# CLINICAL TRIALS REGISTRY

| N/O | TITLE OF STUDY | PHASE | DISEASE INDICATION | Investigational Products (IPs)/IP CLASS/Route of administration | ,DATE OF RECEIPT OF APPLICATION | PRINCIPAL INVESTIGATOR | STUDY CENTRE(S) | SPONSORS & APPLICANT | STATUS & DURATION OF STUDY | PURPOSE/AIM OF STUDY |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | SMAART MAP (new); Renal function domain | Phase III | Renal disease | Paracetamol<br><br>Allopathic drug<br><br>Rectal/Oral/Nasogastric | 28th March 2024/24th May 2024 | Professor Daniel Ansong | Komfo Anokye Teaching Hospital<br><br>Department of Child Health, Kwame Nkrumah University of Science and Technology | Imperial College London | Application approved, 27 months | PRIMARY OBJECTIVE<br>Our primary objective is to test whether regularly dosed paracetamol given over 66 hours (corresponding to 72 hours exposure) will reduce levels of creatinine in children at high risk of renal impairment compared to standard of care; thus determining if paracetamol can reduce the evolution of kidney injury in severe malaria.<br>SECONDARY OBJECTIVES<br>Secondary objectives are to assess the impact of regularly dosed paracetamol during admission in children with elevated creatinine and severe malaria on:<br>• mortality and readmission by 90 days.<br>• markers of liver function (AST and ALT).<br>• on Grade 3 or 4 adverse events, and adverse events of any grade related to paracetamol. An additional objective is, where it is possible, to store urine in order to assess other markers of kidney function, such as the urine albumin creatinine ratio at 72 hours. |
| 2 | SMAART MAP (new); Anaemia domain | Phase III | Anaemia | Whole Blood and Packed Blood Cells Transfusion | 28th March 2024/24th May 2024 | Professor Daniel Ansong | Komfo Anokye Teaching Hospital<br><br>Department of Child Health, Kwame Nkrumah University of Science and Technology | Imperial College London | Application approved, 27 Months | PRIMARY OBJECTIVE<br>Our primary objective is to test whether giving a whole blood transfusion compared to red cell concentrates in children with severe malaria and severe anaeemia leads to improved haemoglobin recovery and reduces the need for secondary transfusions.<br>SECONDARY OBJECTIVE<br>Our secondary objective is to assess the impact of whole blood vs red cell concentrate transfusions on other clinical outcomes such as mortality and readmission at 90 days and to understand the safety profile of both types of transfusions further by comparing grade 3 and 4 adverse events (AEs) and AEs of any grade related to the transfusions. |
| 3 | SMAART MAP (new); Cerebral malaria domain | Phase III | Cerebral malaria | Levetiracetam<br><br>Allopathic drug<br><br>Intravenous | 28th March 2024/24th May 2024 | Professor Daniel Ansong | Komfo Anokye Teaching Hospital<br><br>Department of Child Health, Kwame Nkrumah University of Science and Technology | Imperial College London | Application approved, 27 Months | PRIMARY OBJECTIVE(S)<br>Our primary objective is to test whether that levetiracetam given to children with seizures in their current episode of malaria but prior to admission will help prevent further seizures.<br>SECONDARY OBJECTIVE(S)<br>•Our secondary objective is to assess the impact of levetiracetam on other outcomes including mortality and readmission at 90 days and to investigate its safety profile in this patient population by grade 3 and 4 adverse events (AEs), solicited AEs, and AEs of any grade related to anticonvulsants. •An additional objective is, where it is possible, to store blood spots on filter papers, in order to further assess the pharmacokinetics of levetiracetam in this patient population. |
| 4 | SHINE-1 | Phase III | Human Papilloma Virus (HPV) | Innovax 9 (Recombinant Human Papillomavirus 9-valent Vaccine (Escherichia Coli)<br><br>Vaccine<br><br>Intramuscular | 3rd July 2024 | Dr. Nana Akosua Ansah | Navrongo Health Research Center (NHRC) | PATH | Application approved, 32 months | Primary Objective:<br>• To evaluate NI of immune response for the Innovax 9vHPV vaccine administered in a single-dose schedule to that of Gardasil 9 against oncogenic HPV types (HPV-16, -18, - 31, -33, -45, -52, and -58) in healthy girls 9– 14 years of age, 24 months after vaccination.<br>• To evaluate NI of immune response for the Innovax 9vHPV vaccine administered in a single-dose schedule to that of Gardasil 9 against oncogenic HPV types (HPV-16, -18, - 31, -33, -45, -52, and -58) in healthy young women 15–20 years of age, 24 months following vaccination.<br><br>Secondary Objective (Immunogenicity)<br>To evaluate NI of immune response for the Innovax 9vHPV vaccine administered in a single-dose schedule to that of Gardasil 9 against HPV types 6 and 11, 24 months following vaccination |
| 5 | URIB-PAP | Phase I | Human Papilloma Virus (HPV) | Urine collection device for HPV testing<br><br>Medical device<br><br>Intravaginal | 20th June 2024 | Dr. Kwaku Asah-Opoku | Korle-Bu Teaching Hospital (KBTH) | University of Michigan Department of Obstetrics and Gynecology | Application approved, 11 months, | Aim(s)<br><br>• To explore the acceptability and feasibility of our device among KBTH healthcare clinicians.<br>• To validate that our device facilitates highly accurate urine-based HPV screening.<br>• To explore the acceptability and feasibility of our device among KBTH patients.<br>Specific objectives<br>• Examine clinician acceptability of our device.<br>• Examine clinician perspectives on the feasibility of utilizing our device to screen patients.<br>• Compare detection rates of HPV for our device versus Pap smears.<br>• Examine patient satisfaction with our device versus Pap smears.<br>• Understand patient experiences, perspectives, and attitudes regarding HPV screening. |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 6 | AZIDUS BUPRENORPHINE | Bioequivalence Study | Analgesic | Buprenorphine<br><br>Allopathic Drug<br><br>Oral | 30th July 2024 | Dr. George Obeng Adjei | Azidus Laboratories Tema Freezone | Wes Pharma Inc,USA | Application approved, 2 months | Primary Objective(s):<br>The objective of this pilot study is to evaluate the Test formulation in comparison to the Reference Standard and to generate pharmacokinetic data that can be used to design a pivotal bioequivalence study |
| 7 | PMC RTSS SUB STUDY | Phase III | Malaria | Sulphadoxine/Pyrimethamine + Amodiaquine, Sulphadoxine/Pyrimethamine, RTS,S/AS01E Vaccine<br><br>Allopathic drug and Vaccine<br><br>Oral and intramuscular injection | 8th May 2023 | 1.Dr. Dennis Adu-Gyasi 2. Fr. Kwaku Poku Asante | Kintampo Health Research Center | Kintampo Health Research Center | Application Approved, 40 months | Primary objective<br>The primary objective of the study is determination of whether children who have received PMC with SP or SPAQ together with the RTS,S/AS01E vaccine have lower levels of naturally acquired immunity to malaria, as measured by antibodies to blood stage malaria antigens, than children who have received the malaria vaccine alone when they reach the ages of 18 and 24 months of age, the age at which they cease to be eligible to receive PMC.<br>Secondary objectives of the study include -<br>1. Determination of whether children who have received PMC with SP or SP+AQ together with the RTS,S/AS01E vaccine have lower titres of anti-CSP antibody than children who have received the malaria vaccine alone at 10 months of age (one month after they have received three priming doses of the vaccine), at 19 months of age, (one month after they have received a booster dose of vaccine), and when they reach the age of 24 months.<br>2. Determination of whether children who have received PMC with SP or SPAQ together with the RTS,S/SAS01E malaria vaccine have lower cellular immune responses to the CSP protein than children who have received RTS,S/AS01E alone when they reach the ages of 18 and 24 months.<br>3. Determination of whether the immune response to priming and booster doses of the RTS,S/AS01E vaccine is influenced by the presence of asymptomatic malaria parasitaemia at the time of vaccination |
| 8 | REALISE | Phase III | Soil-Transmitted Helminth Infections | Albendazole-Ivermectin<br><br>Allopathic drug<br><br>Oral | 9th May 2024 | Dr. Abraham Rexford Oduro<br>Dr. Joseph Kwadwo Opare | Nzema East District, Western Region | Laboratorios Liconsa SA | Application Approved, 3 years | Primary objective<br>1. To evaluate and compare the safety of the FDC against ALB via mass drug administration (MDA).<br>Secondary objective<br>1. To evaluate the effectiveness of one round of MDA with FDC compared to ALB against Trichuris trichiura.<br>Exploratory objectives<br>1. To evaluate the effectiveness of one round of MDA with FDC compared to ALB against Strongyloides stercoralis by serology.<br>2. To evaluate the effectiveness of one round of MDA with FDC compared to ALB against hookworm.<br>3. To evaluate the effectiveness of one round of MDA with FDC compared to ALB against Ascaris lumbricoides.<br>4. Describe the frequency of scabies before and after the intervention in the two treatment arms.<br>5. To implement genomic surveillance as a tool to evaluate MDA effectiveness and monitor drug resistance emergence in T. trichiura.<br>6. To assess the role of the gut microbiome on the effectiveness of one round of MDA with ALB and FDC. |
| 9 | IMBRAVE 152 | Phase III | Liver Cancer | Atezolizumab/Bivacizumab/Tiragolumab/Tiragolumab Placebo<br><br>Monoclonal antibody<br><br>IV Infusion | 15th November 2023 | 1. Dr. Edward Amankwah Frimpong<br>2. Dr. Asare Offei | 1. Korle-Bu Teaching Hospital (KBTH)<br>2. Sweeden Ghana Medical Centre | F. Hoffmann-La Roche Ltd | Application Approved, 2 years 8 months | Primary Objectives:<br>• To evaluate the efficacy of atezolizumab plus bevacizumab plus tiragolumab compared with atezolizumab plus bevacizumab<br>Secondary Objectives:<br>• To evaluate the efficacy of atezolizumab plus bevacizumab plus tiragolumab compared with atezolizumab plus bevacizumab<br>• To evaluate the safety of atezolizumab plus bevacizumab plus tiragolumab compared with atezolizumab plus bevacizumab<br>• To characterize the PK profile of atezolizumab plus bevacizumab plus tiragolumab<br>• To evaluate the immune response to tiragolumab and atezolizumab |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 10 | NANOX.ARC | | Radiographic abnormalities | Nanox.ARC<br><br>Medical device<br><br>NA | 11th March 2024 | Dr. George Boateng KYEI | University of Ghana Medical Centre (UGMC) | NANO-X IMAGING LTD | Application Approved, 2 years | Primary Objective:<br>• To assess safety and clinical performance of Nanox.ARC DTS in providing additional information to conventional 2D radiography when evaluating adult individuals with known or suspected radiographic abnormalities.<br><br>Secondary Objectives<br>• To evaluate the ability of Nanox.ARC DTS to reduce the need for a CT/MRI or other advanced imaging modality<br>• To evaluate the ability of Nanox.ARC DTS to increase the level of confidence of the reader in identifying/excluding an abnormality.<br>• To evaluate physician reading time of Nanox.ARC DTS compared to CT/MRI or other advanced imaging modality<br>• To evaluate the length and extent of the learning curve of reading the tomosynthesis images<br><br>Safety Objectives<br>The safety objective is to collect safety information, including type and number of adverse<br>events, serious adverse events, and device issues. |
| 11 | REVIVE | Phase III | Advanced HIV | Zithrolide (Azithromycin)<br><br>Allopathic drug<br><br>Oral | 14th March 2024 | Dr. Yasmine Oladele I. Hardy<br>Prof. Daniel Ansong | Kumasi (Bantama, Suntreso and Atonsu) | Hamilton Health Sciences through its Population Health Research Institute (PHRI) | Application Approved, 3 years 8 months | Primary Objective:<br>The primary objective is to determine whether azithromycin is an effective and safe intervention to reduce excess mortality in adults with advanced HIV (CD4 ≤ 100 cells/mm3).<br><br>Secondary Objective:<br>Secondary objectives include exploring effects on mortality and hospitalisation at early and late timepoints, impact on incident infection, and cause of death. |
| 12 | MICRONUTRIENT SUPPLEMENTATION | Phase III | | Micronutrient (Effervescent powder; Orange flavored; Contains multiple vitamins and minerals)<br><br>Food supplement<br><br>Oral | 15th April 2024 | Prof. Francis Bruno Zotor | University of Health and Allied Sciences | InnoNext Sàrl | Application Approved, 3 years 8 months | The primary objective of the study to determine if micronutrient supplement improves the vitamin D status of the study participants with or without additional Nutrition Training and Healthy Lifestyle Coaching (herein referred to as NuTHLiC). Vitamin D status will be assessed as serum 25(OH) D in serum.<br>The secondary objectives of the study are to:<br>1. Determine if micronutrient supplementation improves the status of vitamin B12, zinc, magnesium and iron of the study participants that will receive a micronutrient supplement with or without Additional nutrition Training and Healthy Lifestyle Coaching (herein referred to as NuTHLiC). The nutrient status will be assessed as serum vitamin B12, serum zinc, serum magnesium, serum ferritin and RBC Hb.<br>2. Assess the effectiveness of additional NuTHLiC on the nutrient status through the assessment of the nutrient biomarkers as per point 1.<br>3. Assess the effectiveness of the micronutrient supplement with or without additional NuTHLiC on lifestyle habits and overall wellbeing through targeted questionnaires as assessed by theparticipants. |
| 13 | MALHELMINTH STUDY | | Helminths infection/Malaria | Sulphadoxine-pyrimethamine and Amodiaquine - (SPAQ), Albendazole (ALB), Praziquantel (PZQ)/Allopathic drug<br><br>Allopathic drug<br><br>Oral | 29th December 2023 | 1. Dr Muhammed Afolabi<br>2. Dr Kwaku Poku Asante | Kintampo Health Research Centre (KHRC) | London School of Hygiene & Tropical Medicine | Application Approved, 13 months | Aim:<br>To evaluate the effectiveness and cost-effectiveness of integrating mass drug administration for helminth control with seasonal malaria chemoprevention in Ghanaian children<br>Objectives:<br>• Evaluate the effectiveness of combining SMC and deworming drugs in reducing the prevalence of anaemia and the intensity of malaria-helminth co-infections among a population of pre-school and school age children resident in a high burden country.<br>• Determine the cost and cost-effectiveness of delivering an integrated malaria-dewormingapproach to the children. |
| 14 | KALUMA STUDY | Phase III | Malaria | KLU156 | 27th October, 2023 | 1. Dr. Samuel Harrison<br>2. Dr. Patrick Odum Ansah | 1. KHRC 2.NHRC | Novartis Pharma AG | Application Approved, 3years 9 months | Purpose<br>This study aims to confirm the efficacy, safety and tolerability of KLU156, a fixed dose combination of ganaplacide (KAF156) and a solid dispersion formulation of lumefantrine (lumefantrine-SDF), when administered once daily for three days in adults and children ≥ 5 kg body weight and ≥ 2 months of age suffering from uncomplicated P. falciparum malaria (with or without other Plasmodium spp. co-infection).<br>In the Extension phase, the safety, tolerability and efficacy of repeated treatment with KLU156 will be assessed for a maximum of two years in patients who did not experience early treatment failure (ETF), who did not experience any study treatment-related SAE (Serious Adverse Event) previously and who gave informed consent to participate in the Extension phase. |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 15 | SOY PEPTIDE STUDY | Phase II | Malnutrition in cancer patient | Soy Protein Peptide Supplements (Vegalbum Supplement )<br>Food supplements<br>Oral | 10th February 2023 | Prof. Christiana Nsiah-Asamoah | Cape Coast Teaching Hospital (CCTH) | South China University of Technology | Application Approved, 12 months | Objective:<br>The aims of this study are<br>(1) to evaluate the efficacy of food-borne (soybean) peptides in reducing malnutrition in cancer patients and<br>(2) the secondary objective is to assess the impact of the peptides on hemoglobin levels, kidney function, liver function, and C-reactive protein levels in cancer patients. |
| 16 | IAVI C105 STUDY | Phase II | Lassa Fever Disease | rVSVΔG-LASV-GPC Vaccine<br>Vaccine<br>Intramuscular Administration | 7th August 2023 | Prof. Kwadwo Koram | Noguchi Memorial Institute for Medical Research | International AIDS Vaccine Initiative (IAVI)/ Susan Adu-Amankwah | Application Approved/4 years 3months | Safety<br>• To evaluate the safety and tolerability of the rVSVΔG-LASV-GPC vaccine at 2 different dosage levels in adults, including PLWH, and in children. Immunogenicity<br>• To determine binding LASV-GPCspecific antibody responses induced by rVSVΔG-LASV-GPC vaccine<br>• To determine neutralizing LASV-GPCspecific antibody responses induced by rVSVΔG-LASV-GPC vaccine in a subset of participants in each group |
| 17 | VERTEX Trial-BANK HOSPITAL | Phase II/III | Kidney Disease | Inaxaplin (VX-147)<br>Allopathic drug<br>Oral | 22nd November 2023 | Dr. Charlotte Osafo | The Bank Hospital | Vertex Pharmaceuticals Incorporated | Application Approved 4 years | Primary objectives<br>•To evaluate the efficacy of VX-147 to reduce proteinuria<br>•To evaluate the efficacy of VX-147 on renal function as measured by eGFR slope<br>Secondary objectives<br>•To evaluate the efficacy of VX-147 to decrease the risk of the composite clinical outcome<br>•To evaluate the safety and tolerability of VX-147<br>•To identify the optimal dose from Phase 2 to carry forward to Phase 3<br>•To characterize the plasma pharmacokinetics (PK) of VX-147 |
| 18 | CIELO Trial | Phase III | Encephalitis | Satralizumab<br>Monoclonal antibody<br>Subcutaneous injection through thigh/abdomen | 20th December 2022 | Prof. Fred Stephen Sarfo | Komfo Anokye Teaching Hospital (KATH) | F-Hoffman LA Roche/ Chugai Pharma Co. LTD | Application Approved 5years 5months | This study will evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of satralizumab compared with placebo in each of the following cohorts:<br>•NMDAR autoimmune encephalitis (AIE) cohort: adults and adolescents with definite or probable NMDAR encephalitis<br>•LGI1 AIE cohort: adults with LGI1 encephalitisIn 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. |
| 19 | ROBOCOW | Phase II | Postoperative Respiratory Tract Infections in abdominal surgery | 0.2% Chlorhexidine Digliconate<br>Mouthwash<br>Oral | 10th January 2023 | Dr. Mohammed Sheriff | Tamale Teaching Hospital | Dr. Mohammed Sheriff | Application Approved 5 Months | Primary Objective<br>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.<br>Secondary Objectives<br>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 |
| 20 | GBT440-038 | Phase III | Sickle Cell Disease | Voxelotor (GBT440)<br>Allopathic<br>Oral | 10th February 2023 | 1. Dr. Catherine Segbefia<br>2. Dr. Vivian Paintsil | 1. Korle-Bu Teaching Hospital (KBTH)<br>2. Komfo Anokye Teaching Hospoital (KATH) | Global Blood Therapeutics, Inc. | Application Approved, 24months | The objective of this OLE is to assess the safety of, and SCD related complications with, long term trreatment with Vovelotor in pparticipants who have completed treatment in a GBT-spnsored voxelotor clinical study based on the following parameters<br>a) Adverse Events (AEs), Clinical Laboratory Tests, Physical Examinations (PEs) and other clinical measures.<br>b) Frequency of SCD-related complications. |
| 21 | INTS GMMA STUDY | Phase II | Typhoid | GVGH iNTS-GMMA vaccine (GSK4077164A)<br>Vaccine<br>Intramuscular injection | 17th May 2023 | Professor Ellis Owusu-Dabo | KNUST-IVI Collaborative Centre | GlaxoSmithKline Biologicals SA | Application Approved, 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<br>2. To evaluate the safety and reactogenicity of the iNTS-GMMA vaccine in all participants |
| 22 | VERTEX Trial-KBTH | Phase II/III | Kidney Disease | Inaxaplin (VX-147)<br>Allopathic drug<br>Oral | 8th May 2023 | Dr. Dwomoa Adu | Korle-Bu Teaching Hospital (KBTH) | Vertex Pharmaceuticals Incorporated | Application Approved 4 years | Primary objectives<br>•To evaluate the efficacy of VX-147 to reduce proteinuria<br>•To evaluate the efficacy of VX-147 on renal function as measured by eGFR slope<br>Secondary objectives<br>•To evaluate the efficacy of VX-147 to decrease the risk of the composite clinical outcome<br>•To evaluate the safety and tolerability of VX-147<br>•To identify the optimal dose from Phase 2 to carry forward to Phase 3<br>•To characterize the plasma pharmacokinetics (PK) of VX-147 |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 23 | BLMs4BU | Phase III | Buruli Ulcer | Combination of rifampicin , Clarithromycin and Amoxicillin/Clavulanate<br><br>Allopathic drug<br><br>Oral | 1st February 2023 | Prof. Richard Odame Phillips | St. Peters Catholic Hospital Jacobu Nkawie Government Hospital | University of Zaragoza (UNIZAR) Spain | Application Approved<br>2 year 11 months | 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.<br>Primary objective<br>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. |
| 24 | FITBIT/XIAOMI | Phase III | Monitoring of Vitals in pediatric appendectomy and trauma patients | Fitbit Inspire 2, Xiaomi Mi Smart band 6<br><br>Medical device | 20th March 2023 | Dr. William Appeadu-Mensah | Korle-Bu Teaching Hospital (Paediatric Surgery Unit, Accident Centre) | 1. Dr. Fizan Abdullah<br><br>Ann and Robert H. Lurie Children's Hospital<br>2. Dr. Hassan Ghomrawi<br><br>Northwestern University | Application Approved, 2 Months | Aim(s)<br>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. pecific objectives<br><br>The specific objectives of this study are to:<br>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.<br>2. Compare the vital signs recorded manually to those collected by wearable devices |
| 25 | PMC TRIAL | Phase III | Malaria | Sulphadoxine/Pyrimethamine + Amodiaquine, Sulphadoxine/Pyrimethamine, RTS,S/AS01E Vaccine<br><br>Allopathic drug and Vaccine<br><br>Oral and intramuscular injection | 8th May 2023 | Dr. Kwaku Poku Asante | Kintampo Health Research Centre (KHRC) | PATH | Application Approved, 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<br>clinical malaria among children up to 24 months of age compared with RTS,S/AS01E vaccine administered alone |
| 26 | PLATINUM | Phase IIa | Malaria | INE 963, Cipargamin (KAE609),KLU156/ KAF156/LUM-SDF, Coartem/Riamet<br><br>Allopathic drug<br><br>Oral | 29th March 2023 | Dr. Patrick Odum Ansah | 1. Navorongo Health Research Center (NHRC)<br>2. Kintampo Health Research Center (KHRC) | Novartis Pharma AG | Application Approved 21 Months | Part A: To assess the parasite clearance time (PCT) of oral doses of an antimalarial agent administered as monotherapy in patients with uncomplicated<br>P. falciparum malaria<br>Part B: To assess the effect on adjusted 28-day cure rate of an anti-malarial<br>agent administered orally as combination therapy versus the standard of care<br>(SoC) in patients with uncomplicated P. falciparum malaria |
| 27 | NOVIC TRIAL | Phase III | Postpartum Hemorrhage (PPH) | Jada System (Intrauterine Vacuum Induced Hemorrhage Control Device)<br><br>Medical device<br><br>Vaginal | 5th April 2022 | Dr. Samuel A. Oppong | 1. Korle-Bu Teaching Hospital (KBTH)<br>2. Komfo Anokye Teaching Hospoital (KATH) | Women and Infants Hospital of Rhode Island | Application approved, 48 Months | Study Objectives<br>1. To evaluate the effectiveness of the Jada® System, compared to standard care, in treating PPH, as measured by maternal survival without surgical intervention.<br>2. 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.<br>3. 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. |
| 28 | VERTEX Trial | Phase II/III | Kidney Disease | Inaxaplin (VX-147)<br><br>Allopathic drug<br><br>Oral | 23rd December 2022 | Professor Sampson Antwi | Komfo Anokye Teaching Hospital (KATH) | Vertex Pharmaceuticals Incorporated | Application approved, 4 years | Primary objectives<br>•To evaluate the efficacy of VX-147 to reduce proteinuria<br>•To evaluate the efficacy of VX-147 on renal function as measured by eGFR slope<br>Secondary objectives<br>•To evaluate the efficacy of VX-147 to decrease the risk of the composite clinical outcome<br>•To evaluate the safety and tolerability of VX-147<br>•To identify the optimal dose from Phase 2 to carry forward to Phase 3<br>•To characterize the plasma pharmacokinetics (PK) of VX-147 |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 29 | SWIS (STERILE WATER INJECTION) | Feasibility study | Lower Back Pain | Sterile Water Injection<br><br>Intradermal | 6th December 2022 | Prof. Sue Kruske | Korle-Bu Teaching Hospital (KBTH) | Dr. Jonas Awuku Afari | Application approved, 40 Months | Main Aim<br>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.<br><br>Specific Objectives<br>1. Develop and deliver a training package for midwives on sterile water injections for managing lower back pain.<br>2. Undertake implementation study in a tertiary hospital in Ghana to assess the feasibility and acceptability of implementing SWI for lower back pain.<br>3. Determine birth and neonatal outcomes of women with back pain who receive SWI<br>4. Explore the experiences of women who have had SWI for back pain in labour<br>5. Explore the experiences and perception of midwives and stakeholders regarding the implementation of SWI for managing back pain in labouring women. |
| 30 | COPE TRIAL | Phase III | Fistula | Healeanlo silicone lady Drain Valve menstrual Cup<br><br>Medical device<br><br>Intravaginal | 2nd September 2022 | Dr. Gabriel Y.K. Ganyaglo | 1. Mercy Women's Catholic Hospital in Mankessim<br>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. |
| 31 | PRAISE | Phase II/III | Sickle Cell Disease | Oral FT-4202 Pyruvate Kinase Activator and Placebo<br><br>Allopathic drug<br><br>Oral | 2nd June 2022 | 1. Dr. Prince Agyapong - KHRC<br>2.Dr. Edeghonghon Olayemi - KBTH | 1. Kintampo Health Research Center<br>2. Ghana Institute of Clinical Genetics, KBTH | NOVO NORDISK COMPANY | Application Approved, 43 Months | Objectives of the study are:<br>1. To assess the efficacy of FT-4202 in adolescents and adults with SCD as compared to placebo as measured by improvement in hemoglobin (Hb)<br>2. To assess the efficacy of FT-4202 as compared to placebo on the annualized vaso-occlusive crisis (VOC) rate<br>3. To measure the effects of FT-4202 on clinical measures and sequelae of hemolysis<br>4. To evaluate the effects of FT-4202 on the sequelae of VOC<br>5. To assess changes in fatigue of sickle cell patients taking FT-4202 |
| 32 | PROBIOTIC PILOT STUDY | Pilot study | Malnutrition | Synbiotic (Nutraflora and Maltrin M100 P-95 and L. plantarum (Lp) and Placebo<br><br>Food supplement<br><br>Oral | 27th July, 2021 | Dr Seyram Kaali | Kintampo Municipal Hospital | Dr. Kwaku Poku Asante | Application Approved 27 months | Primary<br>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.<br>Secondary<br>1. To assess compliance of administering a synbiotic product (L. plantarum with Fructooligosaccharide) among pregnant women.<br>2. To assess birth outcomes among participants who receive synbiotic products compared to those on placebo.<br>3. To assess if maternal stool microbiome profoundly changes from immediately after childbirth to one-month post-partum.<br>4. To characterize the diversity of vaginal microbiomes among pregnant women in the study area.<br>5. To determine the safety of the probiotic supplementation among pregnant women from 5 to 6 months until up to two weeks post partum. |
| 33 | ASAAP | Phase III | Malaria | Arthemeter + Lumefantrine, Atovaquone /Proguanil Hydrochloride and Placebo (P-Dragees Rosa Lichtenstein)<br><br>Allopathic drug<br><br>Oral | 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 Approvedl 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.<br>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 6months to 10years. |
| 34 | POLYPHENOL-RICH COCOA POWDER TRIAL | Phase III | Covid-19 | Polyphenol-rich natural cocoa powder<br><br>Food supplements<br><br>Oral | 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.<br>Specific objectives:<br>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<br>2. to determine the effects of natural polyphenol-rich natural cocoa powder (5 % v/w) on selected markers of coagulopathy in COVID-19 patients<br>3. to determine the effects of natural polyphenol-rich natural cocoa powder (5 % v/w) on virologic clearance COVID-19 patients<br>4. to determine the effects of natural polyphenol-rich natural cocoa powder (5% v/w) on disease prognosis COVID-19 patients |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 35 | PIVOT STUDY | Phase II | Sickle Cell Disease | Hydroxyurea and Placebo<br>Allopathic drug<br>Oral | 18th June 2021 | 1. Dr. Yvonne A. Dei-Adomakoh<br>2. Dr.Catherine Segbefia | Korle-Bu Teaching Hospital | Cincinnati Children's Hospital Medical Center | Application Approved<br>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.<br>To identify which study endpoints are suitable for a future Phase III trial of patients with HbSC disease receiving hydroxyurea therapy. |
| 36 | RECOVERY | Phase III | Covid-19 | Infliximab, Dexamethasone<br>Allopathic drug<br>Oral and/or Intravenous | 21st May, 2021 | Dr. John H. Amuasi | Komfo Anokye Teaching Hospital<br>Ghana Infectious Disease Centre | University of Oxford Clinical Trials and ResearchGovernance. | Application Approved<br>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. |
| 37 | BURULIRIFDAC | Phase III | Buruli Ulcer | Rifampicin Capsules, Bacteria binding dressing: acetate fabric coated dialkyl carbamoyl chloride (DACC)<br>Allopathic drug<br>Oral and Topical | 12th December 2020 | Prof. Richard Phillips | •KCCR<br>•Ga East munical hospital<br>•Pakro Health Centre<br>•Wassa Amenfi East Hospital | London school of Hygiene and Tropical Medicine | Application Approved. Study<br>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 |
| 38 | BURULINOX | Phase III | Buruli Ulcer | Nitric oxide releasing gel, Vaseline Gauze dressing materials<br>Allopathic drug + medical device<br>Topical | 24th September 2018 | Prof. Richard Odame Phillips | 1.Kumasi Centre for Collaborative Research in Tropical Medicine<br>2.Agogo Presbyterian Hospital<br>3.Tepa Government Hospital<br>4.Dunkwa Government Hospital | Kumasi Center For Collaborative Research (KCCR) | Application Approved Study<br>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.<br><br>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). |
| 39 | TyVEGHA | Phase IV | Typhoid fever | Vi polysaccharide-tetanus toxoid conjugate vaccine (Vi-TT), Meningococcal Group A conjugate vaccine (MCV-A 5)<br>Vaccine<br>Intramuscular | 9th April 2021 | Prof. Ellis Owusu-Dabo | Agogo Trial Center/KNUST-International Vaccine Institute (IVI) Collaborating Center | International Vaccine Institute | Application Approved Study commenced 3 Years 5 months | •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<br>• To investigate the safety outcomes associated with Vi-TT vaccination in the intervention vaccine recipients compared with the comparator vaccine recipients<br>• 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<br>• To determine the total protection of Vi-TT vaccination against severe TF in the intervention vaccine recipients compared with the comparator vaccine recipients<br>• To determine the overall protection of Vi-TT vaccination against severe TF caused by S. Typhi in intervention clusters compared with control clusters<br>• 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<br>• To investigate the overall protection of Vi-TT vaccination against clinical TF in intervention clusters compared with control clusters<br>• 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<br>• To investigate the immunogenicity profile in a subset of Vi-TT recipients |
| 40 | SEMAGLUTIDE | Bioavailability study | Diabetes | Semaglutide sublingual tablets<br>Allopathic<br>Oral | 30th December 2024 | Prof. George Obeng Adjei | Azidus Laboratories Tema Freezone | GFC Pharma LLC | Application Pending Approval, | To evaluate the bioavailability of Semaglutide sublingual tablets 1 mg following oral (Sublingual) administration in healthy subjects under fasting condition. |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 41 | NEOSEP 1 | Phase III/IV | Neonatal Sepsis | 1.Fomicyt 2. Flumarin<br>Allopathic<br>Oral | | Dr. John Humphrey Amuasi | Komfo Anokye Teaching Hospital | Global Antibiotic Research & Development Partnership (GARDP) | Application Pending Approval, | Part 1 objectives & interventions: The purpose of Part 1 is to confirm that the recommended doses of fosfomycin and flomoxef, when used in combination with each other or with amikacin to be studied in Part 2, will provide adequate drug exposure in neonates with sepsis. A secondary objective is to collect safety data.<br>Part 2 objectives & interventions: The purpose of Part 2 is to provide a ranking of eight different clinically relevant antibiotic regimens for first-line empiric and second-line (after lack of response/deterioration) treatment in terms of 28-day mortality as the primary outcome measure. It will flexibly compare these multiple different relevant treatment regimens to enable the trial to be run in sites worldwide with very different background rates of resistance and patterns of routine clinical care by randomising each participant to locally relevant antibiotic regimens agreed prior to site initiation. |
| 42 | HIBISCUS | Phase III | Sickle cell | Etavopivat<br>Allopathic<br>Oral | 26th November 2024 | 1.Dr Seyram Kaali<br>2. Dr Patrick Ansah | 1. Kintampo Health Research Center<br>2. Navrogo Health Research Center | Novo Nordisk A/S | Application Pending Approval, | Primary Objective<br>To demonstrate superiority of treatment with etavopivat versus placebo in adolescents and adults with SCD<br>Secondary Objectives<br>*To evaluate clinical efficacy measures of etavopivat treatment versus placebo in adolescents and adults with SCD<br>*To evaluate clinical efficacy measures of etavopivat treatment versus placebo in adolescents and adults with SCD<br>*To assess clinically meaningful improvement in fatigue and functional exercise capacity and QOL measures of adolescents and adults with SCD taking etavopivat treatment compared to placebob |
| 43 | BILI-RULER | | Neonatal Jaundice | 1. Bilicare<br>2. Bili-ruler<br>Medical Device | 25th November 2024 | Dr Kwaku Poku Asante | Kintampo Health Research Centre | Bill & Melinda Gates Foundation | Application Pending Approval, | Aims and Objectives<br>The objective of this substudy is to assess the ability of Bili-ruler used in community settings in identification of severe hyperbilirubinemia in neonates, as compared to visual assessment and TCB, among those born in the Pregnancy Risk, Infant Surveillance, and Measurement Alliance (PRISMA)<br>Maternal and Newborn Health (MNH) Study.<br>To achieve this aim, four statistical objectives were identified:<br>1. To estimate the level of agreement between Bili-ruler, visual assessment, and TCB values.<br>2. To estimate the level of agreement between Bili-ruler, visual assessment, and TCB among binary diagnostic categories ('refer to a facility for treatment of hyperbilirubinemia' versus 'do not refer to a facility').<br>3. To describe and estimate the effect of skin color on the level of agreement between Bili-ruler, visual assessment, and TCB<br>4. To describe other sociodemographic and clinical factors affecting the difference between Bili ruler, visual assessment, and TCB values and diagnoses. |
| 44 | TAKE OFF T&T | Phase III | Lymphatic Filariasis | Doxycycline, Moxidectin, and Albendazole<br>Allopathic Drug<br>Oral | 21st August 2024 | Prof. Alexander Yaw Debrah | Kumasi Central Collaboration Research | Kumasi Central Collaboration Research | Application Pending Approval, | Primary Objectives:<br>To assess the effectiveness of the respective treatment regimens doxycycline (DOX), moxidectin +albendazole (MoxA) or standard mass drug administration (MDA) by comparing the proportions of the at baseline Bioline™Filarial test Strip (FTS) positive participants who were included in the trial (eligible participants) and who became FTS-negative at 24 months after treatment onset.<br>For all objectives: follow-ups for untreated participants will be based on the schedule of the assigned treatment group of the community |
| 45 | ZERO POINT FIVE | Phase III | Hookworm infection, Ascaris lumbricoides, and Trichuris trichiura | ZP5-9676<br>Allopathic Drugs<br>Oral | 8th August 2024 | Dr. Kwaku Poku Asante | Kintampo Health Research Centre (KHRC) | Zero Point Five Therapeutics | Application Pending Approval, | Primary objective:<br>• To evaluate the efficacy of ZP5-9676 for the treatment of hookworm (A. duodenale and N. americanus), Ascaris lumbricoides, and Trichuris trichiura in Participants between the ages of 6 months and 59 years.<br><br>Secondary objective:<br>• To evaluate the safety and tolerability of ZP5-9676 for the treatment of hookworm (A. duodenale and N.americanus), Ascaris lumbricoides, and Trichuris trichiura in Participants between the ages of 6 months and 59 years. |
| 46 | AZIDUS CEFUROXIME | Bioequivalence Study | Antibiotic | Cefuroxime Axetil Tablets<br>Allopathic Drugs<br>Oral | 30th July 2024 | Dr. George Obeng Adjei | Azidus Laboratories Tema Freezone | OA&J Pharmaceuticals Ltd | Application Pending Approval, | Primary Objective:<br>To assess the bioequivalence between Test (T) and Comparator (R) formulations |
| 47 | AZIDUS ACECLOFENAC | Bioequivalence Study | Analgesics | Aceclofenac tablets<br>Allopathic Drugs<br>Oral | 30th July 2024 | Dr. George Obeng Adjei | Azidus Laboratories Tema Freezone | OA&J Pharmaceuticals Ltd | Application Pending Approval, | Primary Objective(s):<br>• To evaluate and compare the relative bioavailability of two different test formulations (T1 & T2)<br>• To generate pharmacokinetic data that can be used to design a pivotal bioequivalence study |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 48 | DRAGON | Phase I | Surgery | Drapes and Gown (Laparotomy drape)<br><br>Medical Device | 22nd July 2024 | Prof. Stephen Tabiri | KBTH<br><br>KATH<br><br>TTH<br><br>Greater Accra Regional Hospital<br><br>Sunyani Regional Hospital<br><br>Cape Coast Teaching Hospital<br><br>Effia Nkwanta Regional Hospital<br><br>Eastern Regional Hospital, Koforidua<br><br>Holy Family Hospital, Berekum<br><br>Holy Family Hospital, Techiman<br><br>Salaga Municipal Hospital<br><br>Goaso Municipal Hospital.<br>Ho Teaching Hospital<br>St. Theresa Hospital | University of Birmingham | Application Pending Approval, | Primary Objective:<br>To assess whether reusable drapes and gowns are non-inferior in reducing SSI within 30 days of surgery compared to disposable (single-use) drapes and gowns.<br><br>Secondary Objective<br>• Assess the cost of using reusable versus disposable drapes and gowns<br>• Analyze the carbon footprint of reusable compared to disposable drapes and gowns:<br>• Investigate the rate of surgical site infections (SSIs) associated with reusable versus disposable drapes and gowns.<br>• Evaluate the patient experience of surgical site infections (SPECIES) |
| 49 | AMINO ACID SUPPLEMENTATION | Phase II | Enteric Dysfunction/Nutrition | Amino Acid Mix (AA Mix)<br><br>Food Supplement<br><br>Oral | 10th July 2024 | Dr.Regina Turkson<br><br>Dr.Charles Apprey<br><br>Dr. Seyram Elom Achoribo<br><br>Dr.Mame Yaa Adobea Nyarko, | Princess Marie Louise Children's Hospital (Accra) | International Atomic Energy Commission, Austria | Application Pending Approval, | AIM:<br>• To assess the effect of indispensable amino acids supplementation on<br>• environmental enteric dysfunction among children (18-36 months) with stunting.<br><br>Specific objectives:<br>• Measure the effects of the indispensable amino acid supplementation on the change in child weight from baseline to end line.<br>• Determine the change in gut permeability due to IAA supplementation as assessed by L/R ratio.<br>• Determine the change in gut digestive capacity due to IAA supplementation as assessed by the 13C-sucrose breath test.<br>• Determine the change in plasma protein absorption index by Dual Stable isotope Technique (DSIT).<br>• Determine the changes in bacterial translocation, inflammation, damage, and peptide transport in the gut |
| 50 | TIGER | Phase I | Surgery | Polypropylene Mesh<br><br>Medical device<br><br>Intramuscular | 18th June 2024 | Prof. Stephen Tabiri | 1.Lawra District Hospital<br>2. Debiso District Hospital<br>3. St. Martins De Pores Hospital, Eikwe 4.<br>Holy Family Hospital – Berekum<br>5. Holy Family Hospital – Techiman<br>6. Twifo-Praeso Government Hospita<br>7. Saltpond Government Hospital 8.<br>Salaga Municipal Hospital<br>9.Sandema District Hospital<br>10. War Memorial Hospital, Navrongo<br>11. Bongo District Hospita<br>12. Begoro District Hospital<br>13. Sefwi-Wiawso District Hospital<br>14. Baabiani District Hospital<br>15. St. Peter's Hospital, Jacobu<br>16. SDA Hospital, Agona Wiamose<br>17. SDA Hospital, Kwadaso<br>18. Asaman Hospital, Asaman<br>19. | University of Birmigham, Dr. Birgit Whitman. Research Governance Team | Application Pending Approval, | Primary objective: To assess if medical practitioners (MPs) can effectively perform mesh inguinal hernia repair compared to fully trained surgeons in adult patients with non-complicated inguinal hernia.<br>Secondary objectives:<br>• To compare the impact of the intervention on:<br>o Surgical site infection and reoperation rates at 30 and 90 days after surgery<br>o Recurrence at 90 days and one year after surgery<br>o Hernia-specific quality of life one year after surgery<br>o Change in quality of life from before to after surgery<br>o Chronic postoperative inguinal pain 90 days and one year after surgery<br>o Postoperative inguinal pain 30 days after surgery<br>o Mortality within 30 days after surgery<br>o Duration of surgery<br>• To explore the applicability of the trial's results by assessing the proportion of MPs requiring assistance from fully trained surgeons during inguinal hernia repairs<br>• To explore the economic impact of the interventions on hospital resources use and overall surgery costs. |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 51 | SD Biosensor MRDT | Phase III | Malaria | Standard Q hs-Malaria Ag p.f/p.v&<br>Standard Q hs-Malaria Ag p.f<br><br>Medical device | 2nd July 2024 | Prof Linda Eva Amoah.. | 1. NMIMR 2. Obom health center 3. Kofi Kwei CHPS compound, 4. Moree polyclinic, 5. Ewim Polyclinic | SD BIOSENSOR,INC | Application Pending Approval, | To assess the performance of STANDARDTM Q hs- Malaria P.f/P.v Ag Test and STANDARDTM Q hs- Malaria P.f Ag Testin intended use settings for detecting P. falciparum and P. vivax infections in capillary and venous whole blood samples collected prospectively from patients with symptoms suggestive of malaria in accordance with the Technical Specifications Series for submission to WHO Prequalification – Diagnostic Assessment: Malaria rapid diagnostic tests. |
| 52 | GBT021601-021 | Phase II/III | Sickle Cell Disease | Osivelotor (PF-07940367/GBT021601)<br><br>Allopathic drug<br><br>Oral | 2nd May 2024 | 1. Prof. Alhassan Abdul-Mumin<br>2. Dr. Kokou Amegan-Aho | 1. Trafalgar Campus, Ho-Denu Road, Ho, Volta Region, Ghana 2. Salaga Road, Tamale, Ghana. | Global Blood Therapeutics, Inc. a wholly owned subsidiary of Pfizer | Application Pending Approval, 42 Months | Primary:<br>Part A: To assess the effects of osivelotor in adult participants with SCD as measured by change in hemoglobin (Hb).<br>Part B: To assess the effects of osivelotor (adults: 150 mg QD dose) compared to placebo in adult and adolescent participants with SCD as measured by Hb response and rate of vasoocclusive crisis (VOC) events. Part C: To assess the PK of single and MD of osivelotor in pediatric participants with SCD |
| 53 | MOSA STUDY | Phase III | Monkey pox | Tecovirimat | 9th November, 2023 | | | Panther | Application Pending Approval | Primary<br>The primary objective is to evaluate the clinical efficacy, as assessed by time to lesion(s) resolution, of IP + Standard of Care (SOC) compared to placebo + SOC for subjects with monkeypox.<br>Secondary<br>To evaluate the safety and efficacy, as assessed by mortality, hospitalization,<br>complications, and duration of symptoms of IP + SOC compared to placebo + SOC in subjects<br>with mpox.<br>The safety objectives are to evaluate the safety and tolerability in terms of AEs and SAEs occurrence frequencies and treatment discontinuation of 1/ IP + SOC compared to placebo + SOC in subjects with non-severe mpox diseases 2/ IP + SOC in subjects with severe complications and/or severe immune suppression and/or pregnancy/breastfeeding. |
| 54 | BEMPU | Phase II | Hyppthermia in Infants | Bempu Bracelet<br><br>Medical device | 2nd November, 2020 | Mr. Prince Owusu | •Achimota General Hospital<br>•Greater Accra Regional Hospital<br>•Eastern Regional Hospital<br>•Korle-Bu Teaching Hospital<br>•Central Regional Hospital<br>Princess Marie Luis Children Hospital | Center for learning and childhood development | Application Pending Approval | 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.<br>To assess the acceptability of the bracelet in Health providers and caregivers of Low Birth Weight (LBW) infants by conducting qualitative in-depth interviews.<br>Determine the accuracy of the BEMPU bracelet in classifying hypothermia in the clinical setting.<br>Evaluate the impact of the bracelet |
| 55 | ACTIV TRIAL | Phase III | Covid-19 | S-217622 Tablet and Placebo<br><br>Allopathic drug<br><br>Oral | 27th September 2022 | 1.Dr. Patrick Ansah<br>2. Dr. Seyram Kaali<br>3. Prof. Richard Odame Philips | 1. Kumasi Centre for Collaborative Research (KCCR) 2. Kintampo Health Research Centr (KHRC)<br>3. Navrongo Health Research Centre | SHIONOGI INC.& Co Ltd | Study ended, Final Report yet to be submitted,,16 Months | Primary Objective<br>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.<br>Secondary Objectives<br>Key secondary objective:<br>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.<br>Key secondary objective:<br>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. |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 56 | HOPE KIDS 2 | Phase III | Sickle Cell Disease | Voxelotor (GBT440) and Placebo<br><br>Allopathic drug<br><br>Oral | 16th December 2020 | Dr. Catherine Segbefia | •Korlebu Teaching Hospital<br>Department of Child Health<br>•Sickle cell office Directorate<br>Child(KATH) | Global Blood Therapeutics, inc | Study ended, Final Report yet to be submitted, 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. |
| 57 | VAT00008 | Phase III | Covid-19 | SARS-CoV2 prefusion Spike delta TM with AS03 adjuvant, monovalent, SARS-CoV2 prefusion Spike delta TM with AS03 adjuvant, bivalent, Matching placebo<br><br>Vaccine<br><br>Intramuscular | 26th May, 2021 | 1. Dr. Nana Akosua Ansah<br>2. Dr. Kwaku Poku Asante<br>3. Dr. John Amuasi | *Navrongo Health Research Centre<br>*Kintampo Health Research Centre<br>*Kwame Nkrumah University of Science and Technology (KNUST) | SANOFI | Study ended Final report yet to be submitted 41months<br>15days | 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. |
| 58 | ASTAWOL | Phase II | Onchocerciasis /Filariasis | Rifampicin, Albendazole<br><br>Allopathic drug<br><br>Oral | 25th June 2020 | Prof. Alexander Yaw Debrah | •Bawku west<br>•Builsa South<br>•Nabdam Fumbisi<br>•Garu-Tempane<br>•Kayoro | Kumasi Centre for Collaborative Research (KCCR), Kumasi, Ghana | Study ended Final report yet to be submitted 24 months | The purpose of this study is to<br>•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<br><br>•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 |
| 59 | CECOLIN | Phase III | Human Papiloma Virus (HPV) | Cecolin<br><br>Vaccine<br><br>Intramuscular | 1st September 2020 | Prof. Tsiri Agbenyega | •Agogo Asante Akim North District | PATH | Study ended Final report yet to be submitted, 30 months | 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. |
| 60 | IUMO STUDY | Phase IV | Postpartum Hemorhage | 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 | Study ended Final report yet to be submitted, 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 |
| 61 | AVAREF TV ROTA | Phase III | Gastroenteritis | 1.Trivalent Rotavirus P2-VP8 Subunit Vaccine 2.Rotarix®/ Vaccine | 9th April, 2019 | 1.Prof. George E. Armah<br>2.Dr. Alberta Amu | Dodowa Health Research Centre | PATH | Study ended Final report yet to be submitted<br>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® |
| 62 | EBSI-LSV | Phase I | Lassa Fever | 1.EBSI-LSV 2. Placebo/ Vaccine | 1st September 2021 | 1.Dr Seyram Kaali<br>2.Dr.Patrick Ansah | 1.Kintampo Health Research Centre<br>2.Navrongo Health Research Centre | Emergent BioSolutions (EBS) | Study ended Final report yet to be submitted<br>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.<br>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. |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 63 | 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 | Study ended Final report in the ICHE3 format yet to be submitted 12 months | 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.<br>The purpose is to:<br>•To determine the ease of use of shea butter by clinicians as compared to lidocaine gel as a lubricant for rectal examination.<br>•To determine the complication rate related to the use of shea butter as a lubricant for rectal examination.<br>•To ascertain the complication rate associated with the use of lidocaine gel as a lubricant for rectal examination<br>•To compare the complication rate related to the use of shea butter to that of lidocaine gel. |
| 64 | 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<br>University of Ghana, Legon | Inovio Pharmaceuticals , Inc | Study ended Final report submitted 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.<br>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 |
| 65 | 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 | Study ended Final report submitted, 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 |
| 66 | SPUTNIK LIGHT | Phase III | Covid-19 | 1.Sputnik Light Vector Vaccine 2.Placebo/ Vaccine | 5th March 2021 | 1. Dr. Nana Akosua Ansah<br>2. Dr. Alberta Amu | 1. Navrogo Health Research<br>2. Centre Dodowa Health Research Centre Ghana | Human Vaccine LLC | Study ended Final report yet to be submitted 8 months | The purpose of the study is to<br>• Assess efficacy of the Sputnik-Light vector vaccine against the SARS-CoV-2-induced coronavirus infection compared to placebo<br>•Assess tolerability and safety of the Sputnik-Light vector vaccine against the<br>SARS-CoV-2-induced coronavirus infection compared to placebo<br>•Assess humoral immunogenicity of the Sputnik-Light vector vaccine against the<br>SARS-CoV-2-induced coronavirus infection compared to placebo on Subset A .<br>•Assess protective properties of the SputnikLight vector vaccine against the<br>SARSCoV-2-induced coronavirus infection compared to placebo for prevention of<br>serologically confirmed SARS-CoV-2 infection<br>• 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 |
| 67 | EMODEPSIDE | Phase II | Onchocerciasis | Emodepside (5mg)/ Allopathic drug | 5th November, 2020 | Dr. Nicholas Opoku | •School of Public Health Research Centre, (UHAS).<br>•Municipal Hospital, Hohoe, Volta Region, Ghana<br>•Kpassa, Nkwanta- North District, Oti Region, Ghana | DNDi (Drugs for Neglected Diseases initiative) | Study ended Final report yet to be submitted 67 months | The purpose of this study is to<br>•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<br><br>•Plasma PK of emodepside (solution and tablets), the effect of food on the bioavailability of emodepside |
| 68 | 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 | 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.<br><br>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. |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 69 | CROWN CORONATION | Phase III | Covid-19 | 1.Measles Rubella Vaccine 2.Matching Placebo 3.AstraZeneca vaccine/ Vaccine | 7th September 2020 | Prof. Kwadwo Koram | ••Ga East Municipal Hospital •Korle-Bu Teaching Hospital •UGMC •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 | Study ended Final report yet to be submitted 8 Months . | 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. 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. |
| 70 | 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 | 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. This study aims to provide preliminary data on the safety of ivermectin + diethhylcarbamazine + albendazol (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 coendemic for LF and onchocerciasis |
| 71 | 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 | 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. 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 the age of 18 years). |
| 72 | 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 | 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 inlymphatic 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. The purpose of the study is to establish that Doxycycline can improve filarial lymphedema in healthy adolescents or adults (14 – 65 years) |
| 73 | FALCON | Phase III | Surgery | 1.ChloraPrep™ 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 | T | Tamale Teaching Hospital | The University of Birmingham | Study ended Final report submitted 24 Months | 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 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 |
| 74 | 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. |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 75 | MULTIMAL | Phase II | Malaria | 1.Artesunate Pyronaridine (Pyramax 2.Atovaquone Proguanil (Malarone) 3.Clindamycin 4.Foscidomysin5.Artesunate / Allopathic drug | 27th July 2020 | PI(s) Dr. Oumou Maiga (KCCR) | St. Francis Xavier Hospital Assin Fosu, Ghana. Gabon | Department of Tropical Medicine, Bernhard Nocht Institute for Tropical Medicine (BNITM) | Study ended Final report submitted 7 months | The main objective of the project is to investigate two combinations of drugs already used in the market or in late-stage clinical development but not yet tested in the presently proposed combination. These are Artesunate-Pyronaridin-Atovaquone/Proguanil (APAP) and Artesunate-FosmidomycinClindamycin (AFC).<br><br>The two drug combinations will be investigated in a randomized controlledthree-groupp clinical phase II study.<br>This study will aim to describe:<br>• The pharmacokinetics of the investigated drugs when administered in combination therapy<br>• PCR corrected antimalarial efficacy over a 42 day follow up period<br>• Safety and tolerability. |
| 76 | 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 | To compare the efficacy of intramuscular (i.m) morphine as unimodal analgesic with bimodal administration of i.m. morphine and i.v. paracetamol in managing postoperative pain in emergency abdominal surgery.<br>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.<br>To determine the association between the administered analgesic and length of hospital stay. To determine the association between administered analgesic and |
| 77 | 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<br>education intervention improve foot care behaviour, foot care self-efficacy, knowledge of<br>diabetic foot and diabetes distress among persons with diabetes and their caregivers in<br>Ghana?' |
| 78 | CHEETAH | Pilot | Surgery | 1.Sterile Gloves<br><br>2.Sterile Surgical Instrument/Medical device | 1st June 2020 | Professor Stephen Tabiri | •Cape Coast Teaching Hospital<br>•Effiah Nkwanta Regional Hospital<br>•Holy Family Hospital – Berekum<br>•Holy Family Hospital – Techiman<br>•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. |
| 79 | KAE609 | Phase II | Malaria | 1.KAE609 2.COARTEM TABLETS / Allopathic drug | 8th August 2017 | Dr. Abraham Rexford Oduro | 1.Navrongo Health Center<br>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.<br>This study aims to determine the maximum safe dose of the investigational drug KAE609 in Adult patients with acute, uncomplicated Plasmodium falciparum malaria infection.. |
| 80 | 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 milion children less than 5 years are stunted, 50 milllion 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 ssess the acceptability and adherence to nutrient supplementation for 6 weeks among pregnant and lactating women and 6 monh old infants post weaning |
| 81 | SAVING BRAINS KUMASI | 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 for Infants 5.Omega 3 fatty acids/ Food supplements | 1st November 2017 | Prof. Jacob Plange-Rhule | 1.Tafo Government Hospital<br><br>2.Suntreso Government Hospital<br><br>3.Kumasi South Government Hospital | KNUST/Nutriset SAS | Study ended 6months | Malnutrition continues to be a global problem. Globally 156 milion children less than 5 years are stunted, 50 milllion 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 ssess the acceptability and adherence to nutrient supplementation for 6 weeks among pregnant and lactating women and 6 monh old infants post weaning |
| 82 | ALB_IVM | Phase III | Onchocerciasis | Ivermectin, Albendazole<br><br>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<br><br>38 months | To address whether IVM plus ALB given twice per year will be superior over annual treatment or IVM given biannually |
| 83 | MAL 055 | Phase III | Malaria | RTS,S/AS01E/ Vaccine | 1st October 2008 | 1. Prof. E. Tsiri Agbenyaga<br>2. Prof. Seth Owusu Agyei<br>3. Dr. Kwaku Poku Asante | 1. Malaria Research Centre, Agogo.<br>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 |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 84 | MMS | Phase III | Malnutrition | 1.Multiple micronutrient supplement 2.Iron + folic acid tablets/ Food supplements | 2nd October 2012 | Prof. Tsiri Agbenyaga | 1. Barekuma Collaborative Community Development Project<br><br>2. C/O Komfo Anokye Teaching Hospital, Kumasi | Kirk Humanitarian | Study Ended; yet to submit report<br>48 months | |
| 85 | 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<br>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. |
| 86 | 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<br>2. Dr. Frank Baiden<br>3. Dr. Damien Punguyire<br>4. Dr. Kwadwo Nyarko Jectey | 1. Mampong Government Hospital, Mampong<br><br>2. Kintampo Municipal Hospital, Kintampo | (GE) Foundation's Systems Improvement at District Hospitals and Regional | Study ended; yet to submit report in required format.<br>36 months | Evaluating the impact of using continuous positive airway pressure (CPAP) on mortality among children admitted into emergencies wards. an interventional trial to determine if CPAP reduces morality in children 1 month to 5 years of age with acute respiratory distress |
| 87 | 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<br>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. |
| 88 | | 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. 1B vs. 1C) |
| 89 | NON-INVASIVE HAEM DEVICE | Phase III | Hemoglobin deficiency in Pregnant women | 1. Pronto & pronto-7 pulse co-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<br>2 months | Aim<br>The aim of the validation study was to evaluate the accuracy of the Pronto and Pronto 7devices in measuring Hb when compared to measuring Hb using the Hemocue and the ABX Pentra 60 hematology analyzer as the reference standard.<br>Study Objectives:<br>To compare Hb values as measured by the Pronto and Pronto 7noninvasive 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. |
| 90 | ROTARIX | Phase III | Gastroenteritis | Rotarix™/ Vaccine | 6th February 2012 | Prof. George Armah | Navrongo Health Research Centre | PATH | Study Ended<br>7 months<br>Final Report submited | 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 |
| 91 | ARTIMIST | Phase III | Malaria | ArTiMist/ Allopathic drug | 22nd October 2010 | Dr. Patrick Ansah | Navrongo Health Research Centre | ProtoPharma Limited | Study Ended Final report submitted<br>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. |
| 92 | GARDASIL | Phase III | Human Papilom 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<br>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).<br>To evaluate the safety and tolerability of GARDASIL in females 9 to 26 years of age in SubSaharan Africa.<br>Secondary: To estimate Month 7 anti-HPV 6, 11, 16, and 18 geometric mean titers (GMTs) in vaccinated subjects |
| 93 | 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<br>15 months | |
| 94 | OXYTOCIN | III | Postpartum Hemorrhage (PPH) | 1.Oxytocin in uniject™ 10 iu/ Hormone | 12th May 2010 | Dr. Sam Newton | Kintampo Health Research Centre | PATH | Study Ended Final report submitted<br>12 months | To determine the effect of prophylactic administration of oxytocin in uniject on postpartum haemorrhage at home births in the Kintampo north and south districts of Ghana |
| 95 | 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<br>6 months | To determine the 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 |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 96 | 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.<br>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 vovulus |
| 97 | MOXIDECTIN | Phase II | Onchocerciasis | Moxidectin 2mg Tablets/Allopathic | 1st February 2004 | Dr. Kwabla Awadzi | Onchocerciasis Chemotherapy Research Centre Government Hospital | 1. Wyeth Research Division of Wyeth Pharmaceuticals Inc.<br>2. Product Development and Evaluation unit TDR | Study Ended Ended 60 months | |
| 98 | EBA | Phase I | Malaria | (EBA-175 RII-NG) malaria vaccine/ Vaccine | 1st March 2009 | Prof. Kwadwo Ansah Koram | Noguchi Momorial 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 |
| 99 | 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 |
| 100 | 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 |
| 101 | ROTASHIELD | III | Rotavirus Gastroenteritis | RRV-TV Vaccine (rotashield)/ Vaccine | 1st August 2009 | 1. Prof. George E. Armah<br>2. Prof. Fred N. Binka<br>3. Dr. Abraham Hodgson | 1. War Memorial Hospital, Navrongo<br>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 |
| 102 | AZITHROMYCIN PLUS CHLOROQUINE PHOSPHATE | III | Malaria | 1.Azithromycin 2. Chloroquine Phosphate 3. Artemether- Lumefatrine/Allopathic | 1st October 2007 | Dr. Patrick Ansah | Navrongo Health Research Centre | Pfizer Laboratories Incorporated, Pfizer Global Research and Development. | 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 |
| 103 | CRASH-2 | I | Trauma patient with or at risk of hemorrhage | 1.Tranexamic acid 2. Placebo/ | 1st August 2007 | Prof. J. C. B. Dakubo | Korle-Bu Teaching Hospital | London School of Hygiene & Tropical Medicine | 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. |
| 104 | PYRONARIDINE ARTESUNATE VRS COARTEM | III | Malaria | 1.Pyronaridine Artesunate Tablet (PYRAMAX) 2.Artemether-Lumefantrine(COARTEM)/ 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 Falciparium Malaria |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 105 | MAL 050 | III | Malaria | RTSS, AS10E Vaccine/Vaccine | | Prof. Seth Owusu Adjei | Kintampo Health Research Centre | GlaxoSmithKline R&D | Study Ended 17 months | |
| 106 | PFCSP_MVACS_MALARIA | I | Malaria | PfCSP DNA VACCINE (VCL-2510)/Vaccine | 1st August 2005 | Prof. Kwadwo A Koram | Tetteh Quarshie Memorial Hospital | Division of Microbiology and Infectious Diseases (DMID) National Institute of Allergy and Infectious Diseases (NIAID) | Study Ended 18 months | |
| 107 | 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 | |
| 108 | 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 | |
| 109 | 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 | |
| 110 | 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 | |
| 111 | CDA2 | III | Malaria | 1.Chorproguanil-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 | |
| 112 | NOVASIL | II | | NovaSIL | | Prof. David Ofori Agyei Dr. Nii- Ayi Ankrah | Ejura Sekyedumasi Disrict, Ashanti Region | United States Agency for International Development (USAID) Through The Peanut Collaborative Research Support Program | Study Ended 9 months | |
| 113 | TENOFOVIR | II | HIV | Tenofovir Disoproxyl Fumarate (TDF)/Vaccine | 1st February 2004 | Dr. Edith Clarke | Ghana Health Service | Family Health International | Study Ended 20 months | |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 114 | SAVVY | II | | SAVVY (Microbicide) | 1st February 2004 | Dr. William Ampofo<br>Dr. Baafuor Kofi Opoku | 1. Noguchi Memorial Institution for Medical Research.<br>2. Komfo Anokye Teaching Hospital. | Family Health International | Study Ended<br>32 months | |
| 115 | MAL 063 | III | Malaria | RTS,S/AS01E/ Vaccine | 15th April 2011 | Prof. E. Tsiri Agbenyaga | Malaria Research Centre, Agogo. | Malaria Research Centre, Agogo | Study Ended Final report submitted<br>52 months | |
| 116 | PREGACT | III | | 1. Eurartesim oral tablets<br>2. Farmanguinhos artesunate+mefloquine fixed combination oral tablets<br>3. Coarsucam oral tablets/ Allopathic | | 1.Dr. Harry Tagbor<br>2.Dr. Henry Opare Addo | 1.Ejisu Government Hospital, Ejisu<br>2. Juaben Government Hospital, Juaben | Prince Leopold Institute of Tropical Medicine | Study Ended<br>60 months | |
| 117 | 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<br>4 years and 2 months | |
| 118 | RIFAMPIN VS ISONIAZID | III | Tuberclosis | 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<br>60 months | |
| 119 | NOGUCHI FILARIASIS * | | Filariasis | 1.Alere filariasis test strip 2.Sd bioline lymphatic filariasis IgG4 3.Sd bioline oncho/lf IgG4 biplex<br>4.Diethylcarbamazine patch /Allopathic | 7th June 2017 | Prof. Daniel A. Boakye<br>Dr. Nana – Kwadwo Biritwum | Noguchi Memorial Institute For Medical Research | World Health Organization - TDR | Study Ended Final report submitted<br>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. |
| 120 | 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<br>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.<br>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.<br>To measure the anatomic changes using SD-OCT in eyes with DME, nvAMD and ME<br>secondary to RVO at 12 weeks. |
| 121 | HESTIA3 | Phase III | Sickle Cell Disease | 1.Ticagrelor 2.Placebo/Allopathic | 1st August, 2018 | 1. Prof. Alex Osei-Akoto<br>2. Dr Patrick Ansah<br>3. Dr. Catherine Segbefia<br>4.Dr Kokou Hefoume Amegan-Aho | 1. Komfo Anokye Teaching Hospital, Department of Child Health<br>2. Navrongo Health Research Centre<br>3. Department of Child Health, Korle Bu<br>University of Health and Allied Sciences | AstraZeneca AB | Study Ended. Final Report submitted<br>29 Months | Sickle cell disease (SCD) is a genetic, autosomal, recessive blood disorder 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.<br><br>This study is to evaluate the effect (efficacy, safety and tolerability) of ticagrelor versus placebo in reducing the rate of vaso-occlusive crises (VOCs), which is the composite of painful crisis and/or acute chest syndrome (ACS), in paediatric patients (2 to 11 years and 12 to 17 years with sickle cell disease (SCD). |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 122 | PRCR DIPSTICK | Phase II | proteinuria | 1.Test-It™ Protein Creatinine Dipstick<br>2.Urinalysis Reagent Strips<br>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<br><br>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.<br>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. |
| 123 | MAL 073 | Phase IIIb | Malaria | 1.RTS,S/AS01E 2.MR-VAC™<br>3.STAMARIL4.VITAMIN A /Vaccine | 11th December 2015 | 1.Prof. Tsiri Agbenyega<br>Prof. Seth Owusu Adjei | 1.Malaria Research Center, Agogo<br>2.Kintampo Health Research Centre | 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 .<br>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<br>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 |
| 124 | CEPHEID XPERT 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 | St. Martin De Porres Hospital<br><br>Atua Government Hospital<br><br>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. |
| 125 | MPZ STUDY | Phase IIa | Malaria | Ketantin (Meplazumab)<br><br>Monoclonal Antibody<br><br>Intravenous infusion | 5th December 2023 | 1. Dr. Patrick Odum Ansah<br>2. Dr. Oumou Maiga | 1. Navrogo Health Research Centre (NHRC)<br>2. St. Francis Xavier Hospital/KCCR | Jiangsu Pacific Meinuoke Biopharmaceutical Co., Ltd | Application withdrawn, 22 months | Primary Objective<br><br>• To evaluate the safety of meplazumab in an adult population with uncomplicated, symptomatic *P. falciparum* infection<br>SecondaryObjective:<br>• • To evaluate the efficacy of meplazumab<br>as defined by<br>o Early treatment failure<br>o Late clinical failure<br>o Late parasitological failure<br>o Uncorrected ACPR<br>• To evaluate PRR<br>• To determine the recrudescence ) and re-infection<br>• To determine the time to relief of fever<br>• To determine the dose-response trend relationship between 3 dose levels of<br>meplazumab by evaluation of safety, efficacy and ACPR outcomes<br>• To evaluate the pharmacokinetics of meplazumab in serum<br>• To evaluate immunogenicity following meplazumab administration |
| 126 | GBT-2104-133 | Phase III | Sickle Cell Disease | Inclacumab/ Monoclonal antibody | 27th August, 2021 | Professor Alex Osei-Akoto | Komfo Anokye Teaching Hospital (KATH) | Global Blood Therapeutics, Inc. | Study terminated by sponsor 7years 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. |
| 127 | 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 before commencement 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).<br>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). |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 128 | 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 before commencement 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). |
| 129 | INNOVATE | Phase III/II | Covid-19 | 1. Inn0-4800 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 |
| 130 | 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 |
| 131 | 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 DelNS1-2019-nCoV-RBD OPT1. |
| 132 | STEADFAST | Phase II | Sickle Cell Disease | CRIZANLIZUMAB/ Monoclonal antibody | 30th October, 2020 | 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. |
| 133 | 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 | |
| 134 | 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 Recherché And Development | Study Closed by Sponsor. No recruitment was done. 13Conths | |
| 135 | HOPE SCD | III | Sickle Cell Disease | GBT440 300mg /Allopathic | 1st May 2017 | 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 |
| 136 | MITAPIVAT | Phase II/III | Sickle Cell Disease | Mitapivat Allopathic Drug Oral | 24th November 2023 | Dr. Eunice Agyeman Ahmed | Komfo Anokye Teaching Hospital (KATH) | Agios Pharmaceuticals, Inc | Application Withdrawn before approval, | Primary Objectives To determine the recommended Phase 3 dose of mitapivat by evaluating the effect of 2 dose levels of mitapivat versus placebo on: • Anemia in subjects with sickle cell disease (SCD) • Safety Secondary Objectives To evaluate the effect of 2 doses of mitapivat versus placebo on: • Anemia • Markers of hemolysis and erythropoiesis • Patient-reported fatigue • Sickle cell pain crises (SCPCs) • To evaluate the pharmacokinetic and pharmacodynamic effects of mitapivat |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 137 | PROFUSA | | sepsis from pulmonary or wound sources | Lumee Oxygen Sensor<br><br>Medical Device<br><br>Subcutaneous injection | 12th July 2024 | Dr. George Oduro | Komfo Anokye Teaching Hospital (KATH) | Henry M. Jackson Foundation for the Advancement of Military Medicine | Application Withdrawn before approval, | Primary Objective:<br>Compare subdermal tissue oxygen concentrations in core and peripheral body sites measured via the oxygen biosensor platform with systemic blood oxygen levels in participants with suspected sepsis from pulmonary or wound sources<br><br>Secondary Objective<br>• Evaluate variations in tissue oxygen concentration dynamics using the oxygen biosensor platform in patients with differing sources of sepsis<br>• To evaluate the safety and tolerability of the biosensor technology |
| 138 | PEARL STUDY | Phase III | Respiratory Syncitial Virus Infections | RSVt Vaccine | 16th October 2023 | 1. Dr Seyram Kaali<br>2. Dr. Kokou Amegan-Aho<br>3. Dr. Alberta Amu<br>4. Dr. John Amuasi<br>5. Dr. Patrick Ansah<br>6. Prof. Tsiri Agbenyeg | 1. KHRC 2. UHAS 3. DHRC 4. KCCR 5. NHRC 6. Malaria Research Centre Agogo. | Sanofi Pasteur Inc | Application Withdrawn, 2 years 11 months | Efficacy<br>1. To demonstrate the clinical efficacy of RSVt vaccine for the prevention of<br>RT-PCR confirmed RSV LRTD after 2 doses, over RSV Season 1<br>2. To demonstrate the clinical efficacy of RSVt vaccine for the prevention of RT PCR confirmed RSV URTD after 2 doses over RSV Season 1<br>3. To demonstrate the clinical efficacy of RSVt vaccine for the prevention of RT-PCR confirmed RSV associated with the occurrence of LRTD, leading to hospitalization after 2 doses over RSV Season 1<br>Safety<br>To describe the safety profile of the RSVt vaccine.<br>Immunogenicity<br>To describe the RSV A and B serum-neutralizing and RSV serum anti-F IgA and IgG antibody responses to the study intervention |
| 139 | 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<br>2. Dr. Patrick Ansah<br>3. Dr. John Amuasi<br>4.Dr Kwaku Poku Asante | 1. Dodowa Health Research Centre<br>2. Navrongo Health Research Centre<br>3. Kumasi Center for Collaborative Research (KCCR)<br>4. Kintampo Health Research Centre | Sinocelltech Ltd.. | Application Withdrawn, 19 Months | Stage 1 immunization<br>□ 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.<br>□ 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.<br>□ To evaluate the protective efficacy of stage 1 immunization against different SARS-CoV-2 variants.<br>□ To evaluate the safety of SCTV01E in stage 1.<br>Stage 2 immunization<br>□ To evaluate the protective efficacy of SCTV01E against symptomatic COVID-19 occurring from 7 days after the 3rd dose in population previously unvaccinated with COVID-19 vaccine<br>□ 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 7 days after the 3rd dose, respectively, in population previously unvaccinated with COVID-19 vaccine.<br>□ To evaluate the protective efficacy of stage 2 immunization against different SARS-CoV-2 variants.<br>□ To evaluate the safety of SCTV01E in stage 2 |
| 140 | VERO CELL COVID 19 TRIAL | Phase III | Covid-19 | Inactivated (Vero Cell)/Vaccine | 10th February 2022 | 1. Dr Alberta Amu 2. Dr. Patrick Ansah | 1.Dodowa Health Research Center<br>2.Navrongo Health Research Center | Institute of Medical Biology Chinese Academy of Medical Sciences | 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<br>2.To evaluate the solicited AEs within 7 days after each dose.<br>3.To evaluate the efficacy of SARS-CoV-2 Vaccine, Inactivated (Vero Cell) after at least one dose of immunization.<br>4. To evaluate the efficacy of SARS-CoV-2 Vaccine, Inactivated (Vero Cell)<br>against symptomatic and laboratory-confirmed (RT-PCR method) severe COVID-19 cases.<br>5. To evaluate the efficacy of SARS-CoV-2 Vaccine, Inactivated (Vero Cell) for<br>symptomatic and laboratory confirmed (RT-PCR method) COVID-19 cases caused by different SARS CoV-2 variants. |
| 141 | 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 | 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 |
| 142 | EBOLA Z | II | Ebola | chimpanzee adenovirus Type 3 – vectored Ebola Zaire vaccine (ChAd3-EBO-Z)/Vaccine | Jan-15 | 1.Dr. Kwaku Poku Asante<br>2.Prof. Kwadwo A Koram | 1.Kintampo Health Research Centre<br>2.OCRC, Hohoe | GlaxoSmithKline Biologicals | Application withdrawn N/A | |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 143 | 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 | |
| 144 | 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 | |
| 145 | ZEBOV 2 | II | Ebola | 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 | |
| 146 | HYDRANON | I | | Hydranon solution | 1st March 2008 | Prof. David Ofori-Adjei | Noguchi Memorial Institute For Medical Research | General Resonance Technology 1llc | Application Withdrawn N/A | |
| 147 | SALIF, | IIIb | HIV | 1.TDF/FTC/RPV 2.TDF/FTC/EFV/Vaccine | 4th September 2013 | 1. Dr. Isaac Osei<br>2. Dr. Samuel Abora<br>3. Dr. Fred Adomako – Boateng | Navrongo Health Research Centre<br>Upper East Regional Hospital<br>Kumasi Centre for Collaborative Research | Janssen-Cilag International NV (Sponsor) represented by Clinical Research Africa Ltd. | Application Withdrawn N/A | |
| 148 | NOGUCHI SCD | Ib | Sickle Cell Disea | 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 Pittsburg, Representative: Amma Owusu-Ansah, MD | Application Withdrawn N/A | |
| 149 | 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 goodlaboratoryand clinical performance and high usability within antenatal care (ANC)settings in previous studies.There is a need for further evidenceon 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. |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 150 | 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 | |
| 151 | INO-9112 COVID 19 | Phase I | Covid-19 | 1. INO-4800 followed by Electroporation (EP)<br>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 closed by FDA due to unresponsiveness of applicant, 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. |
| 152 | POST MASTECTOMY PAIN RELIEF | | Anaesthesia | Erector Spinae block using bupivacaine/ Local anasthetics | 2nd December 2021 | Dr. Nana Addo Boateng | Komfo Anokye Teaching Hospital (KATH) | Self-Funding | Application closed by FDA due to unresponsiveness of applicant | General objective:<br>The main objective of the study is to determine the postoperative analgesic effect of Erector Spinae Plane (ESP) Block after mastectomy.<br>Specific objectives:<br>1. To compare the total morphine consumption within 24 postoperative hours between patients<br>receiving ESP block with bupivacaine and ESP block with saline for mastectomy at the Komfo Anokye Teaching Hospital, Kumasi, Ghana.<br>2. 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.<br>3. 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.<br>4. 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. |
| 153 | SMAART-II | Phase III | STROKE | A polycap capsule contains Ramipril 5mg, Atenolol<br>50mg, Hydrochlorothiazide 12.5mg, Simvastatin 20mg, Aspirin 100mg. | 16th August 2023 | Dr. Fred Stephen Sarfo | Komfo Anokye Teaching Hospital (KATH) | University of California, San Francisco | Application closed by FDA | To deploy a hybrid study design to:<br>• firstly, demonstrate the efficacy of a polypill (Polycap ®) containing fixed doses of antihypertensives, a statin, and antiplatelet therapy taken as two capsules, once daily orally in reducing composite vascular risk over 24 months vs. usual care among 680 recent stroke patients encountered at 12 hospitals in Ghana.<br>• Secondly, SMAART II seeks to develop an implementationstrategy for routine integration and policy adoption of Polypill for post-stroke cardiovascular risk reduction in an under-resourced system burdened by suboptimal care and outcomes. |
| 154 | LETICIA | Phase II | Aneamia | 1.LETICIA protocol diet (provided by study)<br>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 | Application closed by FDA since Sponsor/PI failed to start study after approval. | 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. |
| 155 | TENOFOVEK BE I | Bioequivalence | | 1.Tenofovek (tenofovir) 300mg film coated tablets 2.Viread (tenofovir) 300mg/Allopathic | 11th September 2015 | 1. Prof. Seth Owusu Agyei<br>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. | |
| 156 | ELDON CARD NYN | Feasibility stu | 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.<br>N/A | |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 157 | AX-100 HIVI | | HIV | 1.AX-100Immun 2.AX-100ImmunPlus | 9th december 2014 | Dr. Kwaku Poku Asante | Kintampo Health Research Centre | Neopharmacie Limited , Germany | Incomplete CTA; Application closed by FDA.<br>N/A | |
| 158 | 4P | III | Pregnancy Induced Hypertension and Preeclampsia | Polypil/Allopathic | 9th August 2013 | 1. Dr. Emmanuel Kwabla Srofenyoh<br>2. Dr. Patrick Frimpong | Ridge Hospital Accra<br>La General Hospital | Julius Centre for Health Sciences and Primary Care, University Medical Centre Utrecht, The Netherlands | Incomplete CTA; Application closed by FDA.<br>N/A | |
| 159 | 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.<br>N/A | |
| 160 | INSUGENIV | Phase IV | Diabetes | Insugen/Hormone | 17th december 2013 | N/A | Korle-Bu Teaching Hospital | BIOCON LTD | Incomplete CTA; Application closed by FDA.<br>N/A | |
| 161 | AIM-LVRNA009 | Phase II/III | Covid-19 | 1. SARS-CoV-2 mRNA vaccine (LVR<br>2. Saline Placebo/Vaccine | 21st June 2022 | Dr. Patrick Odum Ansah | 1. Navrongo Health Research Centre<br>2. Kumasi Centre for Collaborative Research 3.Dodowa Health Research Centre 4. Kintampo Health Research Centre<br>5. Ghana Infectious Disease Centre 6. Korle Bu Teaching Hospital (KBTH) | AIM Vaccine Co. Ltd, | Not Approved,17-24 months. | Primary efficacy objective:<br>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 |
| 162 | MYCOPIROX_LAGRAY | Phase IV | mixed Infection Vaginitis in Females | Mycopirox Vaginal cream | 15th june 2010 | Dr. Luitgard Darko | | Lagray Chemical Company, Ltd. | Not Approved<br>N/A | |
| 163 | TNBC STUDY | Phase IIa | Breast Cancer | Tobemstomig, Nab-Paclitaxel, Pembrolizumab<br>Monoclonal Antibody | 28th December 2023 | Dr. Hannah Naa Gogwe Ayettey Anie | Korle-Bu Teaching Hospital | F. Hoffmann-La Roche Ltd | Study terminated by sponsor, 18 months | Primary Objective:<br>□ To evaluate the efficacy of tobemstomig plus nab-paclitaxel compared with pembrolizumab plus nab-paclitaxel in the FAS<br>Secondary Objective:<br>□ To evaluate the efficacy of tobemstomig plus nab-paclitaxel compared with pembrolizumab plus nab-paclitaxel in the FAS<br>□ To evaluate the efficacy of tobemstomig plus nab-paclitaxel compared with pembrolizumab plus nab-paclitaxel in SP263-positive analysis set and 22C3-positive analysis set and SP142-positive analysis set<br>□ To evaluate the safety of tobemstomig plus nab-paclitaxel compared with pembrolizumab plus nab-paclitaxel in the SAS<br>□ To characterize the tobemstomig PK profile<br>□ To evaluate the immunogenicity to tobemstomig |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 164 | 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., | Study terminated by the sponsor 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). |
| 165 | ANTIPSYCHOTIC STUDY | Phase IV | Antipsychotic Induced Movement Disoders | Omega 3 Fish Oil<br>Food supplement<br>Oral | 15th December 2021 | Debrah Akosua Bema | Accra Psychiatric Hospital | Dr. Sammy Ohene. P. O. Box KB 77 Korle-Bu | Study terminated by sponsor, 29 Weeks | 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. Secondary:<br>To determine the demographic and clinical characteristics of psychiatric patients with antipsychotic induced movement disorder.<br>To determine the efficacy of omega 3 supplementation in relieving the symptoms of AIM disorders<br>To evaluate the impact of omega 3 supplementation on the clinical outcomes of psychosis, cognitive function and quality of life/ adherence of participants.<br>To determine the correlations between the demographic and clinical parameters and the outcomes of therapy<br>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 |
| 166 | STAND | Phase III | Sickle Cell Disease | 1.CRIZANLIZUMAB<br>2.PLACEBO/ Monoclonal antibody | 30th September, 2019 | 1.Dr. Yvonne Dei Adomakoh<br>2.Dr. Vivian Paintsil | 1. Ghana Institute of Clinical Genetics, Korle-Bu<br>Sickle Cell Office Directorate of Child Health, | Novartis Pharma AG | Study terminated by FDA. Yet to submit the final re[port.<br>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 it interactions with its ligands.<br>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. |
| 167 | ANTiCOV | Phase III | Covid-19 | Nitazoxanide, Ciclesonide, Paracetamol, Ivermectin, Artesunate Amodiaquine (ASAQ)<br>Allopathic drug<br>Oral | 15th July, 2020 | John Humphrey, AMUASI | Komfo Anokye Teaching Hospital | •Bernhard Nocht Institute for Tropical Medicine | Study terminated by sponsor yet to submit Final report ,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.. |
| 168 | COVID 19 CHO-CELL(TERMINATED) | Phase II/III | Covid-19 | 1.Recombinant two-component COVID-19 vaccine (CHO cell)<br>2. ReCOV Placebo/Vaccine | 16th November 2021 | Dr. Patrick Ansah | 1. Dodowa Health Research Centre<br>2. Navorongo 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.<br>2. To evaluate SARS-CoV-2 neutralizing antibody of ReCOV on Day 14 after 2 doses vaccination in adults aged 18 years and older.<br>3. To evaluate the efficacy of ReCOV in preventing RT-PCR confirmed symptomatic COVID-19 in adults aged 18 years and older.<br>4. To evaluate the safety and reactogenicity of ReCOV in adults aged 18 years and older. |
| 167 | MoRiOn | Phas II | Onchocerciasis | 1.Rifanpentine (Priftin®) 2.Moxifloxacin (Avelox®) 3.Doxycycline/Vaccine | 28th April, 2017 | Prof. Alexander Yaw Debrah | 1.Enchi Government Hospital<br>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 Rifapentine plus Moxiflocaxin using immunohistology compared to no treatment and treatment with Doxycycline. |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 168 | COVID-19 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. |
| 169 | IMR-SCD | Phase IIb | Sickle Cell Disease | 1.IMR-687 2.IMR-687 Placebo/Allopathic | 13th August 2020 | 1. Dr. Seyram Kaali 2. Dr. Olayemi Edeghongon | •Korle-Bu Teaching Hospital •Kintampo Health Research Centre | IMARA Inc. | Early termination by Sponsor 1 Year 7 Months | This is a phase 2b, randomized, double-blind, placebo-controlled, multicenter 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 (Hbbth1/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 60 mg/kg improved erythroblast differentiation, suggesting a role for this compound in the improvement of ineffective erythropoiesis, a problem in a number of hemoglobin disorders |
| 170 | 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. |
| 171 | TADO | III | Sickle Cell Disease in Pediatrics | Prasugrel/Allopathic | 20th may 2013 | Prof. Tsiri Agbenyega Dr. Catherine Idara Segbefia | Malaria Research Center, Agogo Korle-Bu Teaching Hospital, Accra – Korle Bu | Eli Lilly and Company Indianapolis | Prematurely terminated 24 months | |
| 172 | WOMAN | III | Postpartum Hemorrhage | Tranexamic acid(cyklokapronr injection)/ Allopathic | 10th sept 2009 | 2. Dr.Opare Addo Henry Sakyi 3. Dr. Kwadwo Asamoah Nyarko-Jectey 4. Dr. Chris Opoku Fofie 5. Dr. Chris Bawa | 1. Ashanti Mampong Municipal Hospital 2.Komfo Anokye Teaching Hospital | Clinical Trials Unit, London School of Hygiene and Tropical Medicine | Terminated by Sponsor Prematurely ended. | |
| 173 | NEOVITA | III | | Vitamin A | | Dr. Sam Newton | Kintampo Health Research Centre | PATH | Premature Termination 36 Months | |
| 174 | PROBIOTIC (MILD COGNITIVE IMPAIRMENT) | Phase I | Mild cognitive impairment | Probiotic (Lactobacillus reuteri) Food supplement Oral | 14th April 2023 | Michael Quansah | Korle-Bu Teaching Hospital (KBTH) | Western Sydney University, Australia | Application Approved, 6 Months | Aim To determine the therapeutic effects of probiotics in mild cognitively impaired individuals (MCI) at Korle-Bu Teaching Hospital. Specific objectives • 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. |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 175 | 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 | |
| 176 | HOHOE ANTIMALARIAL | III | Malaria | 1.Dihydroartemisinin 2.Piperaquine oral tablets 3.Artesunate 4. Sulfamethoxypyrazine. 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 | |
| 177 | YAWS | III | Yaws | Azithromycin ,Injection Benzathine Penicillin Allopathic Drug Oral | | Dr. Cynthia Kwakye-Maclean | Ga West District | 1. University of Ghana School of Public Health 2. World Health Organization 3. Ghana Health Service, Ga | 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 | |
| 178 | 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 | |
| 179 | CEREBETA | | Cholesterol concentration | Barley beta glucan Food supplement Oral | 13th may 2016 | Mrs. Rose T. Odotei Adjei | Suntreso Government hospital | Best Environmental Technologies | FDA DISSOCIATED itself from any data Findings N/A | |
| 180 | AQUAMAT | III | Malaria | Artesunate, Quinine Allopathic | 10th october 2012 | Prof. Tsiri Agbenyega | Komfo Anokye Teaching Hospital | WORLD HEALTH ORGANIZATIO N | FDA DISSOCIATED itself from any data Findings | |
| 181 | AZI4YAWS | III | Yaws | Azythromycin Allopathic | 23rd April 2015 | Prof. Adu Sarkodie | 2. West Akyem Municipality 3. Upper West Akyem 4. Nkwanta North District | World Health Organization, Geneva - Switzerland | any data or findings from the study due to violation of its guidelines for conducting clinical trials. | |

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 |
| 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 | ALBIVM | Comparison of Ivermectin alone with Albendazole (ALB) plus Ivermectin (IVM) in their efficacy against Onchocerciasis in the Volta Region, Ghana. |

# CLINICAL TRIALS REGISTRY

| | | |
|---|---|---|
| 7 | ALBIVM K'SI | Comparism 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 | AMINO ACID SUPPLEMENTATION | The Efficacy of Amino Acid Supplementation in Treating Environmental Enteric Dysfunction among Children at Risk of Malnutrition; A Randomized Controlled Trial |
| 10 | 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 |
| 11 | ANTIPSYCHOTIC STUDY | A RANDOMIZED CONTROLLED TRIAL OF OMEGA-3 FATTY ACIDS IN THE TREATMENT OF ANTIPSYCHOTIC-INDUCED MOVEMENT DISORDERS IN GHANA |
| 12 | AQUAMAT | An Open Randomized Comparism of Artesunate versus Quinine in the Treatment of Severe Falciparum Malaria in African Children. |
| 13 | 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 |
| 14 | ASAAP | A Multicentre Phase III Non-Inferiority Trial to Evaluate Safety, Tolerability and Efficacy of Artemether-Lumefantrine+Atovaquone-Proguanil Tri-Therapy Versus Artemether-Lumefantrine Bi-Therapy for the Treatment of Uncomplicated Malaria in African Children Aged 6 Months To 10 Years (ASAAP PROJECT) |
| 15 | 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 |
| 16 | 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 |
| 17 | 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. |
| 18 | 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. |
| 19 | AZIDUS ACECLOFENAC | An open label, balanced, randomized, two treatments, two periods, two sequences, single dose, crossover, relative bioavailability study of two different formulations of Aceclofenac tablets 100 mg (T1 & T2) of OA&J Pharmaceuticals Ltd, Ghana in healthy adult human subjects under fasting condition |
| 20 | AZIDUS BUPRENORPHINE | An open label, balanced, randomized, two treatments, two periods, two sequences, single dose, crossover, bioequivalence study of Buprenorphine 16 mg Sublingual tablets of Wes Pharma Inc and Buprenorphine hydrochloride 8 mg (8 mg x 2 tablets) sublingual tablets of Hikma Pharmaceuticals USA Inc in healthy adult human subjects under fasting condition |
| 21 | AZIDUS CEFUROXIME | An open label, balanced, randomized, two treatments, two periods, two sequences, single dose, crossover, bioequivalence study of Cefuroxime Axetil 500 mg Tablets of OA&J Pharmaceuticals Ltd, Ghana and Zinnat (Cefuroxime Axetil) 500 mg film-coated tablets of GlaxoSmithKline UK in healthy adult human subjects under fed condition |
| 22 | AZI4YAWS | Randomized Controlled Trial Comparing Efficacy of a Single Dose of Treatment of Yaws with 20mg/kg versus 30mg/kg of Azithromycin. |
| 23 | AZITHROMYCIN PLUS CHLOROQUINE PHOSPHATE | Azithromycin Plus Chloroquine Phosphate versus Artemether-Lumefatrine for the Treatment of Uncomplicated Plasmodium falciparium Malaria in Children in Africa. |
| 24 | BEMPU | Hypothermia Prevention in low birth weight and preterm Infants |
| 25 | BILI-RULER | Improving community-based diagnosis of neonatal jaundice using a simple icterometer: The Bili-Ruler Study |
| 26 | BLMs4BU | SHORTENING BURULI ULCER TREATMENT: WHO RECOMMENDED VS. A NOVEL BETA-LACTAM-CONTAINING THERAPY – PHASE III EVALUATION INWEST AFRICA |
| 27 | BURULINOX | Evaluation of nitric oxide generating dressing (EDX) to improve management of buruli ulcer disease – a prospective randomized open-blinded end point. |
| 28 | 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

| | | |
|---|---|---|
| 29 | 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. |
| 30 | 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. |
| 31 | CEREBETA | Efficacy of Beta-Glucans from Barley and Maintenance of Normal Blood LDL-Cholesterol Concentrations: A Randomized Control Study in Ghana. |
| 32 | CPAP | Clinical Trial Evaluating the Difference in Mortality Rates in Children in Ghana Receiving Continuous Positive Airway Pressure (CPAP) Versus Those Who Do Not. |
| 33 | 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 |
| 34 | CALLASCOPE | Clinical Studies and in-Depth Interviews for Portable, low-cost and Speculum-Free Cervical Cancer Screening in Ghana |
| 35 | 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 |
| 36 | CEPHEIDXPERT HIV-1 | An Investigation to Evaluate the Performance of the Cepheid XpertR HIV-1 VL XC Test |
| 37 | 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 |
| 38 | 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 |
| 39 | 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). |
| 40 | 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 |
| 41 | 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) |
| 42 | 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 |
| 43 | 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 (DelNS1-2019-nCoV-RBD-OPT1) in Adults Aged 18 Years and Older |
| 44 | COVID 19 MOUTHWASH | Viral Shedding Dynamics and the Effect of Antimicrobial Mouthwashes on the Detection of SARS-CoV-2 in Ghana. |
| 45 | 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. |
| 46 | DOLF_IDA | Safety and Efficacy of Combination Therapy with Ivermectin, Diethylcarbamazine and Albendazole (IDA) for Individuals with Onchocerciasis |
| 47 | DRAGON | Multicentre non-inferiority cluster randomised trial testing Disposable versus Reusable drApes and Gowns for green operating theatres |
| 48 | EBA | Double-Blinded, Placebo-Controlled Dosage-Escalation Study and Immunogenicity of EBA-175 RII-NG Malaria Vaccine Administered Intramuscularly in Semi Immune Adults |
| 49 | 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 |
| 50 | 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 |
| 51 | 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 |
| 52 | 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 |
| 53 | EMODEPSIDE | A phase II, Randomised, double-blind, parallel – group trial to investigate Emodepside (BAY 44-4400) in subjects with onchocerca volvulus infection. |
| 54 | ESM UBT | A Multi-Centre Prospective Trial on the Impact of the Introduction of Condom-Based Uterine Balloon Tamponade for Uncontrolled Postpartum Hemorrhage |
| 55 | FALCON | Pragmatic Multicentre Factorial Randomized Controlled Trial Testing Measures to Reduce Surgical Site Infection in Low and Middle Income Countries |
| 56 | 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 |
| 57 | FITBIT/XIAOMI | Feasibility of a wireless monitoring system as an alternative to current bedside monitors |
| 58 | FORTIFIED BUILLON 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 |
| 59 | GARDASIL | Evaluation of Safety And Immunogenicity Of Gardasiltm In Healthy Females Between 9 And 26 Years Of Age In Subsaharan Africa |
| 60 | GBT021601-021 | A Phase 2/3 Randomized, Multicenter Study of Osivelotor Administered Orally to Participants with Sickle Cell Disease and an Open-Label Pharmacokinetics Study in PediatricParticipants with Sickle Cell Disease |
| 61 | GBT 2104-131 | A Randomized, Double-blind, Placebo-controlled, Multicenter Study to Assess the Safety and Efficacy of Inclacumab in Participants with Sickle Cell Disease Experiencing Vasoocclusive Crises. |
| 62 | GBT-2104-132 | A Randomized, Double-blind, Placebo-controlled, Multicenter Study of a Single Dose of Inclacumab to Reduce Re-admission in Participants with Sickle Cell Disease and Recurrent Vaso-occlusive Crises |
| 63 | GBT-2104-133 | An Open-Label Extension Study to Evaluate the Long-Term Safety of Inclacumab Administered to Participants with Sickle Cell Disease Who Have Participated in an Inclacumab Clinical Trial. |
| 64 | GBT440-038 | An Open-Label Extension Study of Voxelotor Administered Orally to Participants with Sickle Cell Disease Who Have Participated inVoxelotor Clinical Trials |
| 65 | GMZ 2 | Randomized, Controlled, Double-Blind, Multicentre Study To Evaluate The Efficacy, Safety And Immunogenicity Of GMZ2 Candidate Malaria Vaccine In Gabonese, Burkinabe, Ghanaian And Ugandan Children Aged 12-60 Months |

# CLINICAL TRIALS REGISTRY

| | | |
|---|---|---|
| 66 | HIBISCUS | A global phase 3, randomised, double-blind and placebo-controlled study evaluating the efficacy and safety of etavopivat in adolescents and adults with sickle cell disease |
| 67 | HESTIA4 | A Multi-centre, Phase I, Open-label, Single-dose Study to Investigate Pharmacokinetics (PK) of Ticagrelor in Infants and Toddlers, Aged 0 to less than 24 Months, with Sickle Cell Disease |
| 68 | HESTIA3 | A Randomised, Double-Blind, Parallel-Group, Multicentre, Phase III Study to Evaluate the Effect of Ticagrelor versus Placebo in Reducing the Rate of Vaso-Occlusive Crises in Paediatric Patients with Sickle Cell Disease |
| 69 | HOHOE ANTIMALARIAL | A Phase III of the Assessment of the Efficacy, Tolerability and Ease of Administration of, Dihydroartemisinin Plus Piperaquine and and Artesunate Plus Sulfamethoxypyrazine Plus Pyrimethamine for preventing Malaria in Ghanaian Children |
| 70 | HOPE SCD | A Phase 3, Double-blind, Randomized, Placebo-controlled, Multicenter Study of GBT440 Administered Orally to Patients With Sickle Cell Disease |
| 71 | HOPE KIDS 2 | A phase 3,Randomised,Double-Blind, Placebo-Controlled Study of Voxelotor(GBT440) in Pediatric Participants with Sickle Cell Disease. |
| 72 | HYDRANON | Hydranon® solution (GR-08) in healthy adult volunteers |
| 73 | IAVI C105 | A Phase 2 Randomized, Double-Blinded, Placebo-Controlled Clinical Trial to Evaluate the Safety, Tolerability, and Immunogenicity of rVSVΔG-LASV-GPC Vaccine in Adults and Children Residing in West Africa |
| 74 | IMBRAVE 152 | A phase III, randomized, double-blind, placebo-controlled, study evaluating Atezolizumab and Bevacizumab, with or without Tiragolumab, in patients with untreated locally advanced or Metastatic Hepatocellular Carcinoma |
| 75 | IMR-SCD-301 | A Phase 2b Study to Evaluate the Safety and Efficacy of IMR-687 in Subjects with Sickle Cell Disease |
| 76 | INNOVATE | Phase 2/3 Randomized, Blinded, Placebo-Controlled Trial to Evaluate the Safety, Immunogenicity, and Efficacy of INO-4800, a Prophylactic Vaccine against COVID-19 Disease, Administered Intradermally Followed by Electroporation in Adults at High Risk of SARS-CoV-2 Exposure |
| 77 | INO-9112 COVID 19 | Phase 1 Open Label, Randomized Study to Evaluate the Safety, Tolerability, and Immunogenicity of an Intradermal Booster Dose of INO-4800 alone or in combination with INO-9112 followed by Electroporation in Adults who Completed a Primary Immunization Series Against SARS-CoV-2 with mRNA Vaccines |
| 78 | INVACT | In Vivo Efficacy of Artemisinin Combination Therapy to Explore Laboratory and Parasitological Markers of Artemisinin Resistance in Uncomplicated Plasmodium falciparum Malaria in Ghana. |
| 79 | IPT & SP | Operational Research on Intermittent Preventive Treatment of Malaria in Infants (IPTi) with Sulfadoxine/Pyrimethamine (S/P) |
| 80 | INSUGEN | Post Market Surveillance Study of Insugen 30/70 |
| 81 | INTS GMMA | A Phase IIa observer-blind, randomized, controlled, age-de-escalation, single center interventional study to evaluate the safety, reactogenicity, and immune response of the GVGH iNTS vaccine against S. Typhimurium and S. Enteritidis, in adults, children andinfants, |
| 82 | INOVIO – LASSA FEVER | Study to evaluate the safety, tolerability and immunogenicity of INO-4500 in Healthy volunteers |
| 83 | IRON FORTIFICATION | Seasonal Impact Of Iron Fortification On Malaria Incidence In Ghanaian Children |
| 84 | IUMO | RANDOMISED CONTROLLED TRIAL: INTRAUTERINE MISOPROSTOL VERSUS SUBLINGUAL MISOPROSTOL IN THE PREVENTION OF POSTPARTUM HEMORRHAGE AT ELECTIVE CAESAREAN SECTION AT KORLE BU TEACHING HOSPITAL. |
| 85 | IVERMECTIN GH | Safety and Efficacy of Ivermectin in the Prevention and Management of COVID- 19 among Ghanaian Populations |

# CLINICAL TRIALS REGISTRY

| | | |
|---|---|---|
| 86 | 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 |
| 87 | KALUMA | A randomized, open-label, multicenter study to compare efficacy, safety and tolerability of KLU156 with Coartem® in the treatment of uncomplicated Plasmodium falciparum malaria in adults and children ≥ 5 kg body weight followed by an Extension phase with repeated KLU156 treatment |
| 88 | KNC 19(NIBIMA) | Repurposing the aqueous Extract of Cryptolepis for Covid-19 therapy |
| 89 | LEDoxy | Doxycycline 200mg/d vs. 100mg/d for 6 weeks to improve filarial lymphedema - a multinational, double-blind, randomized, placebo-controlled trial. |
| 90 | 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 |
| 91 | 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. |
| 92 | 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. |
| 93 | MAL 050 | Randomized, Open, Controlled Study Of The Safety Of The And Immunogenicity Of GSK Biologicals' Candidate Plasmodium Falciparium 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 |
| 94 | 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. Falciparium Infection Across Diverse Malaria Transmission Settings In Africa |
| 95 | 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 |
| 96 | MAL 073 | Phase IIIb 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 |
| 97 | 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. |
| 98 | MALHELMINTHS | Evaluating the effectiveness and cost-effectiveness of integrating mass drugadministration for helminth control with seasonal malaria chemoprevention inGhanaian children |
| 99 | 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 |
| 100 | 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. |
| 101 | MEFLOQCHLOAZITH | A Phase III, Randomized, Opened-Label, Comparative Trial Of Azithromycin Plus Chloroquine Versus Mefloquine For The Treatment Of Uncomplicated Plasmodium Falciparum Malaria In Africa. |
| 102 | MENINGOCOCCAL-A CONJUGATE VACCINE | 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. |
| 103 | MICRONUTRIENT SUPPLEMENTATION | The effect of micronutrient supplementation in combination with healthy lifestyle coaching on nutrition status and well-being: A 6-month intervention study in Ghana. (MICRONUTRIENT SUPPLEMENTATION) |
| 104 | MITAPIVAT | A Phase 2/3, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Mitapivat in Subjects With Sickle Cell Disease. |
| 105 | MMS | The Use Of A Multiple Micronutrient Supplement In Women Of Reproductive Age |
| 106 | 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 |
| 107 | MOSA STUDY | A phase III, multi-country, randomized, placebo-controlled, double-blinded adaptive platform trial to assess the efficacy and safety of treatments for subjects with monkeypox virus disease |
| 108 | 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 |
| 109 | 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': |
| 110 | MPZ-MAL 01 | A Phase 2a, Multicenter, Open-label, Dose-finding, Dose Escalation Study of Meplazumab in Adult Patients Diagnosed with Uncomplicated Plasmodium falciparum Malaria |
| 111 | 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 |
| 112 | MYCOPIROX_LAGRAY | Randomized, open labelled trial to evaluate the efficacy, safety and tolerability of mycopirox vaginal cream in the treatment of mixed infection vaginitis |
| 113 | NANOX.ARC | Multicentric study for assessing safety and clinical performance of Nanox.ARC in providing additional information to conventional twodimensional (2D) radiography when evaluating adult individuals with known or suspected radiographic abnormalities |
| 114 | NEOSEP 1 | An open-label randomized controlled trial comparing novel combination and currently used antibiotic regimens for the empiric treatment of neonatal sepsis with a run-in confirmatory pharmacokinetic phase (NEOSEP 1) |
| 115 | NEOVITA | Feasibility Studies |
| 116 | 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 |
| 117 | NOGUCHI SCD | A Phase 1B Dose – Finding Pharmacokinetics and Pharmacodynamic Study Oof NVX – 508 In Sickle Cell Disease (SCD) Patients |
| 118 | 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 |

# CLINICAL TRIALS REGISTRY

| | | |
|---|---|---|
| 119 | NOVASIL | Safety and Efficacy Evaluation of Novasil: Strategy for the Protection of Humans from Aflatoxin Toxicity |
| 120 | NOVIC TRIAL | Novel vacuum-induced Haemorrhage control for postpartum Haemorrhage: a multicentre randomised trial |
| 121 | OXYTOCIN | Determining the Effect of Prophylactic Administration Of Oxytocin In Uniject™ By A Community Health Officer On Post-Partum Haemorrage At Home Births In The Kintampo North And South Districts Of Ghana |
| 122 | PEARL | Phase III, randomized, observer-blind, placebo-controlled, multi-center, multinational study to evaluate the efficacy, immunogenicity, and safety of a Respiratory Syncytial Virus vaccine in infants and toddlers (PEARL) |
| 123 | PFCSP_MVACS_MALARIA | Partial Double-Blind, Randomized Study of PFCSP DNA/MVA Prime Boost Vaccine |
| 124 | PIVOT | Prospective Identification of Variables as Outcomes for Treatment (PIVOT): A Phase II clinical trial of hydroxyurea for children and adults with HbSC disease |
| 125 | POLYPHENOL-RICH COCOA POWDER TRIAL | Polyphenol-rich Cocoa Powder as Adjuvant Therapy in Patients with Covid-19. |
| 126 | POST MASTECTOMY PAIN RELIEF | ULTRASOUND-GUIDED ERECTOR SPINAE PLANE BLOCK FOR POST-MASTECTOMY PAIN RELIEFve |
| 127 | PLATINUM | : A multi-part, multi-center PLATform study to assess the efficacy, safety, tolerability and pharmacokinetics of anti-malarial agents administered asmonotherapy and/or combination therapy IN patients withUncomplicated Plasmodium falciparum Malaria |
| 128 | PMC-RTSS SUBSTUDY | Characterization of the Impact of Combining Perennial Malaria Chemoprevention with RTS,S/AS01E Malaria Vaccination on Vaccine Induced and Naturally Acquired Immunity to Malaria. |
| 129 | PMC TRIAL | The impact of a combination of the RTS,S/AS01E malaria vaccine and perennial malaria chemoprevention in Ghanaian children |
| 130 | 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) |
| 131 | PREGACT | Evaluating the Safety And Efficacy Of Artemisinin-Based Combination Treatments For African Pregnant Women With Malaria |
| 132 | PRENABELT | A Maternal Device to Reduce the Risk of Stillbirth and Low-Birth Weight |
| 133 | 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) |
| 134 | PROBIOTIC(IN MILD COGNITIVE IMPAIRMENT) | Assessing the Therapeutic Effect of Probiotics on Individuals with Mild Cognitive Impairment |
| 135 | PROFUSA | Continuous monitoring of Tissue Oxygen in Septic Patients using an injectable Biosensor |
| 136 | PYRONARIDINE 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 falciparium malaria |
| 137 | PRCR DIPSTICK | Validation of a Protein Creatinine (PrCr) Dipstick Diagnostic Test for Proteinuria Screening on Antenatal Care Clinics in Ghana |
| 138 | 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 |
| 139 | REALISE | A Pragmatic Phase III Multi-Centre Clinical Trial to Evaluate the Safety and Effectiveness of a Single Dose of an Albendazole-Ivermectin Coformulation vs Albendazole for Preventive Chemotherapy of Soil-Transmitted Helminth Infections in School-Aged Children |
| 140 | RECOVERY | Randomized Evaluation of Covid-19 Therapy (RECOVERY) |
| 141 | REVIVE | Reducing Mortality in Adults with Advanced HIV Disease (REVIVE) |
| 142 | RIFAMPIN VS ISONIAZID | A Randomized Clinical Trial of 4 months Rifampin versus 9 months Isoniazid for treating Latent TB Infection |
| 143 | ROBOCOW | RANDOMIZED PLACEBO-CONTROLLED TRIAL TESTING 0.2% CHLORHEXIDINE MOUTHWASH TO REDUCE POSTOPERATIVE RESPIRATORY TRACT INFECTIONS IN ABDOMINAL SURGERIES |
| 144 | ROTARIX | Immunogenicity of The Human Rotavirus Vaccine (Rotarixtm) At Varying Schedules and Ages in Rural Ghana |
| 145 | ROTASHIELD | The Randomized, Double-Blind, Placebo-Controlled Evaluation of The Efficacy, Immunogenicity, and Safety of 2 Single Doses of RRV-TV in Neonates/Infants |
| 146 | ROTATEQ | Efficacy, Safety and Immunogenicity of RotateqTM Among Infants in Africa and Asia. |
| 147 | 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/EFVin First-line Antiretroviral NNRT/-based Suppressed Patients Switching At Low HIV-1 RNA Into Fixed Dose Combinations |
| 148 | SAR97276A_SANOFI | A Multicentre, Open Label, Efficacy And Safety Of Parenteral Sar97276a In The Treatment Of Symptomatic Uncomplicated And Severe Malaria In Adults And Children |
| 149 | SAVVY | Randomised Controlled Trials of Savvy In HIV |
| 150 | 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 |

# CLINICAL TRIALS REGISTRY

| | | |
|---|---|---|
| 151 | 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 |
| 152 | SD BIOSENSOR MRDT | Clinical Evaluation of Malaria Rapid Diagnostic Test Kits (SD BIOSENSOR MRDT) |
| 153 | SEMIGLUTIDE | A single period study to evaluate the bioavailability of Semaglutide sublingual tablets 1 mgof GFC Pharma LLC in healthy, adult, human subjects under fasting condition. |
| 154 | SHEA LIDO | Comparison of Shea butter and Lidocaine gel for rectal examination- A Non-Inferiority Trial |
| 155 | SHINE-1 | A Phase III observer-blind, randomized, multinational trial to evaluate safety and immunogenicity of Recombinant Human Papillomavirus 9-valent (Types 6/11/16/18/31/33/45/52/58) Vaccine (Escherichia Coli) compared to GARDASIL®9 in a single-dose regimen in healthy girls and young women in Ghana and the Philippines |
| 156 | SMAC | A Comparative, Open Label, Dose And Regimen Optimization Follow-Up Study Of Intravenous And Intramuscular Artesunate In African Children With Severe Malaria. |
| 157 | SMAART | Stroke Minimization through Additive Anti-atherosclerotic Agents in Routine Treatment |
| 158 | SMAART-II | Stroke Minimization through Additive Antiatherosclerotic agents in Routine Treatment II (SMAART-II): A Phase 3 Randomized Clinical Tria |
| 159 | SMAART MAP | Severe Malaria A Research and Trials Consortium – Multisite Adaptive Platform trial: Severe Anemia, Cerebral Malaria and Renal Function Domains |
| 160 | SOYPEPTIDE STUDY | Application of Bioactive Peptide for the Attenuation of Malnutrition in Cancer Patient in a treatment Health Facility in Ghana |
| 161 | SPUTNIK LIGHT | A phase III randomzed 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 |
| 162 | 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) |
| 163 | STAR | POSTOPERATIVE PAIN MANAGEMENT IN EMERGENCY ABDOMINAL SURGERY: BIMODAL VERSUS UNIMODAL ANALGESIA |
| 164 | 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 |
| 165 | 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 |
| 166 | TADO | Double-Blind, Randomized, Efficacy And Safety Comparison Of Prasugrel And Placebo In Pediatric Patients With Sickle Cell Disease |
| 167 | TAKE OFF T&T | Comparing the effectiveness of test and treat approaches with doxycycline or moxidectin plus albendazole versus mass drug administration with Ivermectin plus albendazole for targeted elimination of lymphatic filariasis in Ghana and Tanzania - a phase III clinical trial |
| 168 | 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; Tenofevek 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. |
| 169 | TENOFOVIR | A Phase II Study for Tenofovir Disoproxyl Fumarate for Prevention of HIV |
| 170 | TICER | Task sharing in InGuinal hErnia Repair between surgeons and medical practitioners |
| 171 | TNBC | A Phase II, Multicenter, Randomized, Double-blind Study of RO7247669 Combined With NAB-Paclitaxel Compared with Pembrolizumab Combined With NAB-Paclitaxel in Participants with Previously Untreated, PD-L1 Positive, Locally-advanced Unresectable or Metastatic Triple-negative Breast Cancer. |
| 172 | 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)": |
| 173 | URIB-PAP | Validation of a device for a Urine-based Human Papilloma Virus (HPV) Screening at the Korle Bu Teaching Hospital |
| 174 | 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 |
| 175 | VERO CELL COVID 19 TRIAL | 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 |
| 176 | VR-AD-1005 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 |
| 177 | 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. |
| 178 | WOMAN | Tranexamic Acid For The Treatment Of Postpartum Haemorrhage: An International, Randomized, Double Blind, Placebo Controlled Trial |
| 179 | YAWS | Single Dose Oral Azithromycin Versus Injection Benzathine Penicillin For The Treatment Of Yaws – A Randomized Clinical Trial In Some Endemic Communities In Ghana |
| 180 | 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 |
| 181 | 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 Subjects, HIV-infected |
| 182 | ZERO POINT FIVE | A Phase 3, multi-center, prospective, randomized, double-blind, placebo- controlled study to evaluate the effectiveness and safety of ZP5-9676 for the treatment of Hookworm (Ancylostoma duodenale and Necator americanus), Ascaris lumbricoides, and Trichuris trichiura in pediatric and adult Participants |
| 183 | ZIV AFFLIBERCEPT | Phase I, Safety of ZIV-AFLIBERCEPT in retinal diseases in Ghanaian population |
| 184 | * | Feasibility Studies |
| 185 | N/A | Study not Started/ Application Withdrawn /Not Approved / Terminated / FDA Dissociation from Trial data |
| 186 | NYN | Not yet known |
| 187 | Active Trials | |

# CLINICAL TRIALS REGISTRY

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 188 | Applications pending approval | | | | | | | | | |
| 189 | Study ended | | | | | | | | | |
| 190 | Trials closed by Sponsor before commencement | | | | | | | | | |
| 191 | Application withdrawn by Sponsor before FDA approval | | | | | | | | | |
| 192 | Application closed by FDA due to inability to respond to outstanding issues | | | | | | | | | |
| 193 | Trials Not Approved | | | | | | | | | |
| 194 | Trials terminated by FDA/Sponsor due to safety issues | | | | | | | | | |
| 195 | Dissociation of Trial Data by FDA | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | LAST UPDATED:7TH FEBRUARY 2025 | | | | | | | | | |