

116682 - An epidemiology study to assess Plasmodium falciparum parasite prevalence and malaria control measures in catchment areas of two studies pre- and post RTS,S/AS01E introduction (EPI MAL-002 and EPI-MAL-003) to assess, in field conditions, vaccine benefit:risk in children in sub Saharan Africa. (EPI-MALARIA-005 BOD AME)

**First published:** 22/12/2021

**Last updated:** 23/09/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS43920

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### Study ID

47949

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## **DARWIN EU® study**

No

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### **Study countries**

- Burkina Faso
  - Ghana
  - Kenya
  - Malawi
  - Senegal
  - Tanzania, United Republic of
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### **Study description**

This epidemiology study is planned to run in parallel with the EPI-MAL-002 and EPI-MAL-003 studies, enrolling from the same health and demographic surveillance system (HDSS) (or equivalent system) populations.

The co-primary objectives are to produce longitudinal estimates of parasite prevalence in humans, and record malaria control measures usage in areas where EPI-MAL-002 and EPI-MAL-003 studies will take place.

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### **Study status**

Finalised

## **Research institutions and networks**

### **Institutions**

**GlaxoSmithKline (GSK)**

**First published:** 01/02/2024

Last updated: 01/02/2024

Institution

## Biologicals

Centre de Recherche en Santé de Nouna (CRSN)  
Nouna, Burkina Faso, Centre National de  
Recherche et de Formation sur le Paludisme  
(CNRFP) Ouagadougou, Burkina Faso, Kintampo  
Health Research Centre (KHRC) Kintampo, Ghana,  
Navrongo Health Research Centre (NHRC)  
Navrongo, Ghana, KEMRI-Walter Reed Project  
(KEMRI-WRAIR) Kombewa, Kenya, KEMRI / CDC  
Research and Public Health Collaboration Kisumu,  
Kenya, KEMRI (Ahero Clinical Trials Unit) Kisumu,  
Kenya, Malawi College of Medicine (COM)  
Mangochi, Malawi, Malawi Liverpool Welcome  
Trust (MLW) Blantyre, Malawi, Département de  
Parasitologie, Centre de Recherche de Keur Socé,

Faculté de Médecine, Université Cheikh Anta Diop  
Dakar, Senegal

## Contact details

### Study institution contact

Call Center EU Clinical Trials

Vx.publicdisclosureglobal@gsk.com

Study contact

[Vx.publicdisclosureglobal@gsk.com](mailto:Vx.publicdisclosureglobal@gsk.com)

### Primary lead investigator

Call Center EU Clinical Trials

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 21/01/2014

Actual: 21/01/2014

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### Study start date

Planned: 22/10/2014

Actual: 22/10/2014

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### Date of final study report

Planned: 16/09/2025

Actual: 16/09/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## Study protocol

[gsk-116682-protocol-redact.pdf](#) (1.37 MB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Main study objective:**

To obtain longitudinal estimates of *P. falciparum* parasite prevalence, assess malaria transmission intensity, and evaluate malaria control interventions at EPI-MAL-002 and EPI-MAL-003 study centers pre- and post- introduction of the RTS,S/AS01E malaria vaccine in sub-Saharan Africa.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medical condition to be studied**

Malaria

## Population studied

## **Age groups**

- Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
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## **Estimated number of subjects**

54000

# Study design details

## **Outcomes**

Number of subjects infected with *P. falciparum* parasitaemia (using microscopy) and number of subjects using malaria control interventions (primarily bednets), Number of subjects infected with Plasmodium species other than *P. falciparum*, with uptake of the third dose of DTP pentavalent and the first dose of the measles EPI vaccines, using anti-malarial therapy in the 14 days prior to the visit, with measured fever at the visit or reported fever in the 24 hours prior to the visit, demonstrating care seeking behavior, and/or presenting risk factors.

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## **Data analysis plan**

- The parasite prevalence will be estimated as the proportion of subjects infected among subjects tested. The estimates of parasite prevalence will be done each year and for each site separately.
- The estimates of the use of malaria control measures will be estimated as the number of subjects using malaria control measures divided by the number of subjects for which this information is available. The estimates of the use of malaria control measures will be done each year and for each site separately.
- The trends in parasite prevalence between each cross-sectional malariometric surveys will be tested using the Cochran-Armitage trend test. This hypothesis test will be performed on the parasite prevalence computed on the independent

samples of subjects in each survey separately within each site.

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### **Data source(s)**

Other data source

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### **Data source(s), other**

Prospective patient-based data collection, Collection of centre specific information about interventions from malaria control program in the study area and meteorological data such as rainfall, humidity, and temperature.

Information will be collected with a questionnaire recorded in a separate database for subject-specific data.

Other 2 participating centres are IRD, Dakar, Senegal, and JMP Nat. Inst. Medical Research, Korogwe, Tanzania.

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### **Data sources (types), other**

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## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No