

## JOB DESCRIPTION

<b>Job title:</b>	<b>Senior Clinical Trial Manager</b>	<b>Location:</b>	<b>Kampala, Uganda</b>
<b>Department:</b>	<b>Seasonal Malaria Chemoprevention (SMC)</b>	<b>Length of contract:</b>	<b>One year</b>
<b>Role type:</b>	<b>National</b>	<b>Grade:</b>	<b>11</b>
<b>Travel involved:</b>	<b>Up to 50% travel within Uganda; occasional international travel</b>	<b>Child safeguarding level:</b>	<b>1, high risk</b>
<b>Reporting to:</b>	<b>Line manager: Senior Country Technical Coordinator</b>	<b>Direct reports:</b>	<b>Research Coordinator</b>
	<b>Dotted line manager: SMC Programme Director</b>		

### Organisational background

Established in 2003, Malaria Consortium is one of the world's leading non-profit organisations specialising in the comprehensive prevention, control and treatment of malaria and other communicable diseases among vulnerable and under privileged populations. We increasingly find 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.

Since inception in 2003, Malaria Consortium Uganda, has been established as the leading technical research and implementing organisation for holistic malaria and childhood disease control in the country.

We work closely with the Ugandan Ministry of Health at national and sub-national levels to strengthen staff capacity and provide technical support for the control of malaria and other childhood diseases. We are experts in long lasting insecticidal net (LLIN) distribution, including mass distribution campaigns as well as routine distribution through antenatal care facilities and schools as well as private sector coupon systems. Malaria Consortium Uganda is the Pioneer and the largest implementer of Integrated Community Case management.

Our areas of expertise include:

- disease prevention, diagnosis and treatment
- disease control and elimination

- systems strengthening
- research, monitoring and evaluation leading to best practice
- behaviour change communication
- national and international advocacy and policy development

## Project background

Seasonal malaria chemoprevention (SMC) is a highly effective community-based intervention to prevent malaria infections in areas where the malaria burden is high, and transmission occurs mainly during the rainy season. It involves administering monthly courses of sulfadoxine-pyrimethamine (SP) and amodiaquine (AQ) during this peak transmission period to those most at risk: children under five. In 2019, SMC was implemented in 13 countries in the Sahel region of Africa, targeting over 21 million children. To-date, SMC has not been deployed at scale outside of the Sahel due to concerns over the widespread resistance to SP across much of the African continent.

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. We also started research projects in Mozambique and Uganda to explore the feasibility and impact of SMC outside the Sahel.

The first phase of the SMC pilot project was implemented in between May and October 2021 in two districts of Kotido and Moroto in Karamoja region in N. Eastern, Uganda with promising results. The second phase, to be implemented during the 2022 peak malaria season, will involve conducting a cluster randomised controlled trial (cRCT) to determine the effect of implementing SMC in the same region and conduct randomized control trial to compare the safety and protective efficacy of SPAQ and Dihydroartemisinin- Piperazine (DHAPQ) against malaria attacks among children 3-59 months of age. The research will also involve further work to explore how resistance to SMC drugs affects the effectiveness of the intervention. This study has the potential to inform SMC policy and practice nationally and internationally.

## Job purpose

The Senior Clinical Trial Manager will ensure that research activities during the second phase of the SMC pilot project in Uganda are carried out in accordance with study protocols and to the highest scientific standards. The role will also ensure appropriate dissemination of study findings and advise on the scope of further research in preparation for a potential scale-up of SMC in Uganda and beyond.

## Scope of work

The role will work closely with the Senior Country Technical Coordinator (SCTC)/ Principal Investigators (PIs) and SMC project team on planning, coordinating, quality assuring and completing the second phase of the SMC pilot project in Uganda.

## Key working relationships

Under the direct supervision of SCTC and PI at Malaria Consortium, the Senior Clinical Trial Manager will be responsible for coordination of both the internal and external project stakeholders on phase 2 research activities. The key stakeholders will include the NMCD - MOH), Surveillance, Monitoring and evaluation and Operational Research (SMEOR) Technical Working Group (TWG) and other Implementing Partners on Research.

Externally, the role will interact with the PI at the NMCD - MOH, research partner organisations, the research advisory committee (RAC) and the wider SMC community, in particular through the SMC Alliance's research sub-group.

## Key accountabilities

### 1. Management of research activities (20%)

- In collaboration with the PIs, liaise with relevant ethics committees to ensure necessary ethical approvals are in place before research activities commence
- Work with the PIs and the Research Advisor to ensure that the study is meeting its targets, is producing meaningful outputs and to predict and plan any changes that warrant requests to changes in study protocols, funding or time
- In collaboration with the PI, Project Manager and SMC research and monitoring team, develop and monitor research plans, taking corrective action as required to ensure quality and timely delivery of research outputs
- Manage relationships with research partners to ensure outputs are delivered as per the agreed contracts
- Provide regular progress reports to the PI, Research Advisor, RAC and SMC programme team.
- Provide regular progress updates to the SCTC in country.
- Compile research reports as per donor requirements
- Ensure all study files are maintained and archived appropriately, ensuring data protection and confidentiality requirements are met
- Coordinate the preparation and publication of research findings, ensuring that they meet legislative, contractual and ethical requirements
- Ensure research activities comply with Malaria Consortium's research policy, good clinical practice, data protection and ethical requirements
- Ensure the implementation of dry blood spot samples for sample processing is excellent

### 2. Quality assurance of research outputs (40%)

- Work with the PIs, SMC project team in country and global research team, research partners and the project team to develop, refine and pre-test data collection methods and tools
- Work with the PIs, SMC project team in country and, research partners to establish procedures to ensure adherence to research protocols and administrative requirements, including timely recruitment of trial participants, secure randomisation processes and effective data management and analysis

- Work with research partners and the project team to ensure data collectors and data analysts are appropriately trained and supervised
- Establish appropriate quality assurance mechanisms to monitor the quality of incoming data, taking corrective action as required to ensure they meet high scientific standards

### **3. Research uptake and dissemination of findings (20%)**

- In collaboration with the SCTC, CD and project manager and research Coordinator to proactively engage with relevant national and international stakeholders throughout the project to inform them about the project, seek their views and input as appropriate
- Support the project team in engaging with local stakeholders and communities throughout the project to inform them about the project, seek their views and input as appropriate
- Identify opportunities for the dissemination of study findings nationally and internationally through relevant meetings, working groups or conferences
- Identify opportunities for collaboration and exchange with relevant academic partners
- Share learning internally through the SMC research working group at Malaria Consortium
- Lead the write up and publication of research findings in peer-reviewed journals
- Support the dissemination of study findings to non-academic audiences through appropriate formats and platforms

### **4. Further research (20%)**

- Working with the Research Advisor, SMC technical lead and other team members, develop a strategy for further research to further strengthen the evidence base on the use of SMC outside the Sahel during a potential scale-up phase in Uganda
- In particular, support the global team on the development on further research concerning the role of resistance, eligibility for SMC and cost-effectiveness
- In consultation with the PNCM, support on the development of concept notes and study protocols for 2022/23
- Support the acquisition of funding for 2022/23 research activities
- Engage with SMC programme initiatives, including the research working group, sharing results, good practice and expertise with colleagues across the programme

## **Person specification**

### **Qualifications and experience:**

#### ***Essential***

- Medical background with postgraduate in public health (with focus on epidemiology/biostatistics) or a pertinent social science discipline such as demography
- Experience of designing, implementing and quality assuring complex research projects and in particular large-scale drug and intervention trials, ideally in a global health context
- Good track record in the dissemination of research findings, including at high-profile conferences and publication in peer-reviewed journals

- Experience working in public health in developing countries within government, an international organization or research institution
- Experience of engaging with non-academic audiences about research and research findings, including policy makers, donors and communities
- Good knowledge of malaria and parasite resistance
- Proficient in the development of data entry programmes and in using statistical analysis software (EpiInfo, EpiData, Excel, Access, Stata)
- Experienced in applying qualitative methods of data collection and analysis

### *Desirable*

- Experience of management and participation in complex and multi-component clinical trials
- Good knowledge of SMC and parasite resistance to SP and AQ
- Experience of working with multidisciplinary and multicultural project teams
- Experience of working in Uganda and specifically, Karamoja region,
- Familiar with Uganda's routine HMIS
- Demonstrated ability to work both independently and as part of a team
- Extensive network among relevant stakeholders, including academics, donors and policy makers
- Track record in securing funding for research projects

### **Work based skills:**

#### *Essential*

- Proven ability to manage complex research projects, particularly large-scale drug and intervention trials
- Capacity to absorb and evaluate complex information in order to advise others
- Excellent written and verbal communication skills
- Project management skills
- Excellent interpersonal skills, influencing and communication skills
- Ability to work effectively, collaboratively, and in a mutually supportive manner as part of a team and to take the initiative in solving problems and in project-based activities
- Awareness of ethical and regulatory frameworks governing research
- Excellent computing and IT skills, including web technologies, MS Office and relevant data analysis software
- Ability and willingness to travel within Uganda and overseas if required
- Fluency in English and Portuguese

#### *Desirable*

- Ability to communicate effectively between different disciplines
- Budget management skills

<b>Core competencies:</b>
<b>Delivering results</b>
<b>LEVEL C - Supports others to achieve results:</b> <ul style="list-style-type: none"> <li>✓ Displays a positive and enthusiastic approach and is not deterred by setbacks, finding alternative ways to reach goals or targets.</li> <li>✓ Supports others to plan and deliver results</li> <li>✓ Supports others to manage and cope with setbacks</li> </ul>
<b>Analysis and use of information</b>
<b>LEVEL C- Works confidently with complex data to support work:</b> <ul style="list-style-type: none"> <li>✓ Interprets complex written information</li> <li>✓ Works confidently with data before making decisions: for example, interpreting trends, issues and risks</li> <li>✓ Acquainted with the validity, relevance and limitations of different sources of evidence</li> </ul>
<b>Interpersonal and communications</b>
<b>LEVEL D - Communicates complex technical and/or sensitive/high risk information effectively</b> <ul style="list-style-type: none"> <li>✓ Communicates complex operational, technical and strategic issues clearly and credibly with widely varied audiences</li> <li>✓ Uses varied communication to promote dialogue and shared understanding and consensus across a variety of audiences</li> <li>✓ Influences internal and external audiences on specific issues</li> <li>✓ Scans the internal and external environment for key information and messages to support communications strategies</li> </ul>
<b>Collaboration and partnering</b>
<b>LEVEL C - Builds strong networks internally and participates actively in external networks and think tanks:</b> <ul style="list-style-type: none"> <li>✓ Builds strong networks internally</li> <li>✓ Participates actively in external networks and/or think tanks.</li> <li>✓ Engages with relevant experts to gather and evaluate evidence</li> <li>✓ Shares and implements good practice with internal and external peers</li> </ul>
<b>Leading and motivating people</b>
<b>LEVEL C – Effectively leads and motivates others or direct reports</b> <ul style="list-style-type: none"> <li>✓ Gives regular, timely and appropriate feedback,</li> <li>✓ Acknowledges good performance and deals with issues concerning poor performance</li> <li>✓ Carries out staff assessment and development activities conscientiously and effectively</li> <li>✓ Develops the skills and competences of others through the development and application of skills</li> <li>✓ Coaches and supports team members when they have difficulties</li> </ul>
<b>Flexibility/ adaptability</b>
<b>LEVEL D - Clarifies priorities and ensures learning from experience:</b> <ul style="list-style-type: none"> <li>✓ Clarifies priorities when leading change</li> <li>✓ Sees and shows others the benefits of strategic change.</li> <li>✓ Helps colleague's/team members to practice stress management through prioritization of workloads and modelling of appropriate self-management and care</li> <li>✓ Makes time to learn from experience and feedback, and apply the lessons to a new situation</li> </ul>
<b>Living the values</b>
<b>LEVEL C - Supports others to live Malaria Consortium's values:</b> <ul style="list-style-type: none"> <li>✓ Demonstrates personal integrity by using role position responsibly and fairly</li> <li>✓ Cultivates an open culture within the wider team, promoting accountability, responsibility and respect for individual differences</li> </ul>
<b>Strategic planning and thinking and sector awareness</b>
<b>LEVEL C - Keeps up to date with the internal and external environment:</b> <ul style="list-style-type: none"> <li>✓ Takes into account economic, political and other business factors when drawing up medium and long-term plans, covering both public and private sectors,</li> </ul>

- ✓ Looks beyond the immediate operations to prospects for new business,
- ✓ Engages with appropriate internal and external sources to establish major influences on future plans