**Survey questionnaires**

**SECTION A: SOCIO-DEMOGRAPHICS**

1. Full name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. Place of work (Institution attached to\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3. How old are you? 18-24 years

25-34 years

35-44 years

45-54 years

55-64 years

65-74years

Over 75 years

I prefer not to answer

1. Respondent's gender

Male Female

5. What is the highest level of education you have Bachelors

completed?

Master’s PhD Specify specialty.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

6. What is your profession?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

7. How many years have you been involved in research? Up to 2 years

3-5 years

6-10 years

11 and more years

Refuse to answer

8. Types of clinical research involved in Treatment trials

Prevention trials

Screening trials

Supportive and palliative care trials

Other

If another clinical research\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

9. Nationality \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

10. Countries where you conducted the clinical

research \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION B: Post Trial Access (PTA) KNOWLEDGE**

1. Please explain what post-trial access is in your own words.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. What is the ethical imperative behind PTA? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3. Why should study participants benefit from a successful study intervention product after

completion of a trial? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4. Why should communities from which the study was conducted benefit from a successful study

intervention product after completion of a trial? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Who should be responsible for ensuring PTA?

Trial sponsor Research Institution Ethics Committee Study population/community Government

All of the above None of the above

**SECTION C: BELIEFS ON PTA**

1. PTA arrangements should be included in the study proposals before submission to the ethics committee.

Yes No I do not know

2. If proven more effective than available options, who should receive the study intervention products Participants who stand to benefit from the study after trial completion?

All the research participants

intervention and do not have other treatment options

All patients in the country suffering the disease the intervention is intended to address

No one

Other

If other recipient, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3.How should the successful intervention product be furnished after the trial to the study population?

Free of charge

at a price set by the government

At manufacturer's cost

At a price defined by the drug company

Other

If other price, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4. Who should be in charge of furnishing the Trial sponsor intervention product after the trial, before the Research institution

regulatory approval in the country?

Government Other If other, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5.For how long should the intervention product be furnished to the study population/community?

Up to a year for less than a year Between 2-5 years More than 5 years

While the subjects benefit from the treatment available in the country or the public health system

Up to having the intervention product for life

Other, if other intervention specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION D: TRIAL DESIGN AND IMPLEMENTATION PRACTICES**

1. Are you a: Principal Investigator Trial Sponsor Study Coordinator

Other If other, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

How many Malarias, TB or NTDs clinical trials have you conducted in the past 20 years?

1 2 3

4 5 Over 5

1. What percentage of the clinical trials listed in included PTA?

10-20% 30-40% 50-60% 70-80% 90-100% None

1. Were there any discussions on post-trial access among the investigators and Sponsors?

Yes No I do not know

1. Were there any verbal or written arrangements made on PTA?

Yes, Verbal Yes, Written I do not know

1. Were the PTA arrangements required by the RECs/IRBs as part of the ethics review process?

Yes No I do not know

1. Were the PTA arrangements submitted as part of the ethics review process?

Yes No I do not know

1. Were PTA arrangements confidential i.e. confidential document between the Sponsor and the PI?

Yes No I do not know

1. What post-trial arrangements were made?

Access to knowledge Access to studied intervention by study population

Access to studies intervention by community or population

Other, PTA arrangements, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. When was the post-trial access planned to be implemented?

Immediately after the trial Before any kind of marketing authorization Beyond marketing authorization

1. Who stands to directly benefit from the post-trial arrangement?

Study population General community or population Other direct benefit specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. If written agreements were made, was the Ethics committee aware of the agreement?

Yes No I do not know

13. Please select stakeholders involved in the PTA implementation process and specify their roles

A. Principal investigator (Role)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

B. Trial sponsor (Role)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

C. Ethics committee member (Role) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

D. Regulatory body (Role)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E. Another role\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

14. Did the trial result in the development of any products?

Yes No I do not know

15. If yes, who benefited from the intervention products?

All the research participants

Participants stand to benefit from the study intervention and do not have other treatment options

All patients in the country suffering the disease

the intervention is intended to address

No one

Other (Specify), If others benefited, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

16. What was the benefit from the intervention?

Accessed to knowledge Accessed studied intervention free of charge

Accessed the studied intervention at a subsidized rate

Other, If other benefits, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

17. When was the product accessed?

Immediately after the trial

Before any kind of marketing authorization

Beyond marketing authorization

18. Did you deviate from the PTA plan?

Yes No I don't know

If yes (deviated), specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

19. Please list any challenges encountered in implementation of the PTA arrangements.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

20. Please give us pointers on ways to promote successful implementation of PTA arrangements.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION E: PTA TRAINING**

1. Have you received any training on PTA arrangements in design and implementation of clinical trials?

Yes No I do not know

1. If yes, when?

< 1year ago Between 2-5 years ago

>5 years ago

3. Would you like training on PTA arrangements in design and implementation of clinical trials?

Yes No I don't know

Thank you!

1. Trial Registry site\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. Study Title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3. PI of study\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4. Sponsor of trial\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5. Date of registry\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

6. Start Date of trial \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

7. Date of trial completion\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

8. Study area [Site, City, Country]

Study area site1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study area city1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study area country1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study area site2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study area city2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study area country2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

9. Number of participants enrolled\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

10. IRB approval given?

Yes No

11. IRB Approval Date1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Approval Date2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of IRB 1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of IRB 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

12. Disease type\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

13. Intervention type\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

14. Trial type\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

15. Was PTA considered in the protocol?

Yes No

19. Describe how it was mentioned\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Which sections of the protocol mention PTA, scope, etc.)

20. What post-trial arrangements were made?

Access to knowledge Access to studied intervention by study population

Access to studies intervention by community or population

Government Other (specify) All of the above None of the above

Specify population\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If other, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

21. What is the plan for coverage of expenses related to PTA?

Free of charge at a price set by the government

At the fabrication cost at a price defined by the drug company

Other, if other expense specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

22. Who is in charge of supplying the intervention product after the trial?

Trial sponsor

Research institution

Government

Other,

If other supply product specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

23. For how long is the intervention product planned to be furnished to the study population/community?

For less than a year Up to a year

Between 2-5 years More than 5 years

While the subjects benefit from the treatment having the intervention product available in

the country or the public health system

For life

Other, other product furnished specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

24. When was the post-trial access planned to be Immediately after the trial implemented?

Before any kind of marketing authorization

Beyond marketing authorization

25 Who stands to directly benefit from the post-trial arrangement?

Study population General community or population

Other, if other benefit specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

26. Please select stakeholders involved in the PTA (Role) implementation process and specify their roles

Principal investigator Trial sponsor (Role)

Ethics committee member (Role) Regulatory body (Role)

Other (Role), If other stakeholder’s role specifies\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Phase II survey questionnaires**

1. Have you conducted a clinical trial in Africa on Malaria, TB, and/or any of the NTDs (neglected tropical diseases)?

1.yes 2. No

If yes, please list the countries where the trial took place. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. What was your role in the clinical trial?

□ Principal Investigator

□ Sponsor

□ Study coordinator

□ Other

If other, please specify. \_\_\_\_\_\_\_\_\_\_\_\_

1. Place of work (Institution attached to):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4. Were there any discussions and/or arrangements on post-trial access in any of the trials?

□ Yes

□ No

5. Arrangements made

* meeting and dissemination of finding
* avail in preferential price and freely
* avail the data
* IRB /regulatory role
* PTA accessed
* Money # 1
* not done b/c of acute treatment of malaria and avail as 1st line treatment

6. Would you like training on post-trial access arrangements for future clinical trials?

□ Yes

□ No