GLOBAL HEALTH – AFRICA OPEN LAB – Concept Stage Submission Form Template

Proposal

Important: In order for GSK to complete the timely and accurate review of your proposal, you need to provide the following minimum information on your proposal, either by fill in this template or by providing any other available proposal document or protocol. Please complete the information as it applies to your proposal. Use "Not Applicable" where the requested information does not apply to your proposal.

Please note you can save your proposal any time. A field is required if marked with *

Sponsor Information

Sponsor: This is the external entity (e.g., external investigator, healthcare institution, medical network, academic research organisation) who is accountable for all aspects of the study, including compliance with all applicable ethical codes, laws and regulations that governs the research to be conducted, regardless of whether GSK is fully or partially funding the study.

* **Is the Sponsor an individual or an institution?**

* **Name of the Sponsor:**

Sponsor Institution Type:

Institution Type choices are: Company / Cooperative Group / Hospital / Physician Network / Private Practice / University of Academic Center

* **Sponsor Address:**

* **Country:**

* **Sponsor email Address:**

* **Sponsor phone number:**

* **Is the Principal Investigator contact different from the Sponsor?**

Yes / No

If yes:

* **Name of the Principal Investigator**

* **Principal Investigator email address**

* **Principal Investigator phone number**

GSK

GLOBAL HEALTH – AFRICA OPEN LAB – Concept Stage Submission Form Template

* **Institution Type**

Institution Type choices are: Company / Cooperative Group / Hospital / Physician Network / Private Practice / University of Academic Center

* **Institution Name**

* **Address**

* **Do you have other key personnel participating in the study?**

Yes / No

If yes:

Title	*Name	*Phone	*Email	Affiliation
e.g.: Project Manager				
e.g.: Co-Investigator				
e.g.: Study Coordinator				
e.g.: Other				

* **Are you working with any Cooperative Group, Research Consortium and/or Physician Network?**

Yes / No

* ***If yes***:

* Please specify names:

* **Have you been in contact with any GSK employees with regards to this submission?**

Yes / No

* ***If yes***:

* Please specify names:

How did you hear about the GSK Supported Studies Program?

Choices are: Congress / GSK Medical Contact / Medical Journal / Website / Other.

If Other:

Please specify:

GSK

GLOBAL HEALTH – AFRICA OPEN LAB – Concept Stage Submission Form Template

Support Requested

GSK does not provide support for sponsor pay, incentive to join the study.

*Please indicate which therapeutic area you would like this to be directed:

Global Health – Africa Open Lab

Please note: The Africa Open Lab Project is open only to countries in sub-Saharan Africa.

* **Disease**

Disease choices are: Antimicrobial Resistance (AMR) linked to these infectious diseases / Emerging infectious diseases of relevance for Africa / Enteric infections/ Malaria / Neglected Tropical Diseases / Other/ Other bacterial infections / Respiratory infections / Tuberculosis

***If Other**:*

*Please specify:

* **Supported Study type:**

Human Subject Research applies to research that uses human individual data or human biological materials to evaluate use of a product or a technology in, or by, humans, or to answer a human health-related scientific question

Select one: HSR / Other

***If Other**:*

*Please specify:

If HSR:

* **Study Phase**

Choices are: Non-Interventional / Pilot / Phase I / Phase **I/II** / Phase II / Phase **II/ III** / Phase III / Phase IIIb / Phase IV / N/A

* **Is monetary support required?**

Yes / No

If monetary support is requested/ please complete the table below:

	Amount in GBP
Materials and consumables	
Equipment	
Field Work	
Travel and subsistence	
Research Assistance	
Training	
Other -specify	
Other - specify	
Total	

(Please note the total sum is automatically calculated on the online form, as the amounts are being entered)

* **Any other type of support requested?**

Yes / No

For guidance on type of support, see iss.gsk.com

***If yes**:*

Please specify:

* **In which countries will the study research take place?**

***If multiple**: check ☐ on the online submission form to have more rows*

(If required, more rows can be added)

* **Country of Primary Site**

* **Number of sites**

* **Is this study funded or supported by, or under consideration for funding or support, from another agency or sponsor?**

Yes / No

If yes:

Please specify the additional supporting sources/ entities and the type of support requested:

GLOBAL HEALTH – AFRICA OPEN LAB – Concept Stage Submission Form Template

Scientific Context

The required fields below outlining the scientific context of your proposal are required for GSK to make an assessment of your proposal, guidance on GSK requirements for these sections can be found in the User Guidance of the Submission Portal.

You can also submit your Scientific context as an attachment in the Files tabs on top of the online submission form page, please do however indicate NIA in the question boxes below.

* **Estimated study start date:** *(FSFV / Study Start / Analysis Start)*

Studies may be initiated after a fully signed contract is in place. Please ensure enough time is given when estimating the planned study start date. This may take up to 10 months from when final decision is communicated

Month	*Year*

* **Estimated study completion date:** *(LSLV / Study End / Analysis Complete)*

Month	*Year*

* **Scientific Rationale**

Provide a brief summary of the overall purpose and rationale for this proposed study and/or summary of any relevant background information.

Characters available: 2500

GSK

GLOBAL HEALTH – AFRICA OPEN LAB – Concept Stage Submission Form Template

* Research Question

Characters available: 2500

* Primary Objectives

Please ensure you detail primary objectives

Characters available: 2500

* Key Secondary Objectives

Please ensure you detail secondary objectives

Characters available: 2500

* Inclusion Criteria

Characters available: 2500

* **Exclusion Criteria**

Characters available: 2500

* **Study Population**

Provide a general description of the study population (e.g., number of subjects, subject demographics such as age, sex, and other key characteristics) and specify whether the study is expecting to include Children in Care If the proposed interventional study population includes Children in Care*, provide a justification for the enrolment, including: evidence that the benefits outweigh the risks, the scientific and/or medical question is relevant to children.*

Characters available: 2500

* **Does your proposal involve Children in Care?**

Children in Care (CiC) are children who have been placed under that control or protection of an agency, organisation, institution or entity by the courts, the government or a government body, acting in accordance with powers conferred on them by law or regulation. The definition of CiC can include children cared for by foster parents or living in a care home or institution, provided that the arrangement falls within the definition above. The definition of CiC does not include a child who is adopted or has appointed legal guardian.

Yes / No

* **Does your proposal involve Women of Childbearing Potential (WOCBP)?**

Please note that the appropriate language related to contraception and pregnancy testing may need to be included in the protocol for proposal involving WOCBP.

Yes / No

* **Does your proposal involve patients receiving ionisation radiation? (e.g., involve CT scans, X-rays)**
Please note information regarding ionising radiation will need to be included in the protocol if it is not standard of care.

Yes / No

* **Target enrolment/ sample size:**

e.g.: 100

(Required for clinical studies)

* **Study Design and Methods**

Characters available: 3000

* **References**

Include references to any existing published studies and any other background information you believe is relevant to the review of this proposal

Research Experience

As part of the concept submission, you will be required to provide a copy of your Curriculum Vitae – for your convenience, a CV template is provided in the online submission form.

If the information below is not already available in your CV, please could you provide it here. If all of this information is available in your CV, please check "Not applicable" below in the online submission form.

☐ Not applicable

1) Publications

(Please list up to 20 of your peer reviewed publications, including any "in press", in chronological order, starting with the most recent first. Please give citation in full, including title of paper or book chapter and list of all authors ensuring that your position as author is highlighted (Do not include abstracts))
The maximum number of rows available is 20.

Date	Citation in full	Title of Paper or Book Chapter	Authors

2) Presentations at Scientific Conferences

List up to 5 oral presentations or abstracts presented at scientific seminars/ conferences including the title, the date, venue and title of the conference and include a brief description of the audience.
The maximum number of rows available is 5.

Date	Oral presentation Title	Abstract Title	Conference Name	Country	Brief Description of the Audience

3) Research Grants

List all research funding held (if any) in the last five years (most recent first) for current grants. Please leave blank if you have not held any grant in the past five years.
The maximum number of rows available is 10.

Date	Project Title	Your role within the grant	Awarding Body	Currency	Amount	Grant Period

4) Prizes and Awards

(Please list any prize/ awards you have received in chronological order (most recent first)
The maximum number of rows available is 10.

Date	Prizes and Awards

.