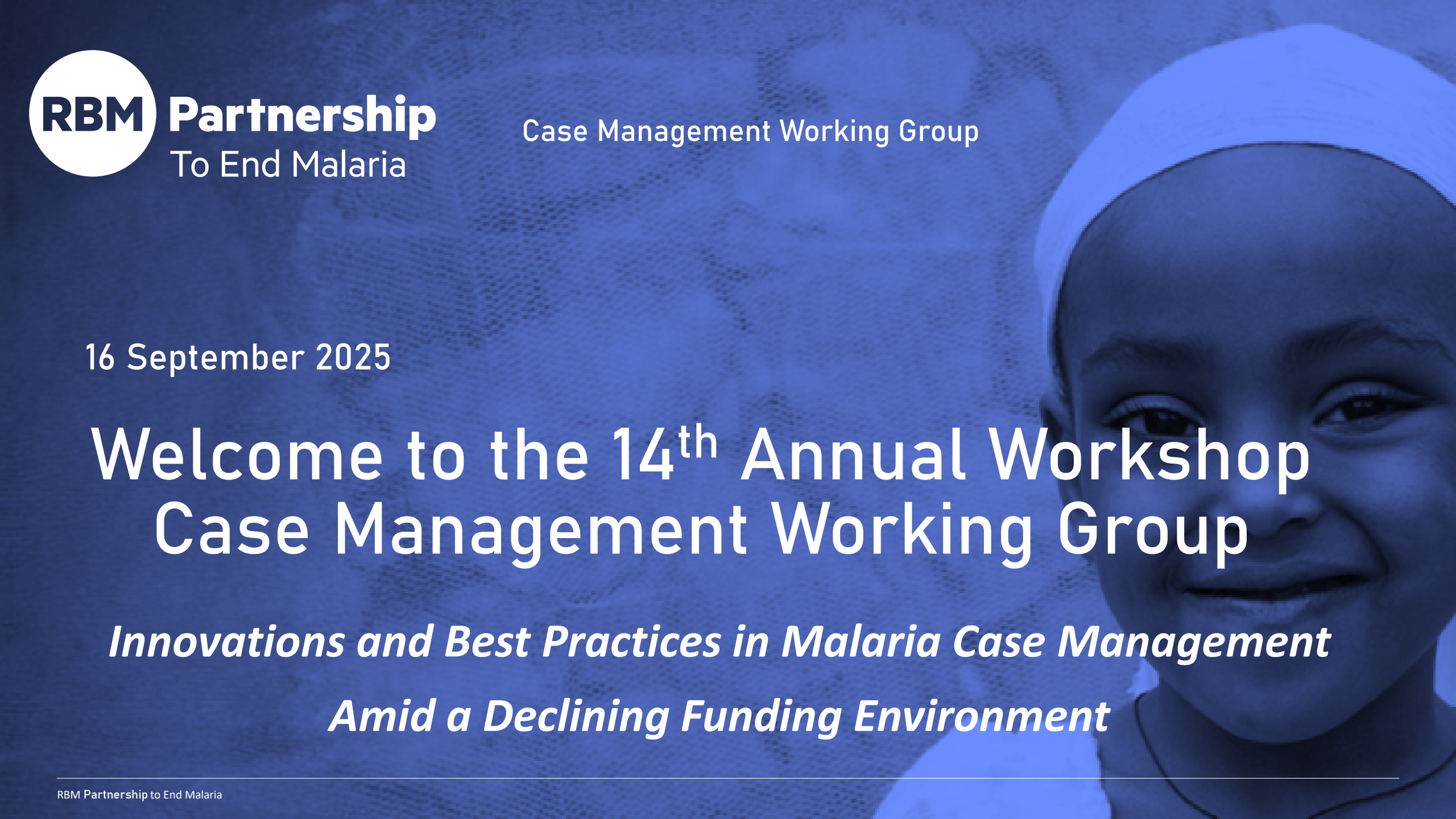
RBM Partnership To End Malaria

Case Management Working Group



16 September 2025

# Welcome to the 14th Annual Workshop Case Management Working Group

## *Innovations and Best Practices in Malaria Case Management Amid a Declining Funding Environment*

RBM Partnership
To End Malaria

16 September 2025

# *Session 2:*
# Work Stream 1 Supply Chain & System Issues

Co-leads Rima Shretta & Abdalah Lusasi, CMWG

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16 September 2025

# Presentation on MFT guidelines

Peter Olumese, WHO

# Multiple first-line therapies as part of the response to anti-malarial drug resistance - An Implementation Guide

*14th Annual RBM Case Management Working Group Workshop*
*16-18 September 2025,*
*Abidjan, Cote d'Ivoire*



**Dr. Peter OLUMESE,**
**Global Malaria Programme**
**WHO, Geneva, Switzerland.**

Global **Malaria** Programme

World Health Organization

# Strategy to respond to Antimalarial drug resistance in Africa

World Health Organization

# Drug resistance

- **Antimalarial drug resistance** is defined as the ability of a parasite strain to survive and/or multiply despite the administration and absorption of a drug given in doses equal to or higher than those usually recommended, but within tolerance of the subject.

World Health Organization

# Artemisinin partial resistance

- **Artemisinin partial resistance** seen as delayed parasite clearance following treatment with artemisinin-based monotherapy or with an ACT
  - In the absence of partner drug resistance, delayed clearance alone does not lead to ACT treatment failure
  - Partner drug resistance has been seen to cause treatment failure even in the absence of artemisinin partial resistance.
  - However, artemisinin partial resistance  puts partner drugs at greater risk because of the increased numbers of parasites exposed to the partner drug alone.

World Health Organization

# Drivers of drug resistance emergence and spread

- **Background drivers**
  - Intrinsic factors linked to the parasite, host, drugs and environmental factors
- **Treatment –related drivers**
  - related to drug use and pressure – how often, at what dose, and for how long a parasite population is exposed to a given drug.
  - the risk of emergence and spread increases when parasites are:
    - exposed to one drug only
    - exposed to sub-therapeutic drug levels

World Health Organization

# Strategy to respond to antimalarial drug resistance in Africa

20 interventions across 4 pillars aiming to mitigate risks and respond to

**Preliminary assessment to prioritize interventions**

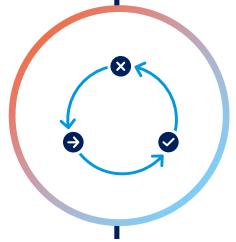
- **Countries' baseline with respect to the status and drivers of resistance**
- **Assessment of strengths and weaknesses of the health and the regulatory systems**

**I** — **Strengthen surveillance of antimalarial drug efficacy and resistance**

**II** — **Optimise and better regulate the use of diagnostics and therapeutics to limit drug pressure through pre-emptive measure**

**III** — **React to resistance by limiting the spread of antimalarial drug resistant parasites**

**IV** — **Stimulate research and innovation to better leverage existing tools and to develop new tools against antimalarial drug resistance**



**Living strategy**

**-** Monitor the implementation and update based on new evidence and learnings

**Key enabling mechanisms**

- **Country ownership**
- **Financing**
- **Advocacy effort**
- **Regional coordination**
- **Routine surveillance system**

# Pillar IV | Stimulate research and innovation to better leverage existing tools and to develop new tools against resistance

*Suggested interventions:*

- Potential innovative ways to increase demand for different drugs and ensure matching supply
  - Explore new schemes in the use of treatments at national level: Deploying the currently available treatments differently, e.g., rotating drugs before high failure rates are detected or by using multiple first-line treatments, could possibly prolong the lifespan of existing ACTs.
  - Research should be expanded to better understand the complexity and relative impact of implementing different schemes of ACTs (e.g. using different ACTs for different age groups or geographies, or rotating ACTs, if they exert opposing selective pressures on local parasite populations).
  - Modelling supported by research should also be pursued to assess the impact of multiple first-line therapies on drug resistance

# The role of MFT

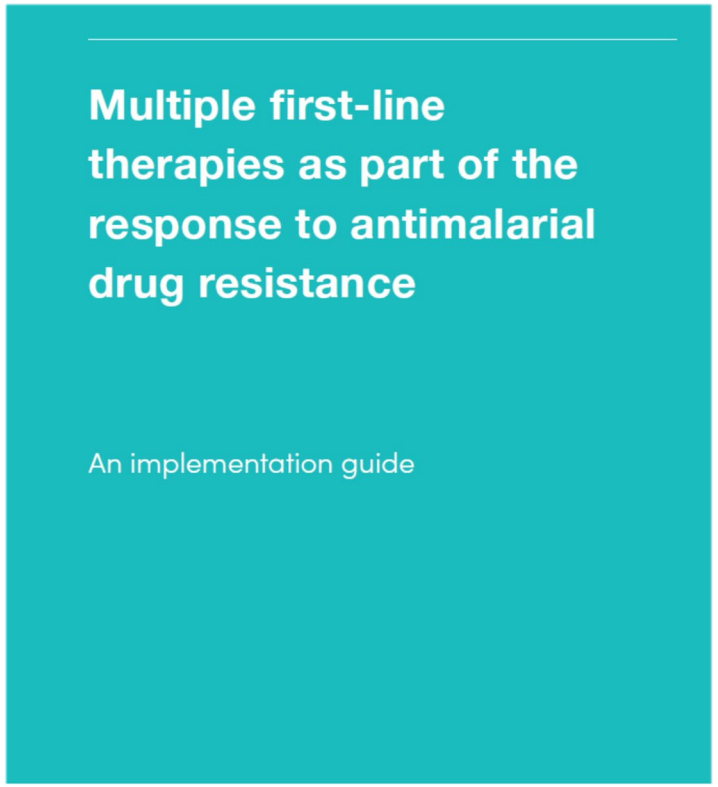
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# Summary of current country context

- AL is the ACT used predominantly in Africa. Although countries have registered other ACTs, they are used in the public sector sequentially as first- or second-line treatment.
- Most countries are unable to currently implement their treatment guidelines effectively, e.g., although 2nd line therapy is provided for in guidelines, they are usually not available and/or no clear guidance and training on its use.
- The private sector in sub-Saharan Africa is significantly larger and less consistent with national policies. Estimates of ACT consumption vary widely, private sector consumption being 40–70%.
    - Maisha Meds has estimated that the private sector in Tanzania, accounts for 75% of ACT consumption, which is much higher than currently reported estimates of 10–35%.

World Health Organization

# MFTs implementation Guide




- A Guide to support adoption and implementation of MFT was published in November 2024.
- https://www.who.int/publications/i/item/9789240103603

World Health Organization

# Definition of multiple first-line therapies (MFT)

- **Aim**: to reduce potential emergence and spread of resistance to antimalarial drug

- **Rationale:** to expose a specific parasite population to several antimalarial molecules to prevent or delay the emergence or spread of drug resistance

- **Definition**: MFT consists of use of two or more effective ACTs in a population for treatment of uncomplicated malaria; can be used either together or in rotation (cycling)

World Health Organization

# Definition of multiple first-line therapies (MFT)

- **Deployment strategies:**
  - ***Simultaneous use:*** modelling suggests that a minimum consumption of each drug is necessary to effectively delay selection for resistance:
    - > 35% if two drugs are used;
    - > 25% if three drugs are used; and
    - >15% if four drugs are used.
  - ***Rotation:*** more effective for deterring resistance as the duration between rotated therapies decreases:
    - benefit of 1 year of rotation similar to that of simultaneous use;
    - 2 years appears to be the longest duration that provides a significant benefit.

World Health Organization

# Summary of MFT deployment strategies

## MFT Deployment strategy

1

### Simultaneous deployment

To effectively delay the selection of resistance, a minimum proportion of each drug must be used:

- >35% if two drugs are used
- >25% if three drugs are used and
- >15% if four drugs are used

To achieve this, segmentation, randomization, or stratification of antimalarial drug use can be applied based on:

- population, such as by age
- level of the health system
- geographical region (usually with rotations)

2

### Rotation

Resistance deterrence is more effective when the duration between rotated therapies is shortened. A 1-year rotation is as effective as simultaneous use, while 2 years appears to be the maximum duration at which there is a significant benefit.

Rotation can be implemented based on:

- time, such as annually or bi-annually
- population, such as by age
- level of the health system
- geographical region

# MFT: Context and key concepts

- **Context**
  - MFT must be a deliberate, managed intervention at all levels of the health system, including the private sector.
  - MFT requires that all the antimalarial drugs used are effective. Therefore, treatment policies must be changed before drug resistance undermines the clinical efficacy of any of the drugs used in MFT.

- **Key concepts**
  - All MFT strategies used in Africa require a relative decrease in use of AL.
  - As lumefantrine and AQ have competing resistance mechanisms, concurrent use is likely to inhibit development of resistance to either drug.
  - Preservation of the efficacy of lumefantrine is critical, as it is a component of both the triple ACT (ALAQ) and ganaplacide–lumefantrine, which are likely to be the next antimalarial products that will become available.
  - The consequences and costs of non-action are likely to be significant

# MFT: Implementation

- MFT approach require meticulous planning and coordination among various sectors
  - It is policy change and requires revision of national treatment guidelines, EMLs, changing to the procurement, and supply  management of medicines, etc.
  - National solutions should be developed to address contextual challenges to effective implementation:
    - the dynamics of the private and public sectors
    - the availability and affordability of medicines
    - the preferences of health-care providers and patients
    - human displacement, cross-border movement and migration
    - the Structure and capacity of the health-care system, procurement systems, and
    - funding structures.

World Health Organization

# Summary requirement for effective MFT implementation

- Alignment of guidelines with national policy – treatment guidelines, EML, regulatory approvals..
- MFT deployment strategy
  - based on country context and feasibility, conduct modelling to evaluate potential impact of different options
  - Ensure effectiveness, accessibility, affordability and acceptability of the antimalarial therapy
  - Cost and funding - full costing (medicines and processes), secure sustainable funding.
  - Procurement – both international supplies and local capacities for effective supply and logistics systems.
  - Capacity –building – health system capacity to comply with the treatment guidelines
  - Social and behaviour change communication – engagement of the community
  - Efficacy and resistance – ensuring efficacy of all medicines in use
  - Private sector involvement – Influence private sector involvement to compile to treatment guidelines and deployment of MFT, more critical in countries where the private sector contributes significantly to malaria case management.

World Health Organization

# MFT: Recommendation for further research (contd)

- Model the effect of changes in prescription of antimalarials in the private sector.
- Estimate the impact of incentivization of the private sector.
- The perception that ASAQ is associated with unacceptable adverse drug reactions differs considerably by country. An analysis of the reasons for these differences might be useful for increasing the acceptability of ASAQ.
- How can the public and private sectors be aligned in their approaches to MFT? Can lessons be learnt from programmes for HIV or tuberculosis?
- The requirement of health systems for effective use of MFTs include:
  - logistics: managing drug stocks, coordinating drug rotation and
  - investment to ensure an acceptable quality of care.

World Health Organization

# MFT: Recommendation for further research

- Mathematical modelling should be used to analyse data and to predict the outcomes of MFT interventions.
  - more data are necessary to improve the models, particularly from the private sector.
- Investigate potential additive or synergistic effects of increasing diagnostic testing plus use of MFT and of use of a single low dose of primaquine plus use of MFT.
- Model the spatiality of malaria transmission.
- Quantify the cost of doing nothing with regards to the numbers of deaths and cases and the financial implications and cost-effectiveness of MFT.
- Evaluate the impact of SMC on the development of AQ resistance in MFT.

World Health Organization

# MFT: Next steps - WHO

- Support early use countries in planning, deploying, and evaluating the implementation, and document lessons.

- Support for the UNITAID funded STOP-AMDR Jhpiego project

World Health Organization

# Thank you

For more information, please contact:

Dr Peter Olumese
Diagnosis, Medicine and Resistance Unit,
Global Malaria Programme
olumesep@who.int

World Health Organization
Global Malaria Programme

World Health Organization

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To End Malaria

16 September 2025

# Update on the STOP AMDR Project (Scaling the optimal use of Multiple ACTs to prevent Antimalarial Drug resistance)

Rima Shretta, Jhpiego



# STOP-AMDR

## Scaling the Optimal Use of Multiple ACTs to Prevent Antimalarial Drug Resistance (STOP-AMDR) project

# Project Overview

Rima Shretta, PhD
Sep 16, 2025

Unitaid

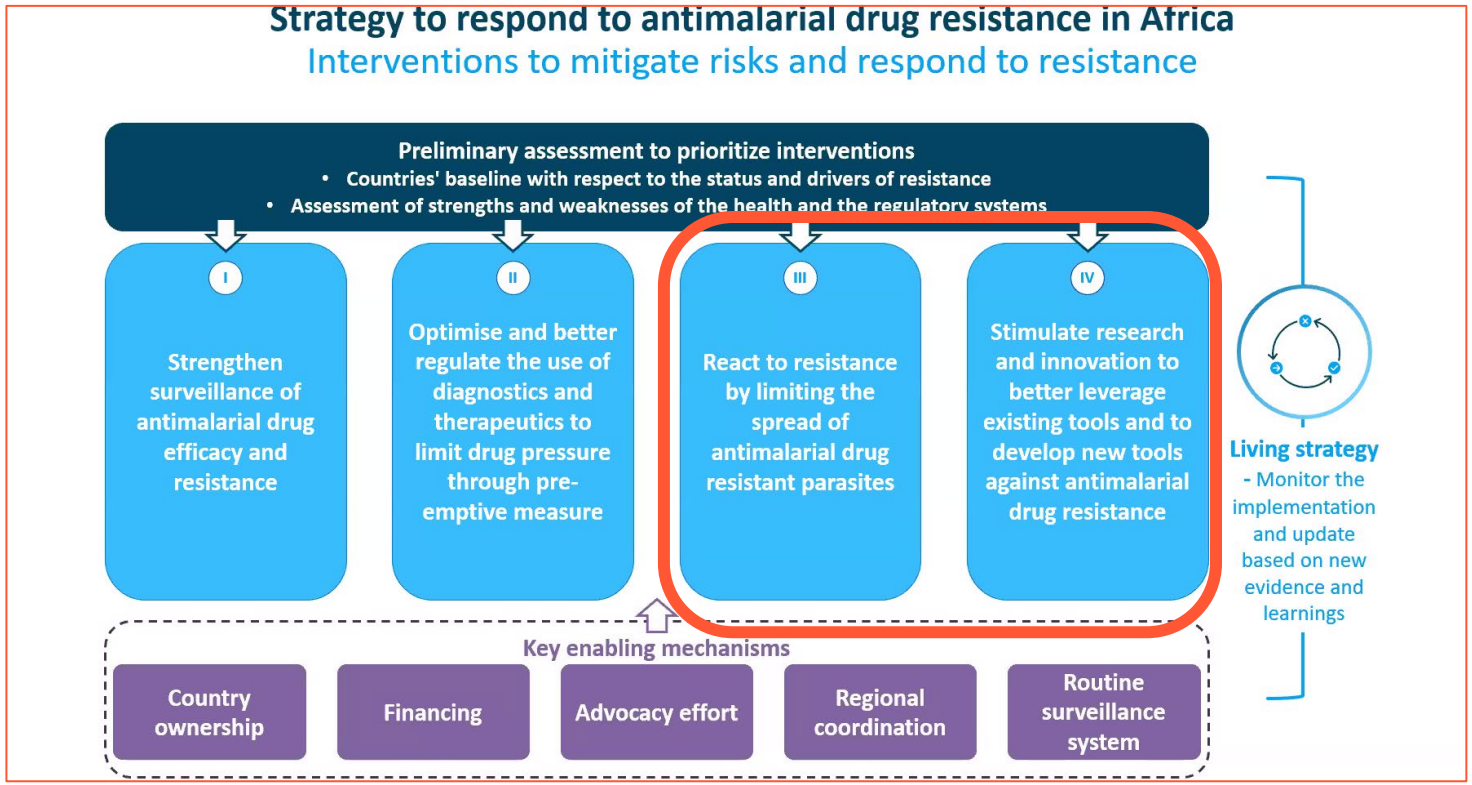
jhpiego
Johns Hopkins University Affiliate

# Outline

- Background
- Project goals and objectives
- Project countries, partners and timelines
- Implementation framework
- Collaboration with broader AMDR ecosystem and partners
- Q&A

# Background

- Artemisinin partial resistance confirmed in some countries in Africa
- WHO Strategy to Respond to Antimalarial Drug Resistance in Africa



# Potential Barriers to ACT diversification/MFTs

- Innovation and availability
- Supply and delivery
- Demand and adoption
- Cost and affordability

# STOP-AMDR Goal & Objectives

**Goal**

Contribute to reduced malaria morbidity and mortality by minimizing the threat and impact of antimalarial drug resistance in Africa

**Objectives**

Accelerate **demand and adoption** of all recommended, quality ACTs



Support ACT diversification, and demonstrate how to implement through multiple first line strategies

**Impact**

- ✓ To contribute to diversifying the use of health products in low- and middle- income countries (LMICs)
- ✓ To generate demand and increase their adoption and use in LMICs
- ✓ To create implementation guidance around multiple first-line treatment strategies for malaria

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# STOP-AMDR Background & Objectives

**Project Timeline:** June 1, 2025 – May 31, 2029



**Approach: Operational research to inform uptake while addressing access barriers**

**OUTCOMES**

- Accelerated introduction and adoption of MFT (including recently introduced ACTs)
- Conditions in place for sustainable, equitable access to MFT (including recently introduced ACTs)
- Strengthened inclusive and demand-driven partnerships for innovative MFT implementation



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# Project Countries

- **Accelerator countries -** Burkina Faso and Kenya: Pilots studies already been conducted; opportunity to scale-up using lessons learned and demonstrate impact.
- **Demonstration countries -** DRC, Nigeria, Rwanda and Uganda: Project will conduct implementation research to assess the barriers and facilitators to MFT implementation (feasibility, acceptability and costs of MFTs) in demonstration sites.
  - Partial artemisinin resistance in Uganda, Rwanda
- Facilitate introduction of MFTs in twelve additional observer countries:
  - **Influence by observation** (Angola, Eritrea, Senegal). Evidence of partial artemisinin resistance (Eritrea), concerns of reduced or declined efficacy (Angola), or regional influence (Senegal). Countries will be invited to annual meetings and other fora as appropriate to benefit from sharing of tools and lessons learned
  - **Influence by extension (**Cameroon, Côte d'Ivoire, Ethiopia, Ghana, Liberia, Madagascar, Malawi, Mozambique and Tanzania). Presence/platform that can be leveraged and used to allow the NMP to benefit from products and learnings. Project will support the inclusion of the MFT strategy in guidelines and policies

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# STOP-AMDR Partners

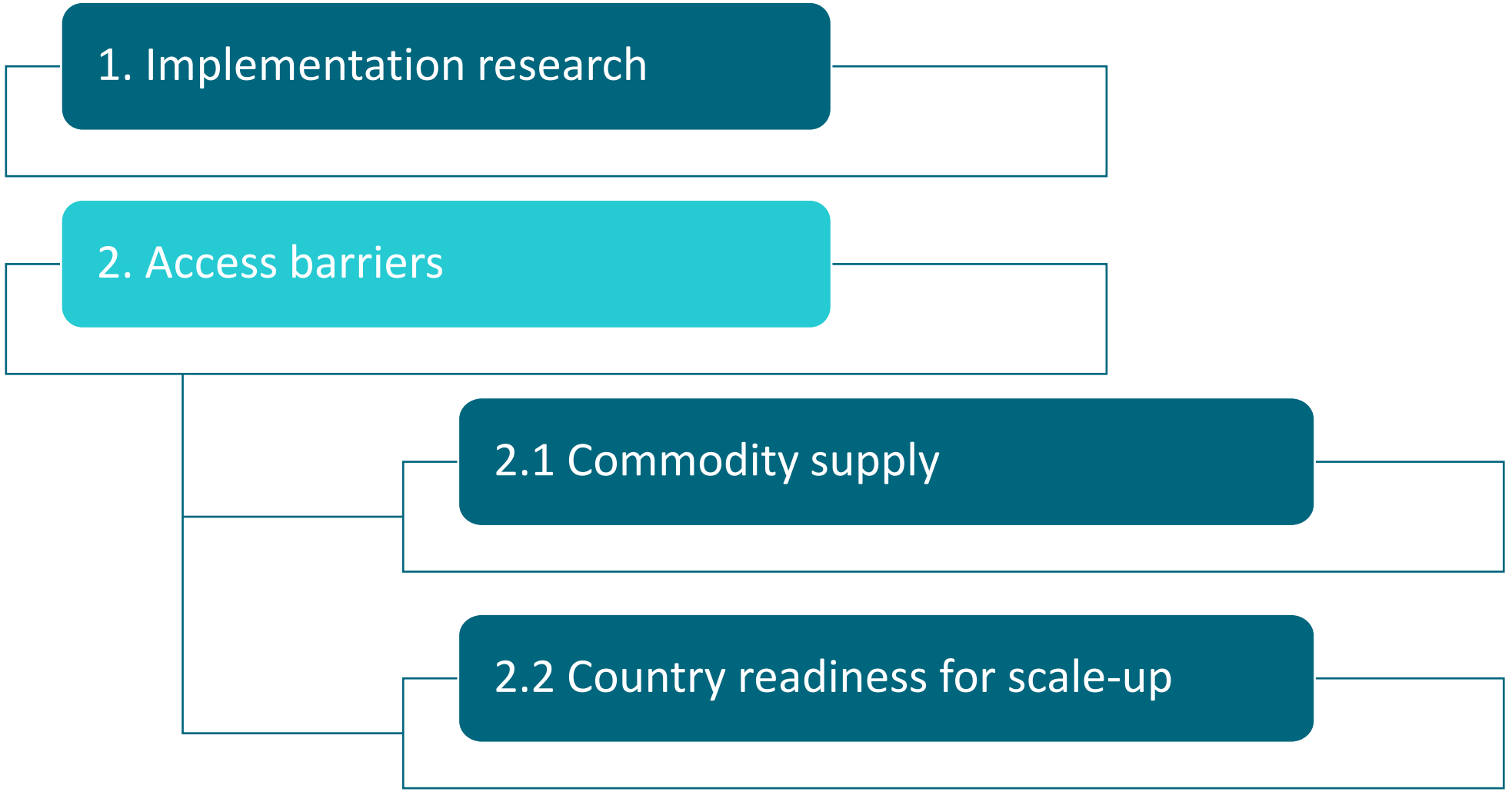
## Country level

- National Malaria Programmes
  - Development of MFT strategy and implementation plan, quantification for new ACTs
- Research institutions: Kinshasa Public Health School (DRC), University Teaching Hospital Calabar and the Centre for Malaria and other Tropical Diseases (Nigeria), University of Rwanda School of Public Health (Rwanda), Makerere School of Public Health (Uganda)
  - Co-design implementation research protocols, ethical clearance, implement research, disseminate learnings
- CSO partnerships: Civil Society for Malaria Control, Immunization and Nutrition (ACOMIN) in Nigeria, Rwanda Interfaith Council on Health and Strive Foundation in Rwanda, Uganda Civil Society Alliance Against Malaria (UCAAM), ASMADE and BURCASO in Burkina Faso, Kenya NGO Alliance against Malaria (KeNAAM), SANRU in DRC
  - SBCC at health provider and community levels, generate demand

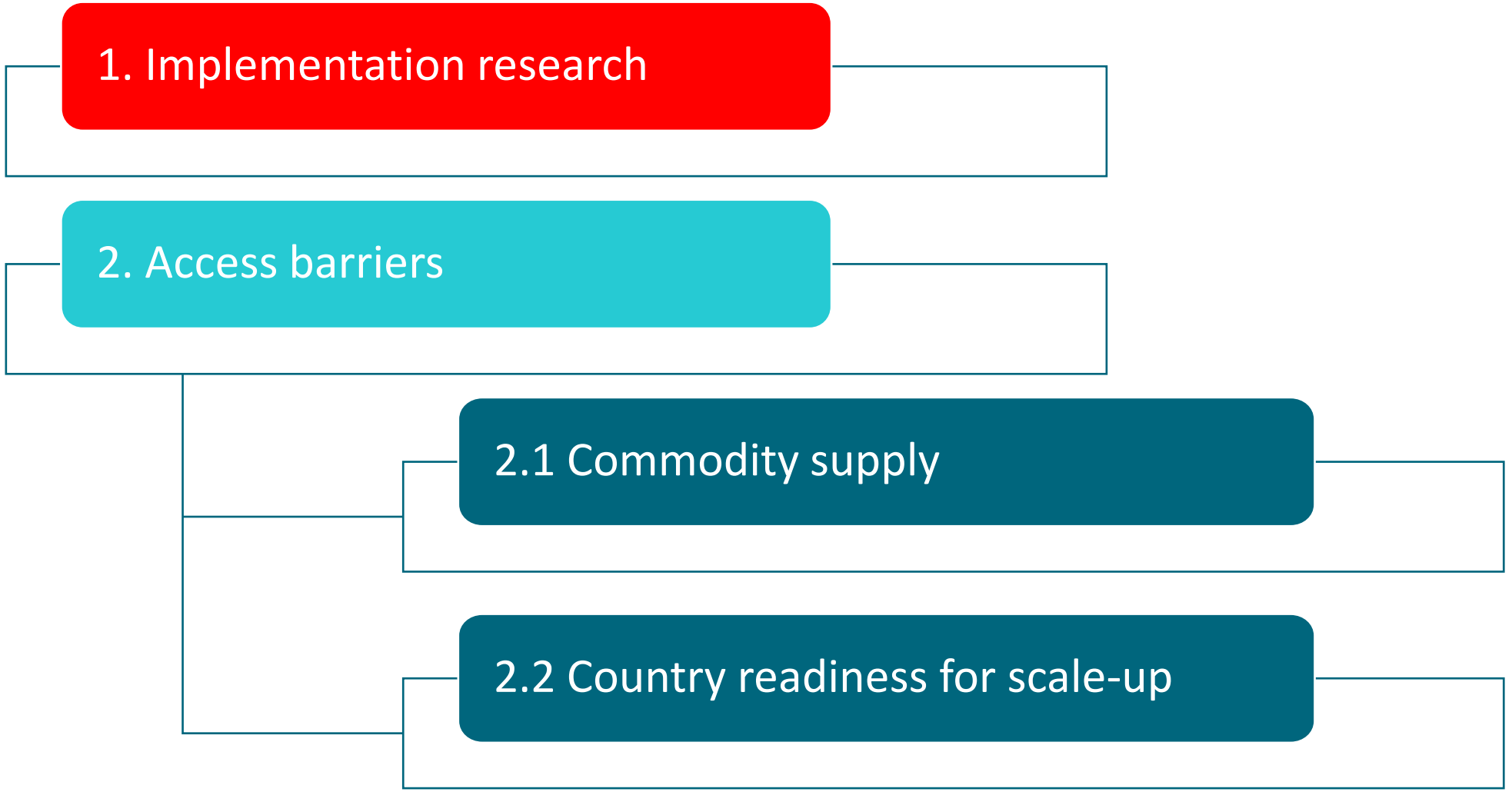
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# Implementation Framework

# STOP-AMDR framework



# STOP-AMDR framewor




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# Implementation research

- Generate evidence on the **feasibility**, **acceptability** and **cost** of implementing MFT strategies (as defined by WHO consultation) for treatment of uncomplicated malaria with recommended ACTs in the DRC, Rwanda, Uganda, and Nigeria
- Research design: mixed methods for data collection with intervention and control geographies (where appropriate) to assess the MFT strategy implemented in each country

1. Which factors should be considered (**feasibility** and **acceptability**) for decision making on policy change from the existing single first line to MFT strategy in demonstration countries?
2. What changes in the various systems (e.g., policy, supply chain and health system) are needed in **public** and **private** sectors to effectively and efficiently implement MFT policy change?
    - How does implementation of MFTs impact malaria treatment-seeking and case management in public and private sectors
3. What is the **cost** of implementing MFT in the demonstration countries?
4. How will **molecular markers** change over the course of the study? How can surveillance support drug resistance monitoring and inform timely decision making and response?

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# Approach in each country

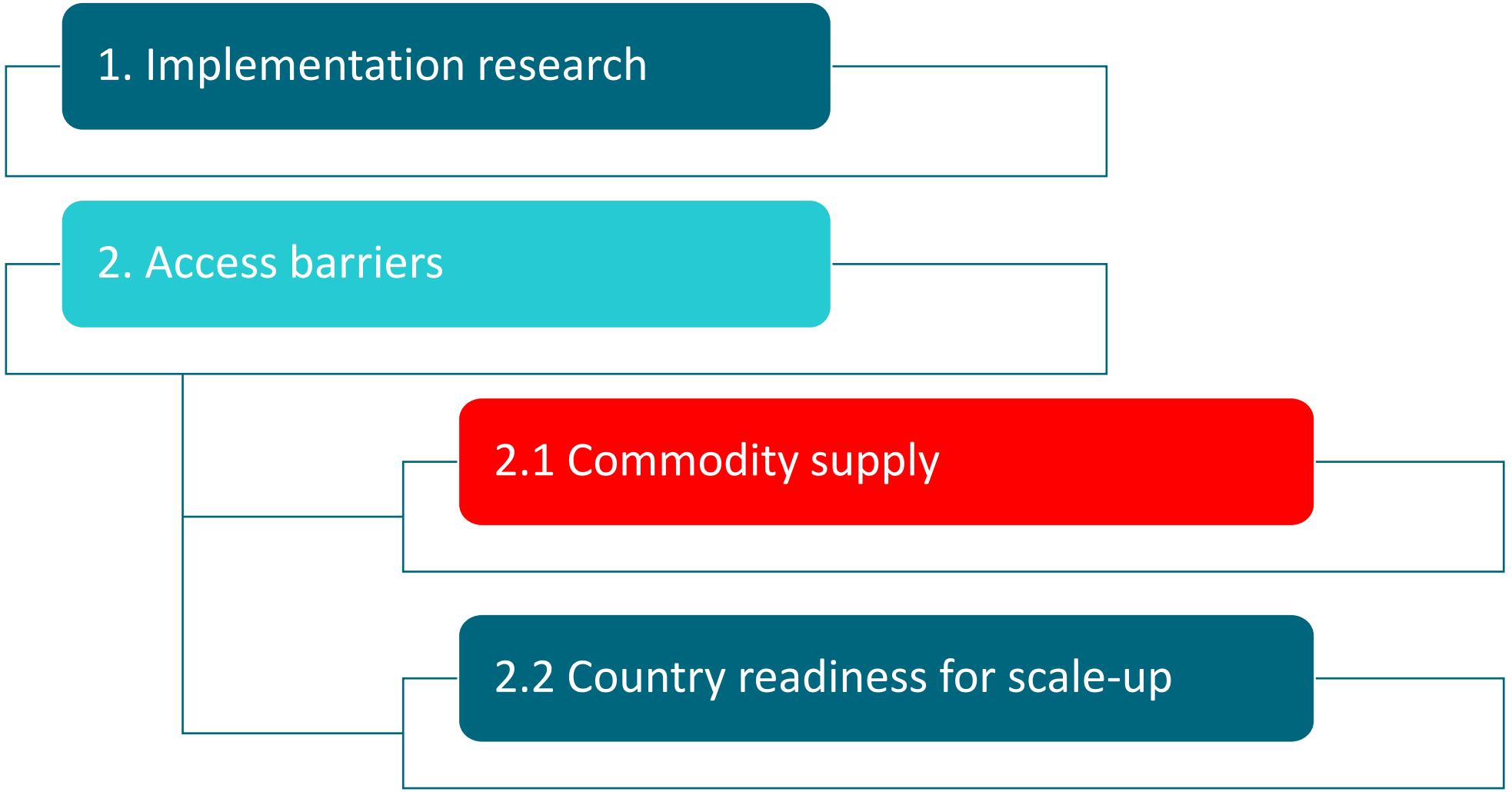
- Approach adopted in each country will vary by context
  - WHO Expert Consultation definitions to inform MFT options considered
  - Existing health systems and supply chain chains to be utilised in each country
  - Existing supply of ACTs to be utilised whenever available
  - Partners working in the respective areas
  - Importance of the private sector
  - Learnings will be disseminated as data is generated

- Data sources
  - Routine monitoring data, record reviews, other sources where available
  - Key informant interviews, in-depth interviews, client exit interviews, household surveys
  - Private sector surveys
  - Molecular surveillance
  - Expenditure reviews, procurement records
  - Models to refine MFT approaches that will avert the most treatment failures and minimize risk of resistant genotypes

*Note: STOP-AMDR not generating evidence to trigger new WHO normative guidance. Leanings will help refine and optimise MFTs in project and non-project countries*

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# STOP-AMDR framework



# Commodity supply

**Ensure uninterrupted availability of newer ACTs at project sites for IR**

- Goal is to make sure project sites have consistent ACT supply to carry out IR
- Newer ACTs used for IR at project sites will be donor-funded and delivered to project sites through national supply chain
- Contingent emergency funding to procure newer ACTs to project sites if there is a supply gap in donor-funded ACTs
- Close coordination with donors/partners and national supply chain systems will be key to achieving this objective

**o**

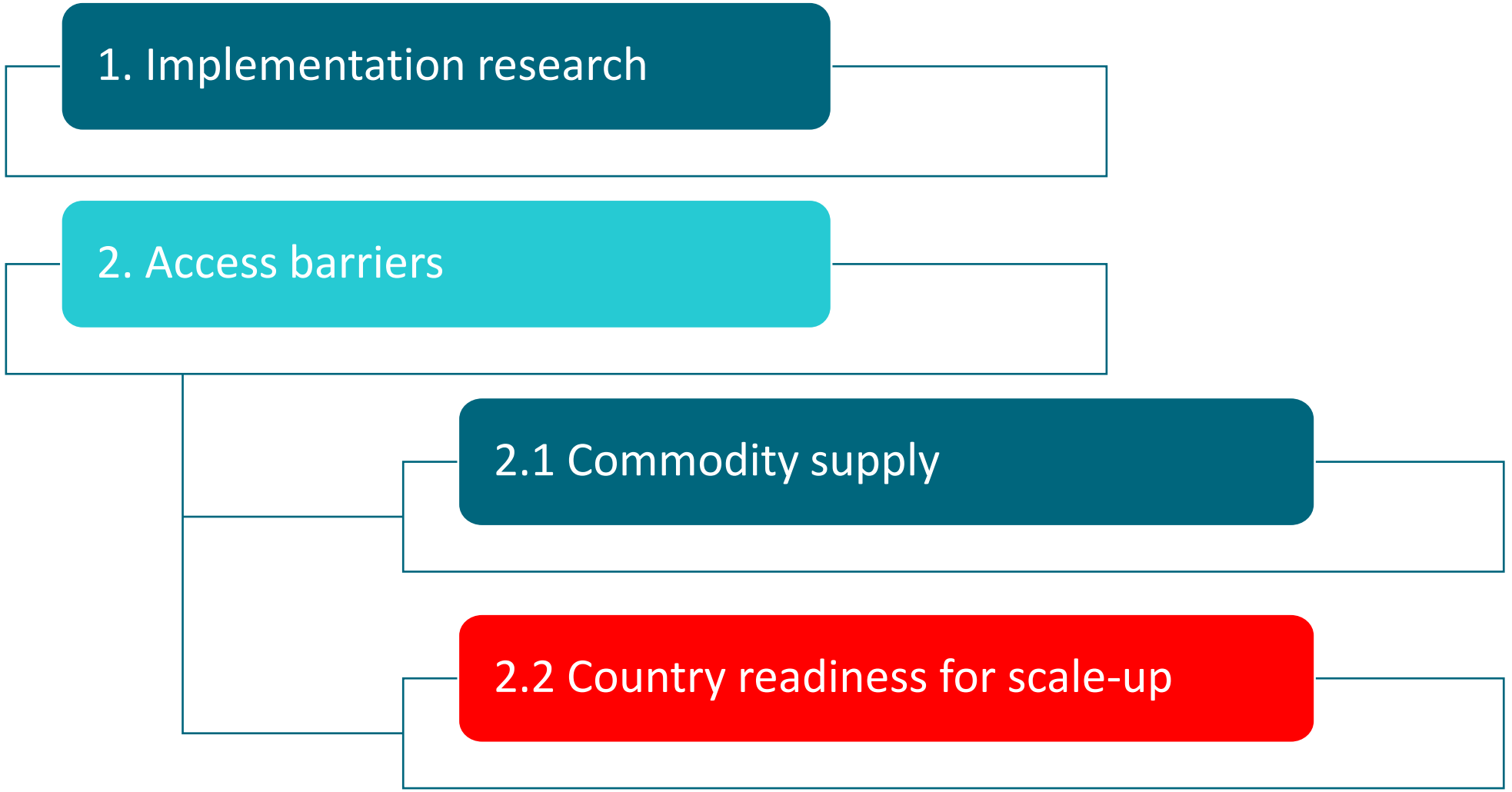
- Goal is to ensure availability of newer ACTs to support nationwide roll out and post-project sustainability of MFT strategy
- The focus is integration of newer ACTs into existing national health systems enabling country to continue to procure newer ACTs for nationwide roll-out of MFT strategy
- Project support complementary to ongoing efforts by other partners and may vary country by country

**Work with partners to contribute to reduced prices of newer ACTs**

- Goal is to improve affordability of newer ACTs (ASPY and DP) for ALL malaria high burden countries
- Ongoing partner efforts (Gates Foundation, Global Fund, MMV, MedAccess) working to reduce prices of ASPY. Project will support efforts by providing regular market intelligence on demand and implementation
- Emergency funding for ACT procurement to contribute to these efforts. We will need to develop a plan for doing this during the inception phase

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# STOP-AMDR framework



# Country readiness for MFT uptake



## Facilitate national uptake of MFT strategy in project countries

- Support NMPs to
  - Finalize MFT strategy tailored to country context
  - Facilitate MFT pilots including supportive interventions in demonstration districts
  - Update existing national policies and treatment guidelines to include MFTs
  - Update national training resources, job aids, supportive supervision, and quality improvement tools
  - Establish processes for on-the-job training, supportive supervision and mentoring of health workers
  - Advocate for strengthened quality assurance systems for drug surveillance and pharmacovigilance
  - Include private sector representatives in TWGs and workshops
  - Develop country level costed MFT scale-up plans, timelines and resources
  - Develop and implement transition plan
- Map, develop plans and implement community and civil society engagement to promote health provider behaviour change, build trust and map critical evidence and learning gaps on MFT

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# Project Advisory Group

- A Project Advisory Group (PAG) with organisations and individuals with relevant experience and insights will be established at the global level to advise the project and help to facilitate information sharing, advocacy, and dialogue among other partners
- PAG members will serve as a strategic resource to the PMT
- Group will meet virtually twice per year to provide advice and feedback, help resolve major problems to ensure that the project is successful – from increasing visibility to seizing targets of opportunity with other initiatives and a vehicle for global advocacy and evidence dissemination
- Key partners including WHO and donors, and country level research and community representatives (CSOs), will be invited. Gates Foundation?

# AMDR ecosystem and stakeholder landscape

## Interventions to **increase access and supply capacity**



**Co-financing**

THE GLOBAL FUND

Gates Foundation



**Volume guarantee**

Gates Foundation

MedAccess



**Generic introduction**

Gates Foundation



**API process improvement**

Gates Foundation

**NextGen MS Strategic Initiative – Access Fund** ($12M + $5M)

**VGs (under discussion) for generic AS-PY**

**Support for generic manufacturing of AS-PY**

**IDEV new synthetic route** ($1.2M)

**MMV grant** ($1.2M)

**Challenges:**

- Reduced potential for price reductions without partner volumes

## Interventions to **increase market information transparency**



**Market landscape analysis**

MMV Medicines for Malaria Venture



**Strategic demand forecasting**

Clinton Health Access Initiative

PMI U.S. President's Malaria Initiative



**Publishing reference price and purchase info**

PMI U.S. President's Malaria Initiative

THE GLOBAL FUND

**CHAI:** Global Malaria Commodity Forecasting

**GF**: PPM Reference Price

**PMI:** generate demand estimates and scenarios based on procurement plans and country feedback, MOP with procurement volumes

**MMV:** create link with manufactures, normative partners, donors and countries to develop and promote innovative, affordable malaria treatments and their deployment approaches.

**Challenges:**

- Lack of demand visibility
- Inaccurate forecasts
- Potential negative impact on supply capacity and pricing

## Interventions to **generate demand**



**Country readiness**

World Health Organization

Gates Foundation

Unitaid

PMI U.S. President's Malaria Initiative

THE GLOBAL FUND



**Policy and evidence**

World Health Organization

Unitaid

PATH

Clinton Health Access Initiative

Gates Foundation

**Unitaid:** Mitigating antimalarial drug resistance in Africa

**BMGF:** Generating market demand and supporting adoption of AS-PY ($2M).
Provide funding to PATH and CHAI to assess drivers of resistance and develop tailored response strategies that include MFT options and ACT choices.

**PMI:** registration, technical guidance, funding for pilot (e.g., Mozambique) , downstream support (supply chain management, training)

**Challenges:**

- Reduced demand and product adoption in partner supported countries/areas.
- Limited urgency for **pre-emptive** mitigation of drug resistance threat.

# Q&A



# AMDR ecosystem and stakeholder landscape

| | Improve availability and affordability of newer ACTs | | | Increase market information transparency | | | Generate demand | |
|---|---|---|---|---|---|---|---|---|
| | Co-payment | Generic introduction | Process improvement | Market landscape analysis | Strategic demand forecasting | Publishing reference price and purchase info | Country adoption and introduction | Policy and evidence |
| S/H | Global Fund, Others? | Gates Foundation, MedAccess | Gates Foundation, MMV, M4All | MMV, Maisha Meds, PSI **STOP-AMDR** | CHAI, PMI (GHSC-PSM) | Global Fund | WHO, Gates Foundation, PMI, Global Fund, MARC-SEA, WB, MMV (ALARM) **STOP-AMDR** | WHO, Gates Foundation, MARC-SEA **STOP-AMDR** |
| Description | Global Fund Access Fund to pay for the price diff with AL | Volume Guarantee for generic ASPY, Introduction of African manufac. | Pyronaridine API cost reduction to drive ASPY price reduction | Private sector market data, country market data | Demand estimates and scenarios based on procurement plans and country feedback | Publication of reference prices | • Gates Foundation (via partners): Support adoption of ASPY in country through funded projects targeted at country guidelines updates, molecular surveillance<br>• PMI, others: Registration, technical guidance, downstream support, TES,, and ACT procurement, supply chain TA | |
| Impact | Lower short-term price for newer ACTs to promote MFT | Increase supplier base and regional supply security, price reduction | Optimize raw material and finished product manufacturing for higher yield and lower unit cost | • Increased transparency to reduce price variation, improve actual demand volume visibility<br>• ACT market share assessment including private sector and informal markets<br>• Modelled estimates based on historical demands – early demand visibility | | | • Support country readiness for MFT by supporting country guidelines, product registration, demand forecasting, procurement, and implementation<br>• Evidence generation on feasibility, acceptability and cost-effectiveness<br>• Evidence disseminating to accelerate regional uptake and influencing WHO guidance | |

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RBM Partnership
To End Malaria

16 September 2025

# Update from MFT start-up phase in Tanzania, Ghana and Cameroon: Sharing experience and learnings to date

Adam Aspinall MMV
Abdalah Lusasi, NMCP Tanzania



# MFT pilot updates: Ghana, Tanzania and Cameroon

Adam Aspinall
Senior Director
Medicines for Malaria Venture

MMV
Medicines for Malaria Venture

Ending malaria, *rewriting the future*

# Background

- MMV pioneered the introduction of Multiple First-Line Treatments (MFT) over 5 years ago, supporting pilot programmes in Kenya and Burkina Faso
- These pilots demonstrated the operational feasibility, acceptability and affordability of MFT and paved the way for wider deployment
- With the rapid spread of partial artemisinin resistance in Africa, WHO held an expert consultation on MFT in 2024 and it features in the WHO's Africa resistance strategy as one of several recommended interventions
- In late 2024 initial funding was granted by MMV to support 3 additional countries - Tanzania, Ghana and Cameroon – to commence the preparation phase for pilot deployments in 2025

# Current status

- Strathmore University has agreed to act as project manager, contracts signed with Strathmore and sub-contracts with Tanzania, Ghana and Cameroon
- Kick-off meetings were held for all countries wk4 Jan / wk 1 Feb to establish common baseline, identify training needs, review deployment plans and drug quantifications
- Start-up phase in H1 2025 for 6 months, during which NMCPs have involved MoH, order required drugs and train the trainers
- First deployments planned for Q3-4 2025 (budget dependent), with 2-year duration to allow 2 drug rotations
- Blood samples will be collected from all sites in order to perform genotyping to evaluate impact of MFT on evolution of resistant parasites
- Protocol and timings are being aligned to the maximum extent with the parallel Jhpiego project (4 pilots, 2 expansion countries) in order to be able to pool data at the end of the project to maximise the operational research dataset
- An MFT information sharing / alignment group is being set up with Jhpiego to review progress and maximise visibility of the project with normative stakeholders



Strathmore University Business School

MMV Medicines for Malaria Venture

# Tanzania

# Pilot deployment study objectives

**Primary objective:**

- To assess the feasibility of deployment of MFT strategy in the treatment of uncomplicated malaria in Tanzania

**Specific objectives:**

- To assess health systems challenges associated of MFT deployment in Tanzania
- To assess acceptability of MFT strategy among health care workers, policy makers and community members
- To evaluate the costs of delivering MFT intervention for the management of uncomplicated malaria in Tanzania
- To assess the cost effectiveness of MFT strategy on mitigation of AMDR in Tanzania
- To determine the impact of MFT strategy on malaria case management in Tanzania.
- To determine the impact of MFT strategy on markers of drug resistance

# Methods

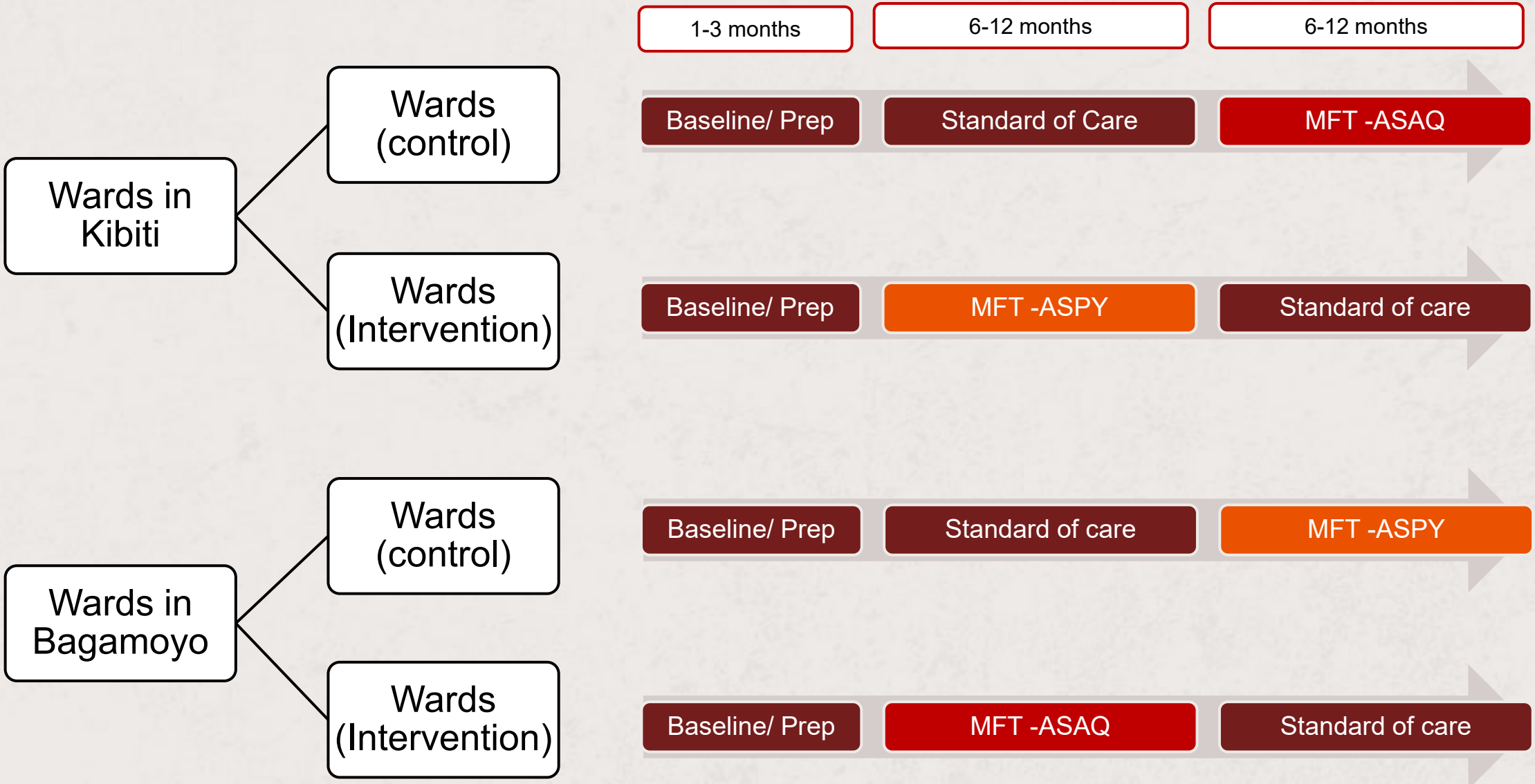
## Study area

- The study sites will be Bagamoyo and Kibiti districts Councils in Pwani region Eastern Tanzania, the two areas that have notable decline of drug efficacy below 90% and markers of artemisinin partial resistance reported

## Study design

- Cluster randomised implementation study to assess the feasibility of deployment of MFT strategy in Tanzanian health system.
  - **Wards will be the randomisation unit** to form **two arms** -a control (standard of care) or an intervention areas (MFT deployed)
  - All facilities in an intervention ward will implement MFT while those in control will implement the current standard of care
  - A subset (N=XX) of patients attended will be consented for collection of DBS to assess markers of drug resistance and parasite genetic diversity at baseline day 0.
  - National (NMCP) and District pharmacist will oversee deployment of drugs to each ward. Drugs will be kept at respective ward health centres.

# Study design and practice



# Preparatory activities

## Study preparation prior approval (H1 2025)

- Development and submission of detailed MFT Pilot study proposal to National Research and Ethics Review Committee
- Development of data collection tools and DHIS2 e-system
- Development of Pharmacovigilance/Safety Monitoring Plan (Use Yellow forms)
- Development of training materials for healthcare workers and Community Health Volunteers (CHVs)
- Procurement and distribution of the new MFTs
- Preparations for launch of the MFT pilot study (including dry run on switch from current first line treatment to the first new drug for MFT)

## MFT implementation

- Official start-up meeting of the MFTs pilot implementation- (conduct open randomisation)
- Pharmacist to re redistribute the available ACT to control areas an distribute MFT to intervention areas
- Consultative meetings with policy makers, healthcare workers and other stakeholders
- Preparation and recruitment of key staff for the study
- Training of pharmacists on quantification and procurement of new MFTs
- Development of Job Aids to facilitate prescribing of new MFTs
- Development of posters to sensitize patients on new MFTs
- Development of schedule for deployment of new MFTs
- Training of healthcare workers and CHVs on MFTs (include DBS for selected HFs)
- Community Engagement Plan

# Status

| Planned Activities | Status | Comment |
|---|---|---|
| MFT core team launch meetings | Feb 2-5, 2025 | Successful reporting and exchange of ideas |
| Ethical review and Protocol Approval | 3rd June 2025 | IRB Certificate Issued |
| Baseline cross sectional survey and ToT training | Ongoing | Field work anticipated to end by mid Sept 2025 |
| Community Engagement and Stakeholder Engagement | Done | Community engagement from PORALG, District councils, Wards/Villages & HFs<br>All Health facility staff were available in the selected HFs in Bagamoyo, Chalinze, Kibiti and Rufiji District Councils |

# Ghana

# Preparation phase: key activities

- Inclusion of pyronaridine-artesunate and DHA-PPQ into NHIS medicines list
  - HTA completed, decision made to include both in NHIS
- Consultation meetings and sensitisation of stakeholders
  - Consultative meeting held with >50 key stakeholders, mtgs with >50 regional directors, >150 school infirmary staff and >50 at the Paediatric Society of Ghana
- Development of training materials
  - Job aids developed and distributed, Powerpoint training deck developed and accessible via GHS website (https://ghs.gov.gh/ )
- Training: Nearly **7000** HCPs trained, including 1,786 clinicians, 480 nurses/midwives, 211 pharmacists and 2000 newly graduated doctors

# Other activities

| Planned Activities | Status | Comment |
|---|---|---|
| MFT core team meetings | Complete | Successful reporting and exchange of ideas |
| Ethics review / protocol approval | ongoing | Final protocol shared |
| Forecasting / procurement of study drugs | ongoing | Quantification done for 2025-2027 for PyAS, AL, ASAQ, DHA-PPQ |
| Configuration of the information system to accommodate MFT | done | Completed as part of a broader review of information systems |
| Pre-intervention survey | ongoing | Being performed by UHAS School of Public Health |

# Cameroon

# Objectives of the Feasibility Study

The overall aim of this pilot study is to assess the feasibility prior to the implementation of multiple first-line treatments for uncomplicated malaria in the ten regions of Cameroon.

The specific aims of the pilot study are as follows:

1) To evaluate health system challenges associated with the use of artemisinin-based combination therapies (ACTs) prior to the implementation of multiple first-line therapies (MFTs) in Cameroon.

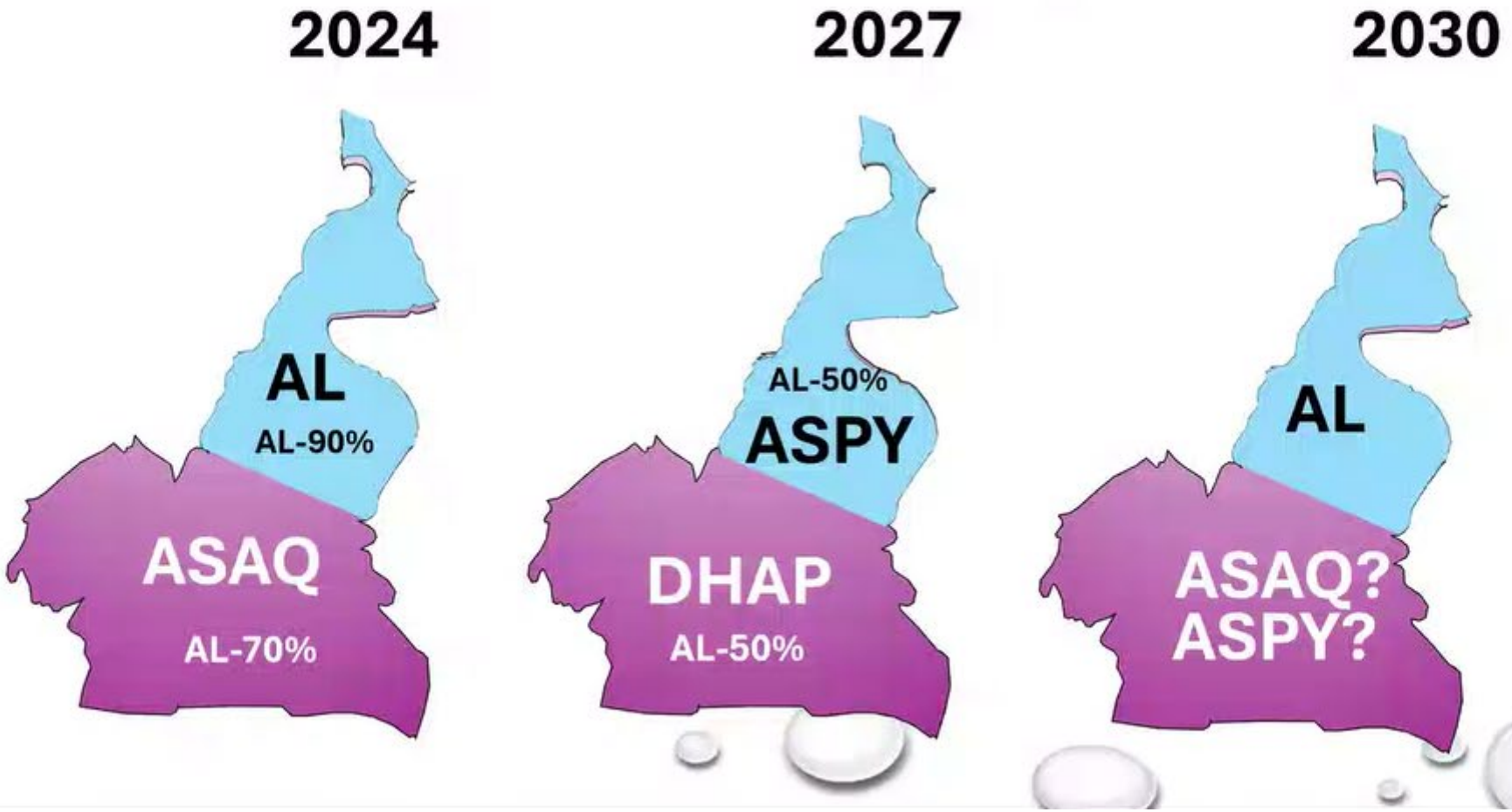
2) To assess the perception and knowledge on malaria and ACTs before the deployment of MFTs in malaria-endemic regions of Cameroon.

3) To determine the baseline prevalence of malaria parasites and anti-malarial drug resistance markers in regions with varying malaria transmission patterns in Cameroon.

# The official launch of the MFT pilot project took place in February.



# CAMEROON'S MFT-ACT POLICY TO MITIGATE AMDR
## PNLP Workshop in Douala [29-03-2025]



# A key stakeholder consultative forum on mitigating AMDR in Cameroon was held in March.

**Objectives:**

- Define strategic priorities and key interventions to mitigate antimalarial drug resistance in Cameroon
- Develop a draft framework for the National Strategic Plan including priority actions, implementation modalities and monitoring mechanisms
- Ensure stakeholder commitment and consensus on the strategic approach to mitigating AMDR

# Current status

| KeyActivities | Status | Comment |
|---|---|---|
| MFT core team meetings | Jan 30 to Feb 1, 2025 | Successful reporting and exchange of ideas |
| Ethical review and Protocol Approval | 4th June 2025 | IRB Certificate Issued |
| Baseline data & sample collection | Ongoing | Field work anticipated to end by mid Sept 2025 |
| Community Engagement and Stakeholder Engagement | Ongoing | Ongoing engagement with MoH for approval of the study drugs |

# Facilitation, mentoring and next steps (Strathmore, IRSS)

| Planned Activities | Status | Comment |
|---|---|---|
| Facilitate in-country MFT deployment kick-off meetings | Jan 26 to Feb 2, 2025 | The Strathmore team travelled to Ghana, Cameroon and Tanzania for the kick-off and closeout. |
| Country progress reviews | June 21-25, 2025<br>July 23-31, 2025 | Prof Soulama participated in Cameroon and Ghana |
| Project Management Support | Done | Provided support to all 3 countries in developing their country specific protocols. |
| Disbursement of Funds | Done | All funds have been disbursed to the 3 countries. |
| Cross-learning conference | Pending | Scheduled for October/Nov 2025 |
| Commencement of deployment phase | TBC | Dependent on budget – budgets being worked up currently |

Strathmore UNIVERSITY BUSINESS SCHOOL

MMV Medicines for Malaria Venture

RBM Partnership
To End Malaria

16 September 2025

# Panel discussion:
# Experience of MFT operationalization.

- Moderator: Rima Shretta, CMWG
- Panelists: Uganda, Rwanda, Nigeria, Malawi, Burkina Faso

The Republic of Uganda



# MFT Strategy Overview-UGANDA

September 16, 2025

Chase Malaria to Zero

The Republic of Uganda

# Progress to Date



## Proposed Implementation:

- Pilot in high-burden districts.
- Target both public and private health sectors.

## ACTs Selected for MFT

AL,DP,ASPY and ASAQ

**Deployment Approach**: Assign specific ACTs to specific geographic zones

Chase Malaria to Zero

The Republic of Uganda

# Supply Chain Readiness



- Orders for DP,ASPY & AL already placed
- Country to receive ordered drugs-October 2025
- Planned implementation in January 2026
- Developed supply chain transition plan for rolling out MFTs
- Completed training materials, job aides, and BCC materials for health worker capacity building
- To conduct trainings of health workers on antimalarial resistance management and MFTs

Chase Malaria to Zero

Rwanda Biomedical Centre
Healthy People, Wealthy Nation

# Rwanda MFT Implementation Status

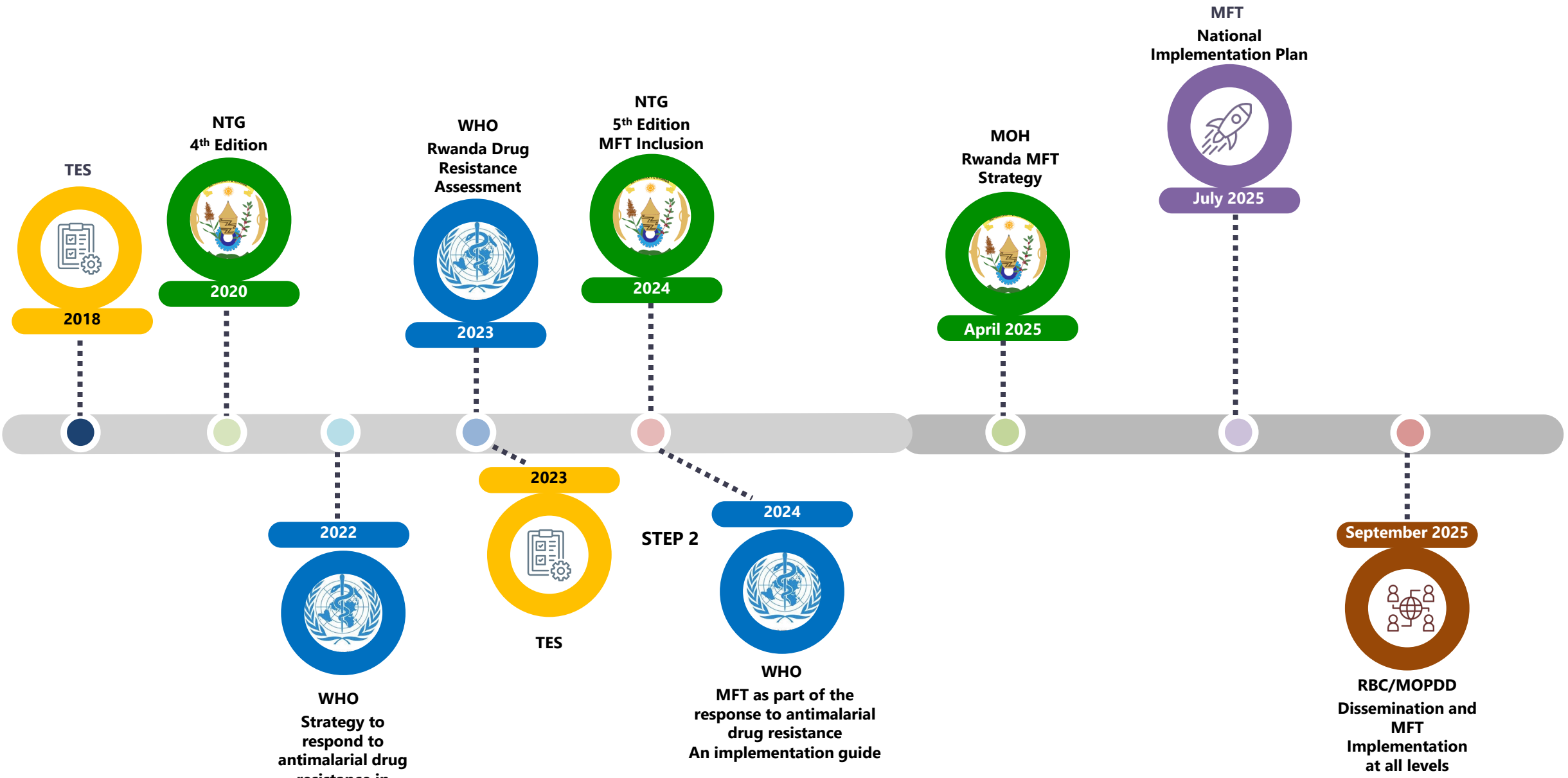
# Data Informed MFT Design

**Abidjan, 16th Sept 2025**

Dr. Aimable MBITUYUMUREMYI
RBC/MOPD Division Manager

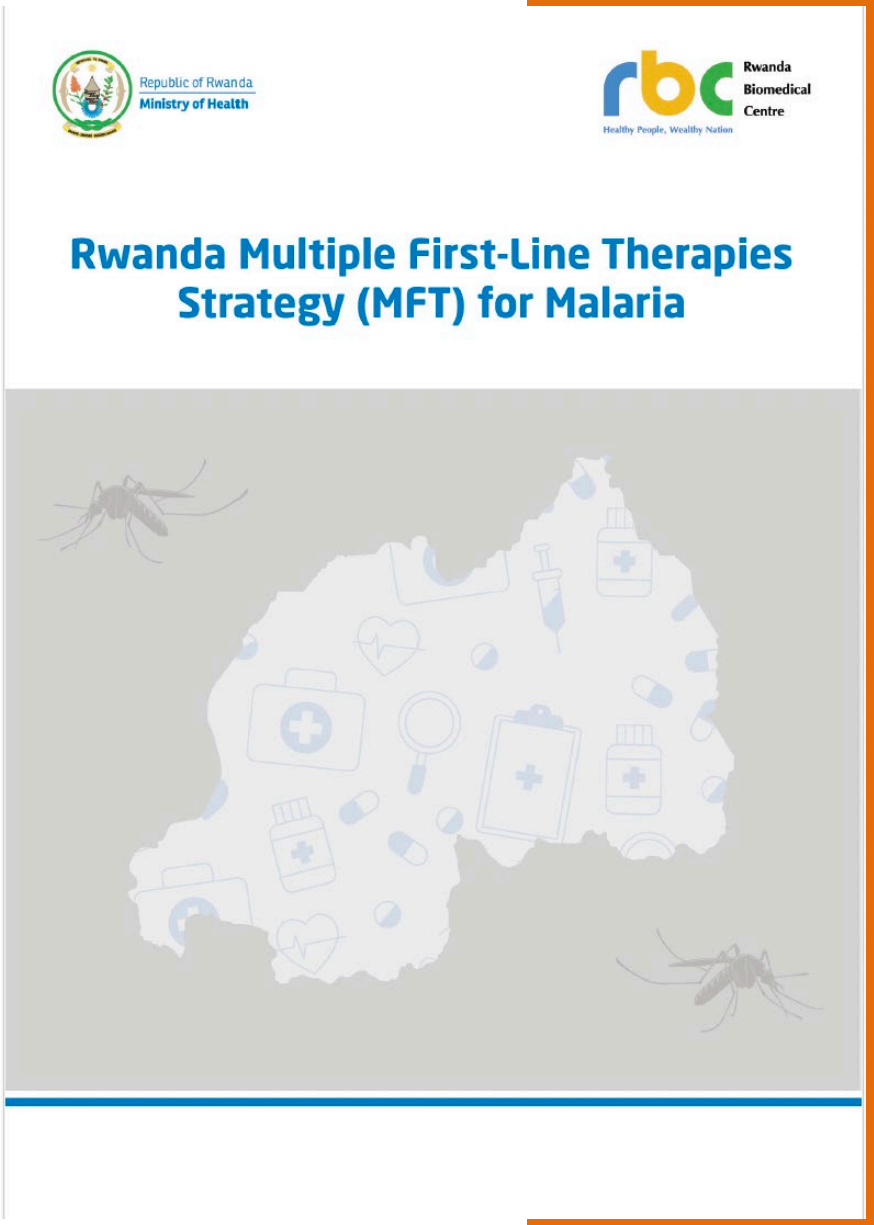
# Rwanda MFT Roadmap

## From TES to Implementation



# *Rwanda MFT Strategy for Malaria*

*2025 - 2027*

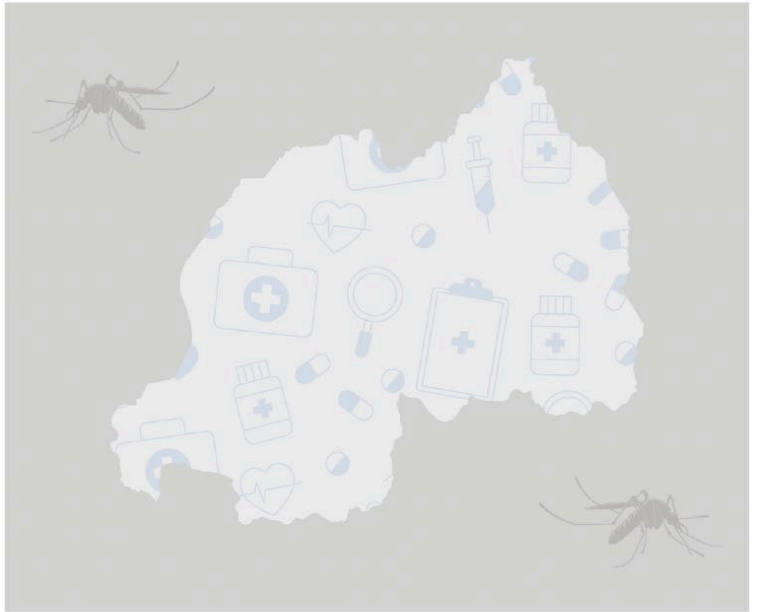


# *Rwanda MFT Implementation Guide*

Republic of Rwanda
Ministry of Health

Rwanda Biomedical Centre
Healthy People, Wealthy Nation

**Rwanda Multiple First-Line Therapies (MFT) Implementation Guide**

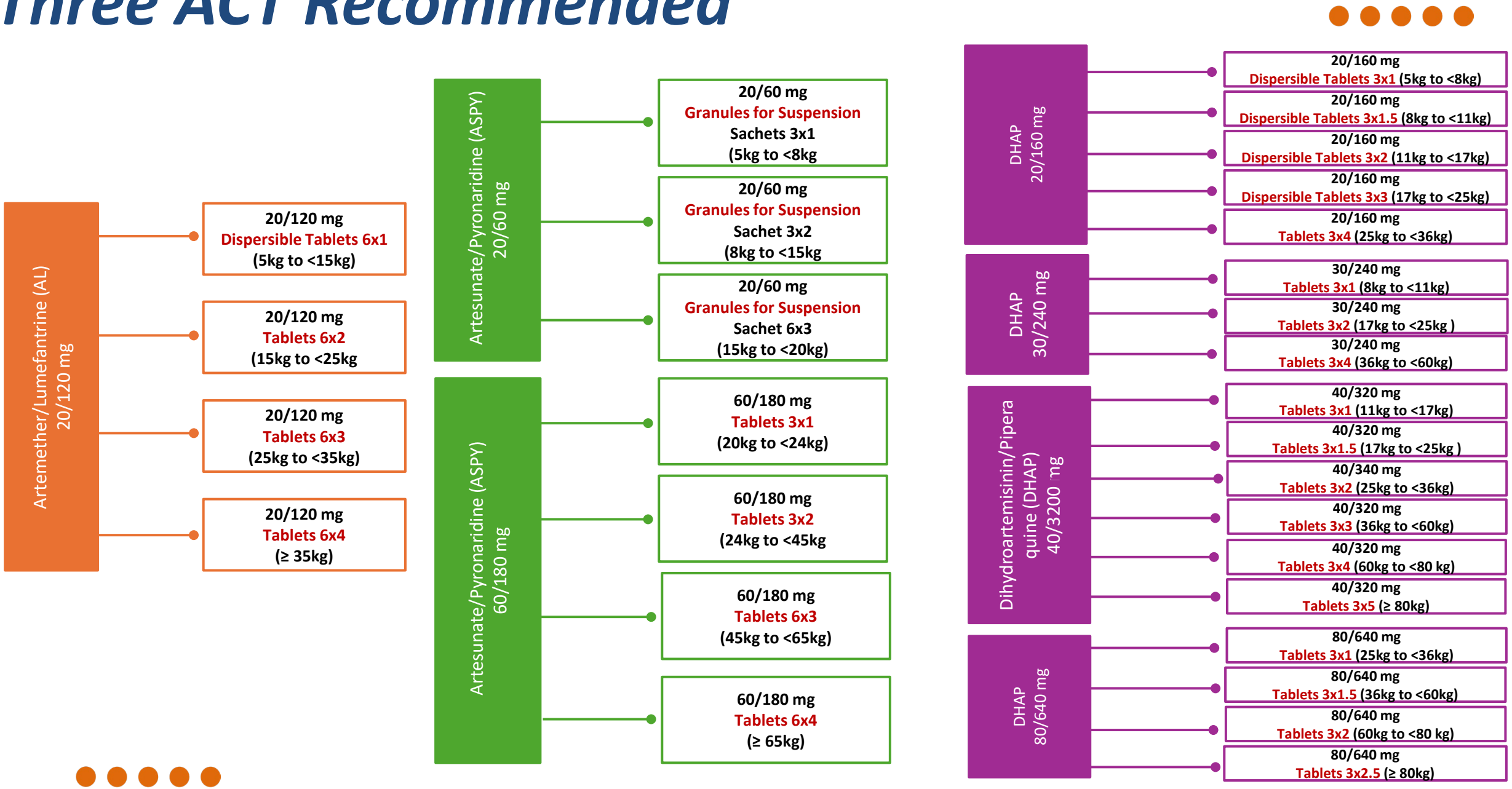


**July 2025**

# Progress- As of September 2025

1. Guidelines Revised (2024)
2. MFT Strategy Developed and Launched(April 2025)
3. MFT Implementation Plan Launched (July 2025)
4. MFT Implementation Disseminated (Sept 2025)

# Three ACT Recommended

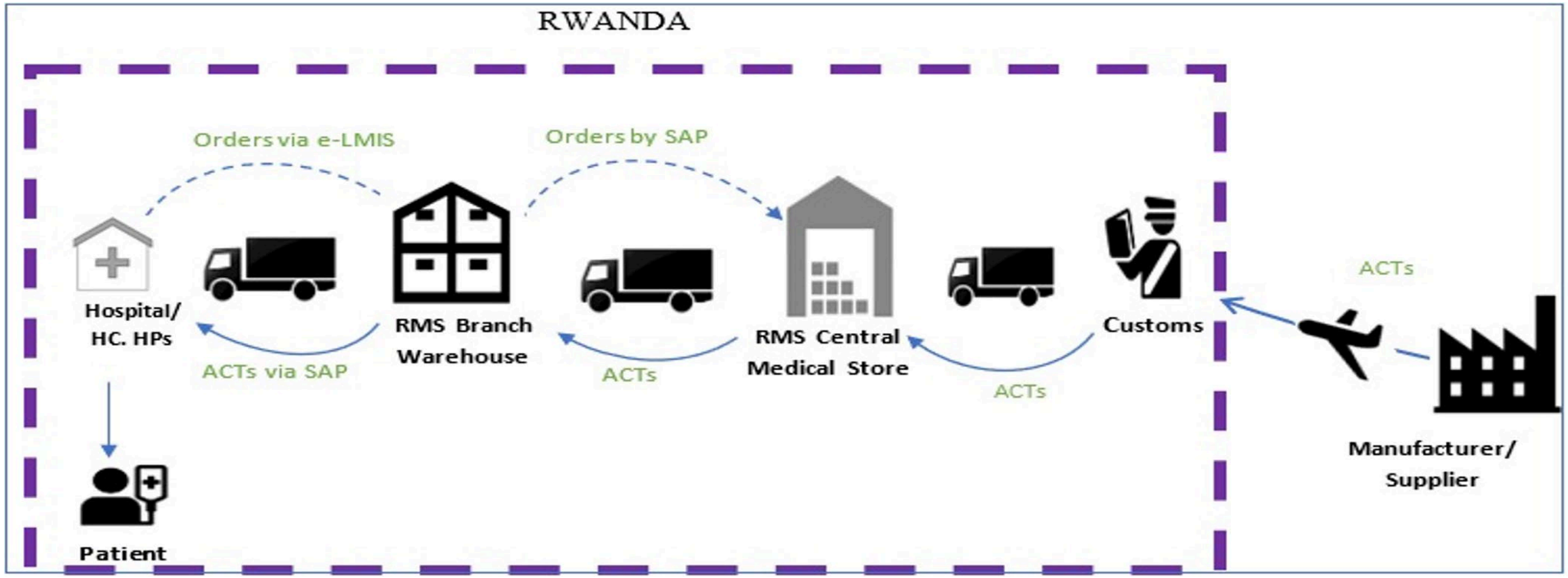



Note: Some formulations may not be available in Rwanda.

***ACTs should be given daily with optimized dose for 3 days***

# Supply Chain and Logistics

- Centralized procurement through RMS, with block-specific allocation based on the rotation schedule.
- The distribution of medicines will follow established national distribution channels.
- Reverse logistics in place to reallocate surplus drugs at the end of each rotation year.
- Buffer stocks maintained to prevent stockouts during transition months. With the use of Zipline drone deliveries for hard-to-reach areas to ensure uninterrupted supply.



# *MFT Strategy Fully Integrated*



**Policy & Strategy**

- The 2024 NTG list AL, DHAP, and ASPY as first-line options. The MFT Strategy, endorsed by MOH/RBC, defines block rotation and implementation. MOH engages all levels and stakeholders for compliance.



**Regulation & Monitoring**

- RFDA ensures that all ACTs are WHO-prequalified, registered in Rwanda, and approved.
- MOH/RBC leads M&E of MFT implementation, including PV, rational use, TES, field supervision, and national progress reviews.



**Supply & Distribution**

- RMS is responsible for procuring MFT ACTs, managing storage, and ensuring block-specific distribution according to the rotation calendar. It maintains adequate buffer stocks to guarantee uninterrupted supply across all facilities.

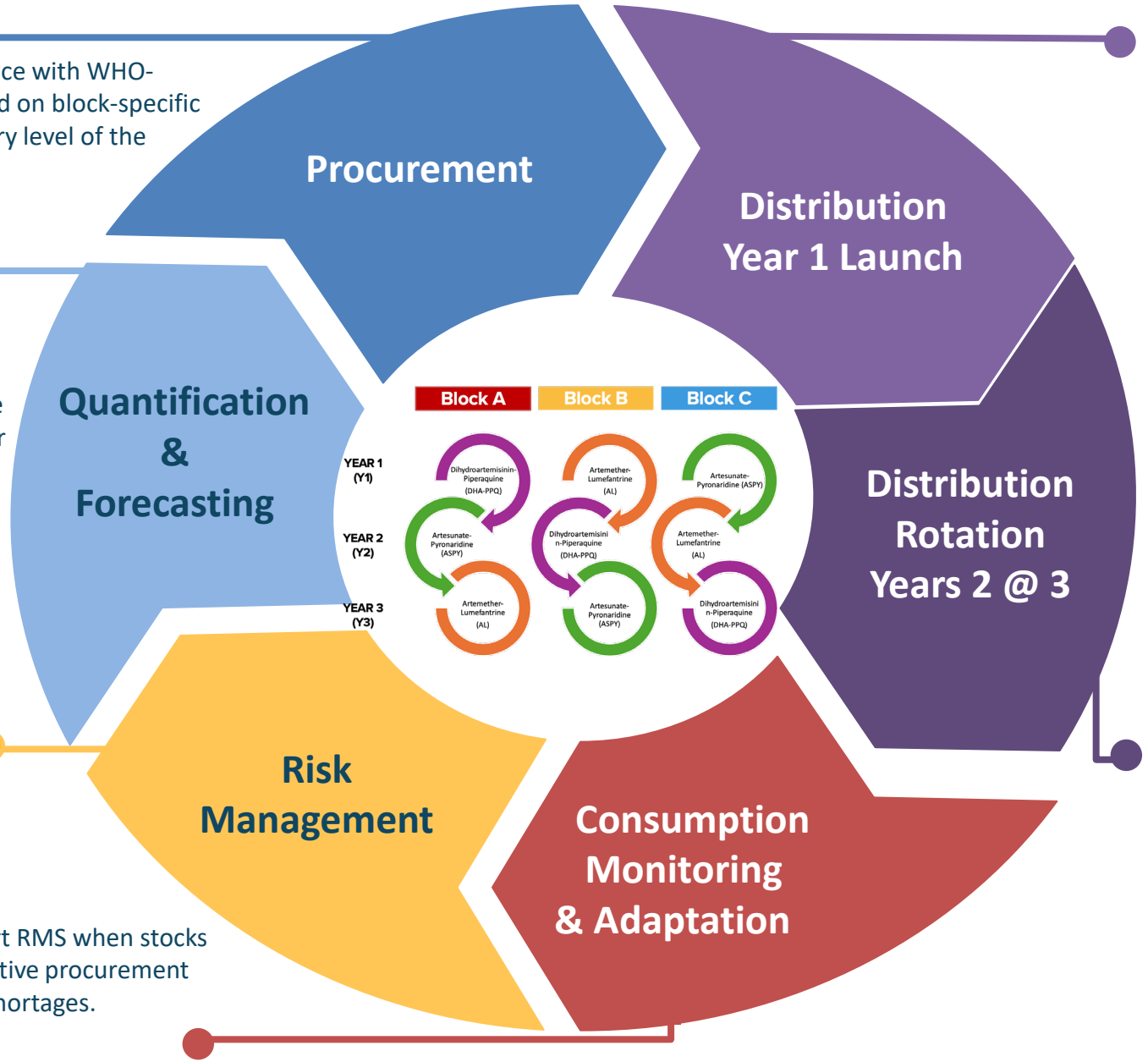
# Supply Chain: From Quantification to Rotation

Orders for each ACT are placed [illegible] in advance with WHO-prequalified manufacturers. Quantities are based on block-specific needs plus a minimum one-month buffer at every level of the system.

RMS and RBC/MOPDD conduct annual ACT quantification using malaria case trends, seasonal patterns, block population sizes, and buffer stock requirements. Forecasts are aligned to the rotation calendar and consider lead times for procurement and delivery.

Continuous monitoring and quick redistribution prevent situations where facilities might take ACTs from other blocks, which would break the MFT cycle and increase resistance risk. Strict compliance supervision ensures blocks use only their assigned ACT as first-line.

Monthly ACT stock tracking by district will alert RMS when stocks approach buffer limits. This allows also adaptive procurement and redistribution plan to prevent shortages.




- Before MFT, all districts used AL. At rollout, blocks assigned to DHAP or ASPY must remove excess AL and replace it with their assigned ACT.
- **Reverse strategy:**
  CHWs identify surplus AL
  → return to health center
  → facility verifies and transports to RMS
  → RMS redistributes AL to AL blocks or urgent needs, following SOPs.
- Designated ACTs for each block are delivered to facilities and CHWs, supported by Zipline drones for hard-to-reach areas.

- Before each rotation, RMS retrieves remaining stocks of the outgoing ACT from the block.
- Reverse logistics reallocates the drug to the incoming block for that ACT.
- New ACT delivered in advance to avoid treatment gaps during the switchover date.



# THANK YOU

aimable.mbituyumuremyi@rbc.gov.rw

# Plan de transition des ACT au Burkina Faso









# Agenda

1. Introduction et contexte
2. Objectifs du plan de transition thérapeutique  des ACT
3. Critères de sélection des régions par type d' ACT
4. État d'avancement de la mise en œuvre du plan de transition
5. Résultats préliminaires de la modélisation mathématique du plan de transition des ACT
6. Prochaines étapes

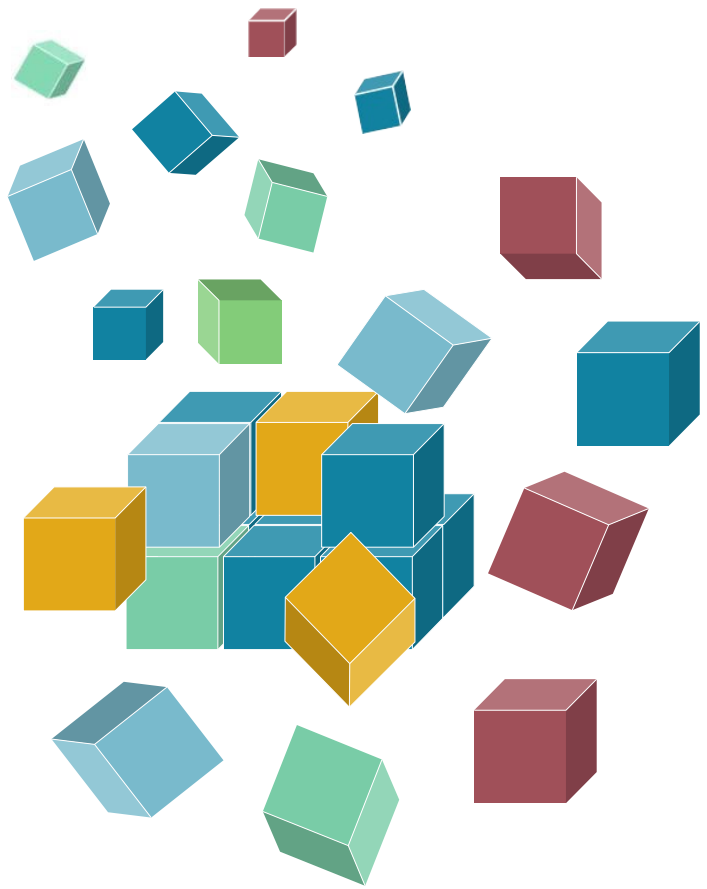
# Pour prévenir l'émergence de la résistance aux ACT et réduire la morbidité et la mortalité liées au paludisme, le Burkina Faso a révisé et adopté un nouveau plan de transition des ACT en 2024.

| | | |
|---|---|---|
| 1 | **Révision des lignes directrices pour la prise en charge des cas** | • Dans **le cadre du renforcement de la prise en charge du paludisme simple**, le Burkina Faso a introduit en 2021, **en plus de l'artéméther-luméfanthrine (AL),** deux nouvelles ACT dans ses directives nationales : **Dihydroartémisinine Pipéraquine (DHAPPQ) et Artésunate Pyronaridine (AP).** |
| 2 | **Elaboration d'un plan de transition en 2022** | • Cependant, le TES 2021 a montré une **efficacité de plus de 90% pour DHAPPQ** alors que celle de la **combinaison AL variait entre 75,1% et 90,6%,** conduisant à **l'élaboration d'un premier plan de transition en 2022.**<br>• En raison de **contraintes budgétaires**, l'**AP** a été effectivement introduit au deuxième trimestre 2023 dans la **région Centre-Ouest** et le **DHAPPQ** au deuxième trimestre 2024 dans la **région Centre-Est.** |
| 3 | **Révision du plan de transition en 2024** | • **Afin de prendre en compte les nouvelles directives de l'OMS** (au moins 25% si 3 médicaments sont utilisés) et de corriger les insuffisances observées lors de la mise en œuvre du plan 2022, le SP Palu, avec l'appui de ses partenaires, a **révisé le plan de 2022 en juillet 2024.** |

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**L'objectif général de ce plan est d'assurer le déploiement de toutes les ACT énumérées dans les lignes directrices pour la gestion des cas, afin de mieux gérer la résistance aux médicaments antipaludiques. Les objectifs spécifiques sont les suivants:**



01 Fournir et déployer efficacement les ACT en fonction des zones définies

02 Renforcer les capacités des acteurs en matière de logistique et de gestion des cas

03 Assurer la coordination, le suivi et l'évaluation du plan de transition, ainsi que la pharmacovigilance des ACT

04 Communiquer sur le respect des directives de soins et renforcer l'engagement avec les acteurs du secteur privé et communautaire

05 Assurer la mobilisation de ressources suffisantes pour la mise en œuvre du plan.

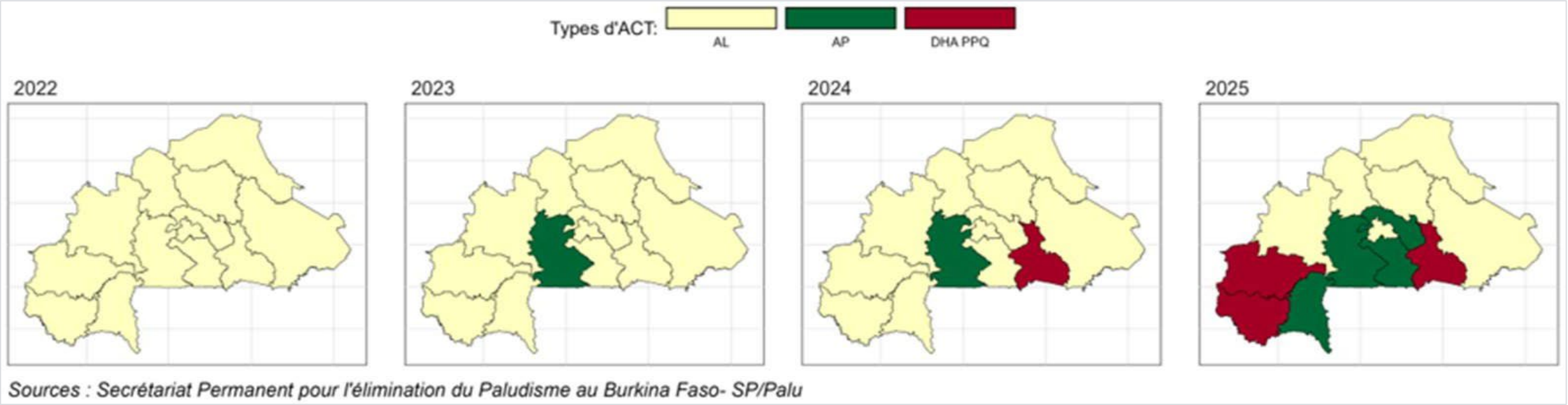
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# Six régions (Centre Est, Centre Ouest, Centre Sud, Sud Ouest, Hauts Bassins, Plateau Central) précédemment utilisant l'AL seront progressivement approvisionnées en DHAPPQ ou AP à partir de 2023 à 2026, en fonction des ressources disponibles.

## Le choix des régions pour le déploiement des nouvelles ACT est basé sur les critères suivants :

- **L'incidence moyenne** des trois (03) dernières années (2021 à 2023) par région (≥490 cas pour 1000 habitants) ;
- **Les contraintes sécuritaires de la région:** Les régions doivent être accessibles en termes de sécurité pour permettre une distribution efficace des nouveaux médicaments et une surveillance adéquate de leur utilisation.
- Considérant **les recommandations de l'OMS (1)** : dans un déploiement simultané de trois (03) médicaments, l'OMS recommande que la consommation de chaque médicament soit supérieure à 25%.



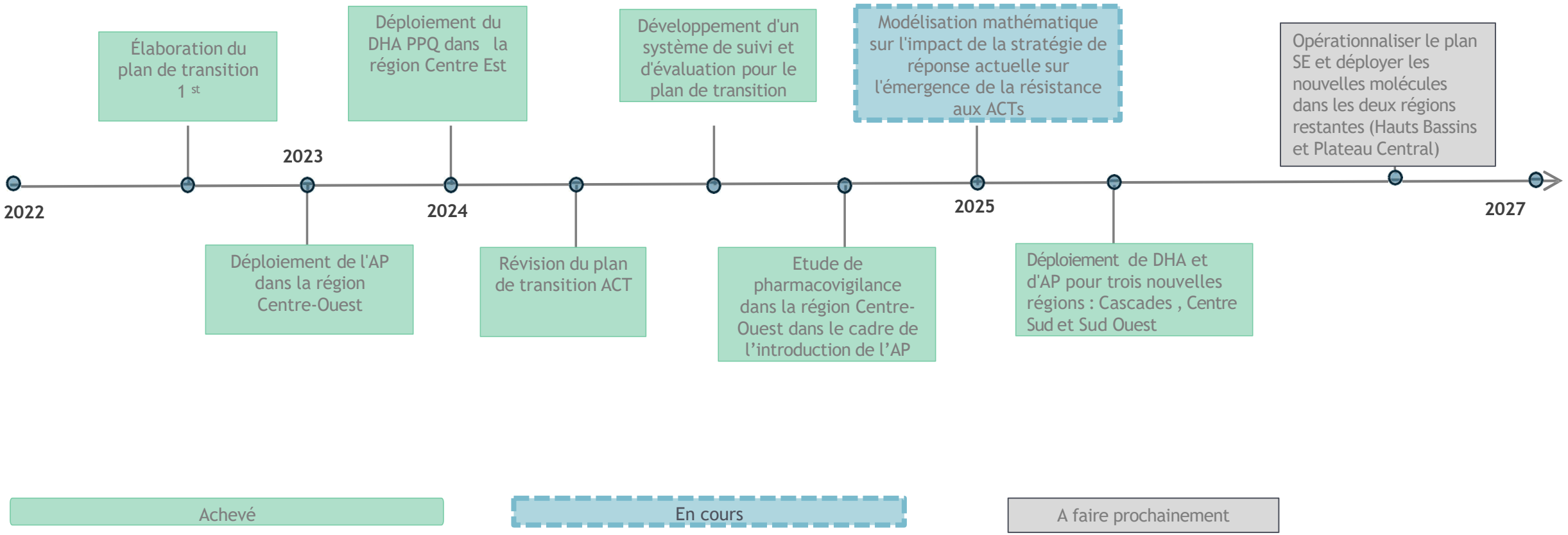

*Sources : Secrétariat Permanent pour l'élimination du Paludisme au Burkina Faso- SP/Palu*

1. Multiple first-line therapies as part of the response to antimalarial drug resistance: an implementation guide.

# Agenda

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# État d'avancement de la mise en du plan de transition



# Agenda

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# Dans l'immédiat, le Burkina devra donner la priorité au financement du plan de transition et approfondir sa compréhension de l'impact potentiel.

**01** Finaliser la modélisation mathématique sur l'impact de la stratégie actuelle sur l'émergence d'une résistance aux ACT, ainsi que l'analyse des coûts des scénarios les plus pertinents. Présenter ensuite les résultats finaux à l'ensemble des acteurs afin de décider de la stratégie à adopter dans le cadre du nouveau PSN

**02** Recherche de ressources financières supplémentaires pour poursuivre la mise en œuvre du plan de transition, en particulier dans les deux régions supplémentaires dont les produits de base n'ont pas encore été acquis.

# MERCI

RBM Partnership
To End Malaria

16 September 2025

# Feedback on supply chain delivery

Rima Shretta, CMWG



STOP-AMDR

Scaling the Optimal Use of Multiple ACTs to Prevent Antimalarial Drug Resistance (STOP-AMDR) project

# Supply chain challenges and solutions

Rima Shretta, PhD
RBM CMWG, Abidjan
Sep 16, 2025

Unitaid

jhpiego
Johns Hopkins University Affiliate

# Supply chain management

*Getting the products to the right place at the right time in the right quantities*






# Procurement and quantification

- Procurement
  - Financing
  - Which newer ACTs to use?
  - Lead times
- Forecasting/quantification
  - Data needed
    - Morbidity
    - Consumption
  - Changes in epidemiology/seasonality
  - Natonal vs subnational

# Supply and delivery

- MFTs:
  - Clear strategy and implementation plan
  - Multiple products
- Data for distribution and supply planning
- Last mile distribution

RBM Partnership
To End Malaria

16 September 2025

# PSI ACTwatch Lite toolkit –

# key results and an overview from Benin, Cameroon and Nigeria on antimalarial drug and diagnostic availability, price and market share

Paul Bounchaud, PSI

# ACTwatch lite

## RBM CMWG

SEPTEMBER 2025

ABIDJAN

PAUL BOUANCHAUD, SENIOR ADVISOR



Transsil fieldworker conducts a product audit with a wholesaler, ACTwatch Lite Nigeria 2024

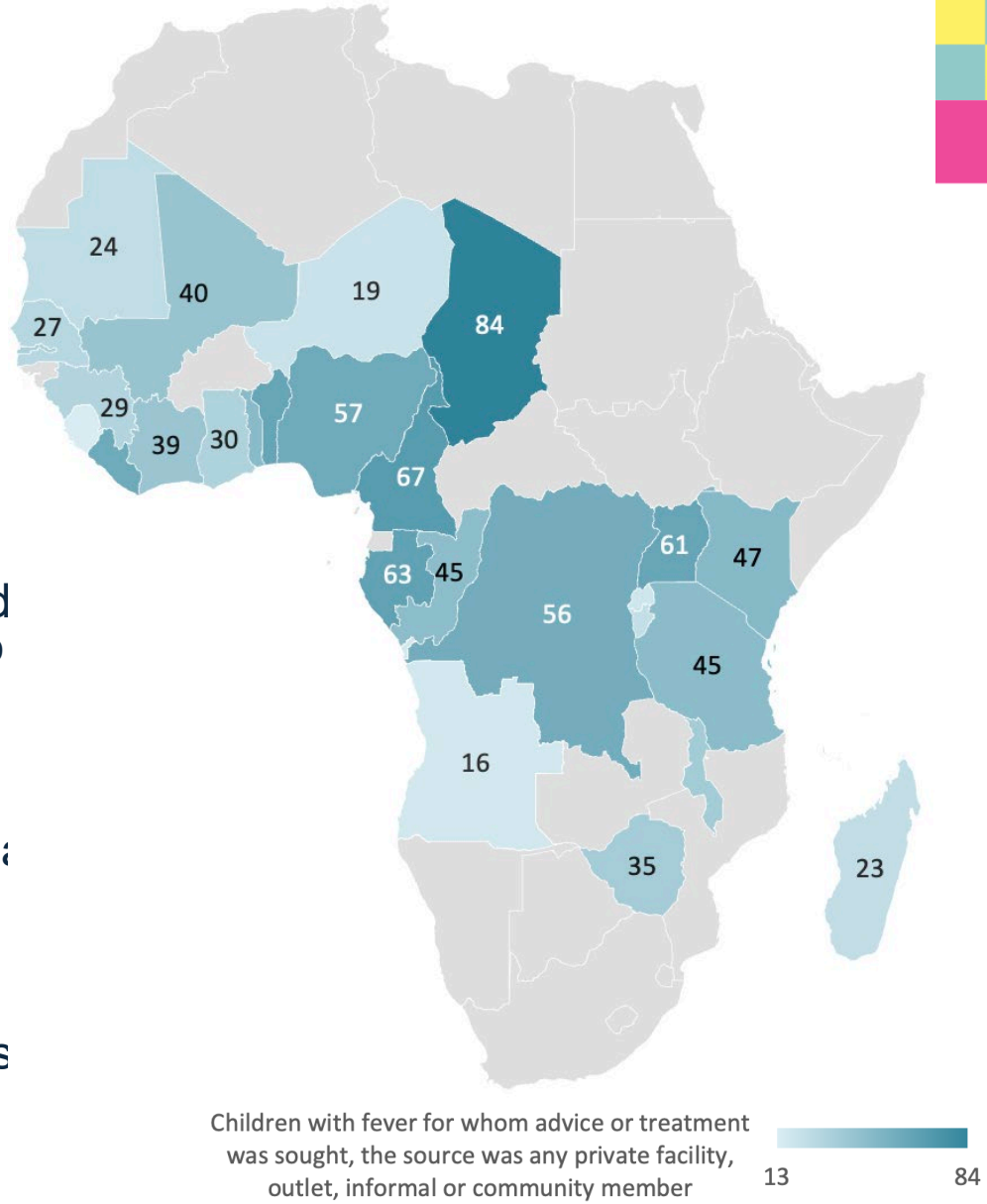


# OUTLINE

- Context
- ACTwatch Lite overview
- Data to action

# PRIVATE SECTOR IS KEY FOR MALARIA CASE MANAGEMENT IN MANY COUNTRIES

- The private sector is the first point of call for many in sub-Saharan Africa – large % of care-seeking for children under 5 with a fever in private facilities, outlets, shops and other non-public sources
- Lack of data about case management in the private sector, and data not feeding into HMIS from the private sector continues to be a major barrier to appropriate private sector engagement and policy making
- Current challenges around funding for global health and malaria programs, often supporting public health systems means likely increased burden on private sector supply chains
- Tracking effects of funding changes on availability and volumes of key malaria commodities is essential to ensure case management adequacy




Source: ICF, 2015 The DHS Program STATcompiler. Funded by USAID. http://www.statcompiler.com. January 29 2025; using most recent DHS/MIS data for each country (year range: 2011 to 2023)

# ACTWATCH LITE USE CASES

| Core applications | Impact |
|---|---|
| **Advocacy** | Use study findings as an advocacy tool to secure necessary resources |
| **Data to action** | Co-create evidence-based interventions with key stakeholders using robust study data |
| **Tracking adherence to policy/guidelines** | Fill evidence gaps around provider adherence to private sector policies |
| **Mapping supply chains** | Identify supply chain challenges and solutions for testing/ treatment |

## Extended use cases

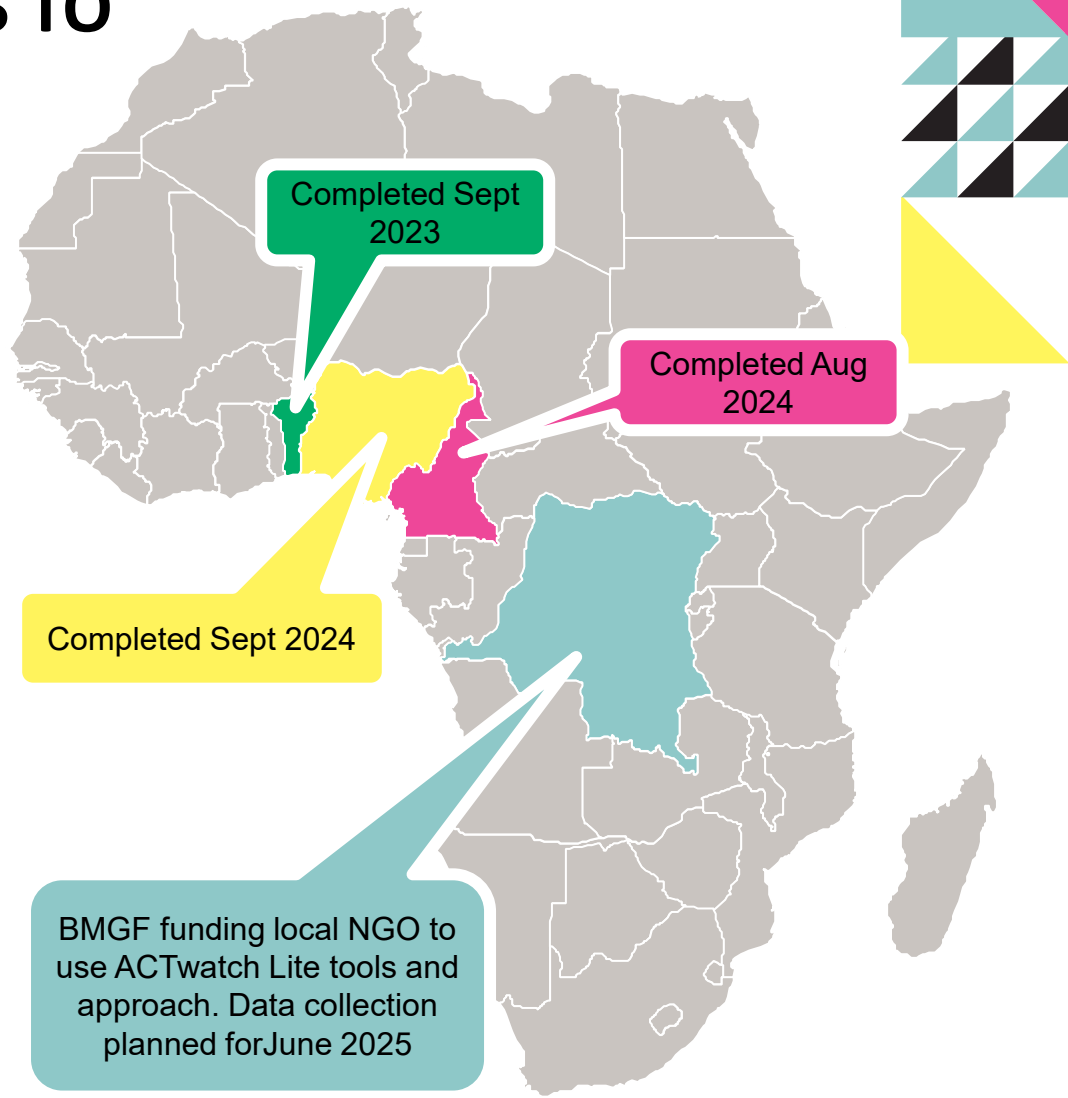
| | |
|---|---|
| **Full market mapping** | Assess both public and private sectors to measure scale and commodity flow |
| **ACTwatch Ultra Lite** | Tailor modules, integrate into existing surveillance systems and adjust follow-up methodology to save costs |
| **Longitudinal tracking** | Repeat implementations to measure changes in key indicators over time |
| **Expanding with new modules** | Introduce modules for drug quality testing; initiate a demand-side module to contextualize supply-side data; consider other health commodities (e.g. antibiotics) |




# ACTWATCH LITE OVERVIEW

# ACTWATCH LITE COMPLETED IN 3 COUNTRIES TO DATE

- Based on the streamlined and updated methods, tools and approaches from ACTwatch
- Malaria treatment, diagnostic and provider data from formal and informal private sector outlets and their supply chains
- Close engagement with stakeholders throughout to ensure ownership and that data is responsive to needs and context
- Data, methodology, and tools rapidly available to NMPs, regulators, supply chain actors & other stakeholders enabling an up-to-date understanding of private sector malaria markets and drivers of market performance to inform strategic and programmatic decision-making for private sector case management
- Toolkit has already had a round of review and inputs from WHO
- Final toolkit will be open access and publicly available



# DESIGN, METHODS, SCOPE

- Representative, cross-sectional probability sample, with national/ sub-national and urban/rural quantitative estimates

- Full private sector market estimates
  - Census of all private sector outlets with the potential to stock antimalarials/testing
  - Audit of all antimalarials and RDTs in stock

- Outlets/wholesalers included
  - Pharmacies, private for-profit health facilities, religious/NGO-run private health facilities, PPMVs (Nigeria), informal outlets (including, e.g. itinerant drug vendors, general retailers)
  - Terminal and intermediate wholesalers and importers

- Data on business characteristics and practices, data reporting/surveillance, stockouts and suppliers

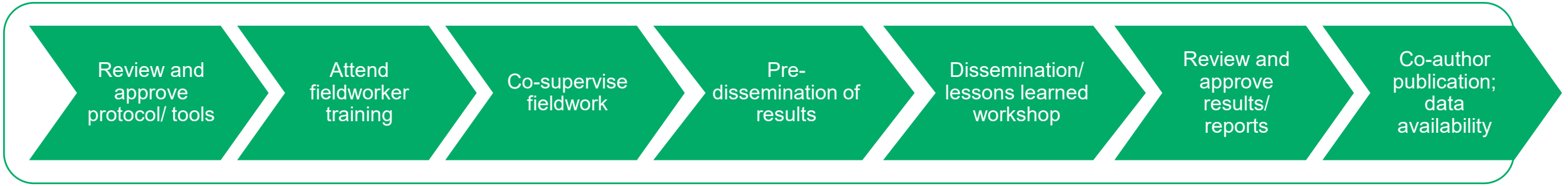
- Rigorous in and out of field quality control and data cleaning/management

# WHAT'S NEW IN ACTWATCH LITE?

- Can be used as a monitoring tool to assess baseline ACT markets and impact over time of case management and policy interventions, such as MFT
- Digital (ODK-based) data collection
  - Database of antimalarial products and RDTs for real-time search and entry by fieldworkers
  - Automated skips, validation and logic checks
  - No data entry; faster data cleaning
  - Lower number of field staff required for quality control

- Private sector focus, combined outlet and supply chain study
- Faster availability of data
- The ACTwatch Lite approach is transferable to other countries, and applicable to contexts with different formal and informal outlets and a variety of wholesaler types

**Stakeholder engagement, from study conception, to fieldwork and analysis/dissemination. Include: NMCPs, pharmacy councils and regulators, supply chain actors, other external parties inc. WHO, PMI, CHAI ...**



# KEY INDICATORS

All levels for antimalarials and RDTs – by type/ brand

- Availability
- Price (retail and markups)
- Market share

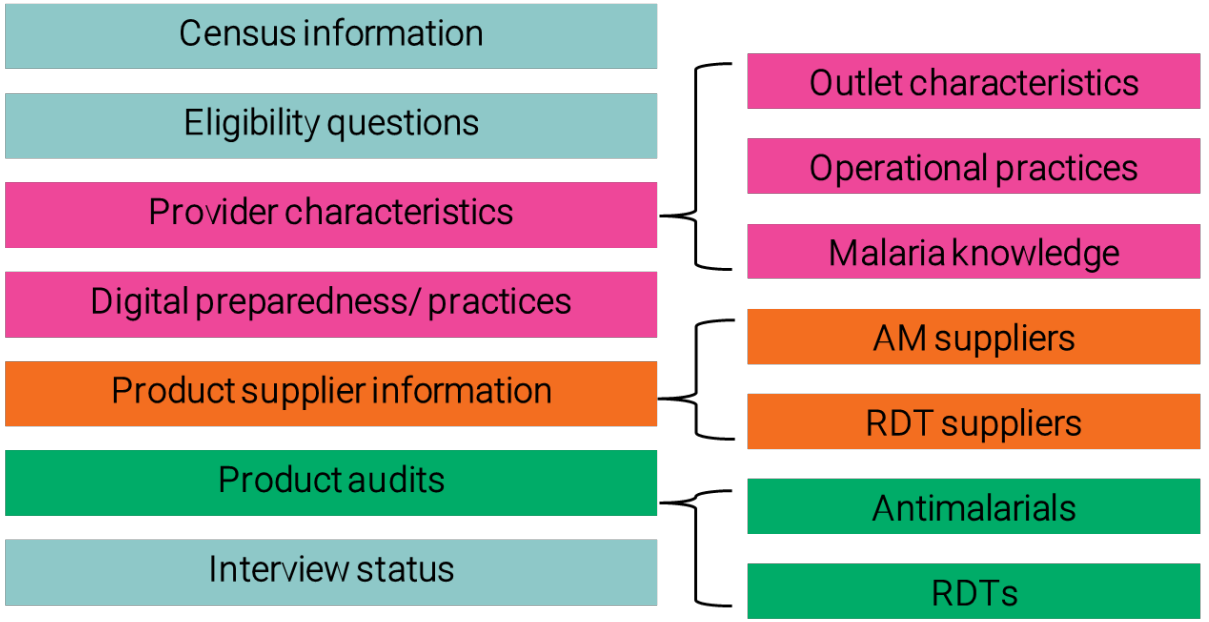
Retail and Wholesale

- Business characteristics and practices
- Malaria case management knowledge
- Provider digital capacity and use
- Common wholesale sources and resupply practices

Importers, Distributors, and local manufactures

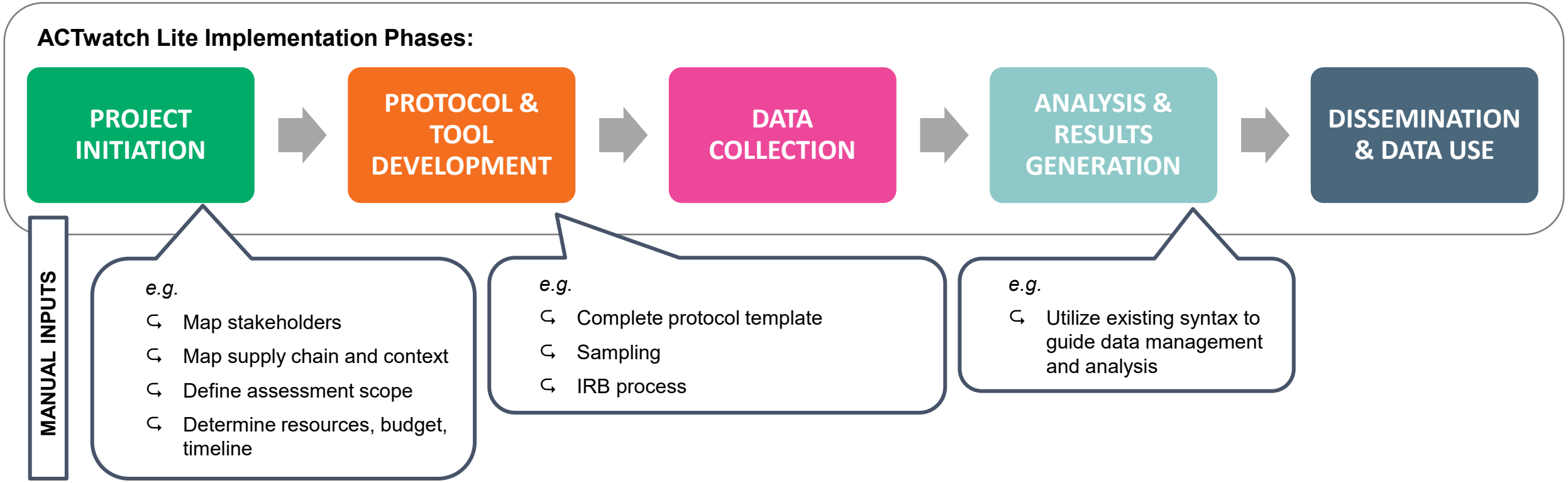
- Distribution footprint in terms of geographic reach and number/range of customers
- Products, pricing, and sales
- Competition
- Regulation

## OUTLET QUESTIONNAIRE FLOW



# ACTWATCH LITE TOOLKIT

- Comprehensive, step-by-step instructions and tools to conduct an ACTwatch Lite study
- Adaptable/ customizable to respond to country needs



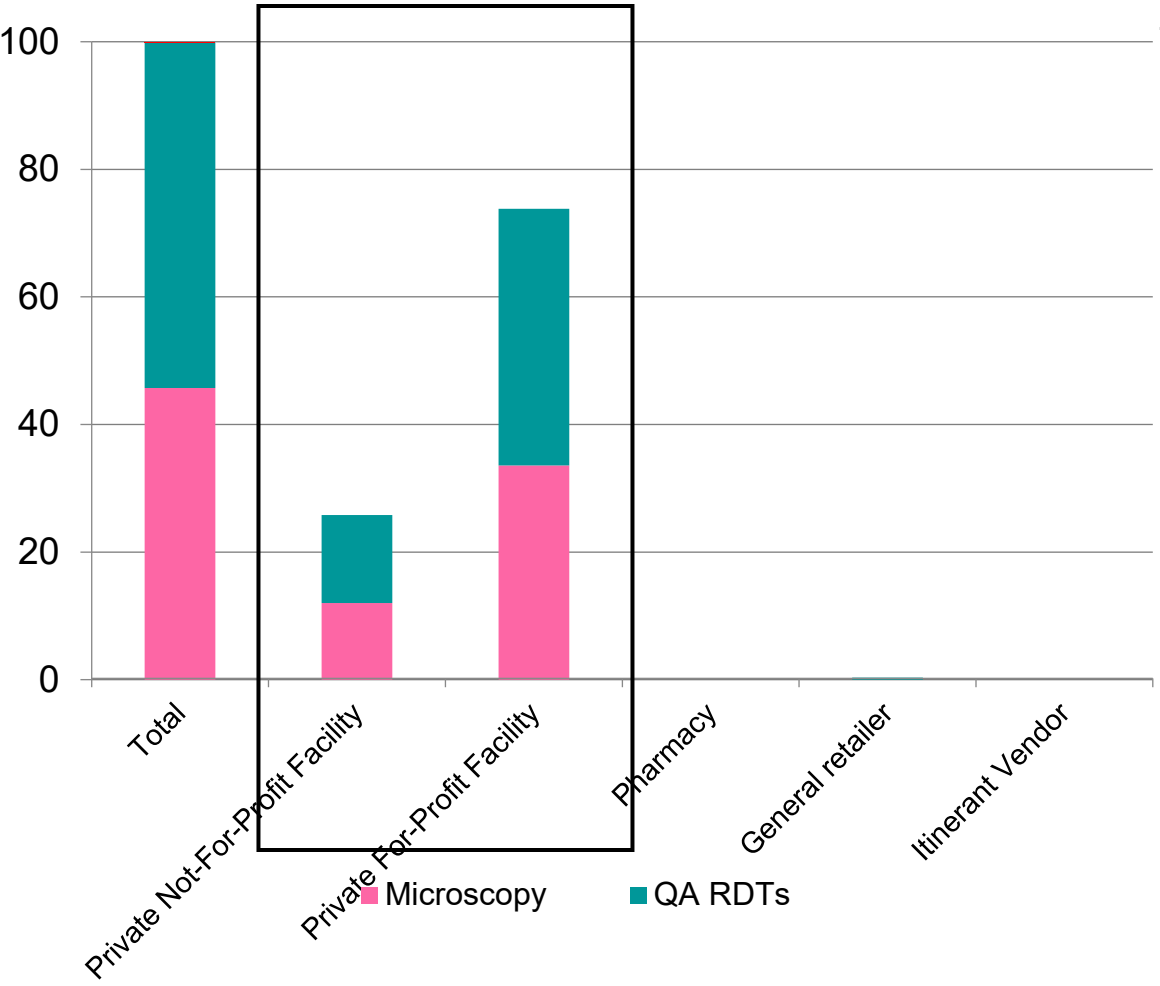


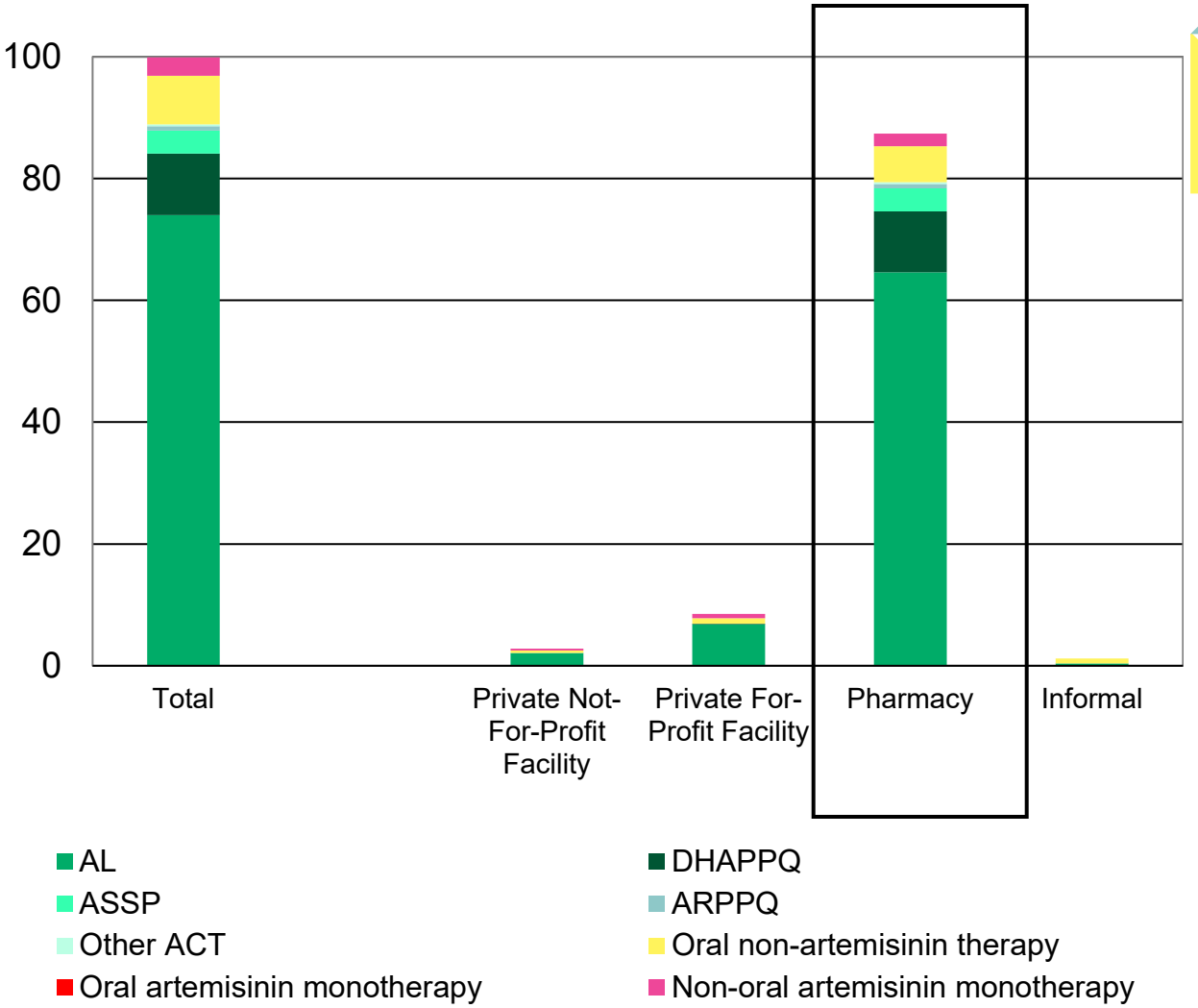
ACTwatch Lite Nigeria fieldworkers collect data at a PPMV
ACTwatch Lite Nigeria, 2024

# DATA TO ACTION

# BENIN

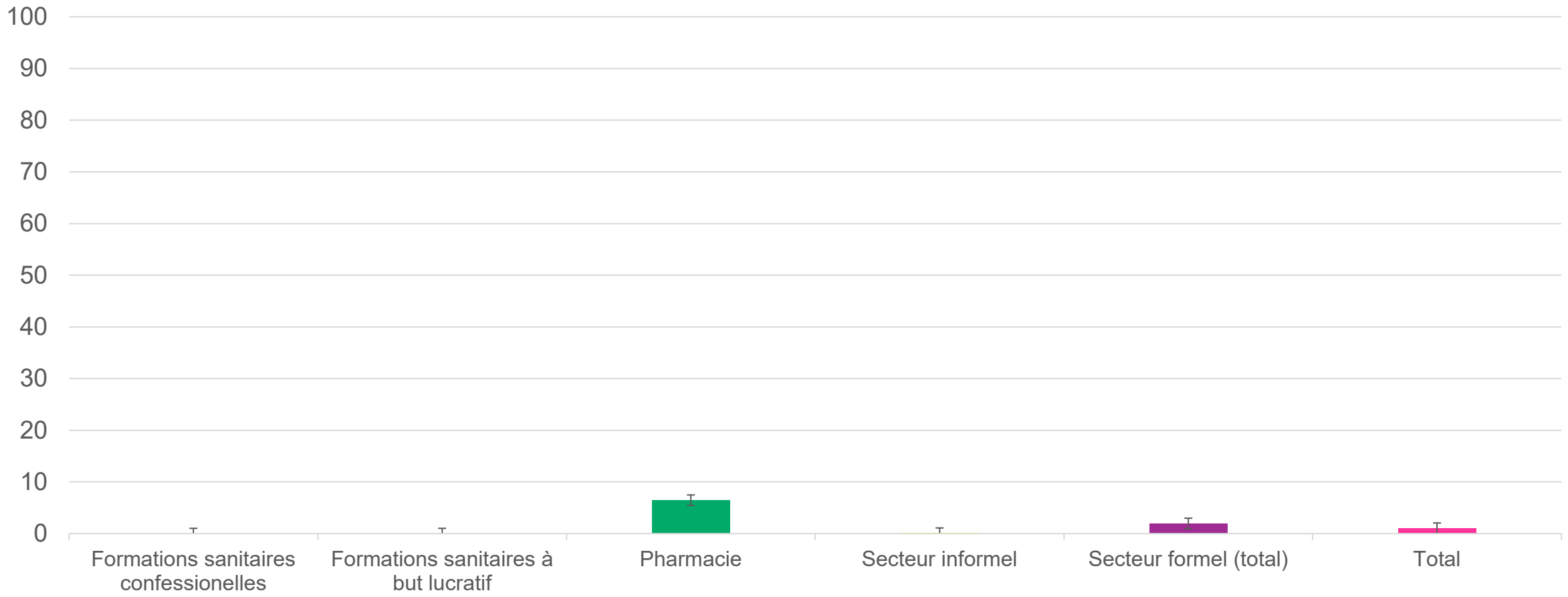
## MARKET SHARE SHOWS OUTLETS WHERE PEOPLE GET TESTED IS NOT WHERE MOST GET TREATED; AL HAS 74% MARKET SHARE



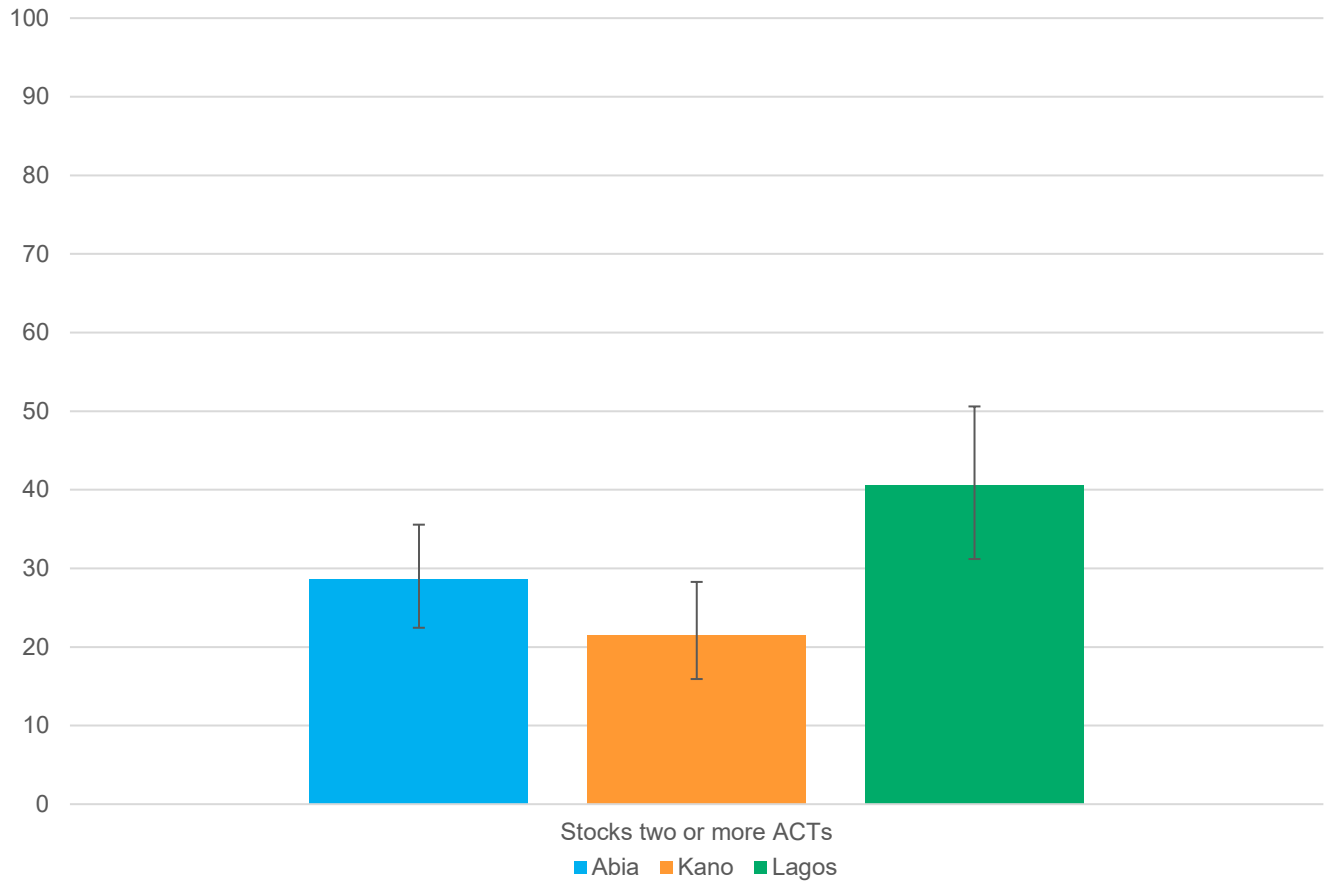
# CAMEROON (LITTORAL & CENTRE)

## 6% OF PHARMACIES HAD ORAL ARTEMISININ MONOTHERAPY IN STOCK ON THE DAY OF THE SURVEY



# NIGERIA (ABIA, KANO, LAGOS)

## MFT READINESS IN NIGERIA'S PRIVATE SECTOR: IN LAGOS 41% OF OUTLETS HAD 2 OR MORE TYPES* OF ACT IN STOCK




*Total antimalarial stocking outlets: Abia=1408 Kano=1543 Lagos=916*

* ACT types: AL, ASAQ, DHAPPQ, ARPPQ, "other"

# SOME KEY THEMES EMERGED ACROSS PILOT COUNTRIES

| Pilot take-aways | Impact, action, or use-case |
|---|---|
| **People seek care in the private sector. In all 3 countries, that means mostly in pharmacies, drug stores and less formal outlets** | • There is a need for policy makers to engage outside of public sector and private hospitals/ facilities to ensure case management interventions (including surveillance/ reporting) have impact at scale |
| **Evidence from all 3 countries of lack of trust in test results; many say they would treat despite negative test results** | • Implications for rational use of antimalarials, resistance and differential diagnoses<br>• More information needed on provider AND patient/client behavior and barriers |
| **ACTs are available widely and AL is predominant, but there is evidence of some private sector capacity for MFT – pharmacies already stock a wide range of ACTs; supply chains exist** | • Demand creation, SBC among providers, and pricing structures may require intervention |
| **Non-ACT market share is probably too high in all three geographies (30% in NGA, 20% CMR, 10% in BEN)** | • For example, in Nigeria, CQ is not approved, but continues to be available. Injectable artemisinins are ++ prevalent in Littoral, Cameroon and Kano, Nigeria.<br>• Additional intervention and regulation is needed to curb availability |

# ACTWATCH LITE TOOLKIT

Toolkit underwent WHO-led technical review July 2025

Full toolkit available upon request from PSI pending final WHO / technical expert sign off

Toolkit and resources to be publicly available through WHO webiste

Final reports and data (Benin, Cameroon & Nigeria) available through www.actwatch.org



# ACTWATCH LITE TOOLKIT



Transsil fieldworkers conduct a product audit in a PPMV
ACTwatch Lite Nigeria, 2024

**Awareness:**

- NMPs, donors, WHO and other partners should see ACTwatch Lite as filling a crucial data gap for private sector malaria case management — not just another survey.

**Uptake:**

- NMPs and implementers should own this approach, integrating it into strategic planning and adapting it for their contexts with minimal external support.

**Openness:**

- Results don’t sit on a shelf. We envision sharing data through HMIS or global platforms to help shape policies.

**Adaptability:**

- ACTwatch Lite is meant to be flexible. We see it working beyond malaria, or even in other supply chain studies, as market needs shift.

# THANK YOU

# QUESTIONS?

www.actwatch.org

**Paul Bouanchaud**
pbouanchaud@psi.org



ACTwatch Lite Cameroon fieldwork team and trainers
ACTwatch Lite Cameroon, 2024

# ANNEXES

# ANNEX 1: DATA TO ACTION, CONTINUED

BENIN

# NOW WHAT? SO WHAT?

| Selected key result | Opportunities for NMPs | Possible Next Steps |
|---|---|---|
| **Evidence of successful policy implementation for regularization of private sector – the informal sector disappeared following 2016 ACTwatch** | Results can be used to advocate for policy changes to improve access to quality assured drugs across the whole market<br>ACTwatch Lite can track policy effects over time, at scale | Understand how policy changes affect access, especially in rural areas |
| **AL has about three quarters of the total market, followed by DHAPPQ ~10%** | ABMed have stopped issuing licenses for new AL brands in Benin following study | Evidence for tracking private sector readiness for MFT<br>Monitor implementation of MFTs in the private sector |
| **Large number of brands and manufacturers, with many non-PQ drugs** | Examine what this means for compliance and regulation in Benin | Monitor complex market with product level data |
| **Pharmacies are distributing most antimalarials but no tests** | Monitor implementation of Test and treat guidelines in the private sector<br>Monitor overtreatment (AMR implications, and missed diagnoses of other conditions) | Product level data allows monitoring this complex market<br>Private sector activities to improve test and treat can help monitor for treatment failure and prevent AMR |

# CAMEROON (LITTORAL & CENTRE)

## NOW WHAT? SO WHAT?

| Selected key result | Opportunities for NMPs | Possible Next Steps |
|---|---|---|
| **This is the first study in Cameroon to look at these indicators** | This ACTwatch Lite study acts as a baseline for future private sector interventions | Explore private sector case management opportunities including enhancing test availability |
| **Study identified oral artemisinin monotherapies in 6% of pharmacies** | The national pharmacy regulator immediately issued a communiqué to all pharmacies to remove these products from sale | Follow-up, spot checks may be required to track implementation |
| **SP and CQ prices lower than ACTs and RDTs** | Financial incentives for consumers to purchase a) less effective treatment, and b) treat without testing | Market shaping activities and SBC should be tested to rationalize case management |
| **ACTs have most market share** | Indicates Cameroon's private sector potential to support multiple first-line treatments | Consider private sector MFT strategies in Cameroon, including SBC, subsidies and supply chain intervention<br>Monitor roll out in private sector |

# NIGERIA (ABIA, KANO, LAGOS)

## NOW WHAT? SO WHAT?

| Selected key result | Opportunities for NMPs | Possible Next Steps |
|---|---|---|
| **Picture emerging of a vibrant private sector** | Multiple opportunities for reinforcing quality of malaria case management in the private sector | |
| **PPMVs are the most common outlet type and account for most volume of antimalarials.** | Private sector case management interventions should focus on PPMVs | Work with regulators and professional bodies to support PPMV quality |
| **Generally, testing and treatment are not happening in the same outlets** | Potential for PPMV testing scale-up. Evidence from Kano suggests it has translated into higher RDT availability | Prototype and test models for testing scale up in private outlets<br><br>Consider role of financial/ non-financial incentives |
| **Low reporting of malaria cases found even in formal private sector. Low levels of supervision reported** | Strengthened private sector surveillance and supervision could support more comprehensive tracking and case management quality assurance | Consider roll out/ scaling of HMIS to private sector outlets; work with professional/regulatory bodies to strengthen supervision |

# ANNEX 2: TOOLKIT OVERVIEW

# 01 MANUAL AND IMPLEMENTATION GUIDE

- Word document including two sections:

A: study & toolkit overview

B: implementation guide

- Implementation guide is color coded by study steps →

| | |
|---|---|
| **1 PROJECT INITIATION** | including stakeholder mapping and initial development of a workplan and budget |
| **2 PROTOCOL AND TOOL DEVELOPMENT** | including refinement of the protocol template, quantitative questionnaire, and qualitative interview guide based on scope and data availability, and submission to IRB for ethical clearance (as required) |
| **3 DATA COLLECTION** | including fieldworker training, pre-tests, set-up, field implementation of the outlet census and qualitative interviews, mop-up, and quality control measures. |
| **4 ANALYSIS AND RESULTS GENERATION** | including data management, cleaning, and analysis using standardized analysis syntax and template results workbooks with shell tables and figures |
| **5 DISSEMINATION AND DATA USE** | including initial presentation of results to stakeholders, and data use/action workshops. |

# 02 INDICATOR TABLE AND QUALITATIVE THEMES

- The Indicator Table forms the core of the toolkit – it provides the structure for protocol, tools, analysis, etc. for the quantitative component of the study
- The qualitative themes provides a qual “indicator table” for qualitative components of the study

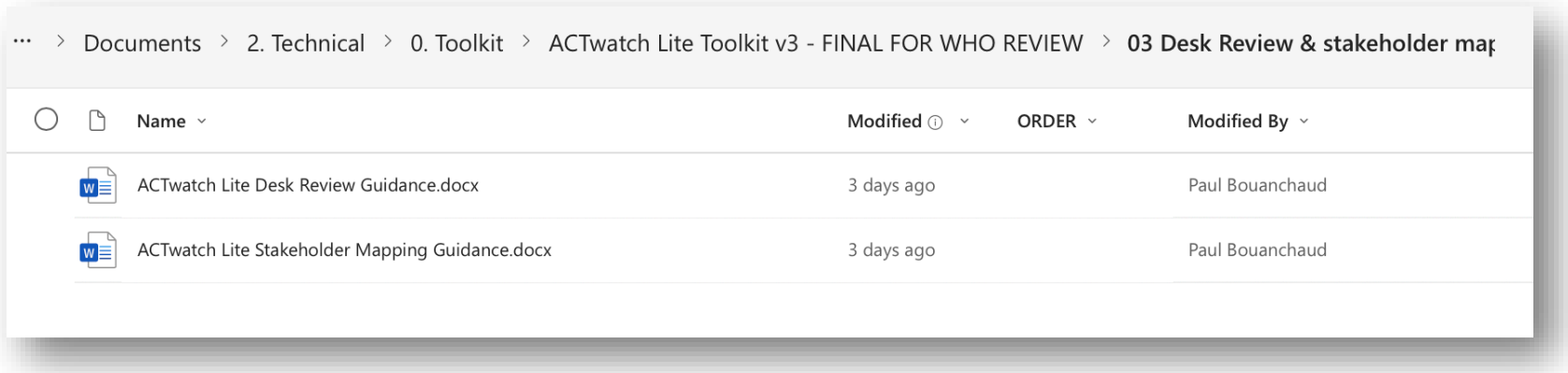
**ACTwatch Lite Quantitative Indicator Table**

| No. | Indicator group | Indicator | Value reported *(note all prices are suggested to be reported in **in local currency and USD**)* | Numerator | Denominato |
|---|---|---|---|---|---|
| ore indicators | | | | | |
| 1.1 | **Market Composition among antimalarial-stocking outlets** | The distribution (proportion) of outlets of a given type among outlets with at least one antimalarial in stock on the day of the survey | % & CI | Number of a given type of outlet with any antimalarial in stock at the time of the survey visit | Number of c |
| 1.2 | **Market Composition among outlets with malaria blooc testing** | The distribution (proportion) of outlets of a given type among outlets with malaria blood testing (microscopy or RDT) available on the day of the survey. | % & CI | Number of outlets of a given type with malaria blood testing (microscopy or RDT) available at the time of the survey visit. | Total numbe available at t |
| 2.1 | **Availability of antimalarial types in all screened outlets** | Proportion of all outlets enumerated that had an antimalarial in stock at the time of the survey visit, among all outlets surveyed | % & CI | Number of outlets with any antimalarial in stock on the day of the survey visit, as confirmed by presence of at least one antimalarial. | Number of c |
| 2.2 | **Availability of antimalarial types in all antimalarial-stocking outlets** | Proportion of antimalarial-stocking outlets with antimalarial medicine in stock on the day of the visit, among all outlets surveyed with one or more antimalarials in stock | % & CI | Number of outlets with a given type of antimalarial in stock on the day of the visit | Number of c |
| 2.3 | **Availability of malaria blood testing in all screened outlets** | Proportion of all outlets enumerated that had any malaria blood testing available at the time of the survey visit, among all outlets surveyed | % & CI | Number of outlets with malaria blood testing available (any, microscopy, RDT, QA RDT). | Number of c |

All excel files in toolkit have a README tab – start here. Each README provides information on the tool content and aims, and instructions for use

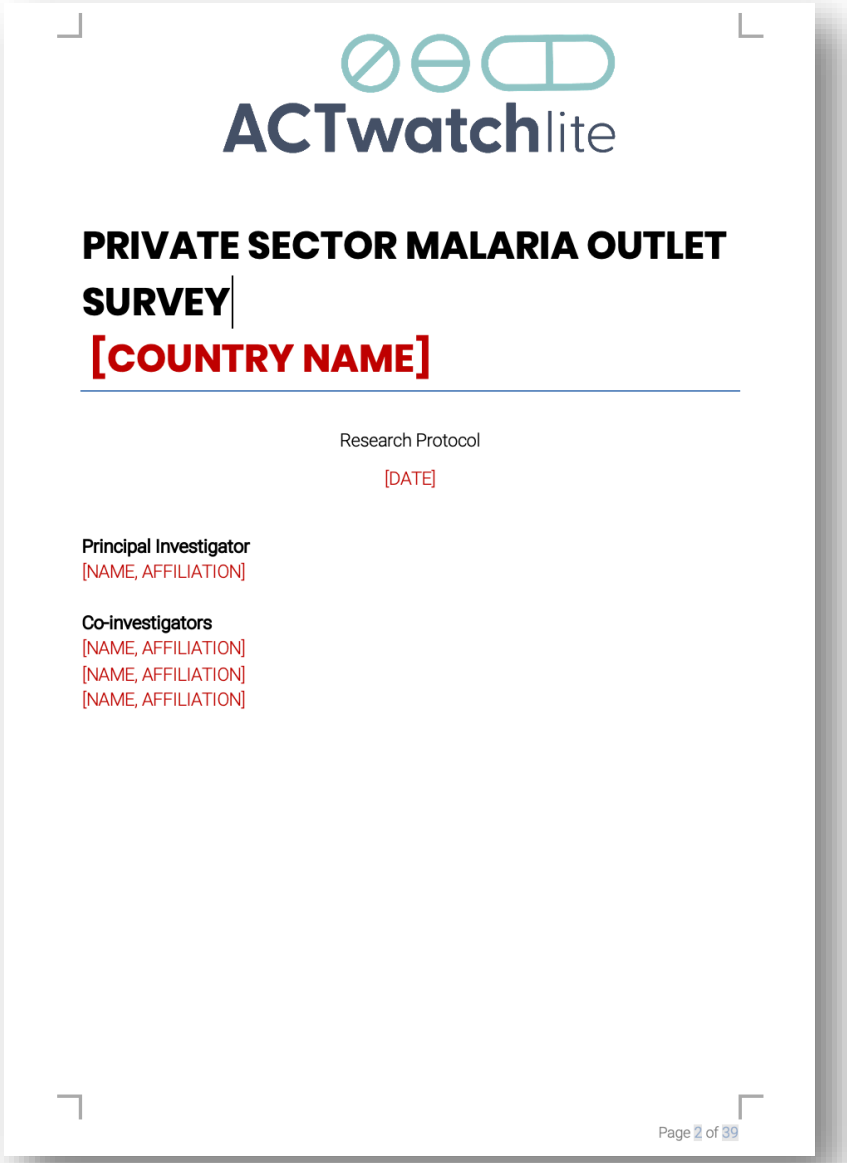
# 03 DESK REVIEW & STAKEHOLDER MAPPING

- Two separate tools
- Desk review includes gathering documents that feed into later parts of the toolkit (i.e. sampling, data collection tools, etc.)
- Stakeholder mapping is essential to ensure early engagement, results ownership and policy influence



# 04 PROTOCOL TEMPLATE AND REFERENCES

- Template of an ACTwatch Lite study protocol, with areas for context-specific input
- Includes information sheets and consent forms
- Folder of pilot study protocols for reference



ACTwatchlite

**PRIVATE SECTOR MALARIA OUTLET SURVEY**

**[COUNTRY NAME]**

Research Protocol

[DATE]

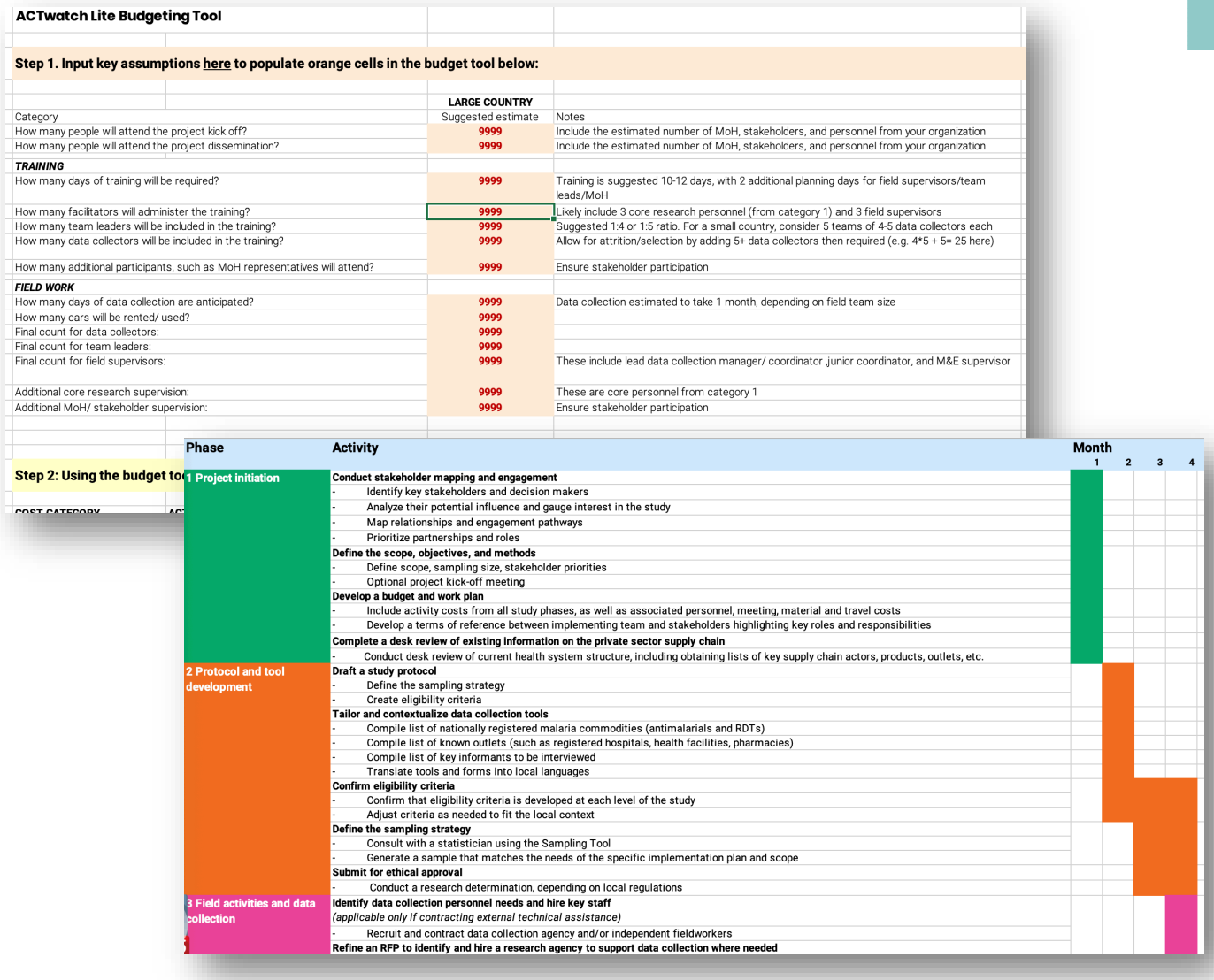
**Principal Investigator**
[NAME, AFFILIATION]

**Co-investigators**
[NAME, AFFILIATION]
[NAME, AFFILIATION]
[NAME, AFFILIATION]

Page 2 of 39

# 05 BUDGET AND WORK-PLANNING TOOLS

- Budget tools and notes
- Includes two model budgets (based on pilot studies), and a budget estimation tool
- Workplan template, with key tasks and indicative timeline



**ACTwatch Lite Budgeting Tool**

**Step 1. Input key assumptions here to populate orange cells in the budget tool below:**

| | LARGE COUNTRY | |
|---|---|---|
| Category | Suggested estimate | Notes |
| How many people will attend the project kick off? | 9999 | Include the estimated number of MoH, stakeholders, and personnel from your organization |
| How many people will attend the project dissemination? | 9999 | Include the estimated number of MoH, stakeholders, and personnel from your organization |
| ***TRAINING*** | | |
| How many days of training will be required? | 9999 | Training is suggested 10-12 days, with 2 additional planning days for field supervisors/team leads/MoH |
| How many facilitators will administer the training? | 9999 | Likely include 3 core research personnel (from category 1) and 3 field supervisors |
| How many team leaders will be included in the training? | 9999 | Suggested 1:4 or 1:5 ratio. For a small country, consider 5 teams of 4-5 data collectors each |
| How many data collectors will be included in the training? | 9999 | Allow for attrition/selection by adding 5+ data collectors then required (e.g. 4*5 + 5= 25 here) |
| How many additional participants, such as MoH representatives will attend? | 9999 | Ensure stakeholder participation |
| ***FIELD WORK*** | | |
| How many days of data collection are anticipated? | 9999 | Data collection estimated to take 1 month, depending on field team size |
| How many cars will be rented/ used? | 9999 | |
| Final count for data collectors: | 9999 | |
| Final count for team leaders: | 9999 | |
| Final count for field supervisors: | 9999 | These include lead data collection manager/ coordinator ,junior coordinator, and M&E supervisor |
| Additional core research supervision: | 9999 | These are core personnel from category 1 |
| Additional MoH/ stakeholder supervision: | 9999 | Ensure stakeholder participation |

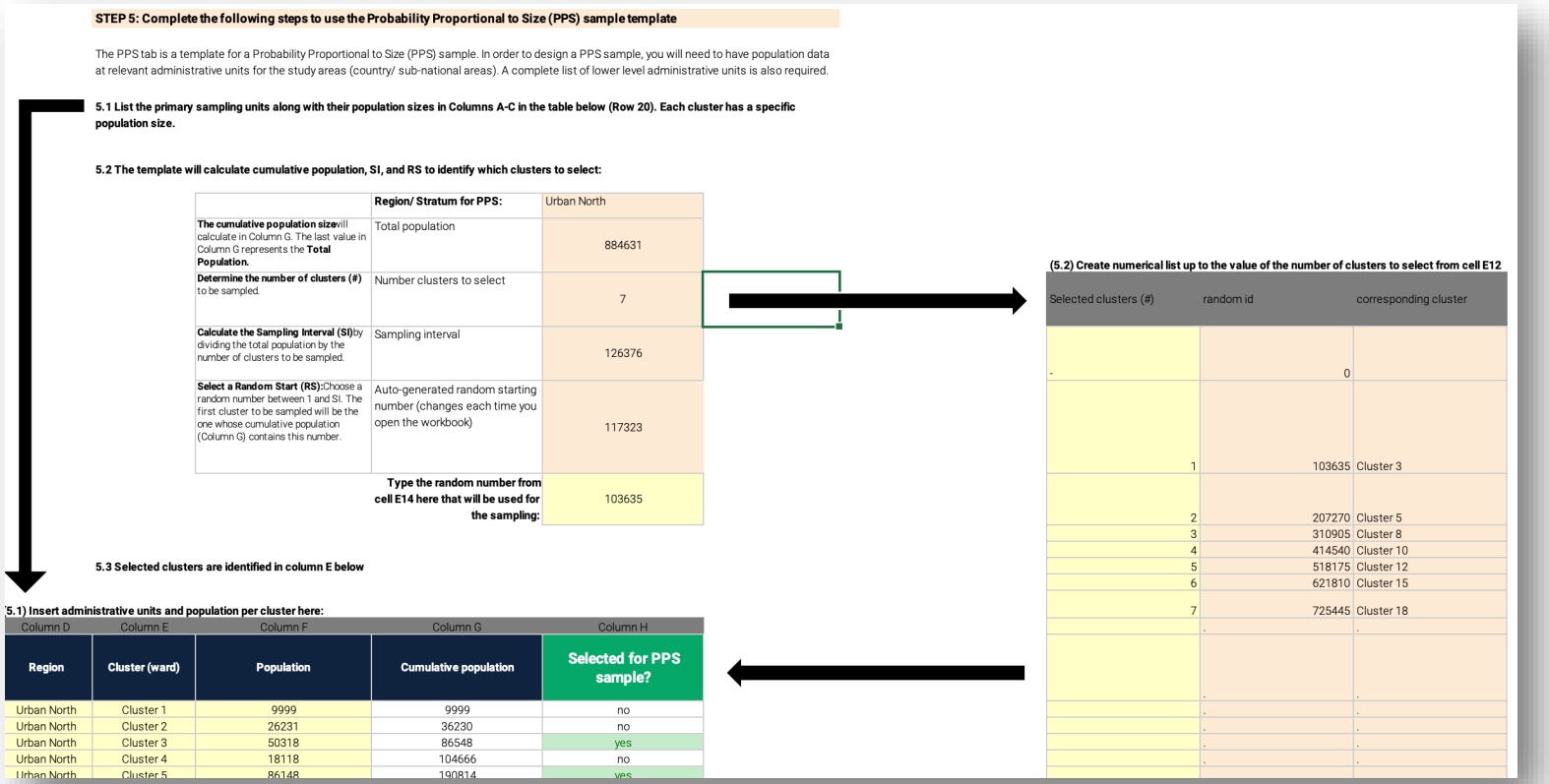
**Step 2: Using the budget to**

COST CATEGORY

| Phase | Activity | Month 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| 1 Project initiation | **Conduct stakeholder mapping and engagement** | | | | |
| | - Identify key stakeholders and decision makers | | | | |
| | - Analyze their potential influence and gauge interest in the study | | | | |
| | - Map relationships and engagement pathways | | | | |
| | - Prioritize partnerships and roles | | | | |
| | **Define the scope, objectives, and methods** | | | | |
| | - Define scope, sampling size, stakeholder priorities | | | | |
| | - Optional project kick-off meeting | | | | |
| | **Develop a budget and work plan** | | | | |
| | - Include activity costs from all study phases, as well as associated personnel, meeting, material and travel costs | | | | |
| | - Develop a terms of reference between implementing team and stakeholders highlighting key roles and responsibilities | | | | |
| | **Complete a desk review of existing information on the private sector supply chain** | | | | |
| | - Conduct desk review of current health system structure, including obtaining lists of key supply chain actors, products, outlets, etc. | | | | |
| 2 Protocol and tool development | **Draft a study protocol** | | | | |
| | - Define the sampling strategy | | | | |
| | - Create eligibility criteria | | | | |
| | **Tailor and contextualize data collection tools** | | | | |
| | - Compile list of nationally registered malaria commodities (antimalarials and RDTs) | | | | |
| | - Compile list of known outlets (such as registered hospitals, health facilities, pharmacies) | | | | |
| | - Compile list of key informants to be interviewed | | | | |
| | - Translate tools and forms into local languages | | | | |
| | **Confirm eligibility criteria** | | | | |
| | - Confirm that eligibility criteria is developed at each level of the study | | | | |
| | - Adjust criteria as needed to fit the local context | | | | |
| | **Define the sampling strategy** | | | | |
| | - Consult with a statistician using the Sampling Tool | | | | |
| | - Generate a sample that matches the needs of the specific implementation plan and scope | | | | |
| | **Submit for ethical approval** | | | | |
| | - Conduct a research determination, depending on local regulations | | | | |
| 3 Field activities and data collection | **Identify data collection personnel needs and hire key staff** *(applicable only if contracting external technical assistance)* | | | | |
| | - Recruit and contract data collection agency and/or independent fieldworkers | | | | |
| | **Refine an RFP to identify and hire a research agency to support data collection where needed** | | | | |

# 06 SAMPLING TOOL

- Contains an excel tool and notes
- Supports the calculation of sample size (based on precision estimate) for an ACTwatch Lite study, and implements PPS selection of PSUs (from a user-provided list)



**STEP 5: Complete the following steps to use the Probability Proportional to Size (PPS) sample template**

The PPS tab is a template for a Probability Proportional to Size (PPS) sample. In order to design a PPS sample, you will need to have population data at relevant administrative units for the study areas (country/ sub-national areas). A complete list of lower level administrative units is also required.

**5.1 List the primary sampling units along with their population sizes in Columns A-C in the table below (Row 20). Each cluster has a specific population size.**

**5.2 The template will calculate cumulative population, SI, and RS to identify which clusters to select:**

| | | |
|---|---|---|
| | **Region/ Stratum for PPS:** | Urban North |
| **The cumulative population size** will calculate in Column G. The last value in Column G represents the **Total Population.** | Total population | 884631 |
| **Determine the number of clusters (#)** to be sampled. | Number clusters to select | 7 |
| **Calculate the Sampling Interval (SI)** by dividing the total population by the number of clusters to be sampled. | Sampling interval | 126376 |
| **Select a Random Start (RS):** Choose a random number between 1 and SI. The first cluster to be sampled will be the one whose cumulative population (Column G) contains this number. | Auto-generated random starting number (changes each time you open the workbook) | 117323 |
| | **Type the random number from cell E14 here that will be used for the sampling:** | 103635 |

**5.3 Selected clusters are identified in column E below**

**(5.1) Insert administrative units and population per cluster here:**

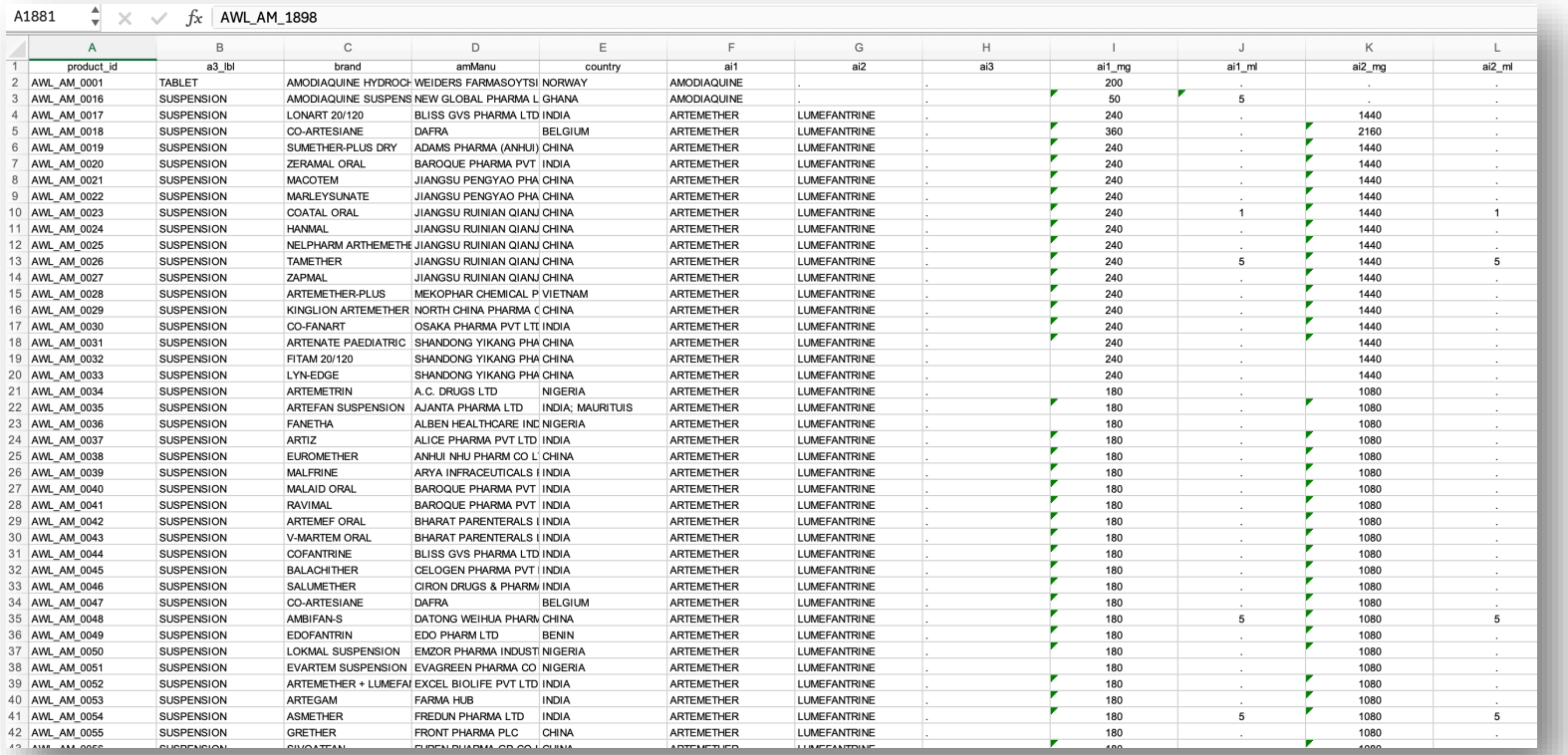
| Column D | Column E | Column F | Column G | Column H |
|---|---|---|---|---|
| **Region** | **Cluster (ward)** | **Population** | **Cumulative population** | **Selected for PPS sample?** |
| Urban North | Cluster 1 | 9999 | 9999 | no |
| Urban North | Cluster 2 | 26231 | 36230 | no |
| Urban North | Cluster 3 | 50318 | 86548 | yes |
| Urban North | Cluster 4 | 18118 | 104666 | no |
| Urban North | Cluster 5 | 86148 | 190814 | yes |

**(5.2) Create numerical list up to the value of the number of clusters to select from cell E12**

| Selected clusters (#) | random id | corresponding cluster |
|---|---|---|
| - | 0 | |
| 1 | 103635 | Cluster 3 |
| 2 | 207270 | Cluster 5 |
| 3 | 310905 | Cluster 8 |
| 4 | 414540 | Cluster 10 |
| 5 | 518175 | Cluster 12 |
| 6 | 621810 | Cluster 15 |
| 7 | 725445 | Cluster 18 |
| . | . | . |
| . | . | . |
| . | . | . |
| . | . | . |
| . | . | . |
| . | . | . |

# 07 PRODUCT MASTER LISTS

- ACTwatch Lite has generated a database of antimalarial and RDT products from WHO/GF PQ lists, and the three pilot studies
- 1880 antimalarials; 68 RDTs to date. The list can be updated as new products are identified
- The database is searched during data collection to populate the product audit by fieldworkers

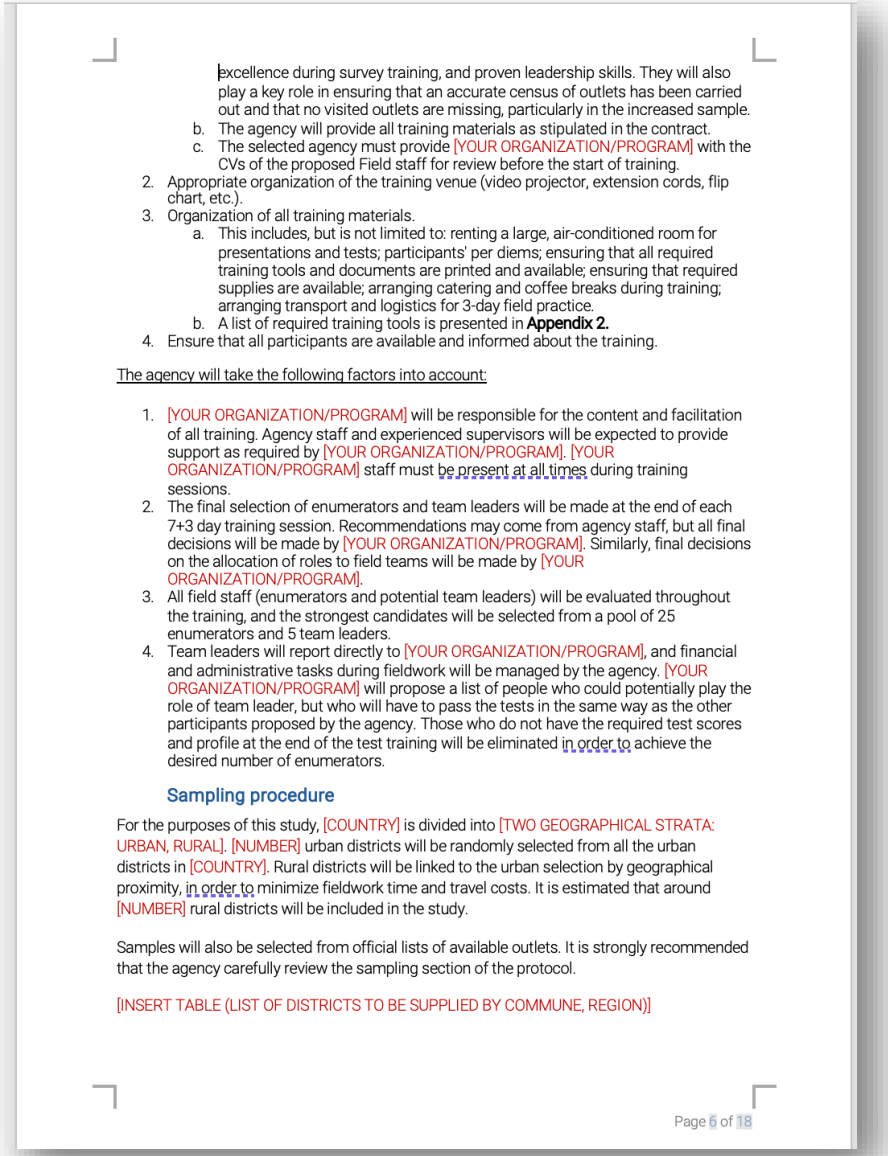


A1881 | AWL_AM_1898

| | A | B | C | D | E | F | G | H | I | J | K | L |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | product_id | a3_lbl | brand | amManu | country | ai1 | ai2 | ai3 | ai1_mg | ai1_ml | ai2_mg | ai2_ml |
| 2 | AWL_AM_0001 | TABLET | AMODIAQUINE HYDROCH | WEIDERS FARMASOYTSI | NORWAY | AMODIAQUINE | . | . | 200 | . | . | . |
| 3 | AWL_AM_0016 | SUSPENSION | AMODIAQUINE SUSPENS | NEW GLOBAL PHARMA L | GHANA | AMODIAQUINE | . | . | 50 | 5 | . | . |
| 4 | AWL_AM_0017 | SUSPENSION | LONART 20/120 | BLISS GVS PHARMA LTD | INDIA | ARTEMETHER | LUMEFANTRINE | . | 240 | . | 1440 | . |
| 5 | AWL_AM_0018 | SUSPENSION | CO-ARTESIANE | DAFRA | BELGIUM | ARTEMETHER | LUMEFANTRINE | . | 360 | . | 2160 | . |
| 6 | AWL_AM_0019 | SUSPENSION | SUMETHER-PLUS DRY | ADAMS PHARMA (ANHUI) | CHINA | ARTEMETHER | LUMEFANTRINE | . | 240 | . | 1440 | . |
| 7 | AWL_AM_0020 | SUSPENSION | ZERAMAL ORAL | BAROQUE PHARMA PVT | INDIA | ARTEMETHER | LUMEFANTRINE | . | 240 | . | 1440 | . |
| 8 | AWL_AM_0021 | SUSPENSION | MACOTEM | JIANGSU PENGYAO PHA | CHINA | ARTEMETHER | LUMEFANTRINE | . | 240 | . | 1440 | . |
| 9 | AWL_AM_0022 | SUSPENSION | MARLEYSUNATE | JIANGSU PENGYAO PHA | CHINA | ARTEMETHER | LUMEFANTRINE | . | 240 | . | 1440 | . |
| 10 | AWL_AM_0023 | SUSPENSION | COATAL ORAL | JIANGSU RUINIAN QIANJ | CHINA | ARTEMETHER | LUMEFANTRINE | . | 240 | 1 | 1440 | 1 |
| 11 | AWL_AM_0024 | SUSPENSION | HANMAL | JIANGSU RUINIAN QIANJ | CHINA | ARTEMETHER | LUMEFANTRINE | . | 240 | . | 1440 | . |
| 12 | AWL_AM_0025 | SUSPENSION | NELPHARM ARTHEMETHE | JIANGSU RUINIAN QIANJ | CHINA | ARTEMETHER | LUMEFANTRINE | . | 240 | . | 1440 | . |
| 13 | AWL_AM_0026 | SUSPENSION | TAMETHER | JIANGSU RUINIAN QIANJ | CHINA | ARTEMETHER | LUMEFANTRINE | . | 240 | 5 | 1440 | 5 |
| 14 | AWL_AM_0027 | SUSPENSION | ZAPMAL | JIANGSU RUINIAN QIANJ | CHINA | ARTEMETHER | LUMEFANTRINE | . | 240 | . | 1440 | . |
| 15 | AWL_AM_0028 | SUSPENSION | ARTEMETHER-PLUS | MEKOPHAR CHEMICAL P | VIETNAM | ARTEMETHER | LUMEFANTRINE | . | 240 | . | 1440 | . |
| 16 | AWL_AM_0029 | SUSPENSION | KINGLION ARTEMETHER | NORTH CHINA PHARMA C | CHINA | ARTEMETHER | LUMEFANTRINE | . | 240 | . | 1440 | . |
| 17 | AWL_AM_0030 | SUSPENSION | CO-FANART | OSAKA PHARMA PVT LTI | INDIA | ARTEMETHER | LUMEFANTRINE | . | 240 | . | 1440 | . |
| 18 | AWL_AM_0031 | SUSPENSION | ARTENATE PAEDIATRIC | SHANDONG YIKANG PHA | CHINA | ARTEMETHER | LUMEFANTRINE | . | 240 | . | 1440 | . |
| 19 | AWL_AM_0032 | SUSPENSION | FITAM 20/120 | SHANDONG YIKANG PHA | CHINA | ARTEMETHER | LUMEFANTRINE | . | 240 | . | 1440 | . |
| 20 | AWL_AM_0033 | SUSPENSION | LYN-EDGE | SHANDONG YIKANG PHA | CHINA | ARTEMETHER | LUMEFANTRINE | . | 240 | . | 1440 | . |
| 21 | AWL_AM_0034 | SUSPENSION | ARTEMETRIN | A.C. DRUGS LTD | NIGERIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 22 | AWL_AM_0035 | SUSPENSION | ARTEFAN SUSPENSION | AJANTA PHARMA LTD | INDIA; MAURITUIS | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 23 | AWL_AM_0036 | SUSPENSION | FANETHA | ALBEN HEALTHCARE IND | NIGERIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 24 | AWL_AM_0037 | SUSPENSION | ARTIZ | ALICE PHARMA PVT LTD | INDIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 25 | AWL_AM_0038 | SUSPENSION | EUROMETHER | ANHUI NHU PHARM CO L | CHINA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 26 | AWL_AM_0039 | SUSPENSION | MALFRINE | ARYA INFRACEUTICALS I | INDIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 27 | AWL_AM_0040 | SUSPENSION | MALAID ORAL | BAROQUE PHARMA PVT | INDIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 28 | AWL_AM_0041 | SUSPENSION | RAVIMAL | BAROQUE PHARMA PVT | INDIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 29 | AWL_AM_0042 | SUSPENSION | ARTEMEF ORAL | BHARAT PARENTERALS I | INDIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 30 | AWL_AM_0043 | SUSPENSION | V-MARTEM ORAL | BHARAT PARENTERALS I | INDIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 31 | AWL_AM_0044 | SUSPENSION | COFANTRINE | BLISS GVS PHARMA LTD | INDIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 32 | AWL_AM_0045 | SUSPENSION | BALACHITHER | CELOGEN PHARMA PVT | INDIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 33 | AWL_AM_0046 | SUSPENSION | SALUMETHER | CIRON DRUGS & PHARM | INDIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 34 | AWL_AM_0047 | SUSPENSION | CO-ARTESIANE | DAFRA | BELGIUM | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 35 | AWL_AM_0048 | SUSPENSION | AMBIFAN-S | DATONG WEIHUA PHARM | CHINA | ARTEMETHER | LUMEFANTRINE | . | 180 | 5 | 1080 | 5 |
| 36 | AWL_AM_0049 | SUSPENSION | EDOFANTRIN | EDO PHARM LTD | BENIN | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 37 | AWL_AM_0050 | SUSPENSION | LOKMAL SUSPENSION | EMZOR PHARMA INDUSTI | NIGERIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 38 | AWL_AM_0051 | SUSPENSION | EVARTEM SUSPENSION | EVAGREEN PHARMA CO | NIGERIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 39 | AWL_AM_0052 | SUSPENSION | ARTEMETHER + LUMEFAI | EXCEL BIOLIFE PVT LTD | INDIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 40 | AWL_AM_0053 | SUSPENSION | ARTEGAM | FARMA HUB | INDIA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |
| 41 | AWL_AM_0054 | SUSPENSION | ASMETHER | FREDUN PHARMA LTD | INDIA | ARTEMETHER | LUMEFANTRINE | . | 180 | 5 | 1080 | 5 |
| 42 | AWL_AM_0055 | SUSPENSION | GRETHER | FRONT PHARMA PLC | CHINA | ARTEMETHER | LUMEFANTRINE | . | 180 | . | 1080 | . |

# 08 TERMS OF REFERENCE TEMPLATES

- ToR templates for research firms and consultants
- Contains core information and highlights areas for input based on context/ study design



excellence during survey training, and proven leadership skills. They will also play a key role in ensuring that an accurate census of outlets has been carried out and that no visited outlets are missing, particularly in the increased sample.
   b. The agency will provide all training materials as stipulated in the contract.
   c. The selected agency must provide [YOUR ORGANIZATION/PROGRAM] with the CVs of the proposed Field staff for review before the start of training.
2. Appropriate organization of the training venue (video projector, extension cords, flip chart, etc.).
3. Organization of all training materials.
   a. This includes, but is not limited to: renting a large, air-conditioned room for presentations and tests; participants' per diems; ensuring that all required training tools and documents are printed and available; ensuring that required supplies are available; arranging catering and coffee breaks during training; arranging transport and logistics for 3-day field practice.
   b. A list of required training tools is presented in **Appendix 2.**
4. Ensure that all participants are available and informed about the training.

The agency will take the following factors into account:

1. [YOUR ORGANIZATION/PROGRAM] will be responsible for the content and facilitation of all training. Agency staff and experienced supervisors will be expected to provide support as required by [YOUR ORGANIZATION/PROGRAM]. [YOUR ORGANIZATION/PROGRAM] staff must be present at all times during training sessions.
2. The final selection of enumerators and team leaders will be made at the end of each 7+3 day training session. Recommendations may come from agency staff, but all final decisions will be made by [YOUR ORGANIZATION/PROGRAM]. Similarly, final decisions on the allocation of roles to field teams will be made by [YOUR ORGANIZATION/PROGRAM].
3. All field staff (enumerators and potential team leaders) will be evaluated throughout the training, and the strongest candidates will be selected from a pool of 25 enumerators and 5 team leaders.
4. Team leaders will report directly to [YOUR ORGANIZATION/PROGRAM], and financial and administrative tasks during fieldwork will be managed by the agency. [YOUR ORGANIZATION/PROGRAM] will propose a list of people who could potentially play the role of team leader, but who will have to pass the tests in the same way as the other participants proposed by the agency. Those who do not have the required test scores and profile at the end of the test training will be eliminated in order to achieve the desired number of enumerators.

### Sampling procedure

For the purposes of this study, [COUNTRY] is divided into [TWO GEOGRAPHICAL STRATA: URBAN, RURAL]. [NUMBER] urban districts will be randomly selected from all the urban districts in [COUNTRY]. Rural districts will be linked to the urban selection by geographical proximity, in order to minimize fieldwork time and travel costs. It is estimated that around [NUMBER] rural districts will be included in the study.

Samples will also be selected from official lists of available outlets. It is strongly recommended that the agency carefully review the sampling section of the protocol.

[INSERT TABLE (LIST OF DISTRICTS TO BE SUPPLIED BY COMMUNE, REGION)]

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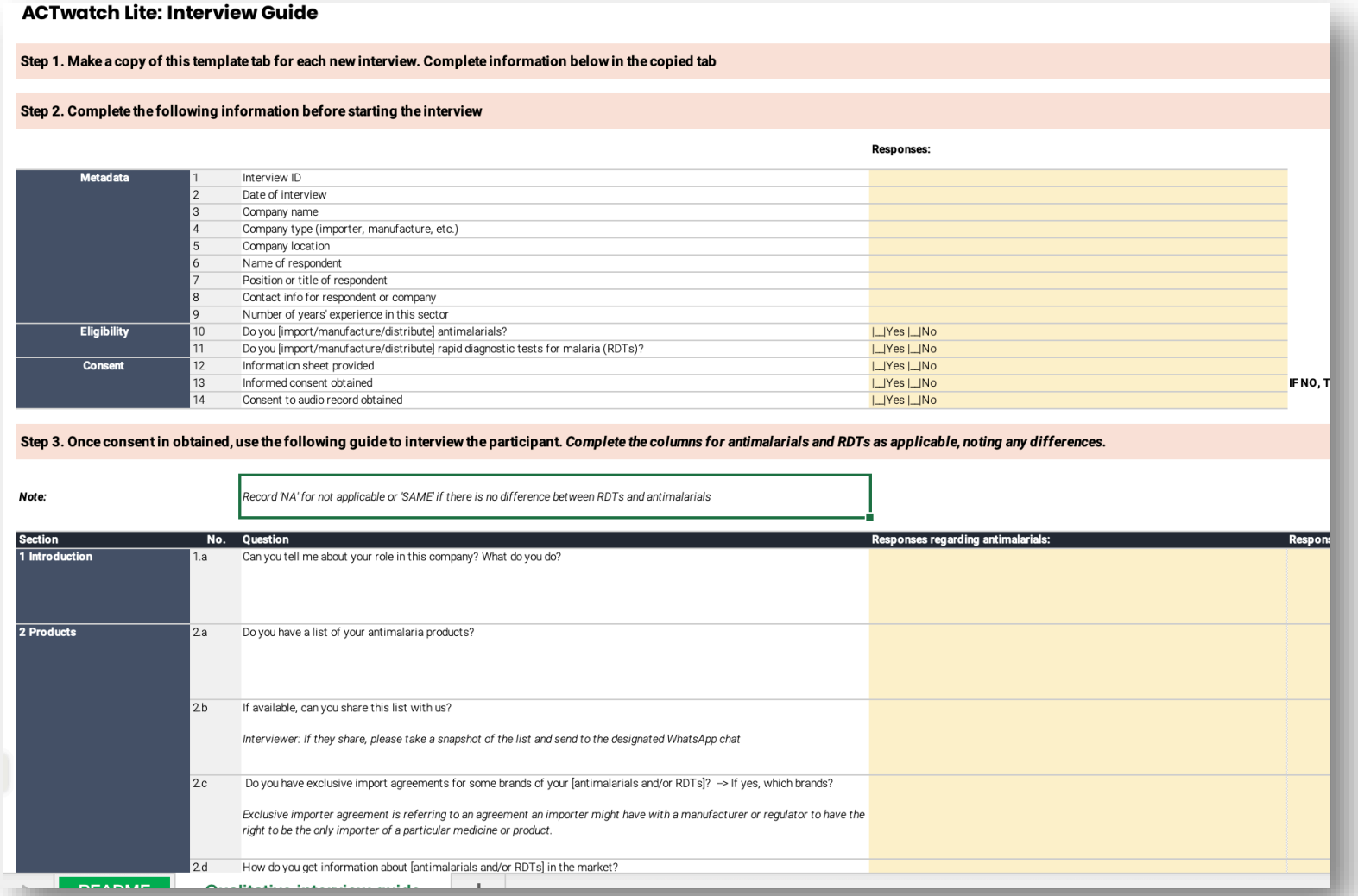
# 09 TRAINING MATERIALS

- Large set of resources for both qual and quant fieldworker training. All designed to be adapted for context
- README and training agenda provide overview and structure

| | | | |
|---|---|---|---|
| **AGENDA** | | | |
| **Classroom** | **Day 1 - Study overview & intro to antimalarials** | | |
| | **Day 2 - Antimalarials cont.** | | |
| | **Day 3 - RDTs and conducting a census** | | |
| | **Day 4 - Questionnaire deep dive** | | |
| | **Day 5 - Interviewing and intro to SurveyCTO** | | |
| | **Day 6 - Audit exam and practicals** | | |
| **Pilot** | **Day 7-10 PILOT** | | |
| **TL only** | **Day 11-12 TEAM LEAD SESSIONS** | | |
| | | | |
| **Day 1 - Study overview and intro to antimalarials** | | | |
| **Time** | **Contents** | **Training material** | **Facilitator/ Notes** |
| 08:30-9:45 | 1.1 Registration, introductions, welcome remarks | --- | |
| | **Module 1** | Module 1 Introduction to ACTwatch Lite-FINAL | |
| 09:45-10:00 | 1.2 Presentation of the training agenda | ^^^ | |
| 10:00-10:15 | 1.3 Ground Rules and Expectations | ^^^ | |
| 10:15-10:30 | Pre-test general knowledge quiz | Quiz_01 [PRINT one copy per participant; answer key provided in the folder] | |
| 10:30-10:50 | Break (Suggested group photo) | | |
| 10:50-11:00 | 1.4 Training objectives | ^^^ | |
| | **Module 1 cont.** | ^^^ | |
| 11:00-11:30 | 1.5 Malaria context | ^^^ | |
| 11:30-12:00 | 1.7. ACTwatch Lite overview | ^^^ | |
| | **Module 2** | Module 2 Auditing antimalarials-FINAL | |
| 12:00-13:00 | 2.1.a Generic and brand names | ^^^ | |
| 13:00 -14:00 | Lunch | | |
| | **Module 2 cont.** | ^^^ | |
| 14:00-14:30 | 2.1.b Manufacture and country | ^^^ | |
| 14:30-15:00 | ***Activity Worksheet 1*** | Worksheet_01 [PRINT one copy per participant; product photos for this activity are in the slides along with answers] | |
| 15:00-16:00 | 2.2 Dosage form, strengths, and salts | ^^^ | |

# 10 QUALITATIVE INTERVIEW GUIDE

- Includes qual tool draft (adaptable to context) and information sheet/consent form template



**ACTwatch Lite: Interview Guide**

**Step 1. Make a copy of this template tab for each new interview. Complete information below in the copied tab**

**Step 2. Complete the following information before starting the interview**

| | | | Responses: |
|---|---|---|---|
| **Metadata** | 1 | Interview ID | |
| | 2 | Date of interview | |
| | 3 | Company name | |
| | 4 | Company type (importer, manufacture, etc.) | |
| | 5 | Company location | |
| | 6 | Name of respondent | |
| | 7 | Position or title of respondent | |
| | 8 | Contact info for respondent or company | |
| | 9 | Number of years' experience in this sector | |
| **Eligibility** | 10 | Do you [import/manufacture/distribute] antimalarials? | |_|Yes |_|No |
| | 11 | Do you [import/manufacture/distribute] rapid diagnostic tests for malaria (RDTs)? | |_|Yes |_|No |
| **Consent** | 12 | Information sheet provided | |_|Yes |_|No |
| | 13 | Informed consent obtained | |_|Yes |_|No |
| | 14 | Consent to audio record obtained | |_|Yes |_|No |

IF NO, T

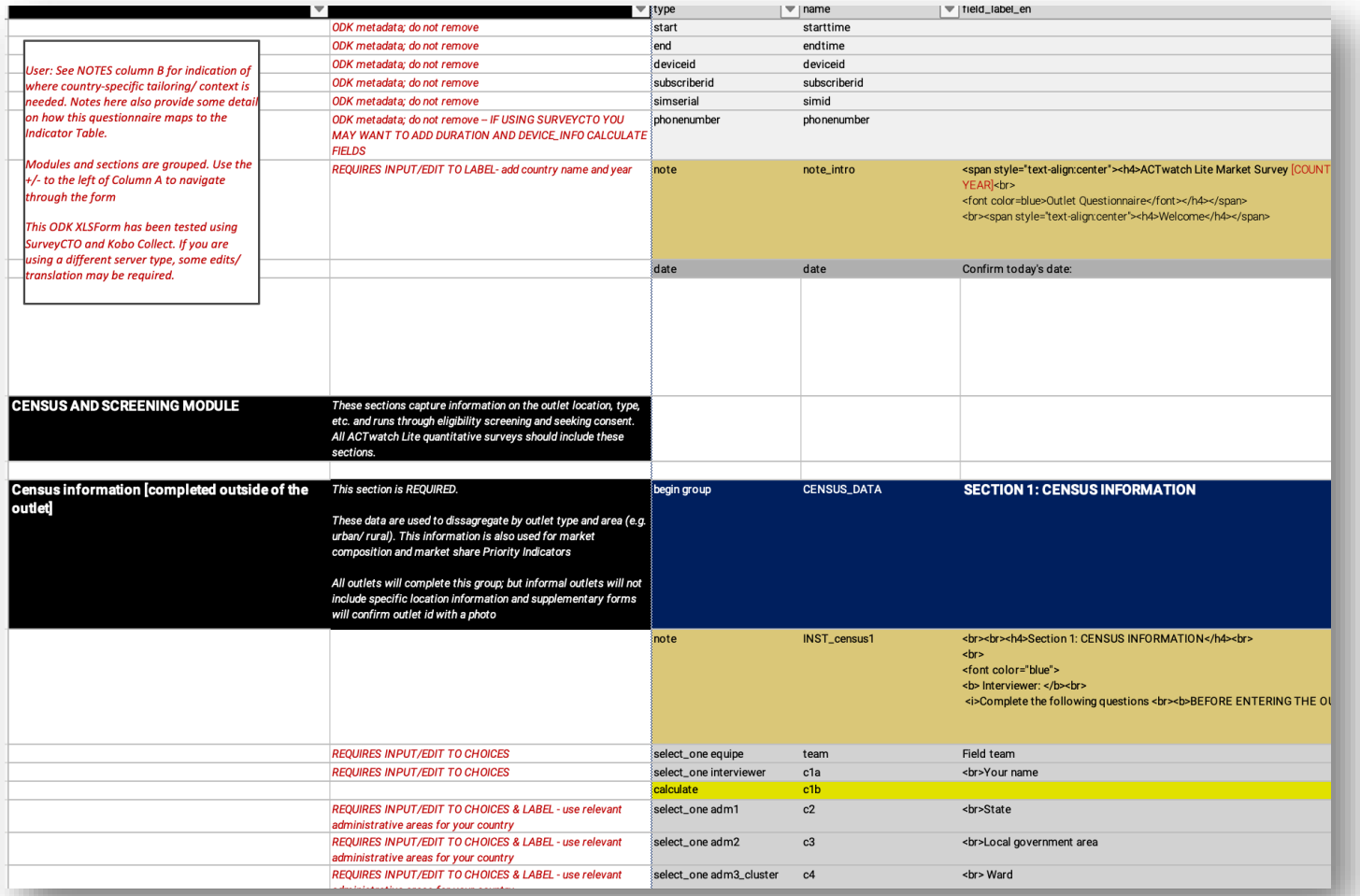
**Step 3. Once consent in obtained, use the following guide to interview the participant.** ***Complete the columns for antimalarials and RDTs as applicable, noting any differences.***

***Note:*** *Record 'NA' for not applicable or 'SAME' if there is no difference between RDTs and antimalarials*

| Section | No. | Question | Responses regarding antimalarials: | Respons |
|---|---|---|---|---|
| **1 Introduction** | 1.a | Can you tell me about your role in this company? What do you do? | | |
| **2 Products** | 2.a | Do you have a list of your antimalaria products? | | |
| | 2.b | If available, can you share this list with us?<br><br>*Interviewer: If they share, please take a snapshot of the list and send to the designated WhatsApp chat* | | |
| | 2.c | Do you have exclusive import agreements for some brands of your [antimalarials and/or RDTs]? –> If yes, which brands?<br><br>*Exclusive importer agreement is referring to an agreement an importer might have with a manufacturer or regulator to have the right to be the only importer of a particular medicine or product.* | | |
| | 2.d | How do you get information about [antimalarials and/or RDTs] in the market? | | |

# 11 QUANTITATIVE DATA COLLECTION TOOL

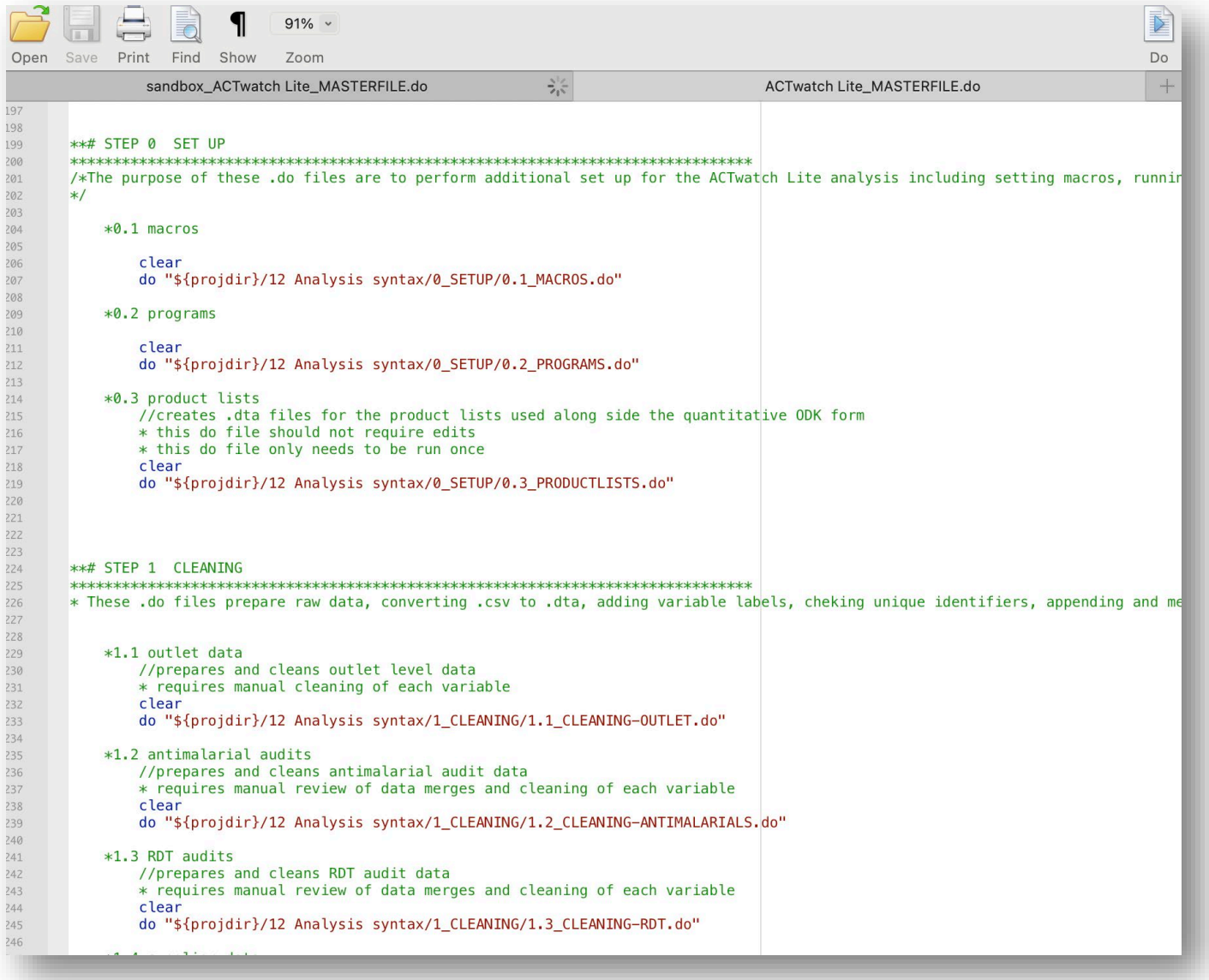
- Includes quant tool draft for ODK (adaptable to context) and information sheet/consent form template
- First two columns of ODK provide information to the user
- Includes additional ODK files folder, with files required to implement study (e.g. product database csv's)



| | | type | name | field_label_en |
|---|---|---|---|---|
| | ODK metadata; do not remove | start | starttime | |
| User: See NOTES column B for indication of where country-specific tailoring/ context is needed. Notes here also provide some detail on how this questionnaire maps to the Indicator Table. Modules and sections are grouped. Use the +/- to the left of Column A to navigate through the form This ODK XLSForm has been tested using SurveyCTO and Kobo Collect. If you are using a different server type, some edits/ translation may be required. | ODK metadata; do not remove | end | endtime | |
| | ODK metadata; do not remove | deviceid | deviceid | |
| | ODK metadata; do not remove | subscriberid | subscriberid | |
| | ODK metadata; do not remove | simserial | simid | |
| | ODK metadata; do not remove – IF USING SURVEYCTO YOU MAY WANT TO ADD DURATION AND DEVICE_INFO CALCULATE FIELDS | phonenumber | phonenumber | |
| | REQUIRES INPUT/EDIT TO LABEL- add country name and year | note | note_intro | <h4>ACTwatch Lite Market Survey [COUNT YEAR]<br><font color=blue>Outlet Questionnaire</font></h4><br><h4>Welcome</h4> |
| | | date | date | Confirm today's date: |
| CENSUS AND SCREENING MODULE | These sections capture information on the outlet location, type, etc. and runs through eligibility screening and seeking consent. All ACTwatch Lite quantitative surveys should include these sections. | | | |
| Census information [completed outside of the outlet] | This section is REQUIRED. These data are used to dissagregate by outlet type and area (e.g. urban/ rural). This information is also used for market composition and market share Priority Indicators All outlets will complete this group; but informal outlets will not include specific location information and supplementary forms will confirm outlet id with a photo | begin group | CENSUS_DATA | SECTION 1: CENSUS INFORMATION |
| | | note | INST_census1 | <br><br><h4>Section 1: CENSUS INFORMATION</h4><br><br><font color="blue"> Interviewer: <br><i>Complete the following questions <br>BEFORE ENTERING THE OU |
| | REQUIRES INPUT/EDIT TO CHOICES | select_one equipe | team | Field team |
| | REQUIRES INPUT/EDIT TO CHOICES | select_one interviewer | c1a | <br>Your name |
| | | calculate | c1b | |
| | REQUIRES INPUT/EDIT TO CHOICES & LABEL - use relevant administrative areas for your country | select_one adm1 | c2 | <br>State |
| | REQUIRES INPUT/EDIT TO CHOICES & LABEL - use relevant administrative areas for your country | select_one adm2 | c3 | <br>Local government area |
| | REQUIRES INPUT/EDIT TO CHOICES & LABEL - use relevant | select_one adm3_cluster | c4 | <br> Ward |

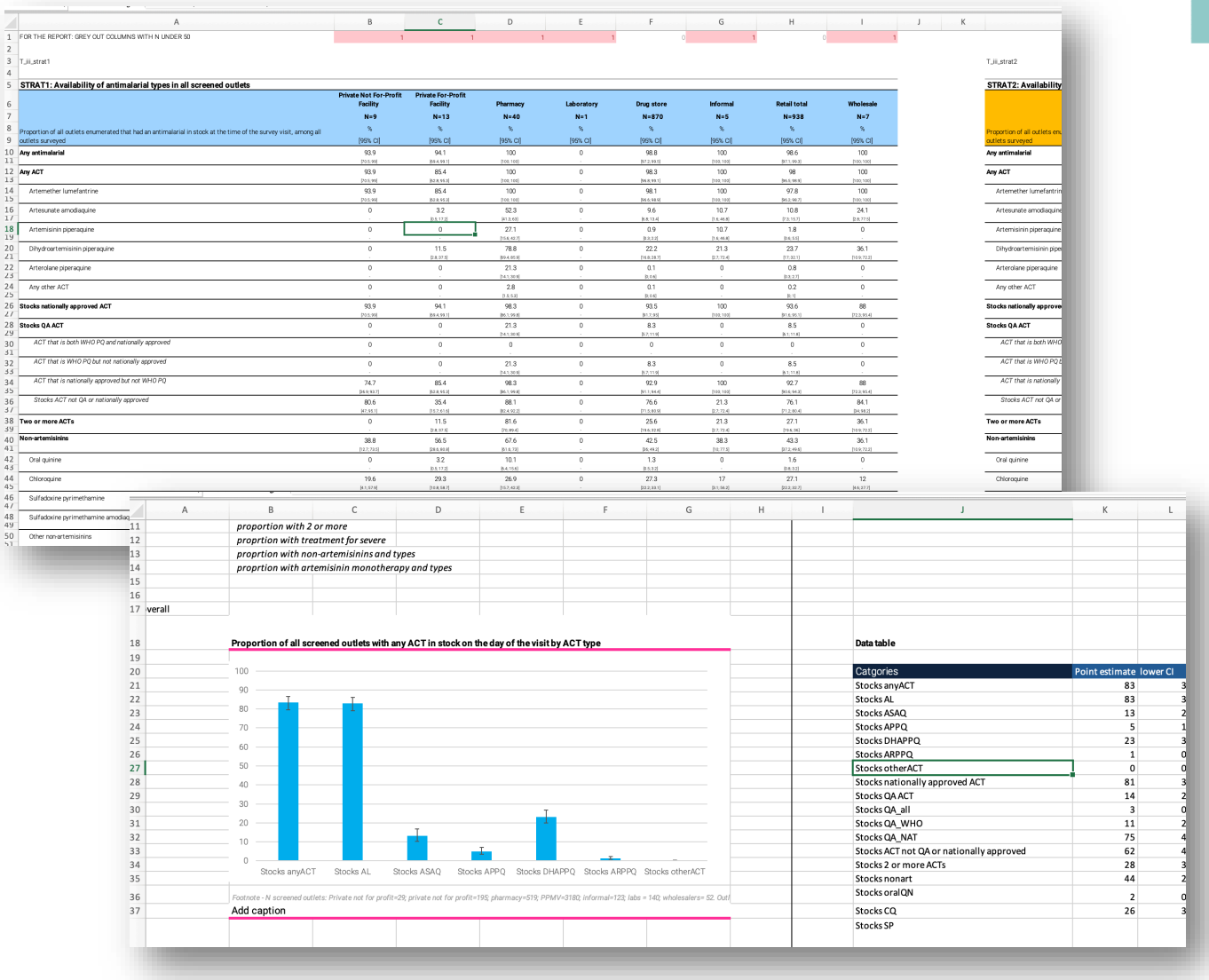
# 12 ANALYSIS SYNTAX

- _ACTwatch Lite analysis guide should be the starting point
- Analysis follows a 4-step process with a hierarchical .do file structure
- .do files contain detailed annotation
- Partially automated, but requires user input throughout
- Note: X. Analysis Sandbox folder for technical reviewer use in root folder



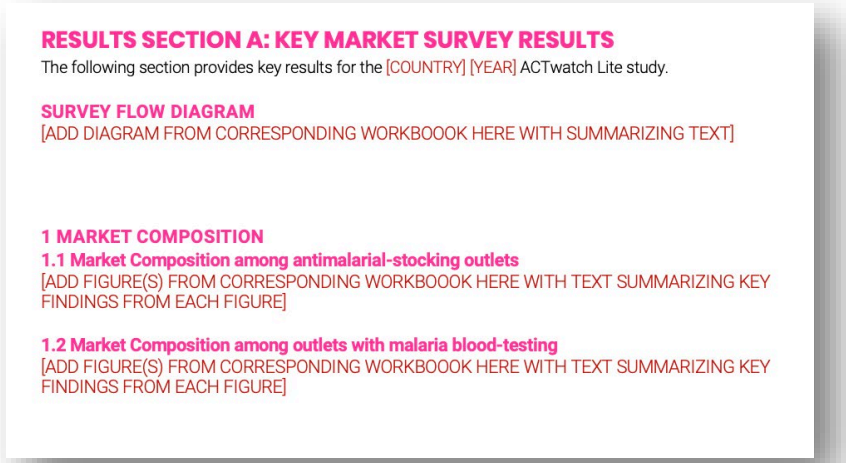
# 13 RESULTS WORKBOOKS

- Analysis approach is designed to output results directly to pre-formatted excel workbooks
- Tables and figures for key indicators created in report-ready format



# 14 REPORT TEMPLATE AND REFERENCES

- A word report template is provided with sections for input clearly highlighted
- ACTwatch Lite pilot study reports also provided in word doc format as references



## RESULTS SECTION A: KEY MARKET SURVEY RESULTS

The following section provides key results for the [COUNTRY] [YEAR] ACTwatch Lite study.

### SURVEY FLOW DIAGRAM

[ADD DIAGRAM FROM CORRESPONDING WORKBOOOK HERE WITH SUMMARIZING TEXT]

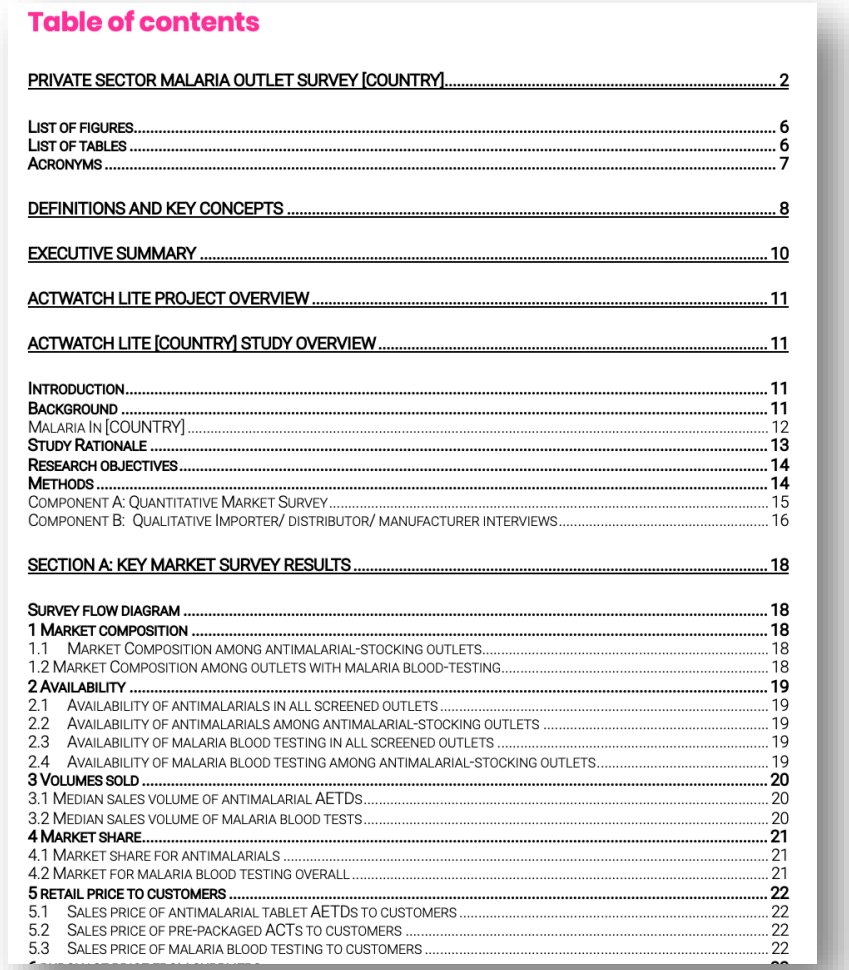
### 1 MARKET COMPOSITION

**1.1 Market Composition among antimalarial-stocking outlets**

[ADD FIGURE(S) FROM CORRESPONDING WORKBOOOK HERE WITH TEXT SUMMARIZING KEY FINDINGS FROM EACH FIGURE]

**1.2 Market Composition among outlets with malaria blood-testing**

[ADD FIGURE(S) FROM CORRESPONDING WORKBOOOK HERE WITH TEXT SUMMARIZING KEY FINDINGS FROM EACH FIGURE]



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RBM Partnership
To End Malaria

16 September 2025

# Afternoon Coffee Break

RBM Partnership To End Malaria

16 September 2025

# Update on the Ganaplacide/Lumefantrine program (Phase 3)

Caroline Boulton, Novartis

NOVARTIS

# Addressing resistance: Ganaplacide-Lumefantrine SDF investigational product



Caroline Boulton, Novartis
RBM case management meeting

September 2025

FA-11507919 09/2005

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# Our partners in clinical development of ganaplacide

MMV
Medicines for Malaria Venture

West African Network for Clinical Trials of Antimalarial Drugs
WANECAM

Gates Foundation

EDCTP

# Ganaplacide (also known as KAF156)

- New **non-artemisinin** antimalarial
- Novel mechanism of action, likely via Plasmodium intracellular secretory pathway*
- Fast-acting; half-life in patients around 40-50 h
- Active against all blood forms of *P. falciparum* and *P. vivax**
- Active against all currently known drug-resistant parasites in vitro including K13 mutants*
- Potent activity against male and female gametocytes in vitro*

- Combined with a new once daily formulation of Lumefantrine (LUM-SDF)
- Ganaplacide/lumefantrine is given once daily for 3 days with food

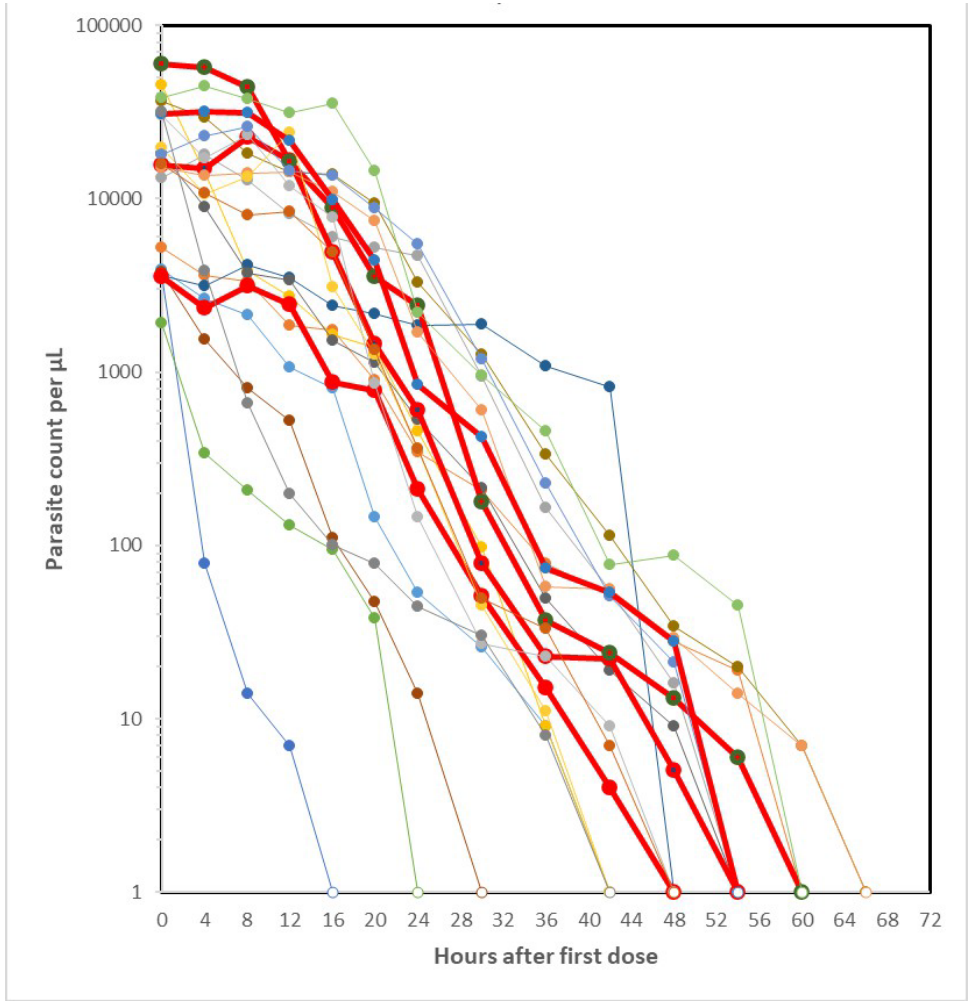
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*References: Meister-S, et al. *Science.* 2011; Kuhen KL, et al. AAC 2014; Leong FJ, et al. AAC 2014; Lim MY, et al. *Nat Microbiol.* 2016; NJ White, et al. *NEJM* 2016; Lamonte, et al 2020.

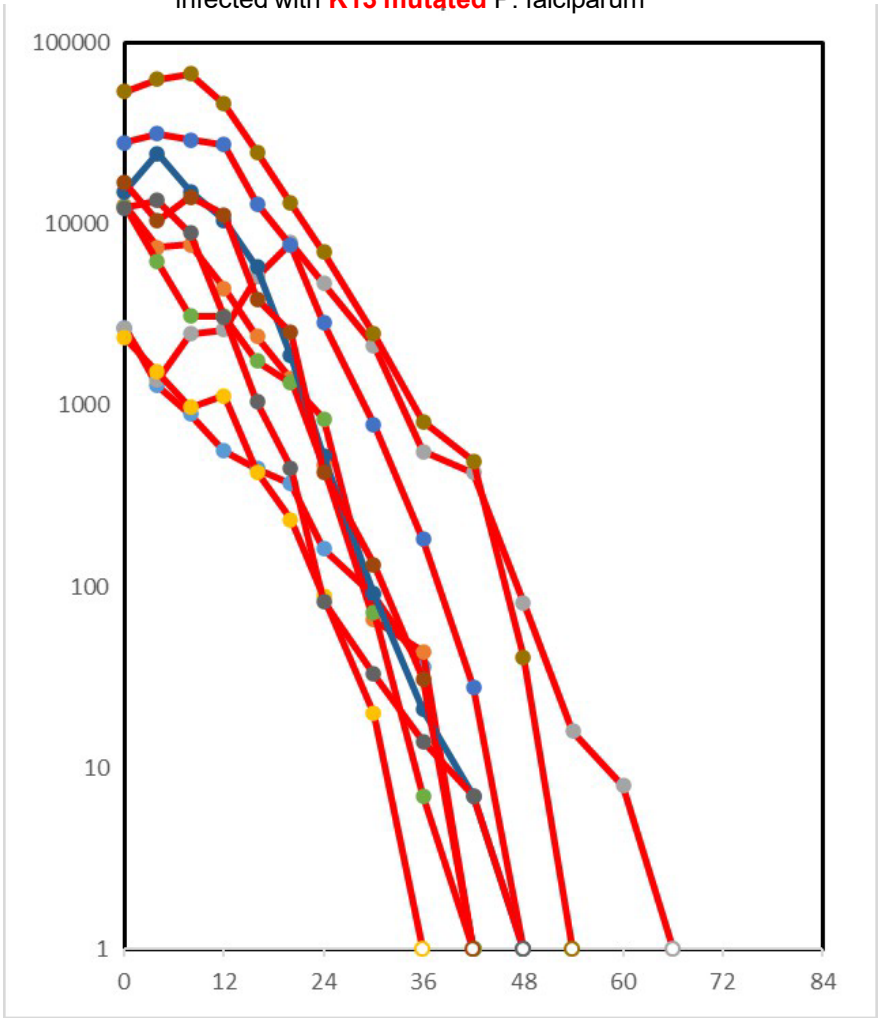
# Ganaplacide Is Active Against Drug-Resistant Parasites

## Clearance time of PfK13 mutated parasites is similar to wild type

Cohort 2: 800mg KAF QD: 4/21 patients infected with **K13 mutated** P. falciparum




Cohort 1: 400mg KAF QD 3D: 10/10 patients infected with **K13 mutated** P. falciparum




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*P. falciparum, Plasmodium falciparum*; QD, once daily.
White NJ, et al. *N Engl J Med.* 2016;375:1152–1160.

# Clinical programme in acute uncomplicated malaria

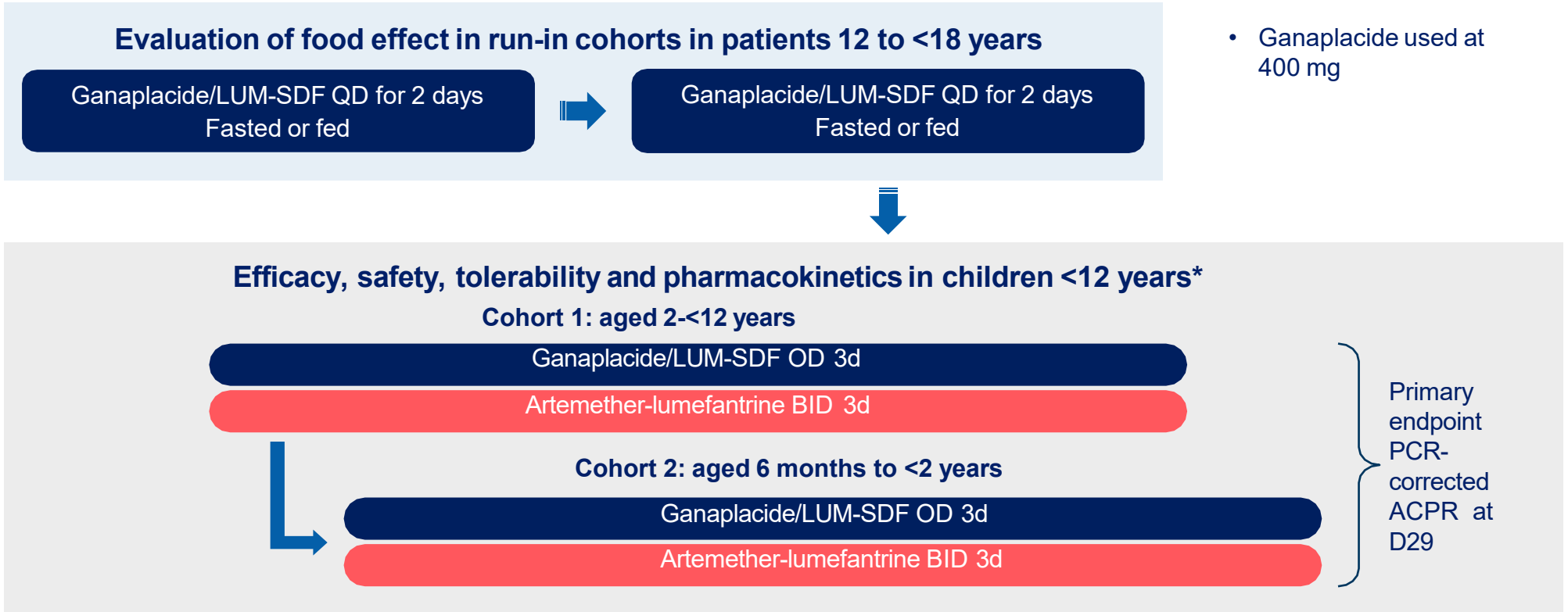
| Study | Outcome |
|---|---|
| Ph2 **monotherapy** study in *P. falciparum and P. vivax*[1] | Rapid clearance and 13*/21 Day 28 cure of single 800 mg dose.<br>Activity demonstrated vs *P. falciparum* and *P. vivax* blood stages |
| Ph2b dose-finding study in patients with acute uncomplicated *P. falciparum* (artemether-lumefantrine control)[2] | 1-3D QD dose regimens of KAF/LUM-SDF compared to artemether-lumefantrine in adults and children > 2 years<br>GanLum 3D QD 400mg/960mg (fasted) met efficacy and safety criteria in adults and children with malaria |
| 'KALUMI' Ph2b i) food effect & ii) efficacy, safety and tolerability of KAF/LUM-SDF 2 or 3 days QD in adolescents and children with *P. falciparum* (artemether-lumefantrine control)<br>NCT04546633 | 2-fold food effect observed with Lum-SDF<br>GanLum 400mg/480mg QD for 3D with a light meal identified as optimal dose/regimen & condition<br>GanLum achieved cure rates (PCR-corrected ACPR at Day 29) of 99%, similar to Coartem |
| 'KALUMA' Ph 3 confirmatory efficacy, safety and tolerability in 1720 adults and children with *P. falciparum* +/- mixed infection (artemether-lumefantrine control) and extension phase<br>NCT05842954 | Dosing completed |

*Includes 1 new infection. SDF, solid dispersion formulations.

1. NJ White et al. *N Engl J Med.* 2016. 2. B Ogutu, et al. *Lancet.* 2023. https://clinicaltrials.gov/study/NCT04546633?term=NCT04546633&rank=1; https://clinicaltrials.gov/study/NCT05842954?term=NCT05842954&rank=1

# KALUMI Ph2b study design

## NCT04546633




- Ganaplacide used at 400 mg

Dosed by body weight band; total number of patients: 295.

B Ogutu, et al. *Lancet.* 2023. https://clinicaltrials.gov/study/NCT04546633?term=NCT04546633&rank=1
I Sagara et al. LB Abstract 9425 Presented at ASTMH 2024, 15 Nov 2024, USA.

# KALUMI footprint and enrolment per country

| Country | Malaria endemicity | No. Of patients enrolled |
|---|---|---|
| BF (4 sites) | High | 59 |
| Mali (3 sites) | High | 132 |
| Gabon | High | 92 |
| DRC | High | 1 |
| IVC | High | 11 |
| **Total** | | **295** |




I Sagara et al. LB Abstract 9425 Presented at ASTMH 2024, 15 Nov 2024, USA.

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# KALUMI: Patient disposition, demography & baseline disease characteristics

| Disposition | N |
|---|---|
| Randomized | 220 |
| Full Analysis Set (FAS) | 220 |
| Safety Set (SAF) | 220 |
| Per-protocol Set (PPS) | 197 |

| | Category | GAN400mg/ LUM-SDF480mg QDx3 (N=110) | Coartem® (N=110) | Statistics |
|---|---|---|---|---|
| Age (years) | | 4.9 (3.5) | 4.6 (3.3) | Mean (SD) |
| | | 4.0 | 4.0 | Median |
| Sex | Male | 50 (45.5) | 68 (61.8) | n (%) |
| Weight (kg) | | 16.5 (7.8) | 15.9 (7.4) | mean (SD) |
| BMI (kg/m$^2$) | | 14.8 (1.8) | 14.8 (1.7) | mean (SD) |
| BMI category (kg/m$^2$) | <16 | 89 (80.9) | 90 (81.8) | n (%) |
| Body temp. (axillary) ($^0$C) | <37.5 | 77 (70.0) | 74 (67.3) | n (%) |
| | 37.5 to <38.5 | 25 (22.7) | 27 (24.5) | n (%) |
| | ≥38.5 | 8 (7.3) | 9 (8.2) | n (%) |
| P. falciparum asexual density (/uL) | | 40846 (51485) | 45076 (49148) | mean (SD) |

I Sagara et al. LB Abstract 9425 Presented at ASTMH 2024, 15 Nov 2024, USA.

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# Primary efficacy endpoint: Corrected ACPR* on Day 29

## GAN/LUM demonstrated non-inferiority to Coartem® (Lower limit of 2-sided 95% CI -2.9% > -10%)

*Per Protocol Set*

| Treatment | N | D29 ACPR Rate (95% CI) | Difference (95% CI) |
|---|---|---|---|
| Gan400mg/Lum480mg | 98 | 99 (99.4,100) | 0 (-2.9,2.8) |
| Coartem® | 99 | 99 (94.5,100) | Ref |

*ACPR: Adequate Clinical and Parasitological Response

I Sagara et al. LB Abstract 9425 Presented at ASTMH 2024, 15 Nov 2024, USA.

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# Key secondary endpoint: PCR uncorrected ACPR rates at D29

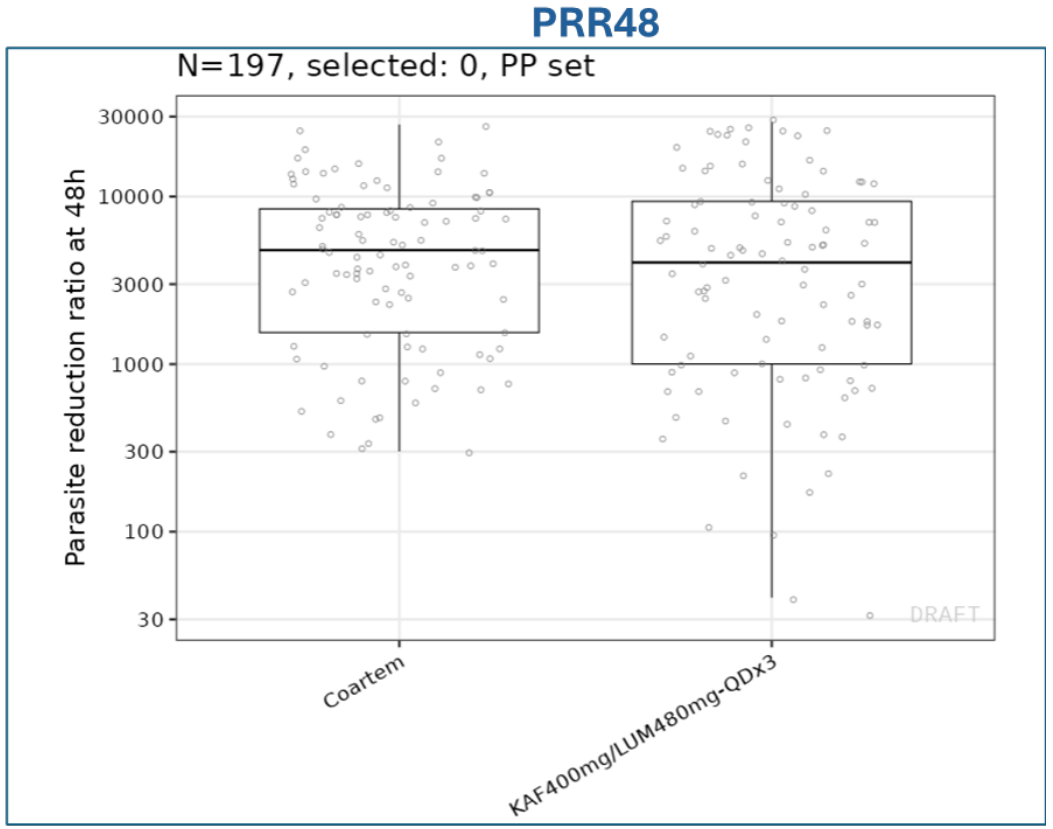
## Similar response rate between treatment groups in FDA-required endpoint

| Treatment | N | D29 ACPR Rate (95% CI) | Difference (95% CI) |
|---|---|---|---|
| Gan400mg/Lum480mg | 95/98 | 96.9 (91.3,99.4) | 1.8 (-3.7,7.4) |
| Coartem® | 94/99 | 94.9 (88.6,98.3) | Ref |

I Sagara et al. LB Abstract 9425 Presented at ASTMH 2024, 15 Nov 2024, USA.

# Parasite Reduction Ratios (PRR): fast clearance in both groups

## Comparable PRR between treatments. All patients cleared at 48h




I Sagara et al. LB Abstract 9425 Presented at ASTMH 2024, 15 Nov 2024, USA.

# Adverse Events reported at ≥ 5% to Day 43

| Preferred term | Gan400mg/LUM480mg QDx3 N=110 n (%) | Coartem N=110 n (%) |
|---|---|---|
| Number of subjects with at least one AE | 74 (67.3) | 61 (55.5) |
| Vomiting* | 32 (29.1) | 12 (10.9) |
| Hypokalaemia | 27 (24.5) | 16 (14.5) |
| Electrocardiogram QT prolonged** | 18 (16.4) | 6 (5.5) |
| Pyrexia | 16 (14.5) | 12 (10.9) |
| Malaria | 13 (11.8) | 15 (13.6) |
| Cough | 6 (5.5) | 4 (3.6) |
| Anaemia | 5 (4.5) | 6 (5.5) |

* Vomiting predominantly in patients <2yrs
**QT Extensions: all asymptomatic and no case >500msec. More assessments in Gan/Lum group
No deaths reported in the study; 4 SAEs all in Coartem treated patients
I Sagara et al. LB Abstract 9425 Presented at ASTMH 2024, 15 Nov 2024, USA.

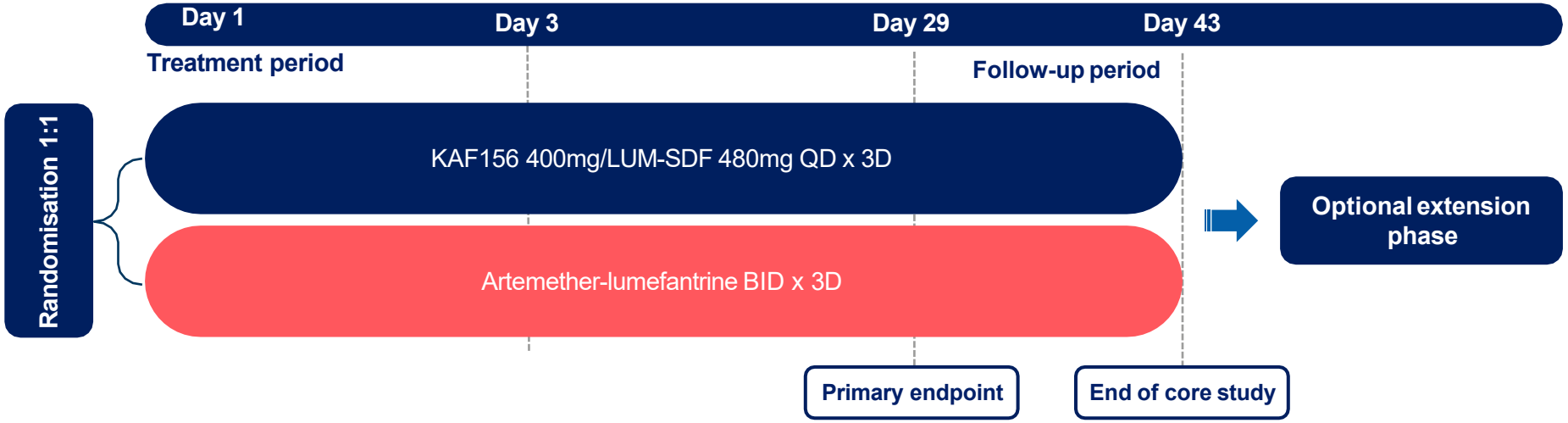
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# Summary

- 400mg ganaplacide /480mg lumefantrine-SDF QD for 3 days was non-inferior to Coartem® BID for 3 days in a pediatric patient population (from 6 months) with acute Pf malaria
- Excellent cure rates observed with both treatments in this study
- AEs were generally mild and overlapping with malaria symptoms. A higher incidence of vomiting was observed in patients <2yrs with this phase 2 formulation

# KALUMA phase 3 trial design

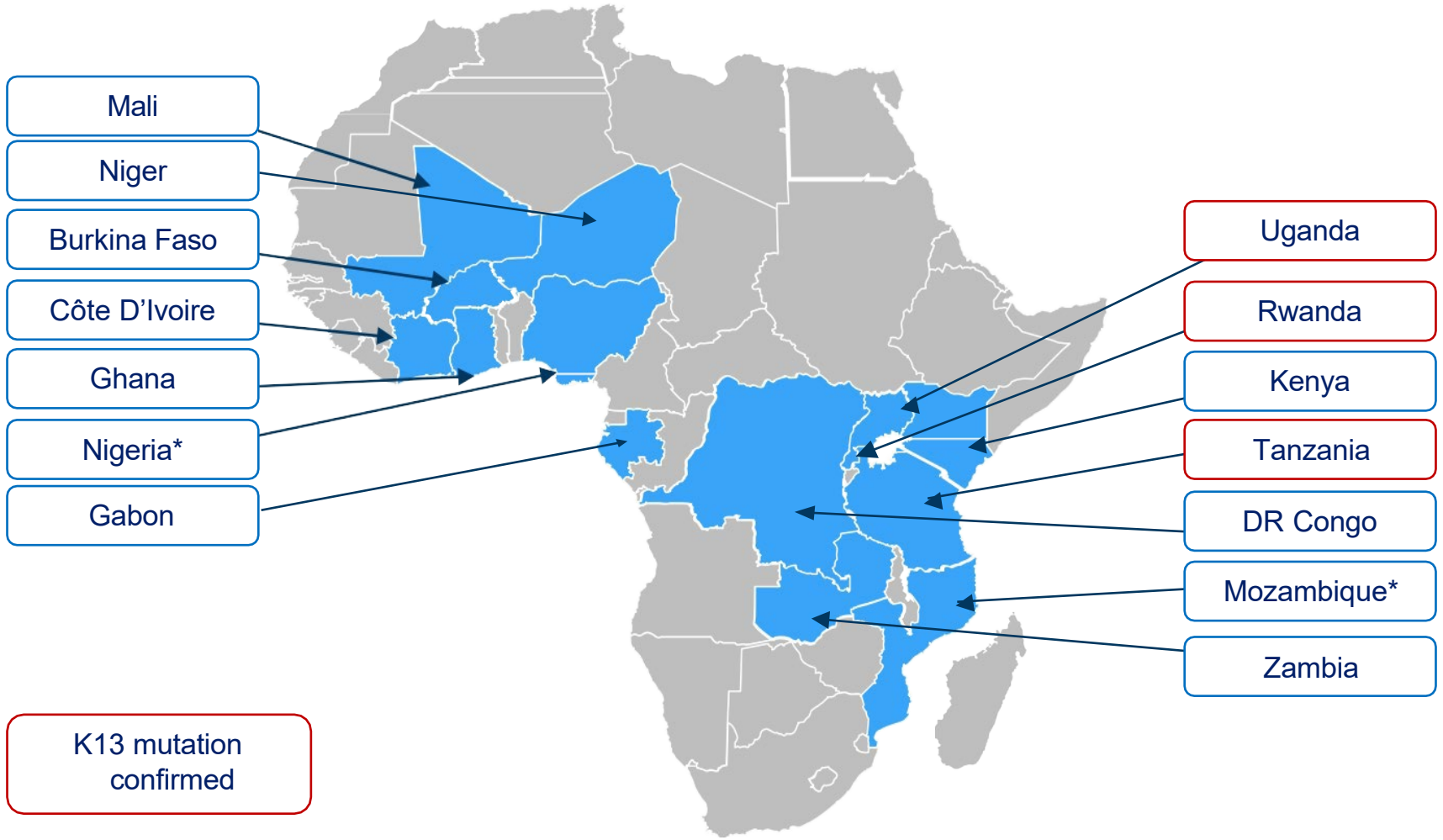
## NCT05842954




| | |
|---|---|
| **Objective** | To confirm the efficacy, safety and tolerability of KLU156, a fixed dose combination of KAF156 and a solid dispersion formulation of lumefantrine, in adults and children ≥10 kg body weight with acute uncomplicated malaria caused by *P. falciparum* (with or without other *Plasmodium sp.*) by demonstrating non-inferiority to artemether-lumefantrine |
| **1° endpoint** | PCR-corrected ACPR at D29 |
| **2° endpoint** | PCR-uncorrected ACPR; gametocyte carriage over time |

Dose by body weight band; Total number of patients: 1500.
https://clinicaltrials.gov/study/NCT05842954?term=NCT05842954&rank=1, https://pactr.samrc.ac.za/Search.aspx PACTR202303470809477

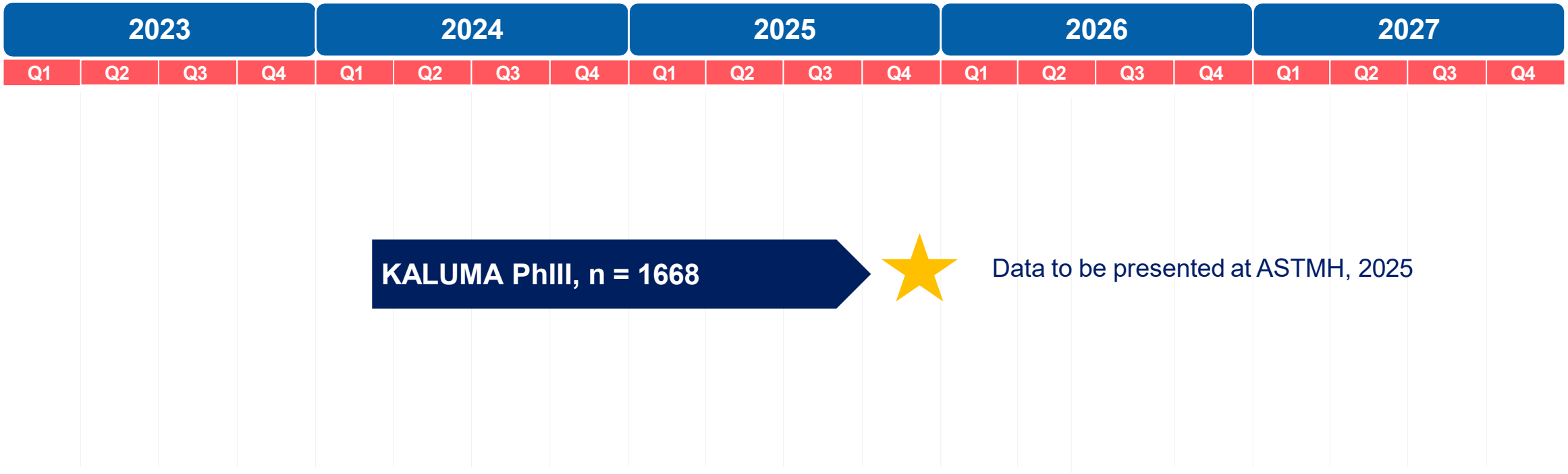
# KALUMA Phase 3 Study Footprint NCT05842954[1-3]




*Not opened to recruitment

1. ClinicalTrials.gov. NCT05842954. https://clinicaltrials.gov/study/NCT05842954 (Accessed April 17, 2025). 2. PACTR. PACTR202303470809477. https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=24331 (Accessed June 4, 2025).
3. WHO Guidelines for Malaria, 2024. https://iris.who.int/bitstream/handle/10665/379635/B09146-eng.pdf?sequence=1 (Accessed on April 22, 2025).

# Ganaplacide/LUM-SDF estimated timelines*




- Health authority submissions will follow in 1Q 2026

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https://clinicaltrials.gov/study/NCT04546633?term=NCT04546633&rank=1,
https://clinicaltrials.gov/study/NCT05842954?term=NCT05842954&rank=1

# Overall conclusion

- Efficacy (PCR-corrected ACPR at Day 29) ≥ 95% observed across Phase 2 clinical studies with GanLum QD when used for 3 days
- Recommended dose 400mg Gan / 480 mg LUM QD for 3 days with a light meal
- Dose adjusted by body weight category (as for Coartem) for patients < 35kg body weight
- Generally comparable safety profile to artemether-lumefantrine; no difference in safety profile observed between adults and children
- Potential for asymptomatic QT extensions and vomiting/spitting in young children

1. Ogutu *et al.*,Lancet Infect Dis 2023; 23: 1051–61 Published Online June 13, 2023 https://doi.org/10.1016/ S1473-3099(23)00209-8

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# Thank you



RBM Partnership To End Malaria

Case Management Working Group

16 September 2025

# MMV update: portfolio, resistance mitigation program and 2026-30 strategy

Adam Aspinall, MMV

# MMV update

Adam Aspinall & Hans Rietveld
MMV Access & Product Management

RBM CMWG, Abidjan, 16th September 2025



MMV
Medicines for Malaria Venture

# Today's menu.

- MMV's portfolio of antimalaria products
- 2026-2030 strategy
- Antimalarial resistance and key responses
- Severe malaria
- A taste of the future: long-acting injectables

# MMV drug portfolio

## RESEARCH >

### Lead optimization

- **Phenotypic** — GHDDI
- **4-aminoquinoline** — LSTM and University of Liverpool
- **GWT1** — Eisai
- **Novel Target** — UTSW
- **PMX** — Liverpool
- **DHODH** — UTSW/UW/Monash
- **Novel Target** — Mitsubishi Tanabe
- **Phenotypic** — H3D
- **Bc1** — Shionogi
- **Miniportfolio** — GSK

### Candidate profiling

- **MMV533 LAI** (Sanofi)
- **MMV609 LAI** — University of Kentucky
- **Hydroxy-quinonoline** — GHDDI

## EARLY DEVELOPMENT >

### Preclinical

- **MMV055** (OHSU USF)
- **MMV183** (TropIQ)
- **Lotilaner** — Tarsus
- **IWY357** — Novartis
- **MMV167 (OHSU USF)**
- **MMV609** — University of Kentucky

### Human volunteers

- **MMV533** (Sanofi)
- **INE963** — Novartis
- **GSK701** — GSK
- **MMV371** (Janssen)

## PRODUCT DEVELOPMENT >

### Patient exploratory

- **Cipargamin** — Novartis
- **ZY19489 + ferroquine** — Zydus
- **M5717 + pyronaridine** — Merck KGaA/Shin Poong
- **Ganaplacide-lumefantrine-Cipargamin** — Novartis

### Patient confirmatory

- **Artemether-lumefantrine amodiaquine FDC** — Tridem/MORU
- **Ganaplacide-lumefantrine** — Novartis
- **Tafenoquine India** — GSK
- **Sulfadoxine-Pyrimethamine Dispersible** — Emzor & Swipha

### Regulatory review

- **Sulfadoxine-pyrimethamine** — Emzor Pharmaceutical
- **Primaquine dispersible** — B&O Pharm

## ACCESS

### Approved/ERP

- **Artemether-lumefantrine Dispersible** — Novartis
- **Artesunate for Injection** — Fosun Pharma
- **Artesunate for Injection** — Ipca
- **Dihydroartemisinin-piperaquine** — Alfasigma
- **Pyronaridine-artesunate** — Shin Poong
- **Pyronaridine-artesunate granules** — Shin Poong
- **Artesunate-amodiaquine** — Sanofi
- **Artesunate-mefloquine** — Cipla
- **Sulfadoxine-pyrimethamine+ amodiaquine dispersible** — Fosun Pharma
- **Sulfadoxine-pyrimethamine+ amodiaquine dispersible** — S Kant
- **Artesunate rectal capsules** — Cipla
- **Artesunate rectal capsules** — Strides Pharma
- **Tafenoquine** — GSK
- **Tafenoquine paediatric** — GSK
- **SPAQ dispersible** — UCL/Stride/Rena Export
- **Sulfadoxine-pyrimethamine** — Universal Corporation
- **Sulfadoxine-Pyrimethamine** — Swipha Pharma Nigeria
- **Artemether-lumefantrine 2-5kg** — Novartis

MMV support to projects may include financial, in-kind and advisory activities.

Footnotes: Included in MMV portfolio after product approval and/or development. DND*i* and partners completed development and registration of ASMQ and ASAQ. | Global Fund Expert Review Panel (ERP) reviewed product – permitted for time-limited procurement, while regulatory/WHO prequalification review is ongoing. | APPROVED WHO Prequalified OR approved/positive opinion by regulatory bodies who are ICH members/observers. | paediatric formulation. | via a bioequivalence study. Past partners are in brackets (-).| Relapse prevention | No progress report in the last 2 years

# Working towards a malaria-free world



# Failure to contain AMDR could result in a public health catastrophe. That's why it's a key pillar of MMV's organizational strategy.

## Curing patients

### by addressing drug resistance and enhancing convenience

Malaria parasites continue to evolve in ways that reduce the efficacy of current antimalarials, highlighting an urgent need for new therapies to replace failing drugs and safeguard existing therapies against escalating resistance.

Pillar 1 | Pillar 2 | Pillar 3 | Pillar 4

WHO estimates that widespread artemisinin partial resistance and high partner drug resistance could result in ~16 million additional malaria cases, ~360 000 hospitalized severe cases and over 80 000 excess deaths per year.

Improved stewardship of existing antimalarials is crucial to ensure efficacy of current treatments for as long as possible. It will also allow more patients to receive lifesaving therapy in the near-term while we develop new innovative treatments.

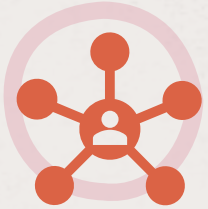
**To preserve existing antimalarials, we will:**

- Support endemic countries to use at least four different first-line artemisinin-based combination therapies (ACTs), to avert overuse of a single combination
- Co-develop and launch triple-combination ACTs, which include two longer-acting partner drugs in addition to an artemisinin-based compound
- Support the use of low-dose primaquine to reduce transmission of *Plasmodium falciparum (P. falciparum)* (the dominant parasite strain responsible for malaria)

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# …and that strategy is centred on a number of transformative bets:

Elimination, AMDR, single dose cure (SDC) and long-acting chemoprevention






**Elimination: rollout of radical cure for *P. vivax***

**Containing resistance today** (MFT, TACTs, NACTs, primaquine, and for pregnant women)

**New generation of tools/MOAs with high barriers to resistance**

- Single-dose cure
- Long-acting chemoprevention platforms

**Targeted access to scale, playing to MMV's strengths**

DRAFT

# MMV is focused on AMDR containment both now and in the longer term.

**Short term (2024-2027)**

- **Driving ACT diversification by** championing deployment of, and evidence generation for multiple first-line treatments

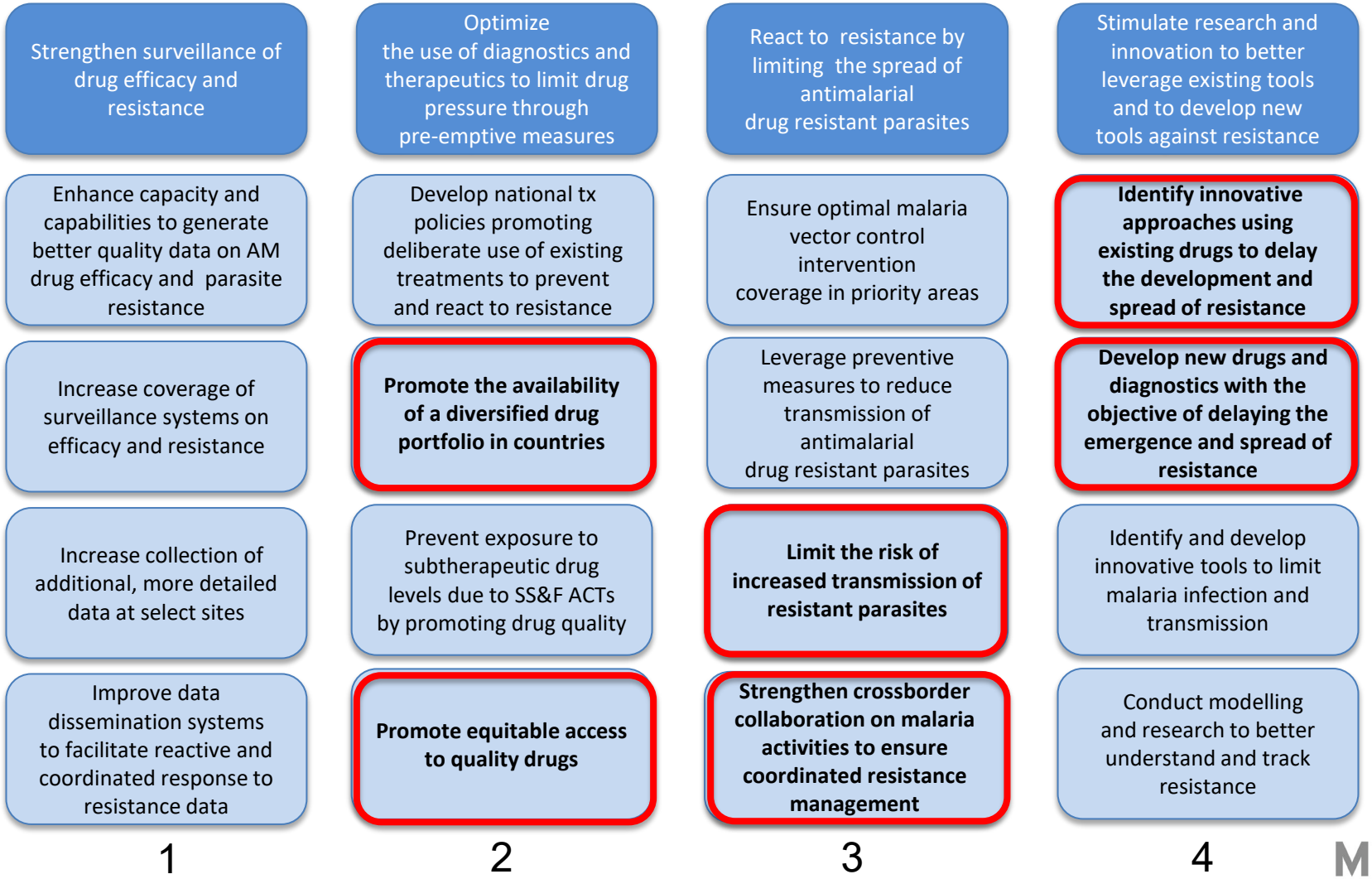
**Medium term (2026-2029)**

- **Adding an extra line of defence** by supporting the development and deployment of triple ACTs (ALAQ, PyAS+PPQ)
- **Stopping malaria transmission** at its source by facilitating broader use of sLDPQ through co-blistering with ACT
- **Developing and introducing novel non-artemisinin-based combination treatments** (NACTs)

**Longer term 2029 onwards**

- **Spearheading the development of single-dose cures** (both to improve treatment compliance and to facilitate the elimination agenda) – which are effective against resistant strains

# Our AMDR containment programmes align with and support WHO's resistance strategy for Africa.




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# Containing antimalarial drug resistance: 2026-2028

## Strategic fit & impact – Pillar 1 (Curing patients by addressing drug resistance and enhancing convenience)

***To preserve existing antimalarials, we will*:**

- Support endemic countries to use at least four different first-line artemisin combination therapies (ACTs), to avert over-use of a single combination
- Co-develop and launch triple-combination ACTs, which include two longer-acting partner drugs in addition to an artemisinin-based compound
- Support the use of low-dose primaquine to reduce transmission of *P. falciparum*

***To expand the non-artemisinin antimalarial portfolio, we will:***

- Develop and launch new non-artemisinin combinations for uncomplicated malaria

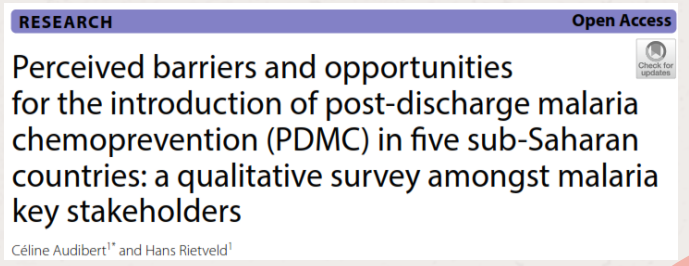
***To improve outcomes and enhance patient convenience, we will:***

- Develop and deliver simpler therapies (e.g. single-dose cure) for uncomplicated malaria

Supporting prevention and transmission-blocking efforts through our other pillars will also delay the development of drug resistance by reducing the overall incidence and spread of disease.

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# Severe Malaria: Opportunities to improve the continuum and quality of care

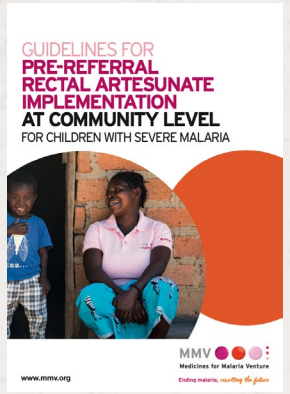

RESEARCH Open Access

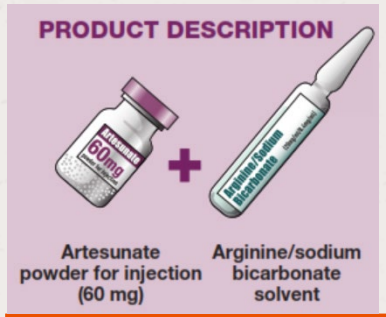
Perceived barriers and opportunities for the introduction of post-discharge malaria chemoprevention (PDMC) in five sub-Saharan countries: a qualitative survey amongst malaria key stakeholders

Céline Audibert[1*] and Hans Rietveld[1]

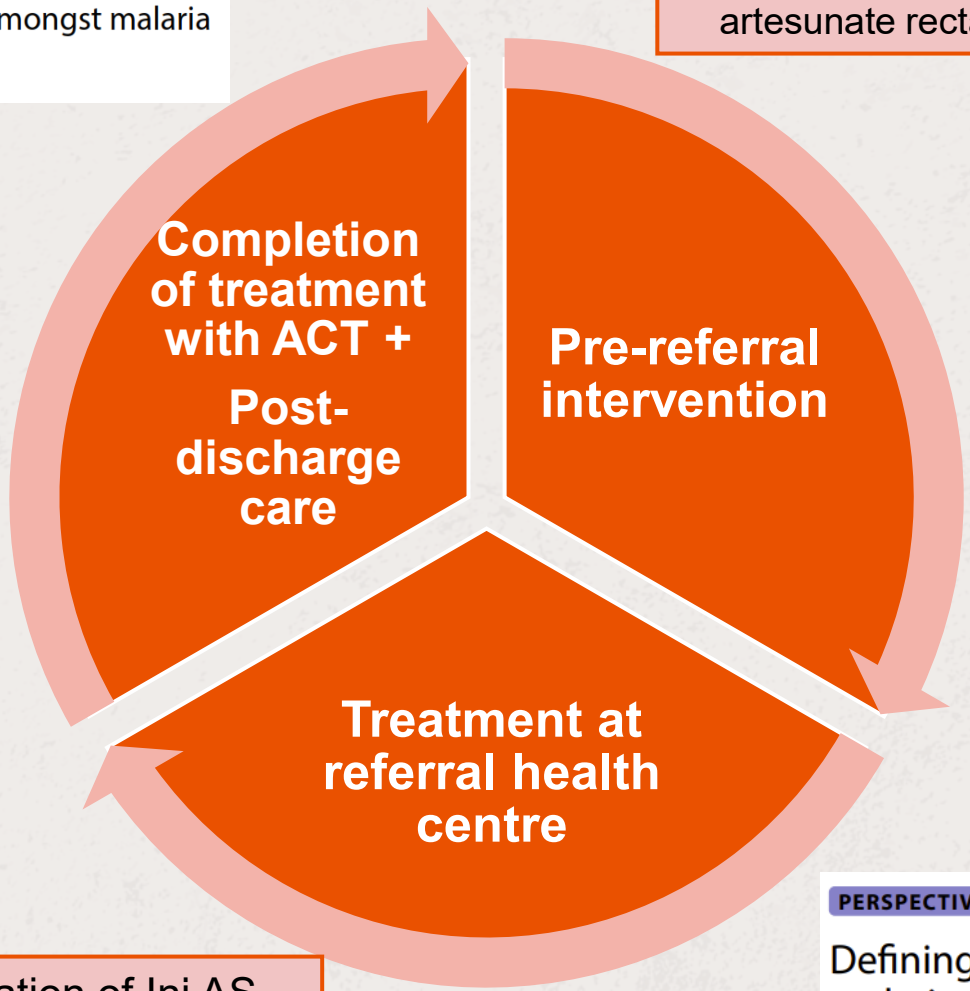
Three months of post-discharge malaria chemoprevention with monthly ACT (dihydroartemisinin-piperaquine)

Real-world stability testing of artesunate rectal capsules (ARC)



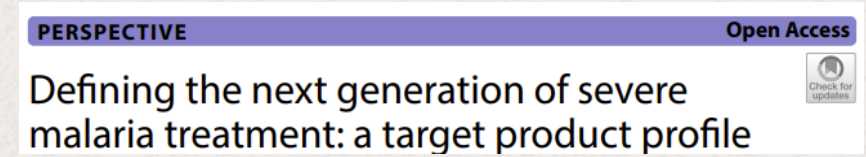

More convenient formulation of Inj AS




SEMA ReACT
SEVERE MALARIA IN REMOTE AREAS CLOSING THE EVIDENCE GAP

When the hospital is too far:
www.youtube.com/watch?v=9TOj8AEebiE

Exploring Drivers and Barriers to Uptake of Rectal Artesunate (RAS) in 6 African Countries: A Qualitative Market Research Study


PERSPECTIVE Open Access

Defining the next generation of severe malaria treatment: a target product profile



www.severemalaria.org

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# Long-acting injectable for malaria prevention

- **A combination of two drugs,** ideally co-injected, to mitigate resistance risk
- **Long protection against infection** (**≥3 month**) after a single intramuscular injection
- **Decreased transmission** through clearance of the parasite reservoir in asymptomatic carriers
- **Broad population** filling the gaps for those not adequately protected by current preventive interventions
- **Access upsides:** no cold chain, affordable, enables age expansion for unprotected children
- **Status:** Phase 1 started for the first long-acting injectable for malaria chemoprevention





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# Thank you for your attention