Primary repository for field data (Collect), JAP uploads, and coverage dashboards.

Manual Data Friction Bottleneck

Time lost sifting through PDFs and sheets to interpret guidelines.

Future GenAI Expert Engine

Transforms static store into instant guidance access without opening documents.

Adoption, Governance & Local Ownership

Improving User Engagement & Accessibility

- Multilingual support
- WhatsApp adaptation of the ESPEN GenAI Assistant
- Deployrnent of a v2 ESPEN website chat widget
- Improved access to maps on the ESPEN Portal

Increasing Operational Efficiency

- Development of v1 JAP (Joint Application Package) Process Assistant
- AI support bot on WhatsApp for campaign workers
- Development of v1 AI Supported ESPEN Collect Protocol Reviewer
- Scoping exercise for multimodal capabilities exploration

Ensuring Long-Term Sustainability & Local Ownership

- User centred design principles
- Advisory body to oversee development
- Handover to an African-based technology partner

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Case Study: The ESPEN GenAI Assistant

The assistant intelligently determines the user's intent. It then queries multiple trusted data and knowledge sources from the ESPEN database and ESPEN's recommended resources simultaneously to deliver an accurate, cited answer. The entire chatbot is built on Open Chat Studio, an open-source chatbot building platform.

Core Capabilities

- Data Retrieval: Instantly query specific data points.
- Trend Analysis: Generate trend visualizations over time.
- Integrated Campaign Planning: Provide information for integrating campaigns by leveraging the Campaign Hub.
- Document & Knowledge Synthesis: Summarize and explain complex topics from multiple official sources, such as WHO road maps and guidelines.
- Portal Navigation & Resource Finding: Help users find the exact location of reports, maps, and tools on the ESPEN Portal.

Solving Bottlenecks: The JAP Process Assistant

Currently in development, a dedicated 4-step tool for ESPEN teams and countries to expedite their JAP Submissions:

1. Validation

Check if correct form has been submitted for review

2. Gate

Confirms before proceeding with advanced calculations of comparing against existing ESPEN data

3. Computation

Comparison against historical submissions, form integrity & ESPEN data

4. Output

CSV file with errors flagged, AI executive summary

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Conclusion

Vision: AI as the engine that transforms raw data into elimination action.

THANK YOU

13-16 April 2026
Lilongwe, Malawi

Start Using the improved ESPEN GenAI Assistant:

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ESPEN Expanded Special Project for Elimination of Neglected Tropical Diseases

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ANNUAL MEETING OF NTD PROGRAMME MANAGERS IN AFRICA

SESSION 7
Digital acceleration and regional data platforms
9:30 -10:30

Campaign Health Hub: country experiences (TFGH)

Health Campaign Intelligence Hub: Country Experiences

- **7th Annual NTD Program Managers Meeting,**
- **Leveraging innovative tools and sustainable financing to advance NTD elimination in Africa,**
- **13-16 April, 2026, Lilongwe, Malawi**

HEALTH CAMPAIGN
EFFECTIVENESS COALITION
Strengthen Systems. Maximize Impact.

The Health Campaign Effectiveness (HCE) Coalition

Founded in 2020, the HCE Coalition's Program Office is run by the Task Force for Global Health (TFGH)

The Coalition Leadership Team comprises global campaign funders, multi- and bi-lateral institutions, and country representatives

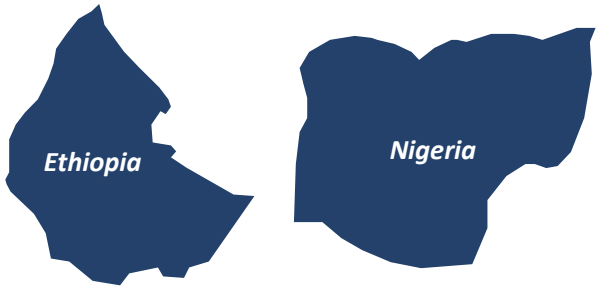
Coalition members work around the world and across multiple disease domains (e.g., NTD, polio, VPDs, malaria, nutrition)

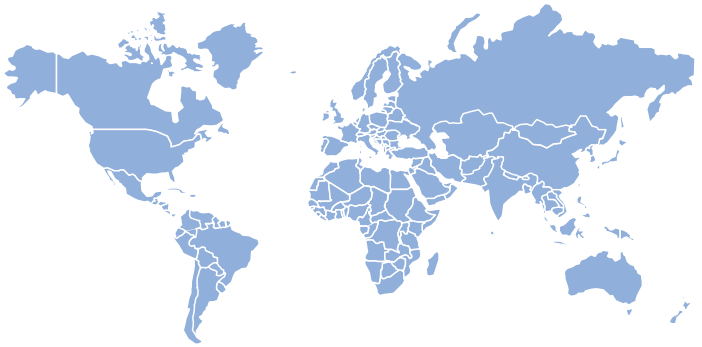
Vision

Country-led health systems use a strategic balance of targeted health campaigns in concert with regular health services to achieve and sustain health-related development goals for all people

HEALTH CAMPAIGN
EFFECTIVENESS COALITION
Strengthen Systems. Maximize Impact.

HCE Coalition CAS Timeline 2023-2028





Phase 1 Proof of Concept

Phase 2 Scale Up [estimated]

2023	2024	2025	2026	2027-28
1. CAS development & endorsement by LT 2. Partner + country socialization	1. **CAS launch & Focus Countries opt-in** 2. **CAS country ownership: customization and planning** (e.g., implementation plan) 3. **CAS MERLA plan developed—TOC defines expected outcomes**	1. **CAS implementation in Focus Countries—early demonstration of value add of collaboration** 2. **Policy change initiated re campaign financing** 3. **Learning, knowledge sharing of best practices** 4. **Alignment of partners to facilitate change**	1. **CAS implementation demonstrates change in Focus Countries** 2. **Analysis of learnings and evaluation of mid-term outcomes** 3. **Policy change implemented: donors and gov** 4. **Model/pathway for scale-up and sustainable change & implementation beyond Ethiopia / Nigeria**	

Mid-term CAS Outcomes

Long-term CAS Outcomes

Health Campaign Intelligence Hub Walkthrough

Acknowledgement

Special thanks goes to colleagues at Linksbridge for producing and sharing this slide set on Health Campaign Intelligence Hub.

Campaign Hub Overview

*The Campaign Hub, established in 2018, is a **cross-program campaign calendar database** designed to enable collaboration and coordination **across four areas: VPDs, Malaria, PC-NTDs, and Nutrition***

Goals & Insights

This aims to provide a variety of insights that support program decision-making

Providing **timely views** into what campaigns are planned

Informing **improved coordination** and **integration** of campaigns

Enabling partners at all levels to **collaborate more efficiently** and effectively

Data Partners & Sources

We compile regular campaign data updates from key campaign partners for each disease area

- **WHO**
- **RBM**
- **GTFCC**
- **Gavi**
- **UNICEF**
- **M&RP**
- **AMP**
- **NTDeliver**
- **Media Monitoring**
- **Country Intel**

POLSIA
ESPEN
IVB
ICG

MNTE
Measles
Nutrition

Information Captured

We capture a variety of standard information across all programs

Planning details
- Campaign type
- Campaign status
- Phase information
- Planned/actual dates
- Funders

Population
- Target population
- Target age groups
- Geographic regions

Program areas
- Diseases targeted
- Interventions used
- Co-deliveries

Coverage
- Administrative
- PCCS
- Geographic
- Therapeutic

Campaign Hub Overview: Data Sources

	AMP	ESPEN	Gavi	GTFCC	ICG	MR&P	Media	NTDeliver	Partner Intel	POLSIA	RBM	UNICEF	WHO IVB	*NTD Calls*	*JRSM*
Cholera												*			
Ebola															
HPV															
JE															
LF															
Malaria	ITN														
MCV										*					
MenA															
Nutrition						*				*		*	*		
Oncho															
Polio			IPV												
Rotavirus															
Schisto															
STH													*		
Td															
Trachoma															
Typhoid															
Yaws															
Yellow Fever												*			

Planned addition/updates

Current Source

Ad Hoc

Weekly

Monthly

Quarterly

Annually

Paused

* Data sources that only represent co-delivered campaigns

Using the Campaign Hub and its data

Ecosystem and program support

Data and dashboards

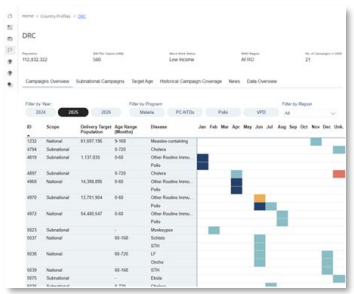
- Gavi IRC app and internal database restructure
- M&RP PSU campaigns tracker
- Malaria database and analytics support
- Integration source for GPEI
- Successful transfer of data models, front-end views, SOPs, and data definitions to partners

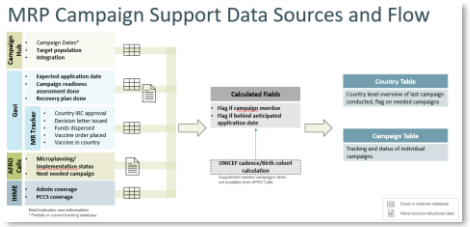
Financial and planning practices

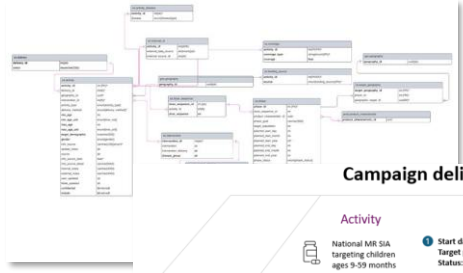
- Polio campaign costing efficiencies
- Target population estimator for Nigeria campaigns
- Analyses on campaign and routine coverage
- VIMC and measles program impact analyses
- Global Vaccine Market Model (GVMM) demand forecasting for vaccine markets
- Ad-hoc support to HCE Coalition, WHO IVB, etc.

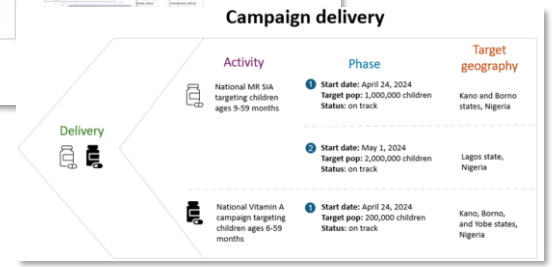
Communications

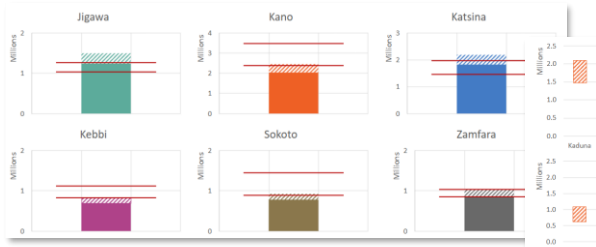
- CE News
- Regular publications to align the community

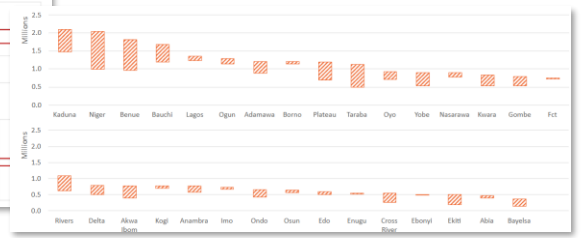


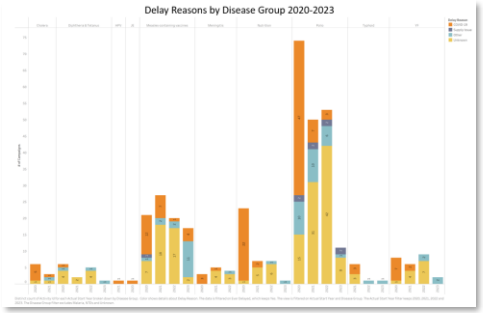


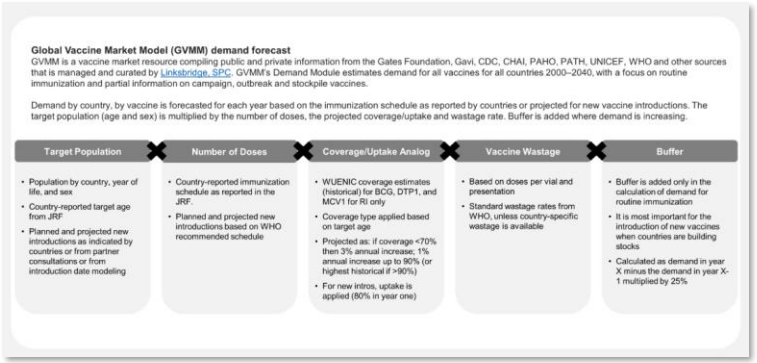




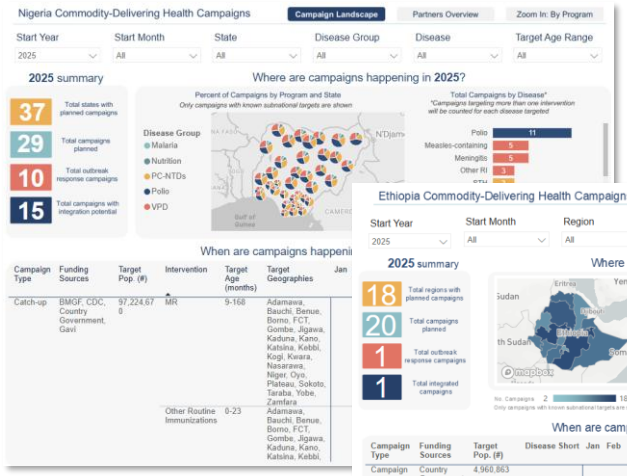


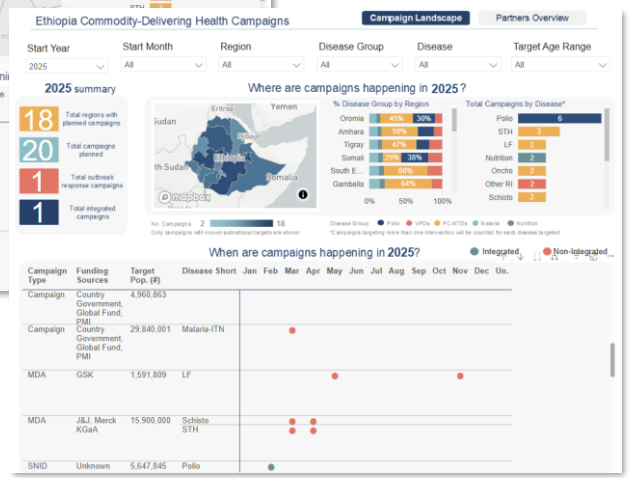


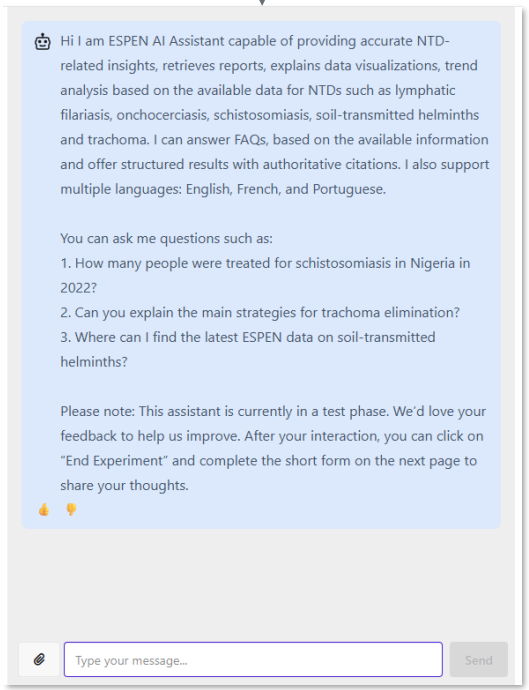


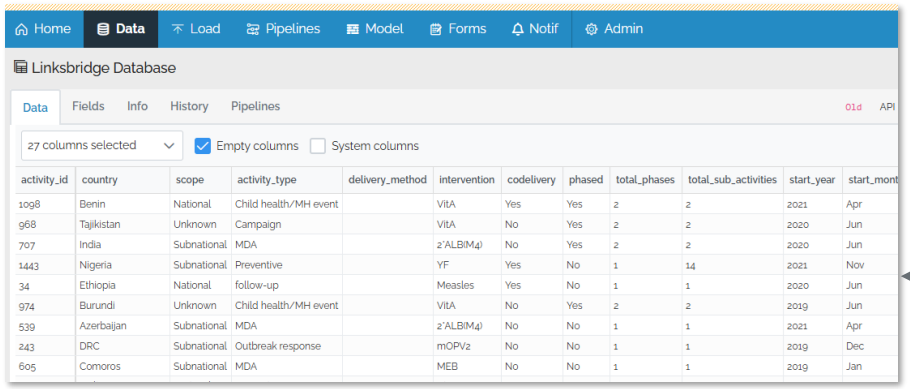


Using the Campaign Hub and its data









Partnerships

Collaborative Action Strategy: Campaign mapping pilot in Ethiopia and Nigeria
HCE Coalition, FMoH Ethiopia, FMoH & NPHCDA Nigeria

NTD AI Chatbot
Expanded Special Project for Elimination of NTD (ESPEN), WHO AFRO

WIISEmart data repository
IVB, WHO HQ

Using the Campaign Hub and its data

Ecosystem and program support

Data and dashboards

- Gavi IRC app and internal database restructure
- M&RP PSU campaigns tracker
- Malaria database and analytics support
- Integration source for GPEI
- Successful transfer of data models, front-end views, SOPs, and data definitions to partners

Financial and planning practices

- Polio campaign costing efficiencies
- Target population estimator for Nigeria campaigns
- Analyses on campaign and routine coverage
- VIMC and measles program impact analyses
- Global Vaccine Market Model (GVMM) demand forecasting for vaccine markets
- Ad-hoc support to HCE Coalition, WHO IVB, etc.

Communications

- CE News
- Regular publications to align the community

In-depth analyses

Missed integration opportunities

IA 2030 DSI Working Group

- Developed optimization algorithm to identify missed integration opps in 7 countries from 2019-2023
- Considered target population, geography, planned start date, precedence, and other program factors
- 85 missed opps identified. Top combinations:
  - Measles + Oral Polio vaccines
  - Oral Polio + Td vaccines
  - Malaria SMC + VitA supplementation
  - Albendazole [for STH] + Oral Polio vaccine

Identifying PZQ codelivery opportunities in four countries

NTD Program

- 14 codelivery opps identified. Most common:
  - Polio (8/14)
  - Malaria SMC (2/14)

Partnerships

Collaborative Action Strategy: Campaign mapping pilot in Ethiopia and Nigeria

HCE Coalition, FMoH Ethiopia, FMoH & NPHCDA Nigeria

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IVB, WHO HQ

Country Use Cases: Nigeria & Ethiopia Campaign Mapping

Country Request

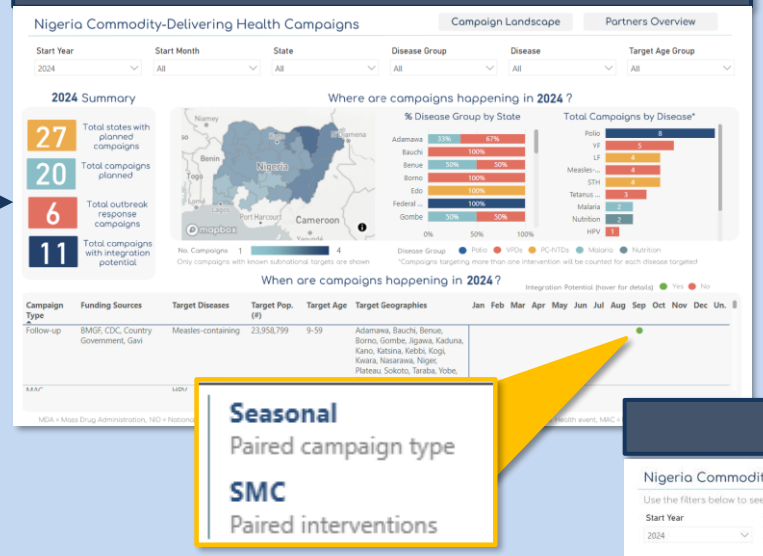
Country HCE Collaborative Action Strategy teams requested support to **map campaigns** occurring in the next three years **to inform program implementation.** Teams expressed the need to:

1. Harmonize campaign planning **data management** across programs
2. List **stakeholders** involved in campaign planning, funding, and delivery
3. Highlight potential opportunities for **collaboration and integration**
4. Identify opportunities for improved **effectiveness** of campaigns

Linksbridge Solution

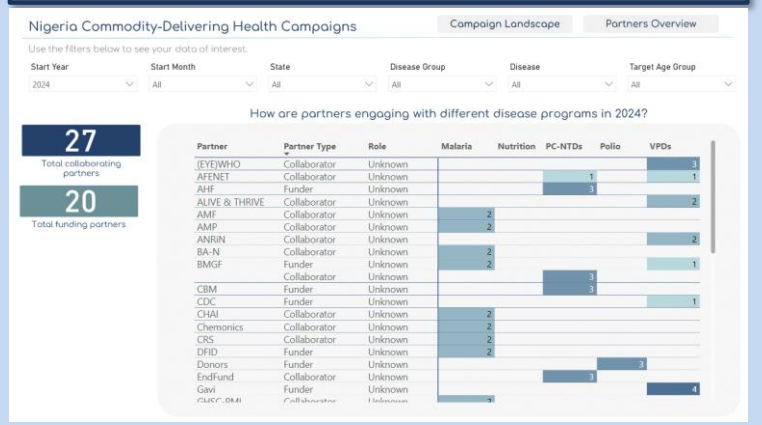
Linksbridge piloted the Nigeria and Ethiopia Campaign Mapping and Integration Tool (adapted from the global Campaign Hub database) to support country efforts to increase campaign efficiencies, promote integration and collaboration, and optimize resources for campaign implementation.

View 1: Campaign and Compatibility Mapping



This tool is used to **map all campaigns** happening in the country and identify **potential opportunities for integration** between campaigns.

View 2: Stakeholder Mapping



Currently, the tool can answer the following key questions:

1. ***What** campaigns are happening, **where**, and **who** are they targeting?*
2. *Who is **funding** the campaigns?*
3. *Which campaigns have **integration potential**?*

Overview: CAS Implementation in Ethiopia

Ethiopia, a CAS focus country, is positioned as a pioneer in a new approach toward campaign effectiveness.

Background

The **Health Campaign Effectiveness (HCE) Coalition** was created in 2020 to improve coordination between growing global health campaign programs.
In 2023, it led the co-development of the **Collaborative Action Strategy (CAS) for Campaign Effectiveness** with 50 global, regional and country-level partners.

Some CAS objectives in Ethiopia

- **Reduce Fragmentation and Enhance Coordination** through stronger ownership and collaboration among campaign partners
- **Streamline Monitoring, Evaluation, and Learning** to enhance information sharing & improve reach
- **Create Efficient, and Integrated Campaigns** including co-delivery of services where appropriate
- **Harmonize Funding Processes** from campaign donors & gov't to support integrated & cost sharing approaches

Opt-in

Customize

Plan

Implement

In 2024, Ethiopia opted into the CAS process, because it provides solutions to its challenges and aligns with its priorities.

*A cross-program TWG customized the global CAS into a **Ethiopian version (E-CAS) with 11 country-specific recommendations** across Planning & Implementation, MERLA, and Financing.*

*A **detailed implementation plan** was drafted with roles, timelines and costs. Campaign integration opportunities were mapped using a specific matrix.*

*In 2025, E-CAS is being formalized and Ethiopia tested its **implementation nationwide** with an integrated measles, RI, nutrition and other MCH campaigns.*

CAS Implementation: Institutionalizing Campaign Coordination to Strengthen PHC

Ethiopia is operationalizing the Collaborative Action Strategy for Campaign Effectiveness (CAS) as a government-owned reform platform — moving from episodic integration to systematized coordination across immunization, nutrition, NTDs, NCDs, MCH, and malaria programs.

1

The Problem

Between 2019 and 2025, Ethiopia conducted an average of **14 health campaigns annually**, often operating in isolation with minimal coordination. This fragmentation led to several critical challenges:

- Duplication of efforts and resources across programs
- Significant strain on subnational health systems, particularly at the district and community levels
- Campaign fatigue among health workers and the population due to uncoordinated demands
- Vertical program silos that prevented the realization of efficiency gains and integrated service delivery.

2

The Solution: E-CAS

In response, Ethiopia proactively customized the global Collaborative Action Strategy (CAS) into its own Ethiopia CAS (E-CAS)

- Developed 11 country-specific recommendations tailored to the national context and health priorities
- The E-CAS framework is built upon the principle of **"One Plan, One Budget, One Report",** fostering a unified approach to campaign management.
- E-CAS is **government-led**, spearheaded by the State Minister for Health, which ensures long-term sustainability and ownership of the reform agenda.

3

2025 Integrated Campaign Results

The first nationwide integrated campaign in 2025 successfully delivered five essential health services through a **single, coordinated platform**. This integrated approach yielded significant improvements in coverage and operational efficiency:

- Measles SIA + Routine Immunization Catch-Up
- Vitamin A supplementation + Deworming
- Sick Child Screening

99%
Measles Coverage
Up from 98% in previous campaigns

+27%
Vitamin A Supplementation
Significant increase in reach

+25%
Deworming Coverage
Increased access for children

60%
Reduction in Project Time
From 25 days to 10 days for campaign preparation

Key Wins

- Operational feasibility of **integrated campaigns proven at a national scale**
- **Cross-program coordination** structures are now active and functional
- **Comprehensive campaign mapping** and an integration matrix have been completed and are in use
- **Strong political will and commitment** sustained at highest levels of government, ensuring continued progress

HEALTH CAMPAIGN EFFECTIVENESS COALITION
Strengthen Systems. Maximize Impact.

The Solution

1. The HCE Coalition undertook 3 years of research in 15 countries, which demonstrated benefits and best practices associated with better coordinated and integrated campaigns

Different campaign components were piloted across Kano, Oyo and Yobe, with varying degrees of integration

Key:	Full integration	Partial integration	Not integrated

Campaign Component	Kano	Oyo	Yobe
Microplanning	• **Partial** (microplanning occurred late and was only partially integrated at a time with each times initial microplanning had already occurred. Malaria teams' inability to full integrate was due to its microplanning being finalized much earlier in the year)		
Training	• **Partial** (NTD was included in the training manual, but it was limited; retraining for NTD team separately occurred and overall training had challenges)		
Stakeholder Coordination	• **Partial** (planning meetings included teams across domains but with inconsistent attendance)		
ACSM	• **Partial** (materials included messaging across domains but with challenges and missed opportunities)		
Logistics & Supplies	• **Not integrated** (though visibility of MR / Polio campaign helped obtain NTD commodities that otherwise would likely have not arrived)		
Financing & Budgeting	• **Not integrated**		
Data, Monitoring & Evaluation	• **Partial** (ODK was integrated though could have included more NTD and malaria related elements; evening review meetings at state and national level included teams across domains but with challenges; data tools – tally sheet, register and denominators were not integrated)		
Team Composition & Implementation	• **Partial** (Polio & NTD house-to-house team were integrated but working together took retraining; NTD, polio teams, and MR team members did refer but in a limited capacity; sharing workload was limited)		

N-CAS had demonstrated numerous achievements across campaign components

First-time collaborative cross-program planning

- ✓ Joint planning across FMOH and NPHCDA bringing together NTD, malaria, and immunization focal points enabled the alignment on joint implementation and coordination

Cross-program best practice sharing

- ✓ Domain-specific norms were beneficial to Evening review norm was a benefit to NTD teams (supported daily supervision)

Stronger stakeholder and community engagement

- ✓ Consistently engaging and coordinating with cross-program stakeholders and community & religious leaders helped amplify campaign visibility and reach hesitant or unreached households

Efficient drugs and vaccines' tracking

- ✓ Drug tracking was strong and NTD teams likely benefited from N-CAS and immunization team visibility

Real-time data monitoring and verification

- ✓ Data reporting and verification done in real time using WhatsApp, Google Sheets, and cross-checks, enhanced data accuracy and rapid decision-making

Tailored implementation approach

- ✓ Adaptive implementation in security challenged areas through decentralized planning, cluster meetings, and flexible scheduling sustained progress despite insecurity

THANK YOU
MERCI BEAUCOUP
OBRIGADO

Digital solutions to improve microplanning (Crosscut)

Today's presentation has five parts.

1

The Digital Landscape

There is growing use of digital solutions to plan all aspects of campaigns for immunization, malaria, and NTDs.

2

The Microplanning Opportunity

NTD programmes are already microplanning, and WHO guidance shows a clear path to higher MDA coverage — but manual workflows and a mapping gap are holding back progress.

3

The ESPEN Geospatial Microplanner

ESPEN introduced the Geospatial Microplanner technology in 2025 to improve planning for mass drug administrations.

4

What We've Learned

Microplanning helps to reach more communities through better use of operational maps.

5

Path Forward

NTD programmes are expanding use of maps and digital solutions to improve MDA results.

A maturing digital ecosystem now supports every stage of health campaign delivery, including microplanning.

Data Providers

WorldPop

Open Street Map

HDX Humanitarian Data Exchange

GRID3

…and others

Microplanning

Crosscut

IASO

Reveal REDEFINING PRECISION

…and others

Campaign Data Collection & Monitoring

ESPEN COLLECT

CommCare by dimagi

ODK

Kobo Collect

RapidPro

…and others

Campaign Supply Chain

Red Rose TECHNOLOGIES

OpenLMIS

mSupply

…and others

Health Information System

dhis2

…and others

The above is a list of some but not all campaign technologies. Some technologies have capabilities across categories: in these cases, only one category is shown.

Better Microplanning Directly Improves NTD Supply Chain Performance

Accurate population data and operational maps — the core outputs of microplanning — are prerequisites for a well-functioning drug supply chain.

Quantification & Drug Requests

- NTD supply chain foundation is the annual drug request submitted to WHO.
- Accurately estimating the need for PC-NTD drugs is a key step in forecasting and quantification.
- When community lists are incomplete or population estimates are wrong, countries either request too few drugs (stockouts) or too many (wastage and write-offs).
- Improved microplanning can produce more accurate eligible population counts
- This improvement flows directly into better drug requests and better subnational allocations of resources.

Improved microplanning is a well-established pathway from better data to higher MDA coverage

Microplanning theory of change pathway

Step 1
Integrated, visible data

All community data in one place.

Before MDA

Step 2
Better planning decisions

Plan who gets visited, where, and by whom — before MDA begins.

Before MDA

Step 3
Improved supervision coverage

Supervisors reach more communities. Gaps get caught early.

During MDA

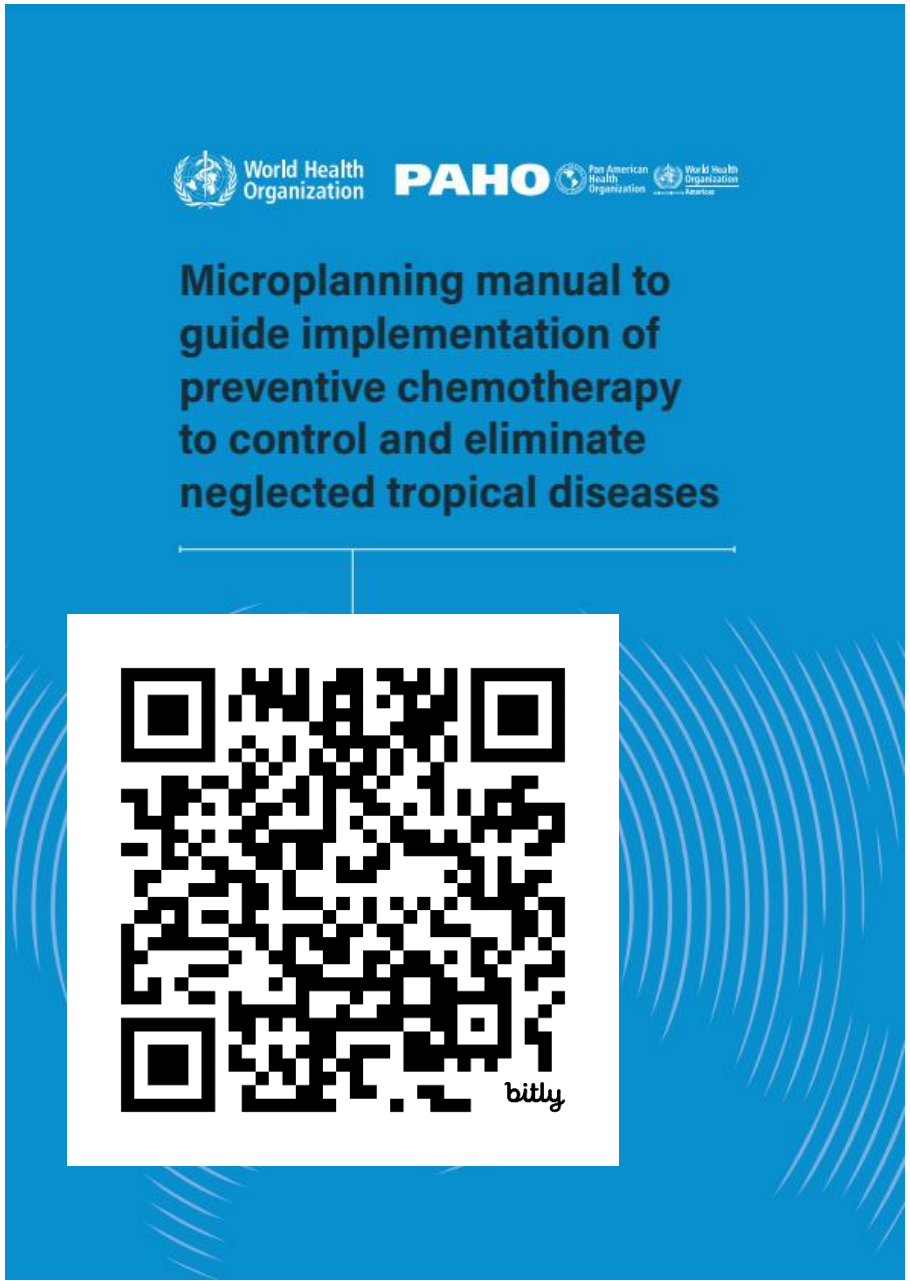
Step 4
More communities treated

Fewer communities are missed. Treatment numbers are more complete.

Step 5
Higher MDA coverage

Treatment coverage above minimum threshold; progress toward 2030 NTD Roadmap targets.

WHO provides guidance for NTD microplanning to improve MDA effectiveness



IU Staff:

Preparing for microplanning	Month					
	01	02	03	04	05	06
Step 1. Prepare map of IU and ensure all areas are covered	x	x				
Step 2. Review existing data to identify challenges, priority areas and populations	x	x				

First-line supervisors:

Microplanning process: Supervisory area	Month					
	01	02	03	04	05	06
Step 1. Prepare operational map of SA	x	x				
Step 2. Estimate target populations	x	x				
Step 3. Select drug distribution channels		x				
Step 4. Plan activities to reach / treat target populations		x	x			
Step 5. Calculate resources and define logistics		x	x			
Step 6. Monitor coverage / use data for action				x	x	

IU Staff:

Microplanning process: Implementation unit	Month					
	01	02	03	04	05	06
Step 1. Validate SA maps to ensure that all areas are covered		x	x			
Step 2. Validate estimated number of the target population at SA and IU levels		x	x			
Step 3. Ensure priority groups are targeted and validate approaches to reach them		x	x			
Step 4. Compile microplans to ensure the most effective approaches			x			
Step 5. Mobilize resources and support logistics			x	x		
Step 6. Monitor coverage and make decisions based on progress				x	x	x

We assessed the state of NTD Microplanning:
56 survey respondents and 13 interviews across 27 AFRO countries

Microplanning is widely practiced in NTD programs.

82% of countries report conducting microplanning, and programs believe the practice should expand further.

Implication: The challenge is not adoption, but improving how microplanning is implemented.

NTD microplanning workflows are manual and fragmented.

97% use Excel to aggregate population estimates

91% exchange templates via email

67% report challenges aggregating population data

Implication: Planning relies on spreadsheets and email chains, slowing data aggregation and introducing error risk.

Operational maps are the one WHO microplanning step NTD programmes consistently skip.

47% rarely or never prepare operational maps to support MDA planning.

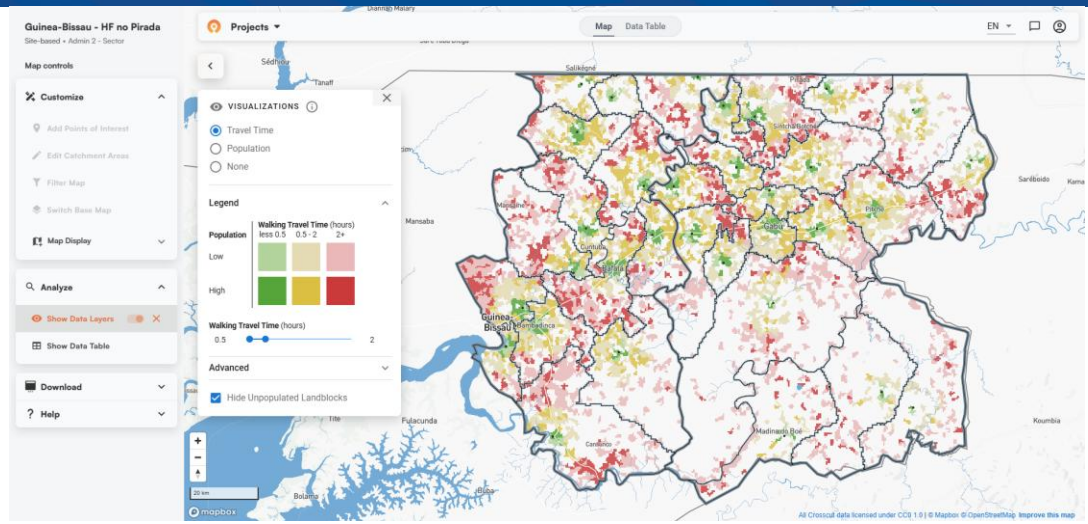
Implication: Programmes want to expand microplanning, but operational maps remain the clearest gap.

The ESPEN Geospatial Microplanner is an easy-to-use software that aims to improve campaign reach through the use of MDA operational maps.

Challenge: Operational maps are the one WHO microplanning step NTD programmes consistently skip.

Response: The Microplanner helps teams to generate operational maps with the goal of reaching more communities

Countries selected from Microplanner features that aligned with their needs



BEFORE MDA: Generate the maps suggested by WHO guidance:

- ✓ Health facility catchment area maps
- ✓ Supervisor territory maps
- ✓ CDD territory maps

BEFORE MDA: Target and plan for hard-to-reach communities:

- ✓ Identify settlements missing from community list
- ✓ Identify communities far from nearby health facilities
- ✓ Identify communities not receiving supervision in previous MDA
- ✓ Identify communities with “never treated” survey responses

DURING MDA: Direct supervision visits to where they are most needed during MDA

- ✓ Integrate with CommCare, ODK, and others to see which communities have or have not been supervised

In 2025, ESPEN supported 4 country implementations and have several others planned for 2026

Nigeria

Geographic Scope:	1 state
Disease:	Oncho
Target Population:	~4.4M
Target Population:	All Eligible Population
Implementing Partner:	The Carter Center

Nigeria

Geographic Scope:	3 LGAs
Disease:	SCH/STH
Target Population:	~0.2M
Target Population:	School-Aged Children
Implementing Partner:	Sightsavers

Guinea-Bissau

Geographic Scope:	2 regions
Disease:	Oncho
Target Population:	~0.6M
Target Population:	All Eligible Population
Implementing Partner:	Sightsavers

Liberia

Geographic Scope:	3 counties
Disease:	Oncho & LF
Target Population Est:	~0.5M
Target Population:	All Eligible Population
Implementing Partner:	Sightsavers

Planned for 2026

Nigeria	Senegal	Liberia	Madagascar	Guinea-Bissau	Burundi	Tanzania	Ghana	Chad
Sightsavers and The Carter Center	CHAI	Sightsavers	Unlimit Health	Sightsavers	Christian Blind Mission	MOH	MOH	Sightsavers

? Plus some others under discussion

African Union | World Health Organization African Region | ESPEN Expanded Special Project for Elimination of Neglected Tropical Diseases | Crosscut

ANNUAL MEETING OF
NTD PROGRAMME MANAGERS IN AFRICA

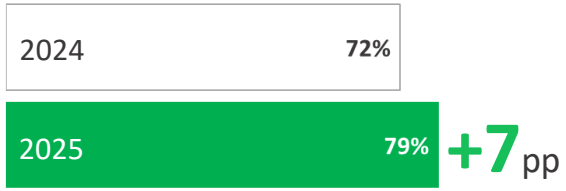
Use of Microplanner in 2025 was associated with higher MDA coverage and supported improved supervision and fewer missed communities

IMPACT ACROSS PILOTS

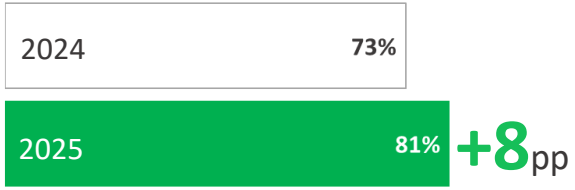
Additional Persons Treated During MDA

+ 61,930 persons

Reported MDA Coverage (%)



Settlements Receiving Supervision (%)



Previously Missed Settlements Receiving Supervision

+ 463 settlements

DRIVERS OF IMPACT IDENTIFIED IN EVALUATION

Improved Data Visibility
Shared spatial views enabled earlier risk identification

Better Coordination
Integrated spatial and supervision data strengthened planning decisions

Improved Equity Targeting
Countries used maps to identify and visit hard-to-reach populations

Flexible Adoption
Countries integrated the Microplanner into their existing workflows

Scalable Technology
3 countries | 4 diseases | 2 languages | 2 partners

Several NTD programs are improving microplanning practices in 2026 to increase MDA effectiveness

- **EXPAND** – More and more programs are engaging in microplanning.
- **SUPPLY CHAIN** – As microplanning improves, programs are improving population estimates for quantification.
- **PLAN EARLY** – Programs are not waiting until the last minute to perform microplanning.
- **MORE MAPS** – Programs are increasing use of operational maps to plan MDAs.
- **INTEGRATE** – Programs are sharing data and coordinating microplanning with other programs (e.g. immunization).
- **MORE DOTS** – Programs are ensuring communities on the treatment list also have dots on the map.
- **MOBILE POPULATIONS** – Programs are adjusting plans and population estimates to target mobile populations.

Interested in learning more?

coite@crosscut.io

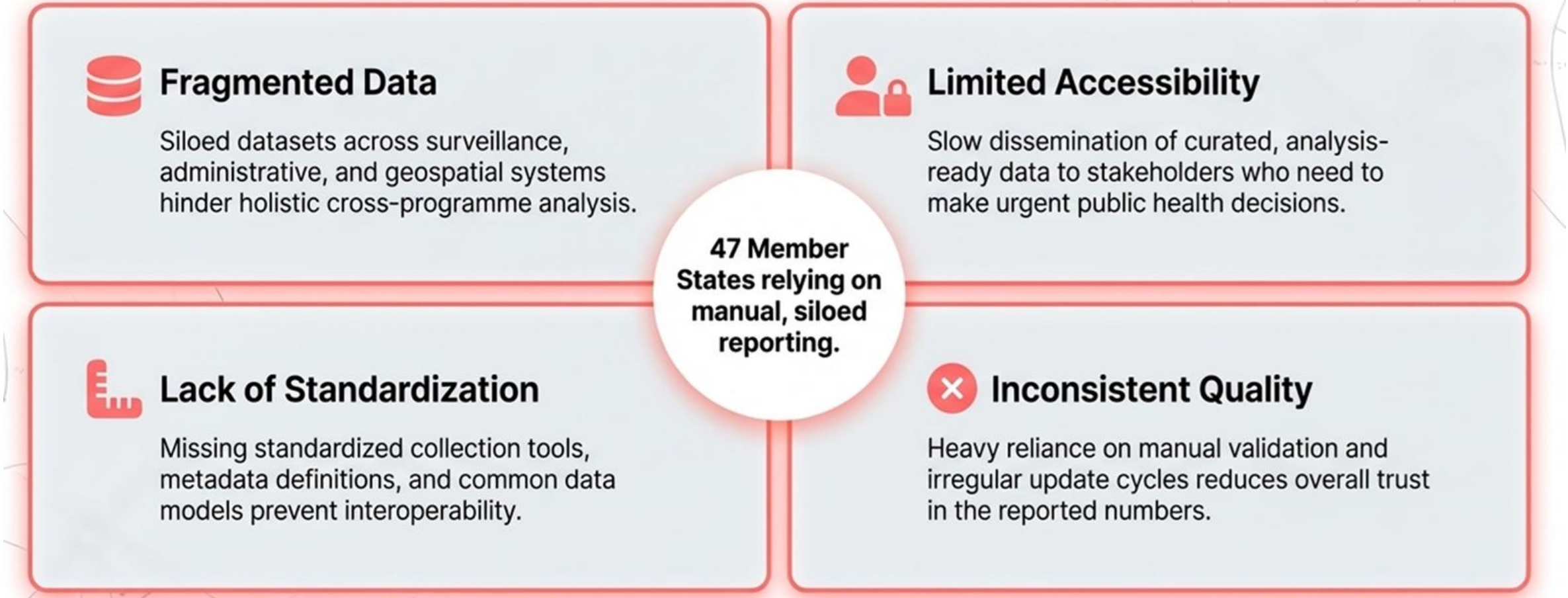
Thank you!

Digital Platforms at WHO AFRO (WHO/ESPEN)

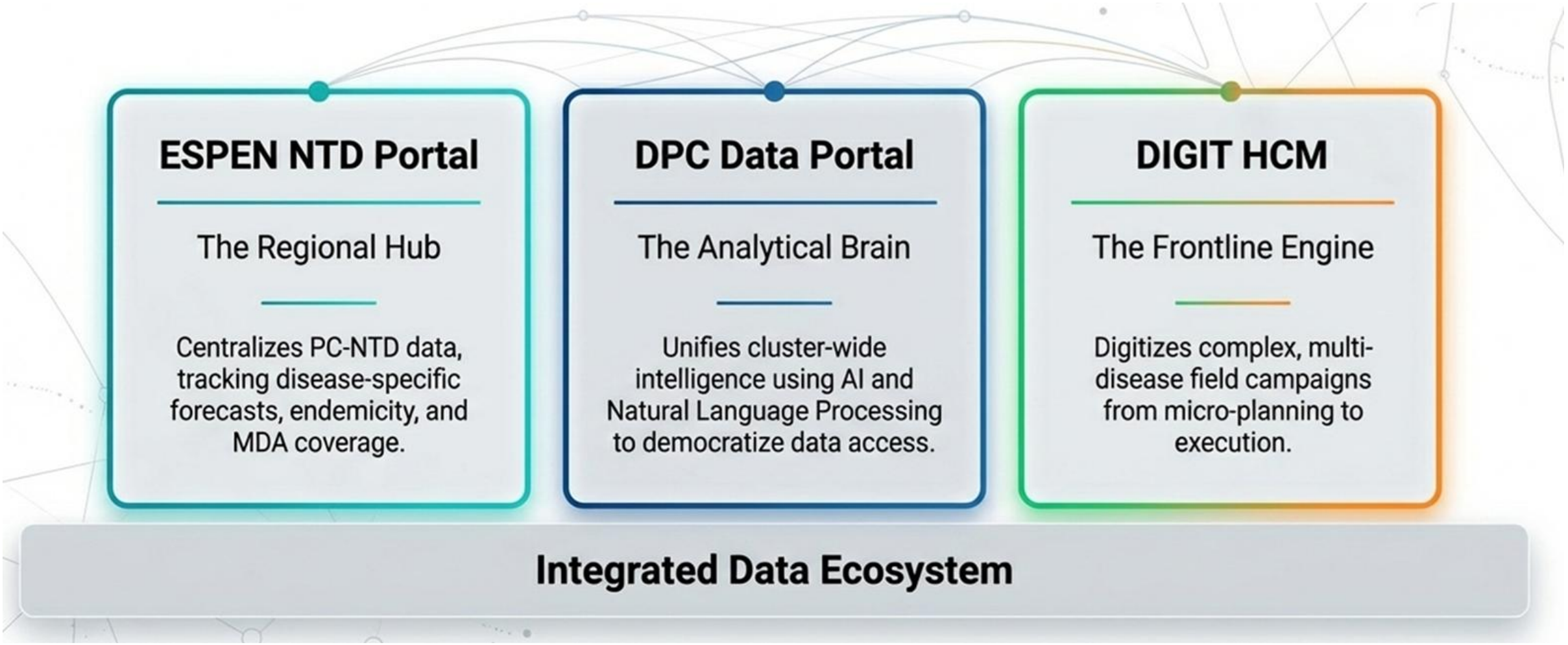
Presentation Overview

- **Introduction**: Digital Health Landscape at WHO AFRO
- **ESPEN NTD Portal**: the Regional Data hub for PC-NTDs
- **DPC Data Portal**: AI-enabled analytics for disease prevention
- **DIGIT Health Campaign Management** (HCM): digitizing field campaigns
- **Wrap-up**: Towards an Integrated Digital Ecosystem

The Case for Digital Health Platforms



WHO-AFRO: Integrated NTD Intelligence Framework



Pillar 1: ESPEN NTD Data Portal v4.0: PC-NTD Hub

April 2017

Launched as the primary public data hub for the 5 PC-NTDs (LF, onchocerciasis, schistosomiasis, STH, trachoma).

The Workflow

Established the core data pipeline: ESPEN Collect (field data) → JAP Upload Tool (reporting) → Portal (visualization).

May 2025

Launch of the v4.0 upgrade.

https://espen.afro.who.int/

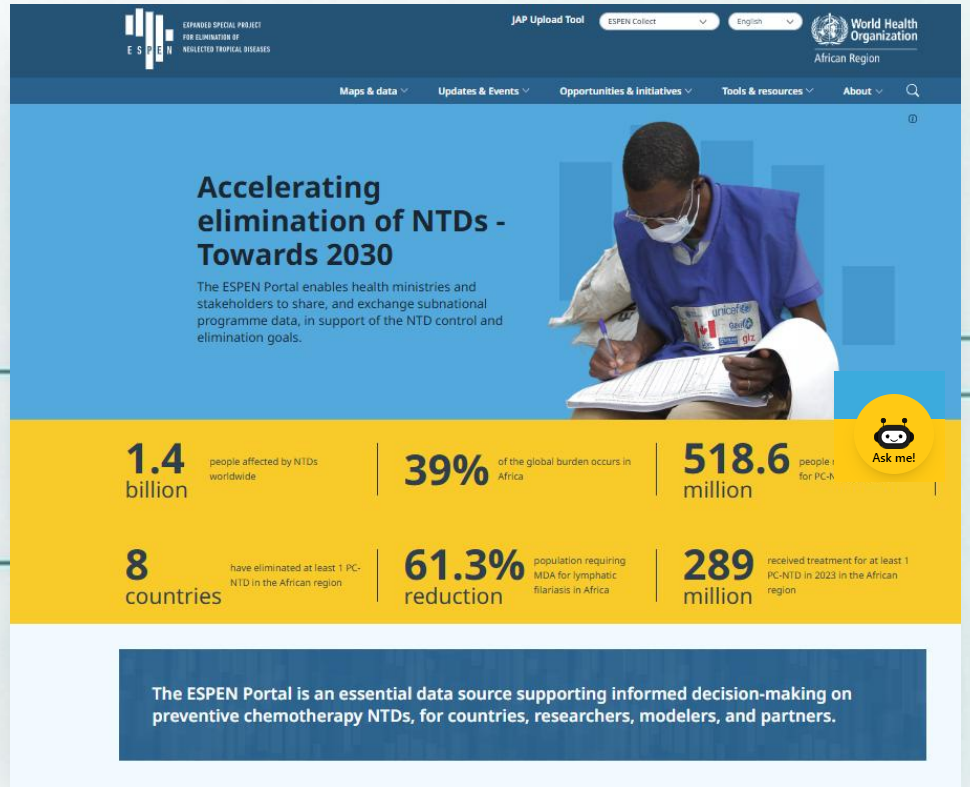
Advanced Analytics and Automation Define the ESPEN Portal v4.0 Experience (https://espen.afro.who.int/)

On-the-Fly Cartography

Generate custom multi-language (EN/FR/PT) static maps dynamically. Filter by disease, intervention type, and year across all 5 PC-NTDs.

GenAI Assistant

A new generative AI chatbot interface allows users to interrogate datasets using natural language queries.



Advanced Planning Tools

Access integrated suites including the Country Health Information Platform (CHIP), Geospatial Microplanner, and Implementation Unit (IU) Planner.

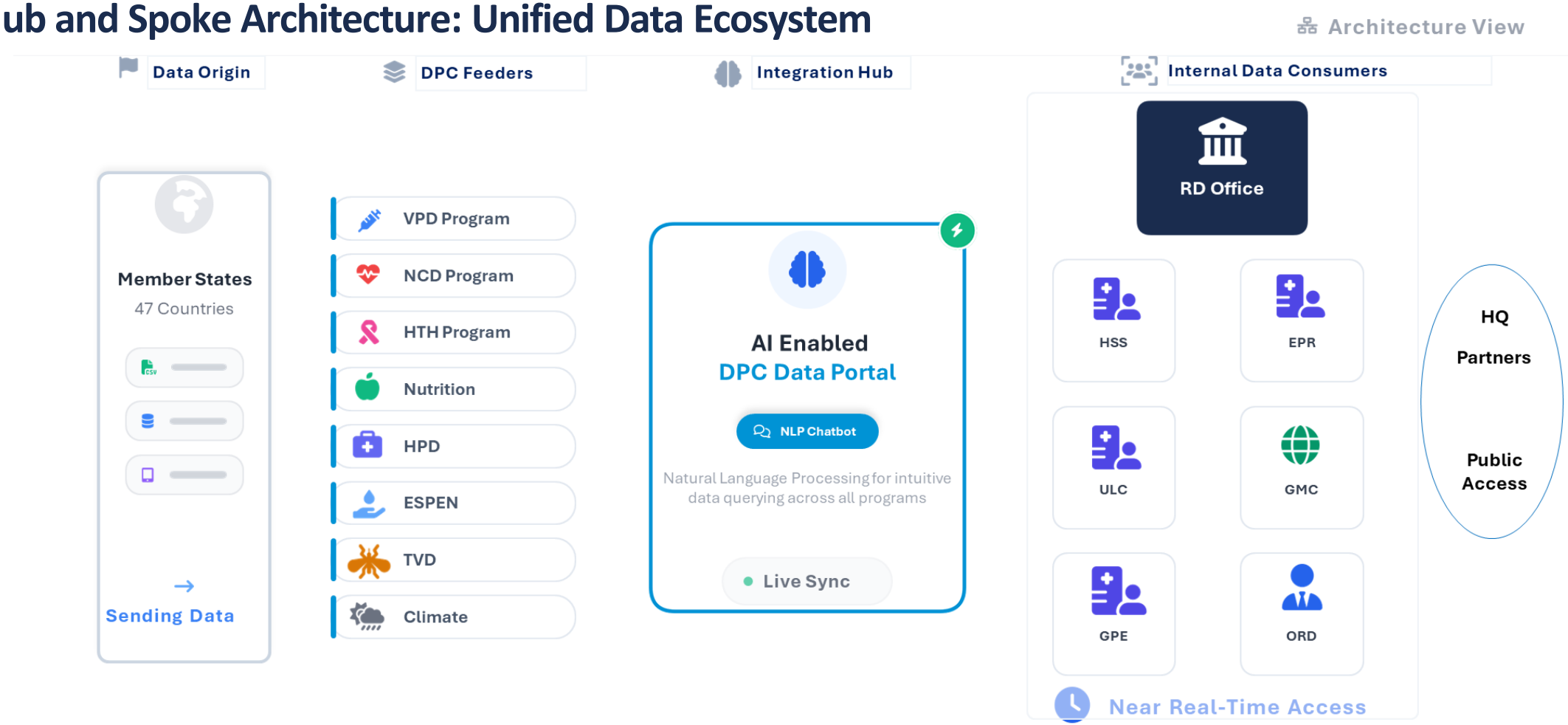
Open Architecture

New APIs allow for seamless external application development and data integration.

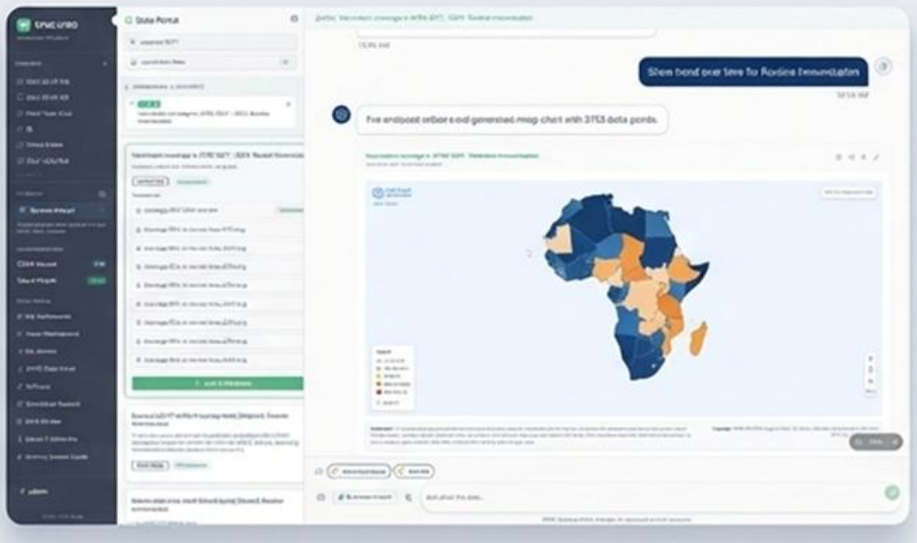
Pillar 2: The DPC Portal: A Unified Framework for Cluster Intelligence (https://dataportal.afro.who.int/)

DPC Data Portal: Vision & Architecture

Hub and Spoke Architecture: Unified Data Ecosystem



Pillar 2: The DPC Portal: A Unified Framework for Cluster Intelligence (https://dataportal.afro.who.int/)



Transitioning from manual data wrangling to intuitive, natural language queries. Users can ask complex questions like 'Show trend over time for Routine Immunization' to instantly generate maps and charts.

- Underpinned by rigorous metadata standards including HL7, LOINC, and SNOMED CT for guaranteed interoperability.

108+
Datasets Published

1.2k
Monthly Views

47
Member States Connected

70%
Time Saved on Manual Processing

DPC Portal: AI-Powered Analytics & Data Products

What We've Accomplished: DPC's Data Journey

Established Infrastructure

- **Integrated DPC Data Warehouse** fully operational serving as central repository
- **DHIS2 Integration** completed for seamless surveillance data ingestion
- **Azure Cloud Infrastructure** deployed ensuring scalability & security
- **CKAN-based Portal** framework established and live

Data Products Delivered

- **Interactive Dashboards** launched for VPD, NCD, and HTH programs
- **Geospatial Visualizations** enabling precise disease mapping
- **Disease Outlook Reports** published on quarterly schedule
- **Country Profiles** and policy briefs disseminated to Member States

Innovation & Standards

- **Standardized Toolkits** developed for unified data collection
- **Automated ETL Pipelines** reducing manual processing time
- **API Access** configured for secure external partner integration
- **Real-time Surveillance** capabilities enhanced for rapid response

Key Impact Metrics

108+ Datasets Published	**1.2k** Monthly Views
47 Member States	**70%** Time Saved

African Union

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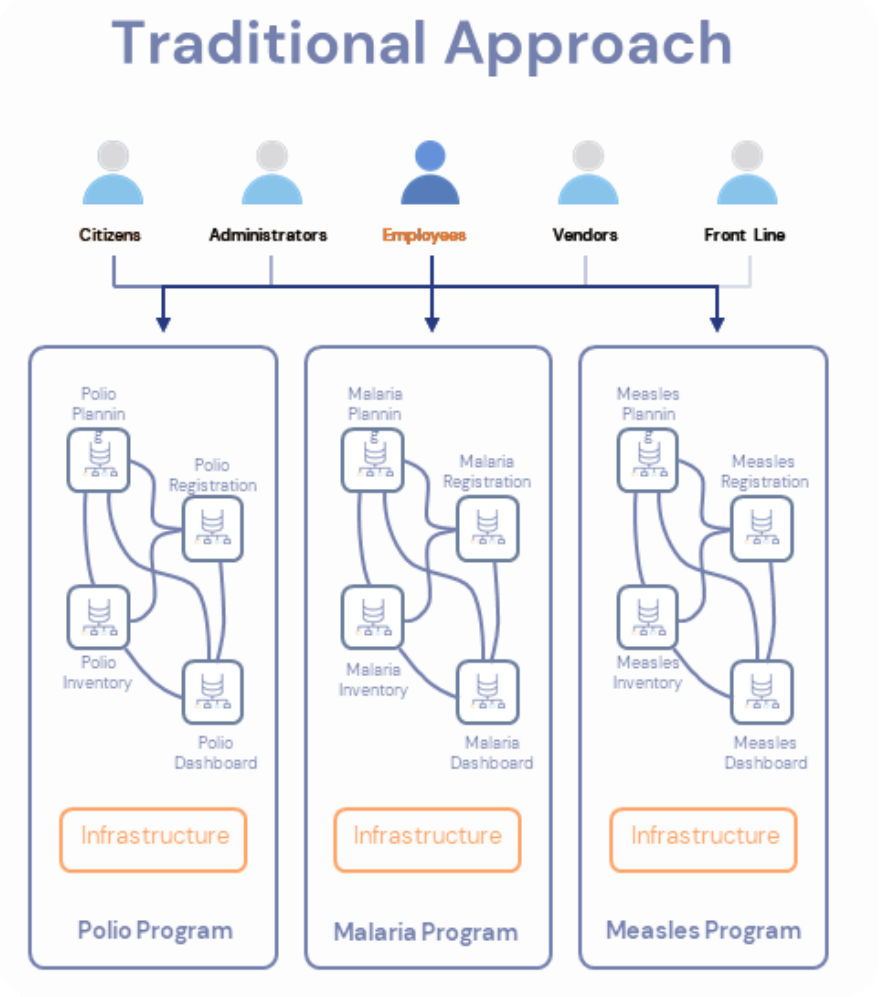
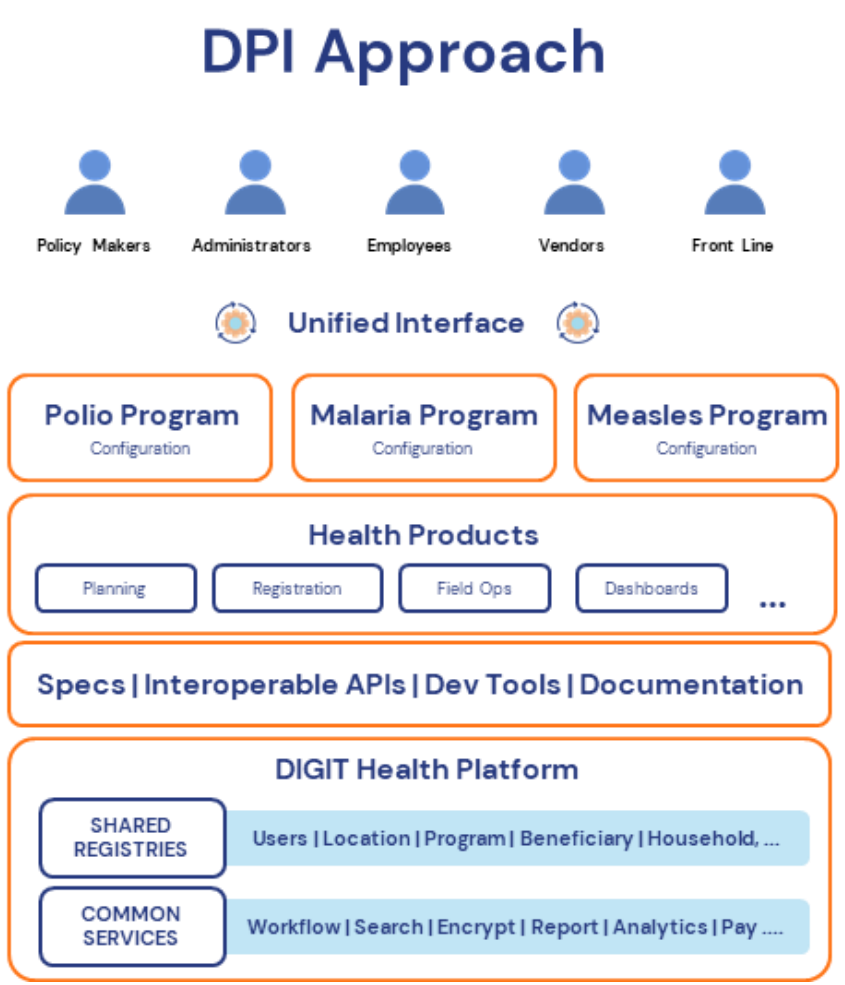
African Region

ESPEN Expanded Special Project for Elimination of Neglected Tropical Diseases

Pillar 3: DIGIT Health Campaign Management

Digitizing Health Campaigns in the African Region





- Single source of data that is reused across programs
- Improved data availability and observability that aids data driven decision making and intervention
- Country ownership and reduced dependency on proprietary tools
- Faster innovation by ecosystem

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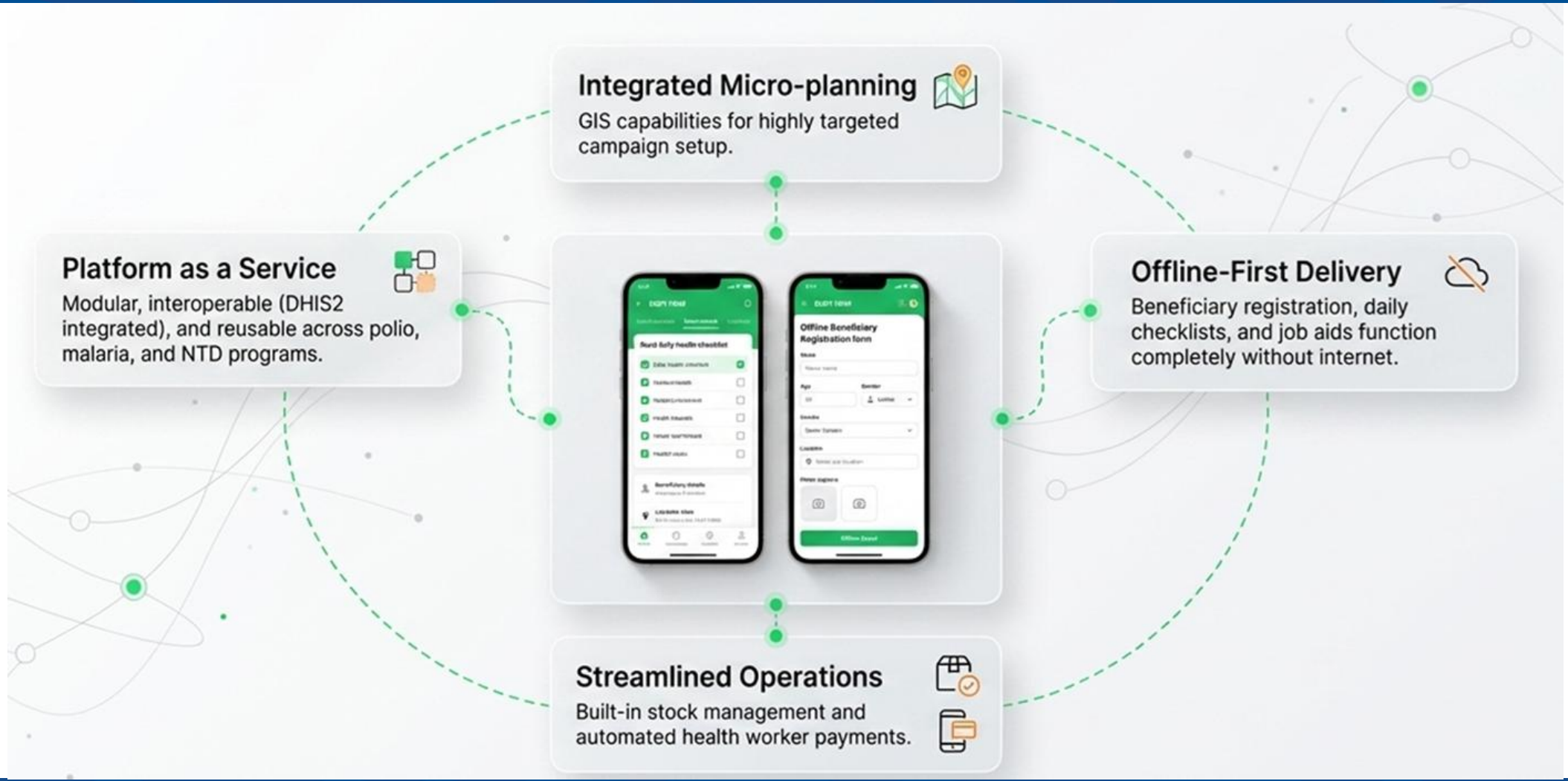
ESPEN EXPANDED SPECIAL PROJECT FOR ELIMINATION OF NEGLECTED TROPICAL DISEASES

DIGIT Health Campaign Management: *Replacing fragmented, proprietary tools with country-owned infrastructure*



Proven impact in the African Region: *Piloted since August 2023 for Malaria, immunization, NTDs, and nutrition interventions*

Footprint & Scale

40+ Million

Population Covered

7 Pilot Countries

- **Malaria:** Benin, Nigeria, Mozambique
- **NTDs:** Senegal, Kenya, Ethiopia
- **Nutrition:** Benin
- **Immunization:** Liberia

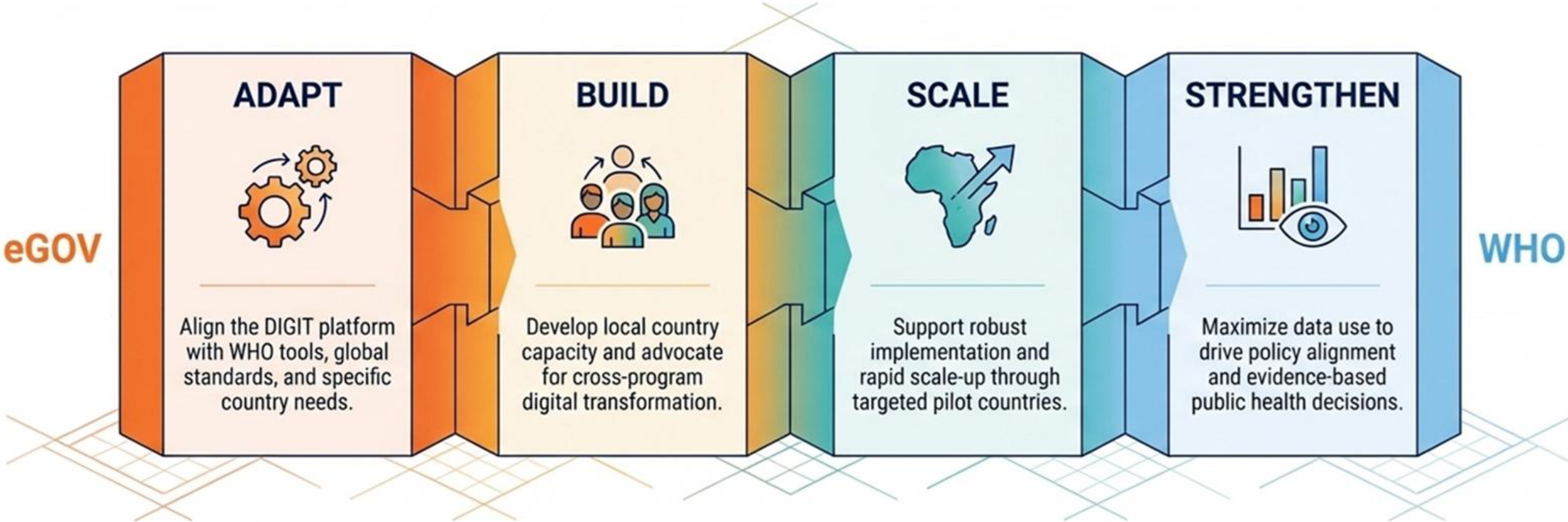
eGov Implementation Progress

- Developed and deployed the DIGIT Health Campaign Management (HCM) platform.
- Collaborated with WHO and national governments on pilot planning and execution.
- Configured the platform for specific health campaigns (Malaria, NTDs, Nutrition).
- Provided technical support and capacity building for local teams.
- Enabled real-time data collection, monitoring, and reporting.
- Facilitated integration with existing systems like DHIS2.

DIGIT Health Campaign Management

Joint Implementation Strategy for the African Region

A coordinated approach to building scalable, interoperable, and country-controlled platforms as a service.



The Way Forward: Building Country Capacity and Driving Adoption

Expand Country Uptake

Transition Member States from proprietary, fragmented systems to open-source WHO-backed infrastructure.

Foster True Interoperability

Continue refining the APIs and shared registries that allow DHIS2, DIGIT, and the DPC Portal to speak the same language.

Strengthen National Capacity

Empower local NTD Programme Managers through targeted training on AI tools, automated dashboards, and digital micro-planning.

Together, we are building a harmonized, data-driven ecosystem to accelerate disease elimination across the African Region.

THANK YOU

13-16 April 2026

Lilongwe, Malawi

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EXPANDED SPECIAL PROJECT FOR ELIMINATION OF NEGLECTED TROPICAL DISEASES

ANNUAL MEETING OF
NTD PROGRAMME MANAGERS IN AFRICA

Health Break

10:30 - 11:00

SESSION 8

The Emerging Role of AI in NTD Programmes: Driving InnovationAcross Surveillance, Diagnostics, and Delivery

10:45 - 11:15

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SESSION 9
Cross-border collaboration for NTD elimination
11:15 - 12:00

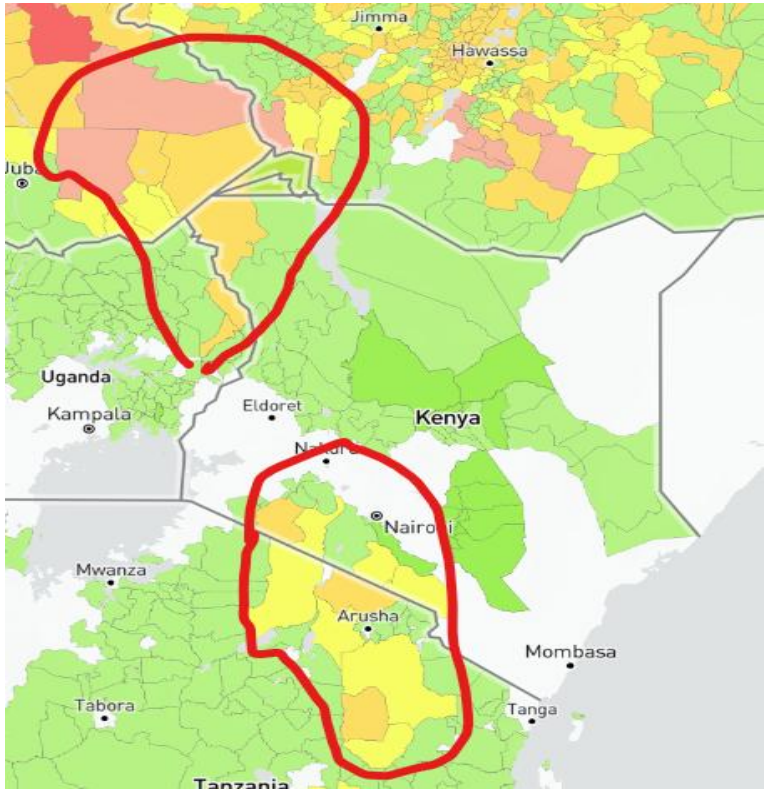
Cross-border NTD initiatives, lessons, operational and governance enablers
Kenya

East Africa NTD Cross-Border NTD Context

- Collaboration with Uganda, Tanzania, Ethiopia, South Sudan none with Somalia
- Ateker Corridor: Kenya, Uganda, South Sudan, Ethiopia
- Maasai Corridor: Kenya & Tanzania
- Highly mobile pastoralist populations

NTD's addressed

- Trachoma
- Lymphatic Filariasis
- Onchocerciasis
- Leishmaniasis (Kala-azar)



Key Activities

- Synchronized MDA campaigns
- Morbidity management and disability prevention
- Impact assessment surveys

a) Joint planning & review meetings

b) Coordination mechanisms

c) Community engagement

Kenya–Uganda Lessons

- Coordination from national to local levels
- Security engagement
- Mobile teams
- Facility linkages & joint reviews

Kenya–Tanzania Experience

- Synchronized MDA
- Contextualized Maasai BCC
- Strong advocacy & supervision
- Improved uptake

Progress & Achievements

- Improved uptake and treatment coverage
- Strengthened inter country coordination
- Joint surveillance and data sharing
- Joint sensitization campaigns
- Joint community sensitization, Radio talk shows & local language messaging
- Cross country learning

Key Challenges

- Migratory populations
- Logistics delays
- Weak WASH integration
- Limited inclusion of some countries

Mitigation Measures

- Mobile outreach teams
- Early logistics planning
- Strengthened coordination
- Joint BCC strategies

Asante sana, Thank you

13-16 April 2026

Lilongwe, Malawi

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ANNUAL MEETING OF
NTD PROGRAMME MANAGERS IN AFRICA

Panel discussion and guided Q&A: Sudan, Ethiopia, Togo, Kenya

SESSION 10

MoU on cross-border collaboration for NTD elimination

12:00 - 13:00

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EXPANDED SPECIAL PROJECT FOR ELIMINATION OF NEGLECTED TROPICAL DISEASES

Lunch Break

13:00 - 14:00

7th ANNUAL MEETING OF NTD PROGRAMME MANAGERS IN AFRICA

Leveraging innovative tools & sustainable financing to advance NTD elimination in Africa

13-16 April 2026

Lilongwe, Malawi

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Parallel Session A – 11.1

Epidemiological mapping study on VL – a critical step for VL elimination

14:00 - 15:30

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Mapping of visceral leishmaniasis in East Africa

THE END FUND

Mapping of Visceral Leishmaniasis in Eastern Africa

NTDs PM meeting

Lilongwe Malawi, April 2026

The END Fund - Who We are and How We Work

The END Fund is a collaborative philanthropic fund dedicated to eliminating the most prevalent NTDs.

Goal: To end the most prevalent NTDs by 2030 and enable 500 million people to live free of NTDs

Mission: To control and eliminate the most prevalent NTDs

Vision: To ensure people at risk of NTDs can live healthy and prosperous lives

Capital is pooled by investors, which enables the END Fund to:

- Deliver treatment at scale
- Accelerate innovations that improve the efficiency and efficacy of drug delivery
- Provide program oversight to monitor quality and impact
- Bring together partners, advocates, and investors
- Leverage investors' capital and core strengths

The END Fund's Disease Summaries - Six NTDs

INTESTINAL WORMS

Hookworm, roundworm and whipworm, which live in the intestines and cause malnutrition, anemia, stunted growth, and impaired cognitive function.

Over 1.5 BILLION PEOPLE IN NEED OF TREATMENT

BILHARZIA

Parasitic worm infection that can cause malnutrition, impair growth and cognitive development, and damage the bladder, kidneys, liver, and intestines.

893 MILLION PEOPLE IN NEED OF TREATMENT

ELEPHANTIASIS

Parasitic roundworm infection that can cause swelling of parts of the body due to fluid build-up. This can lead to severe disfigurement and disability.

OVER 657 MILLION PEOPLE IN NEED OF TREATMENT

TRACHOMA

Bacterial infection of the eye. Repeated infections can cause the eyelid to turn inward and eyelashes to scratch the cornea, leading to extreme pain and irreversible blindness.

178 MILLION PEOPLE IN NEED OF TREATMENT

RIVER BLINDNESS

Eye and skin infection caused by parasitic worms that leads to extreme itching, rashes, skin nodules, and vision impairment.

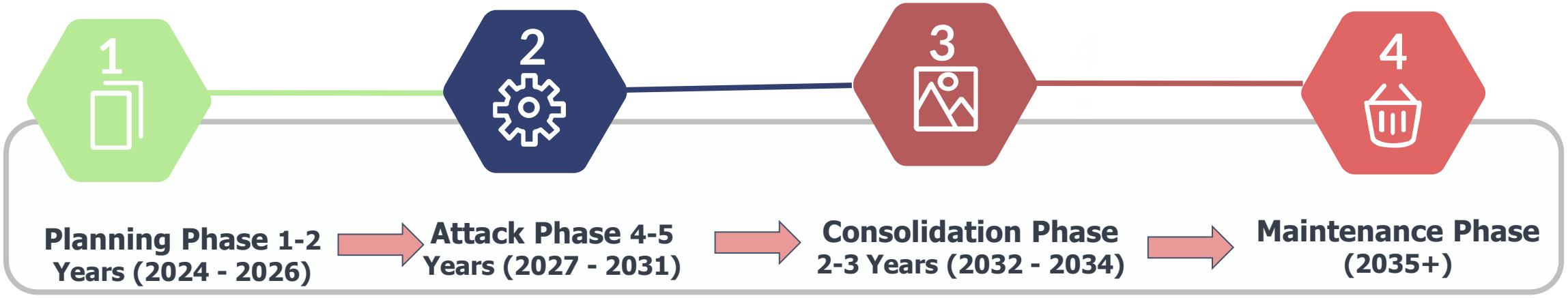
250 MILLION PEOPLE IN NEED OF TREATMENT

KALA AZAR

Parasitic worm infection that causes irregular bouts of fever, weight loss, spleen and liver enlargement, and, if untreated, it is 95% fatal within 2 years.

50,000 – 90,000 NEW CASES OCCUR ANNUALLY

Phases of the VL Elimination Programme in Eastern Africa



1. Policy & Strategy: Nat Strategy, MoU
2. Domestic Funding
3. Establish TWG & AGs
4. Mapping, forecasting, cross border collaboration
5. Prog Capacity Assessment

1. Innovative approaches: Integrated, hot spot areas, migrant population
2. Active & passive case detection, mobile outreach
3. Expansion of services: diagnosis and treatment
4. Conduct Progress review (RTAG, TWG)
5. Procurement system, Vector Control, R&D

1. Strengthen/complete Attack phase
2. Strong surveillance, ACF in remote areas and vulnerable population
3. Development of validation process
4. Fully operational surveillance system, Active case detection for VL & PKDL

1. Country validation by WHO
2. Active and fully integrated surveillance system
3. VL prog part of national PHC
4. Maintain early case detection and rapid response

VL Mapping & Rationale

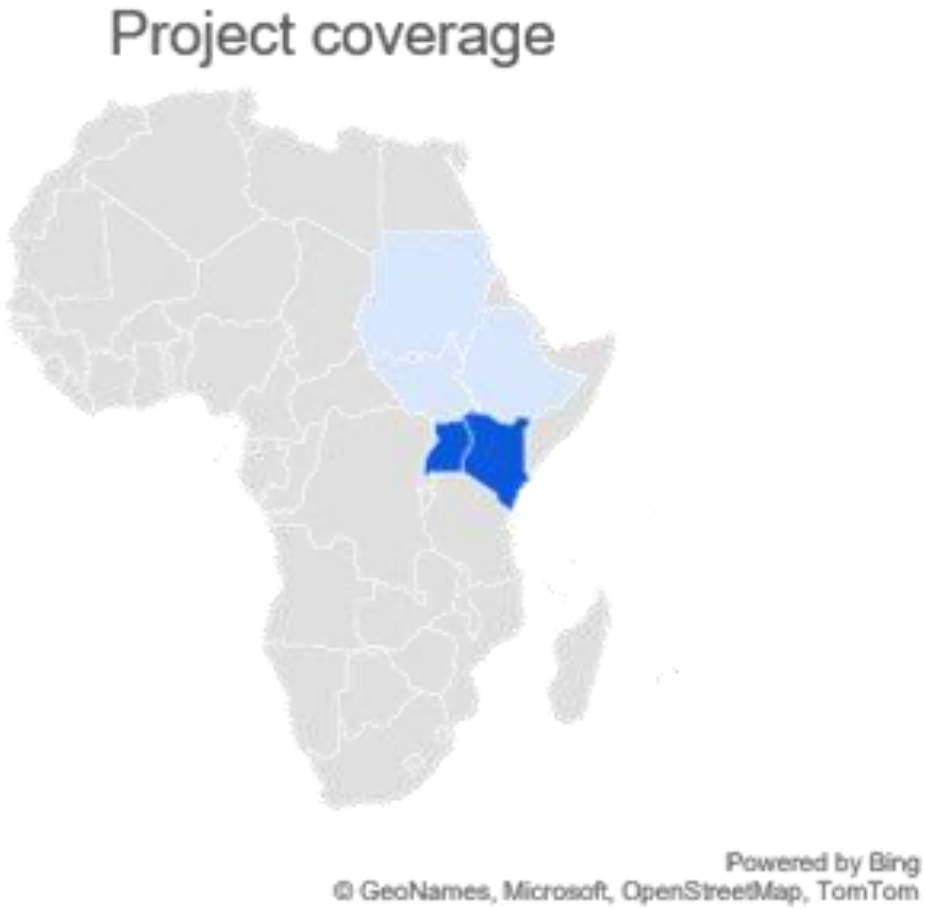
- Mapping is a key component of control and elimination.
- Epidemiological/endemicity mapping – To estimate relative risk of disease across geographical area. Important in quantifying disease burden and geographical spread
- Vector mapping – Understanding the presence, absence, abundance and seasonality in a geographical area
- Identify clusters of VL Infection and areas of high infection
- Identify the population and locations of increased risk of VL infection

VL Mapping & Rationale 2

- Establish a baseline to be used to monitor the success of interventions
- Establish baseline for disease and vector surveillance
- Predict the re-emergence of VL or potential outbreaks
- Targeting resources – In areas with the highest burden or greatest risk
- Support decision making – Provides data for planning, interventions, policy and community control efforts
- Improve public health interventions – Raising awareness and for advocacy
- Generate hypothesis for research – Association between environmental exposure and risk of infection, transmission dynamics etc.

Kala Azar Mapper project

- Implemented by ICIPE and supported by an expert team
- Five countries – Ethiopia, Kenya, South Sudan, Sudan, Uganda
- Deliverables/Questions
  - Epidemiological maps – Which villages the patients come from?
  - Vector maps – Where are vectors found?
  - Risk Maps – What makes these places suitable for transmission of VL?

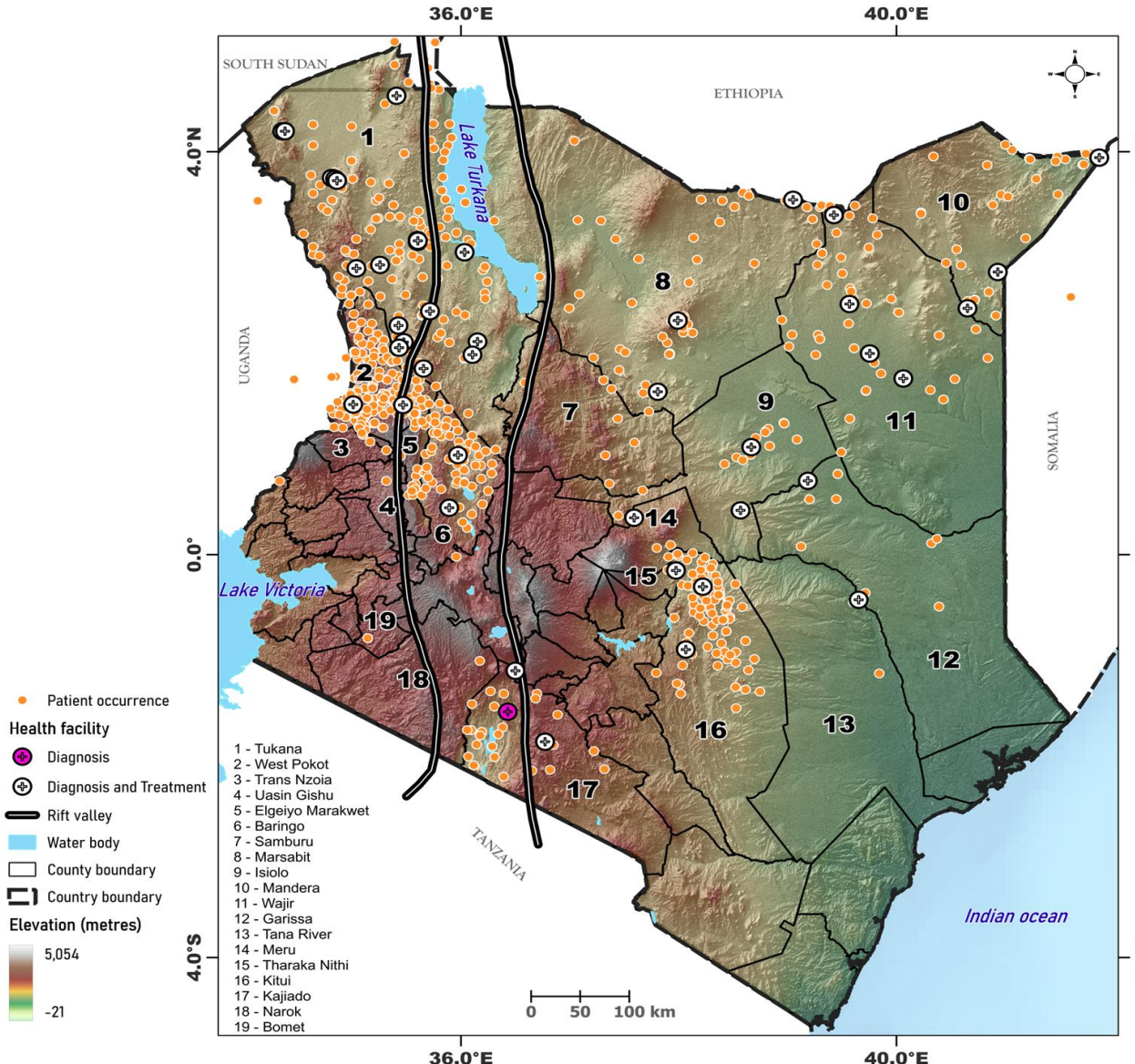


Progress to date

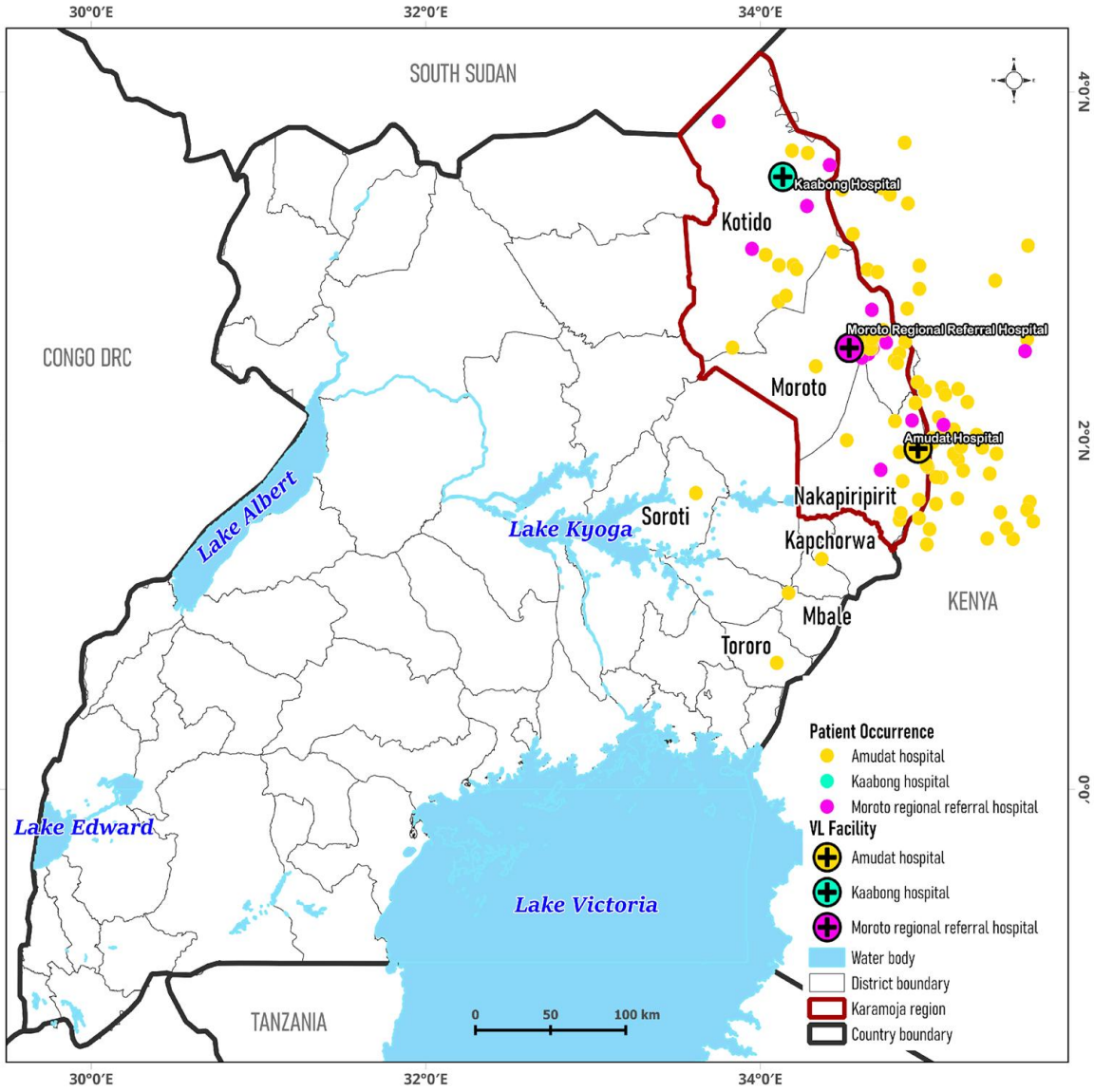
- Kenya and Uganda completed
- Ethiopia & South Sudan – Epidemiological mapping started
- Sudan – Both vector and epidemiological mapping started.

Key findings – Case distribution

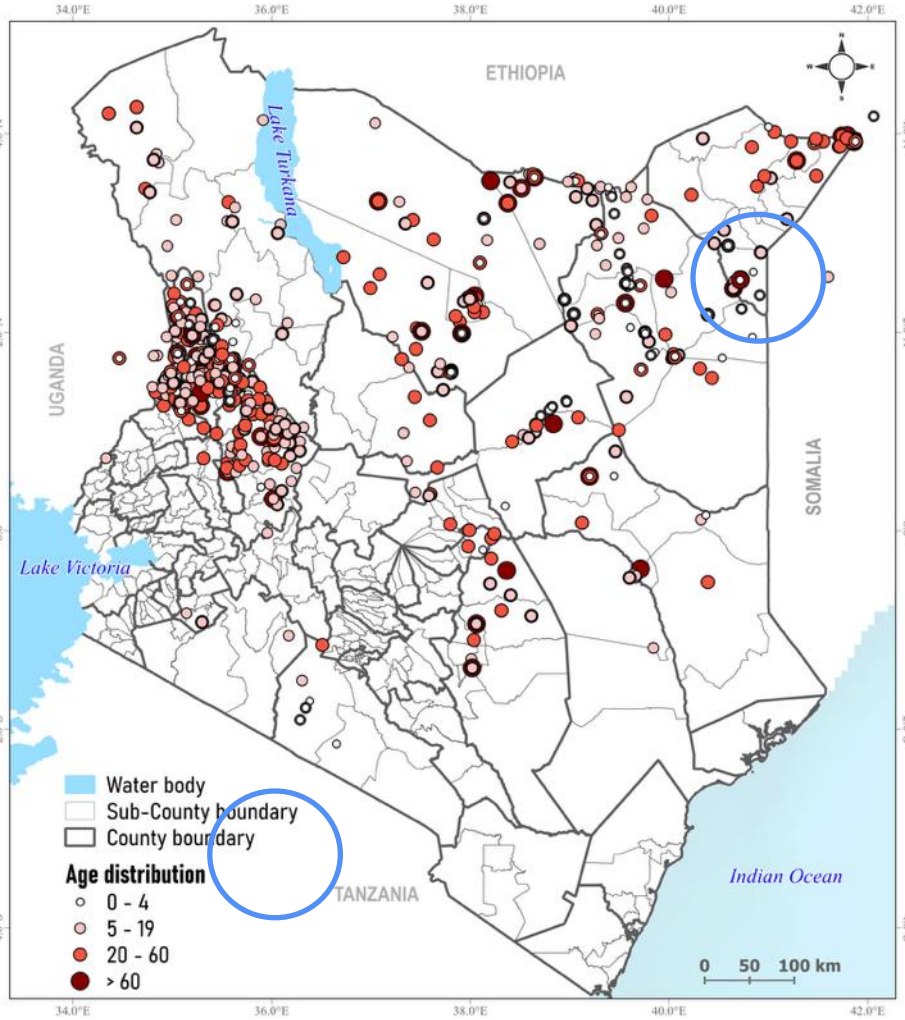
Kenya

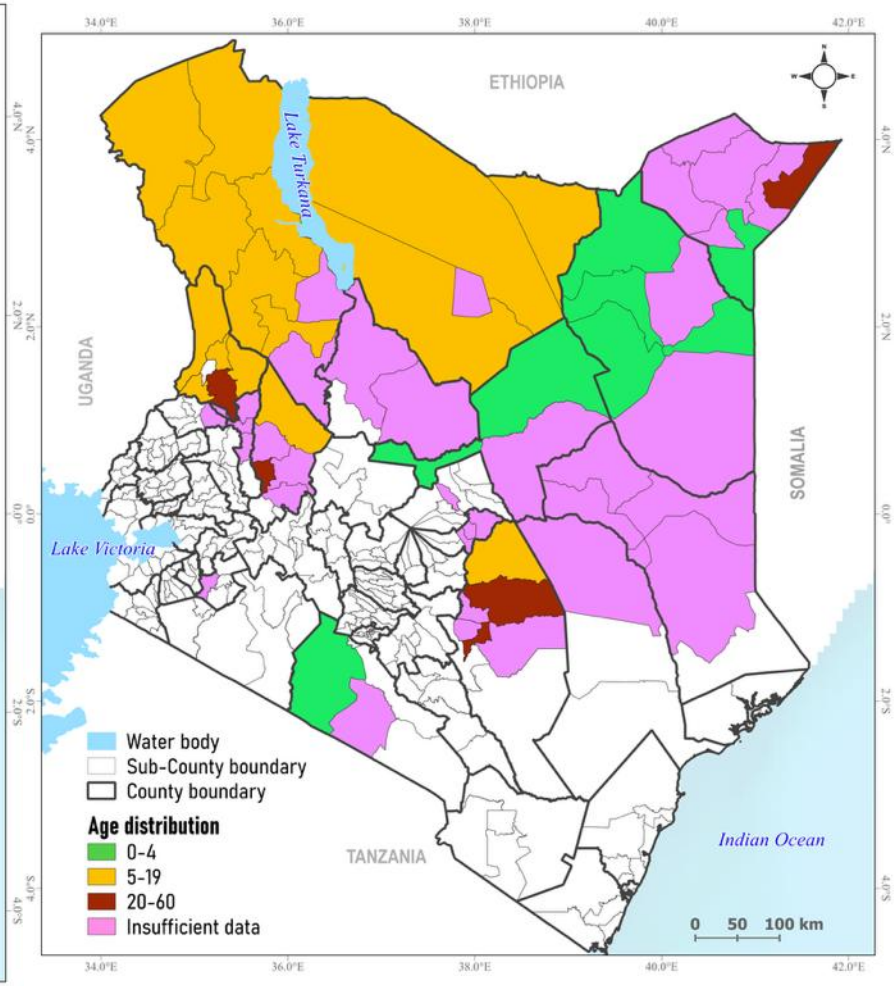


Uganda



Patient age profiles



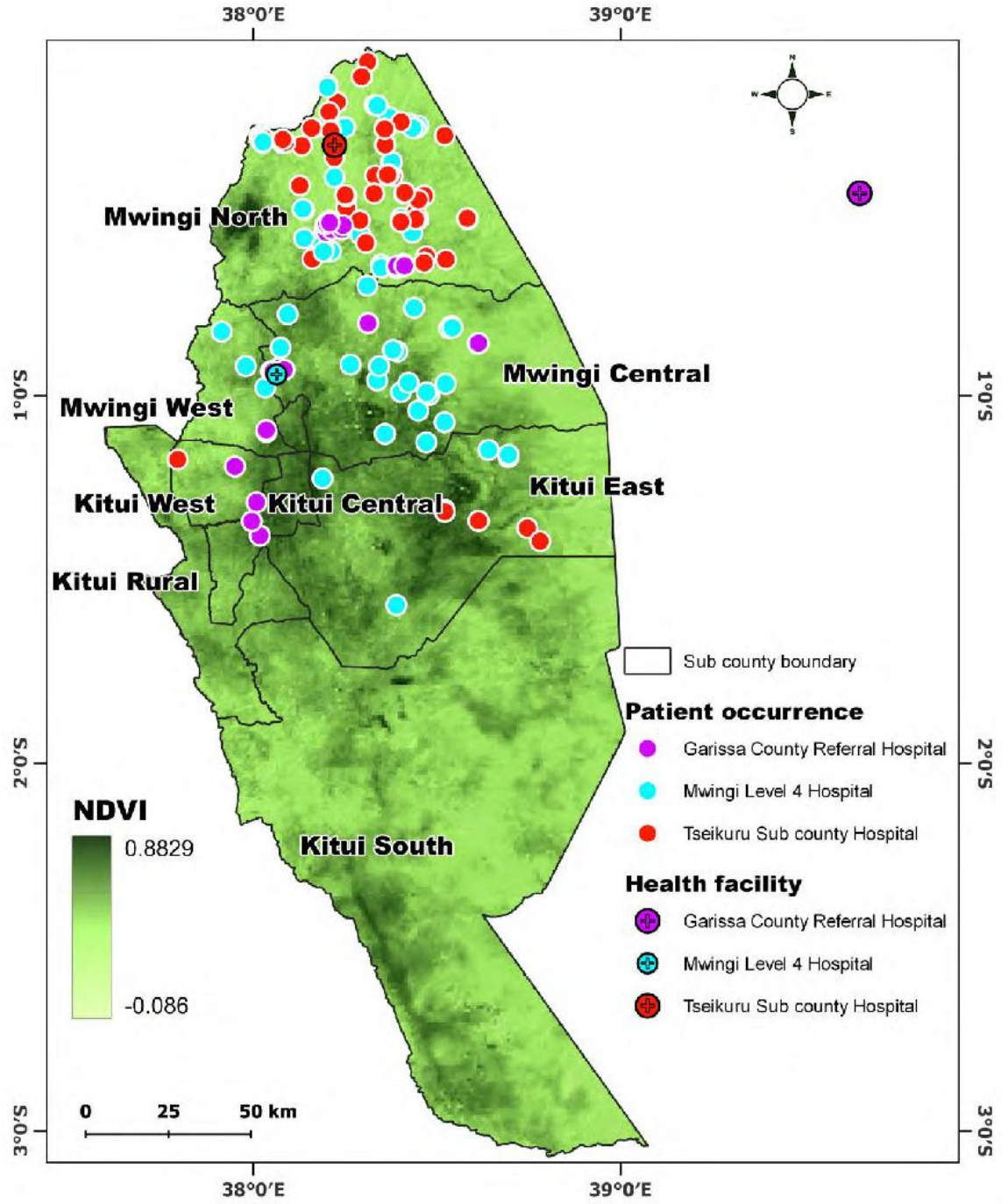


Transmission hypotheses

- In most sub-counties, most patients are in the 5-19 age category.
- 0-4 may represent community transmission.
- >20 may represent occupation/migration related transmission.

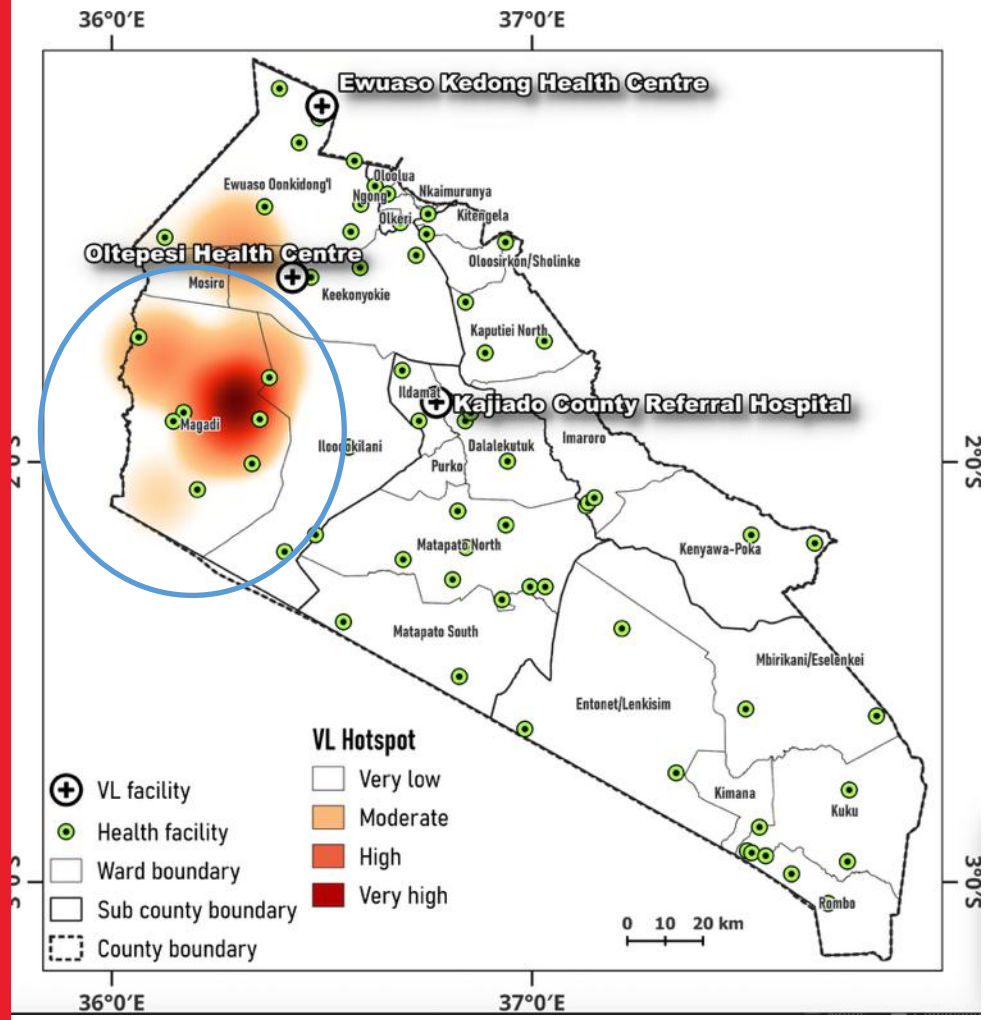
Where do patients seek treatment?

- Most convenient locations
- Type of facility
- Other considerations

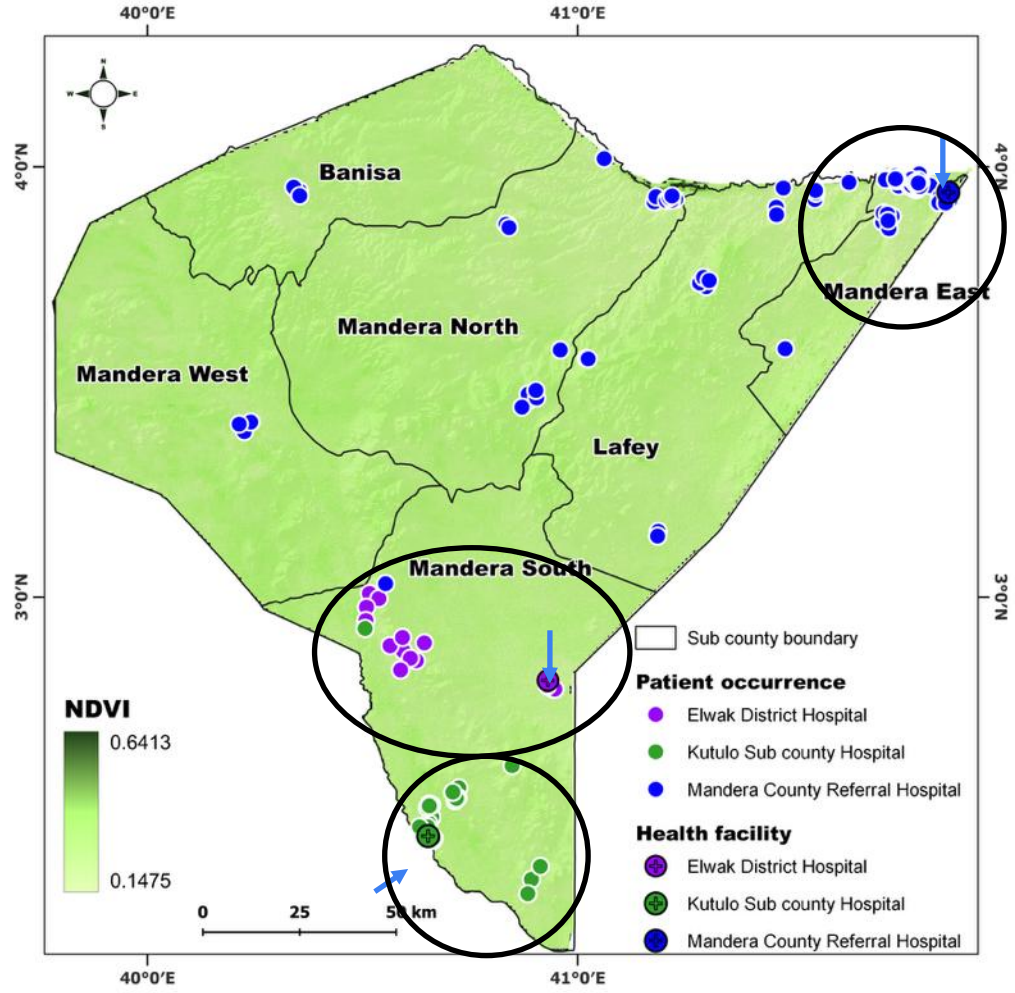


Access to treatment centres

Kajiado

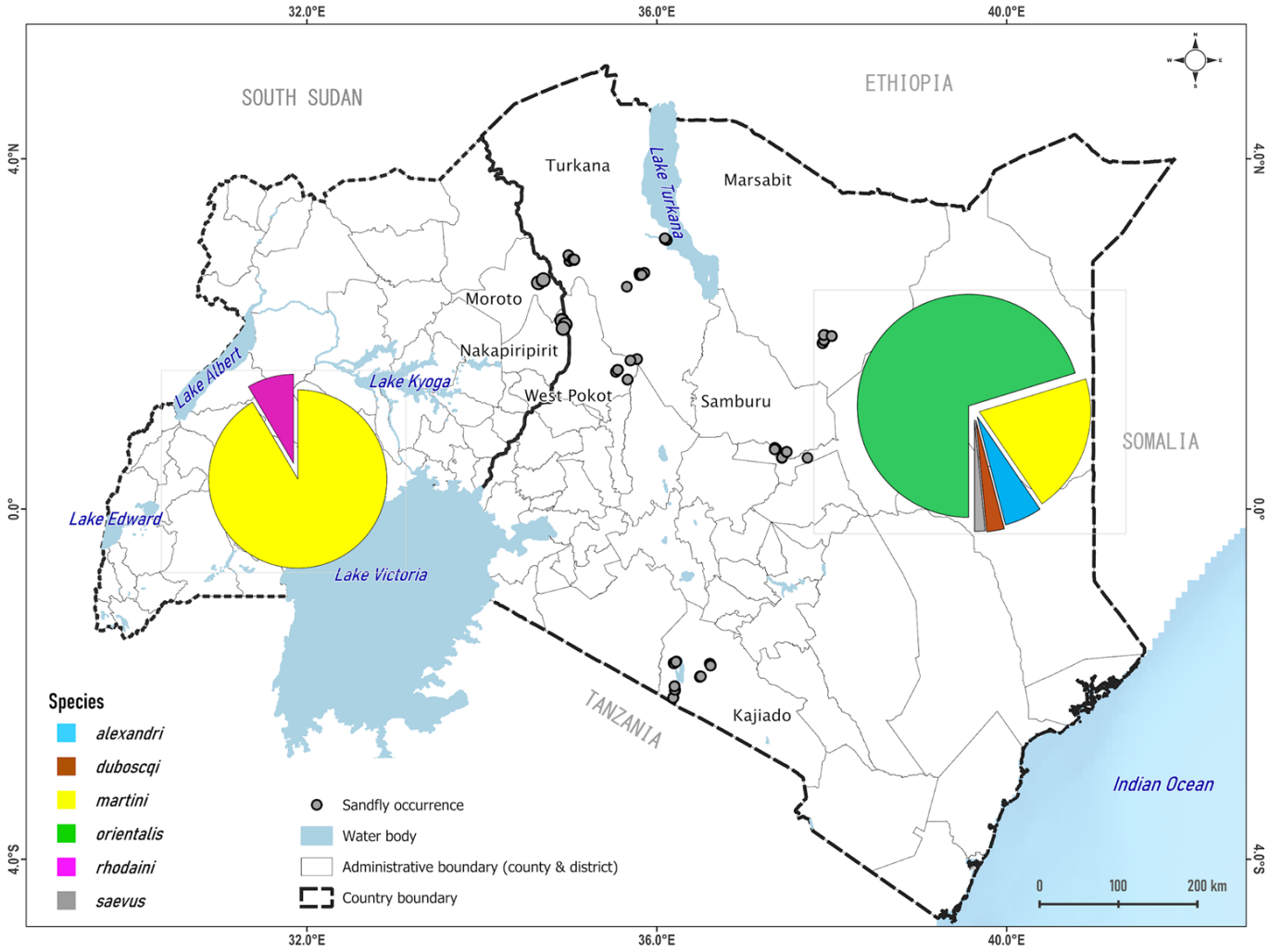


Mandera

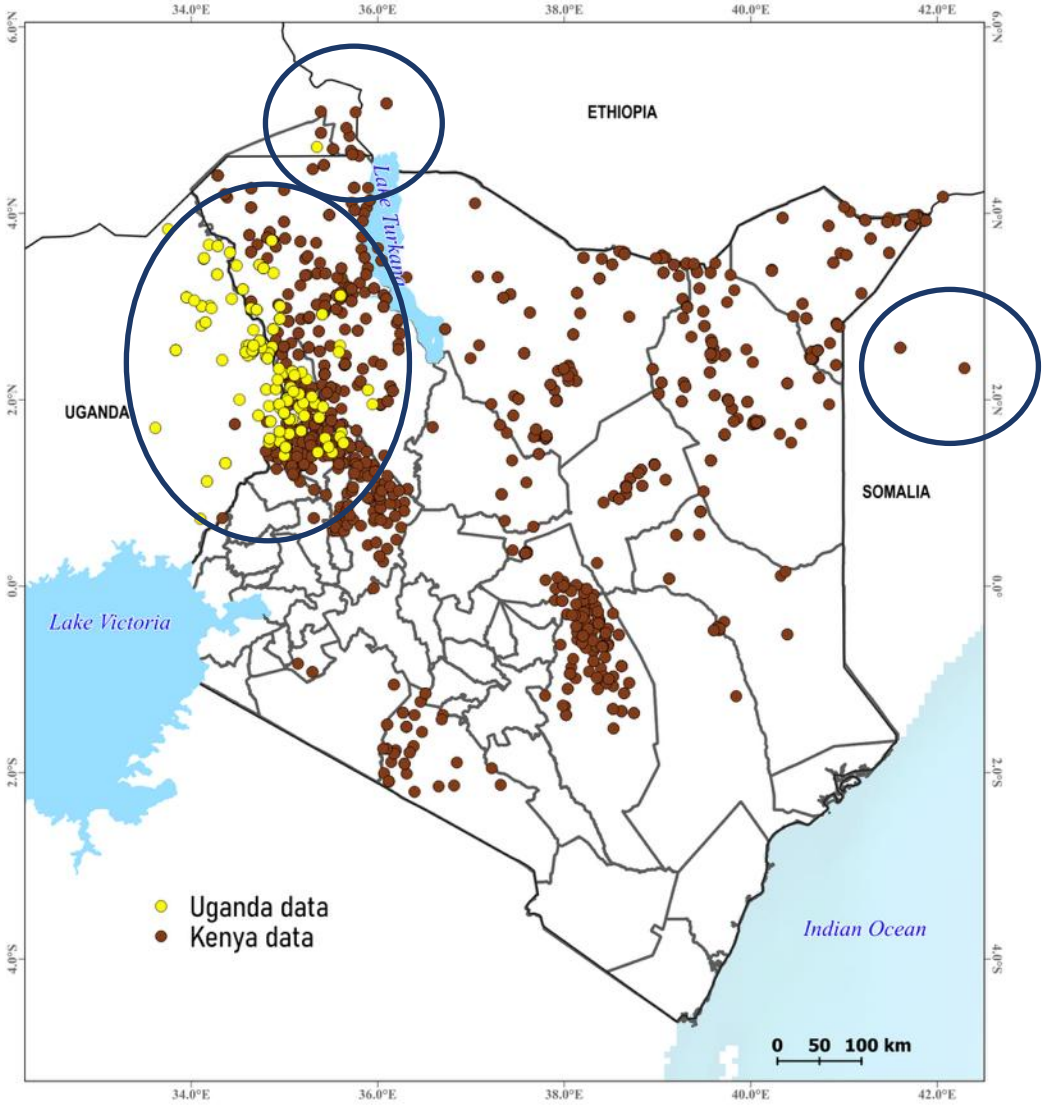


Some patients travel >250 km for treatment.

Vectors distribution in Kenya and Uganda – active survey Data



Cross-border cases



Patients travel across borders for treatment

1. Somalia
2. South Sudan
3. Uganda and Kenya

Most important findings/takeaways

- VL is more widespread in Kenya and Uganda beyond the known areas
- There is some overlap on vector distribution between *Ph. Orientalis* and *Ph. Martini*
- It is important to establish continuous vector surveillance to understand the seasonality of the vector, if applicable, and the abundance.
- An overlay of the vector maps with the diagnostic and treatment facilties can be used for planning the interventions and decision making
- The presence of *Ph. Alexandriae* and *Ph. Rhodaini* should be investigated to ascertain their importance in VL transmission in eastern Africa

Next steps

- Complete VL Mapping in Ethiopia, South Sudan and Sudan by the end of October 2026
- Identify areas that require further research e.g. Transmission dynamics, preference of treatment centers etc
- Prioritize the recommendations for implementation e.g. access to health services, cross border activities.
- Dissemination of the findings
- Ensure incorporation of the findings into the VL elimination programs
- Support the adoption of the findings as part of the VL elimination documents
- Prioritize specific interventions such as active case search in areas where the vectors are present to improve the control and accelerate elimination efforts.

Thank You

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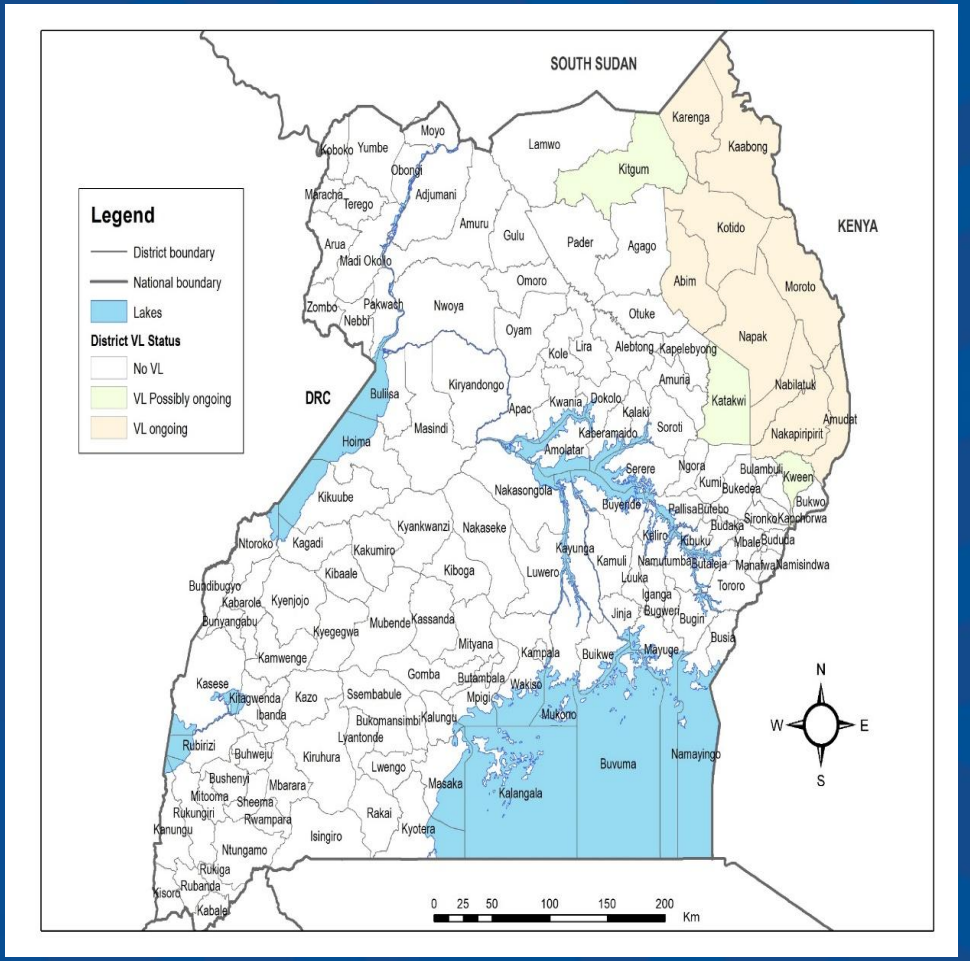
THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

Epidemiological mapping of VL in Uganda

OVERVIEW OF VL IN UGANDA

- **VL endemic in Karamoja region** in Northeastern Uganda(09 districts) with likely ongoing transmission along neighboring districts
- **1.4 million people at risk**,70% residing remote rural areas
- Largely **nomadic**, semi arid with one peak rainy season, insecure, marginalized popn
- **Poor health seeking behaviors, illiteracy and cultural norms** negatively impacted health status of communities in this region
- >**500 new infections** annually,70% being young persons below 15 years
- **150 peripheral Health facilities** across the 09 endemic districts (70 VL diagnostic centres, 05 treatment centres.
- Epi status; Predominantly*(Primary VL 92%, Relapse 8%, PKDL 1%), Males> Females,* Children under 15 years most affected,



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EXPANDED SPECIAL PROJECT FOR ELIMINATION OF NEGLECTED TROPICAL DISEASES

PURPOSE AND OBJECTIVES OF THE MAPPING

Purpose: This was aimed at ;

- Presenting current VL mapping for Uganda: distribution of reported cases, at-risk areas, service gaps and priority actions
- Propose methods and next steps for strengthened surveillance and targeted interventions.

Objectives

- Conducting a training course on sand fly trapping and identification.
- Establishing VL vector occurrence, species diversity and distribution across the Karamoja sub region.
- Determining vector infectivity rates and use the information for transmission potential of the vectors in the region.
- Developing epidemiological map of VL in endemic districts and predict risk of spread in non-endemic districts of north-eastern Uganda.
- Overlaying socio-ecological predictors and develop VL risk map across northeastern Uganda, Karamoja region in particular.

In-country meeting& Data sharing Agreements

Technical coordination meeting completed(May 2025)
Partners including ICIPE, KEMRI, Makerere University, and the Uganda MOH aligned implementation logistics and VL data collection protocols.

Data-sharing agreements established
Formal collaboration with the MOH Uganda enabled access to epidemiological and vector surveillance data for VL mapping

Epidemiological Mapping

Training and Actual Data Collection

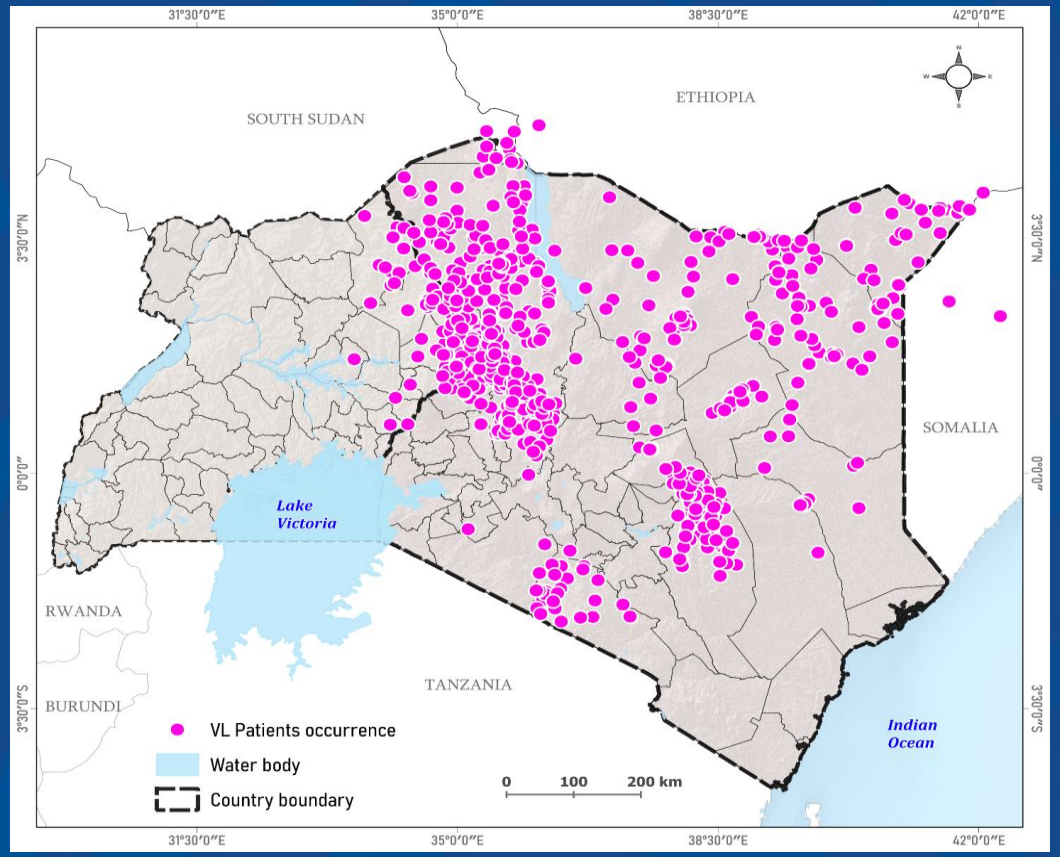
- Training for HROs and data entry officers in VL treatment centres(Amudat & Moroto) utilizing the REDCap form system for patient data
    - >2,500 records captured
    - Sources: Historical patient files and hospital records, DHIS2 extracts, literature data sets, health facility and village locations

Socio-Demographics in Uganda

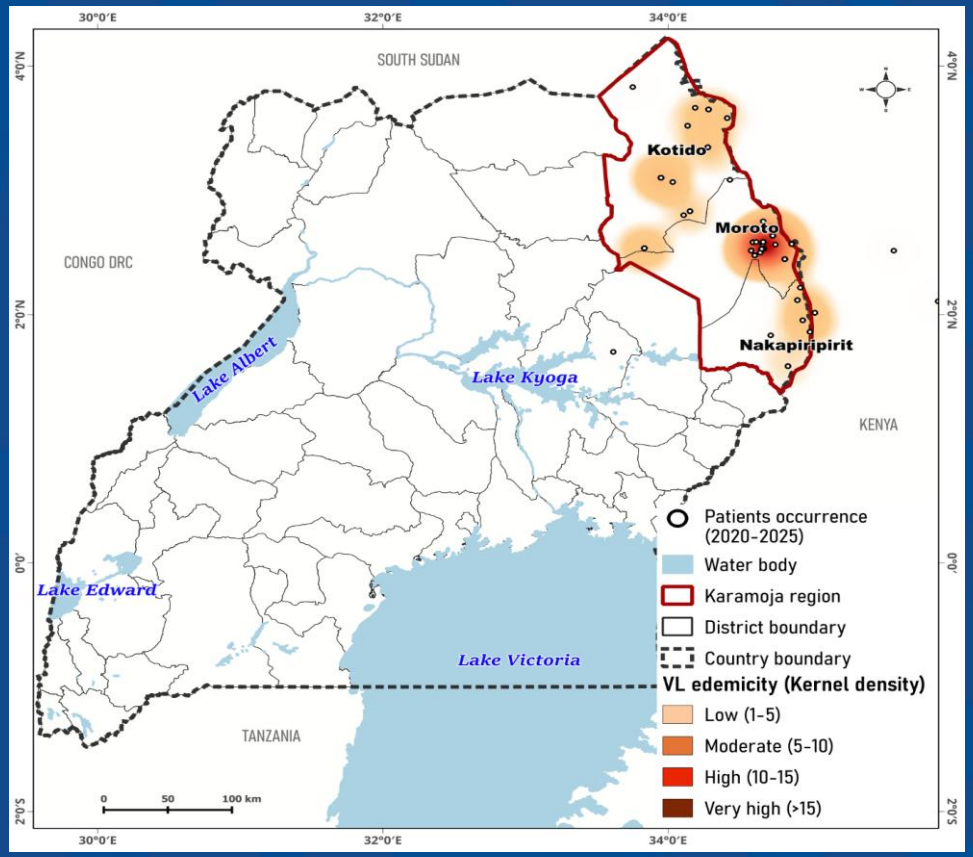
- Predominantly male(72%),female(27.9%) and a negligible proportion with missing sex data (0.1%)
- Age distribution showed a substantial proportion of cases in the 5–14 years group (41%), followed by 15 years and above (35.5%), and 0–4 years (22.4%)
- Most cases were engaged in unspecified occupations (49.6%) or animal herding (16.5%)
- Education levels were predominantly low, with 67.6% having no formal schooling
- Travel history outside the country was uncommon (1.7%)

Epidemiological Mapping

Spatial distribution of patient origin locations for visceral leishmaniasis cases in Kenya and Uganda



Spatial distribution of visceral leishmaniasis risk hotspots in Uganda



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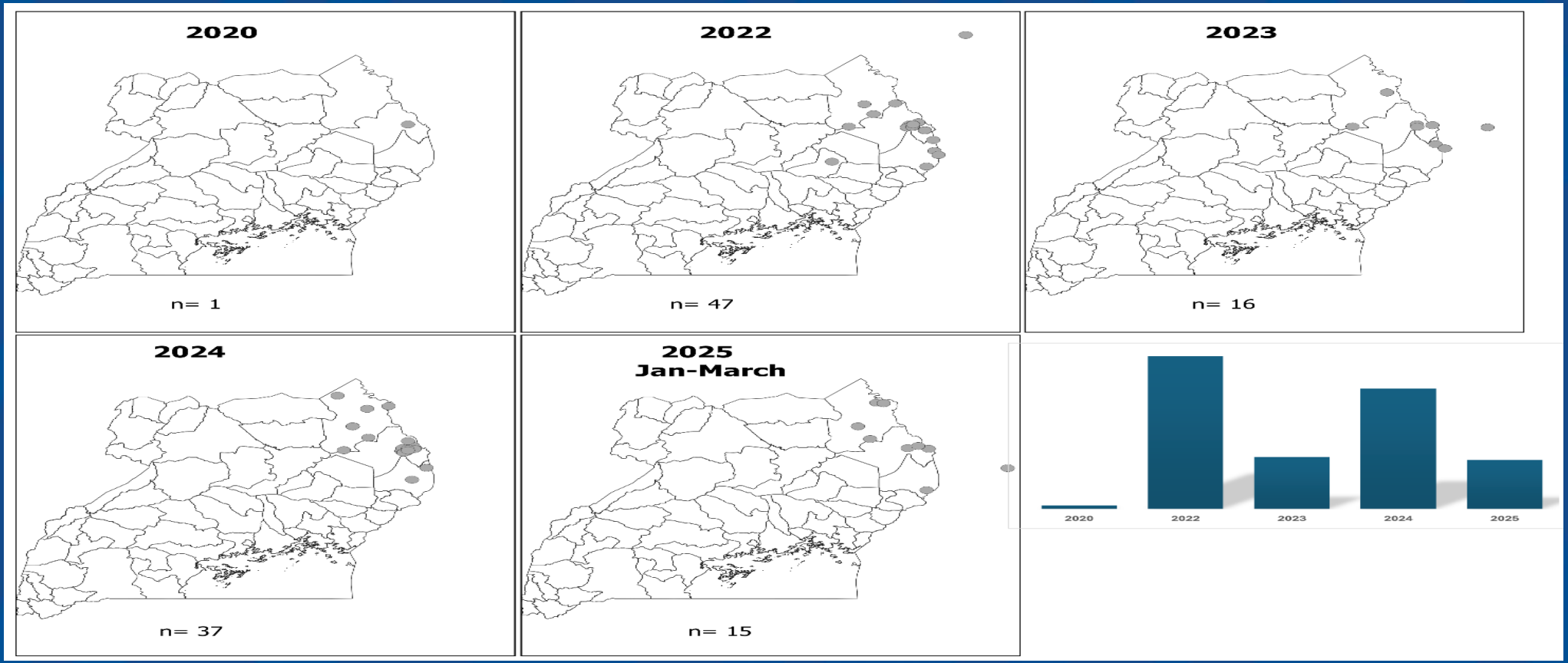
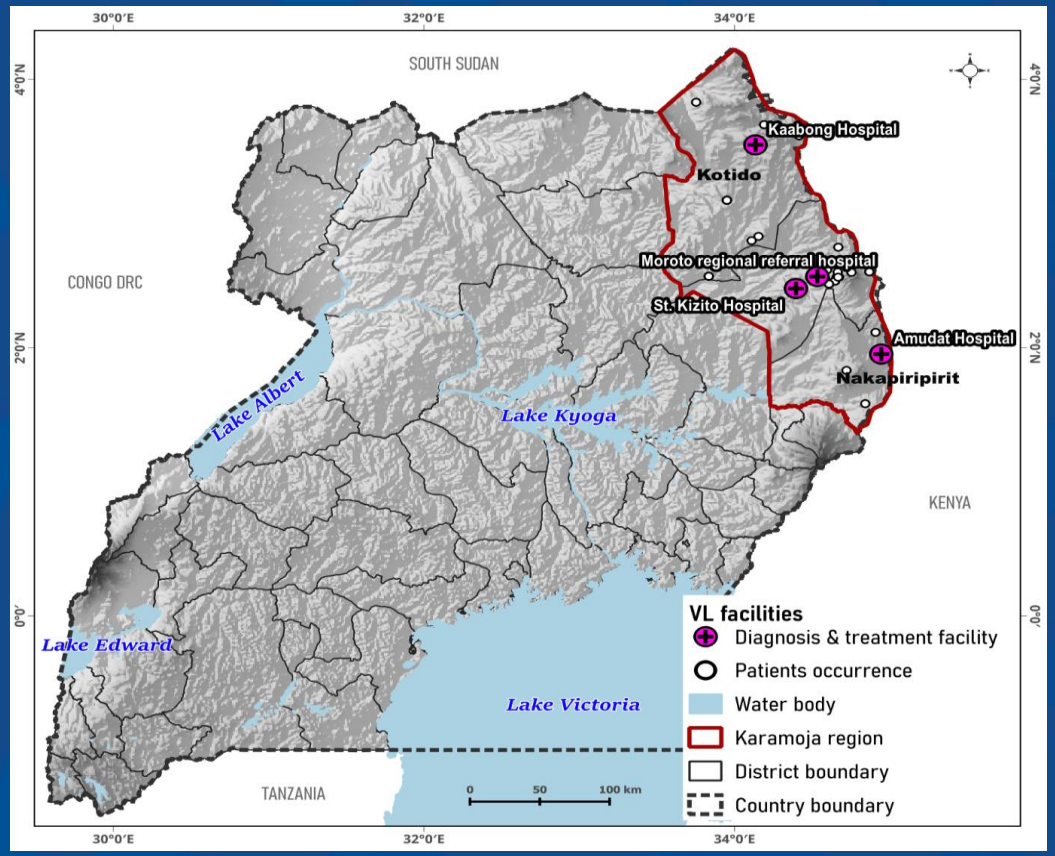
Epidemiological Mapping

Spatio-temporal distribution of visceral leishmaniasis cases in Uganda from 2020 to 2025

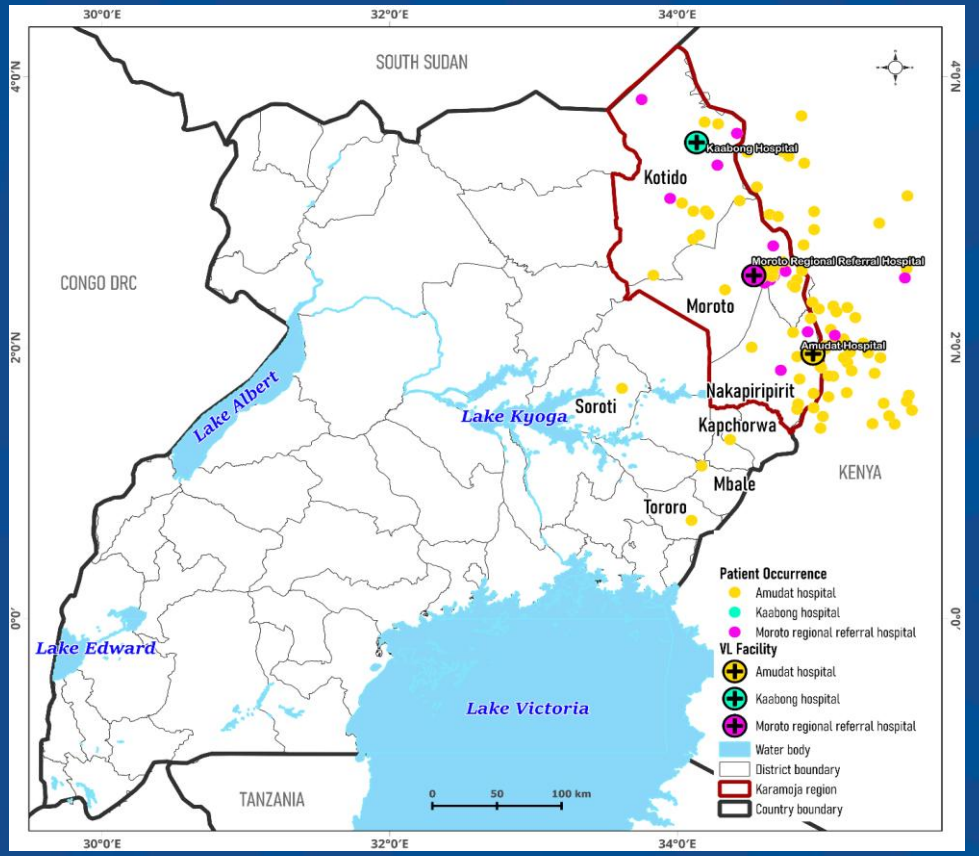


Epidemiological Mapping

Spatial distribution of health facilities offering visceral leishmaniasis diagnosis and treatment services in Uganda



Spatial distribution of patient origin locations for visceral leishmaniasis cases treated in Uganda



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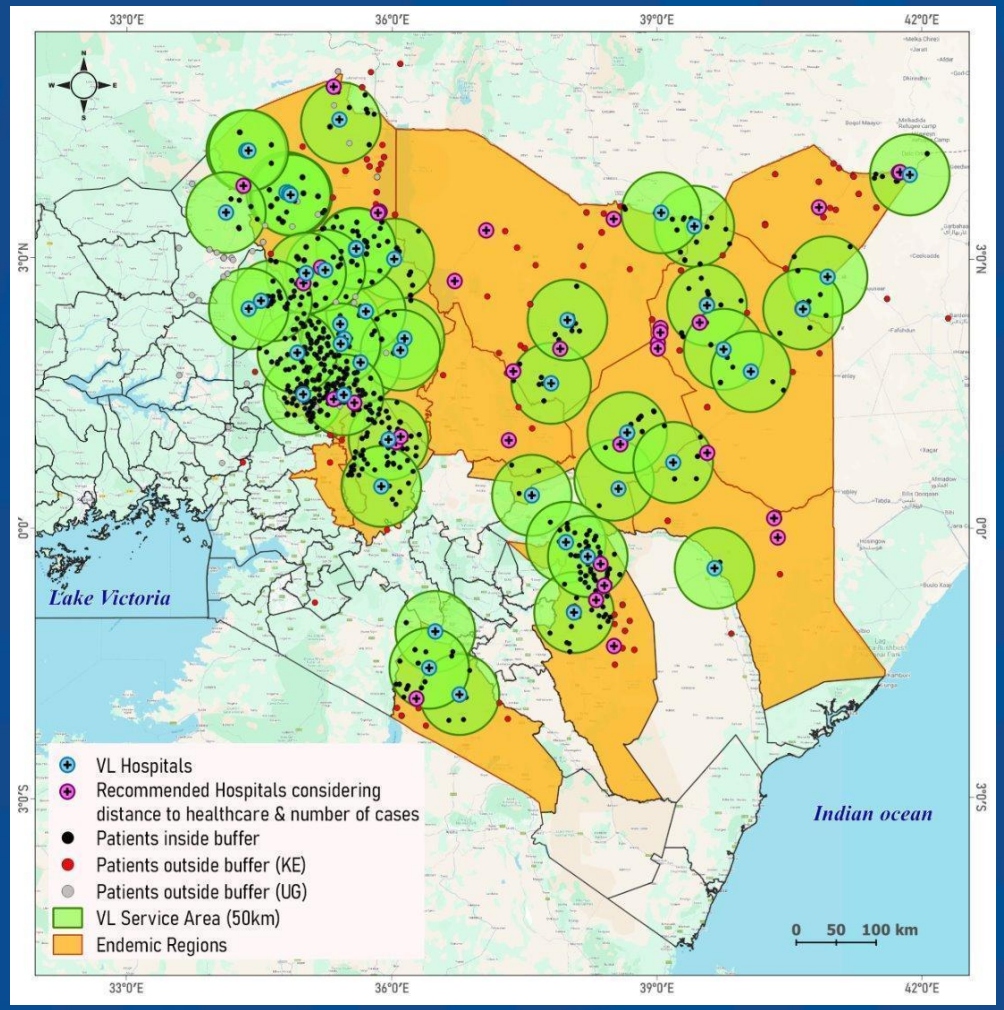
Epidemiological Mapping

Access to Health Care Analytics

- Aimed at identify geographic gaps in service delivery, highlight communities and populations facing the greatest barriers to care, and provide evidence to guide targeted interventions and resource allocation

- Overall plan is to ensure at least 01 treatment centre per endemic district and all peripheral facilities as diagnostic centres

- Limitations such as Facilities without diagnostics, long travel distances for patients, stock-outs risk ,Linkages to TB/HIV services for co-infected patients delay access to services



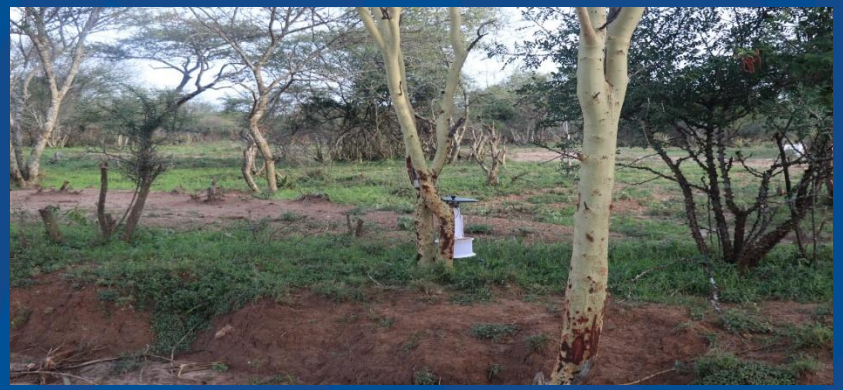
Vector Mapping

Training on sand fly trapping and identification

- 18 participants from MOH, endemic districts and academia trained on identification of VL vectors and vector surveillance techniques
- CDC light traps in various locations in Amudat and Moroto Districts in Karamoja region
- 1672 sandflies were collected, of which 104 are *Phlebotomus*; 102 *P. martini* and 2 *P. rhodaini*.
- A total of 80 females were collected: 78 *P. martini* and 2 *P. rhodaini*. Thirteen *P. martini* were blood-fed
- 10 CDC light traps to the Ugandan Ministry of Health for the team to continue vector surveillance
- REDCap entomology form designed to enable the MOH to centrally and digitally document VL records- to support routine surveillance

Vector Mapping

Set up of sandfly traps



Sandfly sorting

CDC trap previously set indoor

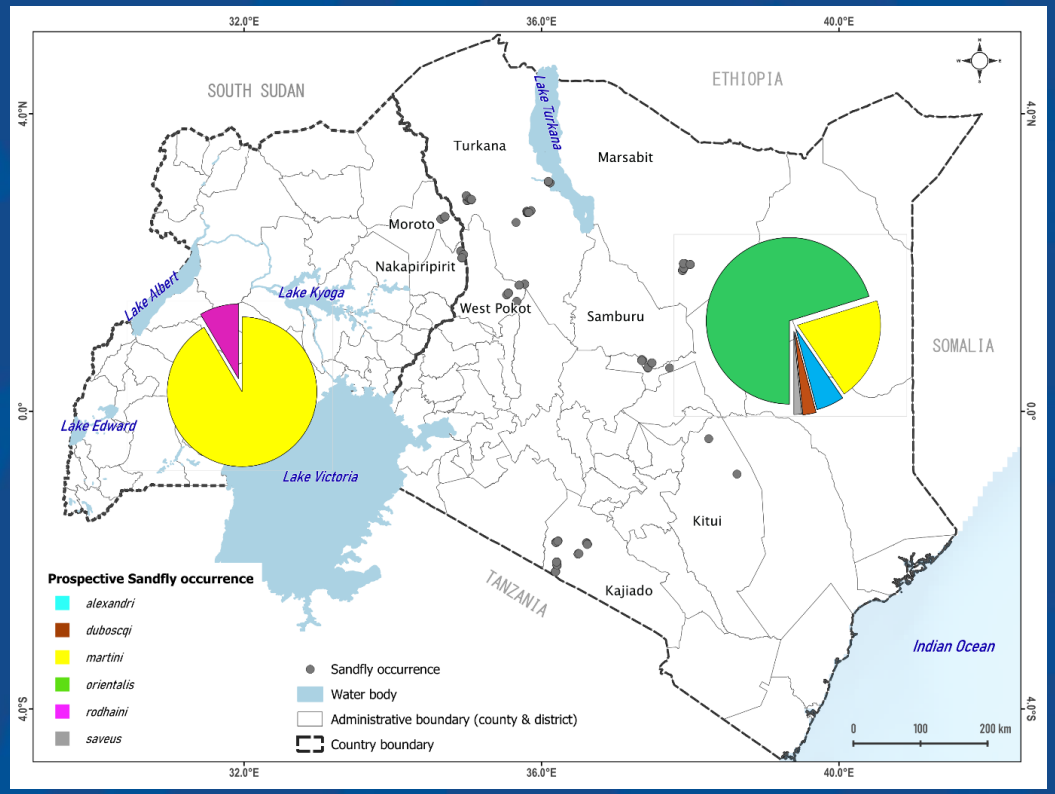
Vector Mapping

Detection of *Leishmania* Infection and Blood Meal Sources

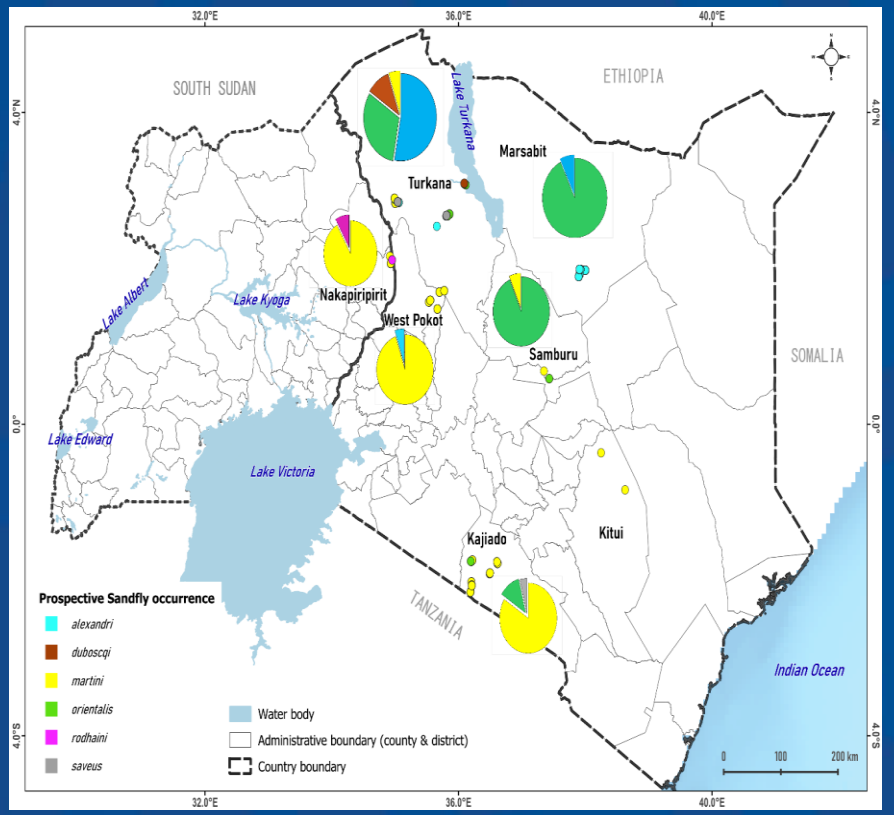
- DNA from individual female phlebotomine sandflies (unfed and blood-fed) was screened for *Leishmania* parasite infection by PCR
- blood-fed cohorts were similarly screened by PCR to identify vertebrate blood meal sources with particular attention to humans
- **None of the phlebotomine sandflies encountered during the prospective survey tested positive for *Leishmania* parasites**
- **Limitation:** No of blood-fed sandflies in this study was too small and the sampling design was not sufficient to support quantitative estimates of host preference

Vector Mapping

Overall sand fly species relative abundance in Kenya and Uganda

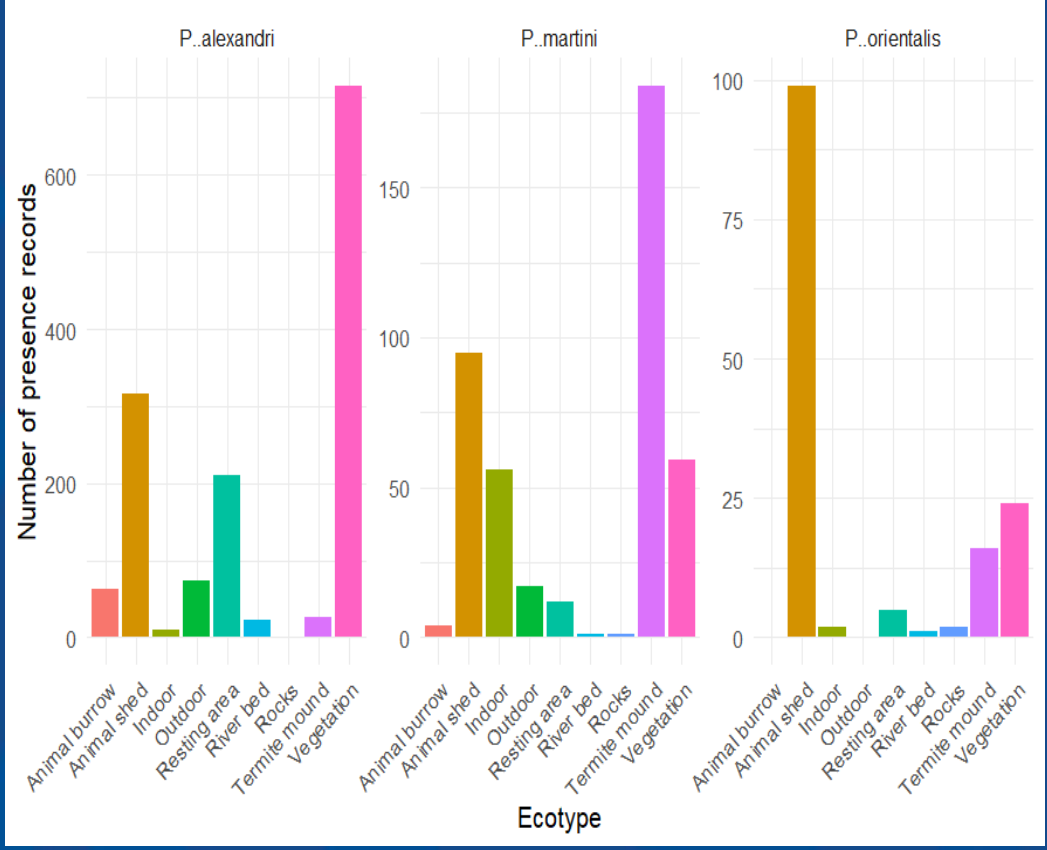


Spatial distribution and relative abundance of sand flies across surveyed

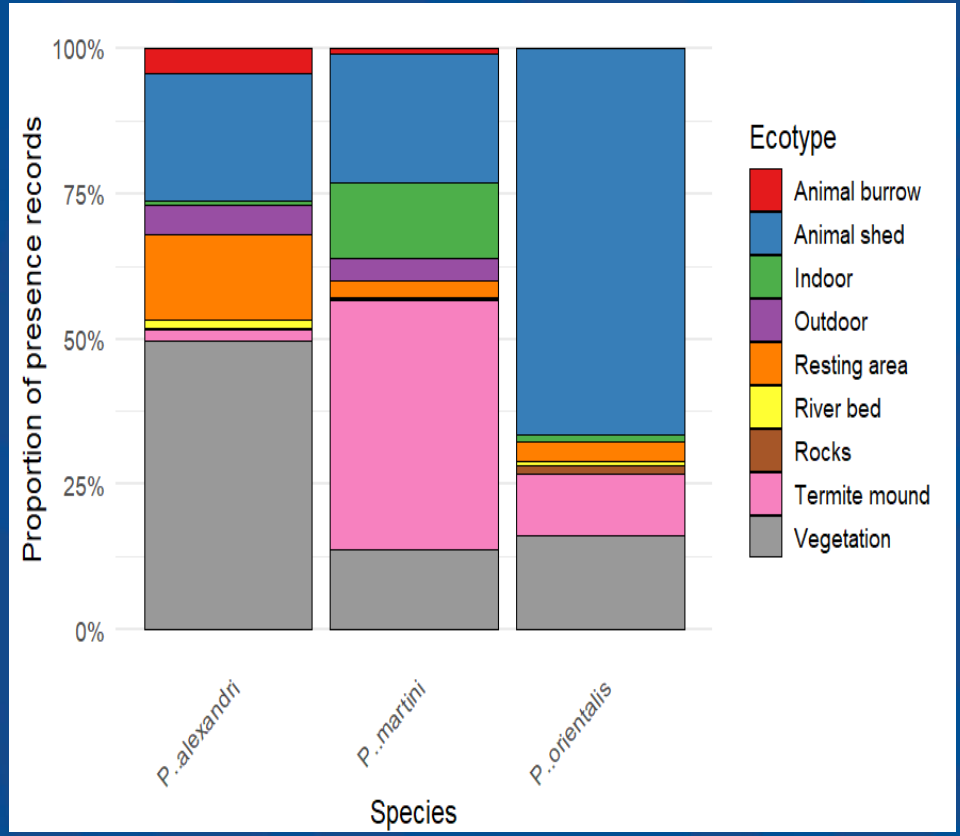


Vector Mapping

Occurrence of phlebotomine sand flies by ecotype in Kenya, Uganda



Occurrence of phlebotomine sand flies by ecotype in Kenya, Uganda

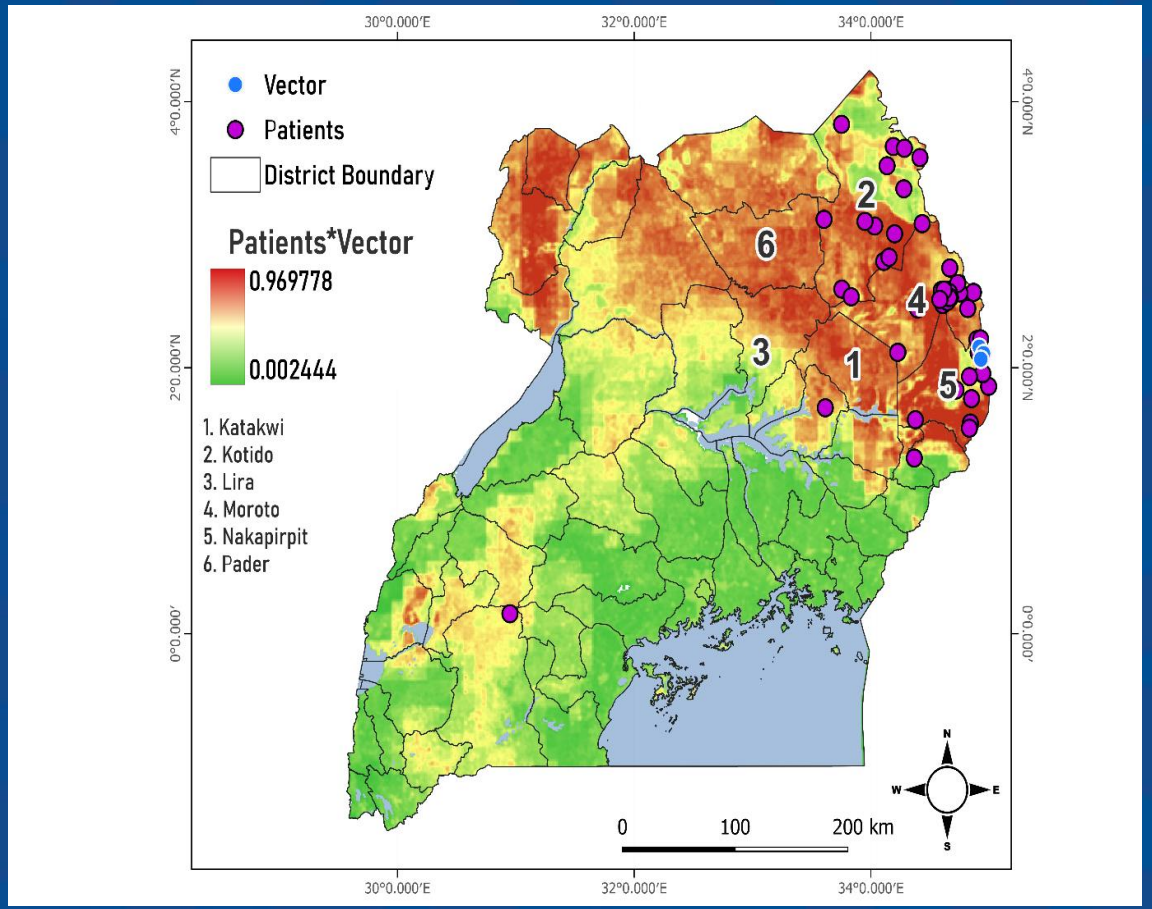


Risk Mapping

Findings& Recommendations

- Prioritize risk-based surveillance and targeted intervention rather than uniform allocation of resources in all areas
- Environmental& demographic factors yield strong influence on the transmission of VL-population density and relative humidity
- Need to focus on vector surveillance, active case detection, and community sensitization efforts
- Need for strengthened regional collaboration and data sharing to improve detection, reporting, and coordinated response to VL transmission across borders
- Country ownership to ensure sustainability and support routine surveillance

Preliminary integrated visceral leishmaniasis risk map for Uganda



THANK YOU

13-16 April 2026

Lilongwe, Malawi

ANNUAL MEETING OF NTD PROGRAMME MANAGERS IN AFRICA

Leveraging innovative tools & sustainable financing to advance NTD elimination in Africa

Wyckliff Omondi,Head, Vector Borne & Neglected Tropical Diseases, KNPHI-MoH

13-16 April 2026

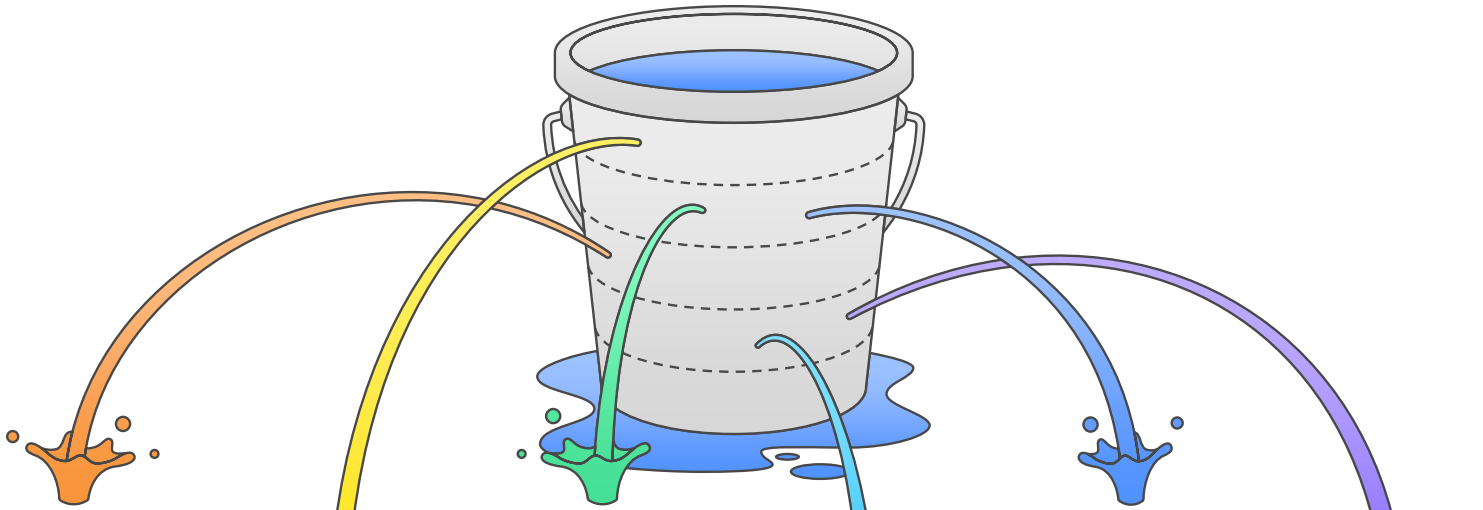
Lilongwe, Malawi

African Union

World Health Organization African Region

ESPEN Expanded Special Project for Elimination of Neglected Tropical Diseases

Leishmaniasis in Kenya: A Neglected Tropical Disease



Visceral Leishmaniasis

Severe and fatal if untreated

Cutaneous Leishmaniasis

Causes disfigurement and stigma

Arid Regions

Predominant occurrence in dry areas

Sandfly Transmission

Bite of infected female sandflies

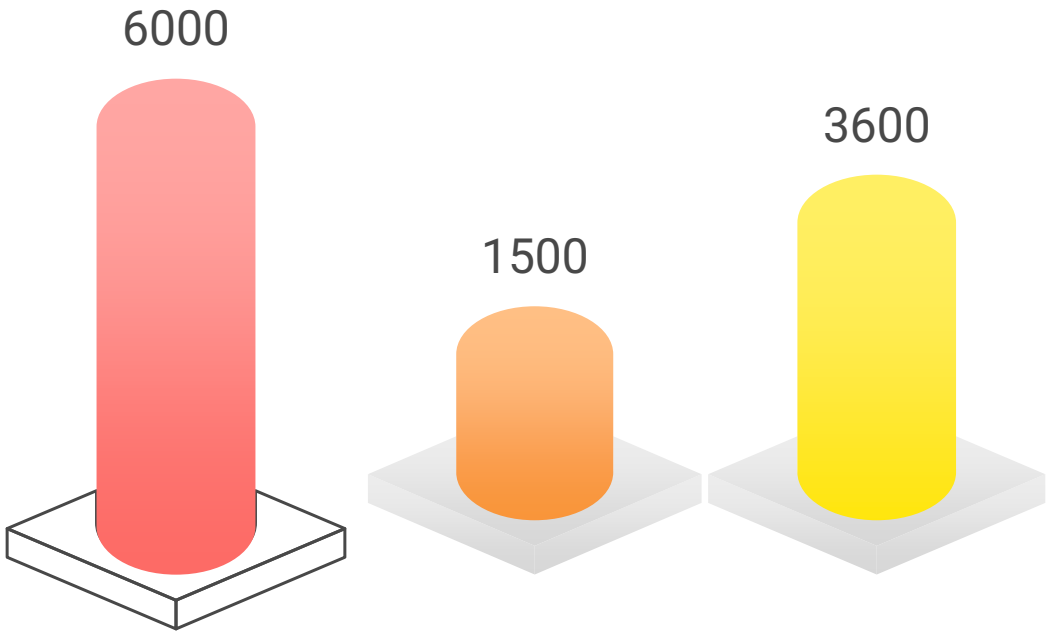
High Global Contribution

Kenya contributes to global cases

Increasing Cases

Steady increase in diagnosed cases

Kenya VL Cases



2022-2025

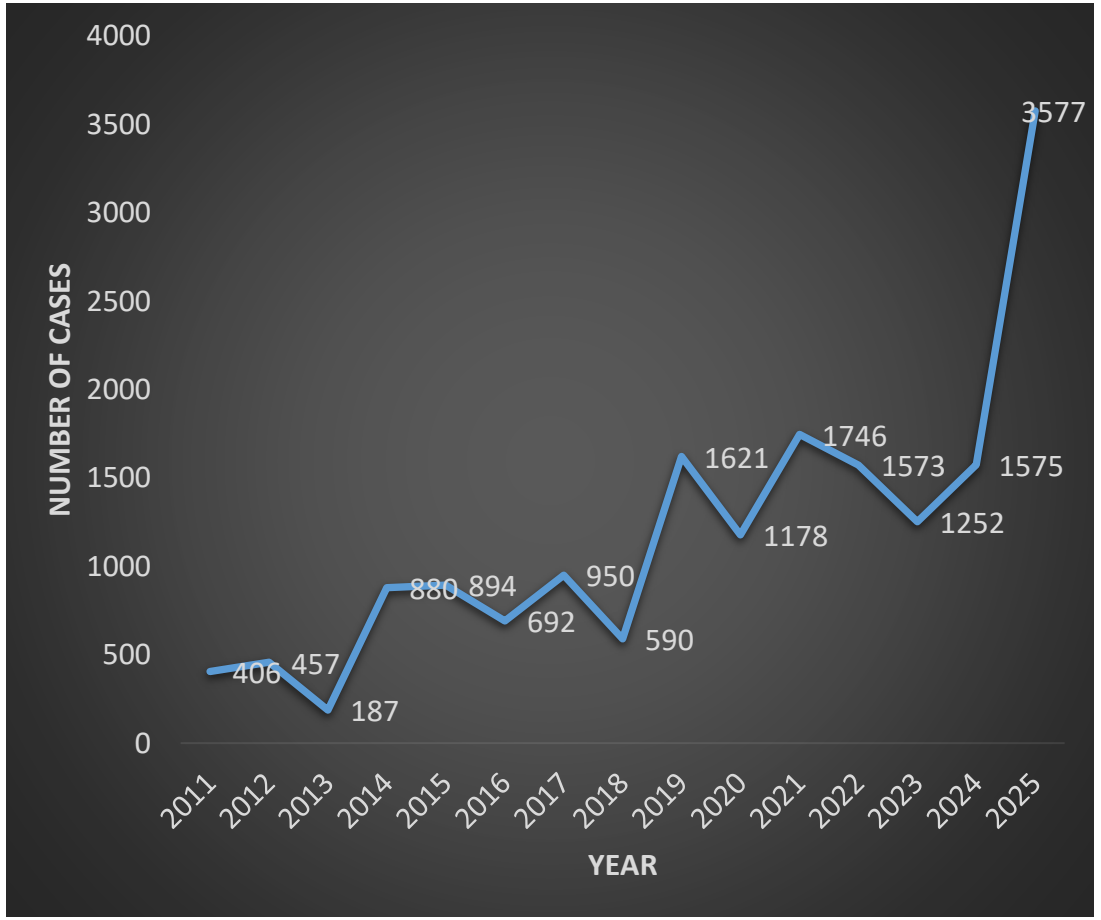
Total cases reported in Kenya

Annual Average

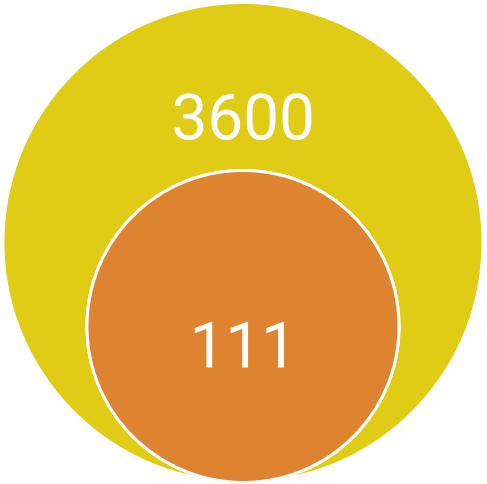
Average cases per year

2025

Cases reported in 2025



Visceral Leishmaniasis Cases and Deaths in Kenya (2025)



Reported Cases

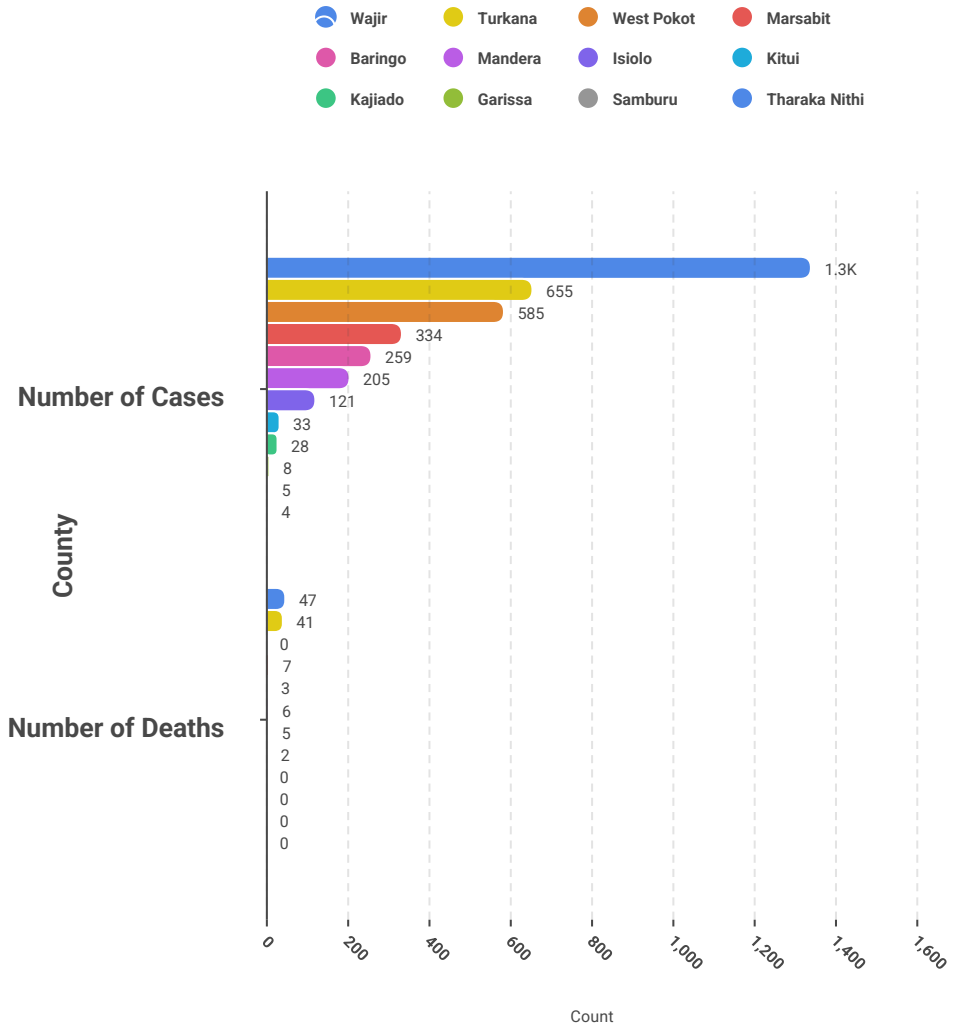
Total cases reported in 2025

Deaths Attributed

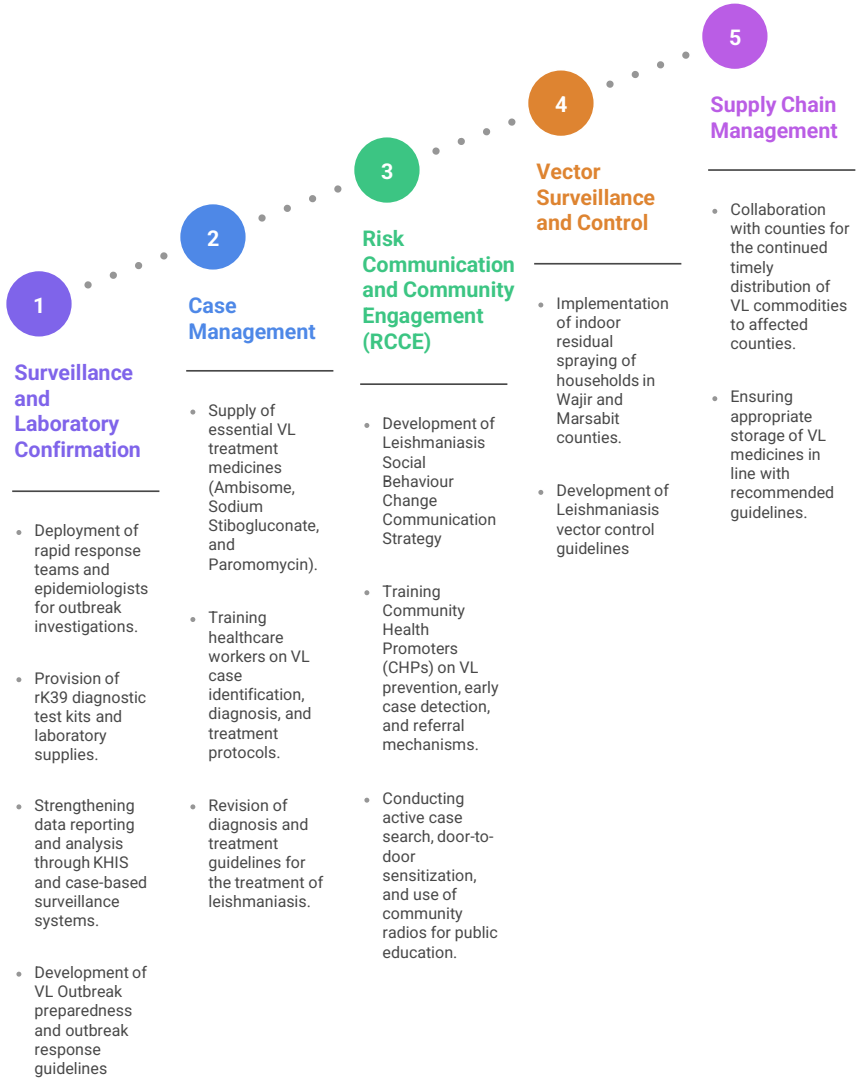
Total deaths attributed to VL in 2025

Leishmaniasis Cases and Deaths by County in Kenya

Wajir county reports the highest number of cases and deaths, while several counties have zero reported deaths.



Leishmaniasis Control Strategy in Kenya



Challanges Hinder Leishmaniasis Elimination

Gaps

Inadequate leishmaniasis elimination

High Fatality

Inadequate healthcare worker training

Delayed Presentation

Limited risk communication

Minimal Control

Minimal vector control activities

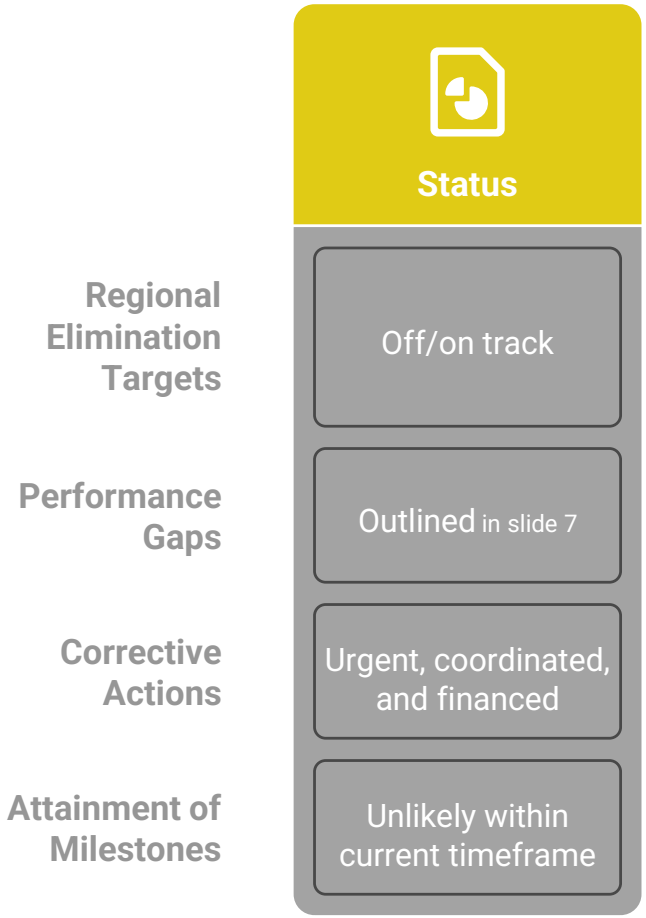
Low Stock

Critically low treatment commodities

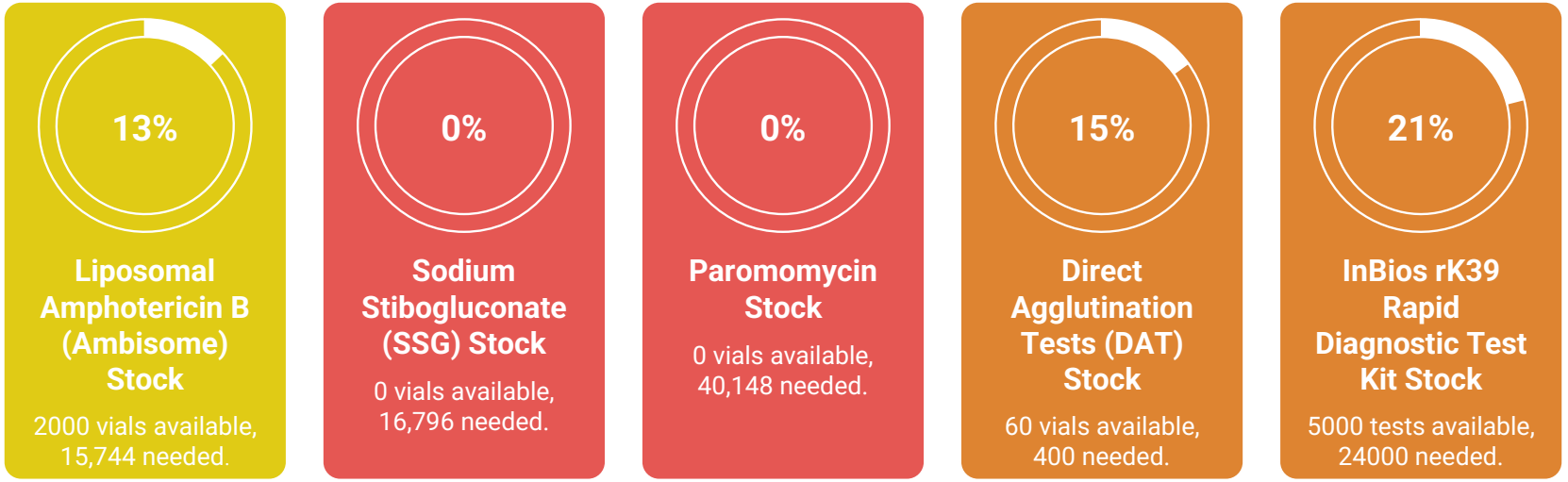
2025 Status Vs Regional and Country Targets

	WHO Regional Strategic Plan	Kenya 2027 Targets	Current Status in 2025
Case Fatality Rate	1% CFR	1% CFR	3.10%
Reduction in Cases	90% reduction	Reduced morbidity by 60%	3577 cases, 257% increase
Detection and Treatment	90% of VL cases detected within 30 days	75% of confirmed VL cases initiated within 30 days	83.40%
VL Deaths in Children	100% decline	100% reduction	CFR for children <15 years is 3.7%
VL-HIV Coinfected Patients	100% started on ART	100% of detected VL cases tested for HIV	33.70%
PKDL Cases	All PKDL cases detected, reported and managed	100% of identified PKDL cases reported and initiated on appropriate treatment	71%

Kenya's Progress Towards Visceral Leishmaniasis Elimination



National VL Commodities Stock Status (January 2026)



Significant shortages exist for key VL commodities, requiring urgent procurement to meet projected needs.

ASANTE SANA! THANK YOU

13-16 April 2026

Lilongwe, Malawi

African Union

World Health Organization
African Region

ESPEN
EXPANDED SPECIAL PROJECT FOR ELIMINATION OF NEGLECTED TROPICAL DISEASES

ANNUAL MEETING OF
NTD PROGRAMME MANAGERS IN AFRICA

• "INNOVATION TO FOSTER ELIMINATION: NEW THERAPIES FOR LEISHMANIASIS"

- **Cherinet Adera (MD, MPH)**
- **Senior Market Access Manager**
  Drugs for Neglected Diseases initiative

ANNUAL MEETING OF NTD PROGRAMME MANAGERS IN AFRICA

Lilongwe, Malawi, 14 April 2026

DNDi

Best Science
for the Most Neglected

• Leishmaniasis: epidemiological context

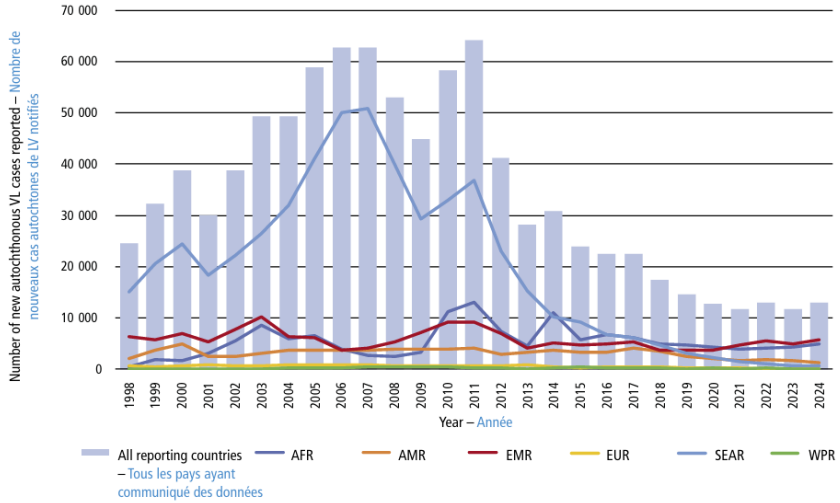
- **Asia**: the elimination programme has achieved great success. Bangladesh validated elimination in 2023; India and Nepal following. Plan to accelerate and sustain elimination in the region
- **Eastern Africa** has the highest burden of visceral leishmaniasis.
  - WHO meeting in Jan 2023 with endemic countries and stakeholders initiated a strategic framework for VL elimination in Eastern Africa – the **Nairobi Declaration**
  - The **Strategic Framework for VL Elimination in East Africa** was launched during the WHO/DNDi Stakeholders Meeting in June 2024
  - WHA side event on 21st May: Signature of the MoU for VL Elimination in EA
- **Latin America:** VL cases decreased slightly in the last 3 years; but VL-HIV co-infection increased to 16% and lethality remains high (9.8%)

"Research and innovation are fundamental enablers of programmatic progress for all NTDs"

Main pillar: access to early diagnosis and **prompt treatment**

Develop **more effective and user-friendly treatment** and diagnostics

Figure 1b **Evolution of numbers of visceral leishmaniasis (VL) cases, by WHO region, 1998–2024**
Figure 1b **Évolution du nombre de cas de leishmaniose viscérale (LV), par Région de l'OMS, 1998-2024**



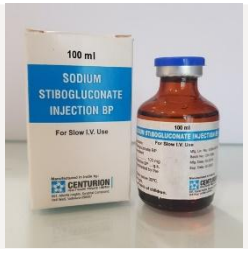
WHO Regions: AFR: African Region, AMR: Region of the Americas, EMR: Eastern Mediterranean Region, EUR: European Region, SEAR: South-East Asia Region, WPR: Western Pacific Region. – Régions de l'OMS: AFR: Région africaine, AMR: Région des Amériques, EMR: Région de la Méditerranée orientale, EUR: Région européenne, SEAR: Région de l'Asie du Sud-Est, WPR: Région du Pacifique occidental

WHO, Weekly Epidemiological Record, 2025

• The limitation of current leishmaniasis drugs

> Limited by toxicity, variable efficacy, parenteral drugs with the exception of oral miltefosine

> There is an urgent need for effective, safe, easy-to-use treatments

				
MEGLUMINE ANTIMONIATE	SODIUM STIBOGLUCONATE (SSG)	LIPOSOMAL AMPHOTERICIN B	PAROMOMYCIN SULFATE	MILTEFOSINE
Slow iv or im infusion	Slow iv or im infusion	2h iv infusion	im	po
20mg/kg/day, 30 days	20mg/kg/day, 30 days	10-30 mg/kg/day total dose, 1-10 days	15 mg/kg, 17 days in combination with SSG	2.5mg/kg/day, 28 days
• painful injections • cardiotoxicity • hepatotoxicity • pancreatitis	• painful injections • cardiotoxicity • hepatotoxicity • pancreatitis	• rigor & chills • nephrotoxicity • hypokalemia • anaphylaxis • requires cold chain	• painful injections • nephrotoxicity • hepatotoxicity • ototoxicity	• potentially teratogenic • gastrointestinal toxicity • hepatotoxicity

- **Variations in efficacy of VL treatment between different regions: the need to adapt treatment regimens**

	MONOTHERAPIES					COMBINATION THERAPIES			
Region	Antimonials	LAmB Multiple dose	Single-dose LAmB	MF	PM	SSG + PM	LAmB + Antimonials	LAmB + MF	MF + PM
South Asia	35 - 95%	> 95%	≥ 94% (10 mg)	90-94%	94.6%	NA	NA	> 97%	> 97% (10d)
East Africa	92%	85% (71-100%) (30 mg)	58% (33-100%)	72%	63.8% (14-96%)	91%	87%	77%	91% (14d, higher dose)
Latin America	77.5%	87.2% (20 mg)	NA	43% (67% for 42d)	NA	NA	83.9%	NA	NA

Adapted from Alves et al, CMR 2018

SSG: sodium stibogluconate
MA: meglumine antimoniate
LAmB: liposomal amphotericin B
PM: paromomycin
MF: miltefosine

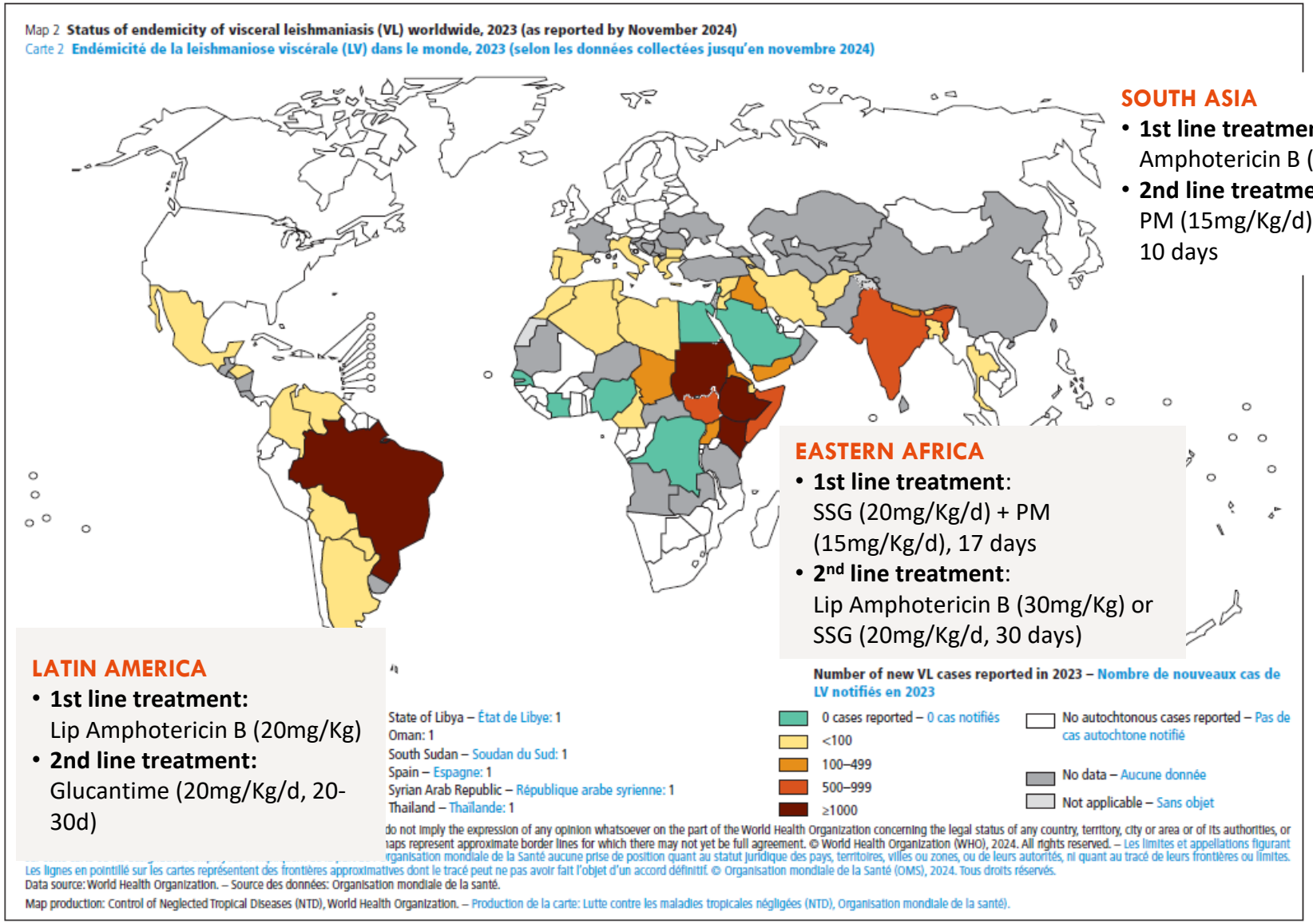
• Visceral leishmaniasis: current treatments per region

94% IN THE 3 HOT SPOTS

Eastern Africa 79% (Djibouti, Chad, Eritrea, Ethiopia, Kenya, Somalia, South Sudan, Sudan and Uganda)

Latin America 10%(Brazil)

South Asia 5% (Bangladesh, India and Nepal)



SOUTH ASIA

- **1st line treatment:** SD Lip Amphotericin B (10mg/Kg)
- **2nd line treatment:** PM (15mg/Kg/d) + MF (2.5mg/Kg/d), 10 days

EASTERN AFRICA

- **1st line treatment**: SSG (20mg/Kg/d) + PM (15mg/Kg/d), 17 days
- **2nd line treatment**: Lip Amphotericin B (30mg/Kg) or SSG (20mg/Kg/d, 30 days)

LATIN AMERICA

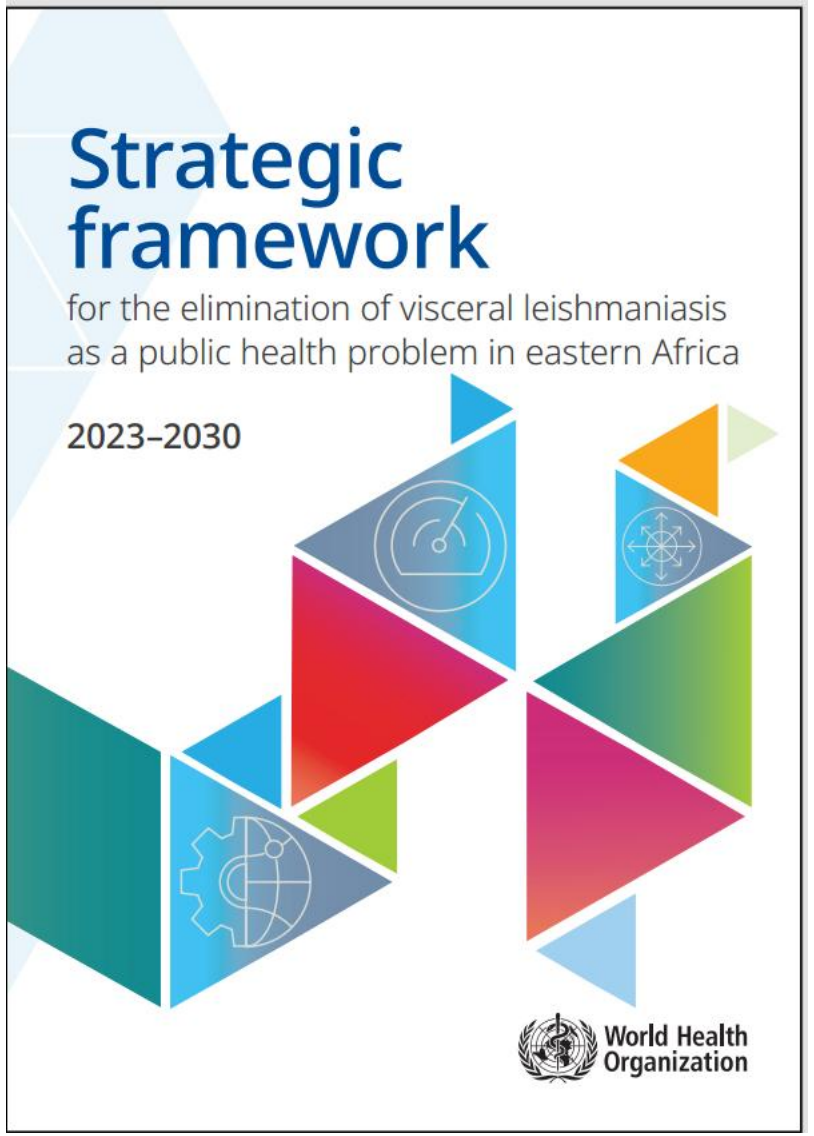
- **1st line treatment:** Lip Amphotericin B (20mg/Kg)
- **2nd line treatment:** Glucantime (20mg/Kg/d, 20-30d)

• Strategic Framework for the Elimination of VL in Eastern Africa

Research and development should alongside address the limitations of the currently available tools, such as the ***development of new point-of-care diagnostic tests and test of cure; and new oral safe treatments that can be deployed at health centres, close to the communities***

Early diagnosis and treatment: case management

- Explore the barriers and opportunities to accessing health services among specific groups of individuals who may fall outside of the health system (internally displaced persons, refugees, migrants); this is critical to inform strong policy recommendations.
- Develop new rapid tests, ideally affordable antigen-based tests, that can be used for diagnosis and test of cure for VL and PKDL; the rk39 rapid diagnostic test has less sensitivity in Africa (85%) than in Asia (95%).
- Devise new treatments, ideally oral, safe, efficacious therapies that can be implemented in health centres, close to the communities.
- Urge policy uptake of proven regimens by strengthening regulatory systems to facilitate rapid introduction of scientific advances into practice (e.g. paromomycin and miltefosine for selected eligible patients and for HIV–VL treatment).
- Implement pharmacovigilance and resistance monitoring surveillance in the region.



DNDi Strategic goals for Leishmaniasis

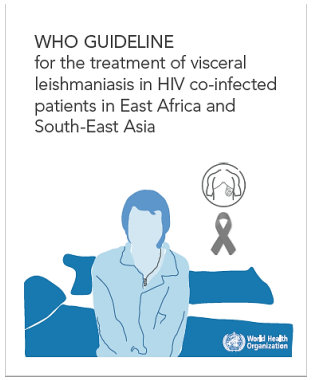
OUR GOALS

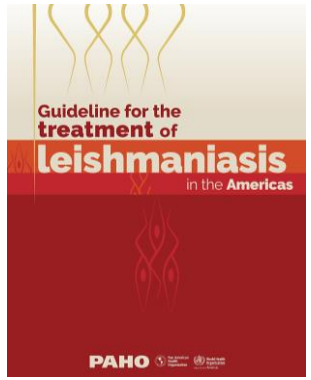
- **To deliver a safe, effective, short-course oral treatment for VL and CL**
- New treatment for **PKDL** and treatment options for **VL in people living with HIV**
- Combination therapy of anti-parasitic and immunomodulator for complicated **CL** forms
- Facilitate conduct of clinical activities and implementation of tools via **platforms and consortia**
- Promote **access to diagnosis and treatment** for patients with leishmaniasis
- To **support Elimination of VL** as a public health problem and **control of CL**

- **Parallel tracks: Conducting R&D for all-new oral therapies while improving treatment with existing drugs**

• New WHO guidelines expected in 2025

Guidelines released in 2022:





[Public notice for comments on the guideline development group participants for the WHO guideline for treatment of visceral leishmaniasis and post-kala-azar dermal leishmaniasis in Eastern Africa and South East Asia]

Clinical Infectious Diseases

MAJOR ARTICLE

IDSA Infectious Diseases Society of America · hivma hiv medicine association · OXFORD

Paromomycin and Miltefosine Combination as an Alternative to Treat Patients With Visceral Leishmaniasis in Eastern Africa: A Randomized, Controlled, Multicountry Trial

Ahmed M. Musa,[1] Jane Mbui,[2] Rezika Mohammed,[3] Joseph Olobo,[4] Koert Ritmeijer,[5] Gabriel Alcoba,[6] Gina Muthoni Ouattara,[7] Thaddaeus Egondi,[7] Prossy Nakanwagi,[7] Truphosa Omollo,[7] Monique Wasunna,[7] Luka Verrest,[8] Thomas P. C. Dorlo,[8] Brima Musa Younis,[1] Ali Nour,[1] Elmukashfi Taha Ahmed Elmukashfi,[1] Ahmed Ismail Omer Haroun,[1] Eltahir A. G. Khalil,[1] Simon Njenga,[2] Helina Fikre,[3] Tigist Mekonnen,[3] Dagnew Mersha,[9] Kasaye Sisay,[9] Patrick Sagaki,[10] Jorge Alvar,[11] Alexandra Solomos,[11] and Fabiana Alves[11]

PLOS NEGLECTED TROPICAL DISEASES

RESEARCH ARTICLE

Safety and efficacy of paromomycin/miltefosine/liposomal amphotericin B combinations for the treatment of post-kala-azar dermal leishmaniasis in Sudan: A phase II, open label, randomized, parallel arm study

Brima Musa Younis[1], Ahmed Mudawi Musa[1], Séverine Monnerat[2], Mohammed Abdelrahim Saeed[1], Eltahir Awad Gasim Khalil[1], Anas Elbashir Ahmed[1], Mujahid Ahmed Ali[1], Ali Noureldin[1], Gina Muthoni Ouattara[3], Godfrey M. Nyakaya[3], Samuel Teshome[3], Truphosa Omollo[3], Michael Ochieng[3], Thaddaeus Egondi[3], Mildred Mmbone[3], Wan-Yu Chu[4], Thomas P. C. Dorlo[5], Eduard E. Zijlstra[2], Monique Wasunna[3], Jorge Alvar[2], Fabiana Alves[2]*

PLOS NEGLECTED TROPICAL DISEASES

RESEARCH ARTICLE

A phase II, non-comparative randomised trial of two treatments involving liposomal amphotericin B and miltefosine for post-kala-azar dermal leishmaniasis in India and Bangladesh

Shyam Sundar[1,2☯], Krishna Pandey[3☯], Dinesh Mondal[4☯], Major Madhukar[3], Roshan Kamal Topno[3], Ashish Kumar[3], Vinod Kumar[3], Deepak Kumar Verma[1], Jaya Chakravarty[2], Rahul Chaubey[1], Poonam Kumari[1], Md. Utba Rashid[4], Shomik Maruf[4], Prakash Ghosh[4], Sheeraz Raja[5], Joelle Rode[6], Margriet den Boer[7], Pradeep Das[3], Jorge Alvar[8], Suman Rijal[5], Fabiana Alves[8]*

Moving from currently existing drugs to new effective, safe and easy-to-use treatments

Long-term strategy: to develop new safe and effective oral treatments for leishmaniasis patients

Target product profile focused on IMPACT for patients

Current treatments

- Largely injectable
- Some toxicity
- Variable efficacy
- Hospitalisation
- Cold chain
- Expensive

NEW SHORT-COURSE THERAPIES

For VL

For CL

New treatments

- Oral
- Safe, well-tolerated
- Improved efficacy
- Integrated approach, at PHC level
- Affordable

- New treatments to include **children and women** of childbearing age
- Treatments to be integrated at **health centres**, close to the communities affected by VL – promoting UHC
- This would have an impact on **time to access** to treatment, preventing disabilities and death, and reducing transmission
- The NCEs will benefit not only **VL patients**, but also **patients with CL, PKDL, and VL in people living with HIV**

Main pillar: access to early diagnosis and prompt treatment

DNDi Leish strategy and portfolio

TRANSLATION

Pre-clinical

- DNDI-8526 (S07 series)

Phase I

- DNDI-6148
- DNDI-6899 (GSK899 DDD853651)
- DNDI-6174
- CpG-D35 (DNDI-2319)

Phase IIa/ Proof-of-concept

- LXE408 for VL
- LXE408 for CL

DEVELOPMENT

Phase IIb/III

New WHO guidelines expected in May

Registration

- Miltefosine + paromomycin for VL (Africa)
- Miltefosine + paromomycin or LAmB for PKDL (Eastern Africa)
- LAmB +/- miltefosine for PKDL (South Asia)
- Miltefosine + thermotherapy for CL

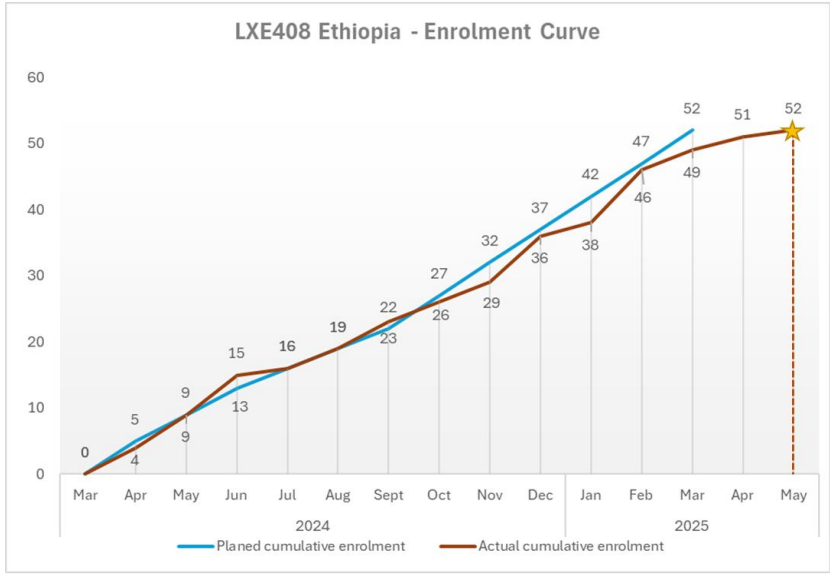
DNDI-6148: on hold

Non interventional Community based study: barriers to contraception

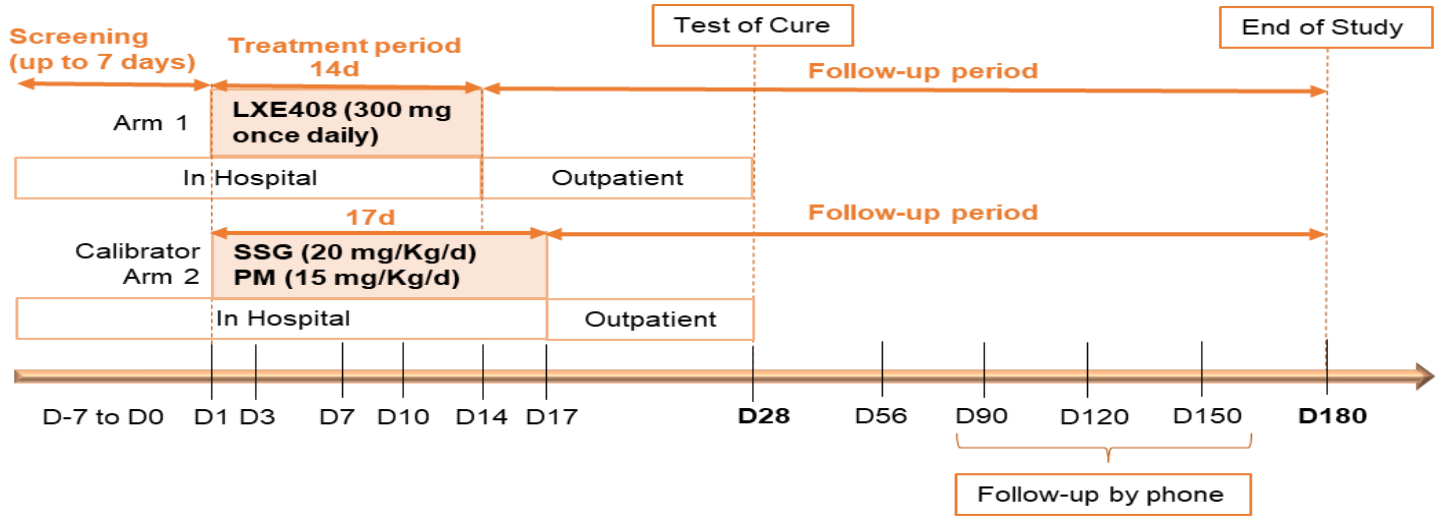
• Phase 2 LXE408 clinical trial in Ethiopia

A randomized, open-label, phase II, single-center study to evaluate the efficacy, safety and pharmacokinetics of LXE408 in patients with primary VL in Ethiopia

- Objectives:
  - to assess the efficacy, safety and pharmacokinetics of LXE408 in patients with VL
  - to explore predictive biomarkers for efficacy; and patient reported symptoms and health related QoL
- Study sites: LRTC, Univ of Gondar
- Patient population: adult male and female patients with confirmed VL and no signs of severe disease
- Total of 52 adult patients, 3:1
- DSMB monitoring progress of study
  3 reviews: study progresses as planned
- Close out visit done
- Results expected in Q2 2026



★ Recruitment completed on 31st May 2025.



Clinical trial protocol synopsis: LXE408 Phase II Ethiopia

• Development programme – summary of approach

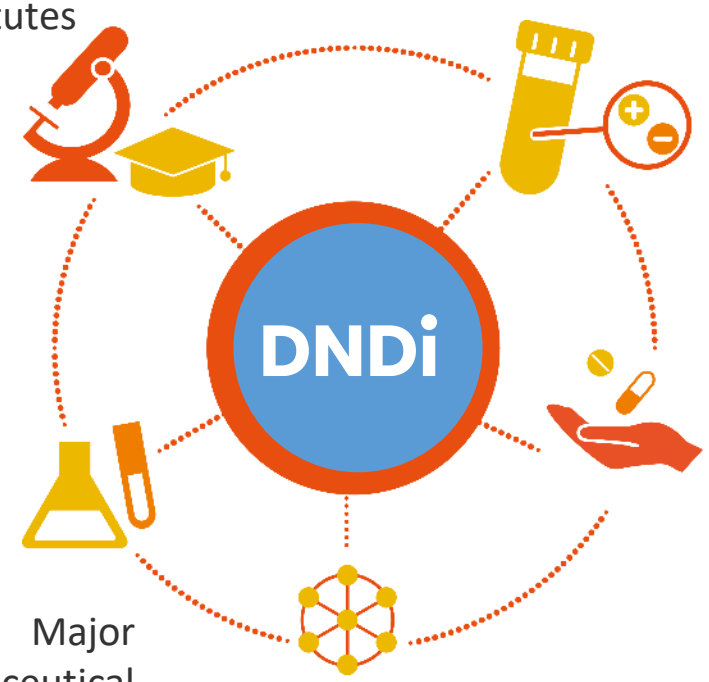
- **Develop NCEs in parallel**, with **data-driven decision making** for progression
- Adapted for the context of the leishmaniasis forms in the **3 regions** – Asia, Africa and Latin America
- **Regulatory consultation** from the early stages of development
- New oral therapies will be **adapted for paediatric populations**
- Extended from VL to other leishmaniasis indications where possible **(CL, PKDL, VL-HIV)**
- Framed by a clear understanding of **access requirements, including patient / community perspectives** (PRO, qualitative research, etc.)
- **Biomarkers** integrated to optimise study design and future drug development in leishmaniasis
- In addition, support the development of **new diagnostic tools**

• Diverse partnerships for NCE development

VL-INNO

Academic and public health research institutes

- University of Dundee
- Swiss TPH
- LMPH, University of Antwerp
- KAMRC, BHU
- RMRI and NIP, ICMR
- Univ of Gondar
- Inst Endemic Diseases
- KEMRI
- IDDO
- ITM
- Uppsala University
- FIOCRUZ
- AMREF



Partners focused on diagnostics

- FIND
- Univ of York
- KEMRI
- Inst Carlos III
- SpotLab

Partnerships for access

- WHO
- MoH, national programmes
- The End Fund

Major pharmaceutical partners

- Novartis
- GSK
- Eisai Co., Ltd.
- Takeda Pharmaceutical Company Limited

Networks in endemic countries

LEAP LEISHMANIASIS EAST AFRICA PLATFORM

redeLEISH
Rede de Pesquisadores e Colaboradores em Leishmanioses
Red de Investigadores y Colaboradores en Leishmaniasis
Network of Investigators and Collaborators in Leishmaniasis

EDCTP

wellcome

GHIT Fund
Global Health Innovative Technology Fund

Thank you!

DNDi

Best Science
for the Most Neglected

Parallel Session B – 11.2

Opportunities for operational innovations with ivermectin-albendazole for STH control

14:00 - 15:30

African Union

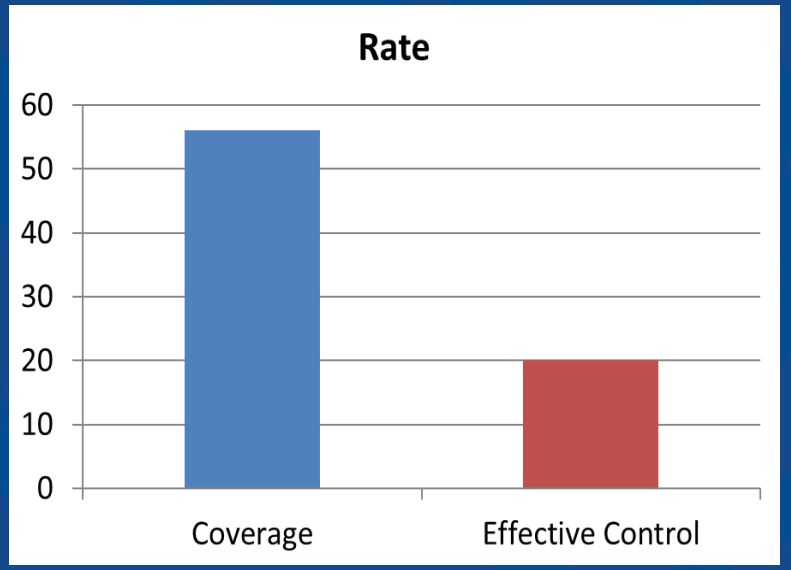
World Health Organization
African Region

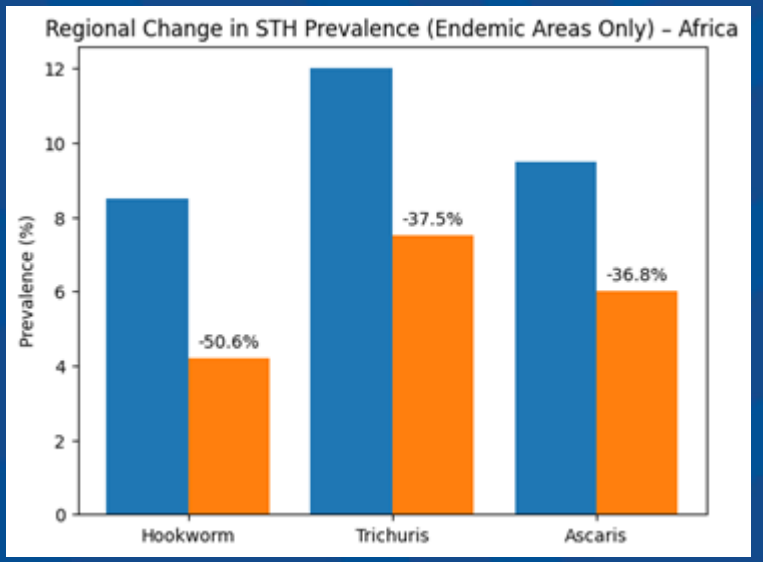
ESPEN
EXPANDED SPECIAL PROJECT FOR ELIMINATION OF NEGLECTED TROPICAL DISEASES

Opening and objectives

STH Control: Strong Progress, Persistent Gaps

- Preventive chemotherapy (PC) is the backbone of STH control
- About 498 million children treated globally (2024)
- ≈56% global coverage; uneven across regions
- Limited coverage for women of reproductive age
- EPHP target: <2% moderate/heavy intensity infections and <20% any STH prevalence
- Gap: Coverage achieved ≠ transmission control





The Unfinished Agenda: Species-Specific Gaps

Albendazole/mebendazole effective for Ascaris and hookworm

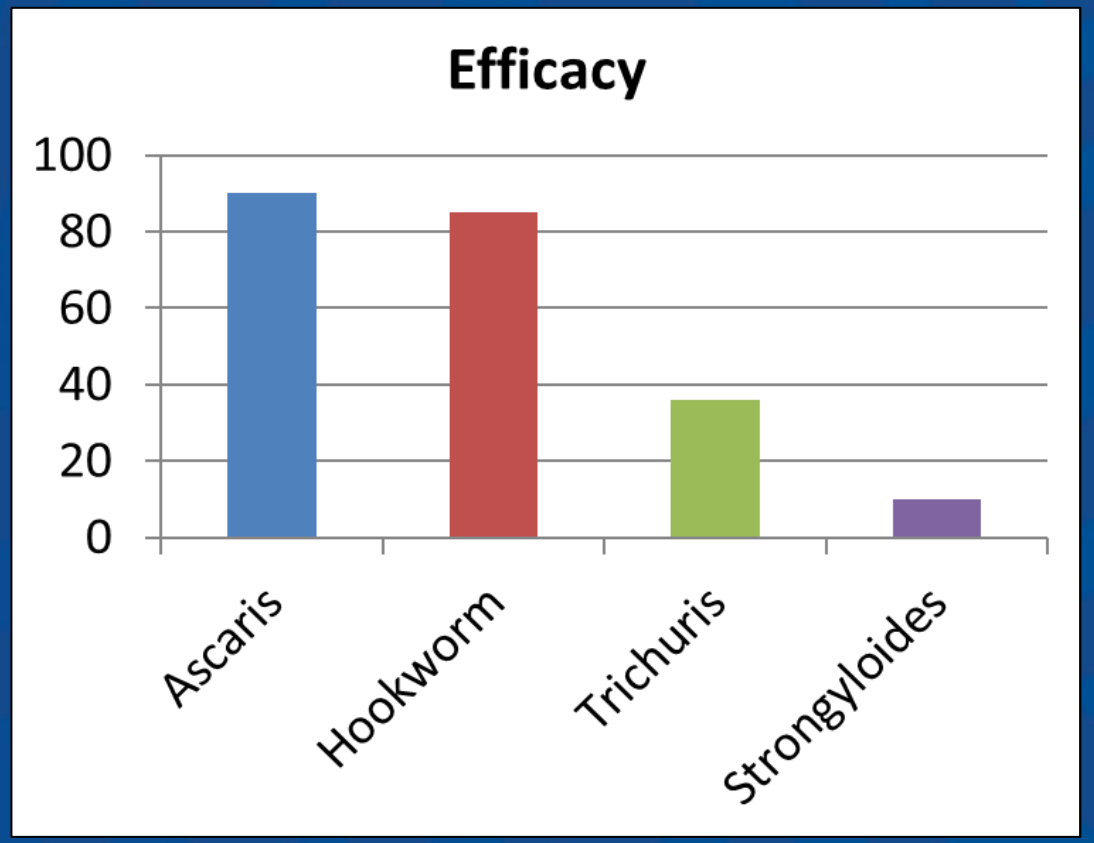
Suboptimal efficacy for Trichuris trichiura

Limited effect on Strongyloides stercoralis

Persistent reservoirs despite high coverage

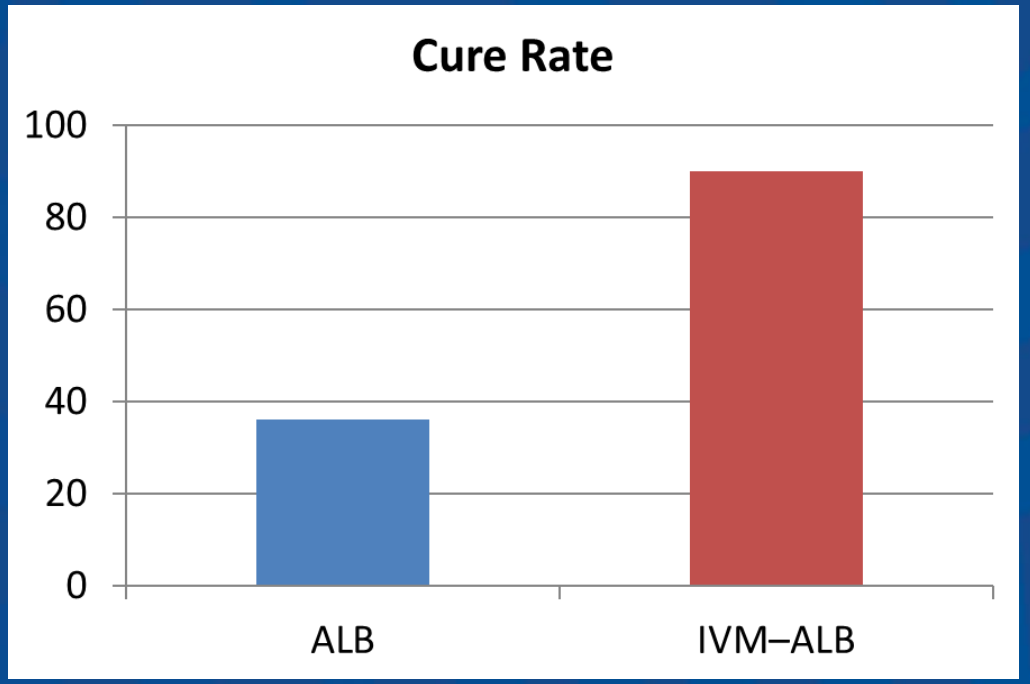
Continued risk of continued transmission

Key message: Achieving coverage is not equal to achieving cure



From Coverage to Impact: IVM–ALB Combination

- IVM–ALB shows superior efficacy vs monotherapy
- Trichuris cure rates: ~36% (ALB) vs >80–97% (IVM–ALB)
- Effective against Strongyloidiasis and other co-endemic conditions
- Supports integrated NTD control (LF, scabies)
- Aligns with WHO Roadmap for improved treatment tools
- Shift: From single-disease to multi-disease impact



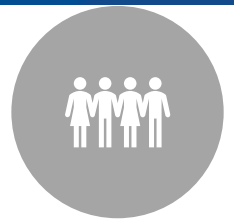
Programmatic Innovation: Fixed-Dose Combination

- Single tablet simplifies dosing vs multiple IVM tablets
- Reduces need for height/weight-based dosing
- Orodispersible formulation improves pediatric delivery
- Lower logistics and operational burden
- Improved adherence and coverage efficiency
- Innovation = operational + pharmacological advancement

The fixed dosed combination is only for SAC and adult. This formulation is not yet prequalified by WHO. It will not be donated

From Evidence to Implementation

Existing ivm–alb platforms in lf programmes



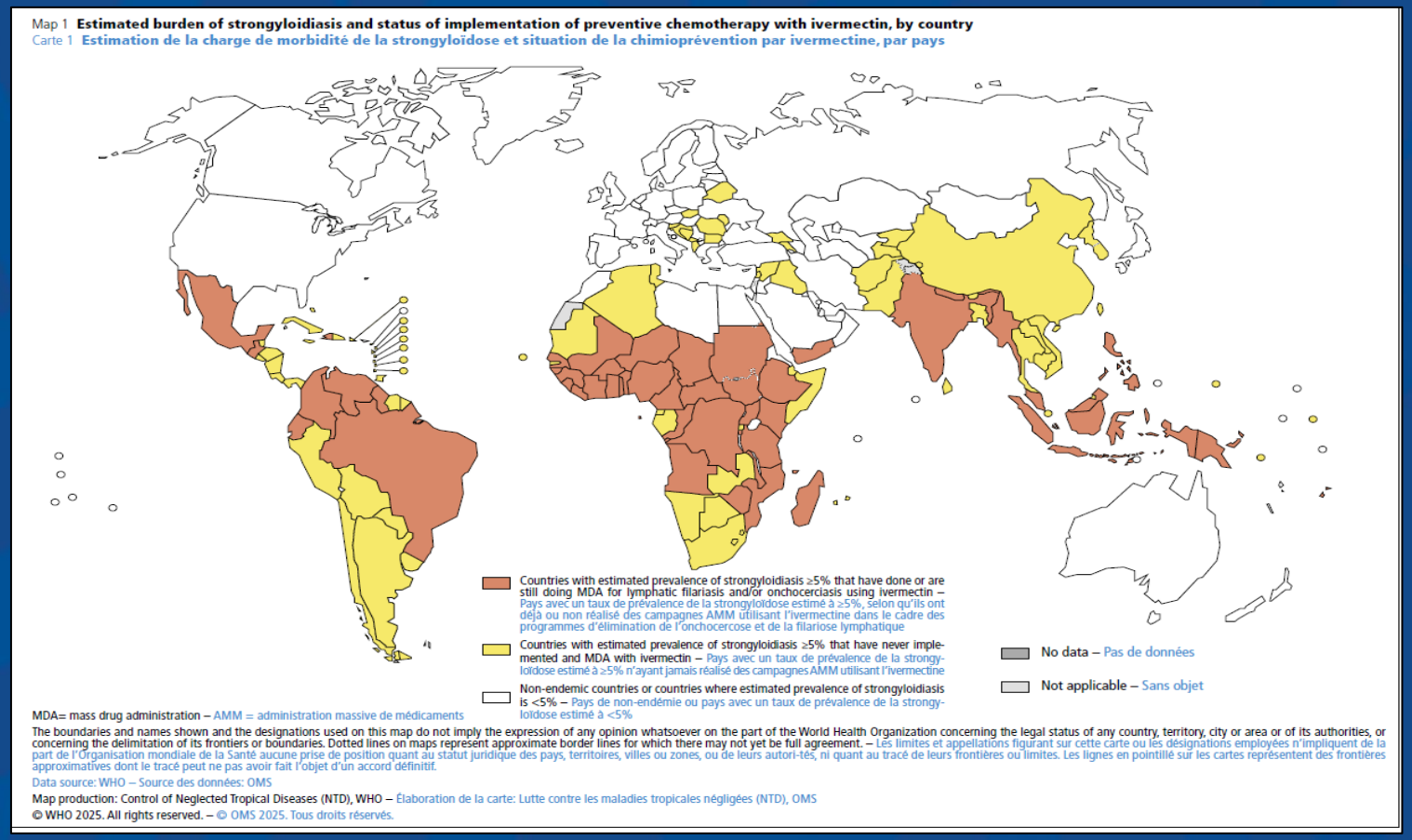
Opportunity to align with sth epidemiology

Target high trichuris and strongyloides burden areas

Who guidelines in development for combination regimens

Key question: how to optimize impact using existing systems?

Estimated burden of strongyloidiasis



Programme Managers and disease experts: Questionnaire to us better understand current implementation practices and the challenges countries may be facing.

Please access it via the QR Code in attachment or via this link: https://redcap.link/vyctxrms

African Union

World Health Organization
African Region

ESPEN
EXPANDED SPECIAL PROJECT FOR ELIMINATION OF NEGLECTED TROPICAL DISEASES

ANNUAL MEETING OF
NTD PROGRAMME MANAGERS IN AFRICA

Session 11.2:

Opportunities for operational innovations with ivermectin-albendazole for STH control: country perspectives to strengthen African NTD programmes

Kenya: Dr Stella Kepha, KEMRI/Wycliff Omondi

Ghana: Dr Joseph Opare, Ghana

Rwanda: Dr Ladislas Nshimiyimana

General objective

- To explore how simplified delivery approaches for ivermectin–albendazole preventive chemotherapy could support more efficient, sustainable, and country-owned NTD programmes in Africa.

Specific objectives

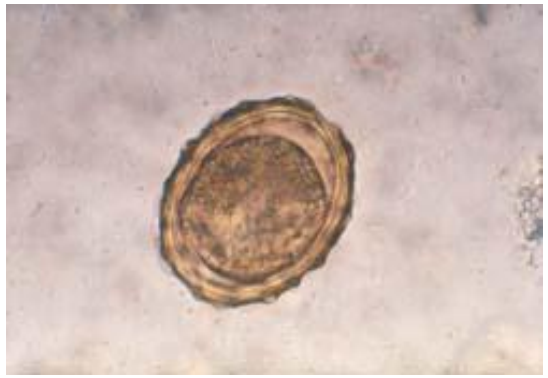
- To update on the current situation and challenges in soil-transmitted helminths control in three African countries.
- To discuss operational challenges associated with integrating ivermectin into preventive chemotherapy programmes for STH control
- To share experiences from countries evaluating ivermectin-albendazole delivery approaches

Perspectives from Kenya – Stella Kepha

Soil-transmitted helminths

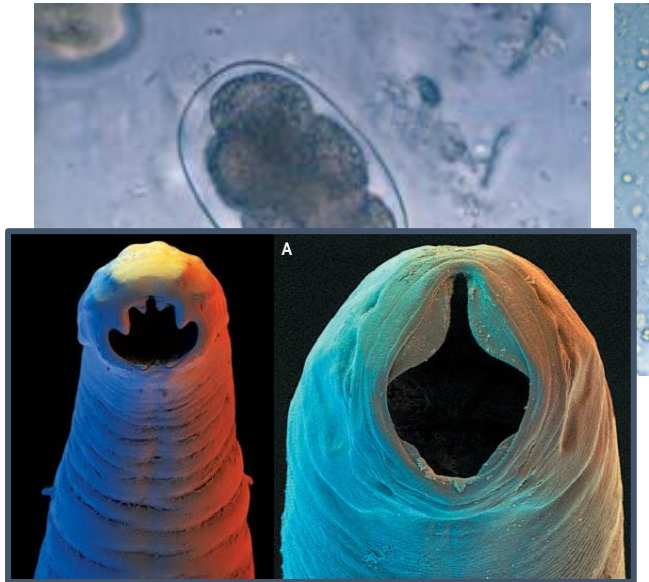
STH are a group of parasites transmitted through contact with environmental sources (soil, water, food) that directly or indirectly were contaminated with human feces that contain eggs or larvae of these parasites.

Ascaris lumbricoides



Trichuris trichiura

Ancylostoma duodenale & *Necator americanus*
Uncinarias



Strongyloides stercoralis

Risk analysis of new strategies in STH treatment

Outcome of STH Drug Combinations Expert Meeting, BMGF, April 2016

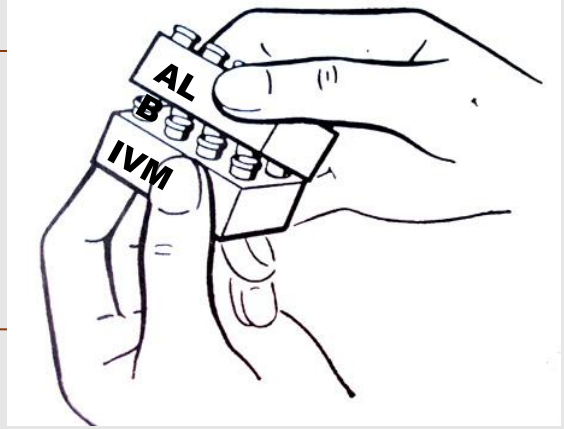
Levels of Investment Risk

	Low Risk	Medium Risk	High Risk
Time to WHO approval	Short	Medium	Long
Cost of development	Low	Medium	High
Data on safety in MDA	Large	Medium	Small

Candidates for Combination STH Treatment

Tier 1 (low investment risk)
albendazole + ivermectin
Tier 2 (medium investment risk)
albendazole + oxantel (or oxantel/pyrantel)
mebendazole + oxantel (or oxantel/pyrantel)
mebendazole + ivermectin
Tier 3 (high investment risk)
albendazole + moxidectin

A long way for a simple idea



J Antimicrob Chemother
doi:10.1093/jac/dkz524

Journal of Antimicrobial Chemotherapy

Safety of high-dose ivermectin: a systematic review and meta-analysis

Miriam Navarro [1]*, Daniel Camprubí[2], Ana Requena-Méndez[2], Dora Buonfrate [3], Giovanni Giorli[3], Joseph Kamgno[4], Jacques Gardon[5], Michel Boussinesq[5], Jose Muñoz[2] and Alejandro Krolewiecki[2,6]

frontiers | Frontiers in Pharmacology

CLINICAL TRIAL
published: 14 July 2022
doi: 10.3389/fphar.2022.914886

Pharmacokinetic Characterization and Comparative Bioavailability of an Innovative Orodispersible Fixed-Dose Combination of Ivermectin and Albendazole: A Single Dose, Open Label, Sequence Randomized, Crossover Clinical Trial in Healthy Volunteers

OPEN ACCESS

Edited by:
Anthony Attama,
University of Nigeria, Nsukka, Nigeria

Jaime Algorta[1], Alejandro Krolewiecki[2,3], Filipe Pinto[4], Silvia Gold[5] and Jose Muñoz[6]*

PLOS | NEGLECTED TROPICAL DISEASES

RESEARCH ARTICLE

Albendazole and ivermectin for the control of soil-transmitted helminths in an area with high prevalence of *Strongyloides stercoralis* and hookworm in northwestern Argentina: A community-based pragmatic study

Adriana Echazú[1,2]*, Marisa Juarez[1], Paola A. Vargas[1,2], Silvana P. Cajal[1], Ruben O. Cimino[1,3], Viviana Heredia[4], Silvia Caropresi[4], Gladys Paredes[4], Luis M. Arias[5], Marcelo Abril[6], Silvia Gold[6], Patrick Lammie[7], Alejandro J. Krolewiecki[1,2]

PLOS | NEGLECTED TROPICAL DISEASES

RESEARCH ARTICLE

Safety and pharmacokinetic profile of fixed-dose ivermectin with an innovative 18mg tablet in healthy adult volunteers

Jose Muñoz[1], Maria Rosa Ballester[2], Rosa Maria Antonijoan[2,3], Ignasi Gich[2,3], Montse Rodríguez[2], Enrico Colli[4], Silvia Gold[5], Alejandro J. Krolewiecki[6]*

Gates Open Research

Gates Open Research 2022, 6:62 Last updated: 05 MAY 2022

Check for updates

STUDY PROTOCOL

An adaptive phase II/III safety and efficacy randomized controlled trial of single day or three-day fixed-dose albendazole-ivermectin co-formulation versus albendazole for the treatment of *Trichuris trichiura* and other STH infections. ALIVE trial protocol [version 1; peer review: awaiting peer review]

Alejandro Krolewiecki[1,2], Wendemagegn Enbiale[3,4], Javier Gandasegui[1], Lisette van Lieshout[5], Stella Kepha[6], Augusto Messa Junior[7], Michel Bengtson[5], Woyneshet Gelaye[3], Valdemiro Escola[7], María Martinez-Valladares[8,9], María Cambra-Pellejà[8,9], Jaime Algorta[10], Helena Martí-Soler[1], Pedro Fleitas[1,2], Maria Rosa Ballester[11-13], Stephen R. Doyle[14], Nana Aba Williams[1], Almudena Legarda[1], Inacio Mandomando[7], Charles Mwandawiro[6], Jose Muñoz[2]

Developing additional data on

- Safety
- Acceptability
- Cost-effectiveness

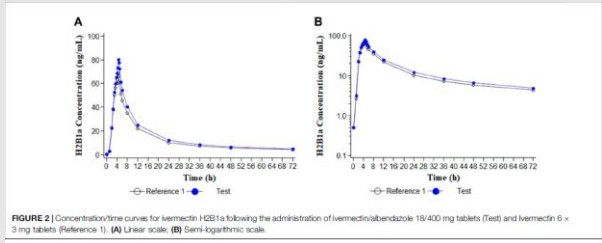


FIGURE 2 | Concentration/time curves for ivermectin H2B1a following the administration of ivermectin/albendazole 18/400 mg tablets (Test) and Ivermectin 6 × 3 mg tablets (Reference 1). (A) Linear scale; (B) Semi-logarithmic scale.

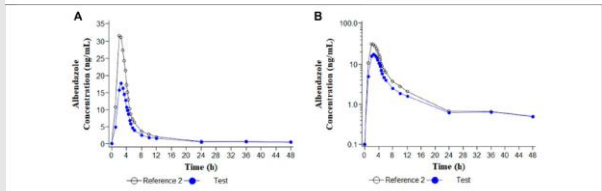
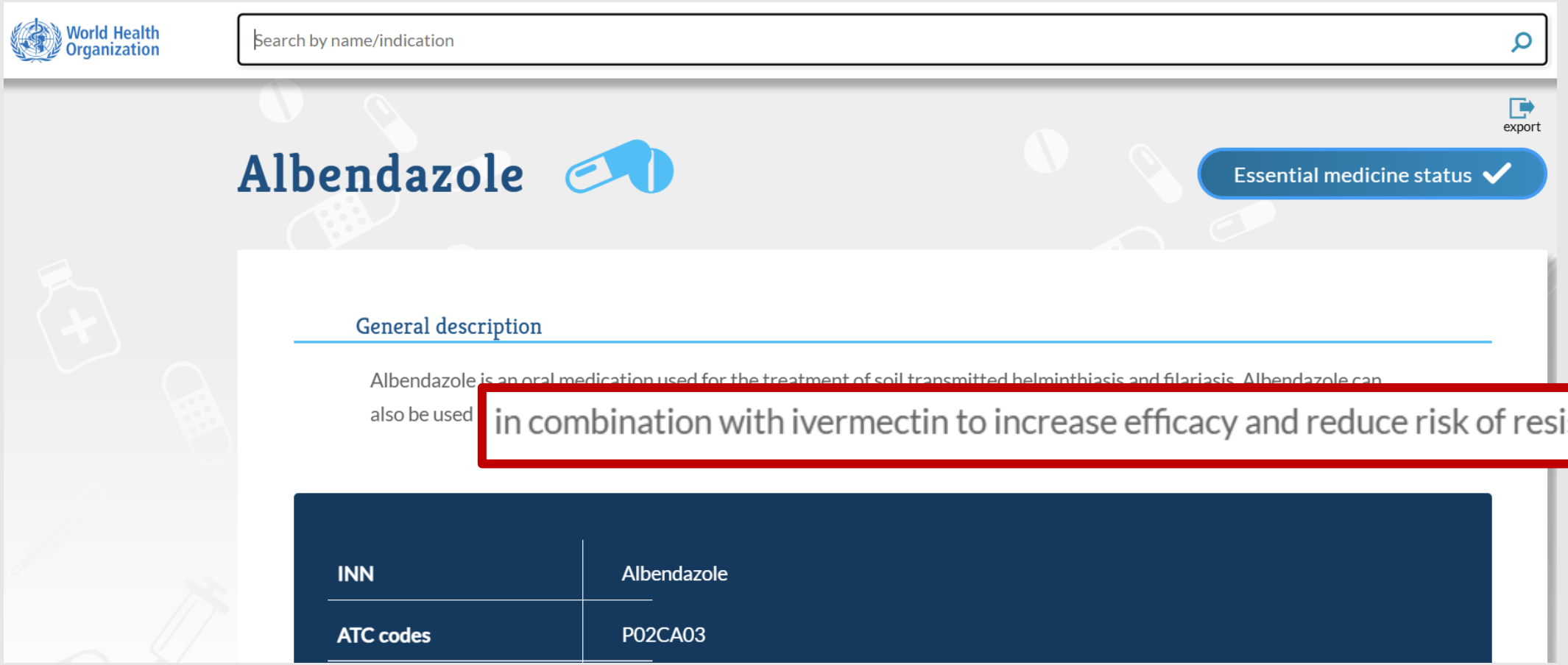


FIGURE 3 | Concentration/time curves for albendazole following the administration of ivermectin/albendazole 18/400 mg tablets (Test) and albendazole tablets (Reference 2). (A) Linear scale; (B) Semi-logarithmic scale.

WHO – Essential Medicines List on ALB + IVM



The innovative component of a new product – ALB/IVM

These are innovations

- Formulation.
  - Co-formulation
  - Orodispersible
  - Mango flavoured
- Dosage (?)
- Access plan

These are NOT innovations

- Molecules
- Indications:
  - Diseases
  - Population
- DDI

This project is supported by the Global Health EDCTP3 Joint Undertaking and its members

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No 101103089

Project funded by

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Education, Research and Innovation SERI

Adaptive Phase II - III safety & efficacy trial of a fixed-dose combination (FDC) of ALB & IVM compared to ALB (n:1223)

5 – 18 years-old infected with *T. trichiura*, hookworms and/or *S. stercoralis*

- Arm 1: ALB 400 mg single-dose n:277
- Arm 2: FDC single-dose n:469
- Arm 3: FDC daily x 3 days n:477

Phase II (n:126)
Infected with *T. trichiura*

Group 1 (n:38) 23 – 30 Kg
- Arm 1: ALB 400mg
- Arms 2 & 3: 9mg IVM/400mg ALB (daily IVM dose: 300 - 391µg/Kg)

COMPLETED

DSMB

Group 2 (n:38) 30 – 45 Kg
- Arm 1: ALB 400mg
- Arms 2 & 3: 18mg IVM/400mg ALB (daily IVM dose: 400 – 600 µg/Kg)

DSMB

Group 3 (n:50) 15 – 23 Kg
- Arm 1: ALB 400mg
- Arms 2 & 3: 9mg IVM/400mg ALB (daily IVM dose: 391 - 600µg/Kg)

DSMB

Phase III (n:1097)
Infected with *T. trichiura* (n:499) hookworms (n:312) and/or *S. stercoralis* (n:286)

Arm 1: ALB 400 mg single-dose

COMPLETED

Arm 2: FDC single-dose
- <45 kg FDC of 400mg ALB/9mg IVM
- ≥45 kg FDC of 400mg ALB/18mg IVM

Arm 3: FDC daily x 3 days
- <45 kg FDC of 400mg ALB/9mg IVM
- ≥45 kg FDC of 400mg ALB/18mg IVM

77

Krolewiecki et al, GOR 2022

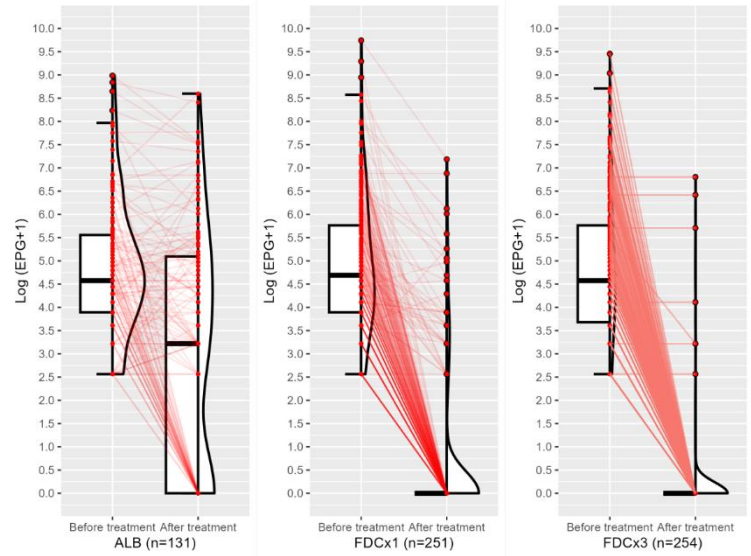
Albendazole–ivermectin co-formulation for the treatment of *Trichuris trichiura* and other soil-transmitted helminths: a randomised phase 2/3 trial

Alejandro Krolewiecki, Stella Kepha, Pedro E Fleitas, Lisette van Lieshout, Wayneshet Gelaye, Augusto Messa Jr, Javier Gandasegui, Jaime Algorta, Valdemiro Novela, Áuria de Jesus, Martin Rona, Dawit Degarege, Dereje Bedane, Jusper Mwahanje, Inácio Mandomando, Charles Mwandawiro, Wendemagegn Enbiale, José Muñoz, on behalf of the Stopping Transmission of Intestinal Parasites (STOP) consortium*

ALIVE: results of the pivotal trial

Efficacy against *T. trichiura*

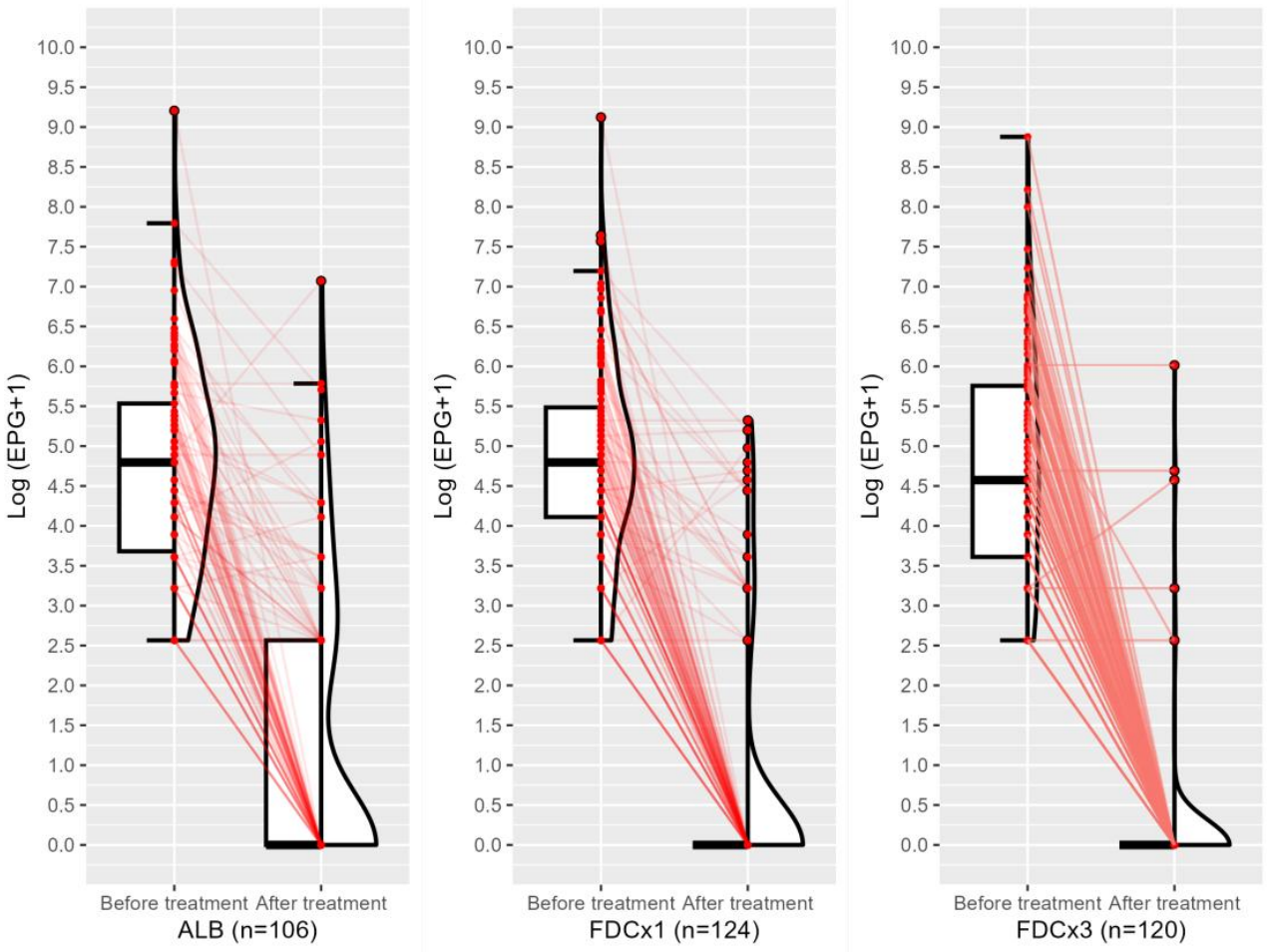
Variable	ALB	FDC x 1	FDC x 3
Cure rate (CR) — % (95% CI)	**35.9** (27.7 – 44.1)	**82.9** (77.5 – 87.2)	**97.2** (95.2 – 99.3)
Difference in CR (vs, ALB)	—	47.0	61.3



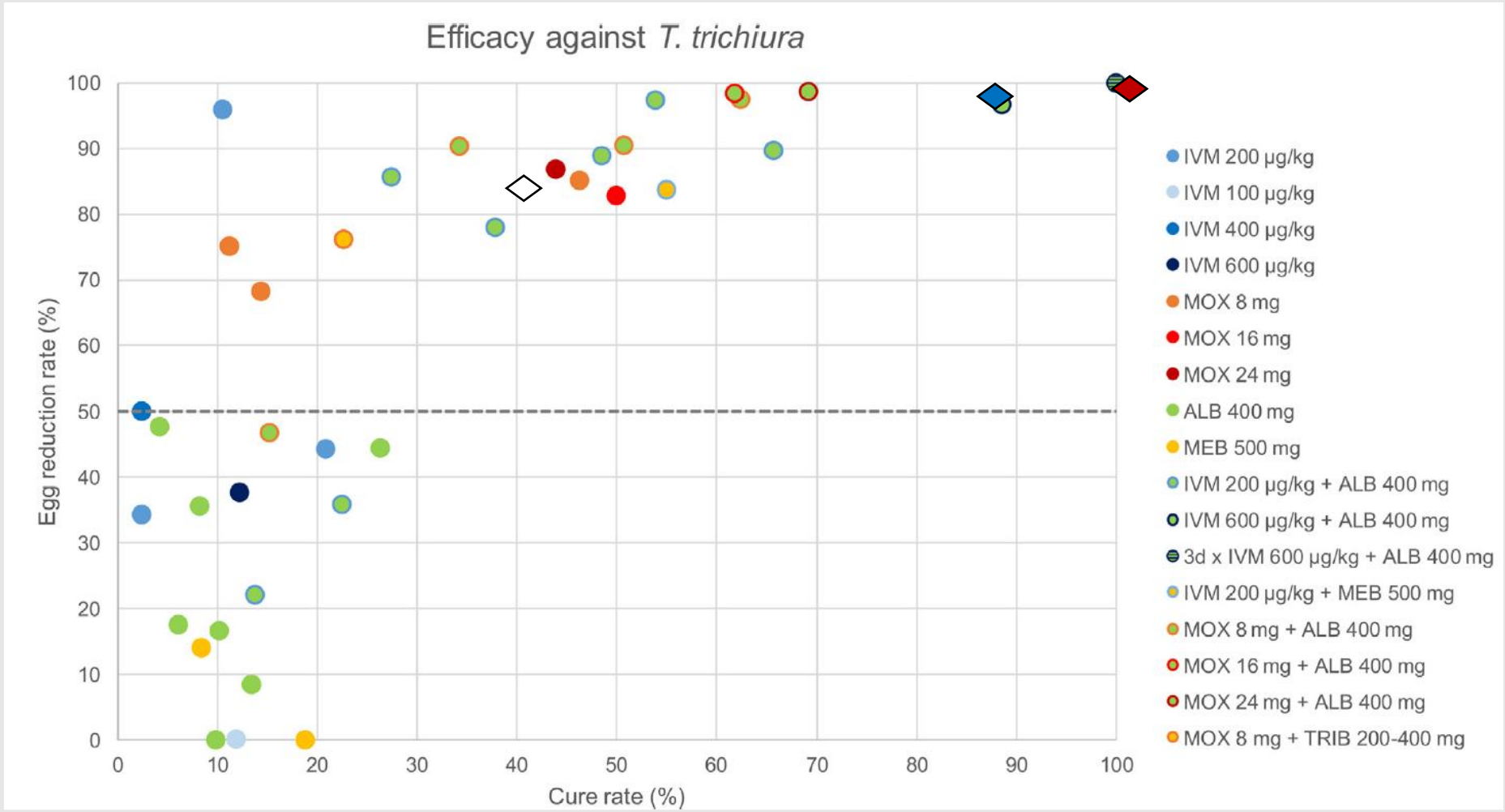
Krolewiecki et al, Lancet ID, 2025 & Fleitas et al, Acta Tropica 2025

Efficacy against hookworm

Variable	ALB	FDCx1	FDCx3
Participants positive for infection			
Before treatment	106	124	120
After treatment	37	25	6
Cure rate — % (95% CI)	65.1 (56.0-74.2)	79.8 (72.8-86.9)	95.0 (91.1-98.9)
Difference in CR (vs. ALB)	-	14.3	29.6



Efficacy against *T. trichiura* across RCTs



ALIVE trial

- FDCx1
- FDCx3
- ALB

Hürlimann et al. Trends Parasitol. 2023;39(4):272-284. doi: 10.1016/j.pt.2023.01.009.

Palatability & acceptability

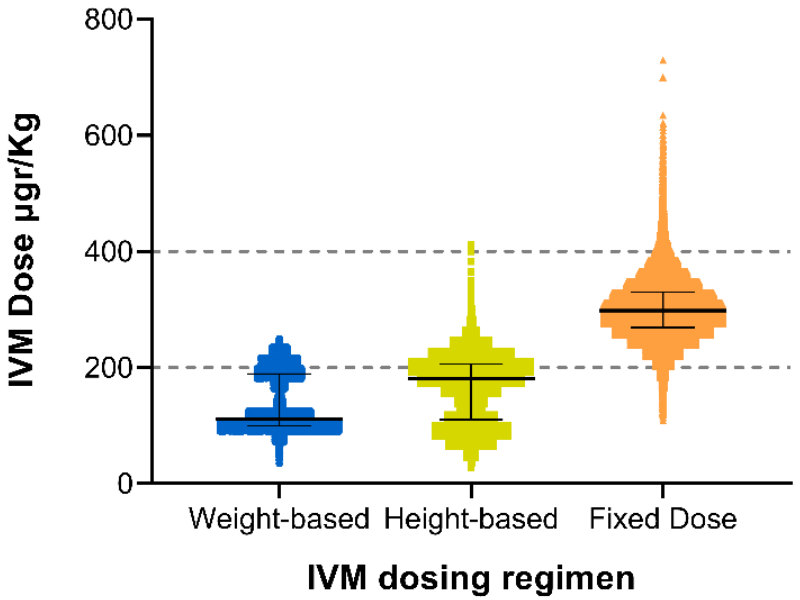
	Very bad	Bad	Acceptable / Ok / Not nice and not bad	Good/Nice	Very good/Very nice
Taste	0 (0.0%)	3 (3.0%)	6 (6.0%)	33 (33.0%)	**58 (58.0%)**
Smell	0 (0.0%)	4 (4.0%)	14 (14.0%)	32 (32.8%)	**50 (50.0%)**
Texture	0 (0.0%)	2 (2.0%)	12 (12.0%)	33 (33.0%)	**57 (57.0%)**
Acceptability	0 (0.0%)	2 (2.0%)	11 (11.0%)	54 (54.0%)	**33(33.0%)**

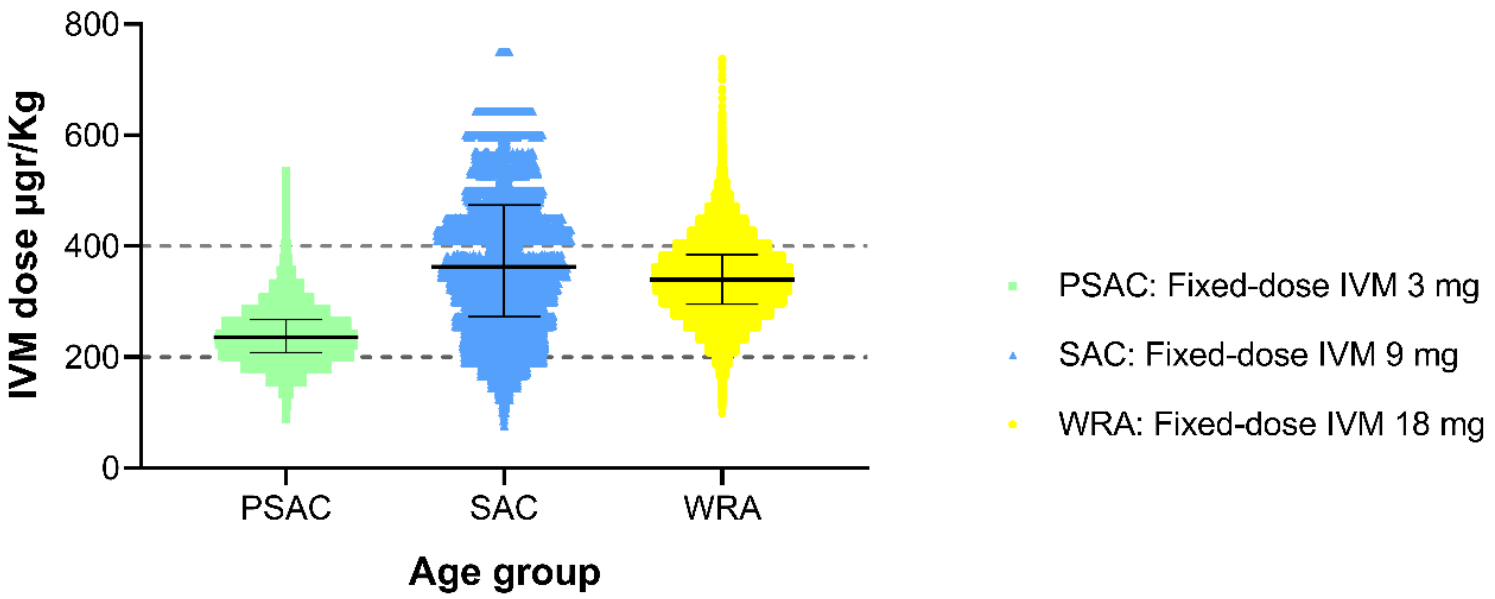
Experience with the intake

Vomited the drug immediately or within 2 hours	I spit it out	Swallowed with some problems	Swallowed with no problems
1 (1.0%)	**0 (0.0%)**	**0 (0.0%)**	**99 (99.0%)**

Can we leave the dose-pole behind?

Individual Participant Data meta-analysis of >700,000 individuals from endemic countries





PLOS Neglected Tropical Diseases

RESEARCH ARTICLE

Fixed-dose ivermectin for Mass Drug Administration: Is it time to leave the dose pole behind? Insights from an Individual Participant Data Meta-Analysis

Adriana Echazu[1,2], Daniela Bonanno[1], Pedro Emanuel Fleitas[3], Julie Jacobson[4], Gabriela Matamoros[5], Charles Mwandawiro[6], Wendemagegn Enbiale[7], Áuria de Jesus[8], Alan Brooks[9]Alejandro Javier Krolewiecki[1,2]*

https://doi.org/10.1371/journal.pntd.0013059

Fixed-dosing of IVM in School-age children

Kenya (N= 1564),
Ethiopia (N= 1025)
Mozambique (N= 1071)
Total= 3660

Dose/Regimen	By weight (N=3584)	By height (N= 3324)	Fix-dose 9 mg (N=3584)
Contraindicated	18; 0.5 % (0.2 0.8)	1; 0.03 % (0 – 0.16)	
Underdose	2084; 58 % (56 – 60)	1235; 37 % (35 – 39)	102; 2,8 % (2,3 – 3,4)
Adequate	**1482; 41.3 % (40 – 43)**	**2088; 62.8 % (61 – 64)**	**3464; 96.6 % (96 – 97)**
Above recommended	0	0	18; 0.5 % (0.2 – 0.7)

Next stage: STOP2030

Overall goal:

Support the achievement of the WHO 2030 NTD Roadmap for STH and beyond.

Project purpose:

Advance and accelerate an innovative pharmacologic tool to support elimination goals against STH species especially those poorly responsive to current treatment regimens.

The intervention: Single tablet, fixed-dose combination of Ivermectin and Albendazole

This project is supported by the Global Health EDCTP3 Joint Undertaking and its members

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No 101103089

Project funded by

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Education, Research and Innovation SERI

Proposed safety and effectiveness study

A multicentre pragmatic trial in Ghana and Kenya, to evaluate safety and effectiveness of FDC as a single dose compared to ALB (400 mg single dose) for the treatment and control of STH

Primary objective

- To evaluate and compare **safety** of a FDC against ALB alone via MDA in two study areas in Kenya and Ghana

Secondary objectives

- To evaluate the effectiveness of one round of MDA with FDC vs. ALB against STH (***T. trichiura, A. lumbricoides,*** **hookworms**) by **microscopy**
- To evaluate the effectiveness of one round of MDA with FDC vs. ALB against ***S. stercoralis*** by **serology**

85

Cohort event monitoring study

6.5 Cohort event monitoring

As well as producing data on rates, cohort event monitoring is particularly effective at identifying previously unrecognized and unsuspected adverse reactions and defining the associated risk factors.

The **SAFETY** *of* **MEDICINES IN PUBLIC HEALTH PROGRAMMES:**

Pharmacovigilance an essential tool

World Health Organization

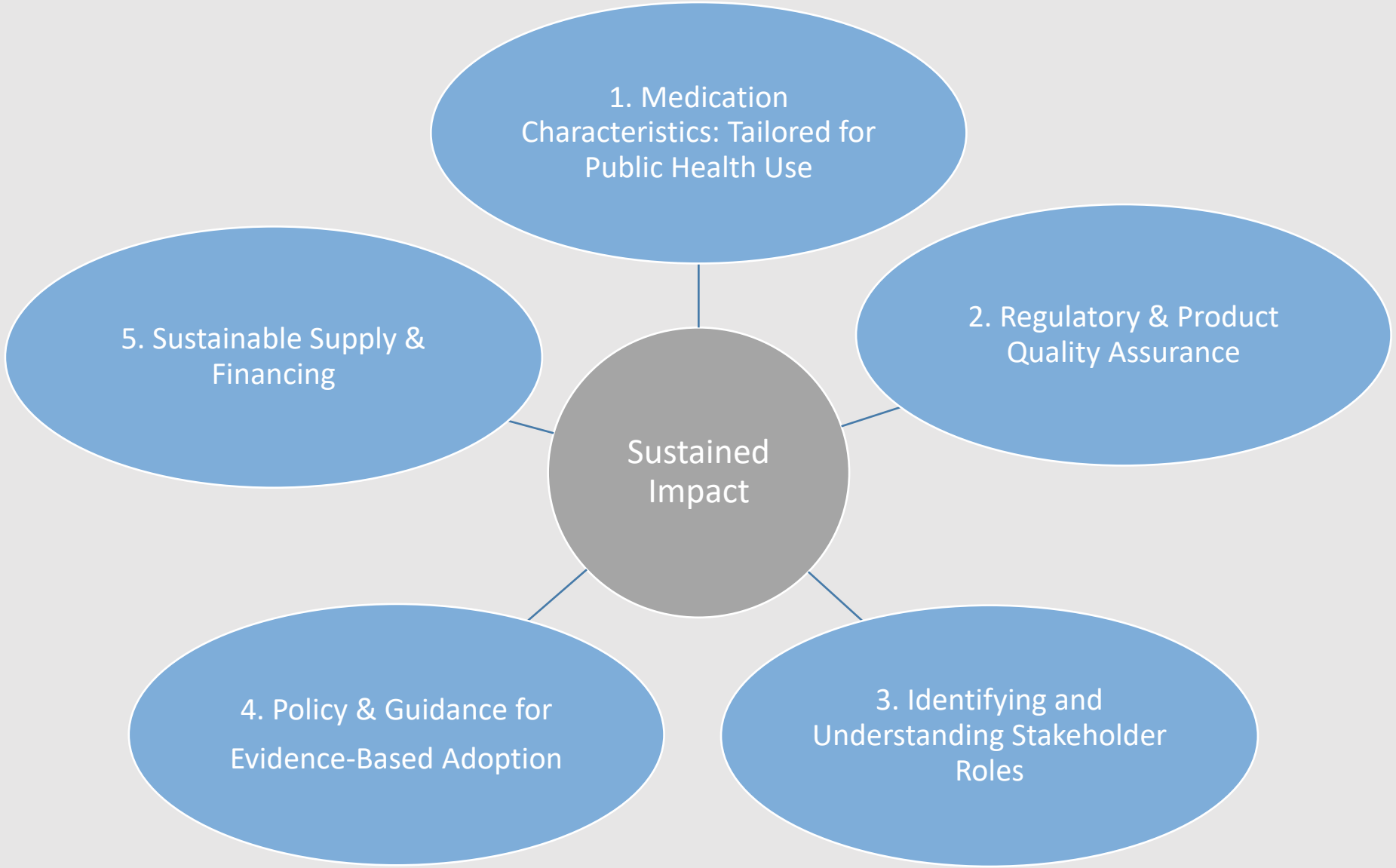
Essentially the method consists of

— establishing a cohort of patients; and

— collecting information on all the adverse events that occur in these patients for a (defined) period after use of the medicine.

WHO, 2006

Access & Stewardship Plan Components for FDC



87

Final remarks, conclusions

- Dosing strategies for IVM are being revisited.
- The fix-dose coformulation of ALB/IVM is due to enter regulatory agencies.
- Acceptability and safety studies are underway.
- The access plan is being developed.
- Integration across programs (these results have implications beyond STH).

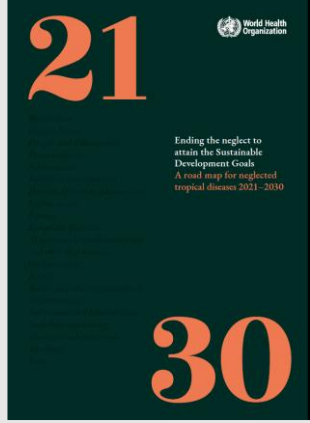
- Progress has been achieved through public-private partnerships

…but more partners are needed to reach the ultimate goal.

Perspectives from Ghana

o

Adressing key aspects of the Roadmap 2021-2030



Soil-transmitted helminthiases including strongyloidiasis

Burden of disease (*A. lumbricoides*, *T. trichiura* and hookworms only)

About 1.5 billion
people estimated to be infected with STH[1] in 2016

About 6300
deaths reported in 2016[1]

About 3.5 million
DALYs in 2016[1]

In 2019, 92 countries required MDA, mostly in tropical and subtropical areas across sub-Saharan Africa, Latin America and Asia but also in some areas of the European Region.

The burden of *S. stercoralis* should be quantified precisely.

Population requiring preventive chemotherapy for STH by WHO region, 2019, million

Pillar 1	*Accelerate programmatic action*
Pillar 2	*Intensify cross-cutting approaches*
Pillar 3	*Change operating models and culture to facilitate country ownership*

Summary of critical actions to achieve targets

- Increase political commitment to ensure sustainable domestic financing.
- Develop more effective medicines and medicine to improve patient outcomes and in case of drug resistance.
- Develop comprehensive surveillance and mapping systems to target treatment and monitor drug resistance.

Ghana in R&D for NTDs

- Participation in clinical trials.
- Leadership in acceptability studies in endemic communities.
  - End users (target population)
  - System (health care workers)

- Submission to Ghana-FDA for country registration.

EMA on ALB/IVM *(30JAN2025)*

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Ivermectin/Albendazole - opinion on medicine for use outside EU

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ivermectin / albendazole

EU-M4all | Human

Page contents

Overview

Product information

Overview

On 30 January 2025, the Committee for Medicinal Products for Human Use (CHMP
accordance with Article 58 of Regulation (EC) No 726/2004 for the medicinal prod
intended for the treatment of soil-transmitted helminth infections and microfilarae

Overview

Ivermectin/Albendazole is a medicine used in adults and children from 5 years of age to treat the following parasitic worm infections:

- soil-transmitted helminth (STH) infections caused by hookworms (*Ancylostoma duodenale, Necator americanus*), roundworms (*Ascaris lumbricoides,Strongyloides stercoralis*) and whipworms (*Trichuris trichiura*). STH infections are intestinal worm infections that spread through soil contaminated by human faeces in areas with poor sanitation;
- proven or suspected microfilaraemia (the presence of worm larvae in the blood) in patients with lymphatic filariasis (LF) caused by *Wuchereria bancrofti*. LF, commonly known as elephantiasis, is a disease that mainly impairs the lymphatic system (a network of vessels that transport fluid from tissues through the lymph nodes and into the bloodstream) and can lead to abnormal enlargement of body parts.

https://www.ema.europa.eu/en/opinion-medicine-use-outside-EU/human/ivermectin-albendazole

European Medicines Agency, 31 January, 2025

"The development of Ivermectin/Albendazole holds a high public health value as it will bring concrete advantages to the effectiveness of mass drug administration programmes in countries where these diseases are endemic. It will help reduce the risk of incorrect dosage, improve adherence, and reduce manufacturing and transport costs. Ultimately, this will allow more people to be treated."

https://www.ema.europa.eu/en/news/new-combination-medicines-treat-parasitic-worm-infections

Ghana - Regulatory environment

- Ghana has a strong and proactive regulatory agency.
  - Several reciprocity agreements with regional agencies

  1st country in the región to register moxidectin for oncho.
  1st country in the world to register ALB/IVM for STH & LF.

- Public-Private collaborations including MoH-Academia-Pharma for evidence generation.

What´s left after the pivotal trial is completed and the products registered by the regulatory agency?

Plenty

Larger safety trials

Achieving WHO prequalification

Acceptability studies

Multi-level

Different regions

Cost effectiveness studies

Essential Medicines list

Access plan

Recommendation

Policy brief

Sustainability in a donation-based environment

Donors

Qualitative data

- Safety and efficacy provided by clinical trials require commplementary data.
- Local contexts need to be considered.
- Acceptability, cost, convenience are key aspects for implementation.
- Early adopter countries are leaders in innovative actions.

Strengths and Weaknesses of National Neglected Tropical Diseases Programmes – A Case Study of Ghana and Kenya

Ivy Osei[1*], Cornelius Debpuur[1], Abraham Oduro[1], Joseph Opare[1], Alan Brooks[2], Julie Jacobson[2], Alejandro Krolewiecki[3], Stella Kepha[4], and Charles Mwandawiro[4]

1. Ghana Health Service P. O. Box MB- 190 Accra, Ghana 2.Bridges to Development Geneva, Switzerland/Washington DC 3. Mundo Sano, Madrid, Spain. Calle Recaredo, 3, 28002 Madrid, Spain 4. Kenya Medical Research Institute (KEMRI) P.O. Box 54840 – 00200, Nairobi, Kenya.

Background
Soil-transmitted helminthiases (STH) remain a major public health concern in endemic countries such as Ghana and Kenya. National Neglected Tropical Disease (NTD) programmes in both countries primarily rely on Mass Drug Administration (MDA) with benzimidazoles. However, concerns regarding suboptimal efficacy against certain STH species and the potential emergence of drug resistance have prompted consideration of alternative treatment strategies, including a fixed-dose combination (FDC) of Albendazole (ALB) and Ivermectin (IVM).This study explored the strengths and weaknesses of the national NTD programmes in Ghana and Kenya to inform the potential uptake of the proposed ALB–IVM FDC for STH management.

Methods
A qualitative comparative case study design was employed. Data were collected through 56 in-depth interviews and 12 focus group discussions with key stakeholders, including national, regional, and district programme implementers, school officials, and parents/caregivers of school-aged children. Data were analysed using a combination of inductive and deductive thematic approaches.

Results
Key strengths identified across both programmes included strong multi-stakeholder collaboration—particularly between the health and education sectors—effective social mobilization and community sensitization strategies, well-established implementation structures, and substantial donor support. However, several challenges persist. These include inconsistent funding resulting in implementation delays, inadequate community sensitization in some areas, suboptimal management of adverse drug reactions (ADRs), periodic drug shortages, parental refusal due to misconceptions, and limited human resources.

Conclusion
Stakeholders expressed positive perceptions of the proposed ALB–IVM FDC, anticipating improved efficacy, broader STH coverage, enhanced adherence due to reduced pill burden, and potential cost savings. To support a successful introduction, respondents recommended intensive community education, comprehensive training for implementers, strategic community entry approaches, and a phased pilot rollout prior to national scale-up.

Keywords: Neglected Tropical Diseases; Soil-transmitted Helminths; Mass Drug Administration; Fixed-Dose Combination; Albendazole; Ivermectin; Ghana; Kenya.

Ghana FDA Requirements for Clinical Trial

- Legal framework for conduct of clinical trials: Public Health Act, 2012 (Act 851)
- Compliance with ICH-GCP (International Council for Harmonization) and national guidelines

Key Requirements:

- Prior approval from an Ethics Review Committee
- Approval from FDA after submission of study protocols
  - FDA may approve, request changes, or reject
- Clinical Trial Certificate must be issued before trial starts
- FDA Import Permit required before shipment of study drugs and any device not already registered in Ghana

Application of Import Permit

- Cover letter stating the quantity and source
- Attached invoice
  - Certificate of Analysis (CoA) if drug
  - Lot Release Certificate if a vaccine
  - Sponsor, manufacturer, trial site details

Import Conditions:

- Up to 10% excess allowed
- Inspection at port of entry
- Use approved electronic import system

Application of Import Permit

Labelling of the investigation product:

- 'For Clinical Trial Use Only'
- Trial name, dosage, expiry date

Post-Import:

- Notify FDA within 48 hours on arrival of the goods
- Contract a clearing agent to apply on the Customs ICUM using the Clinical Trial approval details and that of the Import permit

Country registration – IVM/ALB 9/400 & 18/400

- **In December 2025 Ghana becomes the 1st country to register the product**

Generic	**IVERMECTIN ALBENDAZOLE 9/400 DISPERSIBLE TABLETS** (Each dispersible tablet contains Ivermectin/Albendazole 9mg/400mg)	Laboratories Liconsa Calle Dulcinea S/N Alcala de Henares 28805 Madrid Spain	Laboratories Liconsa SA, Avenida de Miralcampo 7 19200 Azuqueca de Henares , Guadalajara, Spain	Technology Solutions For Global Health Limited, P.O Box Af 3228 Adenta, Accra.	REG Valid for 5 years Expires December 31, 2030	FDA/GD.25 5-120255
Generic	**IVERMECTIN ALBENDAZOLE 18/400 DISPERSIBLE TABLETS** (Each dispersible tablet contains Ivermectin/Albendazole 18mg/400mg)	Laboratories Liconsa Calle Dulcinea S/N Alcala de Henares 28805 Madrid Spain	Laboratories Liconsa SA, Avenida de Miralcampo 7 19200 Azuqueca de Henares , Guadalajara, Spain	Technology Solutions For Global Health Limited, P.O Box Af 3228 Adenta, Accra.	REG Valid for 5 years Expires December 31, 2030	FDA/GD.25 5-120256

Current regulatory status for ALB/IVM

COUNTRY	RA STATUS	TYPE OF PROCEDURE	SUBMISSION DATE	APPROVAL DATE	MAH
EU	Authorized (13 months)	Centralized (Article 58)	December 2023	January 2025	Laboratorios Liconsa, S.A.
Ghana	Authorized (18 months)	National	June 2024	December 2025	Laboratorios Liconsa, S.A.
Honduras	Authorized 18/400 (2 months)	National	December 2025	Febrero 2026	Exeltis

This project is supported by the Global Health EDCTP3 Joint Undertaking and its members

Co-funded by the European Union

European Union's Horizon Europe research and innovation programme under grant agreement No 101103089

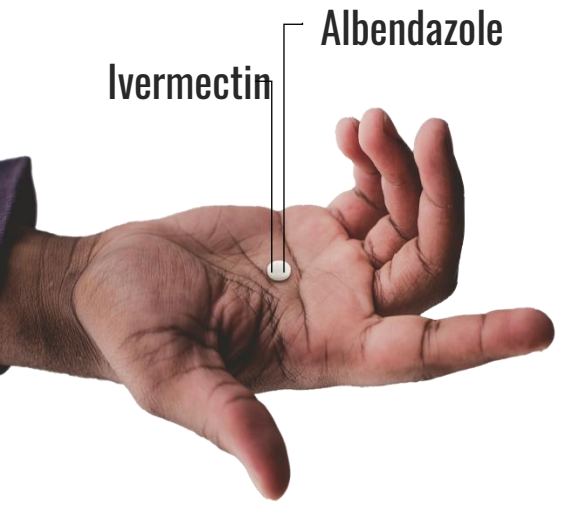
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Education, Research and Innovation SERI

Anticipated uses of the fixed-dose combination

It addresses many strategic gaps in STH & public health programmes



- Covers the **full spectrum of STH parasites**
- Public Health uses **targeting diseases impacting ~1.5 billion.**
  - Mass Drug Administration in moderate to high prevalence areas
  - Distribution through clinics in low prevalence areas
- Keeps dosing simple with **a single pill versus up to 5 pills**
- The oro-dispersible tablet **reduces the risk of choking**,
- Responds to the **WHO call for paediatric formulations**
- Responds to the **call for integration: covers scabies, LF and oncho**
- Facilitates integration with other programs (e.g., vaccne campaigns)
- Decreases the risk of resistance developing

Perspectives from Rwanda

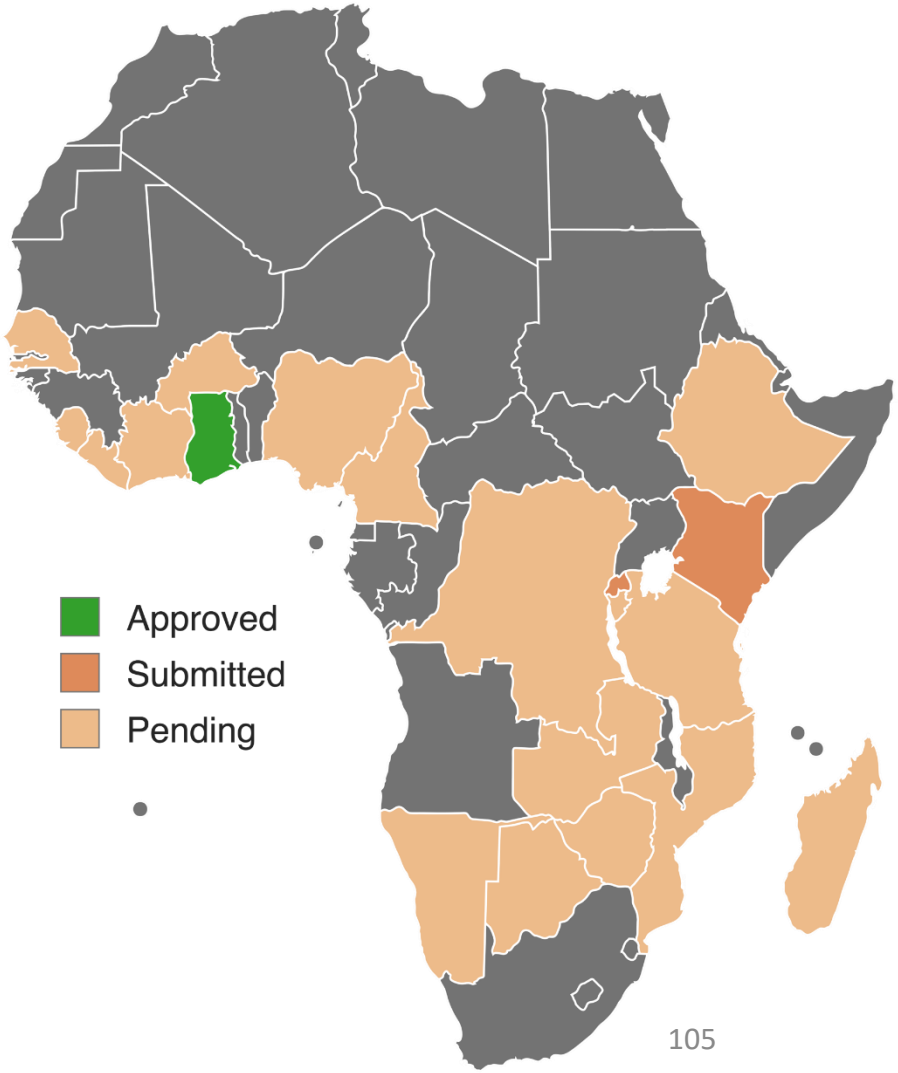
Update status of the registration and pricing of albendazole-ivermectin tablet co-formulation &

Stella Kepha
STOP 2030 consortium

IVM/ALB FDC submission status in Africa

- EMA's CHMP adopted a **positive scientific opinion** in January 2025
- **Approval by Ghana FDA** in December 2025
- **Approval by Honduras' ARSA** in February 2026

- In evaluation by **Kenya PPB** and **Rwanda FDA**
- Submission strategy to follow **WHO's PQ**, expected by July 2026



COUNTRY	RA STATUS	TYPE OF PROCEDURE	SUBMISSION DATE	APPROVAL DATE	MAH
EU	Authorized	Centralized	December 2023	January 2025	Laboratorios Liconsa, S.A.
Ghana	Authorized	National	June 2024	December 2025	Laboratorios Liconsa, S.A.
Kenya	Submission on-going	National	September 2025	+ 12-18 months	
Rwanda	Submission on going	National	March 2026	+12-18 months	
Ethiopia, Nigeria, Mozambique, DR Congo, Madagascar, Zambia, Burkina Faso, Tanzania, Uganda, Sierre Leone, Cameroon, Senegal, Liberia, Ivory Coast, Namibia, Zimbabwe, Bostwana	To be submitted	National	Q3-Q4 2026	Different in each country	

Supply and Financing ivermectin/albendazol fix dose combination of 9/400 and 18/400mg and ivermectin 3mg WHO PQ

- Ivermectin 9/400 and 18/400 price per tablet = 0,33 EUR per tablet (ie person) regardless of dose ordered for minimum order quantities of 10.500 bottles of 40 counts (420,000 tablets in total)
- Liconsa´s ivermectin 3mg is PQ and WHO entered into a long-term with prices around 0,11 USD per tablet linked to volumes. From 2023 until Feb. 2026 only 2.2 million tablets has been provided, which is significantly below the initial projections.
- Transport, insurance etc. paid by purchaser according to destination (i.e FOB)
- Business is “make to order” → Key to have reliable demand estimations
- Standard lead-time can be agreed based on volume

Palatability and acceptability

	Very bad	**Bad**	**Acceptable / Ok / Not nice and not bad**	**Good/Nice**	**Very good/Very nice**
Taste	0 (0.0%)	3 (3.0%)	6 (6.0%)	33 (33.0%)	**58 (58.0%)**
Smell	0 (0.0%)	4 (4.0%)	14 (14.0%)	32 (32.8%)	**50 (50.0%)**
Texture	0 (0.0%)	2 (2.0%)	12 (12.0%)	33 (33.0%)	**57 (57.0%)**
Acceptability	0 (0.0%)	2 (2.0%)	11 (11.0%)	54 (54.0%)	**33(33.0%)**
	Experience with the intake				
	Vomited the drug immediately or within 2 hours	**I spit it out**	**Swallowed with some problems**	**Swallowed with no problems**	
	1 (1.0%)	**0 (0.0%)**	**0 (0.0%)**	**99 (99.0%)**	

7th ANNUAL MEETING OF NTD PROGRAMME MANAGERS IN AFRICA

Leveraging innovative tools & sustainable financing to advance NTD elimination in Africa

Q & A

13-16 April 2026

Lilongwe, Malawi

African Union

World Health Organization
African Region

ESPEN
EXPANDED SPECIAL PROJECT FOR ELIMINATION OF NEGLECTED TROPICAL DISEASES

Closing remarks

Programmatic Innovation: Fixed-Dose Combination

- Single tablet simplifies dosing vs multiple IVM tablets
- Reduces need for height/weight-based dosing
- Orodispersible formulation improves pediatric delivery
- Lower logistics and operational burden
- Improved adherence and coverage efficiency
- Innovation = operational + pharmacological advancement

The fixed dosed combination is only for SAC and adult. This formulation is not yet prequalified by WHO. It will not be donated

Key Messages

Simplifying delivery models for preventive chemotherapy is essential to maintain effective NTD programmes under increasing operational and financial constraints.

Including ivermectin into preventive chemotherapy campaigns may help address persistent infections such as Trichuris trichiura and Strongyloides stercoralis.

Simplified dosing approaches and fixed-dose ivermectin–albendazole combinations may offer opportunities to reduce logistical complexity and pill burden during mass drug administration.

Country experiences and operational research are critical to inform feasible, sustainable and country-owned implementation pathways.

End of Day 3

We resume tomorrow at 8:30

7th ANNUAL MEETING OF NTD PROGRAMME MANAGERS IN AFRICA

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WIFI: Umodozi Park Resort
Password: Park@#2025

Parallel Session B – 11.2

Opportunities for operational innovations with ivermectin-albendazole for STH control

14:00 - 15:30

African Union

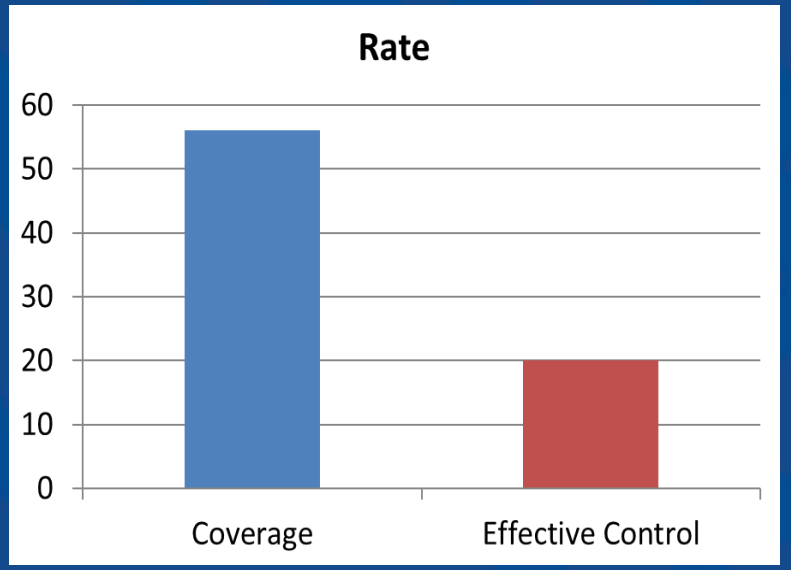
World Health Organization
African Region

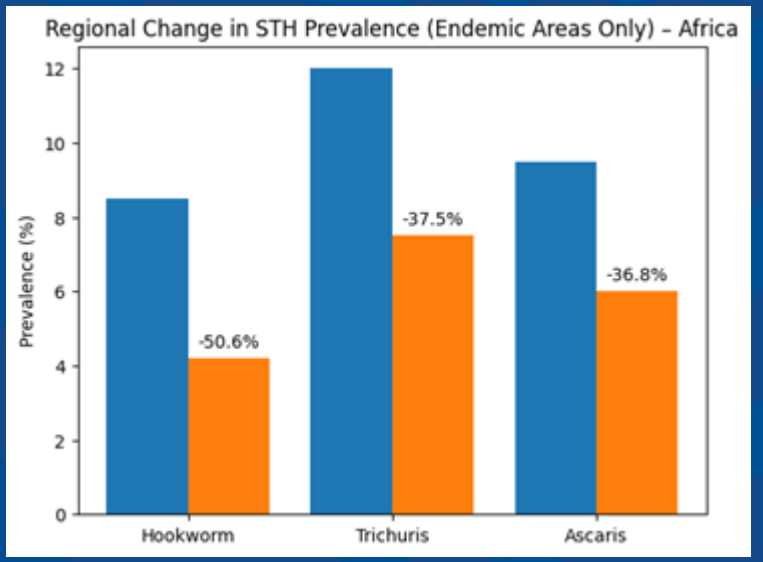
ESPEN
EXPANDED SPECIAL PROJECT FOR ELIMINATION OF NEGLECTED TROPICAL DISEASES

Opening and objectives

STH Control: Strong Progress, Persistent Gaps

- Preventive chemotherapy (PC) is the backbone of STH control
- About 498 million children treated globally (2024)
- ≈56% global coverage; uneven across regions
- Limited coverage for women of reproductive age
- EPHP target: <2% moderate/heavy intensity infections and <20% any STH prevalence
- Gap: Coverage achieved ≠ transmission control





The Unfinished Agenda: Species-Specific Gaps

Albendazole/mebendazole effective for Ascaris and hookworm

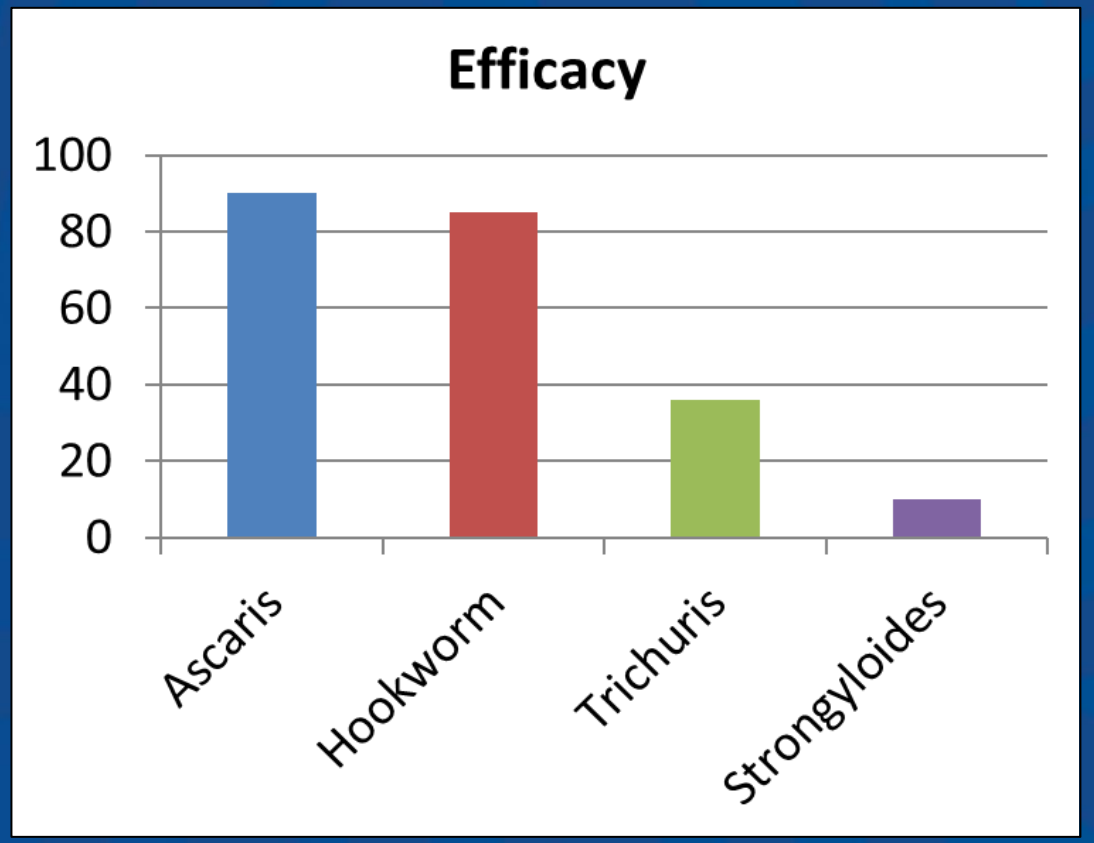
Suboptimal efficacy for Trichuris trichiura

Limited effect on Strongyloides stercoralis

Persistent reservoirs despite high coverage

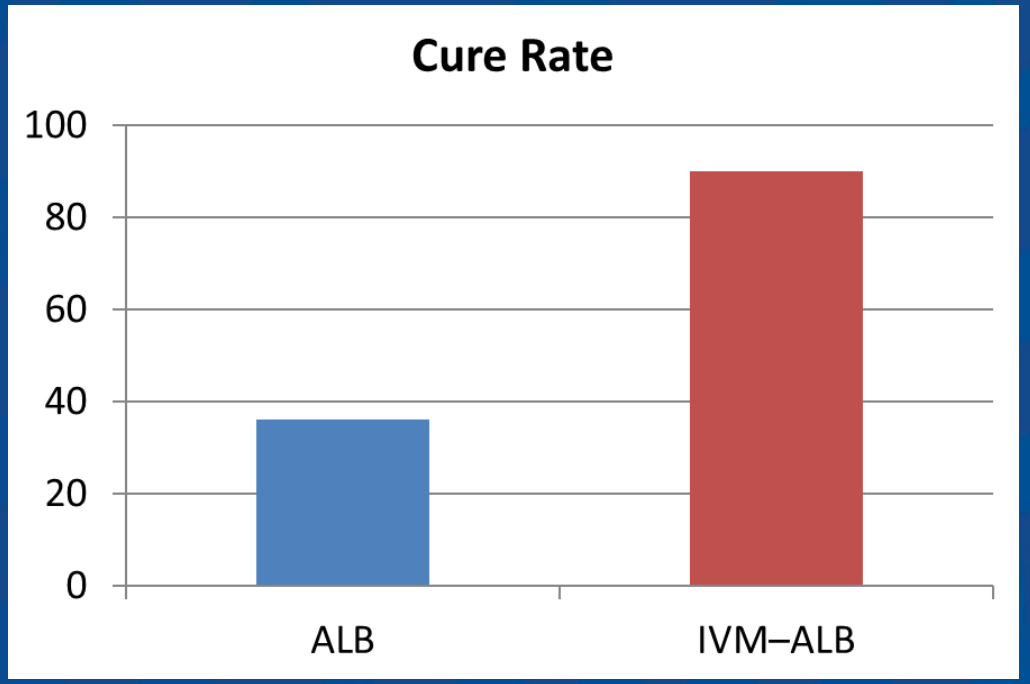
Continued risk of continued transmission

Key message: Achieving coverage is not equal to achieving cure



From Coverage to Impact: IVM–ALB Combination

- IVM–ALB shows superior efficacy vs monotherapy
- Trichuris cure rates: ~36% (ALB) vs >80–97% (IVM–ALB)
- Effective against Strongyloidiasis and other co-endemic conditions
- Supports integrated NTD control (LF, scabies)
- Aligns with WHO Roadmap for improved treatment tools
- Shift: From single-disease to multi-disease impact



Programmatic Innovation: Fixed-Dose Combination

- Single tablet simplifies dosing vs multiple IVM tablets
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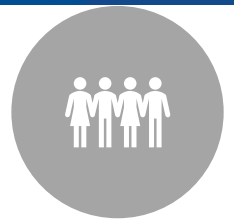
- Lower logistics and operational burden
- Improved adherence and coverage efficiency
- Innovation = operational + pharmacological advancement

The fixed dosed combination is only for SAC and adult. This formulation is not yet prequalified by WHO. It will not be donated

From Evidence to Implementation

Existing ivm–alb platforms in lf programmes



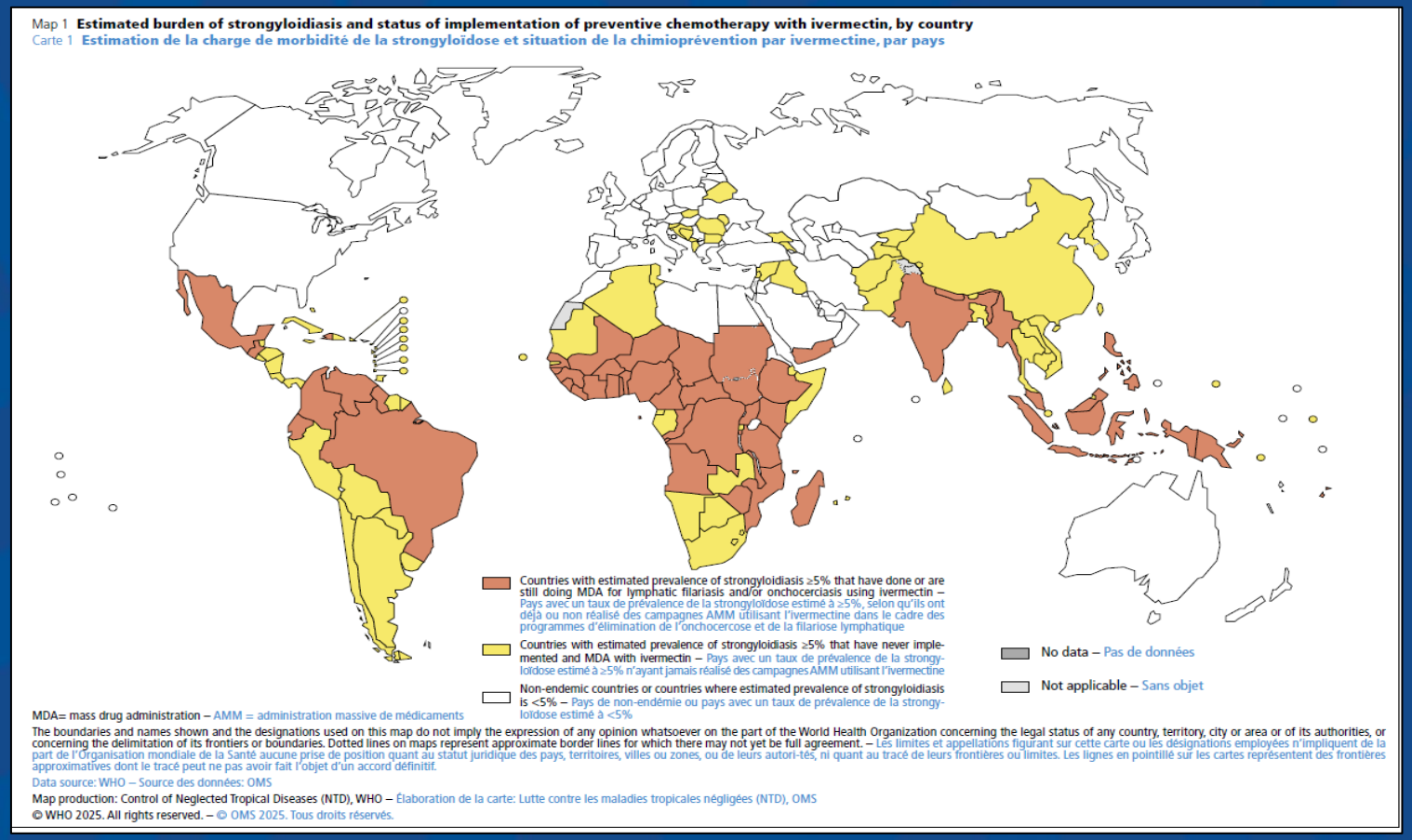
Opportunity to align with sth epidemiology

Target high trichuris and strongyloides burden areas

Who guidelines in development for combination regimens

Key question: how to optimize impact using existing systems?

Estimated burden of strongyloidiasis



Programme Managers and disease experts: Questionnaire to us better understand current implementation practices and the challenges countries may be facing.

Please access it via the QR Code in attachment or via this link: https://redcap.link/vyctxrms

African Union

World Health Organization
African Region

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ANNUAL MEETING OF
NTD PROGRAMME MANAGERS IN AFRICA

Session 11.2:

Opportunities for operational innovations with ivermectin-albendazole for STH control: country perspectives to strengthen African NTD programmes

Kenya: Dr Stella Kepha, KEMRI/Wycliff Omondi

Ghana: Dr Joseph Opare, Ghana

Rwanda: Dr Ladislas Nshimiyimana

General objective

- To explore how simplified delivery approaches for ivermectin–albendazole preventive chemotherapy could support more efficient, sustainable, and country-owned NTD programmes in Africa.

Specific objectives

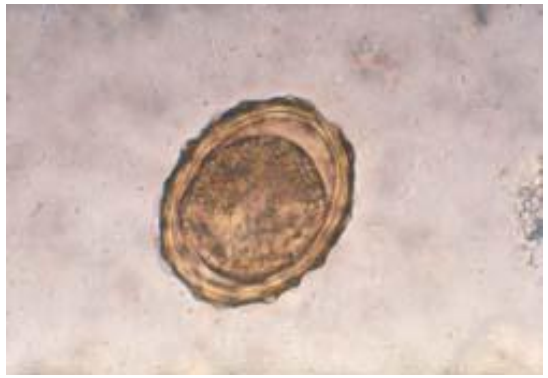
- To update on the current situation and challenges in soil-transmitted helminths control in three African countries.
- To discuss operational challenges associated with integrating ivermectin into preventive chemotherapy programmes for STH control
- To share experiences from countries evaluating ivermectin-albendazole delivery approaches

Perspectives from Kenya – Stella Kepha

Soil-transmitted helminths

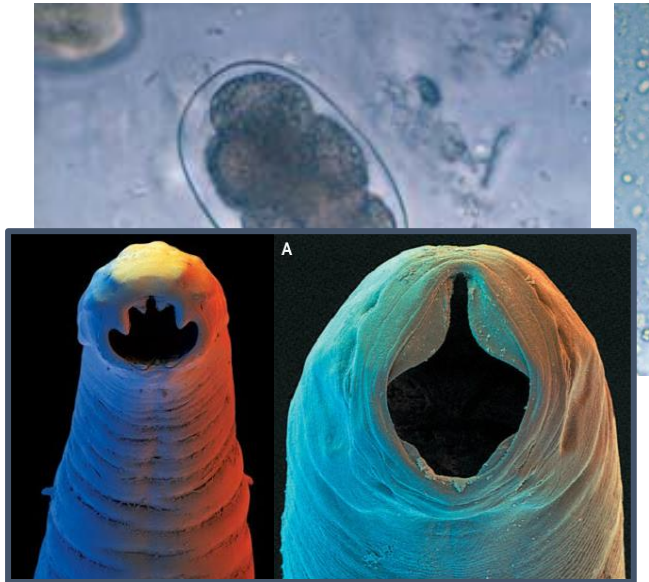
STH are a group of parasites transmitted through contact with environmental sources (soil, water, food) that directly or indirectly were contaminated with human feces that contain eggs or larvae of these parasites.

Ascaris lumbricoides



Trichuris trichiura

Ancylostoma duodenale & *Necator americanus*
Uncinarias



Strongyloides stercoralis

Risk analysis of new strategies in STH treatment

Outcome of STH Drug Combinations Expert Meeting, BMGF, April 2016

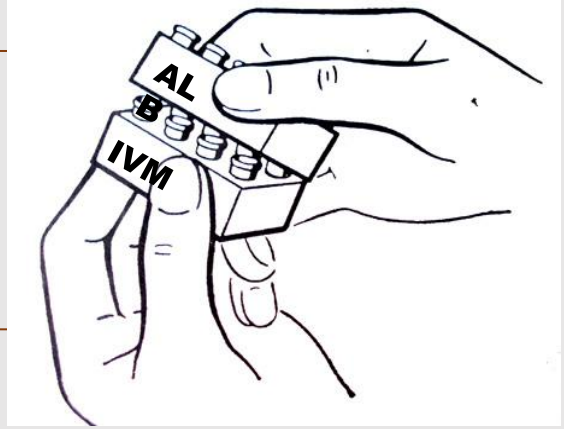
Levels of Investment Risk

	Low Risk	Medium Risk	High Risk
Time to WHO approval	Short	Medium	Long
Cost of development	Low	Medium	High
Data on safety in MDA	Large	Medium	Small

Candidates for Combination STH Treatment

Tier 1 (low investment risk)
albendazole + ivermectin
Tier 2 (medium investment risk)
albendazole + oxantel (or oxantel/pyrantel)
mebendazole + oxantel (or oxantel/pyrantel)
mebendazole + ivermectin
Tier 3 (high investment risk)
albendazole + moxidectin

A long way for a simple idea



J Antimicrob Chemother
doi:10.1093/jac/dkz524

Journal of Antimicrobial Chemotherapy

Safety of high-dose ivermectin: a systematic review and meta-analysis

Miriam Navarro [1]*, Daniel Camprubí[2], Ana Requena-Méndez[2], Dora Buonfrate [3], Giovanni Giorli[3], Joseph Kamgno[4], Jacques Gardon[5], Michel Boussinesq[5], Jose Muñoz[2] and Alejandro Krolewiecki[2,6]

frontiers | Frontiers in Pharmacology

CLINICAL TRIAL
published: 14 July 2022
doi: 10.3389/fphar.2022.914886

Pharmacokinetic Characterization and Comparative Bioavailability of an Innovative Orodispersible Fixed-Dose Combination of Ivermectin and Albendazole: A Single Dose, Open Label, Sequence Randomized, Crossover Clinical Trial in Healthy Volunteers

OPEN ACCESS

Edited by:
Anthony Attama,
University of Nigeria, Nsukka, Nigeria

Jaime Algorta[1], Alejandro Krolewiecki[2,3], Filipe Pinto[4], Silvia Gold[5] and Jose Muñoz[6]*

PLOS | NEGLECTED TROPICAL DISEASES

RESEARCH ARTICLE

Albendazole and ivermectin for the control of soil-transmitted helminths in an area with high prevalence of *Strongyloides stercoralis* and hookworm in northwestern Argentina: A community-based pragmatic study

Adriana Echazú[1,2]*, Marisa Juarez[1], Paola A. Vargas[1,2], Silvana P. Cajal[1], Ruben O. Cimino[1,3], Viviana Heredia[4], Silvia Caropresi[4], Gladys Paredes[4], Luis M. Arias[5], Marcelo Abril[6], Silvia Gold[6], Patrick Lammie[7], Alejandro J. Krolewiecki[1,2]

PLOS | NEGLECTED TROPICAL DISEASES

RESEARCH ARTICLE

Safety and pharmacokinetic profile of fixed-dose ivermectin with an innovative 18mg tablet in healthy adult volunteers

Jose Muñoz[1], Maria Rosa Ballester[2], Rosa Maria Antonijoan[2,3], Ignasi Gich[2,3], Montse Rodríguez[2], Enrico Colli[4], Silvia Gold[5], Alejandro J. Krolewiecki[6]*

Gates Open Research

Gates Open Research 2022, 6:62 Last updated: 05 MAY 2022

Check for updates

STUDY PROTOCOL

An adaptive phase II/III safety and efficacy randomized controlled trial of single day or three-day fixed-dose albendazole-ivermectin co-formulation versus albendazole for the treatment of *Trichuris trichiura* and other STH infections. ALIVE trial protocol [version 1; peer review: awaiting peer review]

Alejandro Krolewiecki[1,2], Wendemagegn Enbiale[3,4], Javier Gandasegui[1], Lisette van Lieshout[5], Stella Kepha[6], Augusto Messa Junior[7], Michel Bengtson[5], Woyneshet Gelaye[3], Valdemiro Escola[7], María Martinez-Valladares[8,9], María Cambra-Pellejà[8,9], Jaime Algorta[10], Helena Martí-Soler[1], Pedro Fleitas[1,2], Maria Rosa Ballester[11-13], Stephen R. Doyle[14], Nana Aba Williams[1], Almudena Legarda[1], Inacio Mandomando[7], Charles Mwandawiro[6], Jose Muñoz[2]

Developing additional data on

- Safety
- Acceptability
- Cost-effectiveness

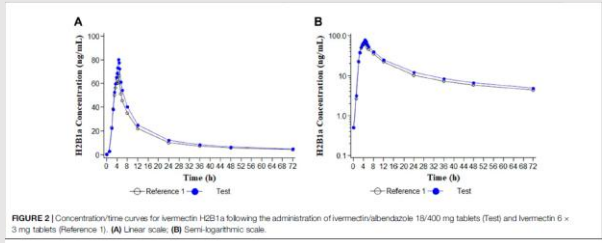


FIGURE 2 | Concentration/time curves for ivermectin H2B1a following the administration of ivermectin/albendazole 18/400 mg tablets (Test) and Ivermectin 6 × 3 mg tablets (Reference 1). (A) Linear scale; (B) Semi-logarithmic scale.

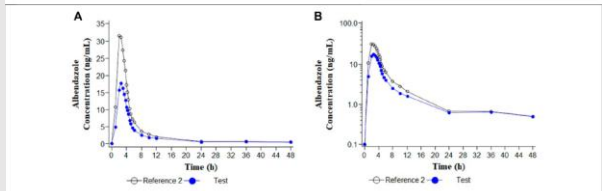
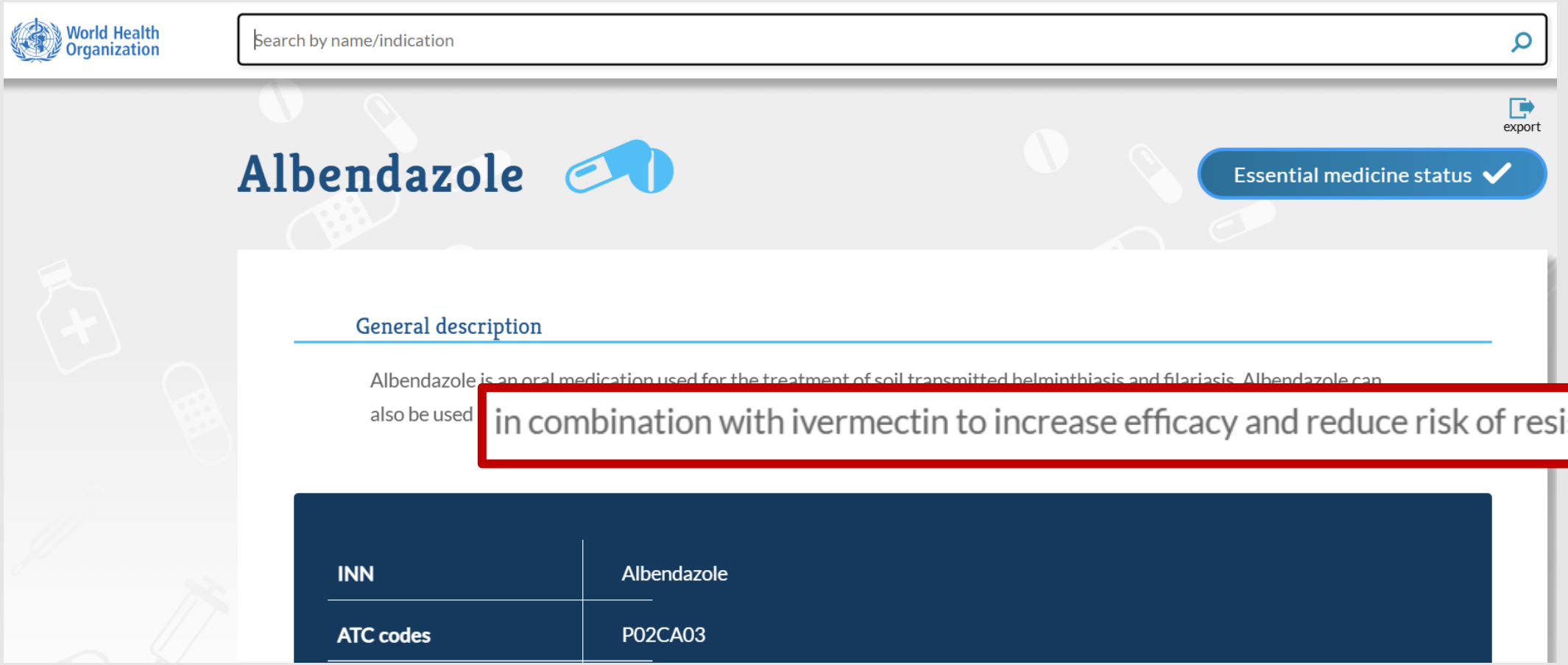


FIGURE 3 | Concentration/time curves for albendazole following the administration of ivermectin/albendazole 18/400 mg tablets (Test) and albendazole tablets (Reference 2). (A) Linear scale; (B) Semi-logarithmic scale.

WHO – Essential Medicines List on ALB + IVM



The innovative component of a new product – ALB/IVM

These are innovations

- Formulation.
  - Co-formulation
  - Orodispersible
  - Mango flavoured
- Dosage (?)
- Access plan

These are NOT innovations

- Molecules
- Indications:
  - Diseases
  - Population
- DDI

This project is supported by the Global Health EDCTP3 Joint Undertaking and its members

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No 101103089

Project funded by

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Education, Research and Innovation SERI

Adaptive Phase II - III safety & efficacy trial of a fixed-dose combination (FDC) of ALB & IVM compared to ALB (n:1223)

5 – 18 years-old infected with *T. trichiura*, hookworms and/or *S. stercoralis*

- Arm 1: ALB 400 mg single-dose n:277
- Arm 2: FDC single-dose n:469
- Arm 3: FDC daily x 3 days n:477

Phase II (n:126)
Infected with *T. trichiura*

Group 1 (n:38) 23 – 30 Kg
Arm 1: ALB 400mg
Arms 2 & 3: 9mg IVM/400mg ALB
(daily IVM dose: 300 - 391µg/Kg)

COMPLETED

DSMB

Group 2 (n:38) 30 – 45 Kg
Arm 1: ALB 400mg
Arms 2 & 3: 18mg IVM/400mg ALB
(daily IVM dose: 400 – 600 µg/Kg)

DSMB

Group 3 (n:50) 15 – 23 Kg
Arm 1: ALB 400mg
Arms 2 & 3: 9mg IVM/400mg ALB
(daily IVM dose: 391 - 600µg/Kg)

DSMB

Phase III (n:1097)
Infected with *T. trichiura* (n:499) hookworms (n:312) and/or *S. stercoralis* (n:286)

- Arm 1: ALB 400 mg single-dose
- Arm 2: FDC single-dose
  - <45 kg FDC of 400mg ALB/9mg IVM
  - ≥45 kg FDC of 400mg ALB/18mg IVM
- Arm 3: FDC daily x 3 days
  - <45 kg FDC of 400mg ALB/9mg IVM
  - ≥45 kg FDC of 400mg ALB/18mg IVM

COMPLETED

18

Krolewiecki et al, GOR 2022

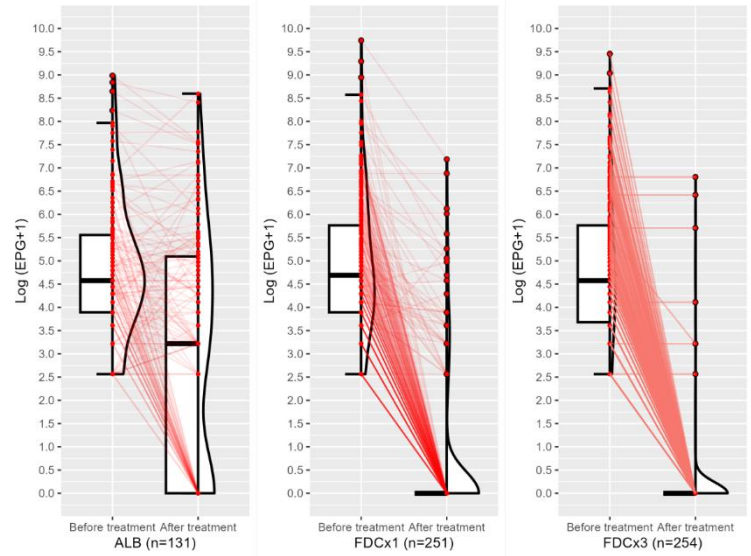
Albendazole–ivermectin co-formulation for the treatment of *Trichuris trichiura* and other soil-transmitted helminths: a randomised phase 2/3 trial

Alejandro Krolewiecki, Stella Kepha, Pedro E Fleitas, Lisette van Lieshout, Wayneshet Gelaye, Augusto Messa Jr, Javier Gandasegui, Jaime Algorta, Valdemiro Novela, Áuria de Jesus, Martin Rona, Dawit Degarege, Dereje Bedane, Jusper Mwahanje, Inácio Mandomando, Charles Mwandawiro, Wendemagegn Enbiale, José Muñoz, on behalf of the Stopping Transmission of Intestinal Parasites (STOP) consortium*

ALIVE: results of the pivotal trial

Efficacy against *T. trichiura*

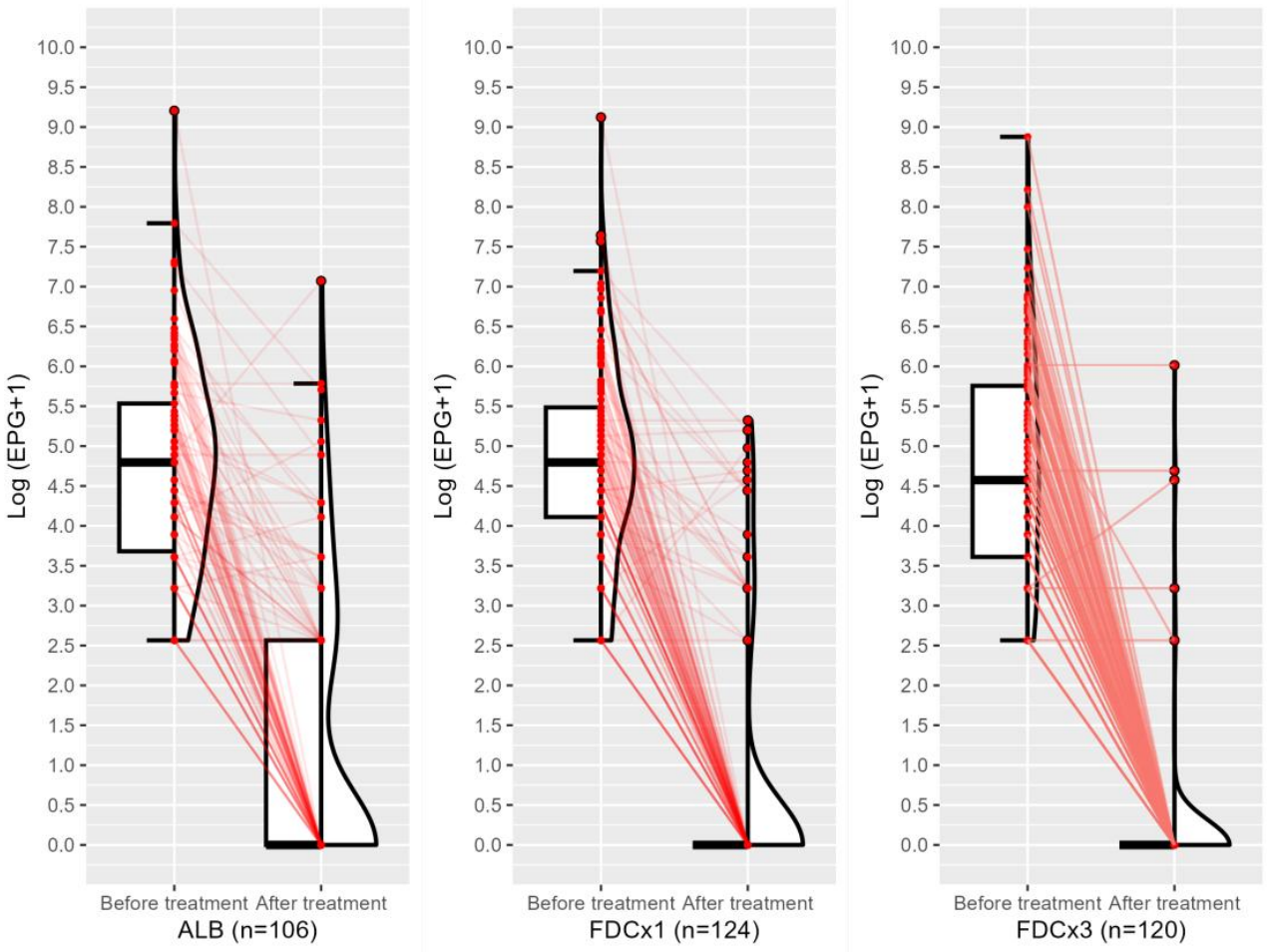
Variable	ALB	FDC x 1	FDC x 3
Cure rate (CR) — % (95% CI)	**35.9** (27.7 – 44.1)	**82.9** (77.5 – 87.2)	**97.2** (95.2 – 99.3)
Difference in CR (vs, ALB)	—	47.0	61.3



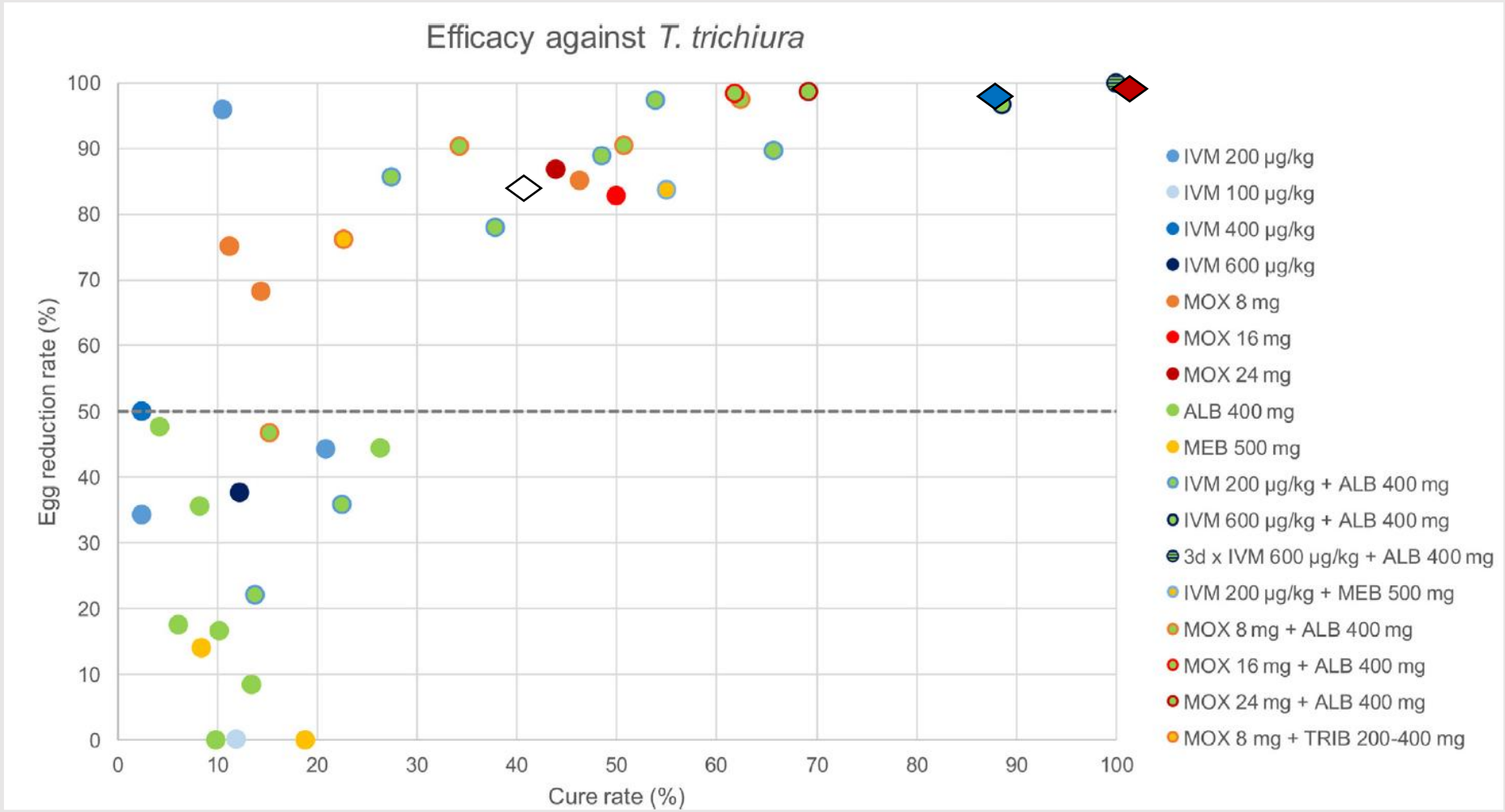
Krolewiecki et al, Lancet ID, 2025 & Fleitas et al, Acta Tropica 2025

Efficacy against hookworm

Variable	ALB	FDCx1	FDCx3
Participants positive for infection			
Before treatment	106	124	120
After treatment	37	25	6
Cure rate — % (95% CI)	65.1 (56.0-74.2)	79.8 (72.8-86.9)	95.0 (91.1-98.9)
Difference in CR (vs. ALB)	-	14.3	29.6



Efficacy against *T. trichiura* across RCTs



ALIVE trial

- FDCx1
- FDCx3
- ALB

Hürlimann et al. Trends Parasitol. 2023;39(4):272-284. doi: 10.1016/j.pt.2023.01.009.

Palatability & acceptability

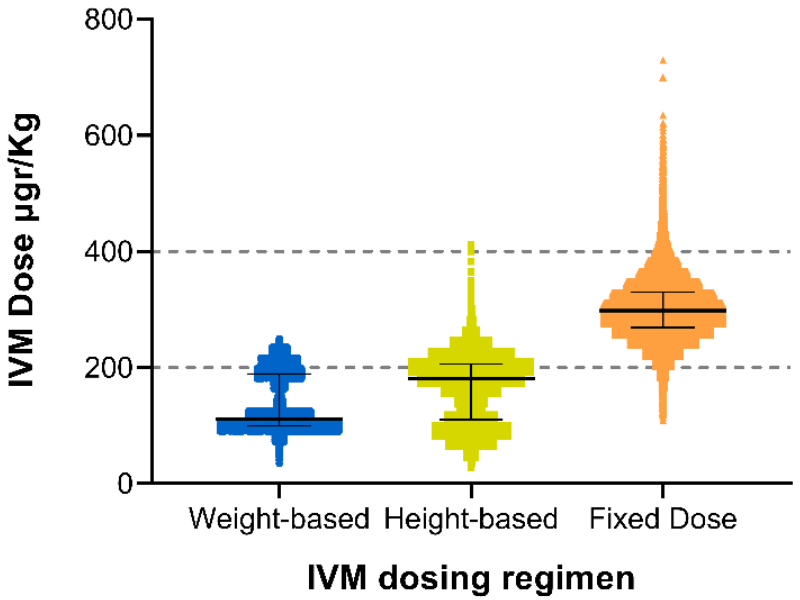
	Very bad	Bad	Acceptable / Ok / Not nice and not bad	Good/Nice	Very good/Very nice
Taste	0 (0.0%)	3 (3.0%)	6 (6.0%)	33 (33.0%)	**58 (58.0%)**
Smell	0 (0.0%)	4 (4.0%)	14 (14.0%)	32 (32.8%)	**50 (50.0%)**
Texture	0 (0.0%)	2 (2.0%)	12 (12.0%)	33 (33.0%)	**57 (57.0%)**
Acceptability	0 (0.0%)	2 (2.0%)	11 (11.0%)	54 (54.0%)	**33(33.0%)**

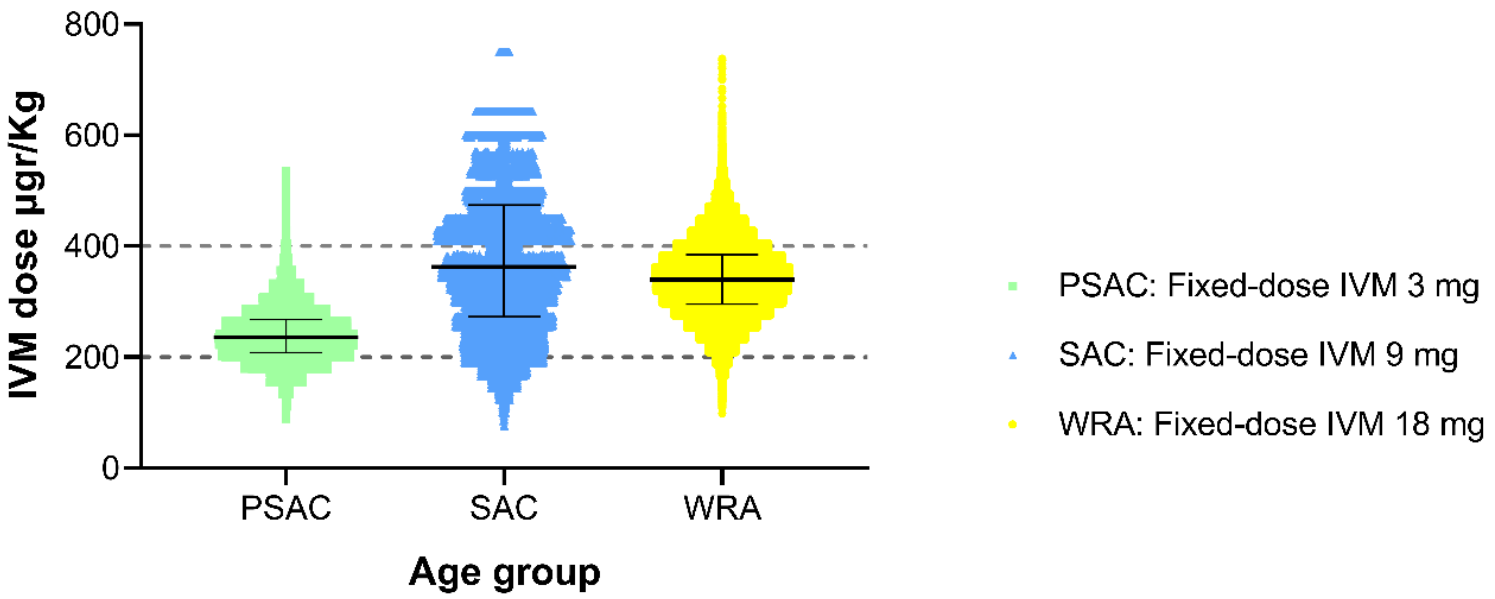
Experience with the intake

Vomited the drug immediately or within 2 hours	I spit it out	Swallowed with some problems	Swallowed with no problems
1 (1.0%)	**0 (0.0%)**	**0 (0.0%)**	**99 (99.0%)**

Can we leave the dose-pole behind?

Individual Participant Data meta-analysis of >700,000 individuals from endemic countries





PLOS Neglected Tropical Diseases

RESEARCH ARTICLE

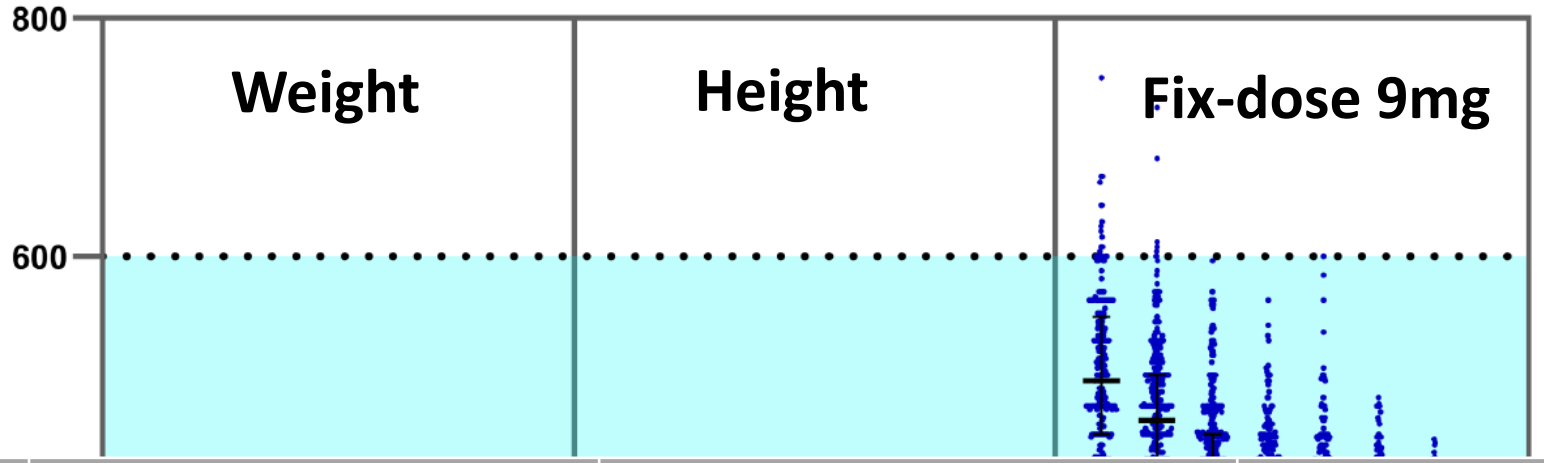
Fixed-dose ivermectin for Mass Drug Administration: Is it time to leave the dose pole behind? Insights from an Individual Participant Data Meta-Analysis

Adriana Echazu[1,2], Daniela Bonanno[1], Pedro Emanuel Fleitas[3], Julie Jacobson[4], Gabriela Matamoros[5], Charles Mwandawiro[6], Wendemagegn Enbiale[7], Áuria de Jesus[8], Alan Brooks[9]Alejandro Javier Krolewiecki[1,2]*

https://doi.org/10.1371/journal.pntd.0013059

Fixed-dosing of IVM in School-age children

Kenya (N= 1564),
Ethiopia (N= 1025)
Mozambique (N= 1071)
Total= 3660



Dose/Regimen	By weight (N=3584)	By height (N= 3324)	Fix-dose 9 mg (N=3584)
Contraindicated	18; 0.5 % (0.2 0.8)	1; 0.03 % (0 – 0.16)	
Underdose	2084; 58 % (56 – 60)	1235; 37 % (35 – 39)	102; 2,8 % (2,3 – 3,4)
Adequate	**1482; 41.3 % (40 – 43)**	**2088; 62.8 % (61 – 64)**	**3464; 96.6 % (96 – 97)**
Above recommended	0	0	18; 0.5 % (0.2 – 0.7)

Next stage: STOP2030

Overall goal:

Support the achievement of the WHO 2030 NTD Roadmap for STH and beyond.

Project purpose:

Advance and accelerate an innovative pharmacologic tool to support elimination goals against STH species especially those poorly responsive to current treatment regimens.

The intervention: Single tablet, fixed-dose combination of Ivermectin and Albendazole

This project is supported by the Global Health EDCTP3 Joint Undertaking and its members

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No 101103089

Project funded by

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Education, Research and Innovation SERI

Proposed safety and effectiveness study

A multicentre pragmatic trial in Ghana and Kenya, to evaluate safety and effectiveness of FDC as a single dose compared to ALB (400 mg single dose) for the treatment and control of STH

Primary objective

- To evaluate and compare **safety** of a FDC against ALB alone via MDA in two study areas in Kenya and Ghana

Secondary objectives

- To evaluate the effectiveness of one round of MDA with FDC vs. ALB against STH (***T. trichiura, A. lumbricoides,*** **hookworms**) by **microscopy**
- To evaluate the effectiveness of one round of MDA with FDC vs. ALB against ***S. stercoralis*** by **serology**

26

Cohort event monitoring study

6.5 Cohort event monitoring

As well as producing data on rates, cohort event monitoring is particularly effective at identifying previously unrecognized and unsuspected adverse reactions and defining the associated risk factors.

The **SAFETY** *of* **MEDICINES IN PUBLIC HEALTH PROGRAMMES:**

Pharmacovigilance an essential tool

World Health Organization

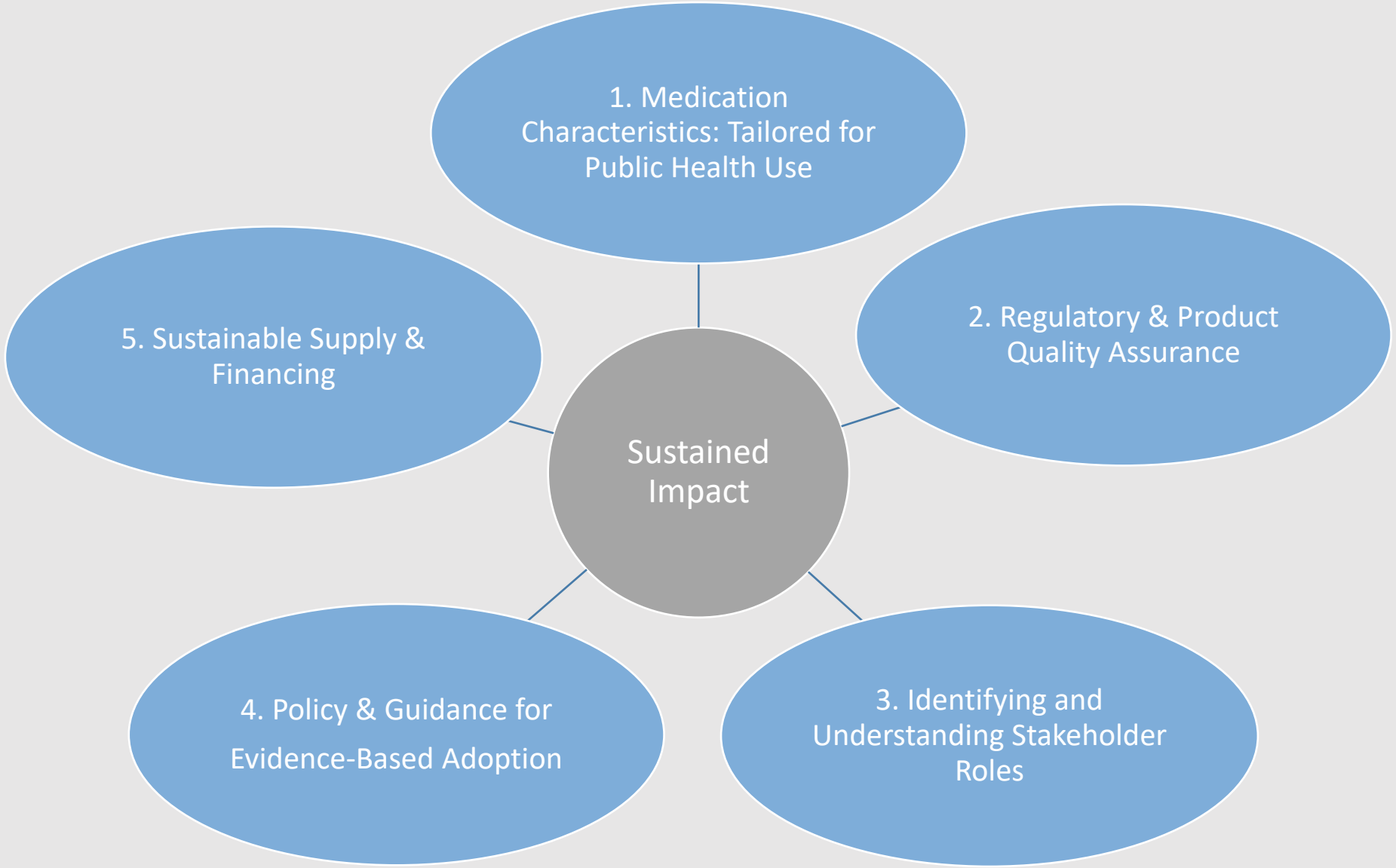
Essentially the method consists of

— establishing a cohort of patients; and

— collecting information on all the adverse events that occur in these patients for a (defined) period after use of the medicine.

WHO, 2006

Access & Stewardship Plan Components for FDC



28

Final remarks, conclusions

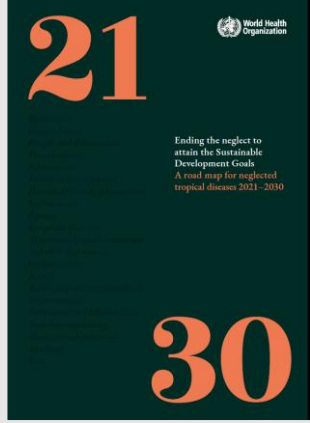
- Dosing strategies for IVM are being revisited.
- The fix-dose coformulation of ALB/IVM is due to enter regulatory agencies.
- Acceptability and safety studies are underway.
- The access plan is being developed.
- Integration across programs (these results have implications beyond STH).

- Progress has been achieved through public-private partnerships

…but more partners are needed to reach the ultimate goal.

Perspectives from Ghana

Adressing key aspects of the Roadmap 2021-2030



Soil-transmitted helminthiases including strongyloidiasis

Burden of disease (*A. lumbricoides*, *T. trichiura* and hookworms only)

About 1.5 billion
people estimated to be infected with STH[1] in 2016

About 6300
deaths reported in 2016[1]

About 3.5 million
DALYs in 2016[1]

In 2019, 92 countries required MDA, mostly in tropical and subtropical areas across sub-Saharan Africa, Latin America and Asia but also in some areas of the European Region.

The burden of *S. stercoralis* should be quantified precisely.

Population requiring preventive chemotherapy for STH by WHO region, 2019, million

Pillar 1	*Accelerate programmatic action*
Pillar 2	*Intensify cross-cutting approaches*
Pillar 3	*Change operating models and culture to facilitate country ownership*

Summary of critical actions to achieve targets

- Increase political commitment to ensure sustainable domestic financing.
- Develop more effective medicines and medicine to improve patient outcomes and in case of drug resistance.
- Develop comprehensive surveillance and mapping systems to target treatment and monitor drug resistance.

Ghana in R&D for NTDs

- Participation in clinical trials.
- Leadership in acceptability studies in endemic communities.
  - End users (target population)
  - System (health care workers)

- Submission to Ghana-FDA for country registration.

EMA on ALB/IVM *(30JAN2025)*

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Ivermectin/Albendazole - opinion on medicine for use outside EU

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ivermectin / albendazole

EU-M4all | Human

Page contents

Overview

Product information

Overview

On 30 January 2025, the Committee for Medicinal Products for Human Use (CHMP
accordance with Article 58 of Regulation (EC) No 726/2004 for the medicinal prod
intended for the treatment of soil-transmitted helminth infections and microfilarae

Overview

Ivermectin/Albendazole is a medicine used in adults and children from 5 years of age to treat the following parasitic worm infections:

- soil-transmitted helminth (STH) infections caused by hookworms (*Ancylostoma duodenale, Necator americanus*), roundworms (*Ascaris lumbricoides,Strongyloides stercoralis*) and whipworms (*Trichuris trichiura*). STH infections are intestinal worm infections that spread through soil contaminated by human faeces in areas with poor sanitation;
- proven or suspected microfilaraemia (the presence of worm larvae in the blood) in patients with lymphatic filariasis (LF) caused by *Wuchereria bancrofti*. LF, commonly known as elephantiasis, is a disease that mainly impairs the lymphatic system (a network of vessels that transport fluid from tissues through the lymph nodes and into the bloodstream) and can lead to abnormal enlargement of body parts.

https://www.ema.europa.eu/en/opinion-medicine-use-outside-EU/human/ivermectin-albendazole

European Medicines Agency, 31 January, 2025

"The development of Ivermectin/Albendazole holds a high public health value as it will bring concrete advantages to the effectiveness of mass drug administration programmes in countries where these diseases are endemic. It will help reduce the risk of incorrect dosage, improve adherence, and reduce manufacturing and transport costs. Ultimately, this will allow more people to be treated."

https://www.ema.europa.eu/en/news/new-combination-medicines-treat-parasitic-worm-infections

Ghana - Regulatory environment

- Ghana has a strong and proactive regulatory agency.
  - Several reciprocity agreements with regional agencies

  1st country in the región to register moxidectin for oncho.
  1st country in the world to register ALB/IVM for STH & LF.

- Public-Private collaborations including MoH-Academia-Pharma for evidence generation.

What´s left after the pivotal trial is completed and the products registered by the regulatory agency?

Plenty

Larger safety trials

Achieving WHO prequalification

Acceptability studies

Multi-level

Different regions

Cost effectiveness studies

Essential Medicines list

Access plan

Recommendation
Policy brief

Sustainability in a donation-based environment

Donors

Qualitative data

- Safety and efficacy provided by clinical trials require commplementary data.
- Local contexts need to be considered.
- Acceptability, cost, convenience are key aspects for implementation.
- Early adopter countries are leaders in innovative actions.

Strengths and Weaknesses of National Neglected Tropical Diseases Programmes – A Case Study of Ghana and Kenya

Ivy Osei[1*], Cornelius Debpuur[1], Abraham Oduro[1], Joseph Opare[1], Alan Brooks[2], Julie Jacobson[2], Alejandro Krolewiecki[3], Stella Kepha[4], and Charles Mwandawiro[4]

1. Ghana Health Service P. O. Box MB- 190 Accra, Ghana 2.Bridges to Development Geneva, Switzerland/Washington DC 3. Mundo Sano, Madrid, Spain. Calle Recaredo, 3, 28002 Madrid, Spain 4. Kenya Medical Research Institute (KEMRI) P.O. Box 54840 – 00200, Nairobi, Kenya.

Background
Soil-transmitted helminthiases (STH) remain a major public health concern in endemic countries such as Ghana and Kenya. National Neglected Tropical Disease (NTD) programmes in both countries primarily rely on Mass Drug Administration (MDA) with benzimidazoles. However, concerns regarding suboptimal efficacy against certain STH species and the potential emergence of drug resistance have prompted consideration of alternative treatment strategies, including a fixed-dose combination (FDC) of Albendazole (ALB) and Ivermectin (IVM).This study explored the strengths and weaknesses of the national NTD programmes in Ghana and Kenya to inform the potential uptake of the proposed ALB–IVM FDC for STH management.

Methods
A qualitative comparative case study design was employed. Data were collected through 56 in-depth interviews and 12 focus group discussions with key stakeholders, including national, regional, and district programme implementers, school officials, and parents/caregivers of school-aged children. Data were analysed using a combination of inductive and deductive thematic approaches.

Results
Key strengths identified across both programmes included strong multi-stakeholder collaboration—particularly between the health and education sectors—effective social mobilization and community sensitization strategies, well-established implementation structures, and substantial donor support. However, several challenges persist. These include inconsistent funding resulting in implementation delays, inadequate community sensitization in some areas, suboptimal management of adverse drug reactions (ADRs), periodic drug shortages, parental refusal due to misconceptions, and limited human resources.

Conclusion
Stakeholders expressed positive perceptions of the proposed ALB–IVM FDC, anticipating improved efficacy, broader STH coverage, enhanced adherence due to reduced pill burden, and potential cost savings. To support a successful introduction, respondents recommended intensive community education, comprehensive training for implementers, strategic community entry approaches, and a phased pilot rollout prior to national scale-up.

Keywords: Neglected Tropical Diseases; Soil-transmitted Helminths; Mass Drug Administration; Fixed-Dose Combination; Albendazole; Ivermectin; Ghana; Kenya.

Ghana FDA Requirements for Clinical Trial

- Legal framework for conduct of clinical trials: Public Health Act, 2012 (Act 851)
- Compliance with ICH-GCP (International Council for Harmonization) and national guidelines

Key Requirements:

- Prior approval from an Ethics Review Committee
- Approval from FDA after submission of study protocols
  - FDA may approve, request changes, or reject
- Clinical Trial Certificate must be issued before trial starts
- FDA Import Permit required before shipment of study drugs and any device not already registered in Ghana

Application of Import Permit

- Cover letter stating the quantity and source
- Attached invoice
  - Certificate of Analysis (CoA) if drug
  - Lot Release Certificate if a vaccine
  - Sponsor, manufacturer, trial site details

Import Conditions:

- Up to 10% excess allowed
- Inspection at port of entry
- Use approved electronic import system

Application of Import Permit

Labelling of the investigation product:

- 'For Clinical Trial Use Only'
- Trial name, dosage, expiry date

Post-Import:

- Notify FDA within 48 hours on arrival of the goods
- Contract a clearing agent to apply on the Customs ICUM using the Clinical Trial approval details and that of the Import permit

Country registration – IVM/ALB 9/400 & 18/400

- **In December 2025 Ghana becomes the 1st country to register the product**

Generic	**IVERMECTIN ALBENDAZOLE 9/400 DISPERSIBLE TABLETS** (Each dispersible tablet contains Ivermectin/Albendazole 9mg/400mg)	Laboratories Liconsa Calle Dulcinea S/N Alcala de Henares 28805 Madrid Spain	Laboratories Liconsa SA, Avenida de Miralcampo 7 19200 Azuqueca de Henares , Guadalajara, Spain	Technology Solutions For Global Health Limited, P.O Box Af 3228 Adenta, Accra.	REG Valid for 5 years Expires December 31, 2030	FDA/GD.25 5-120255
Generic	**IVERMECTIN ALBENDAZOLE 18/400 DISPERSIBLE TABLETS** (Each dispersible tablet contains Ivermectin/Albendazole 18mg/400mg)	Laboratories Liconsa Calle Dulcinea S/N Alcala de Henares 28805 Madrid Spain	Laboratories Liconsa SA, Avenida de Miralcampo 7 19200 Azuqueca de Henares , Guadalajara, Spain	Technology Solutions For Global Health Limited, P.O Box Af 3228 Adenta, Accra.	REG Valid for 5 years Expires December 31, 2030	FDA/GD.25 5-120256

Current regulatory status for ALB/IVM

COUNTRY	RA STATUS	TYPE OF PROCEDURE	SUBMISSION DATE	APPROVAL DATE	MAH
EU	Authorized (13 months)	Centralized (Article 58)	December 2023	January 2025	Laboratorios Liconsa, S.A.
Ghana	Authorized (18 months)	National	June 2024	December 2025	Laboratorios Liconsa, S.A.
Honduras	Authorized 18/400 (2 months)	National	December 2025	Febrero 2026	Exeltis

This project is supported by the Global Health EDCTP3 Joint Undertaking and its members

Co-funded by the European Union

European Union's Horizon Europe research and innovation programme under grant agreement No 101103089

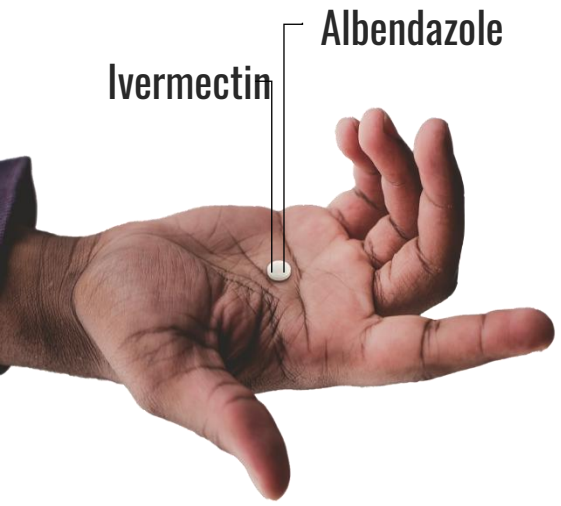
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Education, Research and Innovation SERI

Anticipated uses of the fixed-dose combination

It addresses many strategic gaps in STH & public health programmes



- Covers the **full spectrum of STH parasites**
- Public Health uses **targeting diseases impacting ~1.5 billion.**
  - Mass Drug Administration in moderate to high prevalence areas
  - Distribution through clinics in low prevalence areas
- Keeps dosing simple with **a single pill versus up to 5 pills**
- The oro-dispersible tablet **reduces the risk of choking**,
- Responds to the **WHO call for paediatric formulations**
- Responds to the **call for integration: covers scabies, LF and oncho**
- Facilitates integration with other programs (e.g., vaccne campaigns)
- Decreases the risk of resistance developing

Perspectives from Rwanda

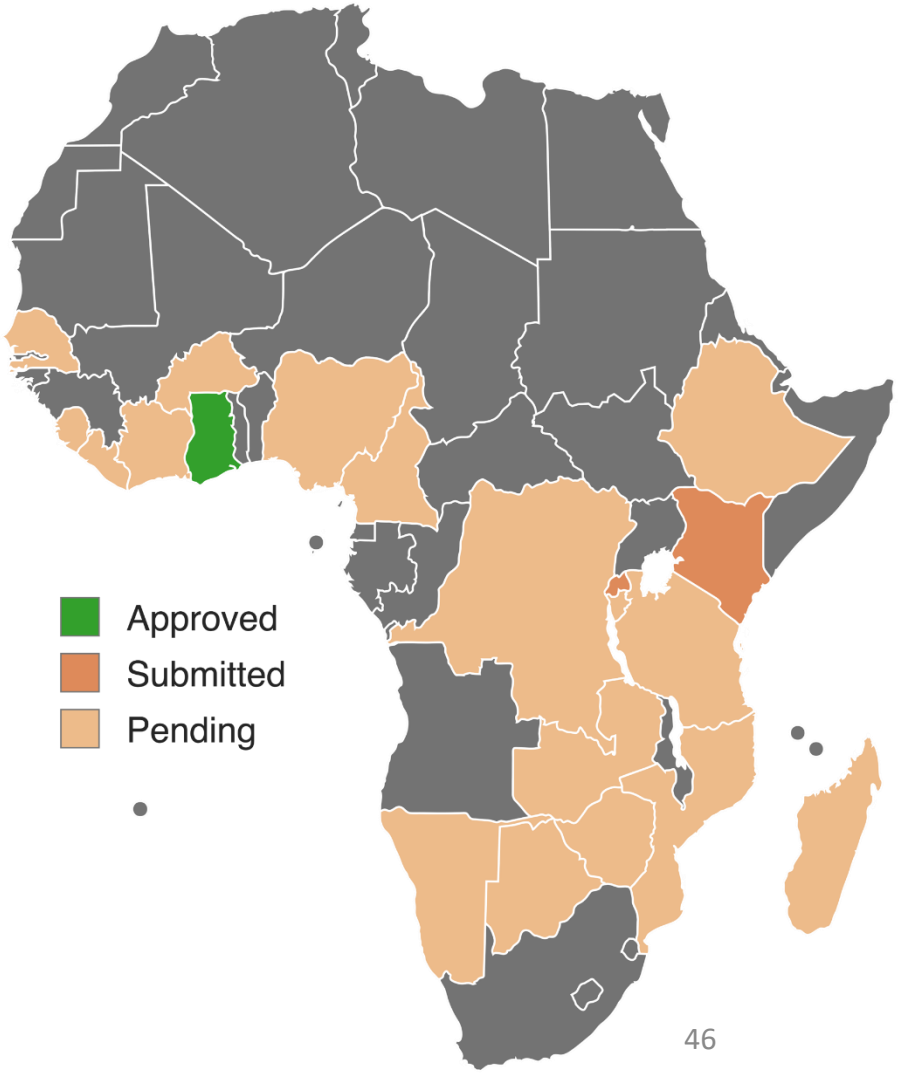
Update status of the registration and pricing of albendazole-ivermectin tablet co-formulation &

Stella Kepha
STOP 2030 consortium

IVM/ALB FDC submission status in Africa

- EMA's CHMP adopted a **positive scientific opinion** in January 2025
- **Approval by Ghana FDA** in December 2025
- **Approval by Honduras' ARSA** in February 2026

- In evaluation by **Kenya PPB** and **Rwanda FDA**
- Submission strategy to follow **WHO's PQ**, expected by July 2026



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Ghana	Authorized	National	June 2024	December 2025	Laboratorios Liconsa, S.A.
Kenya	Submission on-going	National	September 2025	+ 12-18 months	
Rwanda	Submission on going	National	March 2026	+12-18 months	
Ethiopia, Nigeria, Mozambique, DR Congo, Madagascar, Zambia, Burkina Faso, Tanzania, Uganda, Sierre Leone, Cameroon, Senegal, Liberia, Ivory Coast, Namibia, Zimbabwe, Bostwana	To be submitted	National	Q3-Q4 2026	Different in each country	

Supply and Financing ivermectin/albendazol fix dose combination of 9/400 and 18/400mg and ivermectin 3mg WHO PQ

- Ivermectin 9/400 and 18/400 price per tablet = 0,33 EUR per tablet (ie person) regardless of dose ordered for minimum order quantities of 10.500 bottles of 40 counts (420,000 tablets in total)
- Liconsa´s ivermectin 3mg is PQ and WHO entered into a long-term with prices around 0,11 USD per tablet linked to volumes. From 2023 until Feb. 2026 only 2.2 million tablets has been provided, which is significantly below the initial projections.
- Transport, insurance etc. paid by purchaser according to destination (i.e FOB)
- Business is “make to order” → Key to have reliable demand estimations
- Standard lead-time can be agreed based on volume

Palatability and acceptability

	Very bad	**Bad**	**Acceptable / Ok / Not nice and not bad**	**Good/Nice**	**Very good/Very nice**
Taste	0 (0.0%)	3 (3.0%)	6 (6.0%)	33 (33.0%)	**58 (58.0%)**
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	Experience with the intake				
	Vomited the drug immediately or within 2 hours	**I spit it out**	**Swallowed with some problems**	**Swallowed with no problems**	
	1 (1.0%)	**0 (0.0%)**	**0 (0.0%)**	**99 (99.0%)**	

7th ANNUAL MEETING OF NTD PROGRAMME MANAGERS IN AFRICA

Leveraging innovative tools & sustainable financing to advance NTD elimination in Africa

Q & A

13-16 April 2026

Lilongwe, Malawi

African Union

World Health Organization
African Region

ESPEN
EXPANDED SPECIAL PROJECT FOR ELIMINATION OF NEGLECTED TROPICAL DISEASES

Closing remarks

Programmatic Innovation: Fixed-Dose Combination

- Single tablet simplifies dosing vs multiple IVM tablets
- Reduces need for height/weight-based dosing
- Orodispersible formulation improves pediatric delivery
- Lower logistics and operational burden
- Improved adherence and coverage efficiency
- Innovation = operational + pharmacological advancement

The fixed dosed combination is only for SAC and adult. This formulation is not yet prequalified by WHO. It will not be donated

Key Messages

Simplifying delivery models for preventive chemotherapy is essential to maintain effective NTD programmes under increasing operational and financial constraints.

Including ivermectin into preventive chemotherapy campaigns may help address persistent infections such as Trichuris trichiura and Strongyloides stercoralis.

Simplified dosing approaches and fixed-dose ivermectin–albendazole combinations may offer opportunities to reduce logistical complexity and pill burden during mass drug administration.

Country experiences and operational research are critical to inform feasible, sustainable and country-owned implementation pathways.

Health Break

15:30 - 16:00