# Request for Proposals # 2017-028

# Partner Selection for Qualitative Longitudinal Research in Kenya

## Dynamics of Health Care Utilization Strategies in the Context of RTS,S/AS01 Vaccine Introduction

# I. Summary of Deadlines

| ***Steps in RFP*** | ***Responsible Party*** | ***Deadline*** |
|---|---|---|
| **Release of Request for Proposals (RFP)** | PATH | 19 July 2017 |
| Confirmation of Interest sent to PATH | Supplier | 28 July 2017 |
| Fact-finding questions sent to PATH | Supplier | 1 August 2017 |
| PATH response to fact-finding questions | PATH | 7 August 2017 |
| **Proposals due** | Supplier | 31 August 2017 |
| Post Bid Clarification | PATH & Supplier | 14 September 2017 |
| **Notification of selection to successful bidder** | PATH | 21 September 2017 |
| **Conclusion of RFP process** | | |
| ***Projected timeline for contract and commencement of work*** | | |
| Negotiate and execute contract | PATH & Supplier | 1 November 2017 |
| Commence work | Supplier | 1 November 2017 |

# Acronyms and Abbreviations

| | |
|---|---|
| ACT | Artemisinin-based combination therapy |
| CVIA | Center for Vaccine Innovation and Access |
| EMA | European Medicines Agency |
| EPI | Expanded Programme on Immunization |
| FG | Focus group |
| GSK | GlaxoSmithKline Biologicals |
| HH | Household |
| IDI | In-depth interview |
| IRS | Indoor residual spraying |
| ITN | Insecticide-treated net |
| LLIN | Long-lasting insecticide-treated net |
| MOH | Ministry of Health |
| MPAC | Malaria Policy Advisory Committee |
| MVIP | Malaria Vaccine Implementation Programme |
| PIE | Post-introduction evaluation |
| QL | Qualitative longitudinal |
| RFP | Request for proposals |
| SAGE | Strategic Advisory Group of Experts |
| SOW | Scope of work |
| WHO | World Health Organization |

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# II. PATH STATEMENT OF BUSINESS

PATH is an international nonprofit organization that accelerates global health innovation across five platforms – vaccines, drugs, diagnostics, devices, and system and service innovations. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. For more information, please visit www.path.org.

The Center for Vaccine Innovation and Access (CVIA) houses PATH's work along the entire vaccine development and delivery spectrum – from preclinical research on novel candidates through pivotal clinical evaluations and, ultimately, innovative approaches for new vaccine introduction and immunization system strengthening. Overall, the CVIA portfolio encompasses over two dozen vaccines either in development or already in use to protect against 15 different diseases, including diarrheal disease, meningitis, pneumonia, polio and malaria.

# III. BACKGROUND

## A. The malaria vaccine

Malaria due to *Plasmodium falciparum* is a major cause of morbidity and mortality, particularly in sub-Saharan Africa. Existing malaria control measures have had an essential role in significantly reducing the burden of disease in recent years. Nevertheless, despite considerable scale-up of these interventions, malaria transmission, morbidity, and mortality remain high in many endemic settings. Prevention needs to be strengthened still further and new tools are needed.

The RTS,S/AS01 vaccine[1] is the first malaria vaccine to have successfully completed a Phase 3 clinical trial. The trial showed that RTS,S/AS01 could provide meaningful public health benefit by reducing the burden of malaria when used alongside currently available interventions such as bed nets and insecticides.

RTS,S/AS01 is also the first malaria vaccine to have obtained a positive regulatory assessment, which was issued by the European Medicines Agency (EMA) in July 2015. After a thorough review of the Phase 3 trial results, two independent World Health Organization (WHO) advisory groups—the Strategic Advisory Group of Experts (SAGE) on Immunization and Malaria Policy Advisory Committee (MPAC)—met in October 2015 to discuss recommendations on the potential use of this *P. falciparum* malaria vaccine. A highly critical issue was the extent to which the protection demonstrated in children aged 5–17 months in the Phase 3 trial can be replicated in the context of routine health systems, particularly in view of the need for a four-dose schedule that requires new immunization contacts. In order to assess the advisability of introducing the RTS,S/AS01 vaccine for routine use, SAGE and MPAC jointly called for pilot implementation of RTS,S/AS01 in three to five settings in sub-Saharan Africa, at subnational level, covering moderate-to-high transmission settings. WHO officially adopted the joint recommendation of SAGE and MPAC in January 2016 [1].

[1] GlaxoSmithKline Biologicals (GSK) is the vaccine manufacturer and has led the development of RTS,S/AS01 over a 30-year period. Phase 3 clinical trial was conducted between 2009 and 2014 through a partnership involving GSK, the PATH Malaria Vaccine Initiative (with support from the Bill & Melinda Gates Foundation), and a network of African research sites in seven African countries.

## B. The Malaria Vaccine Implementation Programme

WHO's recommendation will be carried out in the context of a Malaria Vaccine Implementation Programme (MVIP). Among its objectives, the MVIP will serve to assess the programmatic feasibility of delivering the required four doses of the RTS,S/AS01 vaccine in children, evaluate the vaccine's potential role in reducing childhood deaths, and further characterize the vaccine safety in the context of a routine immunization programme[2]. Data from the pilots will bridge the knowledge gaps currently inhibiting wider-scale adoption of RTS,S/AS01.

Ministries of Health (MOH) of ten countries responded positively to the call for expressions of interest to participate in the MVIP that WHO issued in December 2015. Kenya, Ghana, and Malawi were selected based on pre-set criteria, including high coverage of long-lasting insecticide-treated nets (LLINs), well-functioning malaria and immunization programmes, a high malaria burden even after scale-up of LLINs, and participation in the Phase 3 RTS,S/AS01 malaria vaccine trial. In each country, the MOH will deliver the malaria vaccine through its national immunization programme in the selected areas and regions. National malaria control programmes will ensure that existing WHO-recommended prevention tools, such as LLINs and artemisinin-based combination therapies (ACTs), continue to be deployed on a wide scale.

The MVIP is being coordinated by WHO in close collaboration with participating MOHs and a range of in-country and international partners, including PATH and GSK. Financial resources for the first phase of the programme (2017–2020) have been committed by Gavi, the Vaccine Alliance, The Global Fund to Fight AIDS, Tuberculosis and Malaria, and UNITAID, with in-kind contributions from WHO, the Bill & Melinda Gates Foundation through a grant to PATH, and donation doses of RTS,S/AS01 from GSK and PATH for use in the pilot.

WHO and partners are engaged in intensive discussions with stakeholders in the selected countries to plan for vaccine introduction and evaluations, with a view to the start of vaccinations in 2018.

## C. Evaluation of malaria vaccine pilot implementation

Evaluations addressing critical questions related to programmatic feasibility, impact and safety of RTS,S/AS01 will be conducted under the leadership of WHO. RTS,S/AS01 will be introduced by the national Expanded Programme on Immunization (EPI) using a cluster-randomized design.

In consultation with Ministries of Health, each country will introduce RTS,S/AS01 in 23-32 clusters (including about 4,000 children each) at the beginning of the programme, while an equal number of clusters will act as comparison areas. Around 240,000 children will be included in the programme in each pilot country (120,000 in the implementation clusters and 120,000 in the comparison clusters)[3].

The division of clusters into implementation or comparison areas will be randomized in order to generate the strongest possible evidence of the effects of the vaccine when used in routine practice and alongside existing malaria control tools.

The first dose of RTS,S/AS01 vaccine will be administered to children as soon after 5 months of age as possible, followed by doses two and three at one month intervals, and a fourth dose 15 to 18 months after

[2] For a complete description of the MVIP and its objectives, please visit http://www.who.int/malaria/media/malaria-vaccine-implementation-qa/en/

[3] WHO is in the process of selecting evaluation partners for the conduct of these evaluations in participating countries. The final number of clusters and participants in the evaluations, and rationale for those numbers, will be agreed between the MOH, WHO and evaluation partners.

dose three. Vaccinated children will be followed to 48 months of age, to enable key outcomes to be evaluated up to 12 months following the fourth dose of RTS,S/AS01 (assuming dose one of RTS,S/AS01 is given at 5 months of age, dose three is given by around 9 months of age, and dose four by age 27 months). The comparison group will be age-matched and will not receive RTS,S/AS01 vaccination.

In each country, the MOH will select the districts and regions to be included in the pilot, and define clusters with the support of in-country stakeholders and WHO. Clusters are intended to be geographic areas that make operational sense from the perspective of the national immunization programme.

In Kenya, these are likely to be sub-counties in the endemic lake region of Western Kenya.

The MOH will also decide on the delivery schedule, based on the aforementioned WHO recommendations; for instance, RTS,S/AS01 dose three delivered at 9 months of age may be co-administered alongside measles. Age-eligible children will be identified by health workers at health facilities and outreach clinics, in the course of the routine child health and vaccination programmes in the pilot areas, and invited for doses of RTS,S/AS01, as they are for other vaccinations.

The MVIP is expected to be implemented in two phases over approximately six years. If vaccination with RTS,S/AS01 starts in early 2018, evaluations should be completed by the end of 2022. The first phase of the programme (2017–2020) will provide initial insights on the programmatic feasibility of delivering the vaccine in real-life settings, and on the safety profile of RTS,S/AS01 in the context of routine use. The second phase of the MVIP (2021–2022) will continue to monitor feasibility and safety while also generating results on the vaccine's impact on child survival. Taken together, these results will help inform future decisions on the wider-scale deployment of the vaccine.

## D. Evaluation of operational feasibility

The feasibility of delivering RTS,S/AS01 according to the recommended schedule will be evaluated through a combination of approaches.

First, cluster-based household surveys will be conducted at three points in the programme: at baseline (prior to start of vaccination), at mid-line, and at end-line (18 and 30 months after initiation of RTS,S/AS01 vaccination). The objective is threefold:

- To generate estimates of the coverage of routine EPI vaccines, as well as the coverage and utilization of recommended malaria control measures such as LLINs and indoor residual spraying (IRS), and to document patterns of health-seeking behavior for febrile children.
- To allow assessment of the effect of RTS,S/AS01 implementation on coverage and utilization of important preventive health interventions and care-seeking behavior.
- To enable examination of the effect of strategies to optimize coverage of the fourth dose, and assessment of whether RTS,S/AS01 implementation is associated with increased coverage of routine vaccination or other key childhood interventions (e.g., anti-helminth administration, Vitamin A supplementation, etc.).

Second, a programmatic assessment tool such as WHO's Post-Introduction Evaluation (PIE) will examine the RTS,S/AS01 vaccination programme's operations with a view to improving the delivery of RTS,S/AS01. The tool will be adapted for the MVIP and used 6 to 12 months after introduction of the vaccine in each country. It will evaluate performance in relation to pre-introduction planning, vaccine storage and wastage, logistics of administering the vaccine, and community receptiveness (among others).

Third, a qualitative assessment will include exploration of any behavior change, and provide insights into whether and why behaviors such as treatment-seeking for febrile children, use of malaria prevention measures, EPI vaccination, etc., change with the introduction of RTS,S/AS01. The qualitative evaluation will complement the quantitative data gathered during representative household cluster surveys.

# IV. RFP OBJECTIVE

PATH is the technical and implementing lead for the third component of the evaluation of feasibility, and is looking to appoint an individual organization or consortium of organizations to carry out qualitative longitudinal research in Kenya [4], as outlined in the following scope of work. This is the objective of the present RFP.

# V. SCOPE OF WORK

## A. Dynamics of Health Care Utilization Strategies in the context of RTS,S/AS01 vaccine introduction: a qualitative longitudinal study

**Design and research questions**

Qualitative research complements—and is often combined with—survey data in order to inform an understanding of what lies behind the quantitative estimates and trends. Qualitative longitudinal (QL) research is distinguished from other qualitative approaches by the way in which time is designed into the research process, making change and continuity a central focus of analytical attention [2,3] [5].

The potential of QL research for understanding some of the processes and causes of change that occur with policy or practice interventions has been highlighted [4]. An empirical understanding of change is particularly important when policy directions or strategies emphasize behavior change or adaptation to changing circumstances [5,6].

This QL study will run alongside malaria vaccine pilot implementation to examine the impact on the behavioral practices of target populations, how and why they are engaged, and how they unfold over time in relation to RTS,S/AS01 vaccine introduction.

The key questions to be addressed by this study are:

I. How is RTS,S/AS01 vaccination being implemented, and what are the dynamics of these processes?

II. How does RTS,S/AS01 introduction impact household health utilization strategies and what are the dynamics of these processes?

Sub-questions include, but are not limited to:

[4] PATH is also commissioning this research in Ghana and Malawi, and RFPs are running on a concurrent timeline to the purpose. Should any individual organization or consortium responding to this RFP be interested in bidding for this work in Ghana and/or Malawi, they are required to submit separate proposals against those RFPs.

[5] Selected references on QL methodology are listed in the bibliography section [7,8,9].

I.
- How is malaria vaccination and the malaria vaccine being received by vaccine and malaria providers? Do understanding and acceptance change over time, and how?
- How is RTS,S/AS01 being delivered and how are strategies and processes being used and modified over time?
- How is RTS,S/AS01 being embedded within and impacting upon existing EPI and malaria provisions?
- How is the introduction of RTS,S/AS01 being mediated between existing vaccine and malaria providers, and what is the scope for integration between these two programmes?
- What impact does RTS,S/AS01 delivery (i.e., additional visits and an extended vaccine administration window) have on child health beyond malaria vaccination?

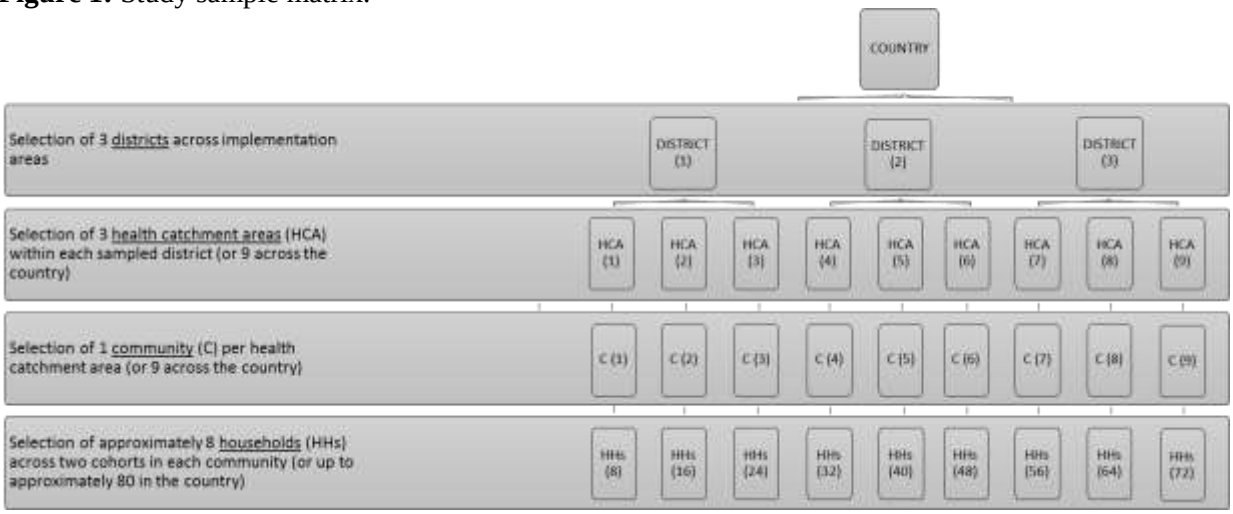
II.
- What is the household/community understanding of malaria vaccination and the malaria vaccine, and how does this change over time?
- How do health biographies impact on household/community experience with malaria, malaria prevention and control, and health-seeking practices? How does this experience change over time?
- What are the pathways to malaria vaccine acceptance in communities and households?
- What motivates households to accept or decline the vaccine for their eligible child? What factors influence the 'accepters' to 'stay' in the programme or, conversely, to drop out?
- What are the changing sources of influence on the households, and what practical opportunities and constraints affect household decisions?
- Overall, how do households/communities experience RTS,S/AS01 pilot implementation?

Tracking continuities and changes in both how the programme is implemented by local health systems and how it is received by household and community members provides the best means to understand the factors that influence the uptake of the vaccine at local level, the sustainability of vaccine acceptance and malaria prevention and control practices over time, and the short- to medium-term effectiveness of programme implementation across different districts and country settings.

**Sampling strategies**

The study will be conducted in the implementation areas (or clusters) where RTS,S/AS01 is being delivered. Three districts will be chosen to reflect variations in health system capability and access. Approximately 25 households with children eligible for RTS,S/AS01 vaccination will be recruited across three randomly chosen communities from three health service areas within each district, achieving a total sample of up to 80 households in each country (see Figure 1). Clusters may be district or sub-district units of randomization; either way, 25 households will be selected from an implementation cluster within the sampled district. Selection of districts and health service areas for the conduct of the study will be finalized following randomization of clusters into implementation and comparison areas. This is expected to be carried out before the end of 2017.

**Figure 1:** Study sample matrix.




The study will explore trajectories of health care utilization and delivery among decision-makers and other authority figures in the household and extended family, leaders and influencers in the broader societal network, and vaccine and malaria service providers (in both the formal and informal systems). This approach is adapted from an ecological framework illustrating the (i) individual, (ii) interpersonal, (iii) community, and (iv) institutional/system levels as embedded health planning systems [10]. It enables the study to work through these different levels and explore their intersections within complex systems. These levels form the basic units of analysis and define the study populations to be included in the study, as follows:

(i) Main caregivers (from selected households);
(ii) Male heads of household and older women (from selected communities);
(iii) Religious and community leaders (from selected communities);
(iv) Health workers and informal providers (EPI and malaria programme within selected health catchment areas), and health workers and programme managers (EPI and malaria programme in selected districts).

Outcomes of interest within each level of the ecological framework include individual and collective decision-making that would either influence health and health care-seeking behaviors or foster an environment that may provide positive or negative support to such behaviors.

**Longitudinal frame**

The longitudinal frame for the study includes a baseline and a range of temporal anchor points that shape and guide the research process, comprising four research encounters.

The baseline for the study will overlap with the start of RTS,S/AS01 vaccinations, and will be implemented during the first visit to the field. The baseline will begin with a period of ethnographic engagement, enabling researchers to build up knowledge of local values and practices on the ground, and begin to document how the programme is being communicated, delivered, and understood in both community and service settings. An ethnographic strategy at baseline allows for a better understanding of local contexts, and for the construction of a joint frame of reference for processes, practices, and meanings to be discussed in interviews and other data.

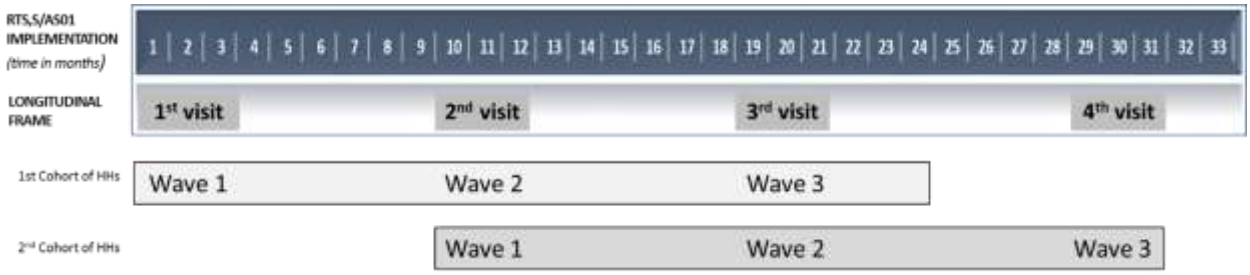
A panel of households will be tracked through three waves of data collection, mirroring critical junctures in the programme:

- Wave 1: The point at which a child in the household is first eligible for RTS,S/AS01.
- Wave 2: The point following delivery of the first three doses (i.e., the milestone that ensures partial efficacy against severe malaria).
- Wave 3: The point following the delivery of the fourth dose (i.e., the milestone that ensures the benefits gained against severe malaria are maintained).

Two cohorts of households will be enrolled into the panel for the study:

- The first cohort will be recruited at the baseline (at the first visit to the field) and comprise households with a child who is eligible for the RTS,S/AS01 vaccine at start of vaccinations.
- The second cohort will be recruited 10 months after the baseline (at the second visit to the field), and comprise households with a child who is newly eligible for malaria vaccination (see Figure 2).

**Figure 2:** Timing of fieldwork visits and data collection waves.




A cohort is commonly defined as "aggregates of individuals who experience the same life event within the same time interval" [9]. Building in two cohorts enables an exploration of modifications in programme implementation over the early stages of the pilot, and how these may impact on household strategies and health trajectories. It also enables an exploration of the ways in which the programme is adapted and becomes 'normalized' in communities over time.

The intention is to sample primarily for 'accepters' (i.e., households whose child has received the first dose of RTS,S/AS01 at the eligible age), but also to selectively sample 'decliners' (i.e., households who did not take up malaria vaccination for their eligible child), for both cohorts. The first cohort will be the main cohort in the study. The second cohort will supplement the first and will be purposively selected to exemplify distinctive and diverging views and practices.

In addition to households constituting the panel, data will be gathered from other study populations in the communities, health facilities, and the health district. New subsamples of individuals representing these populations may be recruited at subsequent waves, or followed up at varying levels of intensity and depth (see Table 1).

**Table 1**: Intensity and scope of follow-up.

| Ecological level | Study populations | 1st visit | 2nd visit | 3rd visit | 4th visit |
|---|---|---|---|---|---|
| **Individual** | Main care givers | ✓ | ✓ | ✓ | ✓ |
| **Inter-personal** | Male heads of HH | ✓ | | ✓ | |
| | Older women | ✓ | | ✓ | |
| **Community** | Religious & community leaders | ✓ | | ✓ | |
| **Institutional/system (health facility level)** | Health workers (EPI & malaria programme) | ✓ | ✓ | ✓ | ✓ |
| | Other providers (e.g. traditional healers, pharmacists, local NGOs) | ✓ | | ✓ | |
| **Institutional/system (district level)** | Health workers and programme managers (EPI and malaria programme) | ✓ | ✓ | ✓ | ✓ |

### Data collection methods

Data collection methods will include in-depth interviews (IDIs) to collect data on individuals' personal perspectives and households' practices, and focus group (FG) discussions to elicit data on the social and cultural norms and generate broad overviews of a particular process or issue of concern to the group or subgroup represented. Furthermore, targeted individual and group interviews will be conducted to map the landscape of local vaccine and malaria (formal and informal) service provision. Attachment 1 provides a detailed specification of the scope of data collection, which should provide the basis for developing the technical and financial proposal. Such scope will be finalized in collaboration with the awardee during the start-up research phase.

### Data collection instruments and strategies

Longitudinal tracking in 'real' time enables data to be built incrementally through and between the cumulative waves of data generation, with each wave of fieldwork informing the next. A retrospective lens at the first wave allows for an understanding of past histories and unfolding biographies within households, which is an important foundation for understanding current health behaviors and aspirations, and decision-making over the course of the study.

Core questions will be built into each return visit to the field, providing the basis of continuity and comparison over time. The flexibility of the longitudinal frame also allows for new lines of questioning to be pursued at each wave, building on particular themes and processes of relevance for individual cases that have emerged from earlier waves of fieldwork.

Data will be collected in the local language(s) and translated into English, as required, for analysis and collation. In-depth interviews and focus group discussions will be audio recorded and audio files transcribed. Short case-histories will be produced for each household, charting history and changing events as the study progresses.

Data will be processed and analyzed using framework-matrix enabling software (e.g., NViVo 9 onward). This allows the data to be analyzed cross-sectionally across the sample and across time, and also longitudinally within individual cases and themes [9].

**Conclusion**

The depth and longitudinal nature of this study will capture household and community experiences in rich ways, complementing quantitative evidence in understanding the mechanisms and conditions that contribute to, or hinder, outcomes and change. Sampling across varying domains of influence will allow for the exploration of themes in the accounts of care givers as well as family and community influencers, and of how different members are engaged. It will also allow different ecological levels to be placed in conversation with one another, enabling an understanding of the interplay between the individual and the broader context, between households and communities and the local health system.

# B. References


[1] World Health Organization. Malaria vaccine: WHO position paper. *Weekly Epidemiological Record*. 2016;4(91):33-52.

[2] Calman L, Brunton L, and Molassiotis A. Developing longitudinal qualitative designs: lessons learned and recommendations for health services research. *BMC Medical Research Methodology*. 2013;13(14):1-10.

[3] Thomson R., Plumridge,L. and Holland J. (eds.) Longitudinal Qualitative Research: a developing methodology: *International Journal of Social Research Methodology.* 2003;6(3). Special Issue.

[4] Lewis J. Analysing Qualitative Longitudinal research in Evaluations. *Social Policy & Society. 2007;*6(4):545-556.

[5] Corden A.and Millar J (eds.) Qualitative Longitudinal research for social policy. Themed section of *Social Policy and Society*. 2007;6(4):529-532.

[6] Duncan S and Harrop A. A user Perspective on Research Quality. *International Journal of Social Research Methodology*. 2006;9(2):159-174.

[7] Neale B. Adding Time into the Mix: Stakeholder Ethics in Qualitative Longitudinal Research. *Methodological Innovations Online* (special issue on ethics). 2013.

[8] Neale B and Flowerdew J. Time, Texture and Childhood: The Contours of Longitudinal Qualitative Research *International Journal of Social Research Methodology.* 2003;6(3):189-199.

[9] Neale B. *What is Qualitative Longitudinal Research?* London, Bloomsbury (selected chapters available from PATH by mid-July 2017).

[10] Green LW and Kreuter MW. Health Program Planning: an Educational and Ecological Approach. McGraw-Hill: New York. 2009.

# VI. REQUIREMENTS

## A. Eligibility

Bidders can be consortia, with preference given to those with at least 50 percent of the member organizations based in Kenya. Members of the consortia may include academic or research institutions, civil society or think tanks, public or for-profit companies. We particularly welcome consortia led by organizations from Kenya, as well as consortia or individual organizations comprising teams from, or having presence across, the pilot countries. Consistent with PATH's goal to build sustainable in-country capacity, if a consortium is led by an organization from a high income country, the proposal should include plans to build capacity in Kenya. Alternatively, individual organizations from Kenya can apply. An individual organization may only bid once on this research in Kenya (i.e., those who opt to propose in partnerships, consortium, etc., may not propose with multiple consortia or as individual entities).

## B. Skills and qualifications

Bidders should possess in-house technical capacity to perform the proposed research, including but not limited to behavioral/social scientists with qualitative research skills (longitudinal research skills a plus), prior work in programme evaluation for large-scale government programmes (immunization programmes a plus), vaccine acceptability and/or feasibility studies, health utilization and health-seeking behavior studies.

Bidder should nominate a Team Leader for this programme. The Team Leader should be a senior researcher who will take the overall responsibility for managing the research team on the ground, overseeing and delivering the study's outputs and outcomes, and serving as liaison to PATH. If the bidder is a consortium, the Team Leader should be in the lead organization.

The Team Leader should possess proven experience in designing and delivering high quality research on time and within budget, excellent knowledge of qualitative research methods, excellent writing and presentational skills, and strong inter-personal and negotiation skills. PATH will critically assess the levels of expertise and time allocated to this function by prospective Bidders. Approval from PATH will be required for appointment or replacement of the Team Leader and any senior staff not in the original proposal.

## C. Sequencing and dependencies

Activities are expected to start in November 2017. The implementation of the Scope of Work outlined above is envisaged to be a collaborative process between the successful Bidder and PATH based on open and regular communications and exchange of information.

As of contract award, the successful Bidder is expected to engage with PATH in the **start-up research** phase, encompassing:

- Participation in a kick-off workshop for research teams awarded in the three pilot countries, to be hosted in one of the countries. The master protocol developed by PATH will be thoroughly reviewed

at this time. The event will include targeted specialized training in QL methodology, as well as set-up of standards and processes and initiation of the following tasks.

- Finalization of the country-specific protocol mirroring the master protocol, which include:
    - Methodological development: finalize sampling design, ethical strategies for working over time, focus group and in-depth interview guides, ethnographic strategies, and any other method or process proposed that will gather and document data to be used in the research.
    - An operational strategy for research implementation, including identification of districts and communities for participation in the study, pretesting of data collection tools, a detailed operational plan that shows timelines of each activity, training strategies and resources for field researchers, and a data management plan.
- Submission to relevant institutional review boards/ethics committees.

Start of the **research implementation** phase in Kenya is contingent upon initiation of RTS,S/AS01 vaccinations, expected in 2018 but with exact timing to be determined by the Ministry of Health. This phase will encompass four fieldwork visits to selected districts and communities. These are to be seen as four discrete periods of field work, in between periods of rest, reflection, and analysis. The first (baseline) visit will begin with a period of ethnographic immersion, and is envisioned to require four to six weeks in the field. Data analysis at each interim stage will include a consultative process of output review. The Team Leader is expected to represent the research and liaise with in-country stakeholders and partners, as requested by PATH.

A four-visit schedule for research implementation should constitute the basis for developing the technical and financial proposal. Progression to the fourth visit is however subject to funding being confirmed.

A **wrap-up** phase will encompass a closure point in participating communities, and final dissemination of results at district and national levels, in collaboration with PATH and other partners. It also includes collaboration with PATH and research teams in other pilot countries on journal articles to summarize findings from this research.

Opportunities for cross-team learning and a cross-national approach to data analysis will be leveraged across the different phases of the research process. It is envisaged that all awardees in the three pilot countries and PATH meet in regional workshops thrice across the study timeline (including the kick-off workshop). Attendance should include key staff not exceeding three people. The venue will rotate among the three countries.

## D. Deliverables

Research deliverables include:

- Country-specific protocol approval from local institutional review board/ethics committee prior to the start of research implementation.
- Interim research reports following each fieldwork visit.
- Final research report.
- At least one article for publication in a peer-reviewed journal.

In addition, the successful Bidder is expected to comply with PATH reporting requirements, and submit for feedback and approval quarterly financial reports based on a template provided by PATH, accompanied by a technical report on progress and achievements.

## E. Contractual payment arrangements

PATH seeks agreement to a contractual payment arrangement where, after an initial advance payment, ongoing payments will be explicitly linked to Supplier performance, effective delivery of programme deliverables, and reimbursement of approved actual expenditures.

## F. Governance

PATH will be responsible for monitoring progress and ensuring that the research is delivering value for money. PATH will also be responsible for managing the commissioning, providing internal quality assurance of the research process and outputs, appointing external quality assurance of relevant drafts, and approving final drafts at each stage of the research.

## G. Ethics

The successful Bidder will be expected to comply with Human Subject Research in conformity to U.S. government regulations for the protection of human subjects, as well as to the regulations and ethical standards of the host country. The Team Leader will be required to undertake online open access Human Subject Protection and Responsible Conduct of Research one-hour trainings.

## H. Open access policy

PATH operates an open access policy which requires that the data from this research be published and the results posted on an appropriate registry.

# VII. INSTRUCTIONS FOR RESPONDING

## A. PATH point of contact

All correspondence relating to this RFP shall be directed to the following email address: proposalhus@path.org.

## B. Confirmation of interest

Bidders are required to transmit a written Confirmation of Interest as soon as possible after publication of the RFP and no later than 28 July 2017. Confirmation of Interest should be submitted by email to the contact address above, indicating:

- Title of the RFP.
- Name and address of Supplier.
- Whether the Supplier is applying as an individual organization or a consortium.
- Proposed Team Leader, one-page biography and location he/she will be working at.
- Single point of contact for the Supplier for all correspondence relating to this RFP.
- Confirmation of ability to meet the 31 August 2017 deadline for submission of a proposal.

## C. Timeline

The proposed timeline set out below indicates the process that PATH intends to follow.

| ***Steps in RFP*** | ***Responsible Party*** | ***Deadline*** |
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| **Conclusion of RFP process** | | |
| ***Projected timeline for contract and commencement of work*** | | |
| Negotiate and execute contract | PATH & Supplier | 1 November 2017 |
| Commence work | Supplier | 1 November 2017 |

PATH reserves the right to modify this schedule as needed. Changes will be posted on http://www.path.org/our-work/rfp-index.php through the deadline for confirmation of interest, and after that will be sent via email simultaneously to all Bidders that have confirmed interest.

## **D.** Fact-finding questions

Any Bidder may request further clarification on matters pertaining to this RFP by submitting their question(s) in writing to the contact address above, using the form provided as attachment 2. Fact-finding questions are due by 1 August 2017. PATH will respond to questions by 7 August 2017.

In order to ensure a fair RFP process, the questions raised and PATH's responses will be notified to all Bidders (except in cases where proprietary information is involved) without disclosure of the initiator.

In relation to this RFP, the Bidder must not at any time during the bidding process make contact with any PATH staff, partner, or any other person who is in any way connected with this RFP.

## E. Proposal format and delivery

The proposal should be submitted in English and set out in four main parts:

a. Executive summary (maximum 1 page):

- This should provide a brief overview of your bid, cross referencing with key areas of the technical proposal, including how you intend to achieve the outputs and your assessment of the resources needed.

b. Technical proposal (maximum 10 pages, excluding requested annex). This should illustrate:

- Your understanding of the task, including:
    - The value of a QL approach and how you would apply the proposed methodology in Kenya.
    - The requirement to generate, analyze, and interpret qualitative, cumulative data that builds up a picture of continuity and change over time, with each wave of fieldwork informing the next.
    - The requirement to recruit, retain, and work ethically with a panel of participants who will be tracked over time.
- Proposed strategic approach for the implementation of the Scope of Work that sets out:
    - Sampling rationale and proposed criteria for selecting districts, health service areas, and communities for the conduct of the study.
    - A strategy to effectively work in pilot regions, enable buy-in and stakeholder engagement, and build trust and rapport in the communities.
    - A strategy to enable ethnographic engagement at the baseline.
    - An outline approach for the safe storage and management of data, including suggested procedures for dataset development (i.e. organization of data files for coding and analysis), and data quality assurance.
    - As assessment of strengths and possible threats for research implementation and plan to overcome them.
    - Plans for any innovative approaches.

- As an annex, an outline workplan breaking down timescales for activities and outputs, which are clearly referenced (where appropriate) to governance and quality assurance mechanisms.

c. Proposed research team (maximum 5 pages, excluding requested annex). This should illustrate:

- Organizational strengths: the Bidder background, organizational capacity and experience to perform qualitative research, reference to past work of similar scope and relevant research publications, partnership experiences, geographical reach, and any other information relevant to the requirement. No supporting documents for the claims are required here. Bidders with or responding from multiple locations should indicate these qualifications for the site/location that will take primary responsibility for the work.

- Roles and responsibilities of each member of the team proposed to work on this research. This may be presented as a matrix of designation, qualification, work experience in years, area(s) of specialty, employee or consultant, institutional affiliation, role in the study, and location from which will operate. The Bidder should show how the proposed team provides the appropriate mix and levels of skills and expertise, with assured availability at the right stage and with the right balance of days and input, for the duration of the study. The Bidder should also explain the recruitment methodology, and procedures for handling team changes.

- As an annex, an updated and detailed CV including a list of publications should be provided for the Team Leader, and a one-page biography with relevant credentials and experience for each named team member.

d. Financial proposal comprising:

- Financial Risk Assessment certified by a designated official (attachment 3). When indirect costs are included in the budget, supporting documentation should be provided as annexes, as indicated in "Additional Information Required" in Section 2.

- A budget detailing all costs associated with delivering the Scope of Work. This should be prepared using the template provided as attachment 4. The template is cross-referenced to the various phases of the overall study, and requires that the fourth visit – subject to funding confirmation - is costed out separately.

- A justification for line items in the budget should be provided using the Budget Narrative template provided as attachment 5. Data to support actual costs and/or methodologies to support cost estimates should be included.

Note that PATH may challenge proposed costs that it does not consider appropriate or do not offer optimal value for money over the lifetime of the programme.

These instructions are designed to help the Bidder produce a Bid that is acceptable to PATH and to ensure that Bids are given equal consideration. It is essential, therefore, that information is provided in the format requested.

Bids should be submitted in commonly recognized MS formats or PDF as attachments to an email to the point of contact listed above. The subject line of the email should read: Kenya RFP # 2017-028. It is recommended that all documents be provided on A4 page dimensions with a minimum font size of 12.

Bids should be submitted by 18:00 hours, CET time, on 31 August 2017. Late Bids will not be accepted in any circumstances.

PATH will not accept responsibility for resolving technical transmission problems with proposals submitted electronically. PATH will not accept hard copy submissions.

## F. Scoring methodology and evaluation criteria

Bids will be assessed against both technical and financial areas by a technical panel drawn from PATH's Center for Vaccine Innovation and Access. An external representative will be appointed to the committee. This may include an external peer reviewer or a relevant official from a partner organization.

The following evaluation criteria and weighting will be applied.

| ***Areas*** | ***Sub Criteria*** | ***Weighting*** |
|---|---|---|
| Technical area: overall approach to research implementation | Appreciation of the SOW and rationale for the study and expected outputs | 9 |
| | Skills and experience in qualitative research practice and ability to develop skills in longitudinal approaches to qualitative enquiry | 9 |
| | Country presence, and suitability to work in pilot areas | 6 |
| | Skills in complex data management systems | 6 |
| Technical area: quality of personnel | Quality of Team Leader | 8 |
| | Composition of the team, breadth and depth of relevant experience, and clarity of roles and responsibilities | 8 |
| | Team availability and continuity, and retention of key staff | 4 |
| | Feasibility of management arrangements, and ability to deliver on complex research programmes | 8 |
| | Demonstrated cross-institutional collaborative research | 2 |
| | *Sub total* | *60* |
| Financial area | Level of financial risk. Adequate financial, administrative and accounting processes in place to ensure proper usage of donor funds | 5 |
| | Assurance that the budget is developed to mitigate any financial risk associated with delays or other potential challenges | 5 |
| | Competitiveness of total costs including fee rates, expenses, transparent pricing structure, and value for money | 30 |
| | *Sub total* | *40* |
| | *Overall total* | *100* |

The following scoring methodology will be applied to each of the sub criteria detailed on the table above. The total score for each sub criteria will comprise the score awarded (1 to 4), multiplied by the weighting allocated to each sub criteria.

| | |
|---|---|
| 1 | Poor – Inappropriate or poor response to important criteria, indicating that the Bidder has misunderstood important aspects of the SOW. Important information is missing. The Bidder has limited experience in similar field of assignments. The workplan omits important activities and is inconsistent. There is no clarity in allocation of tasks and responsibilities. |
| 2 | Satisfactory – Generic response to major requirements of the SOW and/or does not respond to specific features of the SOW. The proposal is not specifically tailored to the requirements. Although proposal is suitable, there are insufficient details regarding dealing with critical requirements. The Bidder has experience but not dealt with critical issues. All key activities are included but are not detailed. Staffing arrangements are adequate. |
| 3 | Good – The response is well detailed and is specifically tailored to the requirements of the SOW. Enough flexibility that will allow for adaptation to changes that may occur during service execution. Extensive experience of the Bidder in the area of assignment. All important activities are indicated in the workplan, and their timing is appropriate. Staff skills and needs are matched precisely. |

| | |
|---|---|
| 4 | Very good – In addition to the requirements listed above under "good", important issues are approached in an innovative and efficient way, indicating that the Bidder has outstanding response and solutions. The proposal details ways to improve the results and the quality of the assignment by using advanced approaches, methodologies, and knowledge. The Bidder has outstanding, advanced expertise in areas of the assignment. Sequence and timing of activities are very well defined. The team is integrated, and members have worked together extensively in the past. |

## G. Post-bid clarification

When proposals are in final review for potential award, PATH may enter into Post-Bid Clarification discussions with the Bidders to ensure we are fully content with the feasibility, scale, and value for money offered by the proposals. The final agreed proposal and a revised Scope of Work will then form the basis of PATH's requirements, against which the successful Bidder will be contracted.

## H. Conclusion of the process

Bidders will be notified of PATH's decision by 21 September 2017. Final award is subject to the terms and conditions included in this request for proposals, as well as successful final contract negotiations of all applicable terms and conditions affecting this work.

# VIII. TERMS AND CONDITIONS OF THE SOLICITATION

Participation in the bidding process confirms that the Bidder accepts the following Terms and Conditions.

## A. Notice of non-binding solicitation

PATH reserves the right to reject any or all bids received in response to this solicitation, and is in no way bound to accept any proposal.

## B. Confidentiality

All information provided by PATH as part of this solicitation must be treated as confidential. In the event that any information is inappropriately released, PATH will seek appropriate remedies as allowed. Proposals, discussions, and all information received in response to this solicitation will be held as strictly confidential, except as otherwise noted.

## C. Conflict of interest disclosure

Suppliers bidding on PATH business must disclose, to the point of contact listed in the RFP, any actual or potential conflict of interest. Conflicts of interest could be present if: there is a personal relationship with a PATH staff member that constitutes a significant financial interest, board memberships, other employment, and ownership or rights in intellectual property that may be in conflict with the Supplier's obligations to PATH. Suppliers and PATH are protected when actual or perceived conflicts of interest are disclosed. When necessary, PATH will create a management plan that provides mitigation of potential risks presented by the disclosed conflict of interest.

## D. Communication

All communications regarding this solicitation shall be directed to appropriate parties at PATH indicated in Section VII A. Contacting third parties involved in the project, the review panel, or any other party may be considered a conflict of interest, and could result in disqualification of the proposal.

## E. Acceptance

Acceptance of a proposal does not imply acceptance of its terms and conditions. PATH reserves the option to negotiate on the final terms and conditions. We additionally reserve the right to negotiate the substance of the finalists' proposals, as well as the option of accepting partial components of a proposal if appropriate.

## F. Right to final negotiations

PATH reserves the option to negotiate on the final costs and final scope of work, and also reserves the option to limit or include third parties at PATH's sole and full discretion in such negotiations.

## G. Third-party limitations

PATH does not represent, warrant, or act as an agent for any third party as a result of this solicitation. This solicitation does not authorize any third party to bind or commit PATH in any way without our express written consent.

## H. Proposal validity

Proposals submitted under this request shall be valid for 120 days from the date the proposal is due. The validity period shall be stated in the proposal submitted to PATH.

## I. Cost of the bid

Bidders will remain responsible for all costs and expenses incurred by them, their staff, and their advisors, or by any third party acting under their instruction in connection with this RFP. This will be regardless of whether such costs arise as a result of any direct or indirect amendments made to this RFP by PATH at any time. PATH shall have no liability to respondents for the costs of any amendments, changes, discussions, or communications.