ANNEX 1

Horizon Europe (HORIZON)

Description of the action (DoA)

Part A

Part B

DESCRIPTION OF THE ACTION (PART A)

COVER PAGE

Part A of the Description of the Action (DoA) must be completed directly on the Portal Grant Preparation screens.

PROJECT *Grant Preparation (General Information screen) — Enter the info.*	
Project number:	101103089
Project name:	STOP 2030: TOWARDS THE INTERRUPTION OF TRANSMISSION OF SOIL-TRANSMITTED HELMINTHS: PROMOTING IMPLEMENTATION OF RESEARCH RESULTS OF A FIXED-DOSE COMBINATION OF CO-FORMULATED IVERMECTIN AND ALBENDAZOLE
Project acronym:	STOP2030
Call:	HORIZON-JU-GH-EDCTP3-2022-01
Topic:	HORIZON-JU-GH-EDCTP3-2022-CALL1-01-01
Type of action:	HORIZON-JU-RIA
Service:	RTD/D/01
Project starting date:	fixed date: 1 July 2023
Project duration:	36 months

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PROJECT SUMMARY

Project summary

Grant Preparation (General Information screen) — Provide an overall description of your project (including context and overall objectives, planned activities and main achievements, and expected results and impacts (on target groups, change procedures, capacities, innovation etc)). This summary should give readers a clear idea of what your project is about.

Use the project summary from your proposal.

Soil-Transmitted Helminths (STH) remain a significant public health problem with recognized obstacles for control and elimination with the current benzimidazole regimens in Mass Drug Administration (MDA) campaigns. Renewed targets from WHO for 2030 include elimination of STH morbidity in pre-school and school age children (PSAC & SAC), increased country governance and financial support and a strongyloidiasis control program; 2030 has also been targeted by WHO for controlling NTDs to attain the Sustainable Development Goals.

The current proposal aims at accelerating the implementation of an innovative health technology, a fixed-dose combination (FDC) tablet of co-formulated albendazole and ivermectin, with adequate safety and significantly superior efficacy against T. trichiura in a registrational randomized clinical trial. This trial is being conducted in Ethiopia, Kenya and Mozambique with the guidance of EMA and sponsored by EDCTP (STOP projects) with a Phase II trial completed and a Phase III currently recruiting.

This project, STOP2030, seeks to complement the results of the safety and efficacy trial with a field-based safety and effectiveness clinical study, acceptability studies in Ghana and Kenya, modelling and cost-effectiveness exercises. The resulting information will be consolidated to build a multidisciplinary package for policy making and WHO guidance with the support of advocacy and communication activities to reach stakeholders and maximize the exploitation and impact of the FDC for STH control and elimination.

The Consortium assembled to execute the STOP2030 proposal combines expertise in complementary fields from program assessment and implementation through Ministries of Health in sub-Saharan African countries, advocacy, state of the art technology, leadership in clinical research and a pharma that has shown commitment for generating access to drugs against NTDs and has recently obtained WHO prequalification for generic ivermectin.

LIST OF PARTICIPANTS

PARTICIPANTS

Grant Preparation (Beneficiaries screen) — Enter the info.

Number	Role	Short name	Legal name	Country	PIC
1	COO	Liconsa	LABORATORIOS LICONSA SA	ES	990555950
2	BEN	ISGLOBAL	FUNDACION PRIVADA INSTITUTO DE SALUD GLOBAL BARCELONA	ES	951414122
3	BEN	FMS ESPANA	FUNDACION MUNDO SANO ESPANA	ES	885624551
4	BEN	KEMRI	KENYA MEDICAL RESEARCH INSTITUTE	KE	997741225
5	BEN	GHS	GHANA HEALTH SERVICE	GH	894057343
6	BEN	GRL	GENOME RESEARCH LIMITED	UK	999981343
7	AP	Bridges	BRIDGES TO DEVELOPMENT	CH	896766941

LIST OF WORK PACKAGES

Work packages

Grant Preparation (Work Packages screen) — Enter the info.

Work Package No	Work Package name	Lead Beneficiary	Effort (Person-Months)	Start Month	End Month	Deliverables
WP1	Consortium Coordination and Management	1 - Liconsa	51.00	1	36	D1.1 – Data Transfer Agreement D1.2 – Terms of reference for project committees D1.3 – Risk management record (Y1) D1.4 – Communication Plan D1.5 – Risk Management record (Y2)
WP2	Biomedical Sciences: Safety and Effectiveness studies	2 - ISGLOBAL	201.00	1	36	D2.1 – Registration number of clinical study D2.2 – Study approval package D2.3 – Clinical monitoring plan D2.4 – Clinical data management plan (cDMP) D2.5 – Midterm recruitment report D2.6 – Report on the status of posting results D2.7 – Genomic protocol
WP3	Modelling and database management	4 - KEMRI	28.00	1	36	D3.1 – Data management plan D3.2 – Locked and cleaned database available D3.3 – Updated Data Management Plan
WP4	Acceptability, feasibility, and adherence	5 - GHS	36.00	1	12	D4.1 – Formative study on Acceptability & Feasibility completed D4.2 – Protocol for KAP study on Acceptability & Feasibility protocol & implementation plan completed

Work packages

Grant Preparation (Work Packages screen) — Enter the info.

Work Package No	Work Package name	Lead Beneficiary	Effort (Person-Months)	Start Month	End Month	Deliverables
						D4.3 – Implementation acceptability & Feasibility study in Ghana D4.4 – Implementation Acceptability & Feasibility study in Kenya D4.5 – Data analysis and interpretation D4.6 – Exploitation and dissemination plan
WP5	Policy, access, advocacy, and communications	7 - Bridges	131.00	1	36	D5.1 – WHO Pathway D5.2 – Communications and Advocacy D5.3 – Draft Stewardship plan D5.4 – Final Stewarship plan D5.5 – Launched Project - WEBSITE D5.6 – Global Access Plan

Work package WP1 – Consortium Coordination and Management

Work Package Number	WP1	Lead Beneficiary	1. Liconsa
Work Package Name	Consortium Coordination and Management		
Start Month	1	End Month	36

Objectives

Obj 1.1 To set-up a project management structure that ensures efficient operational management including administrative, financial, and legal issues, and appropriate liaison with EDCTP.
Obj 1.2 To provide the overall direction and to drive the progress of the project, steering efforts of the partners for the achievement of the project's objectives.
Obj 1.3 To ensure a good project integration enabling the appropriate communication and work dynamics to help drive the whole Consortium as a team towards successful completion.
Obj 1.4 To ensure that the work is appropriately managed according to the project roadmap, undertaken to the highest quality levels and within the established timelines and costs.

Description

Led by Dr. Alejandro Krolewiecki, from Laboratorios Liconsa, S.A. the Scientific Coordination and Management teams will (1) guarantee overall and transdisciplinary management of the project's evolution from the ethical, implementation, and cost perspectives (2) deal with strategic direction by gathering and reacting to new ideas (3) optimizing the use of the capacities and resources of the project partners (4) supervising WP leaders as they execute their role and (5) monitor progress and achievement of objectives.

The coordination of the Consortium will combine expertise in project management in all administrative and financial aspects, including interactions with regulatory agencies and drug importation procedures, of the project with the scientific leadership of Dr. Krolewiecki, who is the Chief Investigator of the ALIVE clinical trial of the STOP project and is joining the Liconsa team for this new stage of the project. Dr. Krolewiecki brings his expertise in global health, dedicated to STH as leading author of multiple scientific projects and member of the STH-Advisory Committee at Task Force for Global Health and of the Drug Efficacy sub-group of the STH & Schisto Technical Advisory Group at WHO.

Task 1.1: Daily management and Contract management (months 1-36)
Task Leader: Liconsa
Partners involved: ISGlobal, FMS España, KEMRI, GHS, GRL, Bridges.

WP1 will guarantee the supervision of the project and strategic decision making. It will also help to promptly identify risks and implement appropriate contingency measures. This task will also deal with:
A. Liaison with the EDCTP.
B. All contractual and other legal issues related to the project, which will primarily focus on partnership management (including enabling relationships with third parties, external collaborators and stakeholders)
C. Formalisation of updates of the work plan, roles and resource assignments as needed.
In particular, it will comprise Grant Agreement and Consortium Agreement implementation and amendments, support to partners in legal issues, production of non-disclosure agreements, and Intellectual Property Rights (IPR) management.

Task 1.2: Communication (months 1-36)
Task Leader: Liconsa
Partners involved: ISGlobal, FMS España, KEMRI, GHS, GRL, Bridges.

Especially important for the success of the project will be the establishment and maintenance of an open and proactive interaction among the members of the Consortium, the main ambassadors of the project.
To this end, an effective internal communication system will be established and formalized to ensure the existence of channels that allow fluid and bidirectional communication among Consortium members. The use of electronic devices (internal e-mail, corporate WhatsApp group, collaborative platforms, and video conferences, etc) will be utilized to facilitate communication needs.
Likewise, the appropriate communication messages and tools will be defined within the organization itself, in order to strengthen and align the members´ communication. In addition, ongoing communication with EDCTP and relevant stakeholders will be a priority.

Furthermore, the communication team will also be responsible for scheduling and organizing annual meetings where all Consortium members will self-assess the progress of the project, review next steps and discuss challenges.

Task 1.3.a: Project quality and risk management (months 1-36)
Task Leader: Liconsa
Partners involved: ISGlobal, FMS España, KEMRI, GHS, GRL, Bridges.

This activity is devoted to support the Coordination and overall management structure in:
A. Support in leadership and linkage of project components. Work plan control and updates, implementation of corrective actions.
B. Identifying and recording risks to have them categorized and prioritized accordingly. Risks will be classified by likelihood and impact based on which they will be prioritized and mitigation actions will be identified.
C. Support to Work Package Leaders (WPL) in day-to-day management, decision-making, conflict resolution and consensus building.
D. Promotion of synergies and efficiency throughout the project. Creation of tools for efficient communication and co-operative work among partners. Support to meeting organisation and production of the corresponding minutes. Implementation of derived actions into the work plan, and follow-up.

High-quality standards will be applied to all the work undertaken. Good performance will be a priority of the project, and this will be fostered by openness about achievements, friendly peer-pressure, and constructive criticism. Special relevance will be given to this activity in General Assembly meetings, where members of all Consortium´s partners attend in order to instil the importance of quality procedures in the Consortium.
Finally, quality control and internal peer-review of deliverables and scientific publications will be implemented in order to ensure that any result arising from the project complies with the highest international standards.

Task 1.3.b: Continuous assessment and evaluation (months 1-36)
Task Leader: Liconsa
Partners involved: ISGlobal, FMS España, KEMRI, GHS, GRL, Bridges.

Project leadership will be enabled by a robust management structure. Leadership decisions will also be influenced substantially by the project's General Assembly, and most importantly by the Steering Committee on the daily running of the project. To monitor project progress closely, regular communications will take place (e.g., at least once every 2 months) in the framework of the Steering Committee.
Additionally, annual meetings of the General Assembly will always include specific sessions for each WP to highlight results and provide public accountability of the progress achieved. These communications will reinforce the timely gathering of contributions, the achieving of milestones, the identification of risks, and the delivery of deliverables.

Task 1.3.c: Reporting and Financing (months 1-36)
Task Leader: Liconsa
Partners involved: ISGlobal, FMS España, KEMRI, GHS, GRL, Bridges.

This activity will be devoted to:
A. Financial management: budget management, cost control and justification, EDCTP contribution distribution control (supporting the contractual obligations of the Scientific Coordinator). Budget assignment is expected to be somewhat flexible and help steer efforts in the most productive way; for that, specific, transparent procedures will be included in the Consortium Agreement
B. Periodic Reporting: setting up of reporting mechanisms, providing education and support to partners in appropriate reporting, including facilitation of the task via web-based systems as needed.
Reporting and administration are usually one of the main areas of difficulty for partners. Thus, it is especially important that: a) partners are aware of important determinants of reporting and finances (including the provision of audit certificates, etc.); b) the processes involved are closely monitored; and c) partners get bilateral support to avoid any distortions in the workflow. This will ensure timely delivery of the required reports to the EDCTP.

All these tasks will be reinforced by giving them appropriate visibility in the different Consortium meetings. Special attention will be paid to the correlation between effort reporting and cost justification, and to help partners manage the relationships between financial flows (funding, justification, expenditure, payments) so as to ensure 'distortion-free' scientific progress. This activity will also include coordination of other administrative procedures as needed during the project, especially those particular procedures that stem from the Grant Agreement but also those created to ensure the fulfilment of contractual obligations.

Work package WP2 – Biomedical Sciences: Safety and Effectiveness studies

Work Package Number	WP2	Lead Beneficiary	2. ISGLOBAL
Work Package Name	Biomedical Sciences: Safety and Effectiveness studies		
Start Month	1	End Month	36

Objectives
Obj 2.1 To design and execute a pragmatic trial for the establishment of the safety and effectiveness of a FDC of co-formulated IVM and ALB against STH, as a single dose in school settings of T. trichiura transmission areas Obj 2.2 To design and conduct a nested study to evaluate the impact of the intervention on the seroprevalence of strongyloidiasis. Obj 2.3 To evaluate the effectiveness of deworming programmes using genomic epidemiology data to understand parasite-diversity, transmission, and predict the emergence of anthelmintic resistance.

Description
This work package will be led by the team at ISGlobal, currently in charge of the registrational safety and efficacy ALIVE trial for the STOP and II projects. As a continuation of those activities, ISGlobal will coordinate the biomedical studies to provide further evidence to be integrated with the data generated in WPs 3 & 4 for evaluation by WHO and other relevant stakeholders of the FDC for the treatment, control, and elimination of STH, based on the promising results obtained up to date. The main activity comprises a pragmatic clinical trial to assess the safety and effectiveness of the FDC. This trial will combine the efforts of the field activities of the partners in GHS and KEMRI as well as the team at the WSI contributing with genomic epidemiology tools and Mundo Sano with contributions in medical monitoring through a medical team experienced in monitoring research activities in SSA. The data generated in this WP will serve to feed the modelling activities coordinated by KEMRI for WP3 and the policy, communication and advocacy objectives by Bridges and Mundo Sano in WP5. Task 2.1. Trial design, implementation and coordination (months 1-36) Task Leader: ISGlobal Partners involved: Liconsa, FMS España, KEMRI, GHS, GRL To prepare the submission package with all study documents for Institutional Review Board (IRB) evaluations (including study protocol, statistical analysis plan, informed consent forms and investigational brochure) as well as periodic reports to DSMB and IRBs. It also includes the coordination of drug importation activities to deliver the FDC, ALB and IVM to the field sites for the studies involving drug procurement within this and other WPs. Task 2.1a Selection of study sites (months 1-6) Task Leader: ISGlobal Partners involved: Liconsa, KEMRI, GHS Activities related to the selection of the areas with the adequate epidemiological setting for the conducting the study with adequate support from local services and endorsement by the Ministries of Health, in coordination with the teams at GHS and KEMRI. Task 2.1b Development of a clinical monitoring plan (months 1-15) Task Leader: ISGlobal Partners involved: Liconsa, FMS España. Procedures will be designed and implemented along with the monitoring system in order to ensure that GCP guidelines are followed. Training and guidelines will be developed for the implementation of adequate, thorough and feasible pharmacovigilance activities through collaboration with the pharmacovigilance team from Laboratorios Liconsa in partnership with national pharmacovigilance teams. Task 2.2 Production of study-related databases and materials (months 4-12) Task Leader: ISGlobal Partners involved: Liconsa, KEMRI.

All the materials for the execution of the study including CRFs, randomization lists and pharmacy logs and the databases for the storage and analysis of the data will be developed by the epidemiology and statistics team at ISGlobal in accordance with regulatory rules. These study specific databases will be designed in coordination with WP3 in order to be imported to the databases designed for the study and modelling activities.

Task 2.3 Develop and implement study protocol for sub-studies (months 1–36)
Task Leader: ISGlobal
Partners involved: Liconsa, FMS España, KEMRI, GHS, GRL

Through the platform of the safety & effectiveness study, nested studies will strengthen the project contribution to demonstrate the opportunities created by the FDC through 2 nested studies.

Task 2.3a. Genomic epidemiology sub-study (months 1– 36)
Task Leader: GRL
Partners involved: ISGlobal, KEMRI, GHS

Protocols and IRB related documents will be generated to incorporate the sequencing of a sub-group of stool samples collected for the prevalence studies of the pragmatic trial. The tasks include sample preparation, storage, shipment to WSI, sequencing and data analysis. Included in this sub-study is the arrangement for a trainee from SSA to be trained at the WSI in the UK.

Task 2.3b. Impact of the intervention on Strongyloides stercoralis prevalence (months 1 – 36)
Task Leader: ISGlobal
Partners involved: FMS España, KEMRI, GHS

As a secondary goal of the pragmatic trial, this nested study in a population subgroup will be developed to assess the serologic responses to the NIE assay performed on blood spots in a subgroup of participants. Study protocols, analysis plan and laboratory SOPs will be developed in coordination with the teams of GHS and KEMRI.

Work package WP3 – Modelling and database management

Work Package Number	WP3	**Lead Beneficiary**	4. KEMRI
Work Package Name	Modelling and database management		
Start Month	1	**End Month**	36

Objectives
Obj 3.1: Data analysis and modelling inform evidence-based decision making on FDC in study countries, by WHO, regulators, development partners and Pharma for publication, and presentation Obj 3.2: A database that is cleaned, locked and available for scientifically robust statistical analysis on FDC effectiveness, safety, acceptability, and feasibility is available

Description
Modelling of FDC impact on the prevalence and intensity of infection and costing/cost-effectiveness is required to support introduction planning, policy and national decision making. This work will be led by KEMRI and conducted in partnership with other Consortium members and builds on the outputs from STOP. The STOP2030 modelling will work in the new selected sites in Ghana and Kenya incorporating new data available from safety and effectiveness trials as well as acceptability and feasibility as appropriate. The modelling results will inform decision-making on policies and guidelines, as well as development partners and pharma in preparation for sustainable supply and financing (WP5). In order for these multicentre studies to be successful the Consortium will need scientifically robust, aligned databases, data management, and analysis support for aggregated results to support policy making and decision making. The resulting data systems will ensure a robust database for use in generating the full range of study results including regulatory submissions. Task 3.1a: Model scenario for FDC vs routine treatment with monotherapy in the national programmes in Ghana and Kenya, including impact on prevalence and intensity of infection and costing (Months 1-24).

Task Leader: KEMRI
Partners involved: ISGlobal, GHS, Bridges

KEMRI will first construct the model, running and refining the model based on currently available data from STOP trial which includes safety and efficacy from the clinical trials as well as the incremental cost-effectiveness ratio of FDC compared with ALB per case averted and DALY averted. KEMRI will then use the model to propose the optimal use of FDC in Ghana and Kenya for maximum impact. As the project progresses, KEMRI will refine the modelling of effectiveness and cost-effectiveness based upon the emerging research data (effectiveness, acceptability, feasibility)

Task 3.1b: Model potential global impact based on implementation scenario developed in partnership with Bridges (WP5) (Months 18-36)
Task Leader: KEMRI
Partners involved: FMS España, GHS, Bridges

Building on the work based on Ghana and Kenya, the KEMRI team will work to model the broader impact and cost effectiveness of use of FDC in support of STH control and elimination globally.

Task 3.2a: Data management plan and system developed (Month 6)
Task Leader: KEMRI
Partners involved: Liconsa, ISGlobal, FMS España, GHS

Data management plan and system established in coordination with multicentre study sites and managed to support study data collection and analysis. KEMRI will decide on database structure, management, and software to be used for both the safety and effectiveness trials, as well as the acceptability and feasibility studies. KEMRI will work with ISGlobal on the needs for the safety and effectiveness trials, and Ghana on the acceptability, feasibility and adherence.

Task 3.2b: Data management and cleaning (Month 7-33)
Task Leader: KEMRI
Partners involved: ISGlobal, GHS, GRL

The team will support cleaning of data, reconciling with partners, and locking of the database for analysis in collaboration with Consortium partners. Data set will be completed, locked, and primary analysis conducted by the KEMRI team per the analysis plan, and shared with partners for analysis per WP3, WP4 and WP5.

Work package WP4 – Acceptability, feasibility, and adherence

Work Package Number	WP4	**Lead Beneficiary**	5. GHS
Work Package Name	Acceptability, feasibility, and adherence		
Start Month	1	**End Month**	12

Objectives
Obj 4.1 To conduct a multi-country knowledge, attitudes and practices (KAP) survey to inform the design of the feasibility and acceptability study Obj 4.2 To develop a multi-country acceptability, feasibility and adherence study design aligned to the needs of WHO and MOHs of endemic countries for FDC use within STH programmes Obj 4.3 To conduct a multi country acceptability, feasibility and adherence study and make findings available for use by WHO, national governments and supporting partners.

Description
Completing clinical studies and manufacturing a new medicine alone is not sufficient to ensure it will be used in LMICs. Among the key considerations governments, WHO and development partners will want to understand are the product's acceptability to individuals, parents and communities, the feasibility of implementing it within the health system, and the adherence to dosing schedules being considered. These data contribute to the establishment of guidance from WHO and inform national policies (addressed in WP5).

The Consortium, under Ghana's leadership, will develop a protocol and support the implementation of a multicentre study to address acceptability, feasibility, and adherence. It is anticipated that the study will have three arms:
· Comparator: Tablets of IVM and ALB per WHO dosing guidance
· Oro-dispersible FDC: Single dose (Directly Observed Therapy)
· Oro-dispersible FDC: Single dose for 3 consecutive days (first day Directly Observed Therapy)
The multicentre study will be implemented by study teams in Ghana and Kenya. Ghana, under the leadership of Dr Abraham Oduro (Director, Research and Development Division, Ghana Health Service) and Dr Kofi Asemanyi-Mensah (Programme Manager of Neglected Tropical Diseases), will lead the development of the protocol in consultation with Consortium members. They will also lead the implementation of the protocol in Ghana and support implementation by the study team in Kenya, under the leadership of Charles Mwandawiro and Stella Kepha.
A two-phased study is envisaged. The first phase would be a formative study to explore programme and community factors related to feasibility and acceptability of FDC. The second phase of the study would be a comparative study across the 3 arms above on acceptability and feasibility, in the two countries and a study of adherence to the 3-day regimen.
Task 4.1 (Month 1-4) Design and implement the formative study
Task leader: GHS
Partners involved: FMS España, KEMRI, Bridges

GHS will develop and lead the implementation of a formative study in Ghana and Kenya to inform the acceptability and feasibility of FDC. The formative qualitative study will examine NTDP implementation and identify contextual (programme and community) factors related to MDA that could influence the feasibility and acceptability of an FDC. We will conduct document review of the MDA programmes in Ghana and Kenya, as well as key informant interviews with key stakeholders of NTDP. A protocol for the formative study will be submitted to all relevant IRBs in both countries for review and approval prior to implementation.
Task 4.2a (Month 1-6) Acceptability & Feasibility Protocol & Implementation Plan Completed
Task leader: GHS
Partners involved: FMS España, KEMRI, Bridges

The Ghana team will develop the acceptability and feasibility study protocol with input from Consortium members, particularly KEMRI and Bridges, and in consultation with WHO. The target population for this study will be informed by the endemicity of STH in Kenya and Ghana. Both quantitative and qualitative methods will be used in the study. The quantitative component will be a survey using a structured questionnaire targeting students, teachers, and parents. The qualitative component will include focus group discussions with selected members of the same groups plus IDI with community drug distributors, and program implementers. Assessment of feasibility will involve key informant interviews with NTDP managers at various levels of service delivery, and teachers. Follow up visits to a sample of Arm 3 recipients would be made to assess adherence to the 3-day regimen. The protocol will be submitted to all relevant IRBs in both countries for review and approval prior to implementation.

In addition to providing data to support the value proposition and communications on the FDC, these results will be used to help define and advise on the best integration of FDC into STH programs for maximum impact
Task 4.2b (Months 1-6) Coordination of trial design with data management and analysis plan in WP3
Task leader: GHS
Partners involved: ISGlobal, KEMRI, Bridges

Based on the protocols in 4.1 and 4.2 as well as in consultation with KEMRI (WP3), finalize the data management plan, including collection, storing, cleaning and analysis.
Task 4.3a (after trial design is complete 12 Months) Study Implementation Ghana (GHS)
Task leader: GHS
Partners involved: KEMRI, Bridges

Ethical clearance from the Ghana Health Service Ethics Review Committee will be obtained and study sites for the study identified. The study sites will be selected to represent the major STH endemic areas in Ghana. Qualitative and quantitative data will be collected.
Task 4.3b (after trial design is complete 12 Months) Study Implementation Kenya (KEMRI)
Task leader: KEMRI
Partners involved: GHS, Bridges

Coordinate with KEMRI team to obtain relevant IRB clearance, identify study sites, and conduct study in Kenya. The study sites will be selected to reflect major STH endemic areas in Kenya. Qualitative and quantitative data will be collected.
Task 4.3c (after trial is complete 6 Months) Data analysis and interpretation
Task leader: KEMRI

Partners involved: Liconsa, ISGlobal, FMS España, GHS, Bridges

After data cleaning by KEMRI, Ghana will lead on data analyses and interpretation in collaboration with Consortium members.
Task 4.3d (after analysis is complete 12 Months) Report and dissemination
Task leader: GHS
Partners involved: FMS España, KEMRI, Bridges

Ghana will lead in the development of reports for sharing and presenting the data in consultation with Consortium members including preparation of publication/s on study findings. Dissemination will be coordinated with WP5 for sharing with WHO and the Consortium's communications and advocacy plan.

Work package WP5 – Policy, access, advocacy, and communications

Work Package Number	WP5	**Lead Beneficiary**	7. Bridges
Work Package Name	Policy, access, advocacy, and communications		
Start Month	1	**End Month**	36

Objectives

Obj 5.1 Define a pathway to WHO guidance for use of FDC in STH and other NTD control and elimination efforts (Bridges)
Obj 5.2 Support the development of scenarios for a sustainable supply and financing of FDC (Bridges, Liconsa)
Obj 5.3 Develop and implement a Comprehensive Communication and Promotion Plan that will contribute to the dissemination and application of the Project's results, have an impact on the community, and influence the decision-making of policymakers on the use of the FDC. (Mundo Sano)

Description

Development of a new medicine needs to be complemented by activities that anticipate and address factors that otherwise risk slowing or stopping implementation and therefore impact. Wherever possible such activities should be implemented in parallel in order to compress timelines, accelerate pace to impact, and improve project efficiency.
This WP is led by Alan Brooks, RN PHD and Dr Julie Jacobson of Bridges to Development, who will lead work on objective 5.1. Objective 5.2 will be led by Bridges and Liconsa. Objective 5.3 will be led by Mundo Sano with support of Bridges. Consortium members KEMRI and GHS will have particularly important complementary roles in this work package but their contribution to the work is accounted for in other work packages.

Task 5.1a (Months 1-4) Implementation Scenarios
Task leader: Bridges
Partners involved: Liconsa, ISGlobal, FMS España, KEMRI, GHS, GRL.

Bridges will work with Consortium members, most notably, KEMRI and GHS, to determine the most feasible scenarios for scaling up the use of FDC in MDA. The scenarios will be developed by first considering current MDA approaches in different contexts within each country and the epidemiological settings in the country, followed by how an FDC might optimally be implemented within those contexts to realize public health impact aligned with the 2030 goals. The team will then consult with WHO and key partners to help refine the scenarios for use in additional contexts and settings. The scenarios will inform modelling and WHO guidance tasks for the project. This work will also be communicated back to WP3 to inform modelling efforts.
Task 5.1b (Months 1-30) Engage WHO to define mechanisms for providing guidance on use of a FDC
Task leader: Bridges
Partners involved: Liconsa, FMS España.

LMICs and development partners will look for guidance from WHO on the use and scale up of the FDC in NTD programmes, particularly to treat STH, supporting control and elimination efforts. Bridges will facilitate exploration with WHO of potential mechanisms available to provide FDC product recommendations for NTD programmes, leading to a decision on the most efficient and appropriate pathway for FDC guidance. Pathways to be explored include Essentials Medicine List, Pre-qualification, WHO guidance, WHO guidelines, operationalization manuals, and the new Consolidated Scientific Advice process. WHO's policy information needs will provide guidance on initial field study

designs, such as rationale for study sites including baseline prevalence and intensity of infection data as well as sample size across the multi-centre studies. WHO will be briefed approximately twice yearly on study progression to ensure close adherence to identified guidance processes.
Task 5.2a (Months 12-36) Explore supply models and implications for sustainable access (supply and financing) and recommend access strategy
Task leader: Bridges
Partners involved: Liconsa, FMS España, KEMRI, GHS

The Consortium will work in parallel with the field trials to determine options for ensuring access to FDC in African countries following completion of the project. From the supply perspective, Liconsa anticipates making manufacturing plans at pace with emerging models of and insights into potential demand. The planning will take into account current uses of ALB and IVM, the burden of disease, introduction scenarios, and emerging insights into financing.

Liconsa and Bridges will consider alternative pricing models tailored to the needs of LMICs, for example tiered relative to those of middle-income countries. They, primarily Bridges, will also review and engage with other development partners who are considering alternatives to traditional donation programmes for NTD medicines like paediatric praziquantel and moxidectin. The pricing models and demand will be used to inform financing estimates for development partner and country planning and development of an access strategy.

The data emerging from this task will inform and be informed by WP3 modelling activities including its impact and cost-effectiveness estimates.
Task 5.3a (Months 1-4) Develop a Comprehensive Communication and Promotion Plan
Task leader: FMS España
Partners involved: Liconsa, ISGlobal, KEMRI, GHS, GRL, Bridges

Mundo Sano will develop a plan as a tool at the service of the Consortium's institutional image and management, with internal and external communication goals, strategies and specific actions. It is not a static piece, but characterized by its flexibility and ease of adaptation to the Consortium's priorities and objectives as the project progresses. The Communications Plan will have the following specific goals:
1) To put on the agenda the implementation of FDC in SSA countries.
2) To position the STOP2030 Consortium, increasing the visibility of the brand and its reputation.
3) Contribute to the positioning of the funding entity.
In order to achieve the proposed goals, Mundo Sano, with the support of Bridges, will design communication strategies and actions to be implemented in the short, medium and long term, which includes: activities such as mapping stakeholders, internal and external, developing the Consortium's visual identity, creating and FAQ, and website for the project. The team will also create a crisis communications plan and train Consortium members in media communications skills. The plan will also include identifying opportunities for Consortium members (KEMRI, GHS) to inform other countries about the study results, e.g. through NTD programme manager meetings. Communication and advocacy activities will keep pace with emerging field data and project results.

Task 5.3b (Months 5-36) Engage stakeholders to utilize (exploit) emerging study data to inform decision making
Task leader: FMS España
Partners involved: Liconsa, KEMRI, GHS, Bridges

Mundo Sano, with the support of Bridges, will implement the communication and promotion plan, once the communication strategies and actions have been defined. As an example:
· We will work on installing the use of FDC in specialized media in countries of interest for the project (Africa and other countries where the Consortium partners come from); and in journals and/or newsletters of the Consortium members, strategic allies and NGOs.
· Be content creators of news about the project that will be shared on the Consortium's institutional website.
· Implement training and updating campaigns for health personnel, and communication and prevention campaigns for nearby communities in order to generate a positive impact on them and on health personnel.
· Create digital content to be published periodically on the Consortium's digital channels.
All of this will be supported by quarterly activity reports to evaluate progress and results

STAFF EFFORT

Staff effort per participant

Grant Preparation (Work packages - Effort screen) — Enter the info.

Participant	WP1	WP2	WP3	WP4	WP5	Total Person-Months
1 - Liconsa	36.00	1.00				37.00
2 - ISGLOBAL	6.00	96.00	3.00		1.00	106.00
3 - FMS ESPANA	5.00	11.00			55.00	71.00
4 - KEMRI		21.00	25.00	20.00	20.00	86.00
5 - GHS	3.00	48.00		16.00	2.00	69.00
6 - GRL		24.00				24.00
7 - Bridges	1.00				53.00	54.00
Total Person-Months	51.00	201.00	28.00	36.00	131.00	447.00

LIST OF DELIVERABLES

Deliverables

Grant Preparation (Deliverables screen) — Enter the info.

The labels used mean:

Public — fully open (⚠ automatically posted online)
Sensitive — limited under the conditions of the Grant Agreement
EU classified —RESTREINT-UE/EU-RESTRICTED, CONFIDENTIEL-UE/EU-CONFIDENTIAL, SECRET-UE/EU-SECRET under Decision 2015/444

Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D1.1	Data Transfer Agreement	WP1	1 - Liconsa	R — Document, report	PU - Public	6
D1.2	Terms of reference for project committees	WP1	1 - Liconsa	R — Document, report	PU - Public	6
D1.3	Risk management record (Y1)	WP1	1 - Liconsa	R — Document, report	PU - Public	12
D1.4	Communication Plan	WP1	1 - Liconsa	R — Document, report	PU - Public	6
D1.5	Risk Management record (Y2)	WP1	1 - Liconsa	R — Document, report	PU - Public	24
D2.1	Registration number of clinical study	WP2	2 - ISGLOBAL	R — Document, report	PU - Public	6
D2.2	Study approval package	WP2	2 - ISGLOBAL	R — Document, report	PU - Public	12
D2.3	Clinical monitoring plan	WP2	2 - ISGLOBAL	R — Document, report	PU - Public	12
D2.4	Clinical data management plan (cDMP)	WP2	2 - ISGLOBAL	R — Document, report	PU - Public	12
D2.5	Midterm recruitment report	WP2	2 - ISGLOBAL	R — Document, report	PU - Public	20
D2.6	Report on the status of posting results	WP2	2 - ISGLOBAL	R — Document, report	PU - Public	36
D2.7	Genomic protocol	WP2	6 - GRL	R — Document, report	PU - Public	12
D3.1	Data management plan	WP3	4 - KEMRI	DMP — Data Management Plan	PU - Public	6

Deliverables

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Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D3.2	Locked and cleaned database available	WP3	4 - KEMRI	DATA — data sets, microdata, etc	PU - Public	24
D3.3	Updated Data Management Plan	WP3	4 - KEMRI	DMP — Data Management Plan	PU - Public	18
D4.1	Formative study on Acceptability & Feasibility completed	WP4	5 - GHS	R — Document, report	PU - Public	3
D4.2	Protocol for KAP study on Acceptability & Feasibility protocol & implementation plan completed	WP4	5 - GHS	R — Document, report	PU - Public	3
D4.3	Implementation acceptability & Feasibility study in Ghana	WP4	5 - GHS	R — Document, report	PU - Public	12
D4.4	Implementation Acceptability & Feasibility study in Kenya	WP4	4 - KEMRI	R — Document, report	PU - Public	12
D4.5	Data analysis and interpretation	WP4	5 - GHS	R — Document, report	PU - Public	6
D4.6	Exploitation and dissemination plan	WP4	5 - GHS	R — Document, report	PU - Public	12
D5.1	WHO Pathway	WP5	7 - Bridges	R — Document, report	PU - Public	34
D5.2	Communications and Advocacy	WP5	3 - FMS ESPANA	R — Document, report	PU - Public	36
D5.3	Draft Stewardship plan	WP5	7 - Bridges	R — Document, report	PU - Public	18
D5.4	Final Stewarship plan	WP5	7 - Bridges	R — Document, report	PU - Public	36

Deliverables

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Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D5.5	Launched Project - WEBSITE	WP5	3 - FMS ESPANA	DEC —Websites, patent filings, videos, etc	PU - Public	3
D5.6	Global Access Plan	WP5	7 - Bridges	R — Document, report	PU - Public	36

Deliverable D1.1 – Data Transfer Agreement

Deliverable Number	D1.1	**Lead Beneficiary**	1. Liconsa
Deliverable Name	Data Transfer Agreement		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	6	**Work Package No**	WP1

Description
Safeguard the data protection as per the applicable laws: define the clauses for the transfer or personnel data

Deliverable D1.2 – Terms of reference for project committees

Deliverable Number	D1.2	**Lead Beneficiary**	1. Liconsa
Deliverable Name	Terms of reference for project committees		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	6	**Work Package No**	WP1

Description
Define the different project Committees, scope, frequency and participant

Deliverable D1.3 – Risk management record (Y1)

Deliverable Number	D1.3	**Lead Beneficiary**	1. Liconsa
Deliverable Name	Risk management record (Y1)		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP1

Description
List of potential risk and mitigation plans to either avoid or minimize

Deliverable D1.4 – Communication Plan

Deliverable Number	D1.4	**Lead Beneficiary**	1. Liconsa
Deliverable Name	Communication Plan		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	6	**Work Package No**	WP1

Description
Internal Communication plan to define the internal communication channels and tools to promote the exchange of ideas and the sharing of information among the Consortium's members.

Deliverable D1.5 – Risk Management record (Y2)

Deliverable Number	D1.5	Lead Beneficiary	1. Liconsa
Deliverable Name	Risk Management record (Y2)		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	24	Work Package No	WP1

Description
List of potential risk and mitigation plans to either avoid or minimize

Deliverable D2.1 – Registration number of clinical study

Deliverable Number	D2.1	Lead Beneficiary	2. ISGLOBAL
Deliverable Name	Registration number of clinical study		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	6	Work Package No	WP2

Description
Trial registration in public access trial repositories

Deliverable D2.2 – Study approval package

Deliverable Number	D2.2	Lead Beneficiary	2. ISGLOBAL
Deliverable Name	Study approval package		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	12	Work Package No	WP2

Description
Final version of study protocol, regulatory and ethics approval

Deliverable D2.3 – Clinical monitoring plan

Deliverable Number	D2.3	Lead Beneficiary	2. ISGLOBAL
Deliverable Name	Clinical monitoring plan		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	12	Work Package No	WP2

Description
Plan establishing the guidelines for conducting monitoring visits and timelines

Deliverable D2.4 – Clinical data management plan (cDMP)

Deliverable Number	D2.4	**Lead Beneficiary**	2. ISGLOBAL
Deliverable Name	Clinical data management plan (cDMP)		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP2

Description
Description of the data management life cycle for the data to be collected, processed and/or generated by STOP2030 project

Deliverable D2.5 – Midterm recruitment report

Deliverable Number	D2.5	**Lead Beneficiary**	2. ISGLOBAL
Deliverable Name	Midterm recruitment report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	20	**Work Package No**	WP2

Description
Detail on patient recruitment numbers for the time point when 50% of the study population were expected to be recruited and future patient recruitment numbers

Deliverable D2.6 – Report on the status of posting results

Deliverable Number	D2.6	**Lead Beneficiary**	2. ISGLOBAL
Deliverable Name	Report on the status of posting results		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	36	**Work Package No**	WP2

Description
Overview of the status of posting results in the study

Deliverable D2.7 – Genomic protocol

Deliverable Number	D2.7	**Lead Beneficiary**	6. GRL
Deliverable Name	Genomic protocol		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP2

Description
Protocol for reporting on genomic data generation and submission to open access repositories, standardisation of code description and availability

Deliverable D3.1 – Data management plan

Deliverable Number	D3.1	Lead Beneficiary	4. KEMRI
Deliverable Name	Data management plan		
Type	DMP — Data Management Plan	Dissemination Level	PU - Public
Due Date (month)	6	Work Package No	WP3

Description
Includes Safety/Effectiveness and Acceptability/Feasibility studies

Deliverable D3.2 – Locked and cleaned database available

Deliverable Number	D3.2	Lead Beneficiary	4. KEMRI
Deliverable Name	Locked and cleaned database available		
Type	DATA — data sets, microdata, etc	Dissemination Level	PU - Public
Due Date (month)	24	Work Package No	WP3

Description
Database for safety and effectiveness and acceptability, feasibility, and adherence cleaned and locked ready for analysis

Deliverable D3.3 – Updated Data Management Plan

Deliverable Number	D3.3	Lead Beneficiary	4. KEMRI
Deliverable Name	Updated Data Management Plan		
Type	DMP — Data Management Plan	Dissemination Level	PU - Public
Due Date (month)	18	Work Package No	WP3

Description
Includes Safety/Effectiveness and Acceptability/Feasibility studies

Deliverable D4.1 – Formative study on Acceptability & Feasibility completed

Deliverable Number	D4.1	Lead Beneficiary	5. GHS
Deliverable Name	Formative study on Acceptability & Feasibility completed		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	3	Work Package No	WP4

Description
Protocol for the formative study on acceptability and feasibility to be implemented in Ghana and Kenya

Deliverable D4.2 – Protocol for KAP study on Acceptability & Feasibility protocol & implementation plan completed

Deliverable Number	D4.2	**Lead Beneficiary**	5. GHS
Deliverable Name	Protocol for KAP study on Acceptability & Feasibility protocol & implementation plan completed		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	3	**Work Package No**	WP4

Description
Protocol for the KAP study on acceptability and feasibility study to be implemented in Ghana and Kenya

Deliverable D4.3 – Implementation acceptability & Feasibility study in Ghana

Deliverable Number	D4.3	**Lead Beneficiary**	5. GHS
Deliverable Name	Implementation acceptability & Feasibility study in Ghana		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP4

Description
Obtain ethical clearance and complete data collection in Ghana

Deliverable D4.4 – Implementation Acceptability & Feasibility study in Kenya

Deliverable Number	D4.4	**Lead Beneficiary**	4. KEMRI
Deliverable Name	Implementation Acceptability & Feasibility study in Kenya		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP4

Description
Obtain ethical clearance and complete data collection in Kenya

Deliverable D4.5 – Data analysis and interpretation

Deliverable Number	D4.5	**Lead Beneficiary**	5. GHS
Deliverable Name	Data analysis and interpretation		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	6	**Work Package No**	WP4

Description
Analyse and interpretate data in collaboration with Consortium members

Deliverable D4.6 – Exploitation and dissemination plan

Deliverable Number	D4.6	**Lead Beneficiary**	5. GHS
Deliverable Name	Exploitation and dissemination plan		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP4

Description
Develop reports for sharing, presentation and publications in consultation with Consortium members

Deliverable D5.1 – WHO Pathway

Deliverable Number	D5.1	**Lead Beneficiary**	7. Bridges
Deliverable Name	WHO Pathway		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	34	**Work Package No**	WP5

Description
Efficient pathway from clinical studies to WHO normative guidance, contributing to WHO guidance for use of FDC in national STH and NTD programmes

Deliverable D5.2 – Communications and Advocacy

Deliverable Number	D5.2	**Lead Beneficiary**	3. FMS ESPANA
Deliverable Name	Communications and Advocacy		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	36	**Work Package No**	WP5

Description
Design and implementation of a comprehensive communication and promotion plan that contributes to the Consortium's general medium-, short- and long-term objectives

Deliverable D5.3 – Draft Stewardship plan

Deliverable Number	D5.3	**Lead Beneficiary**	7. Bridges
Deliverable Name	Draft Stewardship plan		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	18	**Work Package No**	WP5

Description
Report outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse or abuse of health technologies

Deliverable D5.4 – Final Stewarship plan

Deliverable Number	D5.4	**Lead Beneficiary**	7. Bridges
Deliverable Name	Final Stewarship plan		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	36	**Work Package No**	WP5

Description
Report outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse or abuse of health technologies

Deliverable D5.5 – Launched Project - WEBSITE

Deliverable Number	D5.5	**Lead Beneficiary**	3. FMS ESPANA
Deliverable Name	Launched Project - WEBSITE		
Type	DEC —Websites, patent filings, videos, etc	**Dissemination Level**	PU - Public
Due Date (month)	3	**Work Package No**	WP5

Description
Project Website and as per good practices, all work packages leads will be listed.

Deliverable D5.6 – Global Access Plan

Deliverable Number	D5.6	**Lead Beneficiary**	7. Bridges
Deliverable Name	Global Access Plan		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	36	**Work Package No**	WP5

Description
The global access plan covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.

LIST OF MILESTONES

Milestones

Grant Preparation (Milestones screen) — Enter the info.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
1	Kick-off meeting	WP1	1-Liconsa	Meeting minutes	1
2	Annual project meeting (Y2)	WP1	1-Liconsa	Meeting minutes	12
3	Annual Project Meeting (Y3)	WP1	1-Liconsa	Meeting minutes	24
4	FDC Regulatory evaluation and approval	WP1	1-Liconsa	Submission registration and Marketing Authorizations. This is not included within the scope of this Call, but previous one. But this represent overall a key MILESTONE. Planned to at least submit for Marketing Authorization and hopefully the be approved.	24
5	Study Institutional Review Board (IRB) approval	WP2	2-ISGLOBAL	Countries' Institutional Review Board (IRB) report	12
6	First participant enrolled in the trial	WP2	2-ISGLOBAL	Updates at clinical trial registries' webpages	12
7	50% of subjects included in trial	WP2	2-ISGLOBAL	Recruitment Report (includes an overview of recruited subjects by study site, potential recruiting problems, and, if applicable, a detailed description of implemented and planned measures to compensate delays in the study subject recruitment), updates at clinical trial registries' webpage	18
8	Last patient- last visit (LPLV)	WP2	2-ISGLOBAL	Updates at clinical trial registries' webpages	27
9	Database lock	WP2	2-ISGLOBAL	Extract of database	30
10	Primary data analysis complete	WP4, WP2, WP5, WP3	6-GRL	Report issued and publication in peer-review journal prepared	32

Milestones

Grant Preparation (Milestones screen) — Enter the info.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
11	Formative Research implemented	WP4	4-KEMRI	Formative study report	4
12	Ethical approval obtained	WP4	5-GHS	Ethical approval certificate	6
13	Report and dissemination	WP4	5-GHS	Final study report	36
14	Summary of anticipated WHO guidance pathway for FDC	WP5	7-Bridges	Report Issued	10
15	White paper on sustainable supply and financing models	WP5	7-Bridges	Report Issued	15
16	Communications & advocacy plan	WP5	7-Bridges	Report Issued	6

LIST OF CRITICAL RISKS

Critical risks & risk management strategy

Grant Preparation (Critical Risks screen) — Enter the info.

Risk number	Description	Work Package No(s)	Proposed Mitigation Measures
1	Reporting and administration challenges (low likelihood, medium severity)	WP1	Providing both indications/templates, processes involved closely monitored and awareness of important determinants of reporting and finances.
2	Insufficient reporting of adverse events (low likelihood, medium severity)	WP2	Analysis of demography, variability among schools and spatial distribution of adverse event occurrence. Selection of a sub-set of school for in depth monitoring. Retraining of the teams in study procedures and use of questionnaires adapted to each culture along with use of Health Centre data to confirm

Critical risks & risk management strategy

Grant Preparation (Critical Risks screen) — Enter the info.

Risk number	Description	Work Package No(s)	Proposed Mitigation Measures
3	Delay in trial start due to delays of the IRB approval (medium likelihood, medium severity)	WP2	In case the results of the pilot study are delayed, the activities of the trial will start later than expected. We will ensure communication with countries' IRB through African partners who have close relationship and experience with local IRB.
4	Unexpected safety issues with the experimental arms (low likelihood, high severity)	WP2	There is a pharmacovigilance system in place to detect these events. In case unexpected safety events appear, the investigators will follow a detailed "adverse event management plan" that will be included in the final trial protocol. The DSMB is part of this plan
5	Available baseline data particularly in Ghana may not be reflective of current endemicity (medium likelihood, low severity)	WP4	Baseline surveys will be required and should be considered for site selection if burden is insufficient to meet study objectives. Alternative sites should be considered early in case they are required.
6	Regulatory authorities in Ghana and Kenya do not give or delay decision on FDC Dossier (medium likelihood; medium risk)	WP4, WP2, WP5, WP1, WP3	Parallel submission to EMA will also provide support to the national decision-making process. Pragmatic trial will be amended to a Safety & effectiveness trial should it be required by the IRBs and Informed Consent Forms will be ready to be incorporated. Close engagement with WHO for proper channel for WHO support (PQ, EML etc) which will also support national decision-making
7	Public health emergency of international concern (low likelihood; low risk)	WP4	Suspend community activities until recovery; use PPEs as per WHO and national policies.
8	Changes in leadership at WHO may change perspectives on the value of the FDC and/or slow response (low likelihood; medium risk)	WP5	Early engagement with new WHO STH Focal point when current focal point retires and early engagement with new Director of the NTD Team when hired
9	Failure in the safety of the drug that transcends the media (low likelihood; high risk)	WP5	In the face of an adverse scenario, we must spend time dealing with the problem and not thinking about how to deal with it. To this end, we will previously work on the design of the crisis strategy, the protocol to be implemented, the training of the spokesperson(s) and the crisis team. During the crisis, the published information will be compiled, and the evolution of the situation will be monitored and analyzed in all its aspects in order to define how and when to act
10	The combination treatment is not seen as a valuable	WP5	Define the value proposition and additional benefit to the program and clearly communicate

Critical risks & risk management strategy

Grant Preparation (Critical Risks screen) — Enter the info.

Risk number	Description	Work Package No(s)	Proposed Mitigation Measures
	contribution to the STH program WP5 Mitigation (low likelihood; medium risk)		this to partners and countries working closely with the WHO and pharma partners as donation programs transition

PROJECT REVIEWS

Project Reviews

Grant Preparation (Reviews screen) — Enter the info.

Review No	Timing (month)	Location	Comments
RV1	18	To be decided	Tentative review meeting to take place after the periodic report is received
RV2	36	To be decided	Tentative review meeting to take place after the final report is received

JU CONTRIBUTIONS

PIC	Legal Name	Membership	IKOP	Non-EU part of IKOP	Financial Contribution	IKAA
885624551	Fundación Mundo Sano España	No	€ 0.00	€ 0.00	€ 0.00	€ 0.00
894057343	GHANA HEALTH SERVICE	No	€ 0.00	€ 0.00	€ 0.00	€ 0.00
951414122	FUNDACION PRIVADA INSTITUTO DE SALUD GLOBAL BARCELONA	No	€ 0.00	€ 0.00	€ 0.00	€ 0.00
990555950	Laboratorios Liconsa, S.A.	No	€ 0.00	€ 0.00	€ 0.00	€ 0.00
997741225	KENYA MEDICAL RESEARCH INSTITUTE	No	€ 0.00	€ 0.00	€ 0.00	€ 0.00
999981343	GENOME RESEARCH LIMITED	No	€ 0.00	€ 0.00	€ 0.00	€ 0.00