

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
1	GBT-2104-133	Phase III	Sickle Cell Disease	Inclacumab/ Monoclonal antibody	27 th August, 2021	Professor Alex Osei-Akoto	Komfo Anokye Teaching Hospital (KATH)	Global Blood Therapeutics, Inc.	Application Pending Approval 7 years 5 months	The primary objective of this study is to evaluate the long-term safety of every 12-week dosing of inclacumab in participants with sickle cell disease (SCD) who have completed a prior inclacumab clinical trial. Additional objectives are to evaluate the incidence of vaso-occlusive crises (VOCs), hospitalizations, missed work/school days, red blood cell (RBC) transfusions, and quality of life (QoL) with long-term use of inclacumab.
2	NOVIC TRIAL	Phase III	Postpartum Hemorrhage (PPH)	Jada System (Intrauterine Vacuum Induced Hemorrhage Control Device)/ Medical device	5th April 2022	Dr. Samuel A. Oppong	1. Korle-Bu Teaching Hospital (KBTH) 2. Komfo Anokye Teaching Hospital (KATH)	Women and Infants Hospital of Rhode Island	Application approved, 48 Months	<p>Study Objectives</p> <ol style="list-style-type: none"> To evaluate the effectiveness of the Jada® System, compared to standard care, in treating PPH, as measured by maternal survival without surgical intervention. To assess the safety of the Jada® System, compared to standard care, in treating PPH, as measured by rate of composite adverse events potentially related to the device, including genital tract injury, uterine perforation or rupture and endometritis. To estimate the cost-effectiveness of the Jada® System, compared to standard care, in treating PPH, as measured by incremental cost per quality-adjusted life year.
3	VERTEX Trial	Phase II/III	Kidney Disease	VX-147/ Allopathic drug	23rd December 2022	Professor Sampson Antwi	Komfo Anokye Teaching Hospital (KATH)	Vertex Pharmaceuticals Incorporated	Application approved, 4 years	<p>Primary objectives</p> <ul style="list-style-type: none"> •To evaluate the efficacy of VX-147 to reduce proteinuria •To evaluate the efficacy of VX-147 on renal function as measured by eGFR slope <p>Secondary objectives</p> <ul style="list-style-type: none"> •To evaluate the efficacy of VX-147 to decrease the risk of the composite clinical outcome •To evaluate the safety and tolerability of VX-147 •To identify the optimal dose from Phase 2 to carry forward to Phase 3 •To characterize the plasma pharmacokinetics (PK) of VX-147
4	SWIS (STERILE WATER INJECTION)	Feasibility study	Lower Back Pain	Sterile Water Injection	6th December 2022	Prof. Sue Kruske	Korle-Bu Teaching Hospital (KBTH)	Dr. Jonas Awuku Afari	Application approved, 40 Months	<p>Main Aim</p> <p>This study explores the feasibility, acceptability, and outcomes of implementing sterile water injections (SWI) for the management of lower back pain among birthing women in Ghana.</p> <p>Specific Objectives</p> <ol style="list-style-type: none"> Develop and deliver a training package for midwives on sterile water injections for managing lower back pain. Undertake implementation study in a tertiary hospital in Ghana to assess the feasibility and acceptability of implementing SWI for lower back pain. Determine birth and neonatal outcomes of women with back pain who receive SWI Explore the experiences of women who have had SWI for back pain in labour Explore the experiences and perception of midwives and stakeholders regarding the implementation of SWI for managing back pain in labouring women.

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
5	ACTIV TRIAL	Phase III	Covid-19	S-217622/ Allopathic drug	27th September 2022	Dr. Patrick Ansah	1. Kumasi Centre for Collaborative Research (KCCR) 2. Kintampo Health Research Centre (KHRC) 3. Navrongo Health Research Centre	SHIONOGI INC. & Co Ltd	Application Approved, 16 Months	<p>Primary Objective To determine if S-217622 will reduce the time to sustained symptom resolution through Day 29. Time to sustained symptom resolution is defined as the time from start of study intervention to the first day of 4 consecutive days with complete resolution of 13 COVID-19 symptoms on participant self-assessment AND alive and without hospitalization for any reason by Day 29. Hospitalization is defined as ≥24 hours of acute care, in a hospital or similar acute care facility, including emergency rooms, urgent care clinics, or facilities instituted to address medical needs of those with COVID-19.</p> <p>Secondary Objectives Key secondary objective: To determine the effect of S-217622 compared with placebo on the change from baseline in quantitative log10 SARS-CoV-2 RNA levels by PCR on NP swab at Day 4. Key secondary objective: To determine whether S-217622 reduces COVID-19 related hospitalization (adjudicated) and all deaths regardless of occurrence outside of hospital or during hospitalization (not adjudicated) through Day 29.</p>
6	COPE TRIAL	Phase III	Fistula	(i) Healeanto silicone lady Drain Valve menstrual Cup (ii) Foley catheter will connect the cup to a leg bag (cup+)/ Medical device	2nd September 2022	Dr. Gabriel Y.K. Ganyaglo	1. Mercy Women's Catholic Hospital in Mankessim 2. Tamale Fistula Center in Tamale	Korle Bu Teaching Hospital	Application Approved, 15 Months	The aims of the study are to examine the effectiveness, comparative effectiveness, and acceptability of two vaginal menstrual cup models (cup and cup+) as a temporizing alternative to managing urinary leakage from vesico-vaginal fistula in both a clinical setting and a community setting, and to quantify non-surgical fistula management costs.
7	PRAISE	Phase II/III	Sickle Cell Disease	1. Oral FT-4202 Pyruvate Kinase Activator 2. Placebo/Allopathic drug	2nd June 2022	Dr Prince Agyapong	1. Kintampo Health Research Center 2. Ghana Institute of Clinical Genetics, KBTH	NOVO NORDISK COMPANY	Application Approved, 43 Months	<p>Objectives of the study are:</p> <ol style="list-style-type: none"> To assess the efficacy of FT-4202 in adolescents and adults with SCD as compared to placebo as measured by improvement in hemoglobin (Hb) To assess the efficacy of FT-4202 as compared to placebo on the annualized vaso-occlusive crisis (VOC) rate To measure the effects of FT-4202 on clinical measures and sequelae of hemolysis To evaluate the effects of FT-4202 on the sequelae of VOC To assess changes in fatigue of sickle cell patients taking FT-4202
8	FORTIFIED BUILLON CUBES		Malnutrition	Shrimp Flavour Stock Cubes/Food supplement	13th December 2021	Prof. Seth Adu-Afarwah	University of Ghana	Helen Keller International (Through a grant from the Bill & Melinda Gates Foundation)	Application Approved, 9 months	This study aims to assess the impacts of household use of multiple micronutrient-fortified bouillon cubes (containing vitamin A, folic acid, vitamin B12, iron, and zinc in addition to iodine), compared to control bouillon cubes fortified with iodine only, on: a) Micronutrient status among women 15-49 years of age and children 2-5 years of age after 9 months of intervention b) Haemoglobin concentrations among women 15-49 years of age and children 2-5 years of age after 9 months of intervention. c) Breast milk micronutrient among lactating women 4-8 months postpartum after 3 months of intervention.
9	ANTIPSYCHOTIC STUDY	Phase IV	Antipsychotic Induced Movement Disorders	Omega-3 Fatty Acids / Food supplement	15th December 2021	Debrah Akosua Bema	Accra Psychiatric Hospital	Dr. Sammy Ohene. P. O. Box KB 77 Korle-Bu	Application Approved, 29 Weeks	<p>The primary objective of this study is to determine the use of once daily dose of 1000mg omega 3 fish oil as a clinically effective and safe intervention for reducing the burden associated with antipsychotic induced movement disorders.</p> <p>Secondary: To determine the demographic and clinical characteristics of psychiatric patients with antipsychotic induced movement disorder. To determine the efficacy of omega 3 supplementation in relieving the symptoms of AIM disorders To evaluate the impact of omega 3 supplementation on the clinical outcomes of psychosis, cognitive function and quality of life/ adherence of participants. To determine the correlations between the demographic and clinical parameters and the outcomes of therapy To understand the experiences of patients who have used other complementary and alternative medicines aside omega 3 fish oil as adjunct to conventional therapy, in an attempt to be free from their symptoms</p>

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
10	PROBIOTIC		Malnutrition	1.Synbiotic (Nutraflora and Maltrin M100 P-95 and L. plantarum (Lp) 2.Placebo/ Food supplement	27th July, 2021	Dr Seyram Kaali	Kintampo Municipal Hospital	Dr. Kwaku Poku Asante	Application Approved 6 months	Primary A pilot trial to evaluate the administration of probiotic supplementation among pregnant women in the third trimester and effective colonization of the gut microbiome of their infants one-month post-partum. Secondary 1. To assess compliance of administering a synbiotic product (L. plantarum with Fructooligosaccharide) among pregnant women. 2. To assess birth outcomes among participants who receive synbiotic products compared to those on placebo. 3. To assess if maternal stool microbiome profoundly changes from immediately after childbirth to one-month post-partum. 4. To characterize the diversity of vaginal microbiomes among pregnant women in the study area. 5. To determine the safety of the probiotic supplementation among pregnant women from 5 to 6 months until up to two weeks post partum.
11	EBSI-LSV	Phase I	Lassa Fever	1.EBSI-LSV 2. Placebo/ Vaccine	1st September 2021	1.Dr Seyram Kaali 2.Dr.Patrick Ansah	1.Kintampo Health Research Centre 2.Navrongo Health Research Centre	Emergent BioSolutions (EBS)	Application Approved 2 years	1. To evaluate the safety and tolerability of increasing dose levels of EBS-LASV vaccine administered as a single dose or two-dose series. 2. To evaluate the humoral immune response to EBS-LASV vaccine at various dose levels and dosing schedules for the purpose of selecting two regimens (dose and schedule) for further evaluation in a Phase 2 study.
12	ASAAP	Phase III	Malaria	1. Artemether Lumefantrine 2.Atovaquone-Proguanil 3. Placebo of Atovaquone-Proguanil/ Allopathic drug	4th October 2021	1. John Humphrey, AMUASI 2. Dr Oumou Maiga Ascofare	St. Francis Xavier Hospital	Kumasi Centre for Collaborative Research (KCCR), Kumasi, Ghana	Application Approved 21 months	The overall aim of this phase III clinical trial(main study = study II) is to develop a readily deployable highly efficacious, safe and well tolerated antimalarial triple combination therapy for young children. This is achieved by evaluating the efficacy, safety and tolerability of artemether-lumefantrine (AL) + atovaquone-proguanil (AP) tri-therapy (AL+AP) compared to standard AL therapy (+placebo) for the treatment of uncomplicated Plasmodium falciparum malaria in African children aged 6 to 59 months
13	POLYPHENOL-RICH COCOA POWDER TRIAL	Phase III	Covid-19	Polyphenol-rich natural cocoa powder/ Food supplements	10th January 2022	Prof. George Obeng Adjei	Ga East Municipal Hospital, Ghana Infectious Disease Centre	Ghana Cocoa Board	Application Approved, 4 Months	General objective is to evaluate effects of polyphenol-rich cocoa as adjuvant therapy in COVID 19 patients. Specific objectives: 1. to determine the effects of natural polyphenol-rich natural cocoa powder (5 % v/w) (as adjuvant therapy) on symptom resolution and illness duration in COVID-19 patients 2. to determine the effects of natural polyphenol-rich natural cocoa powder (5 % v/w) on selected markers of coagulopathy in COVID-19 patients 3. to determine the effects of natural polyphenol-rich natural cocoa powder (5 % v/w) on virologic clearance COVID-19 patients 4. to determine the effects of natural polyphenol-rich natural cocoa powder (5% v/w) on disease prognosis COVID-19 patients
14	PIVOT STUDY	Phase II	Sickle Cell Disease	1.Hydroxyurea 2.Placebo/ Allopathic drug	18th June 2021	Dr. Yvonne A. Dei-Adomakoh	Korle-Bu Teaching Hospital	Cincinnati Children's Hospital Medical Center	Application Approved 5 years	To measure the toxicities of hydroxyurea treatment on laboratory parameters. To assess the effects of hydroxyurea treatment on a variety of sickle-related clinical and laboratory parameters in a large cohort of children and adults with HbSC disease. To identify which study endpoints are suitable for a future Phase III trial of patients with HbSC disease receiving hydroxyurea therapy.
15	RECOVERY	Phase III	Covid-19	1.Dexamethasone 2.Empagliflozin	21st May, 2021	Dr. John H. Amuasi	Komfo Anokye Teaching Hospital Ghana Infectious Disease Centre	University of Oxford Clinical Trials and Research Governance.	Application Approved 2 years	For each pairwise comparison with the 'no additional treatment' arm, the primary objective is to provide reliable estimates of the effect of study treatments on all-cause mortality at 28 days after randomisation (with subsidiary analyses of cause of death and of death at various timepoints following discharge). The secondary objectives are to assess the effects of study treatments on duration of hospital stay; and, among patients not on invasive mechanical ventilation at baseline, the composite endpoint of death or need for invasive mechanical ventilation or ECMO.

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	,DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
16	VR-AD-1005 STUDY	Phase II	Cholera	VR-AD-1005/Allopathic drug	1st July 2021	Dr. Ernest Kenu	Pentecost Hospital, Madina, Madina Polyclinic –	Vanessa Research Holdings, Inc.,	Application Approved. Study not yet commenced 1 year 2 months	To assess the efficacy and safety of VR-AD-1005 for the treatment of acute diarrhea in cholera in combination with standard rehydration treatment with or without antibiotics (as indicated by WHO or other applicable guidelines) versus standard treatment alone. Efficacy is measured as reduction in stool output and/or duration of diarrhea between the start of treatment until final diarrheal stool before recovery or end of study treatment (treatment duration 120 hours).
17	HOPE KIDS 2	Phase III	Sickle Cell Disease	1.Voxelotor 2.Placebo/Allopathic drug	16th December 2020	Dr. Catherine Segbefia	*Korlebu Teaching Hospital Department of Child Health *Sickle cell office Directorate Child(KATH)	Global Blood Therapeutics, inc	Application Approved. Study not yet commenced 38 Months	The purpose is to evaluate the effect of voxelotor compared to placebo on the transcranial Doppler(TCD) time-averaged mean of the maximum velocity(TAMMV) arterial cerebral blood flow at 24 weeks in SCD participants >2 to < 15 years of age with conditional (170 to <200cm/sec) TCD flow velocity.
18	VAT00008	Phase III	Covid-19	1.SARS-CoV2 prefusion Spike delta TM with AS03 adjuvant, monovalent 2.SARS-CoV2 prefusion Spike delta TM with AS03 adjuvant, bivalent 3.Matching placebo / Vaccine	26th May, 2021	Dr. Kwaku Poku Asante	*Navrongo Health Research Centre *Kintampo Health Research Centre *Kwame Nkrumah University of Science and Technology (KNUST)	SANOFI	Application Approved. Actively Enrolling at KCCR and Navorongo while Kintampo closed enrolment 18 months	To assess, in participants who are SARS-CoV-2 naïve, the clinical efficacy of the CoV2 preS dTM-AS03 vaccines for the prevention of symptomatic COVID-19 occurring ≥ 14 days after the second injection.To assess the safety of the CoV2 preS dTM-AS03 vaccines compared to placebo throughout the study.
19	BURULIRIFDAC	Phase III	Buruli Ulcer	1.Rifampicin 2.Clarithromycin 3.Dialkylcarbamoyl chloride (DACC) Dressing/Allopathic drug	12th December 2020	Prof. Richard Phillips	*KCCR *Ga East municipal hospital *Pakro Health Centre *Wassa Amenfi East Hospital	London school of Hygiene and Tropical Medicine	Application Approved. Study not yet commenced 2 Years 6 Months	Compare the time to clearance of viable Mycobacterium from wounds of patients treated with high-dose rifampicin and DACC dressings (HR-DACC) to those receiving standard dose rifampicin and DACC dressings
20	EMODEPSIDE	Phase II	Onchocerciasis	Emodepside (5mg)/ Allopathic drug	5th November, 2020	Dr. Nicholas Opoku	*School of Public Health Research Centre, (UHAS). *Municipal Hospital, Hohoe, Volta Region, Ghana *Kpassa, Nkwanta-North District, Oti Region, Ghana	DNDI (Drugs for Neglected Diseases initiative)	Application Approved. Study commenced 67 months	The purpose of this study is to *Ensure the safety and tolerability of emodepside after single oral doses administered as solution (liquid service formulation, LSF) or immediate release (IR) tablets in healthy male subjects *Plasma PK of emodepside (solution and tablets), the effect of food on the bioavailability of emodepside
21	BURULINOX	Phase III	Buruli Ulcer	1.Nitric Oxide generating dressing (EDX110TM) 2.Vaseline Gauze dressing materials / Allopathic drug + medical device	24th September 2018	Prof. Richard Odame Phillips	1.Kumasi Centre for Collaborative Research in Tropical Medicine 2.Agogo Presbyterian Hospital 3.Tepa Government Hospital 4.Dunkwa Government Hospital	Kumasi Center For Collaborative Research (KCCR)	Application Approved yet to commence 36 MONTHS	Buruli ulcer is a neglected disease caused by infection with Mycobacterium ulcerans (Mu), which manifests as large, disfiguring skin ulcers mainly in children aged 5 to 15 years. Access to treatment in rural areas can be challenging and late presentation is typical, due to fear, stigma, suspicion about conventional medicine and economic consequences for poor families. The current recommended regimen of oral rifampicin together with intramuscular streptomycin or clarithromycin for 8 weeks is far from ideal, particularly given the increasing global threat of antimicrobial resistance. Although the disease can be cured in most patients who adhere to this regimen, healing rates are highly variable even in patients with seemingly similar lesions. The purpose of the study is to compare the healing measured by the percentage area reduction of EDX110 dressing with oral rifampicin and clarithromycin (EDX-RC) versus 'Usual Care' with routine Vaseline gauze dressing and oral rifampicin and clarithromycin (VG-RC).

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
22	TyVEGHA	Phase IV	Typhoid fever	1.Typhbar TCV (Vi polysaccharide-tetanus toxoid conjugate vaccine) 2.Meningococcal Group A conjugate vaccine (MCV-A 5) / Vaccine	3rd March 2021	Prof. Ellis Owusu-Dabo	Agogo Trial Center/KNUST-International Vaccine Institute (IVI) Collaborating Center	International Vaccine Institute	Application Approved commenced months Study 3 Years 5	<p>The purpose of the study is to</p> <ul style="list-style-type: none"> To determine the total protection conferred by single-dose vaccination with Vi-TT against blood culture-confirmed symptomatic S. Typhi infection in the intervention vaccine clusters, compared with the control vaccine clusters To investigate the safety outcomes associated with Vi-TT vaccination in the intervention vaccine recipients compared with the comparator vaccine recipients To determine the overall protection of Vi-TT vaccination against blood culture-confirmed symptomatic infection caused by S. Typhi in intervention clusters compared with control clusters To determine the total protection of Vi-TT vaccination against severe TF in the intervention vaccine recipients compared with the comparator vaccine recipients To determine the overall protection of Vi-TT vaccination against severe TF caused by S. Typhi in intervention clusters compared with control clusters To investigate the total protection of Vi-TT vaccination against clinical TF (defined below in "Trial Outcome Measures") in the intervention vaccine recipients compared with the comparator vaccine recipients To investigate the overall protection of Vi-TT vaccination against clinical TF in intervention clusters compared with control clusters To measure the indirect protection conferred by single-dose vaccination with Vi-TT against blood culture-confirmed symptomatic S. Typhi infection in the intervention vaccine clusters, compared with the control vaccine clusters To investigate the immunogenicity profile in a subset of Vi-TT recipients compared with the comparator vaccine recipients.
23	SPUTNIK LIGHT	Phase III	Covid-19	1.Sputnik Light Vector Vaccine 2.Placebo/ Vaccine	5th March 2021	1. Dr. Nana Akosua Ansah 2. Dr. Alberta Amu	1. Navrogo Health Research 2. Centre Dodowa Health Research Centre Ghana	Human Vaccine LLC	Application Approved Enrolment closed participants are in follow up 8 months	<p>The purpose of the study is to</p> <ul style="list-style-type: none"> Assess efficacy of the Sputnik-Light vector vaccine against the SARS-CoV-2-induced coronavirus infection compared to placebo Assess tolerability and safety of the Sputnik-Light vector vaccine against the SARS-CoV-2-induced coronavirus infection compared to placebo Assess humoral immunogenicity of the Sputnik-Light vector vaccine against the SARS-CoV-2-induced coronavirus infection compared to placebo on Subset A . Assess protective properties of the SputnikLight vector vaccine against the SARSCoV-2-induced coronavirus infection compared to placebo for prevention of serologically confirmed SARS-CoV-2 infection Assess efficacy of the Sputnik-Light vector vaccine against the SARS-CoV-2-induced coronavirus infection compared to placebo based on severity of COVID-19 disease
24	SHEA LIDO	Phase III	Rectal Examination	1.Optilube Active Sterile Lubricating Jelly 2.Shealube/ Lubricating gel	10th September 2020	Dr. Kekeli Kodjo Adanu	Ho Teaching Hospital	University of Health and Allied Sciences	Application Approved commenced Study 12 months	<p>This study is a randomized controlled trial which compares the effectiveness, complications and ease of use of shea butter as a surgical lubricant to lidocaine gel.</p> <p>The purpose is to:</p> <ul style="list-style-type: none"> To determine the ease of use of shea butter by clinicians as compared to lidocaine gel as a lubricant for rectal examination. To determine the complication rate related to the use of shea butter as a lubricant for rectal examination. To ascertain the complication rate associated with the use of lidocaine gel as a lubricant for rectal examination To compare the complication rate related to the use of shea butter to that of lidocaine gel.
25	CECOLIN	Phase III	Human Papiloma Virus (HPV)	1.Cecolin® 2.Gardasil® / Vaccin	1st September 2020	Prof. Tsiri Agbenyega	*Agogo Asante Akim North District	PATH	Application Approved months 30	<p>The purpose of this study is to demonstrate the non-inferiority of Cecolin® administered on 0, 6-month; 0, 12-month; and 0, 24-month two-dose regimens, to Gardasil® using a 0, 6-month two-dose regimen, based on HPV immunoglobulin G (IgG) antibody levels measured one month after the last dose for HPV types 16 and 18.</p>

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	,DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
26	ASTAWOL	Phase II	Onchocerciasis/Filariasis	1.Rifampicin 2.Albendazole/ Allopathic drug	25th June 2020	Prof. Alexander Yaw Debrah	•Bawku west •Buiisa South •Nabdram Fumbisi •Garu-Tempane •Kayoro	Kumasi Centre for Collaborative Research (KCCR), Kumasi, Ghana	Application Approved Enrolling Actively 24 months	The purpose of this study is to •To show efficacy (Depletion of Wolbachia) of the combination of Rifampicin plus Albendazole against lymphatic filariasis using PCR compared to treatment with albendazole and "no treatment" (other than ivermectin) - Lymphatic Filariasis (LF) trial •To show efficacy (depletion of Wolbachia and interruption of embryogenesis in female adult worms) of the combination of Rifampicin plus Albendazole, using PCR and immunohistology compared to treatment with albendazole and "no treatment" (other than ivermectin) – Onchocerciasis trial
27	MDGH-MOX	Phase I	Onchocerciasis	Moxidectin tablet (2mg)/ Allopathic drug	February 2020	Dr. Nicholas Opoku	School of Public Health Research Centre, University of Health and Allied Health Sciences, Ho.	Medicines Development for Global Health	Application Approved Enrolling Actively 12 months	To characterize the pharmacokinetics and safety of moxidectin in children (aged 4 to 11 years) and adolescents (aged 12 to 17 years) and to enable determination of an optimal dose for treatment of children 4 to 11 years
28	INOVIO	1b	Lassa Fever	1.INO-4500 2.CELLECTRA™ 2000 3.SSC-0001/ Vaccine	30th September 2019	Prof. Kwadwo Ansah Koram	Noguchi Memorial Institute for Medical Research University of Ghana, Legon	Inovio Pharmaceuticals, Inc	Application Approved Enrolling Actively 20 Months	The LASV DNA vaccine expressing the glycoprotein precursor (LASV GPC, Josiah strain matched) paired with intradermal EP is a promising vaccine platform that has been shown to elicit protective immunity and completely protect guinea pigs and non-human primates (NHP) against viremia, illness (acute and chronic), and death after Lassa virus exposure [26, 27] and protect NHPs from hearing loss [unpublished data]. This LASV DNA vaccine, INO-4500, targets GPC because it represents the most conserved region in this genetically diverse virus. In the case of Lassa virus infection, the generation of a robust T cell response appears to be the key to protection from infection. As such, the DNA-EP platform is highly amenable to this disease target. The purpose of this study is to evaluate the tolerability and safety of INO-4500 administered by ID injection followed by EP in healthy adult volunteers
29	STAND	Phase III	Sickle Cell Disease	1.CRIZANLIZUM AB 2.PLACEBO/ Monoclonal antibody	30th September, 2019	1.Dr. Yvonne Dei Adomakoh 2. Dr. Vivian Paintsil	1.Ghana Institute of Clinical Genetics, Korle-Bu Sickle Cell Office Directorate of Child Health,	Novartis Pharma AG	Application Approved. Enrolment closed, participants are receiving treatment 8 years 5 months	Sickle cell disease (SCD) is a genetic blood disorder, caused by a single missense mutation in the β-globin gene, progresses into a systemic disease. Vaso-occlusion is the hallmark of SCD and can lead to serious acute and chronic complications. Extensive preclinical data has established P-selectin as a key mediator of VOC in SCD and suggest that its blockade or genetic absence of P-selectin decreases or eliminates its interactions with its ligands, thereby reducing vaso-occlusion. Crizanlizumab is a monoclonal antibody that binds to P-selectin preventing its interactions with its ligands. The purpose of this study is to compare the efficacy and safety of 2 doses of crizanlizumab (5.0 mg/kg and 7.5 mg/kg) versus placebo in adolescent and adult SCD patients (12 years and older) with history of VOC leading to healthcare visit.
30	AVAREF TV ROTA	Phase III	Gastroenteritis	1.Trivalent Rotavirus P2-VP8 Subunit Vaccine 2.Rotarix®/ Vaccine	9th April, 2019	1.Prof. George E. Armah 2.Dr. Alberta Amu	Dodowa Health Research Centre	PATH	Approved study commenced 48 Months	Diarrhea is the second-leading cause of death worldwide among children under the age of five, killing an estimated three quarters of a million children annually and hospitalizing millions more in developing countries. The most common cause of infantile diarrhoea is rotavirus and almost all children are infected by their third birthday regardless of geographical area or economic status. Infection is primarily via fecal oral route and improved sanitation alone will not control infection. Oral rotavirus vaccines have traditionally shown lower efficacy in Low and Middle Income Countries (LMICs) as compared to developed countries. Several theories proposed for this observation includes interference by other intestinal viruses or bacteria, neutralization of vaccine by maternally virus by maternally derived antibodies in breastmilk, etc. Some of these challenges may be obviated by a parenteral administered rotavirus vaccine. This study is therefore to demonstrate the efficacy and safety of the parenteral trivalent rotavirus vaccine in healthy infants (≥6 and <8 weeks old) to prevent severe rotavirus gastroenteritis compared with the orally approved Rotarix®

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	,DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
31	ANTICOV	Phase III	Covid-19	1.Nitazoxanide 2.Ciclesonide 3.Paracetamol 4.Ivermectin 5.Artesunate Amodiaquine (ASAQ) Allopathic drug	15th July, 2020	John Humphrey, AMUASI	Komfo Anokye Teaching Hospital	•Bernhard Nocht Institute for Tropical Medicine	Approved,study commenced 24 Months	The purpose of this study is to compare the efficacy of alternative treatment strategies versus control on the risk of progression to severe respiratory disease. As there is no validated animal model for COVID-19, the efficacy of any potential treatment remains speculative beyond what is known about their pharmacokinetic and in-vitro data. Several repurposed drugs are currently being tested in severe cases or as prophylaxis, and the results may become available by the time the present study is initiated. At the same time, a number of other drug candidates are being evaluated for in-vitro efficacy or in small proof-of concept studies.13 In view of the rapidly evolving landscape in Africa, it was decided to select an adaptive design for the study in order to allow for the flexibility of adding or dropping arms or adjusting the randomisation ratio based on the data as it becomes available. Additionally, given that the control arm in the study may not be acceptable in some countries, it was decided to adopt a master platform-based approach to be allow for integration of data from all sites in the interim analyses, irrespective of their ability to have randomised patients in all treatment arms..
32	LETICIA	Phase II	Aneamia	1.LETICIA protocol diet (provided by study) 2. 3-Fer syrup 3. Usual or Typical diet/ Food supplement	30th August, 2019	Dr. Lawrence Osei-Tutu	Agogo Presbyterian Hospital	Dr. Lawrence Osei-Tutu	Approved, yet to start 12 Months	Iron deficiency is the most common nutritional deficiency worldwide and an important public health problem in Low and Middle Income Countries (LMICs). Causes of anemia in LMICs like Ghana are usually multifactorial including malaria, hemolytic anemias, and chronic blood loss from chronic parasitic infections including schistosomiasis and hookworm. Factors accounting for inadequate supplies of dietary iron and micronutrients include poverty, a lack of nutritional supplementation, and food taboos. Anemia may result when iron deficiency is severe, after the body's iron stores are depleted and supply to the bone marrow is limited. This proof of concept study is to determine whether hospitalized children 6-59 months old who presented with moderate-to-severe anemia and given a combination of iron-rich food and standard iron replacement therapy (the intervention group) will demonstrate a greater final hemoglobin (Hb) concentration after two weeks compared to participants of similar characteristics in the control group who will receive oral iron supplementation in addition to their usual diet.
33	ATEA COVID 19	Phase III	Covid-19	Bemifosbuvir	7th June 2023	1. Dr Seyram Kaali 2. Dr. Nana Akosua Ansah	1. Kintampo Health Research Centre (KHRC) 2. Navrongo Health Research Centre (NHRC) 3. Dodowa Health Research Centre (DHRC)	Atea Pharmaceuticals , Inc.	Pending approval, 13 months	The primary objective is: • To evaluate the efficacy of BEM compared with placebo in reducing all cause hospitalization or all-cause death in COVID-19 outpatients receiving only supportive care. The secondary objectives are: • To evaluate the efficacy of BEM compared with placebo • To evaluate the antiviral activity of BEM compared with placebo on viral load rebound • To evaluate the safety of BEM compared with placebo
34	IUMO STUDY	Phase IV	Postpartum Hemorrhage	Intrauterine Misoprostol and Sublingual Misoprostol/ Allopathic medicine	27th May 2023	Dr. Chidinma Peace Ohachenu	Department of Obstetrics and Gynaecology, Korle-Bu Teaching Hospital, Accra-Ghana.	Dr. Chidinma Peace Ohachenu	Pending approval, 4 months	To evaluate the effectiveness of intrauterine misoprostol compared to sublingual misoprostol in the prevention of postpartum haemorrhage among women undergoing elective caesarean section in Korle-Bu Teaching hospital
35	INTS GMMMA STUDY	Phase II	Typhoid	GVGH INTS-GMMA Vaccine/ Vaccine	17th May 2023	Professor Ellis Owusu-Dabo	KNUST-IVI Collaborative Centre	GlaxoSmithKline Biologicals SA	Pending approval, 3 years 4 months	1. To identify the preferred dose of each component of the INTS-GMMA vaccine (Dose A [low], Dose B [medium], or Dose C [high]) for infant participants 6 weeks of age 2. To evaluate the safety and reactogenicity of the INTS-GMMA vaccine in all participants
36	PMC TRIAL	Phase III	Malaria	RTS,S/AS01E Malaria Vaccine, Sulphadoxine-Pyrimethamine, Amodiaquine/ Allopathic and Vaccine	8th May 2023	Dr. Kwaku Poku Asante	Kintampo Health Research Centre (KHRC)	PATH	Pending approval, 3 years 8 months	The primary objective is to determine the efficacy of the combination of RTS,S/AS01E and PMC with sulphadoxine/pyrimethamine alone (PMC SP) or RTS,S/AS01E and PMC with SP and amodiaquine (PMC-SPAQ) against clinical malaria among children up to 24 months of age compared with RTS,S/AS01E vaccine administered alone

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
37	VERTEX Trial-KBTH	Phase II/III	Kidney Disease	VX-147/ Allopathic drug	8th May 2023	Dr. Dwomoa Adu	Korle-Bu Teaching Hospital (KBTH)	Vertex Pharmaceuticals Incorporated	Pending Approval years	<p>Primary objectives</p> <ul style="list-style-type: none"> •To evaluate the efficacy of VX-147 to reduce proteinuria •To evaluate the efficacy of VX-147 on renal function as measured by eGFR slope <p>Secondary objectives</p> <ul style="list-style-type: none"> •To evaluate the efficacy of VX-147 to decrease the risk of the composite clinical outcome •To evaluate the safety and tolerability of VX-147 •To identify the optimal dose from Phase 2 to carry forward to Phase 3 •To characterize the plasma pharmacokinetics (PK) of VX-147
38	PROBIOTIC (MILD COGNITIVE IMPAIRMENT)	Phase I	Mild cognitive impairment	Probiotic (Lactobacillus reuteri)	14th April 2023	Michael Quansah	Korle-Bu Teaching Hospital (KBTH)	Western Sydney University, Australia	Pending Approval, 6 Months	<p>Aim</p> <p>To determine the therapeutic effects of probiotics in mild cognitively impaired individuals (MCI) at Korle-Bu Teaching Hospital.</p> <p>Specific objectives</p> <ul style="list-style-type: none"> • To determine the bioavailability of probiotics in mild cognitive individuals at Korle-Bu Teaching Hospital. • To determine the clinical effects of probiotics in mild cognitively impaired individuals at Korle -Bu Teaching Hospital. • To determine the molecular effects of probiotics in mild cognitively impaired individuals at Korle -Bu Teaching Hospital. • To determine the molecular effects of probiotics in healthy controls at Korle-Bu Teaching Hospital. • To determine the bioavailability of probiotics in healthy controls at Korle-Bu Teaching Hospital.
39	PLATINUM	Phase II	Malaria	1. INE 963 2. Cipargamin (KAE609) 3. KLU156 4.Coartem/Riamet / Allopathic drugs	29th March 2023	Dr. Patrick Odum Ansah	1. Navorongo Health Research Center (NHRC) 2. Kintampo Health Research Center (KHRC)	Novartis Pharma AG	Pending Approval, 21 Months	<p>Part A: To assess the parasite clearance time (PCT) of oral doses of an antimalarial agent administered as monotherapy in patients with uncomplicated P. falciparum malaria</p> <p>Part B: To assess the effect on adjusted 28-day cure rate of an anti-malarial agent administered orally as combination therapy versus the standard of care (SoC) in patients with uncomplicated P. falciparum malaria</p>
40	FITBIT/XIAOMI		Monitoring of Vitals in pediatric appendectomy and trauma patients	Fitbit Inspire 2 (Fitbit), Xiaomi Mi Smart band 6/Medical device	20th March 2023	Dr. William Appeadu-Mensah	Korle-Bu Teaching Hospital (Paediatric Surgery Unit, Accident Centre)		Pending Approval, 2 Months	<p>Aim(s)</p> <p>To establish the feasibility of a Fitbit/Xiaomi band-based wireless monitoring system for post-operative inpatient monitoring and monitoring of patients following trauma in the accident center. pefic objectives</p> <p>The specific objectives of this study are to:</p> <ol style="list-style-type: none"> 1. Determine the feasibility of implementing a band-based wireless monitoring system for post-operative, in-hospital monitoring of pediatric appendectomy patients, and for emergency department monitoring of pediatric and adult trauma patients. 2. Compare the vital signs recorded manually to those collected by wearable devices

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
41	SOY PEPTIDE STUDY	Phase I	Malnutrition in cancer patient	Soy Protein Peptide Supplements/ Food supplements	10th February 2023	Prof. Christiana Nsiah-Asamoah	Cape Coast Teaching Hospital (CCTH)		Pending Approval, 9 months	Objective: The main purpose of this study is to evaluate the efficacy of food-borne (soybean) peptides in reducing malnutrition in cancer patients.
42	GBT440-038	Phase III	Sickle Cell Disease	Voxelotor/ Allopathic	10th February 2023	1. Dr. Catherine Segbefia 2. Dr. Vivian Paintsil	1. Korle-Bu Teaching Hospital (KBTH) 2. Komfo Anokye Teaching Hospital (KATH)	Global Blood Therapeutics, Inc.	Pending Approval	The objective of this OLE is to assess the safety of, and SCD related complications with, long term treatment with Voxelotor in participants who have completed treatment in a GBT-sponsored voxelotor clinical study based on the following parameters a) Adverse Events (AEs), Clinical Laboratory Tests, Physical Examinations (PEs) and other clinical measures. b) Frequency of SCD-related complications.
43	BMLs4BU	Phase III	Buruli Ulcer	combination of rifampicin , clarithromycin and Amoxicillin/clavulanate/ Allopathic drug	1st February 2023	Prof. Richard Odame Phillips	St. Peters Catholic Hospital Jacobu Nkwawie Government Hospital	University of Zaragoza (UNIZAR) Spain	Pending Approval year 11 months	2 The aim of this study is to determine the ability of amoxicillin/clavulanate combination therapy with rifampicin plus clarithromycin to improve the cure rate of Buruli ulcer (BU) disease compared to a standard regimen of rifampicin plus clarithromycin. Primary objective The primary objective of this clinical trial is to demonstrate the non-inferiority of 4-week coadministration of amoxicillin/clavulanate ((AMX/CLV)) with rifampicin-clarithromycin (RIF/CLA's) compared to the standard 8-week rifampicin-clarithromycin (RIF/CLA's) in cure rates at 12 months post initiation of treatment, thus reducing BU treatment from 8 to 4 weeks.
44	ROBOCOW		Postoperative Respiratory Tract Infections in abdominal surgery	0.2% Chlorhexidine Digliconate/ Mouthwash	10th January 2023	Dr. Mohammed Sheriff	Tamale Teaching Hospital		Pending Approval Months	5 Primary Objective 1. To determine whether perioperative use of 0.2% chlorhexidine mouth wash reduces the rate of postoperative respiratory tract infections in 30 days postoperative period compared to placebo among patients undergoing midline laparotomy. Secondary Objectives 1. To assess the impact of the intervention on 30-day postoperative mortality 2. To determine the impact of the intervention on length of hospital stay 3. To determine whether the intervention impacts on the 30-day unplanned readmission rates due to a respiratory complication 4. To assess the effect of the intervention on time to return to normal activities
45	CIELO Trial	Phase III	Encephalitis	Satralizumab/ Monoclonal antibody	20th December 2022	Prof. Fred Stephen Sarfo	Komfo Anokye Teaching Hospital (KATH)	F-Hoffman LA Roche/ Chugai Pharma Co. LTD	Pending Approval 5months	5years This study will evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of satralizumab compared with placebo in each of the following cohorts: •NMDAR autoimmune encephalitis (AIE) cohort: adults and adolescents with definite or probable NMDAR encephalitis •LG1 AIE cohort: adults with LG1 encephalitis In addition, the study will assess the long-term safety and efficacy of satralizumab during an optional extension period. For efficacy analyses, each cohort will be treated as a separate population and will have independent Type I error control at a 5% significance level. Specific primary and secondary objectives and corresponding endpoints for the study are outlined below.
46	INO-9112 COVID 19	Phase I	Covid-19	1. INO-4800 followed by Electroporation (EP) 2. NO-4800 + INO-9112 followed by Electroporation (EP)/ Vaccine	30th June 2022	Dr. Kwadwo Ansah Koram	Noguchi Memorial Institute for Medical Research, University of Ghana, Legon	Inovio Pharmaceuticals	Application Pending Approval, 15 Months	The overall purpose of this clinical trial is to identify a booster dose of INO-4800 or INO 4800 plus INO-9112 given 6 to 12 months following primary vaccination with an approved or authorized mRNA vaccine for future development.

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
47	POST MASTECTOMY PAIN RELIEF		Anaesthesia	Erector Spinae block using bupivacaine/ Local anaesthetics	2nd December 2021	Dr. Nana Addo Boateng	Komfo Anokye Teaching Hospital (KATH)	Self-Funding	Application Pending Approval	<p>General objective: The main objective of the study is to determine the postoperative analgesic effect of Erector Spinae Plane (ESP) Block after mastectomy.</p> <p>Specific objectives:</p> <ol style="list-style-type: none"> To compare the total morphine consumption within 24 postoperative hours between patients receiving ESP block with bupivacaine and ESP block with saline for mastectomy at the Komfo Anokye Teaching Hospital, Kumasi, Ghana. To compare the numeric rating score at 2,4,6,12 and 24 hours between patients receiving ESP block with bupivacaine and ESP block with saline for mastectomy at the Komfo Anokye Teaching Hospital, Kumasi, Ghana. To compare the time to the first request of rescue analgesia between patients receiving ESP block with bupivacaine and ESP block with saline for mastectomy at the Komfo Anokye Teaching Hospital, Kumasi, Ghana. To compare patients satisfaction within the 24-hour postoperative analgesia between patients receiving ESP block with bupivacaine and ESP block with saline for mastectomy at the Komfo Anokye Teaching Hospital, Kumasi, Ghana.
48	BEMPU	Phase II	Hypothermia in Infants	Bempu Bracelet/ Medical device	2nd November, 2020	Mr. Prince Owusu	<ul style="list-style-type: none"> Achimota General Hospital Greater Accra Regional Hospital Eastern Regional Hospital Korle-Bu Teaching Hospital Central Regional Hospital Princess Marie Luis Children Hospital 	Center for learning and childhood development	Application Pending Approval	<p>To determine the accuracy of the bracelet in identifying hypothermia and evaluate its effect on Kangaroo Mother Care (KMC) practices and neonatal health outcomes in Ghana.</p> <p>To assess the acceptability of the bracelet in Health providers and caregivers of Low Birth Weight (LBW) infants by conducting qualitative in-depth interviews.</p> <p>Determine the accuracy of the BEMPU bracelet in classifying hypothermia in the clinical setting.</p> <p>Evaluate the impact of the bracelet</p>
49	MAL 094	Phase IIb	Malaria	1.RTS,S/AS01E 2.Rabies vaccine (Rabipur™)/ Vaccine	21st November 2016	Prof. Tsiri Agbenyega	Malaria Research Center, Agogo	GlaxoSmithKline Biologicals SA	Study ended Final report yet to be submitted 72 months	<p>As part of GSK and PATH's commitment to develop a malaria vaccine for reduction of malaria disease burden in children and contribution to the malaria elimination goal, characterization of an optimal dosing regimen and boosting schedules are critical. Results of previous efficacy study MAL 055, including the long term follow-up data and efficacy of a fourth dose administered 18 months after the third dose, and the preliminary results of MAL 071 study (recent controlled human malaria infection) were reviewed by the European Medicines Agency (EMA). There was evidence that demonstrated superior protection against malaria infection associated with the use of a fractional third dose in a 0, 1, 7-month schedule with a higher vaccine efficacy against malaria infection.</p> <p>This study intends to establish Proof of Concept for a fractional dose schedule under conditions of natural exposure. The study will be conducted in children 5-17 months old at first vaccination living in areas of mid to high malaria transmission, in line with the age group recommended by the World Health Organization. Results from study will be critical in informing future possibilities for the development of vaccine-based strategies which, in combination with other interventions, may contribute to the malaria elimination agenda.</p>
50	CROWN CORONATION	Phase III	Covid-19	1.Measles Rubella Vaccine 2.Matching Placebo 3.AstraZeneca vaccine/ Vaccine	7th September 2020	Prof. Kwadwo Koram	<ul style="list-style-type: none"> Ga East Municipal Hospital Korle-Bu Teaching Hospital UGMC Hospital Effia-Nkwanta Hospital Pentecost Treatment Center 	Each country serves as its own sponsor but will receive funding from the Covid 19 Therapeutics Accelerator and Gates Foundation through Washington University in St. Louis.	Study ended Final report yet to be submitted 8 Months .	<p>The purpose of this study is to determine that MR vaccine increases the likelihood of making the specific AstraZeneca COVID-19 vaccine more effective in people with prior exposure to the MR vaccine.</p> <p>This study has two different groups: one group will receive the active MR vaccine and one will receive a placebo. Thirty and sixty days later, participants in each group will receive the AstraZeneca COVID-19 vaccine.</p>

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
51	DOLF_IDA ONCHO SAFETY GHANA	Phase II	Onchocerciasis	1.Diethylcarbamazine Citrate I. P 100mg 2.Ivermectin (Stromectol® 3mg) 3.Albendazole (Zentel™ 400mg) / Allopathic drugs	22nd February 2019	Dr. Nicholas Opoku	University of Health and Allied Sciences	Washington University School of Medicine	Study ended Final report submitted 24 Months	<p>Programs for control of onchocerciasis through community directed treatment with ivermectin (IVM) as a form of Mass Drug Administration (MDA) have been in place for almost 30 years. IVM is effective for clearing Mf and it temporarily sterilizes adult female worms, but it is not a microfilaricide and does not kill adult worms. For that reason, MDA with IVM must be repeated for the reproductive life of the adult worms, which is 10-15 years. Thus, there is a widely recognized need for new, safe, short-course treatment drug(s) that can kill or permanently sterilize adult worms.</p> <p>This study aims to provide preliminary data on the safety of ivermectin + diethylcarbamazine + albendazole (IDA) treatment in persons with onchocerciasis when administered after pre-treatment with IVM to clear or greatly reduce microfilariae from the skin and eyes. Widespread use of IDA following IVM pretreatment (I/IDA) has the potential to greatly accelerate elimination of LF in African countries that are endemic for LF and onchocerciasis</p>
52	SMAART	Phase II	Stroke	1.POLYCAP 2.USUAL CARE / Allopathic drug	9th February, 2018	Dr. Fred Stephen Sarfo	Komfo Anokye Teaching Hospital	Kwame Nkrumah University of Science and Technology	Study ended Final report submitted 19 months	<p>There has been unprecedented rise in the prevalence of stroke in Sub-Saharan Africa (SSA), which when compared to stroke profiles in high-income countries (HIC) is characterized by a younger age of onset, higher case fatality rates, and more severe disability among survivors. Stroke survivors in SSA are especially at high risk for recurrent vascular events or death due to several factors including uncoordinated health systems, undiagnosed and under-controlled vascular risk factors, and lack of care affordability. Fixed-dose combination pills, known as "polypills", containing Aspirin, a statin and blood pressure (BP) lowering medication(s) may improve medication adherence and consequently reduce vascular risk as a cost-effective intervention among high risk patients including stroke survivors.</p> <p>This trial is to assess whether a polypill containing fixed doses of 3 antihypertensives, a statin and antiplatelet therapy taken once daily orally would result in carotid intimal thickness regression, improved adherence, and tolerability compared with 'usual care' group on separate individual secondary preventive medications among Ghanaian first time stroke survivors (male or female above</p>
53	LEDoxy	Phase II	Lymphatic Filariasis	1.Doxycycline (Remycin®100mg) 2.Placebo 3.Standard MDA Treatment/ Allopathic drug	12th July, 2017	Prof. Alexander Yaw Debrah	1.Kumasi Centre for Collaborative Research (KCCR), Kwame Nkrumah University of Science and Technology (KNUST) 2.War Memorial Hospital, Navrongo	Kumasi Center For Collaborative Research (KCCR)	Study ended Final report submitted 40 months	<p>The previously demonstrated effect of doxycycline in reversing or stopping the progression of lymphedema of patients with stage 1-3, irrespective of their filarial infections being active or not, provides an opportunity to include the drug as a new tool in lymphatic filariasis (LF) morbidity management programs. However, before recommendations can be made regarding the frequency of its usage or alternate dosing patterns more trials need to be conducted. This multi-national trial is to show efficacy of a lower dosage of doxycycline and to confirm finding in patients with stages 1-3 lymphedema irrespective of active LF infection as well as in people with higher grades of lymphedema.</p> <p>The purpose of the study is to establish that Doxycycline can improve filarial lymphedema in healthy adolescents or adults (14 – 65 years)</p>
54	FALCON	Phase III	Surgery	1.ChlorPrep™ stick 2.Videne® Antiseptic Solution 3.Triclosan Coated PDS and/or Vicryl sutures 4.Non-triclosan coated PDS and/or Vicryl sutures/ Medical device	10th April, 2019	Prof. Stephen Tabiri	Tamale Teaching Hospital	The University of Birmingham	Study ended Final report submitted 24 Months	<p>Improving surgical outcomes is a global health priority. Recent World Health Organisation (WHO) guidelines made 29 recommendations for intraoperative and postoperative measures to prevent SSI, including global perspectives relevant to LMICs, none of the evidence for the recommendations used was derived from resource limited settings, leading to uncertainty about implementation of measures in these settings. A randomised trial that has the potential to evaluate multiple interventions has particular value in this setting, and can establish a high quality evidence base that will inform guidance, and influence revisions to the WHO Surgical Safety Checklist</p> <p>This study assesses whether either (1) 2% alcoholic chlorhexidine versus 10% povidone-iodine for skin preparation, or (2) triclosan-coated suture versus non-coated suture for fascial closure, can reduce surgical site infection at 30-days post-surgery for each of (1) clean-contaminated and (2) contaminated/dirty surgery</p>

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
55	KNC 19 (NIBIMA)	Phase IIb	Covid-19	1.Nibima 2.WHO standard treatment for COVID-19/ Herbal drug	11th September 2020	Prof. Ellis Owusu-Dabo	Komfo Anokye Teaching Hospital	KNUST Office of Grants and Research	Study ended Final report submitted From 3 months to 7 months	The purpose of this trial is to evaluate the: •Efficacy of Nibima in reducing >50% Covid-19 viral load per patient within 14 days of therapy. Evaluate the efficacy of Nibima in increasing the anti-inflammatory and interferon alpha/beta profiles of >50% of the Covid-19 patients within 14 days.
56	MULTIMAL	Phase II	Malaria	Pyronaridine (Pyramax) 2.Atovaquone Proguanil (Malarone) 3.Clindamycin 4.Foscidomysin	27th July 2020	PI(s) Dr. Oumou Maiga (KCCR)	St. Francis Xavier Hospital Assin Fosu, Ghana. Gabon	Tropical Medicine, Bernhard Nocht Institute for Tropical Medicine (BNITM)	Study ended Final report submitted 7 months	outcome of this consideration was that the specific multi-therapeutic ACT combinations, discussed below, were decided on based on the following aspects: efficacy, potential for drug interactions, modes-of-action, half-life of the individual drugs, parasitological stages the drug acts on, dosing, availability of a paediatric formulation and cost.The two drug combinations envisaged to investigate during this study address two particular aspects of treatment of uncomplicated malaria in the sub-Saharan African region. Firstly,
57	STAR TRIAL	Phase IV	Anaesthesia	1.Paracetamol 2.Morphine/Allopathic drug	7th May 2021	Dr. Frank Enoch Gyamfi	Komfo Anokye Teaching Hospital, Kumasi	Dr. Frank Enoch Gyamfi	Study ended Final report submittee 10 months	with bimodal administration of i.m. morphine and i.v. paracetamol in managing postoperative pain in emergency abdominal surgery. To assess the response of patients to i.m. morphine in pain management after emergency abdominal surgery. To assess the response of patients to a combination of i.v. paracetamol and i.m. morphine in managing pain after emergency abdominal surgery. To determine the association between the administered analgesic and length of hospital stay. To determine the association
58	DIABETIC FOOT SELF CARE	Feasibility testing	Diabetes	1.Foot Selfcare Training and Education Plus usual care 2. Usual care./ Training	28th October 2021	Dr.Joseph N. Suglo	Diabetes Clinic, Komfo Anokye Teaching Hospital (KATH) – Ghana	King's College London (KCL)	Study ended Final report in E3 format submitted, 7 months	The primary aim of this research is to evaluate the feasibility of conducting a randomised controlled trial to investigate the effectiveness of a hands-on skills training and education on foot self-care programme for persons with diabetes and their family caregivers in Ghana. The research question is 'can the provision of a family-oriented foot self-care skills training and education intervention improve foot care behaviour, foot care self- efficacy, knowledge of
59	CHEETAH	Pilot	Surgery	1.Sterile Gloves 2.Sterile Surgical Instrument/Medical device	1st June 2020	Professor Stephen Tabiri	•Cape Coast Teaching Hospital •Effiah Nkwanta Regional Hospital •Holy Family Hospital – Berekom •Holy Family Hospital – Techiman •KATH	Birmingham Clinical Trials Unit, University of Birmingham	Study ended Final report submitted. 24 Months	To purpose of this study is to assess whether the practice of using separate, sterile gloves and instruments to close wounds at the end of surgery can reduce surgical site infection at 30-days post-surgery for patients undergoing clean-contaminated, contaminated or dirty abdominal surgery, compared to current routine hospital practice.
60	KAE609	Phase II	Malaria	1.KAE609 2.COARTEM TABLETS / Allopathic drug	1st September 2019	Dr. Abraham Rexford Oduro	1.Navrongo Health Center 2.Kintampo Health Research Centre	Novartis Pharma AG, Switzerland	Study ended; Final report submitted 14months	KAE609 will be evaluated primarily for hepatic safety of single and multiple doses in sequential cohorts with increasing doses. This study aims to determine the maximum safe dose of the investigational drug KAE609 in Adult patients with acute, uncomplicated Plasmodium falciparum malaria infection..

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
61	Saving Brains Navrongo	Phase I	Malnutrition	1. Small Quantity Lipid-based Nutrient Supplement for Pregnant and Lactating mothers (SQLNS P&L) 2. Enhanced Small Quantity Lipid-based Nutrient Supplement for Pregnant and Lactating mothers (eSQLNS P&L) 3. SQLNS for Infants 4. eSQLNS 5. SQLNS nut 6. Omega 3 fatty acids 7. Corn oil/ Food supplements	7th February 2019	Dr. Engelbert A. Nonterah	Navrongo Health Research Centre	Nutriset, SAS	Study ended; Final report yet to be submitted 6 months	Malnutrition continues to be a global problem. Globally 156 million children less than 5 years are stunted, 50 million wasted, while simultaneously 42 million are overweight reflecting the double burden of malnutrition. Prevalence of malnutrition varies by region and country with Asia and Africa being the worst affected regions. This study is to assess the acceptability and adherence to nutrient supplementation for 6 weeks among pregnant and lactating women and 6 month old infants post weaning
62	SAVING BRAINS KUMASI	Phase I	Malnutrition	1. Small Quantity Lipid-based Nutrient Supplement for Pregnant and	1st November 2017	Prof. Jacob Plange-Rhule	1. Tafo Government Hospital 2. Suntreso Government Hospital	KNUST/Nutriset SAS	Study ended 6 months	Malnutrition continues to be a global problem. Globally 156 million children less than 5 years are stunted, 50 million wasted, while simultaneously 42 million are overweight reflecting the double burden of malnutrition. Prevalence of malnutrition varies by region and country with Asia and Africa being the worst affected regions. This study is to assess the acceptability and adherence to nutrient
63	ALB_IVM	Phase III	Onchocerciasis	1. Ivermectin 2. Albendazole/ Allopathic drug	1st April 2014	Dr. Nicholas Opoku	Onchocerciasis Chemotherapy Research Centre Government Hospital.	Case Western Reserve University School of Medicine, 10900 Euclid Ave Cleveland	Study ended; Final report submitted 38 months	To address whether IVM plus ALB given twice per year will be superior over annual treatment or IVM given biannually
64	MAL 055	Phase III	Malaria	RTS,S/AS01E/ Vaccine	1st October 2008	1. Prof. E. Tsiri Agbenyaga 2. Prof. Seth Owusu Agyei 3. Dr. Kwaku Poku Asante	1. Malaria Research Centre, Agogo. 2. Kintampo Health Research Centre	GlaxoSmithKline Biologicals	Study ended; Final report submitted 60 months	This Phase III study of GSK Biologicals candidate malaria vaccine RTS,S/AS01E has been designed to address the key safety and efficacy information required for vaccine licensure. In addition, other disease endpoints that allow the evaluation of the full public health impact and cost effectiveness of vaccine implementation are included. Co-primary objectives will investigate the efficacy against clinical disease in children from 5-17 months of age at first dose and the efficacy in infants 6-12 weeks of age who receive the vaccine in co-administration with EPI antigens
65	MMS	Phase III	Malnutrition	1. Multiple micronutrient supplement 2. Iron + folic acid tablets/ Food supplements	2nd October 2012	Prof. Tsiri Agbenyaga	1. Darekuma Collaborative Community Development Project 2. C/O Komfo Anokye	Kirk Humanitarian	Study Ended; yet to submit report 48 months	
66	PRENABELT		Birth Weight	1. Prenabelt™ 2. Sham prenabelt™ 3. Body Position Sensor/ Medical device	21st April 2015	Dr. Jerry Coleman	Korle-Bu Teaching Hospital, Accra – Korle Bu	Global Innovations for Reproductive Health and Life, USA	Study ended; Final report submitted 7 months	The purpose of this study is to determine the effect of the PrenaBelt on birth-weight and assess the feasibility of introducing it to Ghanaian third-trimester pregnant women in their home setting via an antenatal care clinic and local health-care staff. Data from this study will be used in effect size calculations for the design of a large-scale, epidemiological study targeted at reducing LBW and SB in Ghana and globally.
67	CPAP	Phase III	Infant Acute Respiratory Distress	1. DeVilbiss IntelliPAP CPAP machine (Model DV5 Series) 2. Hudson RCI nasal cannulas/ Medical device	14th May 2013	1. Dr. Harry Tagbor 2. Dr. Frank Baiden 3. Dr. Damien Punguyire 4. Dr. Kwadwo Nyarko Jectey	1. Mampong Government Hospital, Mampong 2. Kintampo Municipal Hospital, Kintampo	(GE) Foundation's Systems Improvement at District Hospitals and Regional	Study ended; yet to submit report in required format. 36 months	Evaluating the impact of using continuous positive airway pressure (CPAP) on mortality among children admitted into emergency wards. an interventional trial to determine if CPAP reduces mortality in children 1 month to 5 years of age with acute respiratory distress
68	AIMS	Phase III	Transfusion-Transmitted Malaria (TTM)	1. Mirasol system for whole blood 2. Standard fresh whole blood/ Blood product	9th July 2013	Dr. Shirley Owusu-Ofori	Komfo Anokye Teaching Hospital	Terumo BCT Europe N.V.	Study ended; Final report submitted 6 months	The objective of this study was to evaluate the efficacy of Mirasol-treated fresh whole blood (WB) to prevent transfusion-transmitted malaria (TTM) by comparing the incidence of TTM between subjects receiving Mirasol-treated fresh WB and subjects receiving standard (untreated) fresh WB.
69		Phase III	Meningitis	Meningococcal A Conjugate Vaccine/ Vaccine	26th June 2007	Dr. Patrick Ansah	Navrongo Health Research Centre	SIIL PATH	Study ended; Final report submitted 54 months	To compare the immunogenicity at 28 days after vaccination of range dosages - 10, 5, and 2.5 µg of the PsA-TT vaccine, when administered to infants in a two-dose schedule at 14 weeks (window 14 to 18 weeks of age) and 9 months of age (window 9 to 12 months of age) concomitantly with EPI vaccines (Groups 1A vs.

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
70	NON-INVASIVE HAEM DEVICE	Phase III	Hemoglobin deficiency in Pregnant women	1. Pronto & pronto-oximeter pulse co-oximeter 2. Hemocue 201+3. Abx pentra 60 hematology analyzer/ Medical device	9th April 2013	Dr. Sam Newton	Kintampo Health Research Centre, Kintampo	PATH	Study Ended Final report submitted 2 months	Aim The aim of the validation study was to evaluate the accuracy of the Pronto and Pronto 7 devices in measuring Hb when compared to measuring Hb using the Hemocue and the ABX Pentra 60 hematology analyzer as the reference standard. Study Objectives: To compare Hb values as measured by the Pronto and Pronto 7 noninvasive Hb devices and HemoCue 201+ machine with those obtained by a venous blood draw using an ABX Pentra 60 hematology analyzer among pregnant women attending ANC clinic in Ghana.
71	ROTARIX	Phase III	Gastroenteritis	Rotarix™/ Vaccine	6th February 2012	Prof. George Armah	Navrongo Health Research Centre	PATH	Study Ended 7 months Final Report submitted	To show the superiority of live, oral Rotarix vaccine administered at 6, 10, and 14 weeks of age versus live, oral Rotarix vaccine administered at 6 and 10 weeks of age in terms of serum rotavirus immunoglobulin A (IgA) seroconversion as the marker of vaccine-induced immunogenicity
72	ARTIMIST	Phase III	Malaria	ArTiMist/ Allopathic drug	22nd October 2010	Dr. Patrick Ansah	Navrongo Health Research Centre	ProtoPharma Limited	Study Ended Final report submitted 5 months	The primary objective of this study was to demonstrate the superiority of ArTiMist™ over intravenous (iv) quinine in establishing parasite success (reduction of parasite counts by ≥ 90% within 24 hours) in children with severe or complicated falciparum malaria, or children with uncomplicated malaria with gastrointestinal complications.
73	GARDASIL	Phase III	Human Papillom Virus (HPV)	Gardasil/ Vaccine	1st November 2010	Dr. Nana Akosua Ansah	Navrongo Health Research Centre	Merck, Sharp and Dohme Corporation	Study Ended Final report submitted 20 months	To estimate the percentage of subjects who seroconvert to each of HPV 6, 11, 16, and 18 at Month 7 (4 weeks Postdose 3). To evaluate the safety and tolerability of GARDASIL in females 9 to 26 years of age in SubSaharan Africa. Secondary: To estimate Month 7 anti-HPV 6, 11, 16, and 18 geometric mean titers (GMTs) in vaccinated subjects
74	SMAC	Phase III	Malaria	1. Intravenous Artesunate 2. Intramuscular Artesunate/ Allopathic	1st January 2013	Prof. Tsiri Agbenyega	Komfo Anokye Teaching Hospital, Kumasi	University Medical Centre Tubingen	Study Ended 15 months	
75	OXYTOCIN	III	Postpartum Hemorrhage (PPH)	1. Oxytocin in uninject™ 10 iu/ Hormone	12th May 2010	Dr. Sam Newton	Kintampo Health Research Centre	PATH	Study Ended Final report submitted 12 months	To determine the effect of prophylactic administration of oxytocin in uninject on postpartum haemorrhage at home births in the Kintampo north and south districts of Ghana
76	AMARYL M	IV	Type 2 Diabetes	Amaryl m oral tablets/ Allopathic	16th October 2009	Dr. Frank Umeh	Korle-Bu Teaching Hospital	Sanofi Aventis	Study Ended 6 months	To determine the clinical Efficacy and Safety of Amaryl M in Patients with Type 2 Diabetes Who are Inadequately Treated by Either Glimpeptide or Metformin Monotherapy or Who are Already Treated with Free Combination of Glimpeptide and Metformin in African Countries
77	MOXIDECTIN- IVERMECTIN	III	Onchocerciasis	1. Moxidectin 2. Ivermectin/Allopathic	1st February 2004	Dr. Nicholas Opoku	Onchocerciasis Chemotherapy Research Centre Government Hospital.	1. Wyeth Research Division of Wyeth Pharmaceuticals Inc. 2. Product Development and Evaluation unit TDR	Study Ended Report submitted 25 months + (12 months ext.)	To determine the Safety, Tolerability, and Efficacy of Orally Administered Moxidectin in Subjects with Onchocerca volvulus

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
78	MOXIDECTIN	Phase II	Onchocerciasis	Moxidectin 2mg Tablets/Allopathic	1st February 2004	Dr. Kwabia Awadzi	Onchocerciasis Chemotherapy Research Centre Government Hospital	1. Wyeth Research Division of Wyeth Pharmaceuticals	Study Ended Ended 60 months	
79	EBA	Phase I	Malaria	(EBA-175 RII-NG) malaria vaccine/ Vaccine	1st March 2009	Prof. Kwadwo Anah Koram	Noguchi Memorial Institute of Medical Research	Division of Microbiology and Infectious Diseases (DMID) National Institute of Allergy and Infectious Diseases (NIAID)	Study Ended Final report submitted 18 months	To determine the Immunogenicity of EBA-175 RII-NG Malaria Vaccine Administered Intramuscularly in Semi-Immune Adults
80	IPT & SP	Phase III	Malaria in Pregnant women	Sulfadoxine-pyrimethamine/Allopathic	1st May 2008	Dr. Abraham Hodgson	Health Facilities in the Kassena Nankana, Navrongo Health Research Centre	London School of Hygiene and Tropical Medicine	Study Ended 32 months	to compare the intermittent preventive treatment of sulfadoxine-pyrimethamine with intermittent screening and treatment of malaria in pregnancy
81	IRON FORTIFICATION III		Malaria	1.Sprinkles vitamine 2.mineral food supplement/ Food supplements	1st July 2009	Prof. Seth Owusu Agyei	Kintampo Health Research Centre	National Institutes of Health	Study Ended 12 months	To determine the seasonal impact of iron fortification on malaria incidence in Ghanaian children
82	ROTASHIELD	III	Rotavirus Gastroenteritis	RRV-TV Vaccine (rotashield)/ Vaccine	1st August 2009	1. Prof. George E. Armah 2. Prof. Fred N. Binka 3. Dr. Abraham Hodgson	1. War Memorial Hospital, Navrongo 2. Bongo Hospital	International Medica Foundation	Study Ended 16 months	To determine the efficacy, immunogenicity, and safety of two single doses of RRV TV in neonates / infants
83	AZITHROMYCIN PLUS CHLOROQUINE PHOSPHATE	III	Malaria	1.Azithromycin 2. Chloroquine Phosphate 3. Artemether-Lumefantrine/Allopathic	1st October 2007	Dr. Patrick Anah	Navrongo Health Research Centre	Pfizer Laboratories Incorporated, Pfizer Global Research and Development, London School of Hygiene & Tropical Medicine	Study Ended Final report submitted 8 months	To compare azithromycin plus chloroquine phosphate with artemether-lumefantrine for the treatment of uncomplicated plasmodium falciparum malaria in children in Africa
84	CRASH-2	I	Trauma patient with or at risk of hemorrhage	1. Tranexamic acid 2. Placebo/ 1. Pyronaridine Artesunate Tablet (PYRAMAX) 2. Artemether-Lumefantrine (CO ARTEM)/ Allopathic	1st August 2007	Prof. J. C. B. Dakubo	Korle-Bu Teaching Hospital	Medicines For Malaria Venture, Switzerland	Study Ended, Lancet publication submitted 24 months	To determine the effects of anti-fibrinolytic treatment on death and transfusion requirement among trauma patients with or at risk of significant haemorrhage.
85	PYRONARIDINE ARTESUNATE VRS COARTEM	III	Malaria	1. Pyronaridine Artesunate Tablet (PYRAMAX) 2. Artemether-Lumefantrine (CO ARTEM)/ Allopathic	1st March 2007	Dr. G. Bedu-Adoo	Komfo Anokye Teaching Hospital	Medicines For Malaria Venture, Switzerland	Study Ended 3 months	To Compare the Safety and Efficacy Of Fixed Dose Formulation Of Oral Pyronaridine Artesunate Tablet with Coartem In Children And Adult Patients With Acute Uncomplicated Plasmodium Falciparum Malaria
86	MAL 050	III	Malaria	RTSS, AS10E Vaccine/Vaccine		Prof. Seth Owusu Adjei	Kintampo Health Research Centre	GlaxoSmithKline R&D	Study Ended 17 months	
87	PFCSP_MVACS_MALARIA	I	Malaria	PFCSP DNA VACCINE (VCL-2510)/Vaccine	1st August 2005	Prof. Kwadwo A Koram	Tetteh Quarshie Memorial Hospital	Microbiology and Infectious Diseases (DMID) National Institute of Allergy and Infectious Diseases (NIAID)	Study Ended 18 months	

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	,DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
88	ROTATEQ	III	Gastroenteritis	Rotateq/Vaccine	1st September 2007	Prof. George E. Armah	Navrongo Health Research Centre	1. Merck & Co. 2. PATH	Study Ended Final report published in Lancet 18 months	
89	MEFLOQCHLOAZITH	III	Malaria	1. Mefloquine 2. Chloroquine 3. Azythromycin/Allopathic	4th August 2004	Dr. Abraham Hodgson	Navrongo Health Research Centre	Pfizer Inc.	Study Ended Final report submitted 12 months	
90	MAL 047	II	Malaria	1.RTS,S/AS02D 2.RTS,S/AS01E/Vaccine		Prof. Seth Owusu Adjei, Dr. Kwaku Poku Asante	Kintampo Health Research Centre	GlaxoSmithKline R&D	Study Ended 19 months	
91	CDA	III	Malaria	1.Chorproguanil-Dapsone-Artesunate (CDA) 2.Artemether-Lumefantrine/Allopathic	19th July 2006	Prof. Seth Owusu Agyei Dr. Kwaku Poku Asante	Kintampo Health Research Centre	GlaxoSmithKline R & D	Study Ended 12 months	
92	CDA2	III	Malaria	Dapsone-Artesunate (CDA) 2.Artemether-Lumefantrine/allopathic	27,June 2006	Prof. Tsiri Agbenyega	Department of Physiology, School of Medical Sciences, KNUST	GlaxoSmithKline R & D	Study Ended 12 months	
93	NOVASIL	II		NovaSIL		Prof. David Ofori Agyei Dr. Nii- Ayi Ankrah	Ejura Sekyedumasi District, Ashanti Region	United States Agency for International Development (USAID)	Study Ended 9 months	
94	TENOFOVIR	II	HIV	Tenofovir Disoproxyl Fumarate (TDF)/Vaccine	1st February 2004	Dr. Edith Clarke	Ghana Health Service	Family Health International	Study Ended 20 months	
95	SAVVY	II		SAVVY (Microbicide)	1st February 2004	Dr. William Ampofo Dr. Baafuur Kofi Opoku	1. Noguchi Memorial Institution for Medical Research. 2. Komfo Anokye Teaching Hospital.	Family Health International	Study Ended 32 months	
96	MAL 063	III	Malaria	RTS,S/AS01E/Vaccine	15th April 2011	Prof. E. Tsiri Agbenyega	Malaria Research Centre, Agogo.	Malaria Research Centre, Agogo	Study Ended Final report submitted 52 months	

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
97	PREGACT	III		1. Eurartesim oral tablets 2. Farmanguinhos artesunate+mefloquine fixed combination oral tablets 3. Coarsucam oral tablets/ Allopathic		1.Dr. Harry Tagbor 2.Dr. Henry Opare Addo	1.Ejisu Government Hospital, Ejisu 2. Juaben Government Hospital, Juaben	Prince Leopold Institute of Tropical Medicine	Study Ended 60 months	
98	ALBIVIM K'SI	III	Onchocerciasis	1. Ivermectin 2. Albendazole/Allopathic	10th November 2015	Prof. Alexander Yaw Debrah	Kumasi Centre for Collaborative Research in Tropical Medicine	University Hospitals Case medical Center	Study Ended, Yet to submit final report 4 years and 2 months	
99	RIFAMPIN VS ISONIAZID	III	Tuberculosis	1. Isoniazid 2. Rifampin/Allopathic/ Allopathic	2nd March 2011	Dr. Joseph Baah Obeng	Komfo Anokye Teaching Hospital Chest Clinic, Kumasi	Canadian Institute of Health Research	Study Ended 60 months	
100	NOGUCHI FILARIASIS *		Filariasis	1. Alere filariasis test strip 2. Sd bioline lymphatic filariasis IgG4 3.Sd	7th June 2017	Prof. Daniel A. Boakye Dr. Nana – Kwadwo Biritwum	Noguchi Memorial Institute For Medical Research	World Health Organization - TDR	Study Ended Final report submitted 10 months	Development of a plan of action for strengthening LF elimination in Ghana, and where appropriate, a plan of action for integrating LF and onchocerciasis elimination efforts, to be proposed to the GHS decision makers.
101	ZIV AFFLIBERCEPT	I	Retinal Vascular diseases	1. Ziv-aflibercept (ZALTRAP) / Allopathic	30th January 2017	Braimah Imoro Zeba	Retina unit, Eye Centre, Korle-Bu, Teaching Hospital, Korle-Bu, Accra	Same as PI	Study Ended Final report submitted 5 months	To evaluate the safety of 1.25mg and 2mg ziv-aflibercept in Ghanaian population with retinal vascular diseases. To determine the safety of intravitreal injections of ziv-aflibercept at 4 and 12 weeks in a Ghanaian population. To measure the visual outcome of treatment with 1.25mg and 2mg ziv-aflibercept in eyes with DME, nvAMD, and ME secondary to RVO at 12 weeks. To measure the anatomic changes using SD-OCT in eyes with DME, nvAMD and ME secondary to RVO at 12 weeks.
102	HESTIA3	Phase III	Sickle Cell Disease	1. Ticagrelor 2. Placebo/Allopathic	1st August, 2018	1. Prof. Alex Osei-Akoto 2. Dr Patrick Ansa 3. Dr. Catherine Segbefia 4. Dr Kokou Hefourme Amegan-Aho	Teaching Hospital, Department of Child Health 2. Navrongo Health Research Centre 3. Department of Child Health, Korle Bu	AstraZeneca AB	Study Ended. Final Report submitted 29 Months	resulting in altered (sickle-shaped) red-blood cells. A vaso-occlusive crisis (VOC) is a severe, acute painful episode that occurs when sickle-shaped red blood cells obstruct the microcirculation and restrict blood flow to an organ or tissue, resulting in ischaemia, necrosis and organ damage. There is a high unmet need for treatment options in SCD and there is a data that platelet inhibition has the potential to reduce the risk for acute vaso-occlusions.
103	PRCR DIPSTICK	Phase II	proteinuria	1. Test-It™ Protein Creatinine Dipstick 2. Urinalysis Reagent Strips 3. Quantitative Spectrophotometric Method/Medical device	16th February, 2018	Dr. Sam Newton	Kintampo Health Research Center	Program For Appropriate Technology In Health (PATH)	Study Ended. Final Report Submitted 19 months	The lack of access to reliable tests for proteinuria measurement in all antenatal care settings, particularly at the periphery, remains a critical gap in the accurate identification of women at high risk for Pre-Eclampsia. In Low Resource Settings, a protein-only measurement via a urine dipstick is the most widely used proteinuria test due in part to its low complexity and low cost. However, the clinical utility of the protein-only dipstick is limited. Test results can be unreliable, as the test cannot adjust for daily fluctuation of body hydration. This leads to protein measurements that are either too low or too high due to the level of urine dilution. More accurate tests, such as the 24-hour urine test, are available only for confirmatory testing in tertiary-level clinics due to their high cost and technical complexity. The purpose of the study is to generate a body of evidence that will determine performance characteristics of the current Protein Creatinine dipstick test and the feasibility of its use in target Ante Natal Care settings.

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
104	MAL 073	Phase IIIb	Malaria	1.RTS,S/AS01E 2.MR-VAC™ 3.STAMARIL4. VITAMIN A /Vaccine	11th December 2015	1.Prof. Tsiri Agbenyega Prof. Seth Owusu Adjei	1.Malaria Research Center, Agogo 2.Kintampo Health Research Centre Hospital	GlaxoSmithKline Pharmaceuticals	Study Ended Final Report submitted 43 months 16 days	In sub-Saharan Africa, most of the Expanded Program on Immunization (EPI) vaccines are given in early infancy while measles, rubella and yellow fever (YF) vaccines are given at 9 months of age. Between the first EPI vaccines and the measles, rubella and YF vaccines, children receive Vitamin A supplementation at 6 months of age. To limit the number of clinic visits for young children and to optimize vaccine implementation a schedule (0, 1.5, 3-month) is proposed. There are however no data of the anti-circumsporozoite protein of Plasmodium falciparum (anti-CS) immune response induced by RTS,S/AS01E when given in co-administration with measles, rubella and YF, in a 0, 1.5, 3-month schedule starting at an older age (5-17 months). This study intends to demonstrate that anti-CS immune response of the candidate malaria vaccine RTS,S/AS01E is not inferior when RTS,S/AS01E is administered at 6, 7.5 and 9 months of age with the third dose given alone or in co-administration with a YF vaccine and a combined measles and rubella vaccine Safety has not been evaluated in co-administration with measles, rubella and YF in a 0, 1.5, 3-month schedule starting at 6 months of age. This study will therefore provide safety information when RTS,S/AS01E is administered at 6, 7.5 and 9 months of age alone or in co-administration with YF vaccine and a combined measles and rubella vaccine
105	CEPHEID XPRT HIV-1	PILOT	HIV	Xpert HIV-1 VL XC Test Assay for detecting HIV-1 RNA in human plasma.	6th June 2019	Prof. Jacob Plange-Rhule	Atua Government Hospital Akosombo Hospital	CEPHEID	Study Ended Final Report yet to be submitted 6 Months	The Xpert® HIV-1 Viral Load XC test is an in vitro reverse transcriptase polymerase chain reaction (RT-PCR) assay for the quantification of Human Immunodeficiency Virus type 1 (HIV-1) RNA in human plasma using the automated GeneXpert® Instrument Systems. It is intended for use as an aid in the diagnosis of HIV-1 infection, as a confirmation of HIV-1 infection, and as an aid in clinical management of patients infected with HIV-1.
106	INNOVATE	Phase III/II	Covid-19	1. InnO-4800 2. Placebo/Vaccine		Susan Adu-Amankwah	Noguchi Memorial Institute for Medical Research	Inovio Pharmaceuticals, Inc	Study Closed/withdrawn by Sponsor 24 months	1. Evaluate the cellular and humoral immune response to INO-4800 administered by ID injection followed immediately by electroporation EP 2. Evaluate the efficacy of INO-4800 in the prevention of COVID-19 disease in subjects who are SARS-CoV-2 negative at baseline
107	LIVZON	Phase III	Covid-19	1.SARS-CoV-2 fusion protein vaccine (code: V-0) 2. Placebo/Vaccine	2nd August 2021	1.Dr Seyram Kaali 2.Dr. Nana Akosua Ansah	1.Kintampo Health Research Centre 2.Navrongo Health Research Centre	Livzon Mabpharm Inc. Institution Pharmaceutical company	Study Closed by Sponsor before commencement. No recruitment was done. 20 months	Efficacy: To evaluate the efficacy of the recombinant SARS-CoV-2 fusion protein vaccine (V-01) for the prevention of symptomatic RT PCR positive COVID-19 (mild or above severity) starting from at least 14 days (≥15 days) after full-course immunization (completing all vaccinations) Safety: To evaluate the incidence of adverse events (AEs) of recombinant SARS-CoV-2 fusion protein vaccine (V-01) from the first vaccination to 28 days after full-course immunization
108	COVID 19 INTRANASAL SPRAY	Phase III	Covid-19	1.Influenza Virus Vector COVID-19 Vaccine for Intranasal Spray 2. Placebo/Vaccine	19th October 2021	Dr. Seyram Kaali	1. KHRC 2. NHRC 3. KCCR 4. Dodowa Health Research Center 5. Ghana Infectious Disease Center 6. KBTH	Beijing Wantai Biological Pharmacy Enterprise Co, Ltd	Study Closed by Sponsor before commencement. No recruitment was done. 20 months	1. To evaluate the protective efficacy of DelNS1-2019-nCoV-RBD-OPT1 for preventing virologically confirmed (RT-PCR positive) symptomatic COVID-19. 2. To evaluate the safety of DelINS1-2019-nCoV-RBD OPT1.
109	STEADFAST	Phase II	Sickle Cell Disease	CRIZANLIZUMAB / Monoclonal antibody	15th February, 2021	Dr. Yvonne Dei Adomako	*Ghana Institute of Clinical Genetics Korlebu *Sickle cell office Directorate Child(KATH)	Novartis Pharma	Study closed by sponsor before commenced 21 Months	The purpose of this study is to explore the effect of P-selectin inhibition with crizanlizumab on renal function in SCD patients with CKD who are receiving standard of care for SCD-related CKD, have Grade A2-A3 albuminuria and Stage 1-3a CKD, and are at risk for rapid decline in their eGFR.
110	ESM UBT *		Postpartum Hemorrhage	Uterine balloon tamponade/Medical device	17th February, 2014	Dr. Ivy Frances Osei	Field Work	Bill and Melinda Gates Foundation, USA	Study not conducted; Funds from Sponsor withdrawn before initiation 8months	

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
111	FERROQUINE	II	Malaria	1. Ferroquine 2. Amodiaquine 3. Artesunate/Allopathic	4th January 2008	Dr. Josephine C. Ocran Prof. Kwadwo Ansah Koram	Noguchi Memorial Institute of Medical Research	Sanofi-Aventis Recherche And Development	Study Closed by Sponsor. No recruitment was done. 13Months	
112	HOPE SCD	III	Sickle Cell Disease	GBT440 300mg /Allopathic	May-17	1. Dr. Yvonne Dei Adomakoh 2. Dr. Vivian Paintsil	1.Center for Clinical Genetics, Korle-Bu Teaching Hospital 2. Paediatric Sickle cell clinic, Komfo Anokye Teaching Hospital	Global Blood Therapeutics Inc. 400 East Jamie Court, Suite 101 South San Francisco, CA 94080, USA	Group 1 and 2 under current protocol completed (none recruited in Ghana); yet to start Main Population Study (Group 3) 17 months	The primary objective is to assess the efficacy of GBT440 in adolescents and adults with SCD as measured by improvement in anemia
113	ABDOV COVID-19 TRIAL	Phase III	Covid-19	SCTV01E (A COVID-19 Alpha/Beta/Delta/Omicron Variants S-Trimer Vaccine)/Vaccine	17th June 2022	1. Dr. Alberta Amu 2. Dr. Patrick Ansah 3. Dr. John Amuasi 4. Dr Kwaku Poku Asante	1. Dodowa Health Research Centre 2. Navrongo Health Research Centre 3. Kumasi Center for Collaborative Research (KCCR) 4. Kintampo Health Research Centre	Sinocelltech Ltd..	Application Withdrawn, 19 Months	<ul style="list-style-type: none"> <input type="checkbox"/> To evaluate the protective efficacy of SCTV01E against symptomatic COVID-19 occurring from 14 days after the 2nd dose in population previously unvaccinated with COVID-19 vaccine. <input type="checkbox"/> To evaluate the protective efficacy of SCTV01E against moderate and above COVID-19, severe and above COVID-19, hospitalization due to COVID-19, and death due to COVID-19 occurring from 14 days. <input type="checkbox"/> To evaluate the protective efficacy of stage 1 immunization against different SARS-CoV-2 variants. <input type="checkbox"/> To evaluate the safety of SCTV01E in stage 1. Stage 2 immunization <ul style="list-style-type: none"> <input type="checkbox"/> To evaluate the protective efficacy of SCTV01E against symptomatic COVID-19 occurring from 7 days after the 3rd dose in population previously unvaccinated
114	VERO CELL COVID 19 TRIAL	Phase III	Covid-19	Inactivated (Vero Cell)/Vaccine	10th February 2022	1. Dr Alberta Amu Dr. Patrick Ansah	1. Dodowa Health Research Center 2. Navrongo Health Research Center	Institute of Medical Biology Chinese Academy of	Application Withdrawn, 18 Months	1.To evaluate the efficacy of SARS-CoV-2 Vaccine, inactivated (Vero Cell) against symptomatic and laboratory-confirmed (RT PCR method) COVID-19 cases 2. To evaluate the solicited AEs within 7 days after each dose. 3. To evaluate the efficacy of SARS-CoV-2 Vaccine, inactivated (Vero Cell) after
115	MEBENDAZOLE	IV	Hookworm infection	Menbendazole/Allopathic	9th January 2017	Prof Michael David Wilson	Kintampo Health Research Centre	Program For Appropriate Technology In Health (PATH)	Application Withdrawn N/A	Soil-transmitted helminth (STH) infections are considered among the most pressing of global health problems, thought to parasitize some 2 billion people worldwide.[] The most recent estimates suggest that between 600 and 800 million people are infected with one or several of the common soil-transmitted helminths (STHs), which are Ascaris lumbricoides, Trichuris trichiura, and hookworm.[] Infection prevalence, incidence, and disease burden are particularly high in tropical and subtropical areas that are already burdened with poor living conditions, over-population, and inadequate sanitation, including some areas of sub-Saharan Africa, Asia, and Latin America.[1,] While adults represent a significant percentage of the infected population, it is children who are the most vulnerable

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
116	EBOLA Z	II	Ebola	chimpanzee adenovirus Type 3 – vectored Ebola Zaire vaccine (ChAd3-EBO-Z)/Vaccine	Jan-15	1.Dr. Kwaku Poku Asante 2.Prof. Kwadwo A Koram	1.Kintampo Health Research Centre 2.OCRC, Hohoe	GlaxoSmithKline Biologicals	Application withdrawn N/A	
117	EBOLA Z (Paediatric)	II	Ebola	chimpanzee adenovirus Type 3 – vectored Ebola Zaire vaccine (ChAd3-EBO-Z)/Vaccine	21st August 2015	Dr. Kwaku Poku Asante	OCRC, Hohoe	Glaxosmithkline Biologicals, Rue De L'institut, 89 – 1330 Rixensart, Belgium	Application withdrawn N/A	
118	ZEBOV	I	Ebola	1.Ad26 Vector expressing the glycoprotein of the ebola virus mayinga variant [Ad26.ZEBOV 2.Modified vaccinia ankara – bavarian nordic vector expressing the glycoproteins of ebola virus, sudan virus and marburg virus and the nucleoprotein of tai forest virus [MVA-BN-Filo]/Vaccine	7th January 2015	Professor Fred Binka	OCRC, Hohoe	Crucell Holland B.V, Represented by Janssen Pharmaceutica (Pty) Ltd	Approved but sponsor withdrew conduct N/A	
119	ZEBOV 2	II	Ebola	1.Ad26 Vector expressing the glycoprotein of the ebola virus mayinga variant [Ad26.ZEBOV 2.Modified vaccinia ankara – bavarian nordic vector expressing the glycoproteins of ebola virus, sudan virus and marburg virus and the nucleoprotein of tai forest virus [MVA-BN-Filo]/Vaccine	6th April 2015	Professor Fred Binka	OCRC, Hohoe	Crucell Holland B.V, Represented by Janssen Pharmaceutica (Pty) Ltd	Application withdrawn N/A	
120	HYDRANON	I		Hydranon solution	1st March 2008	Prof. David Ofori-Adjei	Noguchi Memorial Institute For Medical Research	General Resonance Technology 11c	Application Withdrawn N/A	
121	SALIF,	IIIb	HIV	1.TDF/FTC/RPV 2.TDF/FTC/EFV/Vaccine	4th September 2013	1. Dr. Isaac Osei 2. Dr. Samuel Abora 3. Dr. Fred Adomako –	Navrongo Health Research Centre Upper East Regional Hospital	Janssen-Cilag International NV (Sponsor) represented by Cinical	Application Withdrawn N/A	

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
122	NOGUCHI SCD	Ib	Sickle Cell Disease	NVX-508/ Allopathic	1st May 2017	Amma Twumwaa Owusu Ansah	1. Noguchi Memorial Institute For Medical Research 2. College of Health Sciences 3. University of Ghana	University of Pittsburgh, Representative: Amma Owusu-Ansah, MD	Application Withdrawn N/A	
123	PRCR SPOT	Phase II	Preeclampsia	PRCR Spot/Medical device	15th March 2021	Dr. Hannah Brown Amoakoh	Ridge Hospital, Korlebu Teaching Hospital, Koforidua Regional Hospital	Emily Stephanie Zobrist, PATH, 2201 Westlake Avenue, Seattle, WA 98121, USA	Application Withdrawn by Sponsor	To address the gap in proteinuria measurement solutions, LifeAssay Diagnostics (LAD) has developed and commercialized a low-cost PrCr urine dipstick that has shown good laboratory and clinical performance and high usability within antenatal care (ANC) settings in previous studies. There is a need for further evidence on the clinical utility and operational fit of the LAD Test-it™ PrCr test to inform policy recommendation for its use in Ghana and other LMIC settings.
124	SAR97276A_SANOFI	II	Malaria	SAR97276A/Allopathic	1st October, 2008	Prof. Seth Owusu-Agyei	Navrongo Health Research Centre	Sanofi Aventis Recherche & Developpement	Application Withdrawn by Sponsor before approval	
125	TENOFOVEK BE I	Bioequivalence		1. tenofovir (tenofovir) 300mg film coated tablets 2. Viread (tenofovir)	11th September 2015	1. Prof. Seth Owusu Agyei 2. Dr. Kwaku Poku Asante	Kintampo Health Research Centre	Danadams Pharmaceuticals Industry Limited, Accra-Ghana	Application closed by FDA since Sponsor failed to start study 3 years after approval.	
126	ELDON CARD NYN	Feasibility study	Testing of Maternal and Newborn Blood Group	1. Eldon card 2. Standard laboratory method/Medical device	10th November 2015	Prof. Samuel Ameny Obed	Korle Bu Teaching Hospital, Accra.	Center for Global Child Health, Hospital for sick Children.	Incomplete CTA; Application closed by FDA. N/A	
127	AX-100 HIVI		HIV	1. AX-100 Immun 2. AX-100 ImmunPlus	9th december 2014	Dr. Kwaku Poku Asante	Kintampo Health Research Centre	Neopharmacie Limited, Germany	Incomplete CTA; Application closed by FDA. N/A	
128	4P	III	Pregnancy Induced Hypertension and Preeclampsia	Polypill/Allopathic	9th August 2013	1. Dr. Emmanuel Kwabla Srofenyah 2. Dr. Patrick Frimpong	Ridge Hospital Accra La General Hospital	Julius Centre for Health Sciences and Primary Care, University Medical Centre Utrecht, The Netherlands	Incomplete CTA; Application closed by FDA. N/A	
129	INVACT	III	Malaria	Artemisinin/ Allopathic	13th may 2016	Prof. Kwadwo Ansah Koram	Noguchi Memorial Institute For Medical Research	Global Emerging Infections Surveillance and Response System of the US Armed Forces Health Surveillance Center	Incomplete CTA; Application closed by FDA. N/A	

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	,DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
130	INSUGENIV	Phase IV	Diabetes	Insugen/Hormone	17th december 2013	N/A	Korle-Bu Teaching Hospital	BIOCON LTD	Incomplete CTA; Application closed by FDA. N/A	
131	AIM-LVRNA009	Phase II/III	Covid-19	1. SARS-CoV-2 mRNA vaccine (LVR) 2. Saline Placebo/Vaccine	21st June 2022	Dr. Patrick Odum Ansah	1. Navrongo Health Research Centre 2. Kumasi Centre for Collaborative Research 3. Dodowa Health Research Centre 4. Kintampo Health Research Centre 5. Ghana Infectious Disease Centre 6. Korle Bu Teaching Hospital (KBTH)	AIM Vaccine Co. Ltd.	Not Approved, 17-24 months.	Primary efficacy objective: To evaluate the protective efficacy of LVRNA009 (50 µg) in the prevention of first episodes of virologically-confirmed symptomatic cases of COVID-19 of any severity occurring from 14 days after 2nd dose in the initial set of vaccination in SARS-CoV-2 naive participants
132	MYCOPIROX_LA GRAY	Phase IV	mixed Infection Vaginitis in Females	Mycopirox Vaginal cream	15th June 2010	Dr. Luitgard Darko		Lagray Chemical Company, Ltd.	Not Approved N/A	
133	GBT-2104-132	Phase III	Sickle Cell Disease	1. Inclacumab 2. Placebo/ Monoclonal antibody	5th July, 2021	Professor Alex Osei-Akoto	Komfo Anokye Teaching Hospital (KATH)	Global Blood Therapeutics, Inc.	Study terminated by sponsor 2 years	The primary objective of this study is to evaluate the safety and efficacy of a single dose of inclacumab compared to placebo to reduce the incidence of re admission to a healthcare facility for a vaso-occlusive crisis (VOC) after an admission for an index VOC in participants with sickle cell disease (SCD). Additional objectives of the study are to evaluate the pharmacokinetics (PK) and pharmacodynamics (PD) of inclacumab, the presence of anti-drug antibodies (ADAs), and changes in quality of life (QOL).
134	GBT 2104-131	Phase III	Sickle Cell Disease	1. Inclacumab 2. Placebo/ Monoclonal antibody	5th July, 2021	Professor Alex Osei-Akoto	Komfo Anokye Teaching Hospital (KATH)	Global Blood Therapeutics, Inc.	Study terminated by sponsor 2 years	The primary objective of this study is to evaluate the safety and efficacy of treatment every 12 weeks with inclacumab to reduce the incidence of VOCs in participants with SCD. Additional objectives of the study are to evaluate the pharmacokinetics (PK) and pharmacodynamics (PD) of inclacumab, the presence of anti-drug antibodies (ADAs), and changes in quality of life (QOL).
135	COVID 19 CHO-CELL(TERMINATED)	Phase II/III	Covid-19	1. Recombinant two-component COVID-19 vaccine (CHO cell) 2. ReCOV Placebo/Vaccine	16th November 2021	Dr. Patrick Ansah	1. Dodowa Health Research Centre 2. Navrongo Health Research Centre.	Jiangsu Recbio Technology Co., Ltd.	Study terminated by sponsor 13 months	1. To evaluate the safety and reactogenicity of the recombinant two-component COVID-19 vaccine (CHO cell) (ReCOV for short) in adults aged 18 years and older. 2. To evaluate SARS-CoV-2 neutralizing antibody of ReCOV on Day 14 after 2 doses vaccination in adults aged 18 years and older. 3. To evaluate the efficacy of ReCOV in preventing RT-PCR confirmed symptomatic COVID-19 in adults aged 18 years and older. 4. To evaluate the safety and reactogenicity of ReCOV in adults aged 18 years and older.
136	MoRiOn	Phase II	Onchocerciasis	1. Rifampentine (Priftin®) 2. Moxifloxacin (Avelox®) 3. Doxycycline/Vaccine	28th April, 2017	Prof. Alexander Yaw Debrah	1. Enchi Government Hospital 2. Communities of Aowin/Suaman District W/R	Kumasi Centre for Collaborative Research in Tropical Medicine	Study terminated by sponsor Yet to submit Final report 15 months	Onchocerciasis is caused by the parasite Onchocerca volvulus. More than 37 million people are estimated to be infected with O. Volvulus worldwide. The current therapeutic strategy relies on annual mass drug administration (MDA) based on the drug donation program for Ivermectin. Ivermectin is mainly microfilaricidal and after a few months female worms resume MF production levels high enough for transmission. Therefore, safe microfilaricidal drugs are needed to reach the goal of elimination. The study aims to show efficacy (Wolbachia depletion) of combination Rifampentine plus Moxifloxacin using immunohistology compared to no treatment and treatment with Doxycycline.

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
137	COVID MOUTHWASH	Phase III	Covid-19	1.Corsodyl Mouthwash 2.Wokadine mouthwash 3.Hydrogen Peroxide mouthwas	6th September 2021	Dr. George Boateng Kyei	Noguchi Memorial Institute for Medical Research	Dr. George Boateng Kyei	Study terminated by sponsor Yet to submit Final report 1 year 6 months	To investigate how long it takes for SARS-CoV-2 asymptomatic or presymptomatic persons to shed viable virus. It also seeks to evaluate among these patients the effect of a one-time mouth rinse on the detectable viral load of SARS-CoV-2 and to determine how long it takes for SARS-CoV-2 viral load to remain low after using the mouth rinse.
138	IMR SCD	Phase IIb	Sickle Cell Disease	1.IMR-687 2.IMR-687 Placebo/Allopathic	13th August 2020	Dr. Seyram Kaali	*Korle-Bu Teaching Hospital *Kintampo Health Research Centre	IMARA Inc.	Early termination by Sponsor 1 Year 7 Months	study of subjects aged 18 to 65 years with SCD (HbSS, HbSB0 thalassemia, or HbSB+ thalassemia) to evaluate the safety and efficacy of the PDE9 inhibitor, IMR-687, administered qd for 52 weeks. This study will provide data on IMR-687 doses of ≥ 3.0 to ≤ 4.5 mg/kg and >4.5 to ≤ 6.7 mg/kg. In a relevant model of anemia (Hbth1/th1 mice), oral administration of IMR-687 for 30 days at 30 mg/kg/day (human equivalent dose of 2.4 mg/kg/day) or 60 mg/kg/day (human equivalent dose of 4.9 mg/kg/day) increased RBCs and Hb, and reduced reticulocytes. The degree of these changes was dose dependent, with statistically significant improvement at the higher dose of 60 mg/kg. In addition, IMR-687 at
139	HESTIA4	Phase I	Sickle Cell Disease	Ticagrelor/ Allopathic	16th May, 2018	1. Dr. Patrick Ansah 2. Dr. Catherine Segbefia 3. Dr. Kokou Hefoume Amegan-Aho	1. Navrongo Health Research Centre 2. Korle-Bu Teaching Hospital 3. Volta Regional Hospital	AstraZeneca AB	Study termination 31 Months	Complications of sickle cell disease (SCD) occur very early in life. Painful crises first appear in the fingers and toes (dactylitis) in very young children prior to their first birthday. In addition to painful crises occurring in the very young, SCD can affect organ function early in life. Loss of splenic function begins as early as 5 months of age with associated increase in infection risk. Stroke risk begins at age 2. Given the early onset of symptoms and complications of this disorder, therapies for SCD should be targeted at children, including the very young. There is a need to first establish the pharmacokinetics (PK) of ticagrelor in this age group to allow for modelling or extrapolation in this population. This goal of the study is to evaluate PK data in the 0-2 year old population in order to way for further studies and ultimately use of ticagrelor in this youngest population.
140	TADO	III	Sickle Cell Disease in Pediatrics	Prasugrel/Allopathic	20th may 2013	Prof. Tsiri Agbenyega Dr. Catherine Idara Segbefia	Center, Agogo Korle-Bu Teaching Hospital, Accra – Korle Bu	Eli Lilly and Company Indianapolis	Prematurely terminated 24 months	
141	WOMAN	III	Postpartum Hemorrhage	Tranexamic acid(cyklokaprone injection)/ Allopathic	10th sept 2009	1. Dr. Anthony K. Dah 2. Dr. Opere Addo Henry Sakyi 3. Dr. Kwadwo Asamoah Nyarko-Jectey	1. Ashanti Mampong Municipal Hospital 2.Komfo Anokye Teaching Hospital	Clinical Trials Unit, London School of Hygiene and Tropical	Terminated by Sponsor Prematurely ended.	
142	NEOVITA	III		Vitamin A		Dr. Sam Newton	Kintampo Health Research Centre	PATH	Premature Termination 36 Months	
143	CALLASCOPE *	ii	Cervical cancer	Pocket Colposcope (CALLASCOPE)/ Medical device	12th February 2019	Dr. Emmanuel Srofenyoh	Ridge Hospital, Korle-Bu Teaching Hospital	Duke Global Health Institute	Study ended, FDA DISSOCIATED itself from any data or findings from the study due to violation of its guidelines for conducting clinical trials. 3 months	

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
144	HOHOE ANTIMALARIAL	III	Malaria	1.Dihydroartemisinin 2.Piperaquine oral tablets 3.Artesunate 4. Sulfamethoxyypyrazine. 5. Pyrimethamine oral tablets/Allopathic		Dr. Margaret Kweku	Hohoe Health Research Centre Onchocerciasis Chemotherapy Research Centre, Hohoe Municipal Hospital, Ghana, Ghana Health Service	Malaria Capacity Development Consortium (MCDC)	FDA DISSOCIATED itself from any data or findings from the study due to violation of its guidelines for conducting clinical trials. 7 months	
145	YAWS	III	Yaws	1.Azithromycin 2.Injection Benzathine Penicillin/Allopathic		Dr. Cynthia Kwakye-Maclean	Ga West District	1. University of Ghana School of Public Health 2. World Health Organization 3. Ghana Health Service, Ga West District	Not Approved. FDA DISSOCIATES itself from any data or findings from the study due to violation of its guidelines for conducting clinical trials. N/A	
146	GMZ 2II / III	II	Malaria	GMZ2 candidate malaria vaccine/ Vaccine	19th august 2010	Dr. Frank Atuguba	Navrongo Health Research Centre, Navrongo.	Statens Serum Institute	FDA DISSOCIATED itself from any data or findings 27 onths	
147	CEREBETA		Cholesterol concentration	Barley beta glucan/ Food supplement	13th may 2016	Mrs. Rose T. Odotei Adjei	Suntreso Government hospital	Best Environmental Technologies	FDA DISSOCIATED itself from any data Findings N/A	
148	AQUAMAT	III	Malaria	1. Artesunate 2. Quinine/Allopathic	10th october 2012	Prof. Tsiri Agbenyega	Komfo Anokye Teaching Hospital	WORLD HEALTH ORGANIZATION	FDA DISSOCIATED itself from any data Findings	
149	AZI4YAWS	III	Yaws	Azythromycin/ Allopathic	23rd April 2015	Prof. Adu Sarkodie	1. Ayensuanor District 2. West Akyem Municipality 3. Upper West Akyem District 4. Nkwanta North District	World Health Organization, Geneva - Switzerland	FDA DISSOCIATED itself from any data or findings from the study due to violation of its guidelines for conducting clinical trials. 12 months	
150										
SHORT AND DETAILED NAMES OF TRIALS										
1	4P	A strategy to reduce complications of Hypertensive disorders in Pregnancy and Maternal Mortality by 50% or more. - Polypill for the Prevention of Pregnancy Induced Hypertension and Preeclampsia (4P) Trial								

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
2	ABDOV COVID 19 TRIAL									A randomized, double-blind, positive-controlled Phase III clinical trial to evaluate the efficacy and safety of SCTV01E (A COVID-19 Alpha/Beta/Delta/Omicron Variants S Trimer Vaccine) in population previously unvaccinated with COVID-19 vaccine and aged ≥18 years
3	ACTIVE TRIALS									A Phase 3, multicenter, randomized, double-blind, 24-week study of the clinical and antiviral effect of S-217622 compared with placebo in non-hospitalized participants with COVID-19
4	AIM-LVRNA009									A Global Multi-center, Randomized, Blinded, Placebo-controlled Phase 2/3 Clinical Study to Evaluate the Efficacy, Safety and Immunogenicity of SARS-CoV-2 mRNA Vaccine (LVRNA009) for the Prevention of COVID-19 in Participants Aged 18 Years and Older
5	AIMS									African Investigation Of Mirasol System For Whole Blood. Clinical And Biological Efficacy Of Mirasol Treated Fresh Whole Blood For The Prevention Of Transfusion Transmitted Malaria
6	ALB_IVM									Comparison of Ivermectin alone with Albendazole (ALB) plus Ivermectin (IVM) in their efficacy against Onchocerciasis in the Volta Region, Ghana.
7	ALBIVM K'SI									Comparison of Ivermectin Alone with Albendazole plus Ivermectin in Their Efficacy against Onchocerciasis
8	AMARYL M									Clinical Efficacy and Safety of Amaryl M in Patients with Type 2 Diabetes who are inadequately treated by either Glimepride or Metformin Monotherapy or who are already treated With Free Combination Of Glimepride and Metformin in African Countries.
9	ANTICOV									An Open-Label, Multicenter, Randomized, Adaptive Platform Trial of the Safety and Efficacy of Several Therapies, including Antiviral Therapies, Versus Control in Mild Cases of COVID-19
10	ANTIPSYCHOTI C STUDY									A RANDOMIZED CONTROLLED TRIAL OF OMEGA-3 FATTY ACIDS IN THE TREATMENT OF ANTIPSYCHOTIC-INDUCED MOVEMENT DISORDERS IN GHANA
11	AQUAMAT									An Open Randomized Comparism of Artesunate versus Quinine in the Treatment of Severe Falciparum Malaria in African Children.
12	ARTIMIST									A Phase III, Randomized, Open Labelled, Active Controlled, Multicentre, Superiority Trial Of Artimisttm Versus Intravenous Quinine In Children With Severe Or Complicated Falciparum Malaria, Or Uncomplicated Falciparum Malaria With Gastrointestinal Complications
13	ASAAP									A Multicentre Phase III Non-Inferiority Trial to Evaluate Safety, Tolerability and Efficacy of Artemether- Lumefantrine+Atovaquone-Proguanil Tri-TherapyVersus Artemether Lumefantrine Bi-Therapy for The Treatment of Uncomplicated Malaria in African Children Aged 6 To 59 Months (ASAAP PROJECT -STUDY II)
14	ASTAWOL									The efficacy of Rifampicin 35mg/Kg/d plus Albendazole 400mg/d given for 7 or 14 days against Lymphatic Filariasis and Onchocerciasis- a randomized, controlled, parallel-group, open-label, phase II pilot trial
15	ATEA COVID 19									A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Bemnifosbuvir in High-Risk Outpatients with COVID-19
16	AVAREF									A Phase 3 double-blind, randomized, active comparator-controlled, group-sequential, multinational trial to assess the safety, immunogenicity and efficacy of a trivalent rotavirus P2-VP8 subunit vaccine in prevention of severe rotavirus gastroenteritis in healthy infants.
17	AX-100 HIV									A Double Blind Randomized Control Trial of AX-100 Immun (Liquid) and AX-100 Immun Plus Combination Among Adults Living with HIV In Ghana.
18	AZI4YAWS									Randomized Controlled Trial Comparing Efficacy of a Single Dose of Treatment of Yaws with 20mg/kg versus 30mg/kg of Azithromycin.
19	PLUS CHLOROQUINE									Azithromycin Plus Chloroquine Phosphate versus Artemether-Lumefantrine for the Treatment of Uncomplicated Plasmodium falciparum Malaria in Children in Africa.
20	BEMPU									Hypothermia Prevention in low birth weight and preterm Infants
21	BLMS4BU									SHORTENING BURULI ULCER TREATMENT: WHO RECOMMENDED VS. A NOVEL BETA-LACTAM-CONTAINING THERAPY – PHASE III EVALUATION INWEST AFRICA
22	BURULINOX									Evaluation of nitric oxide generating dressing (EDX) to improve management of buruli ulcer disease – a prospective randomized open-blinded end point.
23	BURULIRIFDACC									A randomized controlled trial to evaluate the effect of High Dose of Rifampicin and Dialkylcarbamoyl chloride (DACC)-coated dressings on outcomes in Mycobacterium ulcerans disease

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
24	CDA		A Multicenter, Randomized, Double Blind Study to Compare the Efficacy and Safety of CDA Versus Artemether-Lumefantrine in the Treatment of Acute Uncomplicated P. Falciparum Malaria in Children and Adults in Africa.							
25	CDA2		A Multicenter, Randomized, Double Blind Study to Compare the Efficacy and Safety of CDA Versus Chlorproguanil-Dapsone in the Treatment of Acute Uncomplicated P. Falciparum Malaria in Children and Adults in Africa.							
26	CEREBETA		Efficacy of Beta-Glucans from Barley and Maintenance of Normal Blood LDL-Cholesterol Concentrations: A Randomized Control Study in Ghana.							
27	CPAP		Clinical Trial Evaluating the Difference in Mortality Rates in Children in Ghana Receiving Continuous Positive Airway Pressure (CPAP) Versus Those Who Do Not.							
28	CRASH-2		A Large Randomized Placebo Controlled Trial, among trauma patients with or at risk of significant Haemorrhage, of the Effects of Anti- Fibrinolytic treatment on Death and Transfusion requirement							
29	CALLASCOPE		Clinical Studies and in-Depth Interviews for Portable, low-cost and Speculum-Free Cervical Cancer Screening in Ghana							
30	CECOLIN		Phase 3 Randomized, Active-Comparator Controlled, Open-Label Trial to Evaluate the Immunogenicity and Safety of Alternate Two-Dose Regimens of a Bivalent Human Papillomavirus (HPV) Vaccine (Cecolin®) Compared to a Licensed Quadrivalent HPV Vaccine (Gardasil®) in Healthy 9-14 Year-Old Girls in Low and Low-Middle Income Countries							
31	CEPHEIDXPERT HIV-1		An Investigation to Evaluate the Performance of the Cepheid XpertR HIV-1 VL XC Test							
32	CIELO		A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter Basket Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Satralizumab in Patients with Anti-N-Methyl-D-Aspartic Acid Receptor (NMDAR) or Anti-Leucine-Rich Glioma-Inactivated 1 (LGI1) Encephalitis							
33	COPE TRIAL		Effectiveness and Acceptability of two models of an Insertable Vaginal Cup for Non-surgical management of obstetric fistula in Ghana: a hybrid type 1 randomized crossover trial							
34	COVID ABDOV		A randomized, double-blind, positive-controlled Phase III clinical trial to evaluate the efficacy and safety of SCTV01E (A COVID-19 Alpha/Beta/Delta/Omicron Variants S Trimer Vaccine) in population previously unvaccinated with COVID-19 vaccine and aged ≥18 years* (COVID ABDOV).							
35	CROWN CORONATION		An international, Bayesian platform adaptive, randomized, placebo-controlled trial assessing the effectiveness of candidate interventions in preventing COVID-19 disease in healthcare workers							
36	CHEETAH		Cluster Randomized Trial of Sterile Glove and Instrument Change at the Time of Wound Closure to Reduce Site Infection: A Trial In Low- And Middle-Income Countries (LMICs)							
37	COVID 19 CHO-CELL		A multicenter, randomized, double-blind, placebo-controlled Phase II/III trial to evaluate the efficacy, safety and immunogenicity of the recombinant two-component COVID-19 vaccine (CHO cell) in adults aged 18 years and older							
38	COVID 19 INTRANASAL SPRAY		A Global, Multi-center, Randomized, Double-blind, Placebo-controlled Phase III Clinical Trial to Evaluate the Protective Efficacy and Safety of Influenza Virus Vector COVID-19 Vaccine for Intranasal Spray (DeINS1-2019-nCoV-RBD-OPT1) in Adults Aged 18 Years and Older							
39	COVID 19 MOUTHWASH		Viral Shedding Dynamics and the Effect of Antimicrobial Mouthwashes on the Detection of SARS-CoV-2 in Ghana.							
40	DIABETIC FOOT CARE		Family-oriented Diabetic Foot Self-care Programme in Ghana; A Feasibility Randomised Controlled Trial with nested qualitative interviews at the Komfo Anokye Teaching Hospital.							
41	DOLF_IDA		Safety and Efficacy of Combination Therapy with Ivermectin, Diethylcarbamazine and Albendazole (IDA) for Individuals with Onchocerciasis							
42	EBA		Double-Blinded, Placebo-Controlled Dosage-Escalation Study and Immunogenicity of EBA-175 RII-NG Malaria Vaccine Administered Intramuscularly in Semi Immune Adults							
43	EBOLA Z		A Phase 2, Randomized, Observer-Blind, Placebo-Controlled, Multi-Country Study to Assess the Safety and Immunogenicity of a Single Intramuscular Dose of GSK Biologicals' Investigational Recombinant Chimpanzee Adenovirus Type 3 – Vectored Ebola Zaire Vaccine. (ChAd3-EBO-Z) (GSK3390107A), in Adults 18 years of age and older in Africa							
44	EBOLA Z (PAEDIATRIC)		A Phase 2, Randomized, Observer-Blind, Placebo-Controlled, Multi-Country Study to Assess the Safety and Immunogenicity of a Single Intramuscular Dose of GSK Biologicals' Investigational Recombinant Chimpanzee Adenovirus Type 3 – Vectored Ebola Zaire Vaccine. (ChAd3-EBO-Z) (GSK3390107A), in children 1 to 17years of age in Africa							
45	EBSI-LSV		A Phase 1 Randomized, Blinded, Placebo Controlled, Dose-Escalation and Dosing Regimen Selection Study to Evaluate the Safety and Immunogenicity of rVSV-Vectored Lassa Virus Vaccine in Healthy Adults at Multiple Sites in West Africa							
46	ELDON CARD		Using Eldon Card for Testing of Maternal and Newborn Blood Group in Comparison with the Standard Laboratory Method of Blood Group Testing in Accra, Ghana							
47	EMODEPSIDE		A phase II, Randomised, double-blind, parallel – group trial to investigate Emodepside (BAY 44-4400) in subjects with onchocerca volvulus infection.							
48	ESM UBT		A Multi-Centre Prospective Trial on the Impact of the Introduction of Condom-Based Uterine Balloon Tamponade for Uncontrolled Postpartum Hemorrhage							
49	FALCON		Pragmatic Multicentre Factorial Randomized Controlled Trial Testing Measures to Reduce Surgical Site Infection in Low and Middle Income Countries							
50	FERROQUINE		Randomized Multicentre Study Evaluating the Safety and Activity of Ferroquine Associated with Artesunate versus a Positive Calibrator (Amodiaquine Associated with Artesunate) In African Adult Patients with Uncomplicated Malaria							
51	BULLON CUBES STUDY		Effect of household use of multiple micronutrient-fortified bouillon on micronutrient status among women and children in two districts in the Northern region of Ghana							
52	GARDASIL		Evaluation of Safety And Immunogenicity Of Gardasilm In Healthy Females Between 9 And 26 Years Of Age In Subsaharan Africa							

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
75	KAE609	A Phase 2, Multi-Center, Randomized, Open - Label, Dose Escalation Study To Determine Safety Of single (QD) and Multiple (3QD) Doses Of KAE609, Given To Adults With Uncomplicated Plasmodium Falciparum Malaria								
76	KNC 19(NIBIMA)	Repurposing the aqueous Extract of Cryptolepis for Covid-19 therapy								
77	LEDOxy	Doxycycline 200mg/d vs. 100mg/d for 6 weeks to improve filarial lymphedema - a multinational, double-blind, randomized, placebo-controlled trial.								
78	LETICIA	Combination Food-Based And Supplemental Iron Replacement Therapy For Children With Moderate-To-Severe Anemia In A Rural Ghanaian Setting:A Proof-Of-Concept Study								
79	LIVZON	A Global, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Phase III Clinical Study to Evaluate the Efficacy, Safety, and Immunogenicity of Recombinant SARS-CoV-2 Fusion Protein Vaccine (V01) in Adults Aged 18 Years and older.								
80	MAL 047	Randomized, Controlled, Partially-Blind Study Of The Safety And Immunogenicity Of Glaxosmithkline Biologicals' Candidate Plasmodium Falciparum Vaccines RTS,S/AS02D And RTS,S/AS01E, When Administered IM According To A Three Dose Schedules In Children Aged 5 To 17 Months Living In Ghana.								
81	MAL 050	Randomized, Open, Controlled Study Of The Safety Of The And Immunogenicity Of GSK Biologicals' Candidate Plasmodium Falciparum Malaria vaccine RTS, S/AS01E when incorporated into an expanded program on immunization (EPI) regimen that includes DTPWHEPB/HIB,OPV, Measles and yellow fever vaccination in infants living in malaria- Endemic Regions- 050								
82	MAL 055	Double Blind (Observer Blind), Randomised, Controlled Multicentre Study To Evaluate In Infants And Children, The Efficacy Of RTS,S/AS10E Candidate Vaccine Against Malaria Disease Caused By P. Falciparum Infection Across Diverse Malaria Transmission Settings In Africa								
83	MAL 063	Randomized, Open, Controlled Study To Evaluate The Immune Response To The Hepatitis B Antigen Of The RTS,S /AS01E Candidate Vaccine, When Administrated As Primary Vaccination Integrated Into An EPI Regimen To Infants Living In Sub-Saharan Africa								
84	MAL 073	Phase IIb randomized, open, controlled, multi-center study to evaluate the immunogenicity and safety of the RTS,S/AS01E candidate malaria vaccine, when administered as primary vaccination at 6, 7.5 and 9 months of age with or without co-administration of measles, rubella and yellow fever vaccines followed by an RTS,S/AS01E booster vaccination 18 months post Dose 3, to children living in sub-Saharan Africa								
85	MAL 094	Phase IIb Randomized, Open-Label, Controlled, Multi-Centre Study of the Efficacy, Safety and Immunogenicity of GSK Biologicals' Candidate Malaria Vaccine RTS,S/AS01E Evaluating Schedules with or without Fractional Doses, early Dose 4 and yearly Doses, in Children 5-17 Months of age Living in Sub-Saharan Africa.								
86	MDGH-MOX-1006	An open-label study of the pharmacokinetics and safety of a single dose of moxidectin per oral in subjects aged 4 to 17 years with (or at risk of) onchocerciasis to identify an optimal dose for treatment of children 4 to 11 years								
87	MEBENDAZOLE	Efficacy and Safety Of A Single Dose Reigimen And A Multi Dose Regimen Of Mebendazole Against Hookworm Infections In Children And Adolescents In Ghana : A Randomized Control Trail.								
88	MEFLOGCHLOAZITHRAL-A	A Phase III, Randomized, Opened-Label, Comparative Trial Of Azithromycin Plus Chloroquine Versus Mefloquine For The Treatment Of Uncomplicated Plasmodium Falciparum Malaria In Africa.								
89	CONJUGATE	A Phase II, Double Blind, Randomized, Controlled, Dose Ranging Study to Evaluate the Safety, Immunogenicity Dose Response and Schedule Response of a Meningococcal A Conjugate Vaccine administered concomitantly with local EPI vaccines in Healthy Infants.								
90	MMS	The Use Of A Multiple Micronutrient Supplement In Women Of Reproductive Age								
91	MoRION	The Efficacy of Rifapentine 900mg/d plus Moxifloxacin 400mg/d given for 14 or 7 days against Onchocerciasis – a Randomized, Controlled, Parallel-Group, Open Label, Phase II Pilot Trial								
92	MOXIDECTIN	Randomized, single-ascending dose, Ivermectin-controlled, double-blind, safety, tolerability, pharmacokinetic and efficacy study of orally administered Moxidectin in subjects with Onchocerca volvulus Infection								
93	MOXIDECTIN-IVERMECTIN	A Phase III Randomized, Single-Ascending-Dose, Ivermectin-Controlled, Double-Blind, Safety, Tolerability, Pharmacokinetic, and Efficacy Study of Orally Administered Moxidectin in Subjects with Onchocerca volvulus Infection ¹ :								
94	MULTIMAL	Multi-Drug Combination-Therapies to prevent the Development of Drug Resistance: Phase II Controlled Clinical Trial Assessing Candidate Regimens of Multiple-Antimalarial Combinations for the Treatment of Uncomplicated Malarial in Africa								
95	MYCOPIROX_LA GRAY	Randomized, open labelled trial to evaluate the efficacy, safety and tolerability of mycopirox vaginal cream in the treatment of mixed infection vaginitis								
96	NEOVITA	Feasibility Studies								
97	NOGUCHI FILARIASIS	Determination of the Prevalence of LF Infection in Districts Not Included in LF Control Activities and of the Basis for Integrated Implementation of LF - Onchocerciasis Elimination Strategies in Potentially Co-endemic Areas								
98	NOGUCHI SCD	A Phase 1B Dose – Finding Pharmacokinetics and Pharmacodynamic Study Oof NVX – 508 In Sickle Cell Disease (SCD) Patients								
99	NON-INVASIVE HAEM DEVICE	A Comparison of Hemoglobin Values as Measured By The Pronto And Pronto 7 Non-Invasive Hemoglobin Devices, The Hemocue Hb 201+, And A Hematology Analyzer Among Pregnant Women Attending Antenatal Care Clinic In Ghana								
100	NOVASIL	Safety and Efficacy Evaluation of Novasil: Strategy for the Protection of Humans from Aflatoxin Toxicity								

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
101	NOVIC TRIAL									Novel vacuum-induced Haemorrhage control for postpartum Haemorrhage: a multicentre randomised trial
102	OXYTOCIN									Determining the Effect of Prophylactic Administration Of Oxytocin In Uniject™ By A Community Health Officer On Post-Partum Haemorrhage At Home Births In The Kintampo North And South Districts Of Ghana
103	PFCSPP_MVACS_MALARIA									Partial Double-Blind, Randomized Study of PFCSP DNA/MVA Prime Boost Vaccine
104	PIVOT									Prospective Identification of Variables as Outcomes for Treatment (PIVOT): A Phase II clinical trial of hydroxyurea for children and adults with HbSC disease
105	POLYPHENOL-RICH COCOA POWDER TRIAL									Polyphenol-rich Cocoa Powder as Adjuvant Therapy in Patients with Covid-19.
106	POST MASTECTOMY									ULTRASOUND-GUIDED ERECTOR SPINAE PLANE BLOCK FOR POST-MASTECTOMY PAIN RELIEFve
107	PLATINUM									: A multi-part, multi-center PLATFORM study to assess the efficacy, safety, tolerability and pharmacokinetics of anti-malarial agents administered as monotherapy and/or combination therapy IN patients with Uncomplicated Plasmodium falciparum Malaria
108	PMC TRIAL									The impact of a combination of the RTS,S/AS01E malaria vaccine and perennial malaria chemoprevention in Ghanaian children
109	PRAISE									An adaptive, Randomized, Placebo-controlled, Double-Blind, Multi-center Study of Oral FT-4202, a Pyruvate Kinase Activator in Patients with Sickle Cell disease (PRAISE)
110	PREGACT									Evaluating the Safety And Efficacy Of Artemisinin-Based Combination Treatments For African Pregnant Women With Malaria
111	PRENABELT									A Maternal Device to Reduce the Risk of Stillbirth and Low-Birth Weight
112	PROBIOTIC									A double-blind randomized control trial of a synbiotic vs. placebo among pregnant women to evaluate colonization of the gut microbiota of their infants with Lactobacillus plantarum (Probiotics pilot in Ghana)
113	PROBIOTIC(IN MILD COGNITIVE									Assessing the Therapeutic Effect of Probiotics on Individuals with Mild Cognitive Impairment
114	ARTESUNATE VRS COARTEM									andomized multicentre clinical study to assess the safety and efficacy of fixed dose formulation of oral pyronaridine artesunate tablet versus coartem in children and adult patients with acute uncomplicated plasmodium falciparum malaria
115	PRCR DIPSTICK									Validation of a Protein Creatinine (PrCr) Dipstick Diagnostic Test for Proteinuria Screening on Antenatal Care Clinics in Ghana
116	PRCR SPOT									Evaluating the clinical utility and operational fit of the lifeAssay Diagnostics Test-It TM PrCr urinary dipstick test to assess risk of pre- eclampsia in referral hospitals in Ghana: A SPOT nested study, developing and VALIDating a Severe Pre-eclampsia adverse Outcome Triage (SPOT) score
117	RECOVERY									Randomized Evaluation of Covid-19 Therapy (RECOVERY)
118	RIFAMPIN VS ISONIAZID									A Randomized Clinical Trial of 4 months Rifampin versus 9 months Isoniazid for treating Latent TB Infection
119	ROBOCOW									RANDOMIZED PLACEBO-CONTROLLED TRIAL TESTING 0.2% CHLORHEXIDINE MOUTHWASH TO REDUCE POSTOPERATIVE RESPIRATORY TRACT INFECTIONS IN ABDOMINAL SURGERIES
120	ROTARIX									Immunogenicity of The Human Rotavirus Vaccine (Rotarix™) At Varying Schedules and Ages in Rural Ghana
121	ROTASHIELD									The Randomized, Double-Blind, Placebo-Controlled Evaluation of The Efficacy, Immunogenicity, and Safety of 2 Single Doses of RRV-TV in Neonates/Infants
123	ROTATEQ									Efficacy, Safety and Immunogenicity of Rotateq™ Among Infants in Africa and Asia.
124	SALIF									A Phase 3b, Randomized, Open-label Clinical Study to Demonstrate non-inferiority in Virologic Response Rates of HIV-1 RNA Suppression <400 Copies/mL of TDF/FTC/RPV Versus TDF/FTC/EFV in First-line Antiretroviral NNRTI-based Suppressed Patients Switching At Low HIV-1 RNA Into Fixed Dose Combinations
125	SAR97276A_SA NOFI									A Multicentre, Open Label, Efficacy And Safety Of Parenteral Sar97276a In The Treatment Of Symptomatic Uncomplicated And Severe Malaria In Adults And Children
126	SAVVY									Randomised Controlled Trials of Savvy In HIV
127	SAVING BRAINS KUMASI									Saving Brains from Malnutrition: Implementation of Evidence-Based Nutritional Supplementation and Psychosocial Stimulation Program for Pregnant and Lactating Women and their Infants Post Weaning, To Improve Cognition and Behavioral Regulation to Deliver Better Social and Economic Prospects Later in Life
128	SAVING BRAINS NAVORONGO									Saving Brains from Malnutrition: Implementation of Evidence-Based Nutritional Supplementation and Psychosocial Stimulation Program for Pregnant and Lactating Women and their Infants Post Weaning, To Improve Cognition and Behavioral Regulation to Deliver Better Social and Economic Prospects Later in Life
129	SHEA LIDO									Comparison of Shea butter and Lidocaine gel for rectal examination- A Non-Inferiority Trial

CLINICAL TRIALS REGISTRY

N/O	TITLE OF STUDY	PHASE	DISEASE INDICATION	Investigational Products (IPs)/IP CLASS	DATE OF RECEIPT OF APPLICATION	PRINCIPAL INVESTIGATOR	STUDY CENTRE(S)	SPONSORS & APPLICANT	STATUS & DURATION OF STUDY	PURPOSE/AIM OF STUDY
130	SMAC	A Comparative, Open Label, Dose And Regimen Optimization Follow-Up Study Of Intravenous And Intramuscular Artesunate In African Children With Severe Malaria.								
131	SMAART	Stroke Minimization through Additive Anti-atherosclerotic Agents in Routine Treatment								
132	SOYPEPTIDE STUDY	Application of Bioactive Peptide for the Attenuation of Malnutrition in Cancer Patient in a treatment Health Facility in Ghana								
133	SPUTNIK LIGHT	A phase III randomized double blind, placebo- controlled international multisite clinical trial in parallel assignment to evaluate efficacy, immunogenicity and safety of the sputnik light vector vaccine in adults in the sars-cov-2 infection prophylactic treatment								
134	STAND	A Phase III, Multi-Centre, Randomized, Double-Blind Study to Assess Efficacy and Safety of Two Doses of Crizanlizumab Versus Placebo With or Without Hydroxyurea/Hydroxycarbamide Therapy in Adolescent and Adult Sickle Cell Disease Patients with Vaso Occlusive Crises (STAND)								
135	STAR	POSTOPERATIVE PAIN MANAGEMENT IN EMERGENCY ABDOMINAL SURGERY: BIMODAL VERSUS UNIMODAL ANALGESIA								
136	STEADFAST	A Phase II, multicenter, randomized, open label two arm study comparing the effect of crizanlizumab + standard of care to standard of care alone on renal function in sickle cell disease patients ≥ 16 years with chronic kidney disease due to sickle cell nephropathy								
137	SWIS	Feasibility, Acceptability, and Outcomes of Sterile Water Injection (SWI) in Managing Lower Back Pain among Labouring Women in a Tertiary Hospital in Ghana: A Mixed-method Study								
138	TADO	Double-Blind, Randomized, Efficacy And Safety Comparison Of Prasugrel And Placebo In Pediatric Patients With Sickle Cell Disease								
139	TENOFOVEK BE	A balanced, randomized, two treatment, two-period, two-sequence single dose crossover, open-label, analyst blind and single centre bioequivalence study test product; Tenofovek of Danadams Pharmaceuticals Industry Ltd., Ghana and reference product; Viread (Gilead Sciences, Inc., CA, USA) in healthy, Ghanaian adult, male, human participants under fasting conditions.								
140	TENOFOVIR	A Phase II Study for Tenofovir Disoproxil Fumarate for Prevention of HIV								
141	TYVEGHA	A cluster-randomized controlled Phase IV trial assessing the impact of a Vi-Polysaccharide conjugate vaccine in preventing typhoid infection in Asante Akim, Ghana (TYVEGHA):								
142	VAT00008	A parallel-group, Phase III, multi-stage, modified double-blind, multi-armed study to assess the efficacy, safety, and immunogenicity of two SARS-CoV-2 Adjuvanted Recombinant Protein Vaccines (monovalent and bivalent) for prevention against COVID-19 in adults 18 years of age and older								
143	VERO CELL COVID 19 TRIAL VR-AD-1005	A Randomized, Double-Blinded, Placebo-Controlled, Phase III, Clinical Trial of SARS-CoV-2 Vaccine, Inactivated (Vero Cell) in Adults Aged 18 Years and Above								
144	STUDY	Assessment of a novel fixed dose combination (FDC) drug VR-AD-1005 for the treatment of acute watery diarrhea in cholera: A phase II, multicenter, randomized, placebo controlled, double blinded efficacy and safety trial								
145	VERTEX	A Phase 2/3 Adaptive, double-blind, placebo-controlled study to evaluate the efficacy and safety of VX-147 in Subjects Aged 18 Years and Older with APOL1-mediated Proteinuric Kidney Disease								
146	WOMAN	Tranexamic Acid For The Treatment Of Postpartum Haemorrhage: An International, Randomized, Double Blind, Placebo Controlled Trial								
147	YAWS	Single Dose Oral Azithromycin Versus Injection Benzathine Penicillin For The Treatment Of Yaws – A Randomized Clinical Trial In Some Endemic Communities In Ghana								
148	ZEBOV	A Phase 1 Study to Evaluate the Safety, Tolerability and Immunogenicity of Heterologous Prime-Boost Regimens Using MVA-BN®-FILO and Ad26.ZEBOV Administered in Different Sequences and Schedules in Healthy Adults								
149	ZEBOV 2	A Randomised, Observer-blind, Placebo-controlled, Phase 2 Study to Evaluate the Safety, Tolerability and Immunogenicity of Three Prime-boost Regimens of the Candidate Prophylactic Vaccines for Ebola AD26ZEBOV and MVA-BN-Filo in Healthy Adults, Including Elderly								
150	ZIV AFFLIBERCEPT	Phase I, Safety of ZIV-AFLIBERCEPT in retinal diseases in Ghanaian population								
151	*	Feasibility Studies								
152	N/A	Study not Started/ Application Withdrawn /Not Approved / Terminated / FDA Dissociation from Trial data								
153	NYN	Not yet known								
154	Active Trials									
155	Applications pending approval									
156	Study ended									
157	Trials closed by Sponsor before commencement									
158	Application withdrawn by Sponsor before FDA approval									
159	Application closed by FDA									
160	Trials Not Approved									
161	Trials terminated by FDA/Sponsor									

