TERMS OF REFERENCE TO ENGAGE A MEDICAL RESEARCH ORGANIZATION FOR CHEMOPREVENTION EFFICACY STUDY IN KWARA STATE.

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Organisational Background

Established in 2003, Malaria Consortium is one of the world's leading non-profit organizations which specializes in the comprehensive prevention, control and treatment of malaria and other communicable diseases among vulnerable and underprivileged populations. We increasingly find that our work on malaria can be effectively integrated with other similar public health interventions for greater impact and therefore expanded our remit to include child health and neglected tropical disease interventions.

Malaria Consortium has been a leading implementer since the World Health Organization (WHO) issued its recommendation to scale up SMC in 2012. With our partners, we led the rapid scale-up through the Achieving Catalytic Expansion of Seasonal Malaria Chemoprevention in the Sahel (ACCESS-SMC) project in 2015–2017, reaching close to seven million children in Burkina Faso, Chad, Guinea, Mali, Niger, Nigeria, and The Gambia. This project demonstrated that SMC is cost-effective, safe and that high coverage can be achieved at scale. Since 2018, we have continued to support national malaria programmes in Burkina Faso, Chad, Nigeria, and Togo, reaching over 12 million children in 2020. In 2023, Malaria Consortium will conduct research to better understand the chemoprevention efficacy and SPAQ resistance markers prevalence among 3 – 59 months children, using Kwara state as the study setting.

Rationale

For the chemoprevention efficacy and SPAQ resistance markers studies in Kwara State, a medical research organization will serve as one of the key collaborating institutions and will be expected to undertake its supportive role effectively for the attainment of the goal and objectives of the planned studies. NIMR will coordinate and work with the PI to conduct the analysis for the SPAQ resistance markers prevalence component of the planned study as well coordinating the transfer of the samples for the chemoprevention efficacy component of the study to the engaged medical research organization. **The medical research organization will be responsible for the analysis of the Chemoprevention Efficacy samples.**

Purpose of the assignment:

A medical research organization is required as a collaborating institution to support the analysis of samples of the chemoprevention efficacy study in Kwara State as specified in the approved study protocol.

Scope of work

The medical research organization will specifically provide support for the analysis of samples collected for the chemoprevention efficacy aspect of the Chemoprevention Efficacy and SPAQ resistance markers studies (CPES).The medical research organization will analyze the blood samples (which are to be sent by NIMR) to identify chemoprevention failure, drug concentrations and drug resistance genotypes amongst the blood samples blood samples taken on days 0, 7, 14, 21 & 28. The medical research organization is expected to sign the Data and Materials Transfer Agreement (DMTA), along with the PI for the study in Kwara state, NIMR and Malaria Consortium. The medical research organization will be required to submit an implementation plan for the tasks after engagement as a collaborating institution for the chemoprevention efficacy and SPAQ resistance markers studies, including the quality assurance mechanisms which they plan to put in place.

Specific tasks

1. Identify and provide dedicated personnel to carry out all the tasks specified to adequately support the study.
2. Collect blood samples for the chemoprevention efficacy study from NIMR and coordinate with the PI in Kwara state and focal person at Malaria Consortium for the analysis of blood samples.
3. Take responsibility for the blood samples collected from NIMR ensuring adequate quality assurance mechanisms are put in place and followed throughout the period of the sample analysis.
4. Sign the Data & Materials Transfer Agreement (DMTA) along with all relevant signatories as per the study protocol.
5. Coordinate with all other collaborating institutions (NMEP, Malaria Consortium, NIMR etc.), ensuring that key tasks/activities are undertaken, and the objectives of the studies are achieved, while adhering to the highest scientific standards.
6. Provide a detailed report outlining the findings from the analysis of the blood samples for the Chemoprevention Efficacy study in Kwara state to Malaria Consortium and NMEP.

Deliverables

1. Completely signed DMTA and any other relevant documentation showing that the blood samples have been successfully collected from NIMR.
2. Data analyzed for the Chemoprevention Efficacy study.
3. Final sample analysis report for the Chemoprevention Efficacy study.
4. Final comprehensive activity report documenting the processes of carrying out the activities, analysis and results, challenges as well as the lessons learned and recommendations.

Specifications for the medical research organi,zation:

- The medical research organization should have at least 10 years' experience in conducting medical research studies, clinical trials, chemopreventive study anlaysis therapeutic efficacy studies etc.

- An organization with experienced laboratory scientists that are readily available to fulfil the assigned tasks, including the analyses of blood samples to achieve the aim and objectives of the studies.

- The medical research organization should have the required equipment to conduct different types of laboratory and blood samples analyses.

- The medical research organization should be able to show evidence of similar completed tasks and projects including blood sample analyses conducted for international organizations, government, and the private sector.

Qualifications for the technical leads of the laboratory units at the medical research firm:

- Registration with the relevant professional body.
- Post graduate degree in medical laboratory science, clinical pathology/microbiology and parasitology, Public Health, Social Science or Research, or related field with a minimum of 10 years National and/ or regional experience.
- At least 10 years' experience in the conduct and analysis of biological and blood samples for complex studies.
- Demonstrated experience in carrying out analysis with teams at national, state and/or LGA levels, liaising with government, and managing relationship with key stakeholders, especially at National and State levels, service delivery points.