**ACTwatch Lite toolkit protocol template**

**Information/ instructions for users**

This template provides a starting point for drafting an ACTwatch Lite study protocol. It is based on protocols used in Benin, Cameroon, and Nigeria, and incorporates standardized methods for private sector malaria outlet surveys.

Why this is important:

* Ensures study design and methods are clearly documented for ethical review and stakeholder understanding.
* Supports alignment with national malaria strategies and priorities.
* Facilitates standardized implementation and comparability across settings.

Use this document as a foundation and adapt it to your local context and regulatory requirements. Local IRB/National Ethical Review Committee or regulatory approvals may require specific format, layout or include protocol sections that are not in this document. Please ensure the final study protocol complies with local regulations.

Review all sections to ensure relevance. Some content has been retained where it may be useful. Other placeholder TEXT IN RED CAPS indicates where country, and/or study-specific content is needed. Use **Annex V: Country-level protocol adaptation checklist** to track progress on adapting this template.

**Instructions: Carefully review each section and update content for your study. Add or remove sections as needed to meet local IRB/National Ethical Review Committee or regulatory requirements. Ensure that the final protocol complies with national formatting and submission standards. This document will serve as the central reference for ethical approvals, fieldwork, analysis, and dissemination.**

A group of blue and grey logos

Description automatically generated

Private Sector Malaria Outlet SurveY

[country name]

Research Protocol

[DATE]

**Principal Investigators**

[NAME, AFFILIATION]

[NAME, AFFILIATION]

**Co-investigators**

[NAME, AFFILIATION]

[NAME, AFFILIATION]

[NAME, AFFILIATION]

**Table of contents**

[Definitions and Key concepts 4](#_Toc205208385)

[Executive summary 5](#_Toc205208386)

[1. Introduction 6](#_Toc205208387)

[2. Background 7](#_Toc205208388)

[3. ACTwatch Lite 7](#_Toc205208389)

[4. Malaria in [COUNTRY NAME] 7](#_Toc205208390)

[Malaria burden and risk 7](#_Toc205208391)

[Malaria case management guidelines 8](#_Toc205208392)

[Diagnosis 8](#_Toc205208393)

[Treatment 8](#_Toc205208394)

[Private health sector and supply chain 8](#_Toc205208395)

[[IF RELEVANT:] Findings from previous ACTwatch studies 8](#_Toc205208396)

[5. Study rationale 8](#_Toc205208397)

[6. Research objectives 9](#_Toc205208398)

[7. Methods 10](#_Toc205208399)

[Study design 10](#_Toc205208400)

[Component 1: Importer and/or local manufacturer component 11](#_Toc205208401)

[Components 2 & 3: Market Surveys 12](#_Toc205208402)

[8. Conceptual framework 12](#_Toc205208403)

[9. Scope 12](#_Toc205208404)

[Geographical coverage 12](#_Toc205208405)

[Stratification 12](#_Toc205208406)

[Study population 12](#_Toc205208407)

[Antimalarial drugs 13](#_Toc205208408)

[Malaria diagnostic tests 13](#_Toc205208409)

[10. Eligibility criteria 14](#_Toc205208410)

[Retail outlets 14](#_Toc205208411)

[Wholesalers 14](#_Toc205208412)

[11. Sample 15](#_Toc205208413)

[Sample size of retail outlets 15](#_Toc205208414)

[Sampling approach 16](#_Toc205208415)

[Booster sample 17](#_Toc205208416)

[Outlet census 17](#_Toc205208417)

[Identifying retail outlets 17](#_Toc205208418)

[Wholesaler sample size 18](#_Toc205208419)

[Identification of wholesale outlets 18](#_Toc205208420)

[12. Team structure 19](#_Toc205208421)

[13. Data collection 19](#_Toc205208422)

[Research agency roles and responsibilities 19](#_Toc205208423)

[Training 20](#_Toc205208424)

[14. Field procedures 21](#_Toc205208425)

[Retail outlets 21](#_Toc205208426)

[Wholesale outlets 22](#_Toc205208427)

[15. Interviews 23](#_Toc205208428)

[16. Field monitoring and quality control 24](#_Toc205208429)

[17. Data management and analysis 25](#_Toc205208430)

[18. Data ownership 28](#_Toc205208431)

[19. Dissemination and data use 28](#_Toc205208432)

[20. Ethical considerations 28](#_Toc205208433)

[21. Confidentiality 28](#_Toc205208434)

[22. Individual consent 29](#_Toc205208435)

[Oral consent 30](#_Toc205208436)

[23. Management of ethically sensitive findings 30](#_Toc205208437)

[24. Study team roles and responsibilities 30](#_Toc205208438)

[Research ethics 31](#_Toc205208439)

[Study activities 31](#_Toc205208440)

[25. Steering Committee and its responsibilities 32](#_Toc205208441)

[26. Timeline 32](#_Toc205208442)

[27. Guidance on country-level protocol adaptations to maintain methodological integrity 33](#_Toc205208443)

[ANNEXES 35](#_Toc205208444)

[Annex I: Study Information Sheets 35](#_Toc205208445)

[Annex I.A Qualitative Study Information Sheet for Importers/ Wholesalers 35](#_Toc205208446)

[Annex I.B Quantitative Study Information Sheets for Formal Outlets 37](#_Toc205208447)

[Annex I.B.ii Quantitative Study Information Sheets for Informal outlets 39](#_Toc205208448)

[Annex  II: Verbal Consent Form 41](#_Toc205208449)

[Annex III: Interview guide 42](#_Toc205208450)

[Annex IV: Market study questionnaire 42](#_Toc205208451)

[Annex V: Country-level protocol adaptation checklist 42](#_Toc205208452)

**List of abbreviations**

|  |  |
| --- | --- |
| ACT | *Artemisinin-based combination therapy* |
| AL | *Artemether-Lumefantrine* |
| AS-AQ | *Artesunate Amodiaquine* |
| CHW | *Community Health Worker* |
| CQ | *Chloroquine* |
| DHS | *Demographic and Health Survey* |
| GMP | *Good manufacturing practices* |
| GPS | *Global Positioning System* |
| HMIS | *Health Management Information System* |
| NGO | *Non-governmental organization* |
| PMI | *US President’s Malaria Initiative* |
| POS | *Point of sale* |
| PPMV | *Patent proprietary medicine vendor* |
| PPS | *Probability Proportionate to Size* |
| PSI | *Population Services International* |
| QAACT | *Quality assured artemisinin combination therapy* |
| RDT | *Rapid diagnostic test* |
| SP | *Sulfadoxine Pyrimethamine* |
| WHO | *World Health Organization* |

**[ADD OTHER CONTEXT-RELEVANT ABBREVIATIONS]**

# Definitions and Key concepts

|  |  |
| --- | --- |
| **ACT** | Artemisin-Based combination |
| **Cluster** | The main sampling unit for the point-of-sale survey. This is the administrative unit used to carry out the surveys. For market research, administrative units of around 10,000-15,000 inhabitants are accepted. This is the case in countries where the ACTwatch project has been carried out in the past, and where at least one health facility or pharmacy could be found. In Nigeria and Benin, such administrative units correspond to health areas and communes, respectively. |
| **Additional or boosted sample** | An additional sample or booster is obtained by expanding the primary administrative unit to correspond to a larger administrative unit in order to obtain some additional outlets. In this survey, an additional sample is envisaged to obtain a higher number of pharmacies and pharmaceutical depots. |
| **Supply chain levels** | This study attempts to map the private sector malaria commodity supply chain and gather information at each level. General supply chain levels have been defined throughout as:   * Retail: outlets that sell directly to consumers (i.e. not for resale) * Wholesale: outlets that sell to other outlets or providers for resale. These may be terminal wholesalers that supply retail outlets or intermediate wholesalers that also or exclusively supply other wholesalers * Importer: entities that import malaria commodities for resale to wholesale or retail outlets |
| **Retail outlet types** | This study aims to capture information on malaria commodity availability, sales volumes, and prices from the private sector. Businesses, facilities, and other entities are referred to as outlets. The types of outlets included in the study are:   * Private not-for-profit (non-governmental (NGO) or mission/faith-based) health facilities including hospitals and clinics. * Private for-profit health facilities including hospitals, clinics, and diagnostic laboratories * Pharmacies including stand-alone retail pharmacies/ community pharmacies and pharmacies linked to health facilities * [LIST AND DEFINE OTHER OUTLET TYPES THAT WILL BE INCLUDED IN THE STUDY] |

[ADD OTHER CONTEXT-RELEVANT DEFINITIONS AND CONCEPTS]

# Executive summary

[TO BE COMPLETED. Provide a concise summary of study background, objectives, methods, and expected outputs and their use or relevance for the malaria program.]

# Introduction

A detailed study of the market for antimalarial products and malaria diagnostic testing services and products in the private sector will be conducted in [COUNTRY] in [YEAR] using methods adapted from the ACTwatch Lite project’s previous rounds in Benin, Cameroon and Nigeria (documentation available from <https://www.psi.org/actwatch-lite>). This project is designed to provide timely, relevant, and high-quality data on the market for antimalarial medicines and malaria diagnostic test services and products, including Rapid Diagnostic Tests (RDTs). The aim of this project is to inform and monitor national and global policy, strategy, and funding decisions to improve malaria case management. The ACTwatch Lite project has developed and used standardized tools and approaches for sampling, data collection and analysis to provide comparable data across countries and overtime.

The survey will provide updated data on the private sector malaria market, including the availability, price, and market share of antimalarials, as well as the availability and price of rapid diagnostic tests for malaria. The survey will collect data on supply chain characteristics, including local and national distribution networks, readiness for digital surveillance and engagement, and digital capacity. [ADD INFORMATION ON ANY PREVIOUS SIMILAR STUDIEDS HERE.] Estimates will be provided for the private sector, for [INCLUDE ANY STRATIFACTION PLANNED, E.G. URBAN/RURAL] levels, as well as for formal and informal outlets. Estimates will also be provided for the main types of outlets: [E.G. HOSPITALS, HEALTH FACILITIES, LABS, PHARMACIES, DRUG SHOPS, AND OTHER INFORMAL OUTLETS]

In addition to evidence on the availability, price, and market composition of malaria commodities in the private sector, this study will provide insight into malaria case management practices in the private sector. Specifically, the study captures [SUMMARIZE ADDITIONAL PROVIDER INTERVIEWS SELECTED FROM THE INDICATOR TABLE TO BE INCLUDED IN THIS STUDY; FOR EXAMPLE? “provider knowledge and reported adherence to case management guidelines, current case reporting practices in private sector outlets and their capacity and readiness to engage in surveillance activities. Note that the indicators and data collected on these topics using the baseline toolkit questionnaire are limited. If these are questions of particular interest, additional indicators/ questions can be added to the provider interview and should be detailed here.]

Therefore, the data collected through this market study will inform interventions to be implemented to support the strengthening of private sector surveillance and case management in [COUNTRY] and provide a means of measuring progress.

# Background

# ACTwatch Lite

Between 2007 and 2016, the ACTwatch project was implemented by Population Services International (PSI) in collaboration with ministries of health in 13 African and Southeast Asian countries to conduct over 50 market surveys on malaria. [IF ACTWATCH OR A SIMILAR STUDY HAS BEEN CONDUCTED PREVIOUSLY IN YOUR COUNTRY, INCLUDE DETAILS HERE. YEAR OF STUDY, KEY RESULTS AND/OR KEY POLICY EFFECTS FROM THE STUDY]. Since the ACTwatch project’s end in 2016, policy adoption and action at national level to engage the private health market in malaria case management has not greatly advanced. A key brake on progress is the lack of robust, contemporary data on private sector malaria markets that can be used by national decision-makers and their global partners to support appropriate intervention design.

To address this information gap, [YOUR ORGANIZATION NAME] is implementing ACTwatch Lite, building on methodologies and tools developed by PSI with funding from the Gates Foundation. The project aims to conduct modernized and streamlined malaria market studies to provide governments and their partners with relevant and more quickly available private sector data for strategic planning and interventions.

In [YEAR], an ACTwatch Lite private sector malaria commodity outlet survey will be conducted in [NAME REGIONS OF COUNTRY NAME]. This survey will focus on the formal and informal private sector and be conducted using electronic data collection forms developed using ODK.

# Malaria in [COUNTRY NAME]

### Malaria burden and risk

[Provide a concise summary of the current malaria burden and response in the country or study area. Include the latest available data on:

* Malaria prevalence, morbidity, and mortality, disaggregated by region and population sub-groups
* Treatment-seeking behavior and testing/treatment coverage (e.g., ACT use), specifically the
* Role of the private sector in malaria case management e.g. size
* Progress against national malaria strategies or interventions
* Recent malaria stratification, including any information on drug resistance
* Size and scope of public vs. private health sectors

Use recent and relevant sources (e.g., MIS, DHS, PMI MOPs, national policy documents), and cite all data sources.

|  |
| --- |
| Figure 1 Map of malaria prevalence |
| [CONSIDER INCLUDING A MAP OF MALARIA PREVALENCE HERE] |
| *Source: [NAME SOURCE]* |

### Malaria case management guidelines

Diagnosis

[OUTLINE CURRENT NATIONAL DIAGNOSTIC GUIDELINES HERE, INCLUDE CITATIONS FOR ANY SOURCES]

Treatment

[OUTLINE CURRENT NATIONAL TREATMENT GUIDELINES HERE FOR BOTH SEVERE AND UNCOMPLICATED MALARIA INCLDUING FOR SPECIFIC GROUPS (PREGNANT WOMEN, INFANTS, ETC.) INCLUDE CITATIONS FOR ANY SOURCES]

### Private health sector and supply chain

[DESCRIBE COUNTRY’S PRIVATE HEALTH SECTOR HERE, INCLUDING OUTLET TYPES, REGISTRATION AND FORMAL/ INFORMAL SECTORS. INCLUDE INFORMATION ABOUT REGUALTIONS AND REGUATORS, AND SUPPLY CHAINS IF AVAILABLE. INCLUDE CITATIONS FOR ANY SOURCES]

### [IF RELEVANT:] Findings from previous ACTwatch studies

In [COUNTRY], ACTwatch studies were conducted in [YEAR]. Results from the last national-level ACTwatch study in [YEAR] showed that... [OUTLINE KEY FINDINGS]

# Study rationale

The [YEAR] Private Sector Malaria Market Survey will provide up-to-date findings on the malaria market, including the availability, price, and market share of antimalarials, as well as the availability and price of malaria blood tests. The survey will collect data on supply chain characteristics, including national, regional, and local distribution networks, provider knowledge, surveillance and digital engagement readiness, and digital capacity. Estimates will be produced for the formal and informal private health sector in both urban and rural areas, and in key outlet types, including private health facilities and retail pharmacies. The study will be carried out in [NAME REGIONS, IF APPROPRIATE]

The study is designed to provide timely, relevant and quality data on the market for antimalarial products. The aim of this data is to inform and monitor national and global policy, strategy and funding decisions to improve malaria case management. This study uses standardized tools and approaches from the ACTwatch Lite project which will be used for sampling, data collection and analysis to provide comparable data across countries and over time.

The evidence generated are essential components in measuring system readiness and performance for malaria case management in the context of recent strategies and investments to improve supply chains and case management including:

[OUTLINE THE KEY NATIONAL/ GLOBAL STRATEGIES OF RELEVANCE TO THE STUDY HERE. WE RECOMMEND DISCUSSING THESE KEY THEMES WITH STAKEHOLDERS.

FOR EXAMPLE:

1. CASE MANAGEMENT GUIDELINES STIPULATING CONFIRMATORY TESTING (RDT OR MICROSCOPY) PRIOR TO TREATMENT. ACT TREATMENT SHOULD ONLY BE GIVEN TO PEOPLE WITH A POSITIVE MALARIA BLOOD TEST.
2. THE BROADENING OF THE MALARIA CASE MANAGEMENT GUIDELINES TO NAME FOUR FIRST-LINE ACT TREATMENTS FOR MALARIA (ARTEMETHER-LUMEFANTRINE, ARTESUNATE-AMODIAQUINE, DIHYDROARTEMISININ-PIPERAQUINE AND ARTESUNATE-PYRONARIDINE).
3. THE SPECIFIC FOCUS ON PRIVATE HEALTH PROVIDERS’ CONTRIBUTION TO MALARIA CASE MANAGEMENT IN THE NATIONAL MALARIA STRATEGIC PLAN [YEAR], INCLUDING STRATEGIES TO BUILD CAPACITY FOR PARASITOLOGICAL CONFIRMATION OF MALARIA AND MANAGEMENT OF SEVERE MALARIA.
4. THE SPECIFIC FOCUS ON THE PRIVATE HEALTH SECTOR’S CONTRIBUTION TO SURVEILLANCE IN THE STRATEGIC PLAN,
5. ONGOING AND RENEWED DIALOGUE ON THE ROLE OF THE PRVIATE SECTOR IN PROVIDING ESSENTIAL HEALTH SERVICES AND CONTRIBUTING TO UNIVERSAL HEALTH COVERAGE, PARTICULARLY CONSIDERING THE COVID-19 PANDEMIC.]

In addition, the data collected as part of the [YEAR] market study will serve as a basis for defining the interventions to be implemented in the market to support the strengthening of case management in the private sector in [COUNTRY] and will provide a means of measuring progress.

# Research objectives

The goal ofthe study is to describe the private sector market for antimalarials and diagnostic tests in [COUNTRY], focusing on product availability, price and market share, companies' digital capability and readiness, and distribution networks. The **specific objectives** are to:

[EXAMPLES ARE PROVIDED BELOW; PLEASE REVIEW AND EDIT THESE TO FIT WITH YOUR STUDY OBJECTIVES AND SPECIFIC CONTEXT.

* Determine the characteristics of the retail market (private health facilities, faith-based health facilities, pharmacies, and pharmaceutical depots, PPMVs and online sources) for antimalarials and malaria diagnostic tests.
* Determine the characteristics of the wholesale market for antimalarial drugs and malaria diagnostic tests; and
* Assess the supply chain structure for antimalarials and RDTs, in terms of importer networks, wholesaler distribution, and common distribution practices.

To achieve these objectives, ACTwatch Lite is designed to provide the following estimates in the private health sector in the three selected states, as well as in urban and rural areas, and within the main outlet types:

1. Availability of all types of antimalarial drugs (ACTs, non-artemisinin combination therapies, monotherapies, etc.) and brands currently on the market.
2. Availability of diagnostic tests for malaria, including microcopy and RDT.
3. Private sector retail prices for all types of antimalarial drugs and brands currently on the market.
4. Private sector retail prices for malaria screening services.
5. Relative market share of antimalarials for all types of antimalarials and common brands with substantial market share.
6. Involvement of the private health sector in national malaria surveillance and reporting.
7. Digital capability of the private healthcare sector and information about online sales

The survey will also provide the following estimates for wholesalers:

1. Availability of all types of antimalarial drugs (ACTs, non-artemisinin combination therapies, monotherapies, etc.) and brands from wholesalers
2. Wholesale buying and selling prices for antimalarial drug by class and for common brands for RDTs.
3. Relative wholesale market share of antimalarials for all types of antimalarials and common brands with substantial market share.
4. Wholesaler distribution networks (scope and scale) and distribution practices.
5. Digital capability of wholesalers and attitudes towards potential digital services in the market.]

The study will have the statistical power required to estimate key market indicators with an accuracy of at least 10 percentage points [SEE [**SAMPLING TOOL**](https://psiorg.sharepoint.com/:f:/r/sites/ACTWatchLite/Shared%20Documents/2.%20Technical/0.%20Toolkit/ACTwatch%20Lite%20Toolkit%20v3%20-%20FINAL%20FOR%20WHO%20REVIEW/06%20Sampling%20tool?csf=1&web=1&e=ddbXI0)**[[1]](#footnote-2)**. 10 IS THE DEFAULT VALUE], in urban and rural areas and for the main types of outlets.

# Methods

# Study design

ACTwatch Lite is a quantitative and qualitative cross-sectional outlet survey with components each used to collect data at various levels of the supply chain for antimalarials and RDTs to comprehensively describe the private sector market. The components are:

[NOTE THAT THESE MAY VARY ACCORDING TO WHICH PARTS OF THE STUDY ARE BEING IMPLEMENTED:]

1. Key informant interviews with importers of antimalarial products and RDTs serving wholesale outlets (importers).
2. Market survey of wholesalers of antimalarial products and RDTs serving retail outlets (wholesale outlets).
3. Market survey of retail outlets supplying antimalarials and/or RDTs and malaria diagnostic testing services (retail outlets).

### Component 1: Importer and/or local manufacturer component

A list of all known importers and local pharmaceutical manufacturers [IF REVELANT/ PRESENT IN COUNTRY], registered with the national drug authority, will be drawn up. Depending on the total number of importers/ local pharmaceutical manufacturers identified, a representative number will be selected for qualitative data collection. The importers will be selected to ensure maximum variability in the sample, based on organization size and geographic scope of distribution. National-level staff from each of the selected importers/ local pharmaceutical manufacturers of antimalarial products and RDTs serving wholesalers across [COUNTRY] will be targeted to complete a quantitative questionnaire. A subsample will be randomly selected for additional in-depth qualitative key informant interviews. Because of their expertise, representatives from these companies are expected to provide information on the overall structure and characteristics of private sector supply chains for antimalarials and RDTs.

These companies will be contacted by a member of the research team to arrange an interview using a standard information sheet (Annex I: Study Information Sheets). The target participants for both the qualitative and quantitative data collection will be senior staff employed in each company who can talk about the company's commercial decision-making and distribution network and any associated wholesalers.

Companies will be contacted with an introduction to the study and purpose. An interview time and date will be set up. At a predetermined date and time, a member of the research team will conduct an interview with targeted staff at the company’s head office, using either the quantitative tool (all importers/manufacturers), or the qualitative and then quantitative tools (sample of importers/manufacturers). First, the members of the research team will obtain consent from the participant (Annex II: Verbal Consent Form). The consent form for the qualitative interviews will include a request for permission to record the interview. If the participant refuses to record but consents to be interviewed, the interview will not be recorded, and careful notes will be taken.

For the qualitative data collection, using a semi-structured interview guide (Annex III: Interview guide), participants will be asked questions about private sector antimalarial drug and RDT supply chains in [COUNTRY], as well as their company’s role in these supply chains, general estimates of the number of suppliers at each level, their perception of key factors affecting supply, and the effectiveness of regulation.

For the quantitative data collection, a short questionnaire will be used to collect data on volumes and types of antimalarial/mRDT products imported and distributed, characteristics of their distribution networks and buyers, and price data (Annex IV: Market study questionnaire).

These interviews will also serve to introduce the study to these head offices, which can then facilitate data collection from their branch offices, as required.

### Components 2 & 3: Market Surveys

**The following method describes the approach of components 2 and 3 (quantitative market research) unless specific reference is made to component 1.**

# Conceptual framework

The ACTwatch Lite private sector outlet study is designed to generate high-quality, context-specific evidence on the availability, affordability, and distribution of antimalarial drugs and diagnostic tools in the private sector. By documenting key indicators such as stock levels, retail and wholesale prices, market composition, and provider practices, the study provides national malaria programs with the data needed to monitor case management performance and identify gaps in access to quality commodities. It also examines digital readiness and participation in surveillance systems, offering insights into the feasibility of integrating private providers into national health information systems.

These data directly inform malaria control strategies by enabling evidence-based planning, resource allocation, and policy development. For example, findings can guide the targeting of training, regulation, and subsidy programs for private providers, support decisions around commodity distribution, and highlight opportunities to expand test-before-treat practices. Ultimately, by strengthening the role of the private sector in delivering effective malaria diagnosis and treatment, and by supporting its integration into surveillance systems, the study contributes to broader malaria control and elimination goals, including those set by national strategic plans and the WHO Global Technical Strategy for Malaria.

# Scope

### Geographical coverage

[DESCRIBE GEOGRAPHIC COVERAGE OF THE STUDY, INCLUDING STATES/REGIONS/SUB-REGIONS INCLUDED, AS APPROPRIATE, WITH JUSTIFICATIONS. CONSIDER INCLUDING A MAP OF SELECTED GEOGRAPHIES]

### Stratification

[ACTWATCH LITE SAMPLE STRATIFICATION MIGHT INCLUDE REGION, URBAN/RURAL, ETC. DESCRIBE ANY STRATIFICATION FOR THE SAMPLING HERE.]

### Study population

The main population of interest in this study is all private outlets likely to sell or supply antimalarial drugs or diagnostic tests for malaria in selected study areas. In this study, outlets are not limited to “bricks and mortar” points of sale, but also to mobile units, such as street vendors. The wholesaler market research component includes wholesalers serving the outlets included in the retail research component. For all outlet types, a full census of any outlet with potential to sell malaria commodities will be screened for inclusion in the study based on criteria in the next section. [ADD A NOTE ON WHAT DATA WILL/ WILL NOT BE COLLECTED FROM INFORMAL OUTLETS E.G. GPS AND PROVIDER INTERVIEW DATA]. In [COUNTRY], the following outlets will be evaluated to determine whether they meet the study criteria:

[INCLUDE THE FULL LIST OF TYPES OF PRIVATE SECTOR OUTLETS TO BE INCLUDED IN THE STUDY HERE. THIS LIST SHOULD BE CONFIRMED WITH KEY STAKEHOLDERS, AND TYPICALLY INCLUDES BOTH FORMAL AND INFORMAL OUTLET TYPES; WE HAVE PROVIDED SOME EXAMPLES BELOW]

|  |  |
| --- | --- |
| Table 1 **Outlet types** | |
| Private not-for-profit health facilities | Non-governmental (NGO) or mission/faith-based health facilities including hospitals and clinics. |
| Private for-profit health facilities | Private hospitals, clinics, and diagnostic laboratories providing diagnosis and treatment at commercial rates. |
| Pharmacies | Pharmacies are licensed by [NAME] and are authorized to sell all classes of medicines including prescription-only medicines. Pharmacies are regulated by [NAME OF REGULATOR]. Pharmacies are owned by registered pharmacists or owners employing the services of a registered pharmacist |
| **Wholesale outlets** | |
| Terminal wholesaler | Wholesalers that supply the above retail outlets and facilities directly |
| Intermediate wholesalers | Wholesalers that supply other wholesalers only |

### Antimalarial drugs

The study will include an audit of all types and formulations of factory-manufactured antimalarials found at outlets in the study area, whether used in in-patient or out-patient settings. The study will exclude complementary products, such as gloves, drops, water and syringes. The study will also exclude homemade remedies, herbal remedies, and other non-factory-made medicinal products.

### Malaria diagnostic tests

The study will focus on the availability and price of malaria microscopy services and RDTs. The survey will exclude microscope components (such as slides and stains) because of the difficulty of distinguishing those used for malaria diagnosis from those used for other diagnostic purposes.

# Eligibility criteria

[EDIT THIS SECTION AS REQUIRED]

### Retail outlets

At retail level, all formal and informal outlets in the private sector likely to sell or distribute antimalarials will be identified. Outlets will be eligible for the study (to complete an interview with the provider or their representative and an audit of antimalarial products and diagnostics) if they meet at least one of three study criteria:

1. One or more antimalarial drugs are in stock on the day of the survey;
2. One or more antimalarial drugs were in stock during the three months preceding the survey; and/or
3. Offer of diagnostic tests for malaria on the day of the survey (RDT or microscopy).

### Wholesalers

Among wholesalers, all pharmaceutical and medical supply businesses identified as the main suppliers of retailers included in the retail outlet market survey (component 3) will be eligible for the survey if the establishment has antimalarials or RDTs in stock at the time of the interview or at any time in the 3 months prior to the interview. Any other wholesaler in the targeted geographical areas who has been engaged in the wholesale of any antimalarial drug and/or malaria rapid diagnostic test in the three months prior to the survey will be eligible for the study.

Inclusion/Exclusion criteria:

|  |  |  |
| --- | --- | --- |
|  | Inclusion | Exclusion |
| Retail outlets | Is located in study area  Provider/ representative/ outlet owner consents to participate  Has one or more antimalarial drugs in stock on the day of the survey;  and/or one or more antimalarial drugs were in stock during the three months preceding the survey;  and/or offer of diagnostic tests for malaria on the day of the survey (RDT or microscopy). | Outlet located outside of study area  No representative available to consent to participate or does not consent. |
| Wholesalers | Identified by an included retail outlet or another source as a source of antimalarials and/or mRDTs (may be located outside study area)  And/or is inside study area and supplies antimalarials and/or mRDTs to wholesale customers  Provider/ representative/ outlet owner consents to participate | No representative available to consent to participate, or does not consent. |
| Importers | Imports antimalarials and/or mRDTs to [COUNTRY] | No representative available to consent to participate, or does not consent. |

# Sample

[REFER ALSO TO THE SAMPLE SIZE CALCULATOR TOOL. NOTE THAT KEY INPUTS TO THE SAMPLE SIZE CALCULATION CAN BE MODIFIED AND SHOULD MATCH BETWEEN THIS DOCUMENT AND THE TOOL].

### Sample size of retail outlets

A series of calculations were carried out to identify the minimum sample size requirements for retail outlets needed to estimate key study indicators with a precision [INCLUDE NUMBER HERE. DEFAULT IS 10] percentage points in [NAME STUDY STRATA HERE]. Data on the expected composition of outlets within [INCLDUE THE NAME OF THE ADMINISTRATIVE LEVEL FOR THE STUDY AREAS WITH A POPULATION OF 10-15K] are based on [EXPLAIN WHERE THE ESTIMATES FOR NUMBER OF KEY OUTLET TYPES PER STUDY AREA COME FROM].

The proposed number of sampled clusters and expected resulting number of outlets are outlined in tables 2 and 3 below. The sample sizes aim to be sufficient to estimate the market indicators (as proportions) with an estimated minimum level of absolute precision of [INCLUDE NUMBER HERE. DEFAULT IS 10]. The following formula and assumptions have been used to estimate the number of outlets required:

Where:

***n*** = desired sample size (by urban/rural area and by outlet type)

**P** = assumption concerning the proportion of the population, equal to [INCLUDE VALUE HERE FROM SAMPLE SIZE CALCULATOR, DEFAULT IS 0.5].

**Z1-α** = normal value of standard deviation 1-α corresponding to an α error (type I) with a two-tailed test

**d** = the desired absolute precision of the estimate / half the width of the desired confidence interval, equal to [INCLUDE VALUE HERE FROM SAMPLE SIZE CALCULATOR, DEFAULT IS 0.1].

**deff** = the sampling effect in the case of multi-stage sampling, estimated as [INCLUDE VALUE HERE FROM SAMPLE SIZE CALCULATOR, DEFAULT IS 2.0] in this study.

**nrr =** non-response rate/ refusal rate, estimated as [INCLUDE VALUE HERE FROM SAMPLE SIZE CALCULATOR, DEFAULT IS 0.05] in this study.

Table 2 Expected number of outlets surveyed

[INSERT TABLE FROM INPUT TAB OF SAMPLE SIZE CALCULATOR]

### Sampling approach

The number of geographic units to be sampled is based on the estimates shown in Table 2 above.

The study will adapt the geographic cluster sampling approach used by ACTwatch Lite and other market surveys. The main sampling approach adopted for market surveys is to sample a set of administrative units (geographical clusters) with a corresponding population of around 10,000 to 15,000 inhabitants.

The appropriate administrative unit in [COUNTRY NAME] corresponding to this desired population size is the [INSERT THE NAME OF THE ADMINISTRATIVE UNIT THAT HAS A POP OF 10-15K PEOPLE], which are an administrative unit grouped together within [NAME THE NEXT ADMINISTRATIVE UNIT ABOVE] the next highest administrative unit, themselves grouped by [STATE/PROVINCE/REGION, ETC.].

[DESCRIBE HOW MANY OF EACH ADMIN DIVISION THERE ARE, AND THE ORGANSIATION OF THEM, INCLUDING GEOGRAPHIC INFORMATION AS RELEVANT].

The sampling approach will follow a probability proportional to size (PPS) design [INCLUDE ANY INFORMATION ABOUT CLUSTER SAMPLING, IF THIS IS BEING USED HERE], stratified by [NAME THE STRATA], with the following steps:

[BELOW, DESCRIBE IN A STEPWISE WAY, HOW THE PPS SAMPLE WILL BE CONDUCTED. WE HAVE INCLUDED AN EXAMPLE FROM THE 2024 NIGERIA STUDY, WHICH EMPLOYED A CLUSTER SAMPLE APPROACH DRAWN SEPARATELY FOR EACH OF THE THREE STATES INCLUDED IN THE STUDY AND STRATIFIED BY URBAN/RURAL, FOR YOUR REFERENCE, BUT THIS SHOULD BE REPLACED WITH THE SPECIFIC INFORMATION ABOUT YOUR SAMPLING APPROACH]

* Within each of the three states included in the study, all local government areas (LGAs) will be listed, with population size and urban/rural designation.
* Using a probability-proportional-to-size (PPS) approach, the predetermined number of urban and rural LGAs will be selected within each state (Table 3)
* For selected LGAs all localities will be listed with population size and urban/rural designation.
* Using a PPS approach 5 localities per urban/ rural LGA will be selected (where localities are the primary sampling unit, as they represent the areas for which censuses will be conducted; the number of primary sampling units taken under PPS is fixed, 5 is an arbitrary, but realistic number given the expected number of localities per LGA and the need for a pragmatic and logistically feasible sampling strategy).

We expect to sample the following numbers of clusters:

Table 3 Expected number of LGAs and localities

|  |  |  |  |
| --- | --- | --- | --- |
| State | Urban / Rural | Number of LGAs | Number of Localities |
| Abia | Urban | 5 | 25 |
|  | Rural | 4 | 20 |
| Kano | Urban | 6 | 30 |
|  | Rural | 4 | 20 |
| Lagos | Urban | 5 | 25 |
|  | Rural | 1 | 5 |
| TOTAL |  | 25 | 125 |

Guided by the sample size calculations above, **a total of 125 clusters will be selected**.

### Booster sample

Once the clusters have been selected, the lists of [LIST THE KEY OUTLET TYPES HERE ON WHICH THE SAMPLE IS BASED, THIS IS TYPICALLY PHARMACIES AND/OR PRIVATE HEALTH FACILITIES] will be obtained and used to estimate the number of outlets of each type expected to be found in the selected clusters. If necessary, additional pharmacies and health facilities will be selected in a targeted manner (based on proximity to selected clusters) from the official lists until a minimum sample of 100 pharmacies and 100 health facilities is obtained overall (which across states would permit a 9.8% margin of error on any outlet level-disaggregated indicator estimates).

The sampling approach for wholesalers is described in section 4, below.

## Outlet census

In the selected health areas, all points with the potential to distribute anti-malarials or malaria diagnostic tests will be identified and screened for participation in the study.

### Identifying retail outlets

The aim of the retail outlet component is to identify all outlets in the selected health areas that currently stock anti-malarials or tests for malaria (RDT or microscopy), or that report having stocked up in the three months prior to the survey. In addition to official retail outlets, medicines are often sold through "unofficial" channels (without official authorization to open issued by the medicines sales regulatory authority). In some contexts, these unofficial channels are an important source of medical commodities in geographically isolated or low-income areas. Consequently, understanding their stocking and pricing practices is very important, and we must take care to include them in the survey. In [COUNTRY] informal outlets might include the following types [NAME INFORMAL OUTLET TYPES] which will be included in the study [OR PROVIDE REASONS FOR EXCLUSION].

In each of the primary sampling units [I.E. ADMINISTRATIVE UNIT WITH A POPULATION OF 10-15K] included in the study, all retail outlets with the potential to sell or distribute antimalarials or tests to a consumer will be sampled (Table 1).[[2]](#footnote-3) A full census will be carried out to enumerate all outlets with the potential to stock malaria commodities, that is, the aim of the outlet survey is to identify every private sector outlet in the study area.

Retail outlets will be identified using 3 approaches:

1. Official lists of various outlet types as available (e.g. list of pharmacies)
2. Consultation with local authorities and officials in the selected health districts/areas. Supervisors will need to identify key informants who can guide them to outlets with the potential to sell medicines, which may include health officials, local political or administrative authorities, and other well-informed community members. In discussions with these key informants, the interviewers should obtain a list of potential retail outlets and draw up a data collection plan.
3. Finally, the “snowball technique” will be used by asking outlets included in the survey through approaches 1 and 2 to identify other outlets with the potential to stock medicines in the surrounding area.

Closed outlets and those refusing to participate will be recorded. If the outlet is not definitively closed, the investigators will make two additional visits to these outlets before recording the outlet/ provider as unavailable for screening or interview.

### Wholesaler sample size

[PROVIDE INFORMATION HERE ON THE ESTIMATED UNIVERSE OF ANTIMALARIAL AND MALARIA RDT WHOLESALERS IN YOUR COUNTRY. OFTEN OFFICIAL LISTS MAY EXIST THAT WILL ALLOW FOR THIS OVERVIEW. IF NO SUCH LIST EXISTS, INCLUDE INFORMATION FROM NATIONAL REGULATORS/ TRADE BODIES, OR NOTE THAT NO INFORMATION EXISTS].

### Identification of wholesale outlets

At each retail outlet where an interview is conducted (eligible, consenting outlets) the questionnaire will capture (1) if the retail outlet also sells malaria commodities wholesale and (2) information on the retail outlet’s primary suppliers (name, location, business practices). The information on primary suppliers (from 2) will be compiled to form a running sampling frame during the retail survey fieldwork. Once fieldwork is complete in a given PSU, the research team will randomly select a sample of identified suppliers.

A current list of wholesalers selected for the study will be sent to study supervisors and will be maintained and updated in real time, to enable supervisors to plan field activities to meet sampling requirements at both retail and wholesale levels.

Only the level of the supply chain closest to retail outlets will be tracked using this approach. Further data on the import and wholesale of antimalarial products will be obtained from importers at national level. These companies will be selected on a targeted basis and invited to participate in an interview with selected team leaders or supervisors responsible for this activity.

To ensure representativeness and methodological rigor, the sampling approach will use the most recent and validated national sampling frames available. These may include population estimates from the national statistics office, recent census data, or health facility master lists validated by the Ministry of Health or National Malaria Control Program (NMCP). For retail outlets, official pharmacy and health facility registries will be used where available, complemented by local administrative records and community mapping exercises.

The selection of sampling units (e.g., communes, health areas, LGAs) will follow a probability proportional to size (PPS) design based on updated population figures. Within selected units, full censuses of eligible outlets will be conducted to construct a robust sampling frame, ensuring inclusion of both formal and informal providers. Where necessary, additional or booster sampling will be employed to ensure adequate representation of key outlet types, such as private pharmacies and informal vendors, especially in urban or underserved areas.

# Team structure

Can we add here narrative and maybe a diagram for team(s) structure for implementing a study? Include stakeholders/ government, core research team, data collection agency, etc?

# Data collection

[THIS SECTION WILL NEED TO BE MODIFIED BASED ON LOCAL CONDITIONS, AND THE PLANNED IMPLEMENTATION. WE OUTLINE SOME ROLES AND RESPONSIBILITIES BELOW FOR AN IMPLEMENTATION OF ACTWATCH LITE THAT USES A DATA COLLECTION AGENCY. OTHER APPROACHES MIGHT INCLUDE DIRECTLY RECRUITING AND MANAGING FIELDWORKERS OR CONSULTANTS. EXAMPLE TORS FOR THESE DIFFERENT SCENARIOS MAY BE FOUND IN THE ACTWATCH LITE TOOLKIT]

## Research agency roles and responsibilities

A research agency or data collection firm will be recruited to conduct data collection. Data collection will be carried out by teams of interviewers and supervisors. The research agency selected will be responsible for data collection at retail and wholesale outlets (components 2 and 3). The ACTwatch Lite study team will provide supervision and quality control of fieldwork. A member of the ACTwatch Lite research team will oversee training and initial data collection as an additional means of ensuring quality. Members of the ACTwatch Lite study team will also provide remote data quality control and support the compilation and sampling of wholesale outlets for the wholesaler interview component.

Fieldworkers should have at least a bachelor’s degree in health sciences, pharmacology or social sciences, or equivalent experience, as well as experience in data collection, speak the main languages of the study areas in which they will be working, and be familiar with the use of mobile phones/tablets for data collection. Preference will be given to field staff with pharmaceutical education or training, for whom the technical details of antimalarial products can be quickly mastered.

The selected data collection agency will determine the number of teams and surveyors within each team that will collect data across study sites. Each team will have a team leader who will assume the combined roles of supervisor and quality controller. Team leaders will be chosen based on previous data collection experience, evidence of excellence during survey training, and proven leadership skills. Team leaders will ensure that information collected in the field is valid and correct, and to assist in the day-to-day management of electronic data. 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. Field data collection will last approximately [INCLUDE ESTIMATED TIME FOR DATA COLLECTION HERE].

The core study team will:

* Present the study to national authorities and partners and engage relevant stakeholders throughout the study development, implementation, and dissemination.
* Be responsible for submission of the study for national IRB/National Ethical Review Committee and regulatory approvals.
* Facilitate interviews with national-level importers at their headquarters.
* Identify and hire a research agency to conduct data collection.
* Conduct training sessions with research agency.
* Supervise fieldwork, including monitoring execution of the research protocol methodology and overseeing data quality control.
* Facilitate dissemination of the study results and use of study data by government and local stakeholders after analysis.

The research agency will provide a field report at the end summarizing all stages of the data collection process and noting any lessons learned. The ACTwatch Lite team member(s) in the field will supervise data collection to ensure quality, that the research protocol is followed, and that the data is well managed (daily download, secure computers, etc.).

### Training

All field agents will be required to undergo project-specific data collection training, using standardized training materials. Field agents will be trained for a total of 10 days. This will include 7 days of classroom theory and 3 days in the field, where teams will practice the survey methodology in a district not included in the main study. These three days will also be used to field-test the remote processes for registering, sampling, and recording wholesale outlets.

Investigators will be trained on the purpose of the study, the importance of consent and how to administer both consent forms and electronic questionnaires. A key element of the training will cover the identification of antimalarial drugs (and RDTs) including the differences between different types, brand names and active ingredients, dose forms and package types. Team leaders will receive a further 2 days’ training to learn field supervision and quality control procedures, as well as how to download, revise and send electronic data to the server.

The number of field agents that undergo training will be higher than the number actually required for data collection. During training, tests will be administered to select the highest performing agents. This will be communicated to all agents before the start of training.

# Field procedures

### Retail outlets

In each of the selected PSU’s (primary sampling units – administrative areas of 10-15k population), surveyors will include all outlets that have the potential to stock antimalarials and diagnostic tests, according to the study inclusion/exclusion criteria. To ensure that all outlets with the potential to sell or distribute antimalarials and diagnostic tests in the sampled area are visited, the following methods will be used before and during data collection:

[OUTLINE PROCEDURES BELOW. WE HAVE INCLUDED EXAMPLE INFORMATION BELOW]

1. Once in the field, supervisors will visit the head doctor or competent local authority of the study area (district or health area) to obtain his/her approval and find out where anti-malarial drugs / tests are usually sold.
2. Based on step 1, the research team will provide interviewers with a list of all private and faith-based health facilities, and pharmacies, registered in the selected health area (and district).
3. After surveying the boundaries of the selected study area, with the help of district chiefs, the surveyors will identify all retail outlets with the potential to store, sell and distribute anti-malarial drugs and tests. Once a retail outlet has been surveyed and the provider interviewed, the surveyors will ask the owners of the retail outlet or their collaborators to indicate the other retail outlets in the health area that can market anti-malarials.

For eligible outlets, interviewers will be asked to provide information on the study and to interview the manager, head pharmacist, or whomever is best positioned to provide reliable information on stock and sales volumes. If there are several providers working in the outlet, the most senior will be asked to complete the interview. If he/she is unavailable, the next most senior provider will be invited to complete the interview, and so on. In all cases, the participant will be interviewed in a discreet location away from colleagues and/or superiors.

In each retail outlet, the provider will first be approached to ask for his or her agreement to participate, using the information sheet and informed consent form described in Annex I: Study Information Sheets and Annex  II: Verbal Consent Form

. Once consent has been obtained, the provider interview will be conducted and then antimalarials and RDTs will be audited. If a retail outlet is closed or the provider is too busy, the interviewer will return at another time. A maximum of three visits will be made to a given outlet; interviewers will be encouraged to make an appointment on the same day as the initial visit and at a time agreed with the provider. This will help to reduce the time spent in a given locality. Records of refusals and of outlets closed at the time of the survey will be kept.

[EDIT ACCORDING TO LOCAL REGULATIONS AND STUDY NEEDS: The geographical coordinates (latitude and longitude) of each facility, outlet and business will be recorded using a GPS (Global Positioning System). The justification for capturing GPS points is to ensure data integrity and verifiability, confirm locations in analysis, and bolster the study's credibility and auditability. If retained, GPS data will be masked (using a random jitter) in final publicly available datasets].

Once the interviewer has identified an outlet, screening questions will be administered to determine the eligibility of the outlet. These screening questions include:

1. Do you have any anti-malarial drugs in stock today?
2. Are there any antimalarial drugs or malaria tests that are sold out today that you have stocked in the’ past three months?
3. Are malaria screening services (RDTs or microscopy) available today?

A provider from all eligible outlets will be invited to participate in the full questionnaires. Ineligible outlets will be recorded, and the interviewer will move to the next outlet.

Data collection will take place during working hours. However, data collection times may be adapted to accommodate certain circumstances (e.g. conducting interviews and audits outside of business hours when requested, night markets in certain villages, etc.).

As some outlets/ vendors may be informal and possibly unlicensed, team members will approach providers with sensitivity and caution, and will emphasize the voluntary and anonymous nature of participation. Team members will be encouraged to schedule appointments for informal vendors if participants prefer to meet at a time when they feel more comfortable participating. In rural areas, where markets may move to different villages on different days, the deployment of interviewers will consider the local market calendar to ensure that fieldwork teams target markets when they are taking place.

In all cases, informal retail outlet operators will be reassured that the interview and audit are to understand the malaria commodity market and that no personal identification information will be collected. GPS coordinates will not be collected from informal outlets.

### Wholesale outlets

Field procedures for wholesale outlets are similar to those for retail outlets. The same field team will be responsible for interviewing wholesalers and retailers. Once listing and selection have been carried out by the research team remotely from data collected among outlets in the field, wholesalers will be approached by members of the field team, who will present the survey to the wholesale staff member responsible for malaria-related sales. Wholesalers will be selected for inclusion by checking whether the establishment has antimalarials or RDTs in stock at the time of the interview or at any time in the 3 months prior to the interview. If they are selected for inclusion, informed consent will be obtained (Annex  II: Verbal Consent Form).

# Interviews

A structured questionnaire has been developed, building on previous rounds of ACTwatch Lite. The questionnaire is applicable for both retail and wholesale outlets, with skip logic programmed so that relevant information is gathered from each. The questionnaires are digitalized using Open Data Kit (ODK) and administered by [INCLUDE SOFTWARE NAME HERE] software on Android devices. During fieldwork, a series of screening questions will be asked at points of sale to determine survey eligibility. Retail outlets will be targeted first and wholesale outlets second, as interviews at retail outlets will provide information on their malaria commodity suppliers to facilitate identification of and sampling frames for wholesale outlets.

Following informed consent (confirmed in the questionnaire), an audit of all available antimalarial drugs and RDTs will be carried out. Digitized questionnaires capture details of current products including dosage form, brand name, active ingredient information, and simple packaging characteristics (such as pack type and size). Interviewers will capture point-of-sale and product-specific information, such as the number of sales over the last 7 days, retail price and wholesale price. The digital questionnaire allows photographs to be taken of anti-malarial products and RDTs (with the provider’s permission), to facilitate survey quality checks and data processing. Before the product audit, the provider will be asked a series of questions about business characteristics and practices, staff training and qualifications, involvement in national malaria data monitoring and reporting, and current and future digital capacity. Interviews at wholesale outlets will additionally gather more detailed information on commercial and distribution practices, such as selling price for a range of different sales volumes, credit terms for buying and selling, activities carried out by the supplier, including distribution services offered to buyers and their costs.

The entire questionnaire, including the new and slightly modified questions, will be pre-tested prior to the study to ensure that the questions are correctly interpreted by the participants. Similarly, study information sheets and consent forms will be pre-tested prior to the study. The pre-test will take place in one or two health areas not included in the final selection, close to the training site.

The draft questionnaire is in Annex IV: Market study questionnaire. The questionnaires will be prepared in English. [INCLUDE INFORMATION ON LOCAL LANGUAGES HERE, INCLUDING TOOL TRANSLATION, PRE-TESTING, AND ANY RELEVANT ACTIVITIES DURING FIELDWORKER TRAINING].

Other documents, such as a photo catalog of commonly encountered antimalarials, the interviewer's field guide, and a list of frequently asked questions, will be loaded onto the same Android tablets as the questionnaires as reference documents. Some paper questionnaires will also be available if required.

# Field monitoring and quality control

[THIS SECTION SHOULD BE MODIFIED ACCORDING TO IMPLEMENTATION PLANS. WE INCLUDE SOME EXAMPLE TEXT HERE:

Quality control of data collection and management will be ensured at three levels:

1. **The research agency** will undertake internal quality control with support from the study team in the field. This will include:

* Appropriate and rigorous selection and training of field teams.
* Adherence to procedures established by study documents, including standard operating procedures, training materials, field manuals, data collection follow-up and quality assurance forms.
* Daily supervision of data collection in the field, including interviews, questionnaires completed by interviewers, and checks on all potentially eligible retail outlets.
* Unannounced checks will be carried out by quality controllers on a random sample of 5% of outlets that met the selection criteria and 5% of those that did not. For those meeting the selection criteria, it is not necessary to administer the whole questionnaire again, but rather a quality control visit to assess whether the interview has been carried out, whether some key questions have been answered appropriately, and whether the correct number of antimalarials and RDTs produced have been recorded, accounting for some change in stock over time since the date of data collection. In the case of retail outlets that do not meet the selection criteria, the check must verify that the selection criteria were properly completed. The aim is to ensure that interviewers don't report "no" to these questions, in order to skip the outlet and reduce their workload.

1. **The Research Manager** will carry out quality control, with support from the research team in the field. This will include:

* Make available the training manual and other detailed training materials (including detailed PowerPoint presentations and activities/exercises) validated with the research team.
* Make available and validate with the research team the forms to be used during data collection to track the number of completed questionnaires (documenting problems encountered in the field) and the questionnaires to be used during spot checks.
* Check data and tracking sheets at each level for each element of data collection and management listed above.
* Verify study procedures through field reports, including completeness of checklists.
* Visit selected study areas to monitor compliance with study procedures.
* Support existing quality controls and carry out additional checks during field work.
* Confirm product information and gather additional information, where necessary, to support high-quality data processing and analysis.

1. Members of the **core research team** will carry out quality control as part of data processing, in parallel with field work. This will include:

* Monitor the GPS coordinates and track internal consistency of data collected on a daily basis, examining any outliers or erroneous/ suspicious activity
* Send data quality notifications to field teams in real time and request revisions or corrective action to rectify errors.

# Data management and analysis

Data will be entered at the time of data collection using questionnaires programmed in Open Data Kit (ODK) and administered by [INCLUDE SOFTWARE NAME] software on Android devices. Android devices will be password-protected to make data inaccessible in the event of loss or theft. Questionnaires will be pre-loaded with details of current common products which can be searched instead of manually entered to facilitate audits of anti-malarials and RDTs where product details are already known. Questionnaire logic will be used to flag any unusual or inconsistent data entries. With respondents' permission, photos of new products will be taken to facilitate data processing and quality control. Logic checks will be applied to data on prices and sales volumes.

In addition to quality control approaches in the field, daily remote quality control will be used to automate daily review of data quality and initiate data management in parallel with data collection to facilitate rapid analysis of results once fieldwork is complete.

Data processing and analysis will be carried out using Stata (©StataCorp, College Station, Texas, USA), with syntax documented in Stata "do" files. Sampling weights will be applied to account for variations in the probability of selection.

FPC (finite population correction) will be applied during analysis to adjust standard errors of estimates as a result of a large proportion of a total population being included in the sample. In this case, FPC applies to the number of PSUs selected within higher level administrative units, where these exceed 5% of the total.

A comprehensive analysis plan describes the precise steps to be taken to compile and analyze the data, using and adapting standard approaches documented in Stata do files. Documentation contains detailed guidelines on data cleaning, weighting, numerators and denominators for calculating key indicators, defining and calculating equivalent adult treatment dosages, etc.

Indicators will be calculated as shown in **Table 4 Key Indicators[[3]](#footnote-4)** and presented by outlet type/ stratum. The study's core indicators at product level will be based on data collected during audits of antimalarial products and RDTs. Results on commercial practices and digital engagement will come from interviews with suppliers after the product audits. Data on distribution networks collected and deduced from interviews with importers, wholesalers and retailers at national level will be combined to describe the supply chain of antimalarial products. Additional analysis will examine possible variables that may predict differences in availability, accessibility, and market share of quality ACTs, such as point-of-sale characteristics, provider knowledge, and availability of microscopic malaria tests and RDTs.

The following indicators will be presented for each type of outlet in each stratum [INCLUDE STUDY STRATA HERE].

Table 4 Key Indicators

|  |  |  |
| --- | --- | --- |
| No. | Indicator group | Indicator |
| Core 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 |
| 1.2 | Market Composition among outlets with malaria blood-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. |
| 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 |
| 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 |
| 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 |
| 2.4 | Availability of malaria blood testing in all antimalarial-stocking outlets | Proportion of antimalarial-stocking outlets that had malaria blood testing available on the day of the survey visit, among all outlets surveyed with one or more antimalarials in stock |
| 3.1 | Median sales volume of antimalarial AETDs [3] | Median number of antimalarial AETDs [3] sold in the week preceding the survey, of any outlets stocking antimalarials |
| 3.2 | Median sales volume of antimalarial AETDs [3] among outlets with any sales of that antimalarial type | Median number of antimalarial AETDs [3] sold in the week preceding the survey among outlets with any sales of that type of antimalarial |
| 3.3 | Median sales volume of malaria blood tests | Median number (N) of malaria blood tests conducted/ sold in the week preceding the survey |
| 3.4 | Median sales volume of malaria blood tests among outlets with any sales of that test type | Median number (N) of malaria blood tests conducted/ sold in the week preceding the survey among outlets with any sales of that test type |
| 4.1 | Market share of antimalarials | Proportion of AETD reportedly sold or distributed in the previous week by outlet type and antimalarial type among all AETDs sold/distributed in the previous week. |
| 4.2 | Market share of malaria blood testing overall | Proportion of malaria blood tests reportedly sold or distributed in the previous week by outlet type and malaria blood test type (RDT, microscopy) as a percentage of all malaria blood tests sold/distributed in the previous week. |
| 4.3 | Market share of antimalarials by brand and manufacturer | Proportion of antimalarials sold or distributed in the previous week by outlet type and top brand-manufacture among all antimalarials sold/distributed in the previous week. |
| 5.1 | Sales price of antimalarial tablet AETDs to customers | Median retail price of adult equivalent treatment dose (AETD) for tablet formulation types |
| 5.2 | Sales price of pre-packaged ACTs to customer | Median retail price of selected pre-packaged therapy |
| 5.3 | Sales price of malaria blood testing to customers | Median retail price of blood testing to consumers including any consultation or service fees |
| 6.1 | Purchase price of antimalarial AETDs from suppliers | Median purchase price of adult equivalent treatment dose (AETD) for tablet formulation types from the outlets supplier (e.g. wholesaler) |
| 6.2 | Purchase price of malaria RDTs from suppliers | Median purchase price of RDTs from the outlet's supplier (e.g. wholesaler) |
| 7.1 | Stock outs of antimalarials | Proportion of outlets reporting stockouts of antimalarials by type on the day of survey, among all antimalarial-stocking outlets |
| 7.2 | Stock outs of RDTs | Proportion of outlets reporting stockouts of mRDTs on the day of the survey, among RDT-stocking outlets |
| Additional provider interview indicators |  |  |
| 8.1 | Outlet characteristics | Opening hours: Proportion of outlets open in the daytime only, evening only, both, or other |
| 8.2 | Outlet characteristics | Proportion with license: Proportion of outlets with the relevant license and registration to sell medicines (note this question should be tailored to country-specific licensing policy or processes for private sector outlet type included e.g. license to sell pharmaceuticals) |
| 8.3 | Outlet characteristics | Proportion with govt inspection/ supervision: Proportion of outlets who have received a government inspection/ supervision in the last year (note this question should be tailored to country-specific policy or process on regulation of each private sector outlet type included e.g. pharmacy regulatory bodies and their inspection process) |
| 9.1 | Staff characteristics | Staff health qualifications: Proportion of outlets with at least one member of staff with selected health qualifications (pharmacist, CHW, etc.) |
| 9.2 | Staff characteristics | Staff malaria training: Proportion of outlets with at least one member of staff who have received any training on malaria; by training type/ topic (treatment, diagnosis, monitoring/ surveillance, all, or other) in the last 12 months |
| 10.1 | Quality Control & Compliance | Proportion of products that meet a minimum quality standard (within expiration date, has expected/ nationally mandated registration number(s) and any other quality criteria relevant to the given country of implementation) |
| 10.2 | Quality Control & Compliance | Proportion of outlets that meet a minimum quality standard for product storage (dry, dark area off floor) |
| 11.1 | Respondent malaria knowledge | Proportion of respondents who identify an ACT (or specific front-line treatment(s)) as the most effective drug for uncomplicated malaria |
| 11.2 | Respondent malaria knowledge | Proportion of respondents who have heard of and used an RDT for malaria |
| 11.3 | Respondent malaria knowledge | Proportion of respondents who report requesting evidence of confirmed malaria (e.g., test result, prescription, or referral) from a customer or patient before selling antimalarials.  Note: In many contexts, antimalarials are available over the counter and national policies may not require confirmation of a malaria diagnosis prior to dispensing. However, in alignment with WHO guidelines for malaria (2021), which recommend test-based treatment of malaria before administering antimalarials, this indicator is used to assess provider adherence to best practice. |
| 11.4 | Respondent malaria knowledge | Proportion of respondents who would provide an antimalarial to a client IF they had a negative malaria blood test and reasons WHY |
| 12.1 | Outlet tech/ digital access & use | Proportion of outlets with functional infrastructure and technology available for the 30 days preceding the interview (where infrastructure includes water, electricity; technology includes internet, phone, tablet/ computer. These may be edited based on needs or expectations in a given country of implementation e.g. countries doing tablet-based surveillance) |
| 13.1 | Outlet participation in monitoring | Proportion of outlets that report any information on malaria cases |
| 13.2 | Outlet participation in monitoring by reporting system | Proportion of outlets that report in to selected reporting systems or using selected forms (expected information systems or forms used to capture data from the private sector should be defined for each country of implementation (e.g. IDSR, HMIS, DHIS2, project-specific NGO lead reporting etc.) |
| 14.1 | Business practices | Proportion of outlets acting as wholesalers (i.e. outlets that report selling antimalarials or RDTs to be resold at another outlet/sells wholesale) |
| 14.2 | Business practices | Proportion of outlets that sell antimalarials or RDTs online |
| 14.3 | Business practices | Customer types: Proportion of malaria commodities sold to each customer type (e.g. local retail customers, online retail, other retail businesses, other resale/ wholesale businesses) |
| 14.4 | Business practices | Supplier types: Proportion of malaria commodities purchased from each supplier type (e.g. pharmacy, wholesale, importer, manufacture, etc.) |
| 14.5 | Business practices | Distribution methods: Proportion of outlets reporting use various methods (pick-up, delivery, third-party carriers) to distribute antimalarials or RDTs to customers |
| 14.6 | Business practices | Procurement methods: Proportion of outlets reporting use of various methods (pick-up, delivery, third-party carriers) to receive antimalarials or RDTs from suppliers |
| 14.7 | Business practices | Payment terms: Proportion of outlets reporting using different method of payment for antimalarials (e.g. cash, credit, etc.) to purchase from suppliers |
| 14.8 | Business practices | Perception of the stability of the wholesale market: Proportion of outlets reporting perceived market instability or fluctuations (e.g. stock outs, price changes) that impact their purchasing practices |

# Data ownership

All data generated through this project will be considered a collective output of the implementing partners and national stakeholders involved in the study. Data ownership will be shared in accordance with the roles and contributions of each partner, as defined in the project’s governance and collaboration agreements.

[DESCRIBE ANY RELEVENT LAWS/ REGULATIONS RELATING TO DATA OWNERSHIP HERE]

The project is committed to promoting equitable access to data while respecting ethical standards, participant confidentiality, and applicable national and international regulations. Data will be made available to stakeholders for analysis and scientific dissemination, in alignment with the principles of transparency, collaboration, and capacity strengthening.

# Dissemination and data use

[DESCRIBE PLANNED DATA USE AND DISSEMINATION ACTIVITIES IN THIS SECTION. INCLUDE INFORMATION ON COLLABORATION WITH STAKEHOLDERS, KEY DATA USER GROUPS, PLANS FOR SHARING RESULTS NATIONALLY AS WELL AS SUBNATIONALLY AND INTERNATIONALLY, INCLUDING CONFERENCES, SCIENTIFIC PUBLICATIONS, WEBINARS, MEETINGS, DELIBERATE EFFORTS TO ENGAGE AND SHARE RESULTS WITH LOCAL STAKEHOLDERS, ETC. ]

# Ethical considerations

[ENSURE THIS SECTION IS ALIGNED WITH NATIONAL RESEARCH REGULATIONS AND GUIDELINES. EXAMPLE TEXT IS PROVIDED BELOW]

As the main objective of the survey is to collect data on the availability, volume and price of antimalarial drugs and RDTs, by means of a questionnaire, the main risk to participants in this study is breach of confidentiality, although this risk is minimized by the precautions taken during the study. For informal outlets, the main risk for these unofficial providers, as for the official ones, is breach of confidentiality and anonymity. The importance of maintaining confidentiality, anonymity, and careful data management will be a key element of investigator training.

There are no direct benefits to participating in the study.

# Confidentiality

Results will not be linked to individuals. All data will therefore be presented in anonymous form in order to protect participants. Every effort will be made to protect the confidentiality and identity of participants. As outlets are businesses (rather than individuals), their location data are not considered personally identifying. Nevertheless, effort will be made to ensure outlets, and their owners and staff cannot be identified through this study.

Depending on local conditions, data from each interview will be uploaded to the secure online server at the end of each day, or as soon as an Internet connection can be established thereafter. All files will be deleted from the server once they have been uploaded to the study team’s secure file location for analysis, following completion of data collection.

Data files downloaded from the SurveyCTO server will contain the trade names, locations and GPS points of formal retailers and wholesalers. (Informal vendors will not have GPS coordinates, names, specific locations or other identifying data collected). Once the data has been cleaned, the trade name will be removed, specific location information will be deleted and replaced by a locality code, and GPS coordinates will be deleted. Publicly available datasets will not contain any personal or commercial identifiers or GPS coordinates.

Data collected in the field (including geo-referencing data) will be stored only on secure servers accessed only by the research team, and on password-protected computers of principal investigators and co-investigators responsible for data analysis. Precautions will be taken when presenting the results of national-level importers in public, as this category is likely to be relatively small. For example, importer results will be presented for generic types of antimalarial rather than for specific brands for which a company may be the sole importer (and therefore identifiable from the brand name).

The importance of confidentiality and protecting the identity of retail outlets will be emphasized when training data collection staff.

# Individual consent

The research team, particularly the investigators, must ensure that each study participant has given free and informed consent. The nature of the study, its aims and objectives, its usefulness, the nature of his or her participation, the risks associated with participation, the lack of direct benefit and respect for participant confidentiality should be explained to him or her before he or she decides to take part in the study. No participant will be interviewed without his/her consent.

An information sheet summarizing the main information of the protocol will be given to each participant (Annex I: Study Information Sheets). The information sheet includes an introduction, the purpose of the study, how to ask the questions, the risks and benefits for those taking part, a statement that the data collected will be confidential and that participation is voluntary, and telephone numbers for those in charge of the study will be available. A copy of the information sheet will be left with participants.

Every precaution will be taken to avoid any breach of confidentiality. If, despite this, a breach should occur, the research team will inform the ethics committees so that appropriate measures can be taken to ensure that the respondents are not harmed.

Participants may stop the survey at any time and may refuse to answer any question. Ethical approval for the point-of-sale survey in Nigeria will be obtained from [NAME IRB/NATIONAL ETHICAL REVIEW COMMITTEE AND OTHER REGUALATORY AUTHORITIES HERE].

### Oral consent

[NOTE THAT VERBAL / ORAL CONSENT MAY BE SOUGHT WHERE LOCAL REGULATIONS ALLOW] It is possible that seeking written consent may lead participants, even from formal structures, to modify their behavior during the study because of the sensitivity of certain information, which could bias the data communicated by them. In order to avoid this type of behavior, we will collect verbal consent from participants (Annex  II: Verbal Consent Form). Prior to data collection, the interviewer will read the consent form to the participant and give him/her time to ask questions. The fieldworker will explain that by participating, the eligible person is consenting to take part in the study.

# Management of ethically sensitive findings

[THIS SECTION INCLUDE PROCEDURES FOR MANAGING ETHICALLY SENSITIVE FINDINGS (EG, ILLEGAL PRACTICES) IN A WAY THAT MAINTAINS PARTICIPANT CONFIDENTIALITY. WE HAVE PROVIDED EXAMPLE TEXT BELOW:]

Ethically sensitive findings (e.g., dispensing of unregistered medicines, falsified test results, illegal sales) will not be reported at the individual or facility level. Instead, aggregate findings may be used to inform programmatic responses, capacity building, or engagement with regulatory stakeholders, ensuring no attribution to specific persons or locations. Any ethically sensitive issues that could pose significant risk will be discussed with the study's ethics oversight body to determine the most appropriate, ethical, and context-sensitive course of action, without breaching participant confidentiality.

If sensitive findings reveal systemic or recurrent risks to public health or safety, researchers will work with relevant national bodies (e.g., professional associations, regulatory agencies) to share anonymized summaries that support improvements in practice or policy, while protecting the identity of all individuals involved. Field and research staff will be trained on how to identify ethically sensitive situations and respond appropriately, including protecting the anonymity of participants and avoiding any actions that may compromise trust or safety.

# Study team roles and responsibilities

[THIS SECTION SHOULD CLEARLY OUTLINE THE ROLES AND RESPONSIBILITIES OF DIFFERENT STAFF/ ORGANIZATIONS INVOLVED IN THE STUDY. WE HAVE PROVIDED EXAMPLE TEXT BELOW:]

### Research ethics

The principal investigator [NAME] is ultimately responsible for the ethical conduct of this study, including the protection of the rights and well-being of participants, as well as the technical quality of the study.

The co-investigators [NAMES] are responsible for the ethical conduct of the study, and for adherence to the protocol, including quality assurance, fieldworker training and supervision, and other logistical, regulatory and methodological responsibilities as necessary.

### Study activities

The research team are responsible for the development of the protocol and tools, overall quality control of the study, analysis and dissemination of results, and development of a toolkit following study completion, in line with donor expectations.

The PI, along with the co-investigators, will oversee and supervise fieldworker training. The Research Manager will also support the project coordination between the research team, national and regional administration as necessary and the research agency. The research agency will be recruited to collect data, including conducting training, supervision and quality control, with remote quality control of data conducted centrally by the study team.

# Steering Committee and its responsibilities

To ensure the relevance, quality, and utility of the ACTwatch Lite study, a multi-stakeholder steering committee could be established. This committee shoul provide strategic oversight, foster alignment with national malaria priorities, and promote transparency and collaboration among key partners.

**Composition**

The Steering Committee could include representatives from:

* The National Malaria Control Program (NMCP)
* Ministry of Health (Planning, regulation, surveillance units as relevant)
* National Medicines Regulatory Authority
* Implementing research institution(s)
* Technical and financial partners (e.g., WHO, PMI, Global Fund, UNICEF)
* Civil society or professional associations (e.g., pharmacy councils)
* [Optional: Regional/Sub-national malaria focal points]

**Responsibilities**

The Steering Committee should:

* Guide study planning and adaptation
* Validate study objectives, geographic scope, and sampling approach
* Provide input on protocol contextualization, ethical approvals, and field planning
* Support implementation and troubleshooting
* Monitor progress during data collection and analysis phases
* Assist in addressing logistical or policy-related barriers
* Ensure relevance and uptake of findings
* Review preliminary results and support interpretation
* Facilitate dissemination of findings through national coordination platforms
* Promote integration of recommendations into malaria control strategies and interventions
* Strengthen ownership and capacity and promote national ownership of study outputs
* Support capacity building through active engagement in all study phases

**Meeting Schedule**

The Steering Committee will convene:

* At study inception
* Prior to data collection
* During preliminary results review
* At the final dissemination workshop
* Ad hoc meetings may be scheduled as needed.

# Timeline

The study timeline is summarized in the table below.

[THE TIMELINE SHOULD BE MODIFIED ACCORDING TO PLANNED ACTIVITIES]

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Month** | | | | | | | | |
| **Step** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** |
| Develop and revise protocol and tools |  |  |  |  |  |  |  |  |  |
| Ethical approval process |  |  |  |  |  |  |  |  |  |
| Recruit and contract data collection agency |  |  |  |  |  |  |  |  |  |
| Programming and testing digital tools |  |  |  |  |  |  |  |  |  |
| Finalize training materials |  |  |  |  |  |  |  |  |  |
| Finalize field procedures |  |  |  |  |  |  |  |  |  |
| Pre-test tools |  |  |  |  |  |  |  |  |  |
| Fieldworker training |  |  |  |  |  |  |  |  |  |
| Data collection |  |  |  |  |  |  |  |  |  |
| Remote quality control and data processing |  |  |  |  |  |  |  |  |  |
| Data analysis |  |  |  |  |  |  |  |  |  |
| Preliminary Report for stakeholder input |  |  |  |  |  |  |  |  |  |
| Data review workshop with stakeholders |  |  |  |  |  |  |  |  |  |
| Final Report |  |  |  |  |  |  |  |  |  |

# Guidance on country-level protocol adaptations to maintain methodological integrity

[THIS GUIDANCE OUTLINES KEY CONSIDERATIONS FOR ADAPTING THE ACTWATCH LITE STUDY PROTOCOL TO SPECIFIC COUNTRY CONTEXTS WHILE PRESERVING METHODOLOGICAL INTEGRITY:]

* Local regulatory and ethical compliance
  + Adapt protocol to national IRB and regulatory body formats.
  + Ensure consent procedures meet local ethical standards.
* Outlet typology and informal sector inclusion
  + Customize outlet definitions to match country context.
  + Decide on inclusion and confidentiality procedures for informal vendors.
* Sampling strategy adaptation
  + Use appropriate administrative units (~10–15k population).
  + Stratify sample using national urban/rural classifications.
* Align Scope with Health System Context
  + Update burden and policy sections with national malaria data.
  + Include current treatment guidelines and supply chain information.
* Training, fieldwork customization, data collection
  + Train fieldworkers in local language, drug names, and norms.
  + Tailor SOPs to local logistics and cultural considerations.
  + Translate tools and pretest locally for clarity.
  + Plan for offline data capture in low-connectivity areas.
* Confidentiality and sensitive findings
  + Emphasize anonymous participation, especially for informal providers.
  + Handle illegal practices sensitively and report only in aggregate.
* Data use and dissemination
  + Plan dissemination aligned with national health planning cycles.
  + Engage NMCP and stakeholders at national and sub-national levels.
* Integration with national surveillance systems
  + Include indicators relevant to DHIS2 or national reporting systems.
  + Assess provider digital capacity and surveillance engagement.

# ANNEXES

## Annex I: Study Information Sheets

### Annex I.A Qualitative Study Information Sheet for Importers/ Wholesalers

|  |
| --- |
| INFORMATION SHEET: IMPORTER/ WHOLESALER INTERVIEWS |
| TO THE BUSINESS FOCAL POINT  [Greeting]  Hello, my name is \_\_\_\_\_\_\_\_\_. I work for [INCLUDE ORGANIZATION NAME],  **Why are we conducting this research?**  We are conducting a study to determine the availability of antimalarial drugs and malaria diagnostic testing services and products in the private sector in [INCLUDE COUNTRY NAME AND ANY GEOGRAPHIC DETAIL, INCLUDING SPECIFIC REGION/STATES, ETC.] The study also aims to describe the private sector supply chain for antimalarial drugs, including national and local distribution networks.  We will visit the head offices of registered drug importers in [COUNTRY] and invite them to participate in the study. The main purpose of this survey is to enable the Government of [COUNTRY] and its public health partners to use the aggregated data to design interventions aimed at strengthening the quality of malaria case management in the private sector.  We believe that your experience in the supply chain of antimalarials and RDTs in [COUNTRY] can contribute to our understanding and knowledge of how we can improve malaria treatment. If you agree to take part, you will be one of around [NUMBER OF] importers included for qualitative interview in this study. You were selected randomly from our list of all importers in the geographic areas covered by the study.  **What information do we collect?**  We would like to ask you questions about   * The types of antimalarials and rapid diagnostic tests (RDTs) you stock, how you decide on your pricing structure, and the revenues these products generate for your business; * Your distribution network and distribution practices, including the size and coverage of your distribution network and the location of your own distribution centers and/or wholesalers; * Your main commercial competitors for antimalarials and RDTs; * Your views on the regulation of importation, distribution, wholesale and retail businesses in your sector;   With your permission, we would like to record details of the antimalarials and RDTs you usually stock, including information on your purchase and sales prices. We would also like to record details of the location of your branches or warehouses and the quantity of products they usually receive, to help us better understand how antimalarials and RDTs circulate in the country.  **How long will the interview last?**  The interview with you should take around 60 minutes, depending on the size and scope of your sales network.  **Are there any advantages to taking part in the study?**  There is no individual benefit to participation, but by answering our questions you will help us improve our understanding of how to increase the availability of malaria diagnosis and treatment for the benefit of the population living in [COUNTRY]. There is no financial benefit associated with this study, nor can we supply or purchase malaria drugs from your point of sale or store  **What are the risks of participating in this study?**  The potential risks for participants in this study are breach of confidentiality and loss of time. Rest assured, we are not here to inspect your business and no directly identifying information about this company will be passed on to anyone outside our research team. As far as time is concerned, we are available to talk to you now or can arrange a time that is most convenient for you. This interview is not intended for tax or legal purposes. Your information will be aggregated with others and treated in the strictest confidence.  **Who will have access to the information I provide?**  We will not share individually identifying information about you or your business practices. The results of this research will be shared in summary form, without the identities of companies or individuals. For example, we will present average results based on information received from all importers included in this study. We will not associate you with a certain brand of antimalarial or RDT if you are the only importer of that product in [COUNTRY]. We will share this information in summary form with other interested organizations or individuals who find it useful for malaria case management in the private sector. We may produce reports, presentations and publications using the data collected in this study, and anonymized data may be used by others for future research without the need for further informed consent.  **What happens if I refuse to participate?**  Participation in this study is voluntary. You are free to decide whether to participate. Even if you agree, you can change your mind at any time. You can refuse to answer any specific question or stop the interview at any time. If you choose not to answer a question, stop the interview, or not participate in the study at all, this will not affect your working conditions now or in the future.  **And if I have any questions?**  If you have any questions, you can ask them now or later. If you have any questions at a later date, please contact the following people:   |  |  | | --- | --- | | [INCLUDE NAME AND CONTACT DETAILS, INCLUDING EMAIL AND PHONE NUMBER, OF PRINCIPAL INVESTIGATOR(S) HERE] | [INCLUDE NAME AND CONTACT DETAILS, INCLUDING EMAIL AND PHONE NUMBER, OF PRINCIPAL INVESTIGATOR(S) HERE] |   If you have any concerns about the conduct of this study, you can also contact [INCLUDE NAME, ADDRESS, PHONE NUMBER AND EMAIL FOR IRB/National Ethical Review Committee HERE]  At the end of the study, a copy of the results will be given to each of the following structures:   * National Malaria Elimination Program (NMEP) * [INCLUDE ANY OTHER RECIPIENTS OF THE RESULTS HERE]   THE PARTICIPANT CAN NOW RECEIVE THE INFORMATION SHEET FOR SAFEKEEPING |

### Annex I.B Quantitative Study Information Sheets for Formal Outlets

|  |
| --- |
| INFORMATION SHEET: FORMAL OUTLET INTERVIEW AND AUDIT |
| **TO SERVICE PROVIDER/ MANAGER/ SALESPERSON:**  [Greeting]  Hello, my name is \_\_\_\_\_\_\_\_\_. I work for [INCLUDE ORGANIZATION NAME],  **Why are we conducting this research?**  We are conducting a study to determine the availability of antimalarial drugs and malaria diagnostic testing services and products in the private sector in [INCLUDE COUNTRY NAME AND ANY GEOGRAPHIC DETAIL, INCLUDING SPECIFIC REGION/STATES, ETC.]. The study also aims to describe the private sector supply chain for antimalarials, including national and local distribution networks, readiness for digital surveillance and engagement, and digital capacity.  We will be visiting around [APPROXIMATE TOTAL NUMBER OF OUTLETS YOU EXPECT TO INCLUDE] retail outlets and wholesalers in [COUNTRY]. The main aim of the survey is to enable the Government of [COUNTRY] and its public health partners to use the aggregated data to design interventions to strengthen the quality of malaria case management in the private sector.  We believe that your experience in providing antimalarials to the community can contribute to our understanding and knowledge of how we can improve malaria treatment in [COUNTRY]. If you agree to take part, you will be one of around [APPROXIMATE TOTAL NUMBER OF OUTLETS YOU EXPECT TO INCLUDE] outlets, wholesalers and importers included for quantitative interview in this study. You were selected to participate because your outlet is located in one of the study areas.  **What information do we collect?**  We would like to ask you several questions about   * Characteristics of this business, practices, and staff, and registration/ licensing * The types of antimalarial drugs and rapid diagnostic tests (RDTs) you carry, their prices, and the quantity sold/distributed. * Suppliers of any malaria commodities you stock.   We would like to request your permission to view the antimalarials and RDTs available at this outlet so that we can accurately capture their product details. We may also ask to take photographs of each antimalarial product. In addition, we would like your permission to note the geographical coordinates of this location.  **How long does the interview last?**  We estimate the interview component will take around 45 minutes, but the product audit varies depending on the number of antimalarials and RDTs you have in stock today.  **Are there any advantages to taking part in the study?**  There is no individual benefit to participation, but by answering our questions you will help us improve our understanding of how to increase the availability of malaria diagnosis and treatment for the benefit of the population living in [COUNTRY]. There is no financial benefit associated with this study, nor can we supply or purchase malaria drugs from your point of sale or store.  **What are the risks of participating in this study?**  The potential risks for participants in this study are loss of time, breach of confidentiality, or potential retaliation. But we are not here to inspect your business, and no specific directly identifying information about this outlet or the participants will be passed on to anyone outside our research team. This includes your name, the name of this business, the GPS coordinates of this business, or the fact that you specifically participated in this study. As far as time is concerned, we are available to speak with you now or later today, at a time that is most convenient for you. This survey is not intended for tax or legal purposes. Your information will be aggregated with others and treated in confidence.  **Who will have access to the information I provide?**  We will not share individually identifying information about you or other participants with anyone outside our research team. The knowledge gained from this research will be shared in summary form, without the identities of individuals or companies. We will share aggregate information with other interested organizations or individuals who find it useful for malaria case management in the private sector. We may produce reports, presentations and publications using the data collected in this study, and anonymized data may be used by others for future research without the need for further informed consent.  **What happens if I refuse to participate?**  Participation in this study is voluntary. You are free to decide whether to participate. Even if you agree, you can change your mind at any time. You can refuse to answer any specific question or stop the interview at any time. If you choose not to answer a question, stop the interview, or not participate in the study at all, this will not affect your working conditions now or in the future.  **And if I have any questions?**  If you have any questions, you can ask them now or later. If you have any questions at a later date, please contact the following people:   |  |  | | --- | --- | | [INCLUDE NAME AND CONTACT DETAILS, INCLUDING EMAIL AND PHONE NUMBER, OF PRINCIPAL INVESTIGATOR(S) HERE] | [INCLUDE NAME AND CONTACT DETAILS, INCLUDING EMAIL AND PHONE NUMBER, OF PRINCIPAL INVESTIGATOR(S) HERE] |   If you have any concerns about the conduct of this study, you can also contact [INCLUDE NAME, ADDRESS, PHONE NUMBER AND EMAIL FOR IRB/ National Ethical Review Committee HERE]  At the end of the study, a copy of the results will be given to each of the following structures:   * National Malaria Elimination Program (NMEP) * [INCLUDE ANY OTHER RECIPIENTS OF THE RESULTS HERE]   **THE PARTICIPANT CAN NOW RECEIVE AN INFORMATION SHEET FOR SAFEKEEPING** |

### Annex I.B.ii Quantitative Study Information Sheets for Informal outlets

|  |
| --- |
| INFORMATION SHEET: INFORMAL OUTLET AUDIT |
| **TO SERVICE PROVIDER/ MANAGER/ SALESPERSON:**  [Greeting]  Hello, my name is \_\_\_\_\_\_\_\_\_. I work for [INCLUDE ORGANIZATION NAME],  **Why are we conducting this research?**  We are conducting a study to determine the availability of antimalarial drugs and malaria diagnostic testing services and products in the private sector in [INCLUDE COUNTRY NAME AND ANY GEOGRAPHIC DETAIL, INCLUDING SPECIFIC REGION/STATES, ETC.]. The study also aims to describe the private sector supply chain for antimalarials, including national and local distribution networks, readiness for digital surveillance and engagement, and digital capacity.  We will be visiting around [APPROXIMATE TOTAL NUMBER OF OUTLETS YOU EXPECT TO INCLUDE] retail outlets and wholesalers in [COUNTRY] The main aim of the survey is to enable the Government of Nigeria and its public health partners to use the aggregated data to design interventions to strengthen the quality of malaria case management in the private sector.  We believe that your experience in providing antimalarials to the community can contribute to our understanding and knowledge of how we can improve malaria treatment in [COUNTRY]. If you agree to take part, you will be one of around [APPROXIMATE TOTAL NUMBER OF OUTLETS YOU EXPECT TO INCLUDE] outlets, wholesalers and importers included for quantitative interview in this study. You were selected to participate because your outlet is located in one of the study areas.  **What information do we collect?**  We would like to ask you several questions about   * The types of antimalarial drugs and rapid diagnostic tests (RDTs) you carry, their prices, and the quantity sold/distributed. * Suppliers of any malaria commodities you stock.   Your name, the outlet name, and the outlet location will not be recorded.  We would like to request your permission to view the antimalarials and RDTs available at this outlet so that we can accurately capture their product details. We may also ask to take photographs of each antimalarial product.  **How long does the interview last?**  We estimate the interview component will take around 45 minutes, but the product audit varies depending on the number of antimalarials and RDTs you have in stock today.  **Are there any advantages to taking part in the study?**  There is no individual benefit to participation, but by answering our questions you will help us improve our understanding of how to increase the availability of malaria diagnosis and treatment for the benefit of the population living in [COUNTRY]. There is no financial benefit associated with this study, nor can we supply or purchase malaria drugs from your point of sale or store.  **What are the risks of participating in this study?**  The potential risks for participants in this study are loss of time, breach of confidentiality, or potential retaliation. But we're not here to inspect your business, and no directly identifying information about this outlet or the participants will be passed on to anyone outside our research team. This includes your name, or the fact that you specifically participated in this study. As far as time is concerned, we are available to speak with you now or later today, at a time that is most convenient for you. This survey is not intended for tax or legal purposes. Your information will be aggregated with others and treated in the strictest confidence.  **Who will have access to the information I provide?**  We will not share individually identifying information about you or other participants with anyone outside our research team. The knowledge gained from this research will be shared in summary form, without the identities of individuals or companies. We will share aggregate information with other interested organizations or individuals who find it useful for malaria case management in the private sector. We may produce reports, presentations and publications using the data collected in this study, and anonymized data may be used by others for future research without the need for further informed consent.  **What happens if I refuse to participate?**  Participation in this study is voluntary. You are free to decide whether to participate. Even if you agree, you can change your mind at any time. You can refuse to answer any specific question or stop the interview at any time. If you choose not to answer a question, stop the interview, or not participate in the study at all, this will not affect your working conditions now or in the future.  **And if I have any questions?**  If you have any questions, you can ask them now or later. If you have any questions at a later date, please contact the following people:   |  |  | | --- | --- | | [INCLUDE NAME AND CONTACT DETAILS, INCLUDING EMAIL AND PHONE NUMBER, OF PRINCIPAL INVESTIGATOR(S) HERE] | [INCLUDE NAME AND CONTACT DETAILS, INCLUDING EMAIL AND PHONE NUMBER, OF PRINCIPAL INVESTIGATOR(S) HERE] |   If you have any concerns about the conduct of this study, you can also contact [INCLUDE NAME, ADDRESS, PHONE NUMBER AND EMAIL FOR IRB/National Ethical Review Committee HERE]  At the end of the study, a copy of the results will be given to each of the following structures:   * National Malaria Elimination Program (NMEP) * [INCLUDE ANY OTHER RECIPIENTS OF THE RESULTS HERE]   **THE PARTICIPANT CAN NOW RECEIVE AN INFORMATION SHEET FOR SAFEKEEPING** |

## Annex  II: Verbal Consent Form

[NOTE THAT THIS CONSENT FORM IS AN EXAMPLE BUT MUST BE ADAPTED TO ADHERE TO LOCAL REGULATIONS]

|  |
| --- |
| Verbal CONSENT FORM |
| |  |  | | --- | --- | | **Study title**  [INCLUDE STUDY TITLE HERE] | Principal Investigators  [INCLUDE NAME AND CONTACT DETAILS, INCLUDING EMAIL AND PHONE NUMBER, OF PRINCIPAL INVESTIGATOR(S) HERE] |   **FOR THE PARTICIPANT:**  I read (or had a witness of my choice read) and understood the information on the purpose of the study “*[INCLUDE STUDY TITLE HERE]".* I had the opportunity to ask any and all questions I had to the members of the research team. The answers were provided in a language I understood. The members of the research team also asked me questions to assess my understanding of the study's objectives.  I understand the advantages and disadvantages of my participation. I also understand that:   * My participation in the study is voluntary and I may withdraw at any time without having to give reason; * My personally identifying data will be deidentified, and I authorize their consultation only by persons collaborating in this research under the responsibility of the investigators; * The researchers involved in this study will have access to any personally identifying data in strict confidence; * The information collected may be published anonymously in scientific journals; * Research files could be inspected by [IRB/National Ethical Review Committee NAME] ethics committee to ensure that the study is running smoothly.   It was clearly explained to me, and I understood that my consent did not relieve the research organizers of their responsibility.  **ORAL CONSENT TO PROCEED**  Would you like to take part in the study?  Check if respondent agrees to participate □  ***For the attention of the investigator :***  I have read the entire consent form to the study participant and the participant has voluntarily agreed to participate in the study. The participant has given his consent.  Investigator's name:  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date : \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_  I, the undersigned, promise to keep confidential the information I have received at the points of sale. I certify that I have explained all the details of the study to the participant indicated above and certify that he has understood and given his consent.  Investigator's name:  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date : \_\_ \_\_ /\_\_ \_\_ /\_\_ \_\_  **THE PARTICIPANT CAN NOW RECEIVE AN INFORMATION SHEET FOR SAFEKEEPING** |

## Annex III: Interview guide

PLEASE SEE TOOLKIT SECTION 10 [“QUALITATIVE INTERVIEW GUIDE”](https://psiorg.sharepoint.com/:f:/r/sites/ACTWatchLite/Shared%20Documents/2.%20Technical/0.%20Toolkit/ACTwatch%20Lite%20Toolkit%20v3%20-%20FINAL%20FOR%20WHO%20REVIEW/10%20Qualitative%20interview%20guide?csf=1&web=1&e=gvHgiv)

## Annex IV: Market study questionnaire

PLEASE SEE TOOLKIT SECTION 11 [“QUANTITATIVE DATA COLLECTION TOOL”](https://psiorg.sharepoint.com/:f:/r/sites/ACTWatchLite/Shared%20Documents/2.%20Technical/0.%20Toolkit/ACTwatch%20Lite%20Toolkit%20v3%20-%20FINAL%20FOR%20WHO%20REVIEW/11%20Quantitative%20data%20collection%20tool?csf=1&web=1&e=0ZBuL8)

## Annex V: Country-level protocol adaptation checklist

| **Adaptation Area** | **Key Actions** | **Completed?** | **Notes** |
| --- | --- | --- | --- |
| **1. Ethical and regulatory compliance** | Align with national IRB and ethical review requirements. | ☐ |  |
|  | Adapt consent procedures to local norms and laws. | ☐ |  |
| **2. Outlet typology** | Define formal and informal outlet types in local context. | ☐ |  |
|  | Confirm which informal outlets will be included or excluded. | ☐ |  |
| **3. Sampling strategy** | Identify appropriate administrative units (~10–15k population). | ☐ |  |
|  | Apply national definitions for urban/rural or other strata. | ☐ |  |
| **4. Study scope and background** | Update malaria burden, treatment-seeking, and resistance data. | ☐ |  |
|  | Reference current national malaria guidelines and policies. | ☐ |  |
| **5. Training and team structure** | Customize training content to reflect local languages and drug market. | ☐ |  |
|  | Define roles and team composition (e.g., MOH, data firm, etc.). | ☐ |  |
| **6. Data collection tools** | Translate questionnaires and consent forms as needed. | ☐ |  |
|  | Test tools in the local setting and revise based on pre-test. | ☐ |  |
| **7. Managing sensitive information** | Train staff to approach informal providers with sensitivity. | ☐ |  |
|  | Describe how illegal or sensitive practices will be reported ethically. | ☐ |  |
| **8. Dissemination strategy** | Align dissemination with national malaria strategic planning cycles. | ☐ |  |
|  | Include national/sub-national engagement plans in the protocol. | ☐ |  |
| **9. Surveillance and Digital readiness** | Assess and describe how private sector outlets engage in malaria surveillance. | ☐ |  |
|  | Include indicators on digital tools and infrastructure where relevant. | ☐ |  |
| **10. Indicators and comparability** | Retain core ACTwatch indicators for cross-country comparability. | ☐ |  |
|  | Clearly document and justify any additions or deletions. | ☐ |  |

1. Protocol author: reference the ACTwatch Lite Sampling Tool [↑](#footnote-ref-2)
2. *If an additional category of outlets not identified prior to data collection has the potential to stock medicines, it must be included in the study, and the field supervisor will immediately inform the data collection firm and research team, who will alert other data collection teams.* [↑](#footnote-ref-3)
3. Protocol author: update the table here with those selected from the Indicator Table tool for this specific implementation [↑](#footnote-ref-4)