|            |                       |              |                         | Investigational   |                                    |   |   |   |   |   |
|------------|-----------------------|--------------|-------------------------|---|------------------------------------|---|---|---|---|---|
|            | TITLE OF<br>STUDY     | PHASE        | DISEASE<br>INDICATION   |   | ,DATE OF RECEIPT OF<br>APPLICATION |   |   |   | STATUS & DURATION OF<br>STUDY             |   |
| <u>N/O</u> | CIELO Trial           | Phase III    | Encephalitis            | CLASS<br>Satralizumab/<br>Monoclonal<br>antibody  | 20th December 2022                 | INVESTIGATOR<br>Prof. Fred Stephen Sarfo            | STUDY CENTRE(S)<br>Komfo Anokye<br>Teaching Hospital<br>(KATH)                                      | F-Hoffman LA<br>Roche/ Chugai<br>Pharma Co. | Application Approved<br>5years 5months    | PURPOSE/AIM OF STUDY         This study will evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of satralizumab compared with placebo in each of the following cohorts:         •NMDAR autoimmune encephalitis (AIE) cohort: adults and adolescents with definite or probable NMDAR encephalitis         •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. |
| 2          | IUMO STUDY            | Phase IV     | Postpartum<br>Hemorhage | Intrauterine<br>Misoprostol and<br>Sublingual<br>Misoprostol/<br>Allopathic<br>medicine | 27th May 2023                      | Dr. Chidinma Peace<br>Ohachenu                      | Department of<br>Obstetrics and<br>Gynaecology, Korle-<br>Bu Teaching<br>Hospital, Accra-<br>Ghana. |   | Application Approved, 4<br>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  |
| 3          | ROBOCOW               | Phase II     |                         | 0.2%<br>Chlorhexidine<br>Digliconate/<br>Mouthwash                                      | 10th January 2023                  | Dr. Mohammed Sheriff                                | Tamale Teaching<br>Hospital   |   | Application Approved<br>5 Months          | Primary Objective1.To determine whether perioperative use of 0.2% chlorhexidine mouth wash<br>reduces the rate of postoperative respiratory tract infections in 30 days<br>postoperative period compared to placebo among patients undergoing midline<br>laparotomy.SecondaryObjectives1.To assess the<br>impact of the intervention on 30-day postoperative mortality2.To<br>determine the impact of the intervention on length of hospital stay3.To<br>determine whether the intervention impacts on the 30-day unplanned<br>readmission rates due to a respiratory complication4.To<br>assess the effect of the intervention on time to return to normal activities  |
| 4          | GBT440-038            | Phase III    | Sickle Cell<br>Disease  | Voxelotor/<br>Allopathic  | 10th February 2023                 | 1. Dr. Catherine Segbefia<br>2. Dr. Vivian Paintsil | 1. Korle-Bu Teaching<br>Hospital (KBTH)<br>2. Komfo Anokye<br>Teaching Hospoital<br>(KATH)          | Global Blood<br>Therapeutics,               | Application Approved,<br>24months         | The objective of this OLE is to assess the safety of, and SCD related<br>complications with, long term trreatment with Vovelotor in pparticipants who<br>have completed treatment in a GBT-spnsored voxelotor clinical study based on<br>the following parameters<br>a) Adverse Events (AEs), Clinical Laboratory Tests, Physical Examinations<br>(PEs) and other clinical measures.<br>b) Frequency of SCD-related complications.  |
| 5          | INTS GMMA<br>STUDY    | Phase II     | Typhoid                 | GVGH INTS-<br>GMMA Vaccine/<br>Vaccine  | 17th May 2023                      | Professor Ellis Owusu-<br>Dabo                      | KNUST-IVI<br>Collaborative Centre   | GlaxoSmithKlin<br>e Biologicals SA          | Application Approved, 3 years<br>4 months | <ol> <li>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</li> <li>To evaluate the safety and reactogenicity of the iNTS-GMMA vaccine in all participants</li> </ol>  |
| 6          | VERTEX Trial-<br>KBTH | Phase II/III | Kidney Disease          | VX-147/<br>Allopathic drug  | 8th May 2023                       | Dr. Dwomoa Adu                                      | Korle-Bu Teaching<br>Hospital (KBTH)  | Vertex<br>Pharmaceutical<br>s Incorporated  | Application Approved<br>4 years           | Primary objectives<br>•To evaluate the efficacy of VX-147 to reduce proteinuria<br>•To<br>evaluate the efficacy of VX-147 on renal function as measured by eGFR slope<br>Secondary objectives<br>•To<br>evaluate the efficacy of VX-147 to decrease the risk of the composite clinical<br>outcome<br>•To<br>evaluate the safety and tolerability of VX-147<br>•To<br>identify the optimal dose from Phase 2 to carry forward to Phase 3<br>•To characterize the plasma pharmacokinetics (PK) of VX-147  |

|     |  |           |  | Investigational   |                                    |                                 |   |   |   |   |
|-----|--|-----------|--|---|------------------------------------|---------------------------------|---|---|---|---|
| N/O | TITLE OF<br>STUDY                              | PHASE     | DISEASE<br>INDICATION  | Products (IPs)/IP<br>CLASS  | ,DATE OF RECEIPT OF<br>APPLICATION | PRINCIPAL<br>INVESTIGATOR       | STUDY CENTRE(S)   | SPONSORS & APPLICANT  | STATUS & DURATION OF<br>STUDY             | PURPOSE/AIM OF STUDY  |
|     | PROBIOTIC<br>(MILD<br>COGNITIVE<br>IMPAIRMENT) |           | Mild cognitive   | Probiotic<br>(Lactobacillus   | 14th April 2023                    | Michael Quansah                 |   | Western<br>Sydney<br>University,<br>Australia   | Application Approved, 6<br>Months         | <ul> <li>Aim</li> <li>To determine the therapeutic effects of probiotics in mild cognitively impaired individuals (MCI) at Korle-Bu Teaching Hospital.</li> <li>Specific objectives</li> <li>To determine the bioavailability of probiotics in mild cognitive individuals at Korle-Bu Teaching Hospital.</li> <li>To determine the clinical effects of probiotics in mild cognitively impaired individuals at Korle -Bu Teaching Hospital.</li> <li>To determine the molecular effects of probiotics in mild cognitively impaired individuals at Korle -Bu Teaching Hospital.</li> <li>To determine the molecular effects of probiotics in mild cognitively impaired individuals at Korle -Bu Teaching Hospital.</li> <li>To determine the molecular effects of probiotics in healthy controls at Korle-Bu Teaching Hospital.</li> <li>To determine the bioavailability of probiotics in healthy controls at Korle-Bu Teaching Hospital.</li> </ul> |
| 8   | BMLs4BU  | Phase III |  | combination of<br>rifampicin ,<br>clarithromycin<br>and<br>Amoxicillin/clavul<br>anate/ Allopathic<br>drug                  | 1st February 2023                  | Prof. Richard Odame<br>Phillips | -   | University of<br>Zaragoza<br>(UNIZAR) Spain   | Application Approved<br>2 year 11 months  | The aim of this study is to determine the ability of amoxicillin/clavulanate<br>combination therapy with rifampicin plus clarithromycin to improve the cure rate<br>of Buruli ulcer (BU) disease compared to a standard regimen of rifampicin plus<br>clarithromycin.<br>Primary objective<br>The primary objective of this clinical trial is to demonstrate the non-inferiority of<br>4-week coadministration of amoxicillin/clavulanate ((AMX/CLV)) with rifampicin-<br>clarithromycin (RIF/CLA's) compared to the standard 8-week rifampicin-<br>clarithromycin (RIF/CLA's) in cure rates at 12 months post initiation of<br>treatment, thus reducing BU treatment from 8 to 4 weeks.  |
| 9   | FITBIT/XIAOMI                                  | Phase III | Monitoring of<br>Vitals in pediatric<br>appendectomy<br>and trauma | Fitbit Inspire 2<br>(Fitbit),<br>Xiaomi Mi Smart<br>band 6/Medical<br>device  | 20th March 2023                    | Dr. William Appeadu-<br>Mensah  |   | <ol> <li>Dr. Fizan<br/>Abdullah</li> <li>Ann and Robert<br/>H. Lurie<br/>Children's<br/>Hospital</li> <li>Dr. Hassan<br/>Ghomrawi</li> <li>Northwestern<br/>University</li> </ol> | Application Approved, 2<br>Months         | Aim(s)<br>To establish the feasibility of a Fitbit/Xiaomi band-based wireless monitoring<br>system for post-operative inpatient monitoring and monitoring of patients<br>following trauma in the accident center. pecific objectives<br>The specific objectives of this study are to:<br>1. Determine the feasibility of implementing a band-based wireless monitoring<br>system for post-operative, in-hospital monitoring of pediatric appendectomy<br>patients, and for emergency department monitoring of pediatric and adult<br>trauma patients.<br>2. Compare the<br>vital signs recorded manually to those collected by wearable devices   |
| 10  | PMC TRIAL                                      | Phase III |  | RTS,S/AS01E<br>Malaria Vaccine,<br>Sulphadoxine-<br>Pyrimethamine,<br>Amodiaquine/<br>Allopathic and<br>Vaccine             | 8th May 2023                       | Dr. Kwaku Poku Asante           | Kintampo Health<br>Research Centre<br>(KHRC)  | PATH  | Application Approved, 3 years<br>8 months | The primary objective is to determine the efficacy of the combination of RTS,S/AS01E and PMC with sulphadoxine/pyrimethamine alone (PMC SP) or RTS,S/AS01E and PMC with SP and amodiaquine (PMC-SPAQ) against clinical malaria among children up to 24 months of age compared with RTS,S/AS01E vaccine administered alone   |
| 11  | PLATINUM                                       | Phase II  |  | <ol> <li>INE 963</li> <li>Cipargamin<br/>(KAE609)</li> <li>KLU156</li> <li>Coartem/Riame<br/>t/ Allopathic drugs</li> </ol> | 29th March 2023                    | Dr. Patrick Odum Ansah          | <ol> <li>Navorongo Health<br/>Research Center<br/>(NHRC)</li> <li>Kintampo Health<br/>Research Center<br/>(KHRC)</li> </ol> | Novartis<br>Pharma AG   | Application Approved 21<br>Months         | Part A: To assess the parasite clearance time (PCT) of oral doses of an<br>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  |

|     | TITLE OF                               |              | DISEASE                  | Investigational  | ,DATE OF RECEIPT OF | PRINCIPAL               |  | SPONSORS & | STATUS & DURATION OF               |   |
|-----|--|--------------|--------------------------|--|---------------------|-------------------------|--|------------|------------------------------------|---|
| N/O | STUDY                                  | PHASE        |                          | CLASS  | APPLICATION         | INVESTIGATOR            | STUDY CENTRE(S)  |            | STUDY                              | PURPOSE/AIM OF STUDY  |
| 12  | 2 NOVIC TRIAL                          |              | Postpartum<br>Hemorrhage | Jada System<br>(Intrauterine<br>Vacuum Induced<br>Hemorrhage<br>Control Device)/<br>Medical device | 5th April 2022      | Dr. Samuel A. Oppong    | 1. Korle-Bu Teaching<br>Hospital (KBTH)<br>2. Komfo Anokye<br>Teaching Hospoital<br>(KATH) | Women and  | Application approved, 48<br>Months | <ul> <li>Study Objectives</li> <li>1. To evaluate the effectiveness of the Jada® System, compared to standard care, in treating PPH, as measured by maternal survival without surgical intervention.</li> <li>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.</li> <li>3. To estimate the cost-effectiveness of the Jada® System, compared to standard to standard care, in treating PPH, as measured by incremental cost per quality-adjusted life year.</li> </ul>   |
| 1;  | 3 VERTEX Trial                         | Phase II/III |                          | VX-147/<br>Allopathic drug   | 23rd December 2022  | Professor Sampson Antwi | Komfo Anokye<br>Teaching Hospital<br>(KATH)  |            | Application approved,<br>4 years   | Primary objectives<br>•To evaluate the efficacy of VX-147 to reduce proteinuria •To<br>evaluate the efficacy of VX-147 on renal function as measured by eGFR slope<br>Secondary objectives •To<br>evaluate the efficacy of VX-147 to decrease the risk of the composite clinical<br>outcome •To<br>evaluate the safety and tolerability of VX-147 •To<br>identify the optimal dose from Phase 2 to carry forward to Phase 3<br>•To characterize the plasma pharmacokinetics (PK) of VX-147  |
| 14  | SWIS (STERILE<br>WATER<br>4 INJECTION) |              |                          | Sterile Water<br>Injection   | 6th December 2022   | Prof. Sue Kruske        | Korle-Bu Teaching<br>Hospital (KBTH)   |            | Application approved, 40<br>Months | <ul> <li>Main Aim</li> <li>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.</li> <li>Specific Objectives</li> <li>1. Develop and deliver a training package for midwives on sterile water injections for managing lower back pain.</li> <li>2. Undertake implementation study in a tertiary hospital in Ghana to assess the feasibility and acceptability of implementing SWI for lower back pain.</li> <li>3. Determine birth and neonatal outcomes of women with back pain who receive SWI</li> <li>4. Explore the experiences of women who have had SWI for back pain in labour</li> <li>5. Explore the experiences and perception of midwives and stakeholders regarding the implementation of SWI for managing back pain in labouring women.</li> </ul>  |
| 15  | 5 ACTIV TRIAL                          | Phase III    |                          | S-217622/<br>Allopathic drug   | 27th September 2022 | Dr. Patrick Ansah       | -  |            | Application Approved,16<br>Months  | Primary Objective<br>To determine if S-217622 will reduce the time to sustained symptom resolution<br>through Day 29. Time to sustained symptom resolution is defined as the time<br>from start of study intervention to the first day of 4 consecutive days with<br>complete resolution of 13 COVID-19 symptoms on participant self-assessment<br>AND alive and without hospitalization for any reason by Day 29. Hospitalization<br>is defined as ≥24 hours of acute care, in a hospital or similar acute care facility,<br>including emergency rooms, urgent care clinics, or facilities instituted to<br>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<br>from baseline in quantitative log10 SARS-CoV-2 RNA levels by PCR on NP<br>swab at Day 4.<br>Key secondary objective:<br>To determine whether S-217622 reduces COVID-19 related hospitalization<br>(adjudicated) and all deaths regardless of occurrence outside of hospital or<br>during hospitalization (not adjudicated) through Day 29. |

|     | TITLE OF                        |              | DISEASE  | Investigational<br>Products (IPs)/IP   | ,DATE OF RECEIPT OF | PRINCIPAL               |   | SPONSORS &  | STATUS & DURATION OF               |   |
|-----|---------------------------------|--------------|--|--|---------------------|-------------------------|---|---|------------------------------------|---|
| N/O | STUDY                           | PHASE        | INDICATION                                       | CLASS  | APPLICATION         |                         | STUDY CENTRE(S)   |   | STUDY                              | PURPOSE/AIM OF STUDY  |
| 1   | 6 COPE TRIAL                    | Phase III    | Fistula  | (i) Healeanlo<br>silicone lady<br>Drain Valve<br>menstrual Cup<br>(ii) Foley catheter<br>will connect the<br>cup to a leg bag<br>(cup+)/ Medical<br>device |                     |                         | <ol> <li>Mercy Women's<br/>Catholic Hospital in<br/>Mankessim</li> <li>Tamale Fistula<br/>Center in Tamale</li> </ol> | Korle Bu<br>Teaching<br>Hospital  | Application Approved, 15<br>Months | The aims of the study are to examine the effectiveness, comparative<br>effectiveness, and acceptability of two vaginal menstrual cup models (cup and<br>cup+) as a temporizing alternative to managing urinary leakage from vesico-<br>vaginal fistula in both a clinical setting and a community setting, and to quantify<br>non-surgical fistula management costs.  |
| 1   | 7 PRAISE                        | Phase II/III | Sickle Cell<br>Disease                           | 1. Oral FT-4202<br>Pyruvate Kinase<br>Activator<br>2.<br>Placebo/Allopathi<br>c drug   | 2nd June 2022       |                         | 1. Kintampo Health<br>Research Center<br>2. Ghana Institute of<br>Clinical Genetics,<br>KBTH                          | NOVO NORDISK<br>COMPANY   | Application Approved, 43<br>Months | Objectives of the study are:<br>1. To assess the efficacy of FT-4202 in adolescents and adults with SCD as<br>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<br>annualized vaso-occlusive crisis (VOC) rate<br>3. To measure the effects of FT-4202 on clinical measures and sequelae of<br>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  |
| 1   | FORTIFIED<br>BUILLON<br>3 CUBES |              | Malnutrition                                     | Shrimp Flavour<br>Stock<br>Cubes/Food<br>supplement  | 13th December 2021  | Prof. Seth Adu-Afarwuah | University of Ghana   | Helen Keller<br>International<br>(Through a<br>grant from the<br>Bill & Melinda<br>Gates<br>Foundation) | Application Approved, 9<br>months  | <ul> <li>This study aims to assess the impacts of household use of multiple micronutrient-fortified bouillon cubes ( contaning vitamin A, folic acid, vitamin B12, iron, and zinc in addition to iodine), compared to control buillon cubes fortified with iodine only, on: a) Micronutrient status among women 15-49 years of age and children 2-5 years of age after 9 months of intervention</li> <li>b) Haemoglobin concentrations among women 15-49 years of age and children 2-5 years of age after 9 months of age and children 2-5 years of age after 9 months of age and children 2-5 years of age after 9 months of intervention.</li> <li>c) Breast milk micrinutrient among lactating women 4-8 months postpartum after 3 months of intervention.</li> </ul>  |
| 1   | ANTIPSYCHOTI<br>C STUDY         | Phase IV     | Antipsychotic<br>Induced<br>Movement<br>Disoders | Omega-3 Fatty<br>Acids / Food<br>supplement  |                     |                         | Accra Psychiatric<br>Hospital   | Dr. Sammy<br>Ohene. P. O.<br>Box KB 77<br>Korle-Bu  | Application Approved, 29<br>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 |

|     |   |           |                        | Investigational  |                                    |  |  |   |                                   |  |
|-----|---|-----------|------------------------|--|------------------------------------|--|--|---|-----------------------------------|--|
| N/O | TITLE OF<br>STUDY                         | PHASE     | DISEASE<br>INDICATION  | Products (IPs)/IP<br>CLASS   | ,DATE OF RECEIPT OF<br>APPLICATION | PRINCIPAL<br>INVESTIGATOR                                    | STUDY CENTRE(S)  |   | STATUS & DURATION OF<br>STUDY     | PURPOSE/AIM OF STUDY   |
|     | PROBIOTIC                                 |           | Malnutrition           | 1.Synbiotic<br>(Nutraflora and<br>Maltrin M100 P-<br>95 and L.<br>plantarum (Lp)<br>2.Placebo/ Food                          |                                    | Dr Seyram Kaali  | Kintampo Municipal<br>Hospital   |   | Application Approved<br>6 months  | <ul> <li>Primary</li> <li>A pilot trial to evaluate the administration of probiotic<br/>supplementation among pregnant women in the third trimester<br/>and effective colonization of the gut microbiome of their infants<br/>one-month post-partum.</li> <li>Secondary</li> <li>1. To assess compliance of administering a synbiotic product<br/>(L. plantarum with Fructooligosaccharide) among<br/>pregnant women.</li> <li>2. To assess birth outcomes among participants who receive<br/>synbiotic products compared to those on placebo.</li> <li>3. To assess if maternal stool microbiome profoundly changes from<br/>immediately after childbirth to one-month<br/>post-partum.</li> <li>4. To characterize the diversity of vaginal microbiomes<br/>among pregnant women in the study area.</li> <li>5. To determine the safety of the probiotic supplementation<br/>among pregnant women from 5 to 6 months until up to two<br/>weeks post partum.</li> </ul> |
| 21  | EBSI-LSV                                  | Phase I   | Lassa Fever            | 1.EBSI-LSV<br>2. Placebo/<br>Vaccine   | 1st September 2021                 | 1.Dr Seyram Kaali<br>2.Dr.Patrick Ansah                      | 1.Kintampo Health<br>Research Centre<br>2.Navrongo Health<br>Research Centre |   | Application Approved<br>2 years   | <ol> <li>To evaluate the safety and tolerability of increasing dose levels of EBS-LASV vaccine administered as a single dose or two-dose series.</li> <li>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.</li> </ol>  |
|     |   | Phase III | Malaria                | 1. Artemether<br>Lumefantrine<br>2.Atovaquone-<br>Proguanil<br>3. Placebo of<br>Atovaquone-<br>Proguanil/<br>Allopathic drug | 4th October 2021                   | 1. John Humphrey,<br>AMUASI 2.<br>Dr Oumou Maiga<br>Ascofare | St. Francis Xavier   | Kumasi Centre<br>for Collaborative<br>Research                  | Application ApprovedI             | The overall aim of this phase III clinical trial(main study = study II) is to develop<br>a readily deployable highly efficacious, safe and well tolerated antimalarial<br>triple combination therapy for young children.<br>This is achieved by evaluating the efficacy, safety and tolerability of<br>artemether-lumefantrine (AL) + atovaquone-proguanil (AP) tri-therapy<br>(AL+AP) compared to standard AL therapy (+placebo) for the treatment of<br>uncomplicated Plasmodium falciparum malaria in African children aged 6 to 59<br>months   |
|     | POLYPHENOL-<br>RICH COCOA<br>POWDER TRIAL | Phase III | Covid-19               | Polyphenol-rich<br>natural cocoa<br>powder/ Food<br>supplements  | 10th January 2022                  | Prof. George Obeng Adjei                                     | Ga East Municipal<br>Hospital, Ghana<br>Infectious Disease<br>Centre         |   | Application Approved, 4<br>Months | <ul> <li>General objective is to evaluate effects of polyphenol-rich cocoa as adjuvant therapy in COVID 19 patients.</li> <li>Specific objectives: <ol> <li>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</li> <li>to determine the effects of natural polyphenol-rich natural cocoa powder (5% v/w) on selected markers of coagulopathy in COVID-19 patients</li> <li>to determine the effects of natural polyphenol-rich natural cocoa powder (5% v/w) on selected markers of coagulopathy in COVID-19 patients</li> <li>to determine the effects of natural polyphenol-rich natural cocoa powder (5% v/w) on virologic clearance COVID-19 patients</li> <li>to determine the effects of natural polyphenol-rich natural cocoa powder (5% v/w) on virologic clearance COVID-19 patients</li> </ol> </li> </ul>                               |
| 24  | PIVOT STUDY                               | Phase II  | Sickle Cell<br>Disease | 1.Hydroxyurea<br>2.Placebo/<br>Allopathic drug   | 18th June 2021                     | Dr. Yvonne A. Dei-<br>Adomakoh                               | Korle-Bu Teaching<br>Hospital  |   | Application Approved<br>5 years   | To measure the toxicities of hydroxyurea treatment on laboratory parameters.<br>To assess the effects of hydroxyurea treatment on a variety of sickle-related<br>clinical and laboratory parameters in a large cohort of children and adults with<br>HbSC disease.<br>To identify which study endpoints are suitable for a future Phase III trial of<br>patients with HbSC disease receiving hydroxyurea therapy.  |
| 25  | RECOVERY                                  | Phase III | Covid-19               | 1.Dexamethason<br>e<br>2.Empagliflozin   | 21st May, 2021                     | Dr. John H. Amuasi   | Komfo Anokye<br>Teaching Hospital<br>Ghana Infectious                        | University of<br>Oxford Clinical<br>Trials and<br>ResearchGover | 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.   |

|     |                     |           |                        | Investigational   |                     |  |  |   |  |   |
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|     | TITLE OF            |           | DISEASE                |   | ,DATE OF RECEIPT OF | PRINCIPAL  |  |   | STATUS & DURATION OF   |   |
| N/O | STUDY               | PHASE     | INDICATION             | CLASS   | APPLICATION         | INVESTIGATOR   | STUDY CENTRE(S)  | APPLICANT   | STUDY  | PURPOSE/AIM OF STUDY  |
| 26  | VR-AD-1005<br>STUDY | Phase II  | Cholera                | VR-AD-<br>1005/Allopathic<br>drug   | 1st July 2021       | Dr. Ernest Kenu  | Pentecost Hospital,<br>Madina, Madina<br>Polyclinic –  | Vanessa<br>Research<br>Holdings, Inc.,                  | Application Approved.Study no<br>yet commenced<br>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).  |
| 21  | 7 HOPE KIDS 2       | Phase III | Sickle Cell<br>Disease | 1.Voxelotor<br>2.Placebo/Allop<br>athic drug  | 16th December 2020  | Dr. Catherine Segbefia   |  | Global Blood<br>Therapeutics,<br>inc                    | Application Approved. Study<br>not yet commenced 38<br>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.  |
| 28  | 3 VAT00008          | Phase III | Covid-19               | 1.SARS-CoV2<br>prefusion Spike<br>delta TM with<br>AS03 adjuvant,<br>monovalent<br>2.SARS-CoV2<br>prefusion Spike<br>delta TM with<br>AS03 adjuvant,<br>bivalent<br>3.Matching<br>placebo / Vaccine | 26th May, 2021      | 1. Dr. Nana Akosua<br>Ansah 2<br>Dr. Kwaku Poku Asante<br>3. Dr. John Amuasi | *Navrongo Health<br>Research Centre<br>*Kintampo Health<br>Research Centre<br>*Kwame Nkrumah<br>University of Science<br>and Technology<br>(KNUST)                               | SANOFI  | Application Approved. Actively<br>Enrolling at KCCR and<br>Navorongo while Kintampo<br>closed enrolment 18<br>months | To assess, in participants who are SARS-CoV-2 naïve,<br>the clinical efficacy of the CoV2 preS dTM-AS03<br>vaccines for the prevention of symptomatic COVID-19<br>occurring $\geq$ 14 days after the second injection.To assess the safety of the<br>CoV2 preS dTM-AS03<br>vaccines compared to placebo throughout the study.   |
| 29  | BURULIRIFDAC        | Phase III | Buruli Ulcer           | 1.Rifampicin<br>2.Clarithromycin<br>3.Dialkylcarbam<br>oyl chloride<br>(DACC)<br>Dressing/Allopath<br>ic drug   | 12th December 2020  | Prof. Richard Phillips   | •KCCR<br>•Ga East munical<br>hospital<br>•Pakro Health Centre<br>•Wassa Amenfi East<br>Hospital  | London school<br>of Hygiene and<br>Tropical<br>Medicine | Application Approved. Study<br>not yet commenced 2<br>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   |
| 3(  |                     | Phase III | Buruli Ulcer           | 1.Nitric Oxide<br>generating<br>dressing<br>(EDX110TM)<br>2.Vaseline<br>Gauze dressing<br>materials /<br>Allopathic drug +<br>medical device  | 24th September 2018 | Prof. Richard Odame<br>Phillips  | 1.Kumasi Centre for<br>Collaborative<br>Research in Tropical<br>Medicine<br>2.Agogo<br>Presbyterian Hospital<br>3.Tepa Government<br>Hospital<br>4.Dunkwa<br>Government Hospital | For<br>Collaborative<br>Research                        | Application Approved Study<br>yet to commence 36<br>MONTHS   | Buruli ulcer is a neglected disease caused by infection with Mycobacterium<br>ulcerans (Mu), which manifests as large, disfiguring skin ulcers mainly in<br>children aged 5 to 15 years. Access to treatment in rural areas can be<br>challenging and late presentation is typical, due to fear, stigma, suspicion about<br>conventional medicine and economic consequences for poor families. The<br>current recommended regimen of oral rifampicin together with intramuscular<br>streptomycin or clarithromycin for 8 weeks is far from ideal, particularly given<br>the increasing global threat of antimicrobial resistance. Although the disease<br>can be cured in most patients who adhere to this regimen, healing rates are<br>highly variable even in patients with seemingly similar lesions.<br>The purpose of the study is to compare the healing measured by the<br>percentage area reduction of EDX110 dressing with oral rifampicin and<br>clarithromycin (EDX-RC) versus 'Usual Care' with routine Vaseline gauze<br>dressing and oral rifampicin and clarithromycin (VG-RC). |

|     | TITLE OF  |           | DISEASE                       | Investigational<br>Products (IPs)/IP  | ,DATE OF RECEIPT OF | PRINCIPAL                     |  | SPONSORS &   | STATUS & DURATION OF                          |  |
|-----|-----------|-----------|-------------------------------|---|---------------------|-------------------------------|--|--|---|--|
| N/O | STUDY     | PHASE     | INDICATION                    | CLASS   | APPLICATION         | INVESTIGATOR                  | STUDY CENTRE(S)  | APPLICANT  | STUDY   | PURPOSE/AIM OF STUDY   |
| 3   | TyVEGHA   | Phase IV  | Typhoid fever                 | 1.Typbar TCV<br>(Vi<br>polysaccharide-<br>tetanus toxoid<br>conjugate<br>vaccine)<br>2.Meningococc<br>al Group A<br>conjugate<br>vaccine (MCV-A<br>5) / Vaccine | 3rd March 2021      | Prof. Ellis Owusu-Dabo        | Agogo Trial<br>Center/KNUST-<br>International Vaccine<br>Institute (IVI)<br>Collaborating Center | Vaccine  |   | The purpose of the study is to<br>•To determine the total protection conferred by single-dose vaccination with Vi-<br>TT against blood culture-confirmed symptomatic S. Typhi infection in the<br>intervention vaccine clusters, compared with the control vaccine clusters<br>• To investigate the safety outcomes associated with Vi-TT vaccination in the<br>intervention vaccine recipients compared with the comparator vaccine<br>recipients<br>• To determine the overall protection of Vi-TT vaccination against blood culture-<br>confirmed symptomatic infection caused by S. Typhi in intervention clusters<br>compared with control clusters<br>• To determine the total protection of Vi-TT vaccination against severe TF in the<br>intervention vaccine recipients compared with the comparator vaccine<br>recipients<br>• To determine the total protection of Vi-TT vaccination against severe TF<br>caused by S. Typhi in intervention clusters compared with control clusters<br>• To investigate the total protection of Vi-TT vaccination against severe TF<br>caused by S. Typhi in intervention clusters compared with control clusters<br>• To investigate the total protection of Vi-TT vaccination against clinical TF<br>(defined below in "Trial Outcome Measures") in the intervention vaccine<br>recipients compared with the comparator vaccine recipients<br>• To investigate the overall protection of Vi-TT vaccination against clinical TF in<br>intervention clusters compared with control clusters<br>• To measure the indirect protection conferred by single-dose vaccination with<br>Vi-TT against blood culture-confirmed symptomatic S. Typhi infection in the<br>intervention vaccine clusters, compared with the control vaccine clusters<br>• To investigate the immunogenicity profile in a subset of Vi-TT recipients<br>compared with the comparator vaccine recipients. |
| 3   | SHEA LIDO | Phase III | Rectal<br>Examination         | 1.Optilube<br>Active Sterile<br>Lubricating Jelly<br>2.Shealube/<br>Lubricating gel   | 10th September 2020 | Dr. Kekeli Kodjo Adanu        | Ho Teaching Hospita  | University of<br>Health and  |   | <ul> <li>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.</li> <li>The purpose is to:</li> <li>To determine the ease of use of shea butter by clinicians as compared to lidocaine gel as a lubricant for rectal examination.</li> <li>To determine the complication rate related to the use of shea butter as a lubricant for rectal examination.</li> <li>To ascertain the complication rate associated with the use of lidocaine gel as a lubricant for rectal examination.</li> <li>To compare the complication rate related to the use of shea butter to that of lidocaine gel.</li> </ul>   |
| 3:  |           | Phase III | Human Papiloma<br>Virus (HPV) | 1.Cecolin®<br>2.Gardasil® /<br>Vaccin   | 1st September 2020  | Prof. Tsiri Agbenyega         | •Agogo Asante Akim<br>North District   | PATH   | Application Approved 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.  |
|     |           |           |                               |   |                     |                               |  |  |   | The purpose of this study is to<br>•To show efficacy (Depletion of Wolbachia) of the combination of Rifampicin<br>plus Albendazole against lymphatic filariasis using PCR compared to treatment<br>with albendazole and "no treatment" (other than ivermectin) - Lymphatic<br>Filariasis (LF) trial  |
| 3,  | ASTAWOL   | Phase II  | Onchocerciasis/Fil<br>ariasis | 1.Rifampicin<br>2.Albendazole/<br>Allopathic drug   | 25th June 2020      | Prof. Alexander Yaw<br>Debrah | •Bawku west<br>•Builsa South<br>•Nabdam Fumbisi<br>•Garu-Tempane<br>•Kayoro                      | Kumasi Centre<br>for Collaborative<br>Research<br>(KCCR),<br>Kumasi, Ghana | Application Approved<br>Actively Enrolling 24 | •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   |

|     |                      |           |                                | Investigational   |                     |   |   |           |  |  |
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|     | TITLE OF             |           | DISEASE                        |   | ,DATE OF RECEIPT OF | PRINCIPAL   |   |           | STATUS & DURATION OF                       |  |
| N/O | STUDY                | PHASE     | INDICATION                     | CLASS   | APPLICATION         | INVESTIGATOR                                      | STUDY CENTRE(S)                                 | APPLICANT | STUDY                                      | PURPOSE/AIM OF STUDY   |
| 35  |                      | Phase III | Gastroenteritis                | 1.Trivalent<br>Rotavirus P2-VP8<br>Subunit Vaccine<br>2.Rotarix®/<br>Vaccine  | 9th April, 2019     |   | Dodowa Health<br>Research Centre                |           | Approved study commenced<br>48 Months      | Diarrhea is the second-leading cause of death worldwide among children under<br>the age of five, killing an estimated three quarters of a million children annually<br>and hospitalizing millions more in developing countries. The most common<br>cause of infantile diarrhoea is rotavirus and almost all children are infected by<br>their third birthday regardless of geographical area or economic status.<br>Infection is primarily via fecal oral route and improved sanitation alone will not<br>control infection. Oral rotavirus vaccines have traditionally shown lower efficacy<br>in Low and Middle Income Countries (LMICs) as compared to developed<br>countries. Several theories proposed for this observation includes interference<br>by other intestinal viruses or bacteria, neutralization of vaccine by maternally<br>virus by maternally derived antibodies in breastmilk, etc. Some of these<br>challenges may be obviated by a parenteral administered rotavirus vaccine.<br>This study is therefore to demonstrate the efficacy and safety of the parenteral<br>trivalent rotavirus vaccine in healthy infants (≥6 and <8 weeks old) to prevent<br>severe rotavirus gastroenteritis compared with the orally approved Rotarix® |
| 30  |                      |           | Gastroententis                 | Vaccine   | 9th Aphi, 2019      |   | Research Centre                                 | PAIN      |  | severe rotavirus gastroententis compared with the orally approved Rotanx®  |
| 36  | NANOX.ARC            |           | Radiographic<br>abnormalities  | Nanox.ARC   | 16th January 2024   | Dr. George Boateng KYEI                           | University of Ghana<br>Medical Centre<br>(UGMC) |           | Application Pending Approval,<br>2 years   | <ul> <li>Primary Objective:</li> <li>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.</li> <li>Secondary Objectives</li> <li>To evaluate the ability of Nanox.ARC DTS to reduce the need for a CT/MRI or other advanced imaging modality</li> <li>To evaluate the ability of Nanox.ARC DTS to increase the level of confidence of the reader in identifying/excluding an abnormality. Image:</li> <li>To evaluate physician reading time of Nanox.ARC DTS compared to CT/MRI or other advanced imaging modality</li> <li>To evaluate the length and extent of the learning curve of reading the tomosynthesis images</li> <li>Safety Objectives</li> <li>Safety objective is to collect safety information, including type and number of adverse events, serious adverse events, and device issues.</li> </ul>  |
| 37  | MALHELMINTH<br>STUDY |           | Helminths<br>infection/Malaria | Sulphadoxine-<br>pyrimethamine<br>and Amodiaquine<br>- (SPAQ),<br>Albendazole<br>(ALB),<br>Praziquantel<br>(PZQ)/Allopathic<br>drug | 29th December 2023  | 1. Dr Muhammed Afolabi<br>2. Dr Kwaku Poku Asante | Research Centre                                 |           | Application Pending Approval,<br>13 months | <ul> <li>Aim:</li> <li>To evaluate the effectiveness and cost-effectiveness of integrating mass drug administration for helminth control with seasonal malaria chemoprevention in Ghanaian children</li> <li>Objectives:</li> <li>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.</li> <li>Determine the cost and cost-effectiveness of delivering an integrated malaria-dewormingapproach to the children.</li> </ul>   |

|     |            |                        |                        | Investigational   |                     |  |   |                                   |   |  |
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|     | TITLE OF   |                        | DISEASE                |   | ,DATE OF RECEIPT OF | PRINCIPAL  |   | SPONSORS &                        |   |  |
| N/O | STUDY      | PHASE                  | INDICATION             | CLASS   | APPLICATION         | INVESTIGATOR   | STUDY CENTRE(S)                             | APPLICANT                         | STUDY   | PURPOSE/AIM OF STUDY   |
| 38  | TNBC STUDY | Phase IIa              | Breast Cancer          | Tobemstomig/<br>Nab-Paclitaxel/<br>Pembrolizumab/<br>Monoclonal<br>Antibody | 28th December 2024  | Dr. Hannah Naa Gogwe<br>Ayettey Anie   | Korle-Bu Teaching<br>Hospital               | F. Hoffmann-La<br>Roche Ltd       | Application Pending Approval,<br>18 months        | Primary Objective:  To evaluate the efficacy of tobemstomig plus nab-paclitaxel compared with pembrolizumab plus nab-paclitaxel in the FAS Secondary Objective: To evaluate the efficacy of tobemstomig plus nab-paclitaxel compared with pembrolizumab plus nab-paclitaxel in the FAS 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 To evaluate the safety of tobemstomig plus nab-paclitaxel compared with pembrolizumab plus nab-paclitaxel in the SAS To evaluate the safety of tobemstomig plus nab-paclitaxel compared with pembrolizumab plus nab-paclitaxel in the SAS To characterize the tobemstomig PK profile To evaluate the immunogenicity to tobemstomig  |
|     | MEPLAZUMAB | Dhase lie              | Malaria                | Ketantin/Monoclo  | 5th December 2023   | 1. Dr. Patrick Odum<br>Ansah   | 2. St. Francis Xavier                       | -                                 | Application Pending Approval,<br>22 months        | Primary Objective<br>• To evaluate the safety of meplazumab in an adult population with<br>uncomplicated, symptomatic P. falciparum infection<br>SecondaryObjective:<br>•••<br>To evaluate the efficacy of meplazumab<br>as defined by<br>• Early treatment failure<br>• Late clinical failure<br>• Late parasitological failure<br>• Late parasitological failure<br>• 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 immunoconicity following menlazumab administration  |
|     |            | Phase IIa<br>Phase III | Malaria                | Atezolizumab/Biv<br>acizumab/Tiragol<br>umab/<br>Monoclonal                 | 15th November 2023  | 2. Dr. Oumou Maiga<br>1. Dr. Edward Amankwah<br>Frimpong<br>2. Dr. Asare Offei | 1. Korle-Bu Teaching                        |                                   | Application Pending Approval,<br>2 years 8 months | <ul> <li>To evaluate immunogenicity following meplazumab administration</li> <li>Primary Objectives: <ul> <li>To evaluate the efficacy of atezolizumab plus bevacizumab plus tiragolumab compared with atezolizumab plus bevacizumab</li> <li>To evaluate the efficacy of atezolizumab plus bevacizumab plus tiragolumab compared with atezolizumab plus bevacizumab</li> <li>Secondary Objectives:</li> <li>To evaluate the efficacy of atezolizumab plus bevacizumab plus tiragolumab compared with atezolizumab plus bevacizumab</li> <li>To evaluate the efficacy of atezolizumab plus bevacizumab plus tiragolumab compared with atezolizumab plus bevacizumab</li> <li>To evaluate the safety of atezolizumab plus bevacizumab</li> <li>To evaluate the safety of atezolizumab plus bevacizumab plus tiragolumab</li> <li>To characterize the PK profile of atezolizumab plus bevacizumab plus tiragolumab</li> <li>To evaluate the immune response to tiragolumab and atezolizumab</li> </ul> </li> </ul> |
| 41  | MITAPIVAT  | Phase II/III           | Sickle Cell<br>Disease | Mitapivat   | 24th November 2023  | Dr. Eunice Agyeman<br>Ahmed  | Komfo Anokye<br>Teaching Hospital<br>(KATH) | Agios<br>Pharmaceutical<br>s, Inc | Application Pending Approval,<br>5years 2months   | Primary Objectives<br>To determine the recommended Phase 3 dose of mitapivat by evaluating the<br>effect of 2 dose levels of mitapivat versus placebo on:<br>• Anemia in subjects with sickle cell disease (SCD)<br>• Safety<br>Secondary Objectives<br>To evaluate the effect of 2 doses of mitapivat versus placebo on:<br>• Anemia<br>• Markers of hemolysis and erythropoiesis<br>• Patient-reported fatigue<br>• Sickle cell pain crises (SCPCs)<br>• To evaluate the pharmacokinetic and<br>pharmacodynamic effects of mitapivat   |

|           |            |                    |  | Investigational                  |   |  |   |   |                      |  |
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|           | TITLE OF   | DUACE              | DISEASE  |                                  | ,DATE OF RECEIPT OF                     | PRINCIPAL  |   |   | STATUS & DURATION OF |  |
| N/O<br>4: | STUDY      | PHASE<br>Phase III | Malaria  | CLASS<br>KLU156                  | APPLICATION<br>27th October, 2023       | INVESTIGATOR<br>1. Dr. Samuel Harrison<br>2. Dr. Patrick Odum<br>Ansah | 1. KHRC                                   | Novartis  |                      | PURPOSE/AIM OF STUDY Purpose 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). 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. |
|           |            | Phase III          |  |                                  |   |  |   |   |                      | Primary<br>The primary objective is to evaluate the clinical efficacy, as assessed by time to<br>lesion(s) resolution, of IP + Standard of Care (SOC) compared to placebo +<br>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 +<br>SOC in subjects<br>with mpox.<br>The safety objectives are to evaluate the safety and tolerability in terms of AEs<br>and SAEs occurrence frequencies and treatment discontinuation of 1/ IP +<br>SOC compared to placebo + SOC in subjects with non-severe mpox diseases<br>2/ IP + SOC in subjects with severe complications and/or severe immune<br>suppression and/or pregnancy/breastfeeding.                                 |
|           | MOSA STUDY | Phase III          | Monkey pox<br>Respiratory<br>Syncitial Virus<br>Infections | Tecovirimat         RSVt Vaccine | 9th November, 2023<br>16th October 2023 |  | 4. KCCR<br>5. NHRC                        | Sanofi Pasteur  |                      | Efficacy 1.<br>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 2.<br>To demonstrate the clinical efficacy of RSVt vaccine for the prevention of RT<br>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-<br>PCR confirmed RSV associated with the occurrence of LRTD, leading to<br>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<br>and IgG antibody responses to the study intervention  |
|           | IAVI C105  | Phase II           | Lassa Fever<br>Disease                                     | rVSV∆G-LASV-<br>GPC Vaccine      | 7th August 2023                         | Prof. Kwadwo Koram   | Noguchi Memorial<br>Institute for Medical | International<br>AIDS Vaccine<br>Initiative (IAVI)/<br>Susan Adu- |                      | Safety<br>• To evaluate the safety and tolerability of the rVSV∆G-LASV-GPC vaccine at 2<br>different dosage levels in adults, including PLWH, and in children.<br>Immunogenicity<br>• To determine binding LASV-GPCspecific antibody responses induced by<br>rVSV∆G-LASV-GPC vaccine<br>• To determine neutralizing LASV-GPCspecific antibody responses induced by<br>rVSV∆G-LASV-GPC vaccine in a subset of participants in each group  |

|     |                                   |           |                                | Investigational   |                     |                                    |  |  |                              |  |
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|     | TITLE OF                          |           | DISEASE                        |   | ,DATE OF RECEIPT OF | PRINCIPAL                          |  |  | STATUS & DURATION OF         |  |
| N/O | STUDY                             | PHASE     | INDICATION                     | CLASS   | APPLICATION         | INVESTIGATOR                       | STUDY CENTRE(S)1. Kintampo HealthResearch Centre(KHRC)2. Navrongo HealthResearch Centre(NHRC)3. Dodowa Health  | APPLICANT  | STUDY                        | PURPOSE/AIM OF STUDY         The primary objective is:         • To evaluate the efficacy of BEM compared with placebo in reducing all cause hospitalization or all-cause death in COVID-19 outpatients receiving only supportive care.         • To evaluate the efficacy of BEM compared with placebo         • To evaluate the efficacy of BEM compared with placebo         • To evaluate the efficacy of BEM compared with placebo         • To evaluate the efficacy of BEM compared with placebo         • To evaluate the antiviral activity of BEM compared with placebo on viral load  |
| 46  | ATEA COVID 19                     | Phase III | Covid-19                       | Bemnifosbuvir   | 7th June 2023       | 2. Dr. Nana Akosua<br>Ansah        | Research Centre<br>(DHRC)  | Pharmaceutical   | Pending approval, 13 months  | rebound<br>• To evaluate the safety of BEM compared with placebo   |
| 47  | SOY PEPTIDE<br>7 STUDY            | Phase I   | Malnutrition in cancer patient | Soy Protein<br>Peptide<br>Supplements/<br>Food<br>supplements   | 10th February 2023  | Prof. Christiana Nsiah-<br>Asamoah | Cape Coast<br>Teaching Hospital<br>(CCTH)  |  | Pending Approval, 9 months   | Objective:<br>The main purpose of this study is to evaluate the efficacy of food-borne<br>(soybean) peptides in reducing malnutrition in cancer patients.  |
| 48  | INO-9112 COVID<br>19              | Phase I   | Covid-19                       | 1. INO-4800<br>followed by<br>Electroporation<br>(EP)<br>2. NO-4800 +<br>INO-9112<br>followed by<br>Electroporation | 30th June 2022      | Dr. Kwadwo Ansah<br>Koram          | Noguchi Memorial<br>Institute for Medical  | Inovio<br>Pharmaceutical                               |                              | 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.  |
| 45  | POST<br>MASTECTOMY<br>PAIN RELIEF |           | Anaesthesia                    | Erector Spinae<br>block using<br>bupivacaine/<br>Local anasthetics  | 2nd December 2021   | Dr. Nana Addo Boateng              | Komfo Anokye<br>Teaching Hospital<br>(KATH)  | Self-Funding   | Application Pending Approval | <ul> <li>General objective:</li> <li>The main objective of the study is to determine the postoperative analgesic effect of Erector Spinae Plane (ESP) Block after mastectomy.</li> <li>Specific objectives:</li> <li>1. To compare the total morphine consumption within 24 postoperative hours between patients</li> <li>receiving ESP block with bupivacaine and ESP block with saline for mastectomy at the Komfo Anokye Teaching Hospital, Kumasi, Ghana.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ul> |
| 50  | D BEMPU                           | Phase II  | Hyppthermia in<br>Infants      | BempuBracelet/M<br>edical device  | 2nd November, 2020  | Mr. Prince Owusu                   | •Achimota General<br>Hospital<br>•Greater Accra<br>Regional Hospital<br>•Eastern Regional<br>Hospital<br>•Korle-Bu Teaching<br>Hospital<br>•Central Regional<br>Hospital<br>Princess Marie Luis<br>Children Hospital | Center for<br>learning and<br>childhood<br>development | Application Pending Approval | To determine the accuracy of the bracelet in identifying hypothermia and<br>evaluate its effect on Kangaroo Mother Care (KMC) practices and neonatal<br>health outcomes in Ghana.<br>To assess the acceptability of the bracelet in Health providers and caregivers<br>of Low Birth Weight (LBW) infants by conducting qualitative in-depth<br>interviews.<br>Determine the accuracy of the BEMPU bracelet in classifying hypothermia in<br>the clinical setting.<br>Evaluate the impact of the bracelet   |

|     |                    |           |                | Investigational  |                     |   |   |   |  |  |
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|     | TITLE OF           |           | DISEASE        | · · · · · · · · · · · · · · · · · · ·                          | ,DATE OF RECEIPT OF | PRINCIPAL   |   | SPONSORS &  | STATUS & DURATION OF                                     |  |
| N/O | STUDY              | PHASE     | INDICATION     | CLASS  | APPLICATION         | INVESTIGATOR                                      | STUDY CENTRE(S)   | APPLICANT   | STUDY  | PURPOSE/AIM OF STUDY   |
| 5   | INOVIO             | 1b        | Lassa Fever    | 1.INO-4500<br>2.CELLECTRA™<br>2000<br>3.SSC-0001/<br>Vaccine   | 30th September 2019 | Prof. Kwadwo Ansah<br>Koram                       | University of Ghana,  | Inovio<br>Pharmaceutical<br>s, Inc                      | Study ended Final report<br>submitted 20 Months          | The LASV DNA vaccine expressing the glycoprotein precursor (LASV GPC,<br>Josiah strain matched) paired with intradermal EP is a promising vaccine<br>platform that has been shown to elicit protective immunity and completely<br>protect guinea pigs and non-human primates (NHP) against viremia, illness<br>(acute and chronic), and death after Lassa virus exposure [26, 27] and protect<br>NHPs from hearing loss [unpublished data]. This LASV DNA vaccine, INO-<br>4500, targets GPC because it represents the most conserved region in this<br>genetically diverse virus. In the case of Lassa virus infection, the generation of<br>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<br>purpose of this study is to evaluate the tolerability and safety of INO-4500<br>administered by ID injection followed by EP in healthy adult volunteers   |
| 5   |                    | Phase I   | Onchocerciasis | Moxidectin tablet<br>(2mg)/ Allopathic<br>drug                 | February 2020       | Dr. Nicholas Opoku                                | Centre, University of<br>Health and Allied  | Medicines<br>Development<br>for Global<br>Health        | Study ended Final report<br>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  |
| 5   | 3<br>SPUTNIK LIGHT | Phase III | Covid-19       | 1.Sputnik Light<br>Vector Vaccine<br>2.Placebo/<br>Vaccine     | 5th March 2021      | 1. Dr. Nana Akosua<br>Ansah<br>2. Dr. Alberta Amu | 1. Navrogo Health<br>Research<br>2. Centre Dodowa<br>Health Research<br>Centre Ghana<br>•School of Public                               | Human Vaccine<br>LLC                                    | Study ended Final report yet to<br>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-<br>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<br>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 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<br>of<br>serologically confirmed SARS-CoV-2 infection<br>• Assess efficacy of the Sputnik-Light vector vaccine against the SARS-CoV-2-<br>induced coronavirus infection compared to placebo based on severity of<br>COVID-19 disease |
| 5   | 4 EMODEPSIDE       | Phase II  | Onchocerciasis | Emodepside<br>(5mg)/ Allopathic<br>drug                        | 5th November, 2020  | Dr. Nicholas Opoku                                | Health Research<br>Centre, (UHAS).<br>•Municipal Hospital,<br>Hohoe, Volta Region,<br>Ghana<br>•Kpassa, Nkwanta-<br>North District, Oti | DNDi (Drugs for<br>Neglected<br>Diseases<br>initiative) | Study ended Final report yet to                          | <ul> <li>The purpose of this study is to</li> <li>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</li> <li>Elasma PK of emodepside (solution and tablets), the effect of food on the bioavailability of emodepside</li> </ul>   |
|     |                    |           |                |  |                     |   |   |   |  | 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.  |
| 5   |                    | Phase IIb | Malaria        | 1.RTS,S/AS01E<br>2.Rabies<br>vaccine<br>(Rabipur™)/<br>Vaccine | 21st November 2016  | Prof. Tsiri Agbenyega                             |   | GlaxoSmithKlin<br>e Biologicals SA                      | be submitted   | This study intends to establish Proof of Concept for a fractional dose schedule<br>under conditions of natural exposure. The study will be conducted in children 5-<br>17 months old at first vaccination living in areas of mid to high malaria<br>transmission, in line with the age group recommended by the World Health<br>Organization. Results from study will be critical in informing future possibilities<br>for the development of vaccine-based strategies which, in combination with<br>other interventions, may contribute to the malaria elimination agenda.  |

|            |    |                                   |           |                         | Investigational  |                     |                               |   |   |  |  |
|------------|----|-----------------------------------|-----------|-------------------------|--|---------------------|-------------------------------|---|---|--|--|
|            |    |                                   |           | DISEASE                 |  | ,DATE OF RECEIPT OF |                               |   |   | STATUS & DURATION OF                         |  |
| <u>N/O</u> | 5  | STUDY                             | PHASE     | INDICATION              | CLASS<br>1.Measles<br>Rubella Vaccine  | APPLICATION         | INVESTIGATOR                  | ••Ga East Municipal<br>Hospital<br>•Korle-Bu Teaching<br>Hospital<br>•UGMC  | APPLICANT<br>Each country<br>serves as its<br>own sponsor<br>but will receive<br>funding from the<br>Covid 19<br>Therapeutics<br>Accelerator and<br>Gates<br>Foundation |  | PURPOSE/AIM OF STUDY         The purpose of this study is to determine that MR vaccine increases the         Ukalibased of making the approxime for a purpose of the study is to determine that MR vaccine increases the   |
|            |    | CROWN<br>CORONATION               | Phase III | Covid-19                | 2.Matching<br>Placebo<br>3.AstraZeneca   | 7th September 2020  | Prof. Kwadwo Koram            | •Effia-Nkwanta<br>Hospital<br>•Bentecost Treatment<br>Center  | through<br>Washington<br>University in St.  | Study ended Final report yet to be submitted | likelihood of making the specific AstraZeneca COVID-19 vaccine more effective<br>in people with prior exposure to the MR vaccine.<br>This study has two different groups: one group will receive the active MR<br>vaccine and one will receive a placebo. Thirty and sixty days later, participants<br>in each group will receive the AstraZeneca COVID-19 vaccine.  |
|            | C  | DOLF_IDA<br>DNCHO<br>SAFETY GHANA | Phase II  | Onchocerciasis          | 1.Diethylcarbam<br>azine Citrate I. P<br>100mg<br>2.Ivermectin<br>(Stromectol®<br>3mg)<br>3.Albendazole<br>(Zentel™ 400mg)<br>/ Allopathic drugs |                     | Dr. Nicholas Opoku            | University of Health<br>and Allied Sciences   | · · ·   | Study ended Final report<br>submitted        | Programs for control of onchocerciasis through community directed treatment<br>with ivermectin (IVM) as a form of Mass Drug Administration (MDA) have been<br>in place for almost 30 years. IVM is effective for clearing Mf and it temporarily<br>sterilizes adult female worms, but it is not a microfilaricide and does not kill<br>adult worms. For that reason, MDA with IVM must be repeated for the<br>reproductive life of the adult worms, which is 10-15 years. Thus, there is a<br>widely recognized need for new, safe, short-course treatment drug(s) that can<br>kill or permanently sterilize adult worms.<br>This study aims to provide preliminary data on the safety of ivermectin +<br>diethhylcarbamazine + albendazol (IDA) treatment in persons with<br>onchocerciasis when administered after pre-treatment with IVM to clear or<br>greatly reduce microfilariae from the skin and eyes. Widespread use of IDA<br>following IVM pretreatment (I/IDA) has the potential to greatly accelerate<br>elimination of LF in African countries that are coendemic for LF and<br>onchocerciasis  |
|            | 58 | SMAART                            | Phase II  | Stroke                  | 1.POLYCAP<br>2.USUAL CARE<br>/ Allopathic drug   | 9th February, 2018  | Dr. Fred Stephen Sarfo        | Komfo Anokye<br>Teaching Hospital   | Kwame<br>Nkrumah<br>University of<br>Science and<br>Technology  | Study ended Final report                     | 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). |
|            | 59 | -EDoxy                            | Phase II  | Lymphatic<br>Filariasis | 1.Doxycycline<br>(Remycin®100mg<br>2.Placebo<br>3.Standard<br>MDA Treatment/<br>Allopathic drug  |                     | Prof. Alexander Yaw<br>Debrah | 1.Kumasi Centre for<br>Collaborative<br>Research (KCCR),<br>Kwame Nkrumah<br>University of Science<br>and Technology<br>(KNUST)<br>2.War Memorial<br>Hospital, Navrongo | For<br>Collaborative  | Study ended Final report<br>submitted        | 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 multinational 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)   |

|     |                            |                     |                       | Investigational  |                                    |                           |  |                |  |  |
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| N/O | TITLE OF<br>STUDY          | PHASE               | DISEASE<br>INDICATION | Products (IPs)/IP<br>CLASS   | ,DATE OF RECEIPT OF<br>APPLICATION | PRINCIPAL<br>INVESTIGATOR | STUDY CENTRE(S)  |                | STATUS & DURATION OF<br>STUDY                                      | PURPOSE/AIM OF STUDY   |
| 60  |                            | Phase III           | Surgery               | 1.ChloraPrep™<br>stick<br>2.Videne®<br>Antiseptic<br>Solution<br>3.Triclosan<br>Coated PDS<br>and/or Vicryl<br>sutures<br>4.Non-triclosan<br>coated PDS<br>and/or Vicryl<br>sutures/ Medical<br>device | 10th April, 2019                   | Prof. Stephen Tabiri      | Tamale Teaching<br>Hospital  | The University | Study ended Final report<br>submitted<br>24 Months                 | Improving surgical outcomes is a global health priority. Recent World Health<br>Organisation (WHO) guidelines made 29 recommendations for intraoperative<br>and postoperative measures to prevent SSI, including global perspectives<br>relevant to LMICs., none of the evidence for the recommendations used was<br>derived from resource limited settings, leading to uncertainty about<br>implementation of measures in these settings. A randomised trial that has the<br>potential to evaluate multiple interventions has particular value in this setting,<br>and can establish a high quality evidence base that will inform guidance, and<br>influence revisions to the WHO Surgical Safety Checklist<br>This study assesses whether either (1) 2% alcoholic chlorhexidine versus 10%<br>povidone-iodine for skin preparation, or (2) triclosan-coated suture versus non-<br>coated suture for fascial closure, can reduce surgical site infection at 30-days<br>post-surgery for each of (1) clean-contaminated and (2) contaminated/dirty<br>surgery |
| 61  | KNC 19 (NIBIMA)            | Phase Ilb           | Covid-19              | 1.Nibima<br>2.WHO<br>standard<br>treatment for<br>COVID-19/<br>Herbal drug   | 11th September 2020                | Prof. Ellis Owusu-Dabo    | Komfo Anokye<br>Teaching Hospital  | of Grants and  | Study ended Final report<br>submitted From 3 months to 7<br>months | The purpose of this trial is to evaluate the:<br>•Efficacy of Nibima in reducing >50% Covid-19 viral load per patient within 14<br>days of therapy.<br>Evaluate the efficacy of Nibima in increasing the anti-inflammatory and<br>interferon alpha/beta profiles of >50% of the Covid-19 patients within 14 days.  |
| 62  |                            | Phase II            | Malaria               | 1.Artesunate<br>Pyronaridine<br>(Pyramax<br>2.Atovaquone<br>Proguanil<br>(Malarone)<br>3.Clindamycin<br>4.Foscidomysin<br>5.Artesunate /<br>Allopathic drug  | 27th July 2020                     |                           | St. Francis Xavier<br>Hospital Assin Fosu,<br>Ghana.<br>Gabon              |                | Study ended Final report<br>submitted 7 months                     | The main objective of the project is to investigate two combinations of drugs<br>already used in the market or in late-stage clinical development but not yet<br>tested in the presently proposed combination. These are Artesunate-<br>Pyronaridin-Atovaquone/Proguanil (APAP) and Artesunate-<br>FosmidomycinClindamycin (AFC).<br>The two drug combinations will be investigated in a randomized controlledthree-<br>groupp clinical phase II study.<br>This study will aim to describe:<br>• The pharmacokinetics of the investigated drugs when administered in<br>combination therapy<br>• PCR corrected antimalarial efficacy over a 42 day follow up period<br>• Safety and tolerability.  |
| 63  | STAR TRIAL                 | Phase IV            | Anaesthesia           | 1.Paracetamol<br>2.Morphine/Allop<br>athic drug  | 7th May 2021                       | Dr. Frank Enoch Gyamfi    | Komfo Anokye<br>Teaching Hospital,<br>Kumasi                               |                | Study ended Final report<br>submittee 10 months                    | To compare the efficacy of intramuscular (i.m) morphine as unimodal analgesic<br>with bimodal administration of i.m. morphine and i.v. paracetamol in managing<br>postoperative pain in emergency abdominal surgery.<br>To assess the response of patients to i.m. morphine in pain management after<br>emergency abdominal surgery. To assess the response of<br>patients to a combination of i.v. paracetamol and i.m. morphine in managing<br>pain after emergency abdominal surgery.<br>To determine the association between the administered analgesic and length of<br>hospital stay. To determine the<br>association between administered analgesic and postoperative complications.  |
|     | DIABETIC FOOT<br>SELF CARE | Feasibility testing | g Diabetes            | 1.Foot Selfcare<br>Training and<br>Education Plus<br>usual care<br>2. Usual care./<br>Training   | 28th October 2021                  | Dr.Joseph N. Suglo        | Diabetes Clinic,<br>Komfo Anokye<br>Teaching Hospital<br>(KATH) –<br>Ghana |                | Study ended Final report in E3<br>format submitted, 7 months       | The primary aim of this research is to evaluate the feasibility of conducting a randomised controlled trial to investigate the effectiveness of a hands-on skills training and education on foot self-care programme for persons with diabetes and their family caregivers in Ghana. The research question is 'can the provision of a family-oriented foot self-care skills training and education intervention improve foot care behaviour, foot care self- efficacy, knowledge of diabetic foot and diabetes distress among persons with diabetes and their caregivers in Ghana?'  |

|     |    |                           |          |                       | Investigational   |                                    |                              |   |                                       |  |   |
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| N/O |    | TITLE OF<br>STUDY         | PHASE    | DISEASE<br>INDICATION | Products (IPs)/IP<br>CLASS  | ,DATE OF RECEIPT OF<br>APPLICATION | PRINCIPAL<br>INVESTIGATOR    | STUDY CENTRE(S)   | SPONSORS & APPLICANT                  | STATUS & DURATION OF<br>STUDY                                | PURPOSE/AIM OF STUDY  |
|     |    | СНЕЕТАН                   | Pilot    | Surgery               | 1.Sterile Gloves<br>2.Sterile<br>Surgical<br>Instrument/Medic<br>al device  |                                    | Professor Stephen Tabiri     | •Cape Coast<br>Teaching Hospital<br>•Effiah Nkwanta<br>Regional Hospital<br>•Holy Family Hospital<br>– Berekum<br>•Holy Family Hospital<br>– Techiman | Birmingham<br>Clinical Trials         | Study ended Final report<br>submitted. 24 Months             | To purpose of this study is to assess whether the practice of using separate,<br>sterile gloves and instruments to close wounds at the end of surgery can<br>reduce surgical site infection at 30-days post-surgery for patients undergoing<br>clean-contaminated, contaminated or dirty abdominal surgery, compared to<br>current routine hospital practice.   |
|     | 66 | KAE609                    | Phase II | Malaria               | 1.KAE609<br>2.COARTEM<br>TABLETS /<br>Allopathic drug   | 1st September 2019                 | Dr. Abraham Rexford<br>Oduro | 1.Navrongo Health<br>Center<br>2.Kintampo Health<br>Research Centre   | Novartis<br>Pharma AG,<br>Switzerland | Study ended; Final report<br>submitted<br>14months           | KAE609 will be evaluated primarily for hepatic safety of single and multiple<br>doses in sequential cohorts with increasing doses.<br>This study aims to determine the maximum safe dose of the investigational<br>drug KAE609 in Adult patients with acute, uncomplicated Plasmodium<br>falciparum malaria infection   |
|     |    | Saving Brains<br>Navrongo | Phase I  | Malnutrition          | 1.Small<br>Quantity Lipid-<br>based Nutrient<br>Supplement for<br>Pregnant and<br>Lactating mothers<br>(SQLNS P&L)<br>2. Enhanced<br>Small Quantity<br>Lipid-based<br>Nutrient<br>Supplement for<br>Pregnant and<br>Lactating mothers<br>(eSQLNS P&L)<br>3.SQLNS for<br>Infants<br>4.eSQLNS<br>5.SQLNS nut<br>6.Omega 3 fatty<br>acids<br>7.Corn oil/ Food<br>supplements |                                    | Dr. Engelbert A. Nonterah    | Navrongo Health<br>Research Centre  | Nutriset, SAS                         | Study ended; Final report yet to<br>be submitted<br>6 months | Malnutrition continues to be a global problem. Globally 156 milion children less<br>than 5 years are stunted, 50 million wasted, while simultaneously 42 million are<br>overweight reflecting the double burden of malnutrition. Prevalence of<br>malnutrition varies by region and country with Asia and Africa being the worst<br>offected regions. This study is to ssess the acceptability and adherence to<br>nutrient supplementation for 6 weeks among pregnant and lactating women<br>and 6 monh old infants post weaning |

|     |                         |           |   | Investigational  |                                    |   |  |   |   |  |
|-----|-------------------------|-----------|---|--|------------------------------------|---|--|---|---|--|
| N/O | TITLE OF<br>STUDY       | PHASE     | DISEASE<br>INDICATION                   | Products (IPs)/IP<br>CLASS   | ,DATE OF RECEIPT OF<br>APPLICATION | PRINCIPAL<br>INVESTIGATOR   | STUDY CENTRE(S)  |   | STATUS & DURATION OF<br>STUDY   | PURPOSE/AIM OF STUDY   |
|     |                         |           |   |  |                                    |   |  |   |   |  |
|     |                         |           |   | 1.Small<br>Quantity Lipid-<br>based Nutrient<br>Supplement for<br>Pregnant and<br>Lactating mothers<br>(SQLNS P&L)<br>2.Enhanced<br>Small Quantity<br>Lipid-based<br>Nutrient<br>Supplement for<br>Pregnant and<br>Lactating mothers<br>(eSQLNS P&L)<br>3.SQLNS for<br>Infants<br>4.eSQLNS for |                                    |   | 1.Tafo Government<br>Hospital<br>2.Suntreso  |   |   | Malnutrition continues to be a global problem. Globally 156 milion children less than 5 years are stunted, 50 million wasted, while simultaneously 42 million are overweight reflecting the double burden of malnutrition. Prevalence of   |
|     |                         |           |   | Infants  |                                    |   | Government Hospital  |   |   | malnutrition varies by region and country with Asia and Africa being the worst   |
|     | SAVING BRAINS<br>KUMASI |           |   | 5.Omega 3 fatty<br>acids/ Food   |                                    |   | 3.Kumasi South   | KNUST/Nutriset  |   | affected regions. This study is to ssess the acceptability and adherence to nutrient supplementation for 6 weeks among pregnant and lactating women  |
| 68  |                         | Phase I   | Malnutrition                            | supplements  | 1st November 2017                  | Prof. Jacob Plange-Rhule  | Government Hospital  | SAS<br>Case Western                                   | 6months   | and 6 monh old infants post weaning  |
|     | ALB_IVM                 |           |   | 1. Ivermectin<br>2. Albendazole/   |                                    |   | Onchocerciasis<br>Chemotherapy<br>Research Centre  | Reserve<br>University<br>School of<br>Medicine,       | Study ended; Final report<br>submitted<br>38 months                   | To address whether IVM plus ALB given twice per year will be   |
| 69  |                         | Phase III | Onchocerciasis                          | Allopathic drug  | 1st April 2014                     | Dr. Nicholas Opoku  | Government Hospital.   | Ave Cleveland   |   | superior over annual treatment or IVM given biannually   |
| 70  | MAL 055                 | Phase III | Malaria                                 | RTS,S/AS01E/<br>Vaccine  | 1st October 2008                   | 1. Prof. E. Tsiri<br>Agbenyaga<br>2. Prof. Seth Owusu<br>Agyei<br>3. Dr. Kwaku Poku Asante  | <ol> <li>Malaria Research<br/>Centre, Agogo.</li> <li>Kintampo Health<br/>Research Centre</li> </ol>     |   | Study ended; Final report<br>submitted<br>60 months                   | This Phase III study of GSK Biologicals candidate malaria vaccine<br>RTS,S/AS01E has been designed to address the key safety and efficacy<br>information required for vaccine licensure. In addition, other disease endpoints<br>that allow the evaluation of the full public health impact and cost effectiveness<br>of vaccine implementation are included. Co-primary objectives will investigate<br>the efficacy against clinical disease in children from 5-17 months of age at first<br>dose and the efficacy in infants 6-12<br>weeks of age who receive the vaccine in co-administration with EPI antigens |
| 71  | MMS                     | Phase III | Malnutrition                            | 1.Multiple<br>micronutrient<br>supplement<br>2.Iron + folic acid<br>tablets/ Food<br>supplements   | 2nd October 2012                   | Prof. Tsiri Agbenyaga   | Collaborative<br>Community<br>Development Project<br>2. C/O Komfo<br>Anokye Teaching<br>Hospital, Kumasi |   | Study Ended; yet to submit<br>report<br>48 months                     |  |
| 72  | PRENABELT               |           | Birth Weight                            | 1.Prenabelt™<br>2. Sham<br>prenabelt™<br>3.Body Position<br>Sensor/ Medical<br>device  | 21st April 2015                    | Dr. Jerry Coleman   | Korle-Bu Teaching<br>Hospital, Accra –<br>Korle Bu   |   | Study ended; Final report<br>submitted<br>7 months                    | The purpose of this study is to determine the effect of the PrenaBelt on birth-<br>weight and assess the feasibility of introducing it to Ghanaian third-trimester<br>pregnant women in their home setting via an antenatal care clinic and local<br>health-care staff. Data from this study will be used in effect size calculations for<br>the design of a large-scale, epidemiological study targeted at reducing LBW<br>and SB in Ghana and globally.  |
| 73  | СРАР                    | Phase III | Infant Acute<br>Respiratory<br>Distress | 1.DeVilbiss<br>IntelliPAP CPAP<br>machine (Model<br>DV5 Series)<br>2. Hudson RCI<br>nasal cannulas/<br>Medical device  | 14th May 2013                      | <ol> <li>Dr. Harry Tagbor</li> <li>Dr. Frank Baiden</li> <li>Dr. Damien Punguyire</li> <li>Dr. Kwadwo Nyarko</li> <li>Jectey</li> </ol> | Government Hospital,<br>Mampong<br>2. Kintampo<br>Municipal Hospital,<br>Kintampo                        | Foundation's<br>Systems<br>Improvement at<br>District | Study ended; yet to submit<br>report in required format.<br>36 months | Evaluating the impact of using continuous positive airway pressure<br>(CPAP) on mortality among children admitted into emergencies<br>wards. an interventional trial to determine if CPAP reduces morality in children<br>1 month to 5 years of age with acute respiratory distress  |

|     |                             |           |   | Investigational  |                     |                         |   |  |  |   |
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|     | TITLE OF                    |           | DISEASE                                       |  | ,DATE OF RECEIPT OF | PRINCIPAL               |   | SPONSORS &                               | STATUS & DURATION OF                               |   |
| N/O | STUDY                       | PHASE     | INDICATION                                    | CLASS  | APPLICATION         | INVESTIGATOR            | STUDY CENTRE(S)                                 | APPLICANT                                | STUDY  | PURPOSE/AIM OF STUDY  |
| 74  | AIMS                        | Phase III | Transfusion-<br>Transmitted<br>Malaria (TTM)  | 1.Mirasol system<br>for whole blood<br>2.Standard fresh<br>whole blood/<br>Blood product   | 9th July 2013       | Dr. Shirley Owusu-Ofori | Komfo Anokye<br>Teaching Hospital               | Terumo BCT<br>Europe N.V.                | Study ended; Final report<br>submitted<br>6 months | The objective of this study was to evaluate the efficacy of Mirasol-treated fresh<br>whole blood (WB) to prevent transfusion-transmitted malaria (TTM) by<br>comparing the incidence of TTM between subjects receiving Mirasol-treated<br>fresh WB and subjects receiving standard (untreated) fresh WB.  |
| 75  |                             | Phase III | Meningitis                                    | Meningococcal A<br>Conjugate<br>Vaccine/ Vaccine   | 26th June 2007      | Dr. Patrick Ansah       | Navrongo Health<br>Research Centre              | SIIL<br>PATH                             | Study ended; Final report<br>submitted 54 months   | To compare the immunogenicity at 28 days after vaccination of range dosages -<br>10, 5, and 2.5 µg of the PsA-TT vaccine, when administered to infants in a two-<br>dose schedule at 14 weeks (window 14 to 18 weeks of age) and 9 months of<br>age (window 9 to 12 months of age) concomitantly with EPI vaccines (Groups<br>1A vs. 1B vs. 1C)   |
| 76  | NON-INVASIVE<br>HAEM DEVICE | Phase III | Hemoglobin<br>deficiency in<br>Pregnant women | 1. Pronto &<br>pronto-7 pulse co-<br>oximeter pulse co-<br>oximeter 2.<br>Hemocue 201+3.<br>Abx pentra 60<br>hematology<br>analyzer/ Medical<br>device |                     | Dr. Sam Newton          | Kintampo Health<br>Research Centre,<br>Kintampo | PATH                                     | Study Ended Final report<br>submitted<br>2 months  | Aim<br>The aim of the validation study was to evaluate the accuracy of the Pronto and<br>Pronto 7devices in measuring Hb when compared to measuring Hb using the<br>Hemocue and the ABX Pentra 60 hematology analyzer as the reference<br>standard.<br>Study Objectives: To<br>compare Hb values as measured by the Pronto and Pronto 7noninvasive Hb<br>devices and HemoCue 201+ machine with those obtained by a venous blood<br>draw using an ABX Pentra 60 hematology analyzer among pregnant women<br>attending ANC clinic in Ghana. |
| 77  | ROTARIX                     | Phase III | Gastroenteritis                               | Rotarix™/<br>Vaccine   | 6th February 2012   | Prof. George Armah      | Navrongo Health<br>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  |
| 78  | ARTIMIST                    | Phase III | Malaria                                       | ArTiMist/<br>Allopathic drug   | 22nd October 2010   | Dr. Patrick Ansah       | Navrongo Health<br>Research Centre              | ProtoPharma<br>Limited                   | Study Ended Final report<br>submitted<br>5 months  | The primary objective of this study was to demonstrate the superiority of ArTiMist <sup><math>M</math></sup> over intravenous (iv) quinine in establishing parasite success (reduction of parasite counts by $\geq$ 90% within 24 hours) in children with severe or complicated falciparum malaria, or children with uncomplicated malaria with gastrointestinal complications.   |
| 79  | GARDASIL                    | Phase III | Human Papilom<br>Virus (HPV)                  | Gardasil/ Vaccine  | 1st November 2010   | Dr. Nana Akosua Ansah   | Navrongo Health<br>Research Centre              | Merck, Sharp<br>and Dohme<br>Corporation | Study Ended Final report<br>submitted<br>20 months | To estimate the percentage of subjects who seroconvert to each of HPV 6, 11,<br>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<br>age in SubSaharan Africa.<br>Secondary: To estimate Month 7 anti-HPV 6, 11, 16, and 18 geometric mean<br>titers (GMTs) in vaccinated subjects   |
| 80  | SMAC                        | Phase III | Malaria                                       | <ol> <li>Intravenous</li> <li>Artesunate</li> <li>Intramuscular</li> <li>Artesunate/</li> <li>Allopathic</li> </ol>                                    | 1st January 2013    | Prof. Tsiri Agbenyega   | Komfo Anokye<br>Teaching Hospital,<br>Kumasi    | University<br>Medical Centre<br>Tubingen | Study Ended<br>15 months                           |   |
| 81  | OXYTOCIN                    |           | Postpartum<br>Hemorrhage<br>(PPH)             | 1.Oxytocin in<br>uniject™ 10 iu/<br>Hormone  | 12th May 2010       | Dr. Sam Newton          | Kintampo Health<br>Research Centre              | PATH                                     | Study Ended Final report<br>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   |
| 82  | AMARYL M                    | IV        | Type 2 Diabetes                               | Amaryl m oral<br>tablets/ Allopathic   | 16th October 2009   | Dr. Frank Umeh          | Korle-Bu Teaching<br>Hospital                   | Sanofi Aventis                           | Study Ended<br>6 months                            | To determine the clinical Efficacy and Safety of Amaryl M in Patients with Type<br>2 Diabetes Who are Inadequately Treated by Either Glimepride or Metformin<br>Monotherapy or Who are Already Treated with Free Combination of Glimepride<br>and Metformin in African Countries  |

|     |  |           |  | Investigational   |                     |   |   |   |   |   |
|-----|--|-----------|--|---|---------------------|---|---|---|---|---|
|     | TITLE OF   |           | DISEASE  |   | ,DATE OF RECEIPT OF | PRINCIPAL   |   |   | STATUS & DURATION OF                                      |   |
| N/O | STUDY  | PHASE     | INDICATION   | CLASS   | APPLICATION         | INVESTIGATOR  | STUDY CENTRE(S)   | APPLICANT   | STUDY   | PURPOSE/AIM OF STUDY  |
|     |  |           |  |   |                     |   |   | 1. Wyeth<br>Research<br>Division of<br>Wyeth<br>Pharmaceutical<br>s Inc.  |   |   |
| 83  | MOXIDECTIN-<br>IVERMECTIN                        | 111       | Onchocerciasis                                     | 1. Moxidectin<br>2.<br>Ivermectin/Allopat<br>hic  | 1st February 2004   | Dr. Nicholas Opoku  | Onchocerciasis<br>Chemotherapy  |   |   | To determine the Safety, Tolerability, and Efficacy of Orally Administered Moxidectin in Subjects with Onchocerca vovulus   |
|     | MOXIDECTIN                                       | Phase II  | Onchocerciasis                                     | Moxidectin 2mg<br>Tablets/Allopathic  |                     | Dr. Kwabla Awadzi   | Onchocerciasis<br>Chemotherapy<br>Research Centre                                     | Research<br>Division of<br>Wyeth<br>Pharmaceutical  | Study Ended Ended<br>60 months                            |   |
| 85  | EBA  | Phase I   | Malaria  | (EBA-175 RII-NG)<br>malaria vaccine/<br>Vaccine   | 1st March 2009      | Prof. Kwadwo Ansah<br>Koram   | Noguchi Momorial<br>Institute of Medical<br>Research                                  | Division of<br>Microbiology<br>and Infectious<br>Diseases<br>(DMID)<br>National<br>Institute of<br>Allergy and<br>Infectious<br>Diseases<br>(NIAID) | Study Ended Final report<br>submitted<br>18 months        | To determine the Immunogenicity of EBA-175 RII-NG Malaria Vaccine<br>Administered Intramuscularly in Semi-Immune Adults   |
| 86  | IPT & SP   | Phase III | Malaria in<br>Pregnant women                       | Sulfadoxine-<br>pyrimethamine/All<br>opathic  | 1st May 2008        | Dr. Abraham Hodgson   | Health Facilities in<br>the Kassena<br>Nankana, Navrongo<br>Health Research<br>Centre |   | Study Ended<br>32 months                                  | to compare the intermittent preventive treatment of sulfadoxine-pyrimethamine with intermittent screening and treatment of malaria in pregnancy   |
| 87  | IRON<br>FORTIFICATION<br>III                     |           | Malaria  | 1.Sprinkles<br>vitamine<br>2.mineral food<br>supplement/<br>Food<br>supplements               | 1st July 2009       | Prof. Seth Owusu Agyei  | Kintampo Health<br>Research Centre  |   | Study Ended<br>12 months                                  | To determine the seasonal impact of iron fortification on malaria incidence in<br>Ghanaian children   |
| 88  | ROTASHIELD                                       | =         | Rotavirus<br>Gastroenteritis                       | RRV-TV Vaccine<br>(rotashield)/<br>Vaccine  | 1st August 2009     | <ol> <li>Prof. George E. Armah</li> <li>Prof. Fred N. Binka</li> <li>Dr. Abraham Hodgson</li> </ol> | Hospital, Navrongo<br>2. Bongo Hospital   |   | Study Ended<br>16 months                                  | To determine the efficacy, immunogenicity, and safety of two single doses of RRV TV in neonates / infants   |
| 89  | AZITHROMYCIN<br>PLUS<br>CHLOROQUINE<br>PHOSPHATE | 111       | Malaria  | 1.Azithromycin<br>2. Chloroquine<br>Phosphate<br>3. Artemether-<br>Lumefatrine/Allop<br>athic | 1st October 2007    | Dr. Patrick Ansah   | Navrongo Health<br>Research Centre  | Research and Development.   | Study Ended Final report<br>submitted<br>8 months         | To compare azithromycin plus chloroquine phosphate with artemether-<br>lumefantrine for the treatment of uncomplicated plasmodium falciparum malaria<br>in children in Africa                                 |
| 90  | CRASH-2  | 1         | Trauma patient<br>with or at risk of<br>hemorrhage | 1.Tranexamic<br>acid<br>2. Placebo/   | 1st August 2007     | Prof. J. C. B. Dakubo   |   | Tropical  | Study Ended,<br>Lancet publication submitted<br>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.  |
| 91  | PYRONARIDINE<br>ARTESUNATE<br>VRS COARTEM        | 111       | Malaria  | Artesunate Tablet<br>(PYRAMAX)<br>2.Artemether-<br>Lumefantrine(CO<br>ARTEM)/<br>Allopathic   | 1st March 2007      | Dr. G. Bedu-Adoo  | Komfo Anokye  | Medicines For<br>Malaria Venture,<br>Switzerland  | Study Ended<br>3 months                                   | To Compare the Safety and Efficacy Of Fixed Dose Formulation Of Oral<br>Pyronaridine Artesunate Tablet with Coartem In Children And Adult Patients<br>With Acute Uncomplicated Plasmodium Falciparium Malaria |

|     |             |       |                 | Investigational                    |                     |   |   |                              |                          |                      |
|-----|-------------|-------|-----------------|------------------------------------|---------------------|---|---|------------------------------|--------------------------|----------------------|
|     | TITLE OF    |       | DISEASE         | Products (IPs)/IP                  | ,DATE OF RECEIPT OF | PRINCIPAL                                       |   |                              | STATUS & DURATION OF     |                      |
| N/O | STUDY       | PHASE | INDICATION      | CLASS                              | APPLICATION         | INVESTIGATOR                                    | STUDY CENTRE(S)                         | APPLICANT                    | STUDY                    | PURPOSE/AIM OF STUDY |
|     |             |       |                 |                                    |                     |   |   |                              |                          |                      |
|     | MAL 050     |       |                 | RTSS, AS10E                        |                     |   | Kintampo Health                         | GlaxoSmithKlin               | Study Ended              |                      |
| 92  |             | ш     | Malaria         | Vaccine/Vaccine                    |                     | Prof. Seth Owusu Adjei                          | Research Centre                         |                              | 17 months                |                      |
|     |             |       |                 |                                    |                     |   |   |                              |                          |                      |
|     |             |       |                 |                                    |                     |   |   |                              |                          |                      |
|     |             |       |                 |                                    |                     |   |   | Division of<br>Microbiology  |                          |                      |
|     |             |       |                 |                                    |                     |   |   | and Infectious               |                          |                      |
|     |             |       |                 |                                    |                     |   |   | Diseases                     |                          |                      |
|     |             |       |                 |                                    |                     |   |   | (DMID)                       |                          |                      |
|     |             |       |                 |                                    |                     |   |   | National                     |                          |                      |
|     |             |       |                 |                                    |                     |   |   | Institute of                 |                          |                      |
|     | PFCSP_MVACS |       |                 |                                    |                     |   |   | Allergy and<br>Infectious    |                          |                      |
|     | _MALARIA    |       |                 | PfCSP DNA                          |                     |   |   | Diseases                     |                          |                      |
|     |             |       |                 | VACCINE (VCL-                      |                     |   | Tetteh Quarshie                         | (NIAID)                      | Study Ended              |                      |
| 93  |             | 1     | Malaria         | 2510)/Vaccine                      | 1st August 2005     | Prof. Kwadwo A Koram                            | Memorial Hospital                       |                              | 18 months                |                      |
|     | ROTATEQ     |       |                 |                                    |                     |   |   | 1. Merck & Co.               | Study Ended Final report |                      |
|     |             |       |                 |                                    |                     |   | Navrongo Health                         | 2. PATH                      | published in Lancet      |                      |
| 94  | •           |       | Gastroenteritis | Rotateq/Vaccine                    | 1st September 2007  | Prof. George E. Armah                           | Research Centre                         |                              | 18 months                |                      |
|     |             |       |                 |                                    |                     |   |   |                              |                          |                      |
|     |             |       |                 | 1 Mofferuine                       |                     |   |   |                              |                          |                      |
|     | MEFLOQCHLOA |       |                 | 1. Mefloquine<br>2. Chloroquine    |                     |   |   |                              |                          |                      |
|     | ZITH        |       |                 | 3.                                 |                     |   |   |                              | Study Ended Final report |                      |
|     |             |       | Malaria         | Azythromycin/Allo                  |                     |   | Navrongo Health                         |                              | submitted                |                      |
| 95  |             |       | Malaria         | pathic                             | 4th August 2004     | Dr. Abraham Hodgson                             | Research Centre                         | Pfizer Inc.                  | 12 months                |                      |
|     | MAL 047     |       |                 | 1.RTS,S/AS02D                      |                     | Prof. Seth Owusu Adjei,                         |   |                              |                          |                      |
|     |             |       | Malaria         | 2.RTS,S/AS01E/                     |                     | Dr. Kwaku Poku Asante                           | Kintampo Health                         | GlaxoSmithKlin<br>e R&D      |                          |                      |
| 96  |             |       | Malaria         | Vaccine                            |                     |   | Research Centre                         |                              | 19 months                |                      |
|     |             |       |                 | 1.Chorproguanil-                   |                     |   |   |                              |                          |                      |
|     |             |       |                 | Dapsone-                           |                     |   |   |                              |                          |                      |
|     |             |       |                 | Artesunate (CDA)                   |                     |   |   |                              |                          |                      |
|     | CDA         |       |                 | 2.Artemether-<br>Lumefantrine/Allo |                     | Prof. Seth Owusu Agyei<br>Dr. Kwaku Poku Asante | Kintampo Health                         | GlaxoSmithKlin               | Study Ended              |                      |
| 97  |             | ш     | Malaria         | pathic                             | 19th July 2006      | DI. KWAKU POKU ASame                            | Research Centre                         |                              | 12 months                |                      |
|     |             |       |                 | Dapsone-                           |                     |   |   |                              |                          |                      |
|     |             |       |                 | Artesunate (CDA)                   |                     |   | Department of                           |                              |                          |                      |
|     | CDA2        |       |                 | 2.Artemether-<br>Lumefantrine/allo |                     |   | Physiology, School of Medical Sciences, | GlaxoSmithKlin               | Study Ended              |                      |
| 98  | •           | ш     | Malaria         |                                    | 27,June 2006        | Prof. Tsiri Agbenyega                           | KNUST                                   |                              | 12 months                |                      |
|     |             |       |                 |                                    |                     |   |   |                              |                          |                      |
|     |             |       |                 |                                    |                     |   |   | United States                |                          |                      |
|     |             |       |                 |                                    |                     |   |   | Agency for                   |                          |                      |
|     |             |       |                 |                                    |                     |   |   | International<br>Development |                          |                      |
|     |             |       |                 |                                    |                     |   |   | (USAID)                      |                          |                      |
|     |             |       |                 |                                    |                     |   |   | Through The                  |                          |                      |
|     |             |       |                 |                                    |                     |   |   | Peanut<br>Collaborative      |                          |                      |
|     | NOVASIL     |       |                 |                                    |                     | Prof. David Ofori Agyei                         | Ejura Sekyedumasi                       | Research                     |                          |                      |
|     |             |       |                 |                                    |                     | Dr. Nii- Ayi Ankrah                             | Disrict, Ashanti                        | Support                      | Study Ended              |                      |
| 99  |             | 11    |                 | NovaSIL                            |                     |   | Region                                  | Program                      | 9 months                 |                      |
|     |             |       |                 |                                    |                     |   |   |                              |                          |                      |
|     |             |       |                 |                                    |                     |   |   |                              |                          |                      |
|     | TENOFOVIR   |       |                 | Tenofovir<br>Disoproxyl            |                     |   |   |                              | Study Ended              |                      |
|     |             |       |                 | Fumarate                           |                     |   | Ghana Health                            |                              | 20 months                |                      |
| 100 |             | II    | HIV             | (TDF)/Vaccine                      | 1st February 2004   | Dr. Edith Clarke                                | Service                                 | International                |                          |                      |

|     |                            |       |                              | Investigational  |                     |   |   |  |  |   |
|-----|----------------------------|-------|------------------------------|--|---------------------|---|---|--|--|---|
|     | TITLE OF                   |       | DISEASE                      | Products (IPs)/IP  | ,DATE OF RECEIPT OF | PRINCIPAL   |   | SPONSORS &   |  |   |
| N/O | STUDY                      | PHASE | INDICATION                   | CLASS  | APPLICATION         | INVESTIGATOR  | STUDY CENTRE(S)   | APPLICANT  | STUDY  | PURPOSE/AIM OF STUDY  |
| 101 | SAVVY                      |       |                              | SAVVY<br>(Microbicide)   | 1st February 2004   | Dr. William Ampofo<br>Dr. Baafuor Kofi Opoku                        | <ol> <li>Noguchi Memorial<br/>Institution for Medical<br/>Research.</li> <li>Komfo Anokye<br/>Teaching Hospital.</li> </ol>                       |  | Study Ended<br>32 months   |   |
|     | MAL 063                    |       |                              |  |                     |   |   | Malaria  | Study Ended Final report   |   |
| 102 |                            | ш     | Malaria                      | RTS,S/AS01E/<br>Vaccine  | 15th April 2011     | Prof. E. Tsiri Agbenyaga  | Malaria Research<br>Centre, Agogo.  | Research<br>Centre, Agogo                            | submitted  |   |
| 103 | PREGACT<br>ALBIVIM K'SI    | 111   |                              | <ol> <li>Eurartesim oral<br/>tablets</li> <li>Farmanguinhos<br/>artesunate+meflo<br/>quine fixed<br/>combination oral<br/>tablets</li> <li>Coarsucam<br/>oral tablets/<br/>Allopathic</li> <li>Ivermectin</li> <li>Albendazole/Allo</li> </ol> |                     | 1.Dr. Harry Tagbor<br>2.Dr. Henry Opare Addo<br>Prof. Alexander Yaw | 1.Ejisu Government<br>Hospital, Ejisu<br>2. Juaben<br>Government Hospital<br>Juaben<br>Kumasi Centre for<br>Collaborative<br>Research in Tropical | Tropical<br>Medicine<br>University<br>Hospitals Case | Study Ended<br>60 months<br>Study Ended, Yet to submit<br>final report<br>4 years and 2 months |   |
| 104 |                            | III   | Onchocerciasis               | pathic   | 10th November 2015  | Debrah  | Medicine  | medical Center                                       | -  |   |
|     | RIFAMPIN VS<br>ISONIAZID   |       | Tuberclosis                  | 1.Isoniazid<br>2.<br>Rifampin/Allopath<br>ic/ Allopathic   | 2nd March 2011      | Dr. Joseph Baah Obeng   | Komfo Anokye<br>Teaching Hospital<br>Chest Clinic, Kumasi   | Canadian<br>Institute of<br>Health<br>Research       | Study Ended<br>60 months   |   |
|     | NOGUCHI<br>FILARIASIS<br>* |       | Filariasis                   | 1.Alere filariasis<br>test strip<br>2.Sd bioline<br>lymphatic<br>filariasis IgG4<br>3.Sd bioline<br>oncho/If IgG4<br>biplex<br>4.Diethylcarbam<br>azine patch<br>/Allopathic   | 7th June 2017       | Prof. Daniel A. Boakye<br>Dr. Nana – Kwadwo<br>Biritwum             | Noguchi Memorial<br>Institute For Medical<br>Research   | World Health<br>Organization -<br>TDR                | Study Ended Final report<br>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.  |
| 107 | ZIV<br>AFFLIBERCEPT        | 1     | Retinal Vascular<br>diseases | 1.Ziv-aflibercept<br>(ZALTRAP) /<br>Allopathic   | 30th January 2017   | Braimah Imoro Zeba  | Retina unit, Eye<br>Centre, Korle-Bu,<br>Teaching Hospital,<br>Korle-Bu, Accra  | Same as PI   | Study Ended Final report<br>submitted<br>5 months  | To evaluate the safety of 1.25mg and 2mg ziv-aflibercept in Ghanaian<br>population with retinal vascular diseases. To determine the safety<br>of intravitreal injections of ziv-aflibercept at 4 and 12 weeks in a Ghanaian<br>population.<br>To measure the visual outcome of treatment with 1.25mg and 2mg ziv-<br>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<br>and ME<br>secondary to RVO at 12 weeks. |

|     |                        |            |                        | Investigational   |                                    |   |  |                            |  |   |
|-----|------------------------|------------|------------------------|---|------------------------------------|---|--|----------------------------|--|---|
| N/O | TITLE OF<br>STUDY      | PHASE      | DISEASE<br>INDICATION  | Products (IPs)/IP<br>CLASS  | ,DATE OF RECEIPT OF<br>APPLICATION | PRINCIPAL<br>INVESTIGATOR   | STUDY CENTRE(S)  |                            | STATUS & DURATION OF<br>STUDY                              | PURPOSE/AIM OF STUDY  |
| 108 | HESTIA3                |            | Sickle Cell<br>Disease | 1.Ticagrelor<br>2.Placebo/Allop   | 1st August, 2018                   | <ol> <li>Prof. Alex Osei-Akoto</li> <li>Dr Patrick Ansah</li> <li>Dr. Catherine Segbefia</li> <li>Dr Kokou Hefoume</li> </ol> | <ol> <li>Komfo Anokye<br/>Teaching Hospital,<br/>Department of Child<br/>Health</li> <li>Navrongo Health<br/>Research Centre</li> <li>Department of<br/>Child Health, Korle<br/>Bu<br/>University of Health<br/>and Allied Sciences</li> </ol> |                            | Study Ended. Final Report<br>submitted<br>29 Months        | Sickle cell disease (SCD) is a genetic, autosomal, recessive blood disorder<br>resulting in altered (sickle- shaped) red-blood cells. A vaso-occlusive crisis<br>(VOC) is a severe, acute painful episode that occurs when sickle-shaped red<br>blood cells obstruct the microcirculation and restrict blood flow to an organ or<br>tissue, resulting in ischaemia, necrosis and organ damage. There is a high<br>unmet need for treatment options in SCD and there is a data that platelet<br>inhibition has the potential to reduce the risk for acute vaso-occlusions.<br>This study is to evaluate the effect (efficacy, safety and tolerability) of ticagrelor<br>versus placebo in reducing the rate of vaso-occlusive crises (VOCs), which is<br>the composite of painful crisis and/or acute chest syndrome (ACS), in<br>paediatric patients (2 to 11 years and 12 to 17 years with sickle cell disease<br>(SCD).   |
| 109 | PRCR DIPSTICK          | Phase II   | proteinuria            | 1.Test-It <sup>™</sup> Protein<br>Creatinine<br>Dipstick<br>2.Urinalysis<br>Reagent Strips<br>3.Quantitative<br>Spectrophotometr<br>ic Method/Medical<br>device | 16th February, 2018                | Dr. Sam Newton  | Kintampo Health<br>Research Center   | Program For<br>Appropriate | Study Ended. Final Report<br>Submitted<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. 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.  |
| 110 | MAL 073                | Phase IIIb | Malaria                | 1.RTS,S/AS01E<br>2.MR-VAC™<br>3.STAMARIL4.<br>VITAMIN A<br>/Vaccine   | 11th December 2015                 |   | 1.Malaria Research<br>Center, Agogo<br>2.Kintampo Health<br>Research Centre  | Pharmaceutical             | Study Ended Final Report<br>submitted 43 months 16<br>days | In sub-Saharan Africa, most of the Expanded Program on Immunization (EPI) vaccines are given in early infancy while measles, rubella and yellow fever (YF) vaccines are given at 9 months of age. Between the first EPI vaccines and the measles, rubella and YF vaccines, children receive Vitamin A supplementation at 6 months of age. To limit the number of clinic visits for young children and to optimize vaccine implementation a schedule (0, 1.5, 3-month) is proposed . There are however no data of the anti-circumsporozoite protein of Plasmodium falciparum (anti-CS) immune response induced by RTS,S/AS01E when given in co-administration with measles, rubella and YF, in a 0, 1.5, 3-month schedule starting at an older age (5-17 months). This study intends to demonstrate that anti-CS immune response of the candidate malaria vaccine RTS,S/AS01E is not inferior when RTS,S/AS01E is administered at 6, 7.5 and 9 months of age with the third dose given alone or in co-administration with measles, rubella vaccine Safety has not been evaluated in co-administration with measles, rubella and YF in a 0, 1.5, 3-month schedule starting at 6 months of age. This study will therefore provide safety information when RTS,S/AS01E is administered at 6, 7.5 and 9 months of age with the third dose given alone or 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 |
| 111 | CEPHEID<br>XPERT HIV-1 | PILOT      | HIV                    | Xpert HIV-1 VL<br>XC Test Assay<br>for detecting HIV-<br>1 RNA in human<br>plasma.  | 6th June 2019                      | Prof. Jacob Plange-Rhule  | St. Martin De Porres<br>Hospital<br>Atua Government<br>Hospital<br>Akosombo Hospital   |                            | Study Ended Final Report yet<br>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.  |

|     |                        |              |                          | Investigational   |                               |   |  |  |  |   |
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|     |                        |              | DISEASE                  |   | ,DATE OF RECEIPT OF           | PRINCIPAL   |  | SPONSORS &                               | STATUS & DURATION OF   |   |
| N/O | STUDY                  | PHASE        | INDICATION               | CLASS   | APPLICATION                   | INVESTIGATOR  | STUDY CENTRE(S)  | APPLICANT                                | STUDY  | PURPOSE/AIM OF STUDY  |
| 112 | GBT-2104-133           | Phase III    | Sickle Cell<br>Disease   | Inclacumab/<br>Monoclonal<br>antibody<br>1. Inclacumab  | 27 <sup>th</sup> August, 2021 | Professor Alex Osei-<br>Akoto                         | Komfo Anokye<br>Teaching Hospital<br>(KATH)  | Global Blood<br>Therapeutics,<br>Inc.    | Application Approved<br>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.<br>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). |
| 113 | GBT-2104-132           | Phase III    | Sickle Cell<br>Disease   | 2.Placebo/<br>Monoclonal<br>antibody  | 5th July, 2021                | Professor Alex Osei-<br>Akoto                         | Komfo Anokye<br>Teaching Hospital<br>(KATH)  | Global Blood<br>Therapeutics,<br>Inc.    | Study terminated by sponsor<br>before commencement<br>2 years                            | Additional objectives of the study are to evaluate the pharmacokinetics (PK)<br>and pharmacodynamics (PD) of inclacumab, the presence of anti-drug<br>antibodies (ADAs), and changes in quality of life (QOL).  |
| 114 | GBT 2104-131           | Phase III    | Sickle Cell<br>Disease   | 1. Inclacumab<br>2.Placebo/<br>Monoclonal<br>antibody   | 5th July, 2021                | Professor Alex Osei-<br>Akoto                         | Komfo Anokye<br>Teaching Hospital<br>(KATH)  | Global Blood<br>Therapeutics,<br>Inc.    | Study terminated by sponsor<br>before commencement<br>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.<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).  |
| 115 | INNOVATE               | Phase III/II | Covid-19                 | 1. Inn0-4800<br>2.<br>Placebo/Vaccine   |                               | Susan Adu-Amankwah                                    | Noguchi Memorial<br>Institute for Medical<br>Research  |  | Study Closed/withdrawn by<br>Sponsor<br>24 months  | <ol> <li>Evaluate the cellular and humoral immune response to INO-4800<br/>administered by ID injection followed immediately by electroporation EP</li> <li>Evaluate the efficacy of INO-4800 in the prevention of COVID-19 disease in<br/>subjects who are SARS-CoV-2 negative at baseline</li> </ol>  |
| 116 | LIVZON                 | Phase III    | Covid-19                 | 1.SARS-CoV-2<br>fusion protein<br>vaccine (code: V-<br>0)<br>2.<br>Placebo/Vaccine                  | 2nd August 2021               | 1.Dr Seyram Kaali<br>2.Dr. Nana Akosua Ansah          | 1.Kintampo Health<br>Research Centre<br>2.Navrongo Health<br>Research Centre   | Institution<br>Pharmaceutical            | Study Closed by Sponsor<br>before commencement. No<br>recruitment was done.<br>20 months | Efficacy:<br>To evaluate the efficacy of the recombinant SARS-CoV-2 fusion<br>protein vaccine (V-01) for the prevention of symptomatic RT PCR positive<br>COVID-19 (mild or above severity) starting from at least 14 days (≥15 days)<br>after full-course immunization (completing all vaccinations)<br>Safety:<br>To evaluate the incidence of adverse events (AEs) of recombinant<br>SARS-CoV-2 fusion protein vaccine (V-01) from the first<br>vaccination to 28 days after full-course immunization  |
|     | COVID 19<br>INTRANASAL | Phase III    | Covid-19                 | 1.Influenza Virus<br>Vector COVID-19<br>Vaccine<br>for Intranasal<br>Spray<br>2.<br>Placebo/Vaccine | 19th October 2021             | Dr. Seyram Kaali                                      | <ol> <li>KHRC</li> <li>NHRC</li> <li>KCCR</li> <li>Dodowa Health</li> <li>Research Center</li> <li>Ghana Infectious</li> <li>Disease Center</li> <li>KBTH</li> </ol> | Beijing Wantai                           | Study Closed by Sponsor<br>before commencement. No<br>recruitment was done.<br>20 months | 1. To evaluate the protective efficacy of DelNS1-2019-nCoV-RBD-OPT1 for<br>preventing virologically confirmed (RT-PCR positive) symptomatic COVID-19.<br>2. To evaluate the safety of<br>DelNS1-2019-nCoV-RBD OPT1.   |
| 118 | STEADFAST              | Phase II     | Sickle Cell<br>Disease   | CRIZANLIZUMAB<br>/ Monoclonal<br>antibody   | 15th February, 2021           | Dr. Yvonne Dei Adomako                                | •Ghana Institute of<br>Clinical Genetics<br>Korlebu<br>•Sickle cell office<br>Directorate<br>Child(KATH)   | Novartis<br>Pharma                       | Study closed by sponsor<br>before commenced<br>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.   |
| 119 | ESM UBT                |              | Postpartum<br>Hemorrhage | Uterine balloon<br>tamponade/Medic<br>al device   |                               | Dr. Ivy Frances Osei                                  | Field Work   | Bill and Melinda<br>Gates<br>Foundation, | Study not conducted; Funds<br>from Sponsor withdrawn before<br>initiation<br>8months     |   |
| 120 | FERROQUINE             | 11           | Malaria                  | 1. Ferroquine<br>2.Amodiaquine<br>3.<br>Artesunate/Allopa<br>thic                                   |                               | Dr. Josephine C. Ocran<br>Prof. Kwadwo Ansah<br>Koram | Noguchi Memorial<br>Institute of Medical<br>Research   | Sanofi-Aventis                           | Study Closed by Sponsor. No recruitment was done.  |   |

|     |                             |           |                       | Investigational   |                     |  |  |  |  |  |
|-----|-----------------------------|-----------|-----------------------|---|---------------------|--|--|--|--|--|
|     | TITLE OF                    |           | DISEASE               |   | ,DATE OF RECEIPT OF | PRINCIPAL  |  |  | STATUS & DURATION OF   |  |
| N/O | STUDY                       | PHASE     | INDICATION            | CLASS   | APPLICATION         | INVESTIGATOR   | STUDY CENTRE(S)  | APPLICANT  | STUDY  | PURPOSE/AIM OF STUDY   |
| 404 | HOPE SCD                    |           | Sickle Cell           | GBT440 300mg  |                     | Adomakoh   | 1.Center for Clinical<br>Genetics, Korle-Bu<br>Teaching Hospital<br>2.Paediatric Sickle<br>cell clinic, Komfo<br>Anokye Teaching | Court, Suite 101<br>South San<br>Francisco, CA               | Group 1 and 2 under current<br>protocol completed (none<br>recruited in Ghana); yet to start<br>Main Population Study (Group<br>3) | The primary objective is to assess the efficacy of GBT440 in adolescents and adults  |
| 121 |                             | 111       | Disease               | /Allopathic   | May-1               | 7 2.Dr. Vivian Paintsil  | Hospital   | 94080,USA  | 17 months  | with SCD as measured by improvement in anemia  |
| 122 | ABDOV COVID-<br>19 TRIAL    | Phase III | Covid-19              | SCTV01E (A<br>COVID-19<br>Alpha/Beta/Delta/<br>Omicron Variants<br>S-Trimer<br>Vaccine)/Vaccine   |                     | 1. Dr. Alberta Amu<br>2. Dr. Patrick Ansah<br>3. Dr. John Amuasi<br>4.Dr Kwaku Poku Asante |  | Sinocelltech<br>Ltd  | Application Withdrawn, 19<br>Months  | <ul> <li>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.</li> <li>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.</li> <li>To evaluate the protective efficacy of stage 1 immunization against different SARS-CoV-2 variants.</li> <li>To evaluate the safety of SCTV01E in stage 1.</li> <li>Stage 2 immunization</li> <li>To evaluate the protective efficacy of SCTV01E against symptomatic COVID-19 occurring from 7 days after the 3rd dose in population previously</li> </ul>  |
|     |                             |           |                       |   |                     |  | 1.Dodowa Health  | Institute of   |  | 1. To evaluate the efficacy of SARS-CoV-2 Vaccine, Inactivated (Vero Cell)   |
| 123 | VERO CELL<br>COVID 19 TRIAL | Phase III | Covid-19              | Inactivated (Vero<br>Cell)/Vaccine  | 10th February 2022  |  | Research Center<br>2.Navrongo Health<br>Research Center  | Medical Biology<br>Chinese<br>Academy of                     | Application Withdrawn, 18<br>Months  | against symptomatic and laboratory-confirmed (RT PCR method) COVID-19<br>cases<br>2.To evaluate the solicited AEs within 7 days after each dose.   |
| 124 | MEBENDAZOLE                 | IV        | Hookworm<br>infection | Menbendazole/All<br>opathic   | 9th January 2017    | Prof Michael David Wilson  | Kintampo Health<br>Research Centre   | Program For<br>Appropriate<br>Technology In<br>Health (PATH) | Application Withdrawn  | Soil-transmitted helminth (STH) infections are considered among the most pressing of global health problems, thought to parasitize some 2 billion people worldwide.[] The most recent estimates suggest that between 600 and 800 million people are infected with one or several of the common soil-transmitted helminths (STHs), which are Ascaris lumbricoides, Trichuris trichiura, and hookworm.[] Infection prevalence, incidence, and disease burden are particularly high in tropical and subtropical areas that are already burdened with poor living conditions, over-population, and inadequate sanitation, including some areas of sub-Saharan Africa, Asia, and Latin America.[1, , ] While adults represent a significant percentage of the infected population, it is children who are the most vulnerable |
| 125 | EBOLA Z                     |           | Ebola                 | chimpanzee<br>adenovirus Type<br>3 – vectored<br>Ebola Zaire<br>vaccine (ChAd3-<br>EBO-Z)/Vaccine |                     | 1.Dr. Kwaku Poku Asante<br>5 2.Prof. Kwadwo A Koram  | 1.Kintampo Health<br>Research Centre   | GlaxoSmithKlin   | Application withdrawn<br>N/A   |  |
| 126 | EBOLA Z<br>(Paediatric)     | 11        | Ebola                 | chimpanzee<br>adenovirus Type<br>3 – vectored<br>Ebola Zaire<br>vaccine (ChAd3-<br>EBO-Z)/Vaccine | 21st August 2015    | Dr. Kwaku Poku Asante  | OCRC, Hohoe  | · · · · · · · · · · · · · · · · · · ·                        |  |  |

|     |             |       |                   | Investigational                      |                     |                         |  |                            |                       |                      |
|-----|-------------|-------|-------------------|--------------------------------------|---------------------|-------------------------|--|----------------------------|-----------------------|----------------------|
|     | TITLE OF    |       | DISEASE           |                                      | ,DATE OF RECEIPT OF | PRINCIPAL               |  | SPONSORS &                 | STATUS & DURATION OF  |                      |
| N/O | STUDY       | PHASE | INDICATION        | CLASS                                | APPLICATION         | INVESTIGATOR            | STUDY CENTRE(S)                              |                            | STUDY                 | PURPOSE/AIM OF STUDY |
|     |             |       |                   |                                      |                     |                         |  |                            |                       |                      |
|     |             |       |                   |                                      |                     |                         |  |                            |                       |                      |
|     |             |       |                   |                                      |                     |                         |  |                            |                       |                      |
|     |             |       |                   | 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,<br>sudan virus and   |                     |                         |  |                            |                       |                      |
|     |             |       |                   | marburg virus                        |                     |                         |  | Crucell Holland            |                       |                      |
|     |             |       |                   | and the                              |                     |                         |  | B.V,                       |                       |                      |
|     |             |       |                   | nucleoprotein of                     |                     |                         |  | Represented by             |                       |                      |
|     |             |       |                   | tai forest virus                     |                     |                         |  |                            | Approved but sponsor  |                      |
|     | ZEBOV       |       |                   | [MVA-BN-                             |                     |                         |  |                            | withdrew conduct      |                      |
| 127 |             | 1     | Ebola             | Filo]/Vaccine                        | 7th January 2015    | Professor Fred Binka    | OCRC, Hohoe                                  | (Pty) Ltd                  | N/A                   |                      |
|     |             |       |                   |                                      |                     |                         |  |                            |                       |                      |
|     |             |       |                   | 1.Ad26 Vector                        |                     |                         |  |                            |                       |                      |
|     |             |       |                   | expressing the                       |                     |                         |  |                            |                       |                      |
|     |             |       |                   | glycoprotein of                      |                     |                         |  |                            |                       |                      |
|     |             |       |                   | the ebola virus                      |                     |                         |  |                            |                       |                      |
|     |             |       |                   | mayinga variant                      |                     |                         |  |                            |                       |                      |
|     |             |       |                   | [Ad26.ZEBOV                          |                     |                         |  |                            |                       |                      |
|     |             |       |                   | 2.Modified                           |                     |                         |  |                            |                       |                      |
|     |             |       |                   | vaccinia ankara –<br>bavarian nordic |                     |                         |  |                            |                       |                      |
|     |             |       |                   | vector expressing                    |                     |                         |  |                            |                       |                      |
|     |             |       |                   | the glycoproteins                    |                     |                         |  |                            |                       |                      |
|     |             |       |                   | of ebola virus,                      |                     |                         |  |                            |                       |                      |
|     |             |       |                   | sudan virus and                      |                     |                         |  |                            |                       |                      |
|     |             |       |                   | marburg virus                        |                     |                         |  | Crucell Holland            |                       |                      |
|     |             |       |                   | and the                              |                     |                         |  | B.V,                       |                       |                      |
|     |             |       |                   | nucleoprotein of<br>tai forest virus |                     |                         |  | Represented by             |                       |                      |
|     | ZEBOV 2     |       |                   | [MVA-BN-                             |                     |                         |  | Janssen<br>Pharmaceutica   | Application withdrawn |                      |
| 128 |             | 11    | Ebola             |                                      | 6th April 2015      | Professor Fred Binka    | OCRC, Hohoe                                  |                            | N/A                   |                      |
|     |             |       |                   |                                      |                     |                         |  |                            |                       |                      |
|     |             |       |                   |                                      |                     |                         |  |                            |                       |                      |
|     |             |       |                   |                                      |                     |                         | Noguchi Memorial                             | General                    | Application Withdrawn |                      |
|     |             |       |                   | Hydranon                             |                     |                         | Institute For Medical                        |                            | N/A                   |                      |
| 129 | HYDRANON    | I     |                   | solution                             | 1st March 2008      | Prof. David Ofori-Adjei | Research                                     | Technology 1llc            |                       |                      |
|     |             |       |                   |                                      |                     |                         | Navrongo Health                              |                            |                       |                      |
|     |             |       |                   |                                      |                     | 1. Dr. Isaac Osei       | Research Centre                              | Janssen-Cilag              |                       |                      |
|     |             |       |                   |                                      |                     | 2. Dr. Samuel Abora     | Upper East Regional                          | International NV (Sponsor) |                       |                      |
|     |             |       |                   |                                      |                     | 2. Dr. Gamuel Abola     | Hospital                                     | represented by             |                       |                      |
|     |             |       |                   | 1.TDF/FTC/RPV                        |                     | 3. Dr. Fred Adomako –   |  |                            | Application Withdrawn |                      |
|     |             |       |                   | 2.TDF/FTC/EFV/                       |                     | Boateng                 | Kumasi Centre for                            | Research Africa            |                       |                      |
| 130 | SALIF,      | IIIb  | HIV               | Vaccine                              | 4th September 2013  |                         | Collaborative                                | Ltd.                       |                       |                      |
|     |             |       |                   |                                      |                     |                         |  |                            |                       |                      |
|     |             |       |                   |                                      |                     |                         |  |                            |                       |                      |
|     |             |       |                   |                                      |                     |                         | 1 Noguobi Momerial                           |                            |                       |                      |
|     |             |       |                   |                                      |                     |                         | 1. Noguchi Memorial<br>Institute For Medical |                            |                       |                      |
|     |             |       |                   |                                      |                     |                         |  | Pittsburg,                 |                       |                      |
|     | NOGUCHI SCD |       |                   |                                      |                     |                         | College of Health                            |                            | Application Withdrawn |                      |
|     |             |       |                   | NVX-508/                             |                     | Amma Twumwaa Owusu      | Sciences 3.University                        | Amma Owusu-                |                       |                      |
| 131 |             | lb    | Sickle Cell Disea | seAllopathic                         | 1st May 2017        |                         | of Ghana                                     | Ansah, MD                  |                       |                      |
|     |             |       |                   |                                      |                     |                         |  |                            |                       |                      |

|     |                      |                   |  | Investigational   |                                    |  |   |                  |   |  |
|-----|----------------------|-------------------|--|---|------------------------------------|--|---|------------------|---|--|
| N/O | TITLE OF<br>STUDY    | PHASE             | DISEASE<br>INDICATION                                    | Products (IPs)/IP<br>CLASS  | ,DATE OF RECEIPT OF<br>APPLICATION | PRINCIPAL<br>INVESTIGATOR                                      | STUDY CENTRE(S)   |                  | STATUS & DURATION OF<br>STUDY   | PURPOSE/AIM OF STUDY   |
| 132 | PRCR SPOT            | Phase II          | Preeclampsia   | PRCR<br>Spot/Medical<br>device  | 15th March 2021                    | Dr. Hannah Brown<br>Amoakoh                                    | Ridge Hospital,<br>Korlebu Teaching<br>Hospital, Koforidua<br>Regional Hospital |                  | Application Withdrawn by<br>Sponsor   | To address the gap in proteinuria measurement solutions, LifeAssay<br>Diagnostics (LAD) has developed and commercialized a low-cost PrCr<br>urine dipstick that has shown goodlaboratoryand clinical performance and high<br>usability within antenatal care (ANC)settings in previous studies. There is a<br>need for further evidenceon the clinical utility and operational fit of the LAD<br>Test-it <sup>™</sup> PrCr test to inform policy recommendation for its use in Ghana and<br>other LMIC settings.   |
| 133 | SAR97276A_SA<br>NOFI | II                | Malaria  | SAR97276A/Allo<br>pathic  | 1st October, 2008                  | Prof. Seth Owusu-Agyei   | Navrongo Health<br>Research Centre  |                  | Sponsor before approval   |  |
| 134 | LETICIA              | Phase II          | Aneamia  | 1.LETICIA<br>protocol diet<br>(provided by<br>study) 2.<br>3-Fer syrup 3.<br>Usual or Typical<br>diet/ Food<br>supplement | 30th August, 2019                  | Dr. Lawrence Osei-Tutu   | Agogo Presbyterian<br>Hospital  | Dr. Lawrence     | Application closed by FDA<br>since Sponsor/PI failed to start<br>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. |
| 135 | TENOFOVEK BE         | Bioequivalence    |  | 1.Tenofovek<br>(tenofovir) 300mg<br>film coated<br>tablets<br>2.Viread<br>(tenofovir)<br>300mg/Allopathic                 | 11th September 2015                | 1. Prof. Seth Owusu<br>Agyei<br>2. Dr. Kwaku Poku Asante       | Kintampo Health<br>Research Centre  | Limited, Accra-  | Application closed by FDA<br>since Sponsor failed to start<br>study 3 years after approval. |  |
| 136 | ELDON CARD<br>NYN    | Feasibility study | Testing of<br>Maternal and<br>Newborn Blood<br>Group     | 1. Eldon card<br>2. Standard<br>laboratory<br>method/Medical<br>device  | 10th November 2015                 | Prof. Samuel Ameny<br>Obed                                     | Korle Bu Teaching<br>Hospital, Accra.   | Health, Hospital | Incomplete CTA; Application<br>closed by FDA.<br>N/A  |  |
| 137 | AX-100 HIVI          |                   | HIV  | 1.AX-100lmmun<br>2.AX-<br>100lmmunPlus  | 9th december 2014                  | Dr. Kwaku Poku Asante  | Kintampo Health<br>Research Centre  | Neopharmacie     | Incomplete CTA; Application<br>closed by FDA.<br>N/A  |  |
| 138 | 4P                   | 111               | Pregnancy<br>Induced<br>Hypertension and<br>Preeclampsia | Polypil/Allopathic  | 9th August 2013                    | 1. Dr. Emmanuel Kwabla<br>Srofenyoh<br>2. Dr. Patrick Frimpong | Ridge Hospital Accra<br>La General Hospital                                     | Medical Centre   | Incomplete CTA; Application   |  |

|                   |                                      |           |   | Investigational   |                              |   |   |   |   |   |
|-------------------|--------------------------------------|-----------|---|---|------------------------------|---|---|---|---|---|
|                   | TITLE OF                             |           | DISEASE                                     |   | ,DATE OF RECEIPT OF          | PRINCIPAL   |   | SPONSORS &  | STATUS & DURATION OF  |   |
| <u>N/O</u><br>139 | INVACT                               | PHASE     | Malaria                                     | CLASS<br>Artemisinin/<br>Allopathic   | APPLICATION<br>13th may 2016 | INVESTIGATOR<br>Prof. Kwadwo Ansah<br>Koram           | STUDY CENTRE(S)<br>Noguchi Memorial<br>Institute For Medical<br>Research  | APPLICANT<br>Global<br>Emerging<br>Infections<br>Surveillance<br>and Response<br>System of the<br>US Armed<br>Forces Health<br>Surveillance<br>Center | STUDY<br>Incomplete CTA; Application<br>closed by FDA.<br>N/A | PURPOSE/AIM OF STUDY  |
| 140               | INSUGENIV                            | Phase IV  | Diabetes                                    | Insugen/Hormone   | e 17th december 2013         | N/A   | Korle-Bu Teaching<br>Hospital   | BIOCON LTD  | Incomplete CTA; Application<br>closed by FDA.<br>N/A          |   |
|                   | AIM-LVRNA009<br>MYCOPIROX_LA<br>GRAY |           | Covid-19<br>mixed Infection<br>Vaginitis in | 1. SARS-CoV-2<br>mRNA vaccine<br>(LVR<br>2. Saline<br>Placebo/Vaccine<br>Mycopirox  |                              | Dr. Patrick Odum Ansah                                | 1. Navrongo Health<br>Research Centre<br>2. Kumasi Centre for<br>Collaborative<br>Research<br>3.Dodowa Health<br>Research Centre<br>4. Kintampo Health<br>Research Centre<br>5. Ghana Infectious<br>Disease Centre<br>6. Korle Bu Teaching<br>Hospital (KBTH) | AIM Vaccine<br>Co. Ltd,<br>Lagray<br>Chemical   | Not Approved,17-24 months.                                    | Primary efficacy objective:<br>To evaluate the protective efficacy of LVRNA009 (50 µg) in the prevention of<br>first episodes of virologically-confirmed symptomatic cases of COVID-19 of any<br>severity occurring from 14 days after 2nd dose in the initial set of vaccination in<br>SARS-CoV-2 naive participants   |
| 142               |                                      | Phase IV  | Females                                     |   | 15th june 2010               | Dr. Luitgard Darko                                    |   | Company, Ltd.   |   |   |
| 143               |                                      | Phase III | Sickle Cell<br>Disease                      | 1.CRIZANLIZU<br>MAB<br>2.PLACEBO/<br>Monoclonal<br>antibody   | 30th September, 2019         | 1.Dr. Yvonne Dei<br>Adomakoh<br>2.Dr. Vivian Paintsil | 1.Ghana Institute of<br>Clinical Genetics,<br>Korle-Bu<br>Sickle Cell Office<br>Directorate of Child<br>Health,   | Novartis<br>Pharma AG   | Study terminated by FDA. Yet                                  | Sickle cell disease (SCD) is a genetic blood disorder, caused by a single missense mutation in the $\beta$ -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. 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.   |
| 144               | ANTICOV                              | Phase III | Covid-19                                    | 1.Nitazoxanide<br>2.Ciclesonide<br>3.Paracetamol<br>4.Ivermectin<br>5.Artesunate<br>Amodiaquine<br>(ASAQ)/<br>Allopathic drug | 15th July, 2020              | John Humphrey, AMUASI                                 | Komfo Anokye<br>Teaching Hospital   | •Bernhard<br>Nocht Institute<br>for Tropical<br>Medicine  |   | 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 |

|     |                                       |              |                        | Investigational  |                                    |   |  |  |  |  |
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| N/O | TITLE OF<br>STUDY                     | PHASE        | DISEASE<br>INDICATION  | Products (IPs)/IP<br>CLASS   | ,DATE OF RECEIPT OF<br>APPLICATION | PRINCIPAL<br>INVESTIGATOR   | STUDY CENTRE(S)  | SPONSORS & APPLICANT                     | STATUS & DURATION OF<br>STUDY  | PURPOSE/AIM OF STUDY   |
| 145 | COVID 19 CHO-<br>CELL(TERMINA<br>TED) | Phase II/III | Covid-19               | 1.Recombinant<br>two-component<br>COVID-19<br>vaccine (CHO<br>cell)<br>2. ReCOV<br>Placebo/Vaccine | 16th November 2021                 | Dr. Patrick Ansah   | 1. Dodowa Health<br>Research Centre<br>2. Navorongo Health<br>Research Centre.   | Jiangsu Recbio<br>Technology Co.<br>Ltd. | , Study terminated by sponsor<br>13 months                                   | <ol> <li>To evaluate the safety and reactogenicity of the recombinant two-component<br/>COVID-19 vaccine (CHO cell) (ReCOV for short) in adults aged 18 years and<br/>older.</li> <li>To evaluate SARS-CoV-2 neutralizing antibody of ReCOV on Day 14 after 2<br/>doses vaccination in adults aged 18 years and older.</li> <li>To evaluate the efficacy of ReCOV in preventing RT-PCR confirmed<br/>symptomatic COVID-19 in adults aged 18 years and older.</li> <li>To evaluate the safety and reactogenicity of ReCOV in adults aged 18<br/>years and older.</li> </ol>   |
| 146 | MoRiOn                                | Phas II      | Onchocerciasis         | 1.Rifanpentine<br>(Priftin®)<br>2.Moxifloxacin<br>(Avelox®)<br>3.Doxycycline/V<br>accine           | 28th April, 2017                   | Prof. Alexander Yaw<br>Debrah   | 1.Enchi<br>Government Hospital<br>2.Communities of<br>Aowin/Suaman<br>District W/R   |  | Study terminated by sponsor<br>Yet to submit Final report<br>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.   |
| 147 | COVID<br>MOUTHWASH                    | Phase III    | Covid-19               | 1.Corsodyl<br>Mouthwash<br>2.Wokadine<br>mouthwash<br>3.Hydrogen<br>Peroxide<br>mouthwas           | 6th September 2021                 | Dr. George Boateng Kyei   | Noguchi Memorial<br>Institute for Medical<br>Research  | Dr. George<br>Boateng Kyei               | Study terminated by sponsor<br>Yet to submit Final report<br>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.  |
| 148 | IMR SCD                               | Phase IIb    | Sickle Cell<br>Disease | 1.IMR-687<br>2.IMR-687<br>Placebo/Allopathi<br>c   | 13th August 2020                   | 1. Dr. Seyram Kaali<br>2. Dr. Olayemi<br>Edeghongon                                     | •Korle-Bu Teaching<br>Hospital<br>•Kintampo Health<br>Research Centre  | IMARA Inc.                               | Early termination by Sponsor<br>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 $\geq$ 3.0 to $\leq$ 4.5 mg/kg and $>$ 4.5 to $\leq$ 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 |
| 149 |                                       | Phase I      | Sickle Cell<br>Disease | Ticagrelor/<br>Allopathic  | 16th May, 2018                     | 1. Dr. Patrick Ansah<br>2. Dr. Catherine Segbefia<br>3. Dr. Kokou Hefoume<br>Amegan-Aho | <ol> <li>Navrongo Health<br/>Research Centre</li> <li>Korle-Bu Teaching<br/>Hospital</li> <li>Volta Regional<br/>Hospital</li> </ol> | AstraZeneca AE                           | Study termination<br>31 Months   | Complications of sickle cell disease (SCD) occur very early in life. Painful crises<br>first appear in the fingers and toes (dactylitis) in very young children prior to<br>their first birthday. In addition to painful crises occurring in the very young, SCD<br>can affect organ function early in life. Loss of splenic function begins as early<br>as 5 months of age with associated increase in infection risk. Stroke risk begins<br>at age 2. Given the early onset of symptoms and complications of this disorder,<br>therapies for SCD should be targeted at children, including the very young.<br>There is a need to first establish the pharmacokinetics (PK) of ticagrelor in this<br>age group to allow for modelling or extrapolation in this population.<br>This goal of the study is to evaluate PK data in the 0-2 year old population in<br>order to way for further studies and ultimately use of ticagrelor in this youngest<br>population.                                    |

|     |                       |       |   | Investigational   |                     |  |  |   |   |                      |
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|     | TITLE OF              |       | DISEASE                                 |   | ,DATE OF RECEIPT OF | PRINCIPAL  |  | SPONSORS &  | STATUS & DURATION OF  |                      |
| N/O | STUDY                 | PHASE | INDICATION                              | CLASS   | APPLICATION         | INVESTIGATOR   | STUDY CENTRE(S)  | APPLICANT   | STUDY   | PURPOSE/AIM OF STUDY |
| 150 | TADO                  | 111   | Sickle Cell<br>Disease in<br>Pediatrics | Prasugrel/Allopat<br>hic  | 20th may 2013       | Prof. Tsiri Agbenyega<br>Dr. Catherine Idara<br>Segbefia   | Center, Agogo<br>Korle-Bu Teaching<br>Hospital, Accra –<br>Korle Bu  | Eli Lilly and<br>Company<br>Indianapolis  | Prematurely terminated<br>24 months   |                      |
| 151 | WOMAN                 | 111   | Postpartum<br>Hemorrhage                | Tranexamic<br>acid(cyklokapronr<br>injection)/<br>Allopathic  |                     | 1. Dr. Anthony K. Dah<br>2. Dr.Opare Addo Henry<br>Sakyi<br>3. Dr. Kwadwo Asamoah<br>Nyarko-Jectey | 1. Ashanti Mampong<br>Municipal Hospital<br>2.Komfo Anokye<br>Teaching Hospital  | Clinical Trials   | Terminated by Sponsor<br>Prematurely ended.   |                      |
|     | NEOVITA               |       |   |   |                     |  | Kintampo Health  |   | Premature Termination<br>36 Months  |                      |
| 152 |                       | III   |   | Vitamin A   |                     | Dr. Sam Newton   | Research Centre  | PATH  |   |                      |
| 153 | CALLASCOPE            | ï     | Cervical cancer                         | Pocket<br>Colposcope<br>(CALLASCOPE)/<br>Medical device   | 12th February 2019  | Dr. Emmanuel Srofenyoh   | Ridge Hospital, Korle-<br>Bu Teaching Hospital   |   | Study ended, FDA<br>DISSOCIATED itself from any<br>data or findings from the study<br>due to violation of its guidelines<br>for conducting clinical trials.<br>3 months |                      |
| 154 | HOHOE<br>ANTIMALARIAL | 111   | Malaria                                 | <ul> <li>1.Dihydroartemisi<br/>nin</li> <li>2.Piperaquine</li> <li>oral tablets</li> <li>3.Artesunate</li> <li>4.</li> <li>Sulfamethoxypyr</li> <li>azine.</li> <li>5. Pyrimethamine</li> <li>oral</li> <li>tablets/Allopathic</li> </ul> |                     | Dr. Margaret Kweku   | Hohoe Health<br>Research Centre<br>Onchocerciasis<br>Chemotherapy<br>Research Centre,<br>Hohoe Municipal<br>Hospital, Ghana,<br>Ghana Health<br>Service                | Malaria<br>Capacity<br>Development<br>Consortium<br>(MCDC                               | FDA DISSOCIATED itself from<br>any data or findings from the<br>study due to violation of its<br>guidelines for conducting<br>clinical trials.<br>7 months              |                      |
| 155 | YAWS                  |       | Yaws                                    | 1.Azithromycin<br>2.Injection<br>Benzathine<br>Penicillin/Allopath<br>ic  |                     | Dr. Cynthia Kwakye-<br>Maclean   | Ga West District   | 1. University of<br>Ghana School<br>of Public Health<br>2. World Health<br>Organization | Not Approved. FDA<br>DISSOCIATES itself from any<br>data or findings from the study<br>due to violation of its guidelines<br>for conducting clinical trials.<br>N/A     |                      |
|     | GMZ 211 / 111         | 11    | Malaria                                 | GMZ2 candidate<br>malaria vaccine/<br>Vaccine   | 19th august 2010    | Dr. Frank Atuguba  | Navrongo Health<br>Research Centre,<br>Navrongo.   | Statens Serum<br>Institute  | FDA DISSOCIATED itself from<br>any data or findings<br>27 onths   |                      |
| 157 | CEREBETA              |       | Cholesterol concentration               | Barley beta<br>glucan/ Food<br>supplement   | 13th may 2016       | Mrs. Rose T. Odotei Adjei  | Suntreso   | Best<br>Environmental<br>Technologies   | FDA DISSOCIATED itself from<br>any data Findings<br>N/A   |                      |
| 158 | AQUAMAT               | 111   | Malaria                                 | 1. Artesunate<br>2.<br>Quinine/Allopathi<br>c   |                     | Prof. Tsiri Agbenyega  | Komfo Anokye   | WORLD<br>HEALTH   | FDA DISSOCIATED itself from any data Findings   |                      |
| 159 | AZI4YAWS              | 111   | Yaws                                    | Azythromycin/<br>Allopathic   | 23rd April 2015     | Prof. Adu Sarkodie   | <ol> <li>Ayensuanor</li> <li>District</li> <li>West Akyem</li> <li>Municipality</li> <li>Upper West</li> <li>Akyem</li> <li>Nkwanta North</li> <li>District</li> </ol> | World Health<br>Organization,<br>Geneva -<br>Switzerland                                | FDA DISSOCIATED itself from<br>any data or findings from the<br>study due to violation of its<br>guidelines for conducting<br>clinical trials.<br>12 months             |                      |
|     |                       |       |   |   |                     |  |  |   |   |                      |
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|     | TITLE OF                |  | DISEASE   | Investigational<br>Products (IPs)/I | P ,DATE OF RECEIPT OF            | PRINCIPAL                       | SPONS                              | SORS &      | & STATUS & DURATION OF   |  |  |  |  |
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| N/O | STUDY                   | PHASE  | INDICATION  | CLASS                               | APPLICATION                      | INVESTIGATOR                    | STUDY CENTRE(S) APPLIC             |             | STUDY PURPOSE/AIM OF STUDY   |  |  |  |  |
|     |                         |  |   |                                     |                                  |                                 |                                    |             |  |  |  |  |  |
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|     |                         |  |   |                                     |                                  |                                 |                                    |             |  |  |  |  |  |
|     |                         |  |   |                                     | SHORT AND DETAILED NAM           |                                 |                                    |             |  |  |  |  |  |
|     |                         |  |   |                                     |                                  |                                 |                                    |             |  |  |  |  |  |
| 1   | 4P<br>ABDOV COVID       |  |   |                                     |                                  | · · ·                           |                                    |             | nancy Induced Hypertension and Preeclampsia (4P) Trial<br>micron Variants S Trimer Vaccine) in population previously unvaccinated with COVID-19 vaccine and aged ≥18 |  |  |  |  |
| 2   | 19 TRIAL                | years  | double-billia, positive   |                                     |                                  |                                 |                                    |             | micron variants S miner vaccine) in population previously unvaccinated with COVID-19 vaccine and aged 210  |  |  |  |  |
| 3   | ACTIVE TRIALS           | A Phase 3, mult  | ticenter, randomized,   | double-blind, 24-w                  | reek study of the clinical and a | antiviral effect of S-217622 of | compared with placebo in non-h     | nospitalize | lized participants with COVID-19   |  |  |  |  |
| Δ   | AIM-LVRNA009            | A Global Multi-c   | ase 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   |                                     |                                  |                                 |                                    |             |  |  |  |  |  |
|     |                         |  | Hobal 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 Investig   | ican Investigation Of Mirasol System For Whole Blood. Clinical And Biological Efficacy Of Mirasol Treated Fresh Whole Blood For The Prevention Of Transfusion Transmitted Malaria   |                                     |                                  |                                 |                                    |             |  |  |  |  |  |
|     |                         |  |   |                                     |                                  |                                 | eiseis is the Matte Design Ober    |             |  |  |  |  |  |
| 6   | ALB_IVM                 | Comparison of  | ivermectin alone with   | Albendazole (ALB                    | ) plus ivermectin (IVM) in thei  | r efficacy against Onchocero    | ciasis in the Volta Region, Ghar   | na.         |  |  |  |  |  |
| 7   | ALBIVM K'SI             | Comparism of Iv  | vermectin Alone with  | Albendazole plus l                  | vermectin in Their Efficacy ag   | gainst Onchocerciasis           |                                    |             |  |  |  |  |  |
| 8   | AMARYL M                | Clinical Efficacy  | and Safety of Amar  | yl M in Patients with               | n Type 2 Diabetes who are ina    | adequately treated by either    | Glimepride or Metformin Monot      | therapy or  | or who are already treated With Free Combination Of Glimepride and Metformin in African Countries.   |  |  |  |  |
| g   | ANTICOV                 | An Open-Label.   | Multicenter, Randor   | nized, Adaptive Pla                 | tform Trial of the Safety and I  | Efficacy of Several Therapie    | es, including Antiviral Therapies. | , Versus C  | s Control in Mild Cases of COVID-19  |  |  |  |  |
| 10  | ANTIPSYCHOTI<br>C STUDY |  |   | ·                                   |                                  |                                 | IC-INDUCED MOVEMENT DIS            |             |  |  |  |  |  |
|     |                         |  |   |                                     |                                  |                                 |                                    | ORDERS      |  |  |  |  |  |
| 11  | AQUAMAT                 |  |   |                                     | Quinine in the Treatment of      | ·                               |                                    |             | ware Or Complicated Folgingrum Malaria, Or Uncomplicated Folgingrum Malaria With Operative time.   |  |  |  |  |
| 12  | ARTIMIST                | A Phase III, Rar<br>Complications  | iuomizeu, Open Lab  | elled, Active Contro                | mea, mancentre, Superiority      |                                 |                                    | vviin Seve  | evere Or Complicated Falciparum Malaria, Or Uncomplicated Falciparum Malaria With Gastrointestinal   |  |  |  |  |
| 1.3 | ASAAP                   |  |   |                                     | Safety, Tolerability and Efficac | cy of Artemether- Lumefantri    | ne+Atovaquone-Proguanil Tri-T      | ⁻herapyVe   | Versus Artemether Lumefantrine Bi-Therapy for The Treatment of Uncomplicated Malaria in African Children   |  |  |  |  |
|     | ASTAWOL                 |  | Aged 6 To 59 Months (ASAAP PROJECT -STUDY II)<br>The efficacy of Rifampicin 35mg/Kg/d plus Albendazole 400mg/d given for 7 or 14 days against Lymphatic Filariasis and Onchocerciasis- a randomized, controlled, parallel-group, open-label, phase II pilot trial |                                     |                                  |                                 |                                    |             |  |  |  |  |  |
|     |                         |  |   |                                     |                                  |                                 |                                    |             |  |  |  |  |  |
| 15  | ATEA COVID 19           | A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Bemnifosbuvir in High-Risk Outpatients with COVID-19<br>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 |   |                                     |                                  |                                 |                                    |             |  |  |  |  |  |
| 16  | AVAREF                  | infants.   |   |                                     |                                  |                                 |                                    |             |  |  |  |  |  |
| 17  | AX-100 HIV              | A Double Blind Randomized Control Trial of AX-100 Immun (Liquid) and AX-100 Immun Plus Combination Among Adults Living with HIV In Ghana.  |   |                                     |                                  |                                 |                                    |             |  |  |  |  |  |
| 18  | AZI4YAWS                | Randomized Controlled Trial Comparing Efficacy of a Single Dose of Treatment of Yaws with 20mg/kg versus 30mg/kg of Azithromycin.  |   |                                     |                                  |                                 |                                    |             |  |  |  |  |  |
| 19  | PLUS<br>CHLOROQUINE     | Azithromycin Pl  | us Chloroquine Phos   | phate versus Arten                  | nether-Lumefatrine for the Tre   | eatment of Uncomplicated P      | lasmodium falciparium Malaria i    | in Childre  | dren in Africa.  |  |  |  |  |
|     | BEMPU                   |  | evention in low birth   | •                                   |                                  |                                 | ·                                  |             |  |  |  |  |  |
|     |                         | <u> </u>   |   |                                     |                                  |                                 |                                    |             |  |  |  |  |  |

| N/O | TITLE OF<br>STUDY | PHASE   | DISEASE<br>INDICATION   | Investigational<br>Products (IPs)/IP<br>CLASS | ,DATE OF RECEIPT OF<br>APPLICATION | PRINCIPAL<br>INVESTIGATOR | STUDY CENTRE(S) |  | STATUS & DURATION OF<br>STUDY | PURPOSE/AIM OF STUDY |  |
|-----|-------------------|---|---|---|------------------------------------|---------------------------|-----------------|--|-------------------------------|----------------------|--|
| 21  | BLMS4BU           | SHORTENING BL   | IORTENING BURULI ULCER TREATMENT: WHO RECOMMENDED VS. A NOVEL BETA-LACTAM-CONTAINING THERAPY – PHASE III EVALUATION INWEST AFRICA |   |                                    |                           |                 |  |                               |                      |  |
| 20  | BURULINOX         | Evoluction of pitric  |   |   |                                    |                           |                 |  |                               |                      |  |
|     | BURULIRIFDAC      | Evaluation of nitric oxide generating dressing (EDX) to improve management of buruli ulcer disease – a prospective randomized open-blinded end point.                               |   |   |                                    |                           |                 |  |                               |                      |  |
| 23  |                   | 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 |   |   |                                    |                           |                 |  |                               |                      |  |

|     | TITLE OF                |   | DISEASE              |                        | ,DATE OF RECEIPT OF   | PRINCIPAL                   |                  |
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| N/O | STUDY                   | PHASE                                     | INDICATION           | CLASS                  | APPLICATION   | INVESTIGATOR                | STUD             |
| 24  | 1 CDA                   | A Multicenter, Rand                       | lomized, Double E    | Blind Study to Comp    | are the Efficacy and Safet                                  | y of CDA Versus Arteme      | ther-Lumefa      |
| 25  | 5 CDA2                  | A Multicenter, Rand                       | lomized, Double E    | Blind Study to Comp    | are the Efficacy and Safety                                 | y of CDA Versus Chlorpr     | roguanil-Dap     |
| 26  | CEREBETA                | Efficacy of Beta-Glu                      | ucans from Barley    | and Maintenance o      | f Normal Blood LDL-Chole                                    | sterol Concentrations: A    | Randomized       |
| 27  | CPAP                    | Clinical Trial Evalua                     | ting the Differenc   | e in Mortality Rates   | in Children in Ghana Rece                                   | iving Continuous Positiv    | e Airway Pre     |
| 28  | CRASH-2                 | A Large Randomize                         | ed Placebo Contro    | olled Trial, among tra | auma patients with or at ris                                | k of significant Haemorrl   | hage, of the     |
| 29  | CALLASCOPE              |   |                      |                        | -cost and Speculum-Free (                                   |                             | 0                |
| 30  |                         |   |                      | •                      | pen-Label Trial to Evaluate<br>w-Middle Income Countrie     | 0                           | J Safety of A    |
| 31  | CEPHEIDXPERT            |   | Evaluate the Perfe   | ormance of the Cep     | heid XpertR HIV-1 VL XC                                     | Test                        |                  |
| 32  |                         | A Phase III, Randor<br>Glioma-Inactivated |                      |                        | ed, Multicenter Basket Stud                                 | dy to Evaluate the Effica   | cy, Safety, P    |
| 33  | COPE TRIAL              | Effectiveness and A                       | Acceptability of two | o models of an Inse    | rtable Vaginal Cup for Non                                  | -surgical management o      | of obstetric fis |
| 34  | COVID ABDOV             | A randomized, doul<br>years" (COVID ABD   |                      | controlled Phase III   | clinical trial to evaluate the                              | e efficacy and safety of S  | SCTV01E (A       |
| 35  | CROWN<br>CORONATION     | An international, Ba                      | yesian platform a    | daptive, randomized    | l, placebo-controlled trial a                               | ssessing the effectivene    | ess of candid    |
| 36  | CHEETAH                 | Cluster Randomize                         | d Trial of Sterile G | ilove and Instrumen    | t Change at the Time of W                                   | ound Closure to Reduce      | Site Infectio    |
| 37  | COVID 19 CHO-<br>CELL   | A multicenter, rando                      | omized, double-bli   | ind, placebo-control   | ed Phase II/III trial to evalu                              | uate the efficacy, safety a | and immuno       |
| 38  | INTRANASAL<br>SPRAY     | A Global, Multi-cent<br>and Older         | er, Randomized,      | Double-blind, Placel   | po-controlled Phase III Clin                                | ical Trial to Evaluate the  | Protective E     |
| 39  | COVID 19<br>MOUTHWASH   | Viral Shedding Dyn                        | amics and the Eff    | ect of Antimicrobial   | Mouthwashes on the Dete                                     | ction of SARS-CoV-2 in      | Ghana.           |
| 40  | DIABETIC FOOT           | Family-oriented Dia                       | betic Foot Self-ca   | re Programme in Gl     | nana; A Feasibility Randon                                  | nised Controlled Trial wit  | th nested qua    |
| 41  | DOLF_IDA                | Safety and Efficacy                       | of Combination T     | herapy with lverme     | ctin, Diethylcarbamazine a                                  | nd Albendazole (IDA) for    | r Individuals    |
| 42  | 2 EBA                   |   |                      |                        | Study and Immunogenicity                                    |                             |                  |
| 43  | BEBOLA Z                |   |                      |                        | olled, Multi-Country Study t<br>/ears of age and older in A |                             | i Immunoger      |
| 44  | EBOLA Z<br>(PAEDIATRIC) |   |                      | •                      | olled, Multi-Country Study t<br>to 17years of age in Africa | 5                           | ל Immunoger      |
| 45  | 5 EBSI-LSV              | A Phase 1 Random                          | ized, Blinded, Pla   | cebo Controlled, Do    | se-Escalation and Dosing                                    | Regimen Selection Stuc      | ly to Evaluate   |
| 46  | ELDON CARD              | Using Eldon Card fo                       | or Testing of Mate   | rnal and Newborn E     | lood Group in Comparisor                                    | with the Standard Labo      | oratory Metho    |
| 47  | EMODEPSIDE              | A phase II, Random                        | iised, double-blind  | l, parallel – group tr | al to investigate Emodeps                                   | ide (BAY 44-4400) in sul    | bjects with or   |
| 48  | BESM UBT                | A Multi-Centre Pros                       | pective Trial on th  | e Impact of the Intro  | oduction of Condom-Based                                    | d Uterine Balloon Tampo     | nade for Und     |
| 49  | FALCON                  | Pragmatic Multicent                       | re Factorial Rand    | omized Controlled T    | rial Testing Measures to R                                  | educe Surgical Site Infe    | ction in Low     |
| 50  |                         | Randomized Multice                        | entre Study Evalu    | ating the Safety and   | Activity of Ferroquine Ass                                  | sociated with Artesunate    | versus a Po      |
| 51  | BUILLON<br>CUBES STUDY  | Effect of household                       | use of multiple m    | icronutrient-fortified | bouillon on micronutrient                                   | status among women an       | d children in    |
| 52  | GARDASIL                | Evaluation of Safety                      | y And Immunoger      | nicity Of Gardasiltm   | n Healthy Females Betwee                                    | en 9 And 26 Years Of Ag     | ge In Subsah     |
|     |                         |   |                      |                        |   |                             |                  |

|  | SPONSORS &<br>APPLICANT | STATUS & DURATION OF<br>STUDY                           | PURPOSE/AIM OF STUDY  |  |  |  |  |  |  |  |
|--|-------------------------|---|---|--|--|--|--|--|--|--|
| Intrine in the Trea  | atment of Acute L       | Incomplicated P. Falciparum Mal                         | aria in Children and Adults in Africa.  |  |  |  |  |  |  |  |
| sone in the Trea   | tment of Acute U        | ncomplicated P. Falciparum Mala                         | aria in Children and Adults in Africa.  |  |  |  |  |  |  |  |
| d Control Study i  | in Ghana.               |   |   |  |  |  |  |  |  |  |
| essure (CPAP) V  | ersus Those Who         | Do Not.   |   |  |  |  |  |  |  |  |
| iffects of Anti- Fibrinolytic treatment on Death and Transfusion requirement |                         |   |   |  |  |  |  |  |  |  |
|  |                         |   |   |  |  |  |  |  |  |  |
| Iternate Two-Do  | se Regimens of a        | Bivalent Human Papillomavirus                           | (HPV) Vaccine (Cecolin®) Compared to a Licensed Quadrivalent HPV Vaccine      |  |  |  |  |  |  |  |
|  |                         |   |   |  |  |  |  |  |  |  |
|  |                         |   |   |  |  |  |  |  |  |  |
| harmacokinetics  | s, and Pharmacoc        | lynamics of Satralizumab in Patie                       | ents with Anti-N-Methyl-D-Aspartic Acid Receptor (NMDAR) or Anti-Leucine-Rich |  |  |  |  |  |  |  |
|  |                         |   |   |  |  |  |  |  |  |  |
| stula in Ghana: a  | t hybrid type 1 rar     | ndomized crossover trial                                |   |  |  |  |  |  |  |  |
| COVID-19 Alpha   | a/Beta/Delta/Omio       | cron Variants S Trimer Vaccine) i                       | n population previously unvaccinated with COVID-19 vaccine and aged ≥18       |  |  |  |  |  |  |  |
|  |                         |   |   |  |  |  |  |  |  |  |
|  |                         | OVID-19 disease in healthcare wo                        | orkers  |  |  |  |  |  |  |  |
| on: A Trial In Low   | /- And Middle-Inco      | ome Countries (LMICs)                                   |   |  |  |  |  |  |  |  |
| genicity of the re   | combinant two-co        | omponent COVID-19 vaccine (CH                           | O cell) in adults aged 18 years and older                                     |  |  |  |  |  |  |  |
| Efficacy and Safe  | ety of Influenza V      | irus Vector COVID-19 Vaccine fo                         | r Intranasal Spray (DelNS1-2019-nCoV-RBD-OPT1) in Adults Aged 18 Years        |  |  |  |  |  |  |  |
|  |                         |   |   |  |  |  |  |  |  |  |
| alitative interview  | s at the Komfo A        | nokye Teaching Hospital.                                |   |  |  |  |  |  |  |  |
| with Onchocercia   | asis                    |   |   |  |  |  |  |  |  |  |
|  |                         | emi Immune Adults<br>ose of GSK Biologicals' Investigat | tional Recombinant Chimpanzee Adenovirus Type 3 – Vectored Ebola Zaire        |  |  |  |  |  |  |  |
| nicity of a Single   | Intramuscular Do        | ose of GSK Biologicals' Investigat                      | tional Recombinant Chimpanzee Adenovirus Type 3 – Vectored Ebola Zaire        |  |  |  |  |  |  |  |
| e the Safety and   | Immunogenicity          | of rVSV-Vectored Lassa Virus Va                         | accine in Healthy Adults at Multiple Sites in West Africa                     |  |  |  |  |  |  |  |
| od of Blood Grou   | p Testing in Accr       | a, Ghana  |   |  |  |  |  |  |  |  |
| nchocerca volvul   | lus infection.          |   |   |  |  |  |  |  |  |  |
| controlled Postpa  | artum Hemorrhag         | е   |   |  |  |  |  |  |  |  |
| and Middle Inco  | me Countries            |   |   |  |  |  |  |  |  |  |
| sitive Calibrator  | (Amodiaquine As         | sociated with Artesunate) In Afric                      | an Adult Patients with Uncomplicated Malaria                                  |  |  |  |  |  |  |  |
| two districts in th  | ne Northern regio       | n of Ghana  |   |  |  |  |  |  |  |  |
| naran Africa   |                         |   |   |  |  |  |  |  |  |  |
|  |                         |   |   |  |  |  |  |  |  |  |

| N/O | TITLE OF<br>STUDY       | PHASE                                  | DISEASE<br>INDICATION | Investigational<br>Products (IPs)/IP<br>CLASS | ,DATE OF RECEIPT OF<br>APPLICATION                               | PRINCIPAL<br>INVESTIGATOR  | STUDY           |
|-----|-------------------------|--|-----------------------|---|--|----------------------------|-----------------|
| 53  | GBT 2104-131            | A Randomized, Do                       | ouble-blind, Placebo  | o-controlled, Multice                         | nter Study to Assess the Sa                                      | fety and Efficacy of Inc   | lacumab in F    |
| 54  | GBT-2104-132            | A Randomized, Do                       | ouble-blind, Placebo  | o-controlled, Multice                         | nter Study of a Single Dose                                      | of Inclacumab to Redu      | ce Re-admis     |
| 55  | GBT-2104-133            | An Open-Label Ext                      | tension Study to Ev   | valuate the Long-Te                           | rm Safety of Inclacumab Ad                                       | ministered to Participar   | nts with Sickl  |
| 56  | GBT440-038              | An Open-Label Ex                       | tension Study of Vo   | oxelotor Administere                          | d Orally toParticipants with                                     | Sickle Cell Disease Wh     | o Have Parti    |
| 57  | GMZ 2                   | Randomized, Cont                       | rolled, Double-Blind  | d, Multicentre Study                          | To Evaluate The Efficacy, S                                      | Safety And Immunogen       | icity Of GMZ    |
| 58  | HOHOE<br>ANTIMALARIAL   | A Phase III of the A                   | Assessment of the I   | Efficacy, Tolerability                        | v and Ease of Administration                                     | of, Dihydroartemisinin     | Plus Piperac    |
| 59  | HOPE SCD                | A Phase 3, Double                      | -blind, Randomized    | d, Placebo-controlle                          | d, Multicenter Study of GBT                                      | 440 Administered Orall     | y to Patients   |
| 60  | HOPE KIDS 2             | A phase 3,Random                       | nised,Double-Blind,   | , Placebo-Controlled                          | Study of Voxelotor(GBT44   | 0) in Pediatric Participa  | nts with Sick   |
| 61  | HYDRANON                | Hydranon® solutio                      | n (GR-08) in health   | ny adult volunteers                           |  |                            |                 |
| 62  | HESTIA4                 | A Multi-centre, Pha                    | ase I, Open-label, S  | Single-dose Study to                          | Investigate Pharmacokineti                                       | cs (PK) of Ticagrelor in   | Infants and     |
| 63  | HESTIA3                 | A Randomised, Do                       | ouble-Blind, Parallel | I-Group, Multicentre                          | , Phase III Study to Evaluate                                    | e the Effect of Ticagreld  | or versus Plac  |
| 64  | IAVI C105               | A Phase 2 Randon                       | nized, Double-Blind   | led, Placebo-Contro                           | olled Clinical Trial to Evaluate                                 | e the Safety, Tolerability | y, and Immur    |
| 65  | IMBRAVE 152             | A phase III, randon                    | nized, double-blind   | , placebo-controlled                          | , study evaluating Atezolizu                                     | mab and Bevacizumab,       | , with or witho |
| 66  | IMR-SCD-301             | A Phase 2b Study                       | to Evaluate the Sat   | fety and Efficacy of                          | IMR-687 in Subjects with Si                                      | ckle Cell Disease          |                 |
| 67  | INNOVATE                | Phase 2/3 Random<br>CoV-2 Exposure     | nized, Blinded, Plac  | cebo-Controlled Tria                          | I to Evaluate the Safety, Imr                                    | nunogenicity, and Effic    | acy of INO-4    |
| 68  | INO-9112 COVID<br>19    | Phase 1 Open Lab<br>Series Against SAI |                       |   | Safety, Tolerability, and Imr                                    | nunogenicity of an Intra   | adermal Boos    |
| 69  | INVACT                  | In Vivo Efficacy of                    | Artemisinin Combir    | nation Therapy to E                           | xplore Laboratory and Paras                                      | sitological Markers of Ar  | rtemisinin Re   |
| 70  | IPT & SP                | Operational Resea                      | rch on Intermittent   | Preventive Treatme                            | ent of Malaria in Infants (IPTi                                  | ) with Sulfadoxine/Pyrir   | methamine (S    |
| 71  | INSUGEN                 | Post Market Surve                      | illance Study of Ins  | ugen 30/70                                    |  |                            |                 |
| 72  | INTS GMMA               |  | •                     |   | de-escalation, single center i<br>rium and S. Enteritidis, in ad | 2                          |                 |
| 73  | INOVIO – LASSA<br>FEVER | Study to evaluate t                    | he safety, tolerabili | ity and immunogeni                            | city of INO-4500 in Healthy                                      | volunteers                 |                 |
| 74  | IRON<br>FORTIFICATION   | Seasonal Impact C                      | Of Iron Fortification | On Malaria Incidenc                           | e In Ghanaian Children   |                            |                 |
| 75  | IUMO                    | RANDOMISED CC                          | NTROLLED TRIAL        | _: INTRAUTERINE I                             | MISOPROSTOL VERSUS S   | UBLINGUAL MISOPRO          | DSTOL IN TH     |
| 76  | IVERMECTIN<br>GH        | Safety and Efficacy                    | y of Ivermectin in th | ne Prevention and M                           | lanagement of COVID- 19 a  | mong Ghanaian Popula       | ations          |

|   | SPONSORS &<br>APPLICANT | STATUS & DURATION OF<br>STUDY     | PURPOSE/AIM OF STUDY  |  |  |  |  |  |  |  |
|---|-------------------------|-----------------------------------|---|--|--|--|--|--|--|--|
| Participants with   | Sickle Cell Disea       | ase Experiencing Vasoocclusive    | Crises.   |  |  |  |  |  |  |  |
| ission in Participa   | ants with Sickle C      | ell Disease and Recurrent Vaso-   | occlusive Crises  |  |  |  |  |  |  |  |
| e Cell Disease Who Have Participated in an Inclacumab Clinical Trial. |                         |                                   |   |  |  |  |  |  |  |  |
| ticipated inVoxel   | otor Clinical Trials    |                                   |   |  |  |  |  |  |  |  |
| Z2 Candidate Ma   | alaria Vaccine In C     | Gabonese, Burkinabe, Ghanaian     | And Ugandan Children Aged 12-60 Months  |  |  |  |  |  |  |  |
| aquine and and A  | Artesunate Plus S       | ulfamethoxypyrazine Plus Pyrime   | ethamine for preventing Malaria in Ghanaian Children                            |  |  |  |  |  |  |  |
| s With Sickle Ce  | ll Disease              |                                   |   |  |  |  |  |  |  |  |
| kle Cell Disease.   |                         |                                   |   |  |  |  |  |  |  |  |
|   |                         |                                   |   |  |  |  |  |  |  |  |
| d Toddlers, Aged  | 0 to less than 24       | Months, with Sickle Cell Disease  | 9   |  |  |  |  |  |  |  |
| acebo in Reducir  | ng the Rate of Va       | so-Occlusive Crises in Paediatric | Patients with Sickle Cell Disease   |  |  |  |  |  |  |  |
| unogenicity of rV   | SV∆G-LASV-GP0           | C Vaccine in Adults and Children  | Residing in West Africa   |  |  |  |  |  |  |  |
| hout Tiragolumat  | o, in patients with     | untreated locally advanced or Me  | etastatic Hepatocellular Carcinoma  |  |  |  |  |  |  |  |
|   |                         |                                   |   |  |  |  |  |  |  |  |
| 4800, a Prophyla  | actic Vaccine aga       | inst COVID-19 Disease, Adminis    | tered Intradermally Followed by Electroporation in Adults at High Risk of SARS- |  |  |  |  |  |  |  |
| oster Dose of INC   | D-4800 alone or ir      | n combination with INO-9112 follo | owed by Electroporation in Adults who Completed a Primary Immunization          |  |  |  |  |  |  |  |
| esistance in Unc  | omplicated Plasm        | nodium falciparum Malaria in Gha  | ana.  |  |  |  |  |  |  |  |
| (S/P)   |                         |                                   |   |  |  |  |  |  |  |  |
|   |                         |                                   |   |  |  |  |  |  |  |  |
| e safety, reactoge  | enicity, and immu       | ne                                |   |  |  |  |  |  |  |  |
|   |                         |                                   |   |  |  |  |  |  |  |  |
|   |                         |                                   |   |  |  |  |  |  |  |  |
|   |                         |                                   |   |  |  |  |  |  |  |  |

THE PREVENTION OF POSTPARTUM HEMORRHAGE AT ELECTIVE CAESAREAN SECTION AT KORLE BU TEACHING HOSPITAL.

| I/O | TITLE OF<br>STUDY         | PHASE                                   | DISEASE<br>INDICATION  | Investigational<br>Products (IPs)/I<br>CLASS | P ,DATE OF RECEIPT OF<br>APPLICATION                          | PRINCIPAL<br>INVESTIGATOR   |   | ONSORS & STATUS<br>PLICANT STUDY | & DURATION OF              | PURPOSE/AIM OF STUDY   |
|-----|---------------------------|---|------------------------|--|---|-----------------------------|---|----------------------------------|----------------------------|--|
| 77  | KAE609                    | A Phase 2, Multi-                       | Center, Randomize      | ed, Open - Label, D                          | ose Escalation Study To Det                                   | ermine Safety Of single     | (QD) and Multiple (3QD) Doses   | Of KAE609, Given To A            | Adults With Uncomplication | ated Plasmodium Falciparum Malaria   |
| 78  | KALUMA                    | A randomized, op repeated KLU156        |                        | er study to compare                          | efficacy, safety and tolerab                                  | ility of KLU156 with Coa    | artem® in the treatment of uncor  | plicated Plasmodium fa           | llciparum malaria in ad    | dults and children $\ge$ 5 kg body weight followed by an Extension phase with  |
| 79  | KNC 19(NIBIMA)            | Repurposing the                         | aqueous Extract of     | Cryptolepis for Cov                          | id-19 therapy   |                             |   |                                  |                            |  |
|     |                           | Doxycycline 200n                        | na/d vs. 100ma/d f     | or 6 weeks to impro                          | ve filarial lymphedema - a m                                  | ultinational, double-blind  | d, randomized, placebo-controlle  | d trial.                         |                            |  |
|     |                           |   |                        | ·  |   |                             | · · · ·   |                                  |                            |  |
| 81  | LETICIA                   | Combination Food                        | d-Based And Supp       | lemental Iron Repla                          | cement Therapy For Childre                                    | en With Moderate-To-Sev     | evere Anemia In A Rural Ghanaia   | n Setting:A Proof-Of-Co          | oncept Study               |  |
| 82  | LIVZON                    |   |                        |  |   |                             | • • •   |                                  |                            | on Protein Vaccine (V01) in Adults Aged 18 Years and older.  |
| 83  | MAL 047                   |   | To 17 Months Livin     | •  | arety And Immunogenicity O                                    | n Glaxosmithkiine Biolog    | gicals Candidate Plasmodium Fa  | inciparum vaccines RTS           | 5,5/A502D And R15,5        | S/AS01E, When Administered IM According To A Three Dose Schedules In   |
| 84  | MAL 050                   |   |                        | • •  | The And Immunogenicity Of<br>nation in infants living in male | 0                           |   | alaria vaccine RTS, S/A          | S01E when incorpora        | ted into an expanded program on immunization (EPI) regimen that include  |
| 85  | MAL 055                   | Double Blind (Obs<br>Settings In Africa | •                      | lomised, Controlled                          | Multicentre Study To Evalua                                   | ate In Infants And Childre  | en, The Efficacy Of RTS,S/AS1   | E Candidate Vaccine A            | gainst Malaria Disease     | e Caused By P. Falciparium Infection Across Diverse Malaria Transmission   |
| 86  | MAL 063                   | Randomized, Ope                         | en, Controlled Stuc    | y To Evaluate The                            | mmune Response To The H                                       | lepatitis B Antigen Of Th   | he RTS,S /AS01E Candidate Va  | ccine, When Administra           | ted As Primary Vaccin      | nation Integrated Into An EPI Regimen To Infants Living In Sub-Saharan Af  |
| 87  |                           | measles, rubella a                      | and yellow fever va    | ccines followed by                           | an RTS,S/AS01E booster va                                     | accination 18 months pos    | est Dose 3, to children living in su                                    | b-Saharan Africa                 |                            | ccination at 6, 7.5 and 9 months of age with or without co-administration of<br>Schedules with or without Fractional Doses, early Dose 4 and yearly Dose |
|     |                           |   |                        | n Sub-Saharan Afri                           |   |                             |   |                                  |                            |  |
|     | MDGH-MOX-                 |   |                        |  |   |                             | trol with seasonal malaria chemo<br>aged 4 to 17 years with (or at risl |                                  |                            | e for treatment of children 4 to 11 years  |
|     |                           |   |                        | - Deieimen And A                             | Multi Dece Decimen Of Meh                                     |                             | uuere lafestiere la Children And  | Adalaasaata ka Chana i           | A Developmined Control     |  |
| 91  | MEFLOQCHLOA               |   | aty Of A Single Dos    | e Reigimen And A                             | Multi Dose Regimen Of Met                                     | bendazole Against Hook      | worm Infections In Children And   | Addiescents in Ghana :           | A Randomized Contro        | or trail.  |
|     |                           |   | lomized, Opened-L      | abel, Comparative                            | Frial Of Azithromycin Plus C                                  | hloroquine Versus Meflo     | oquine For The Treatment Of Un  | complicated Plasmodiun           | n Falciparum Malaria I     | In Africa.   |
|     | AL-A<br>CONJUGATE         |   | le Blind, Randomiz     | ed, Controlled, Dos                          | e Ranging Study to Evaluate                                   | e the Safety, Immunogen     | nicity Dose Response and Sche   | lule Response of a Men           | ingococcal A Conjuga       | te Vaccine administered concomitantly with local EPI vaccines in Healthy   |
| 94  | MITAPIVAT                 | A Phase 2/3, Dou                        | uble-Blind, Random     | ized, Placebo-Cont                           | rolled, Multicenter Study to E                                | Evaluate the Efficacy and   | d Safety of Mitapivat in Subjects                                       | With Sickle Cell Diseas          | е.                         |  |
| 95  | MMS                       | The Use Of A Mu                         | Itiple Micronutrient   | Supplement In Wo                             | nen Of Reproductive Age                                       |                             |   |                                  |                            |  |
| 96  | MoRiOn                    | The Efficacy of R                       | ifapentine 900mg/o     | l plus Moxifloxacin                          | 100mg/d given for 14 or 7 da                                  | ays against Onchocercia     | asis – a Randomized, Controlled   | Parallel-Group, Open L           | abel, Phase II Pilot Tri   | ial  |
| 97  | MOSA STUDY                | A phase III, multi-                     | country, randomize     | ed, placebo-controll                         | ed, double-blinded adaptive                                   | platform trial to assess tl | the efficacy and safety of treatm                                       | ents for subjects with mo        | onkeypox virus disease     | e  |
| 98  | MOXIDECTIN                | Randomized, sing                        | gle-ascending dose     | , Ivermectin-control                         | led, double-blind, safety, tole                               | erability, pharmacokineti   | ic and efficacy study of orally ad                                      | ministered Moxidectin in         | subjects with Onchoc       | cerca volvulus Infection   |
| 99  | MOXIDECTIN-<br>IVERMECTIN | A Phase III Rando                       | omized, Single-Asc     | ending-Dose, Ivern                           | ectin-Controlled, Double-Bli                                  | nd, Safety, Tolerability, F | Pharmacokinetic, and Efficacy S   | tudy of Orally Administe         | red Moxidectin in Subj     | jects with Onchocerca volvulus Infection':   |
| 100 | MPZ-MAL 01                | A Phase 2a, Multi                       | icenter, Open-labe     | , Dose-finding, Dos                          | e Escalation Study of Mepla                                   | zumab in Adult Patients     | Diagnosed with Uncomplicated  | Plasmodium falciparum            | Malaria                    |  |
|     |                           |   | ination-Therapies to   | prevent the Devel                            | opment of Drug Resistance:                                    | Phase II Controlled Clini   | nical Trial Assessing Candidate F                                       | egimens of Multiple-Ant          | timalarial Combination     | is for the Treatment of Uncomplicated Malarial in Africa   |
|     | MYCOPIROX_LA<br>GRAY      |   | en labelled trial to e | valuate the efficacy                         | , safety and tolerability of my                               | ycopirox vaginal cream ir   | in the treatment of mixed infection                                     | n vaginitis                      |                            |  |

| N/O | TITLE OF<br>STUDY           | PHASE                                     | DISEASE<br>INDICATION | Investigational<br>Products (IPs)/IF<br>CLASS | ,DATE OF RECEIPT C           | OF PRINCIPAL<br>INVESTIGATOR    | STUDY CENT              |
|-----|-----------------------------|---|-----------------------|---|------------------------------|---------------------------------|-------------------------|
|     | NANOX.ARC                   |   | I                     | ł   | •                            | providing additional inform     |                         |
| 104 | NEOVITA                     | Feasibility Studies                       |                       |   |                              |                                 |                         |
| 105 | NOGUCHI<br>FILARIASIS       | Determination of th                       | o Provalance of L     | E Infaction in Distric                        | ts Not Included in LE Co     | ontrol Activities and of the E  | lasis for Intograted Im |
|     |                             |   |                       |   |                              |                                 |                         |
| 106 | NOGUCHI SCD                 | A Phase 1B Dose                           | – Finding Pharmad     | cokinetics and Phar                           | macodynamic Study Oof        | f NVX – 508 In Sickle Cell I    | Disease (SCD) Patien    |
|     | NON-INVASIVE<br>HAEM DEVICE | A Comparison of L                         | Iomoglobin Voluos     |   | he Prente And Prente 7       | Non Invocivo Homoglobin I       | Daviago The Homeou      |
| 107 |                             | A Companson or F                          | iemogiobin values     | as measured by T                              |                              | Non-Invasive Hemoglobin         | Jevices, The Hemocu     |
| 108 | NOVASIL                     | Safety and Efficac                        | y Evaluation of No    | vasil: Strategy for th                        | ne Protection of Humans      | from Aflatoxin Toxicity         |                         |
|     |                             |   |                       |   |                              |                                 |                         |
| 109 | NOVIC TRIAL                 | Novel vacuum-indu                         | uced Haemorrhage      | e control for postpar                         | tum Haemorrhage: a mu        | Ilticentre randomised trial     |                         |
| 110 | OXYTOCIN                    | Determining the Ef                        | fect of Prophylacti   | c Administration Of                           | Oxytocin In Uniject™ By      | A Community Health Offic        | er On Post-Partum H     |
|     | PEARL                       | Phase III, randomiz                       | zed, observer-blind   | d, placebo-controlle                          | d, multi-center, multinatic  | onal study to evaluate the e    | fficacy, immunogenic    |
|     | PFCSP_MVACS<br>_MALARIA     | Partial Double-Blin                       | d, Randomized St      | udy of PFCSP DNA                              | /MVA Prime Boost Vacc        | ine                             |                         |
| 113 | PIVOT                       | Prospective Identif                       | ication of Variable   | s as Outcomes for                             | Treatment (PIVOT): A Ph      | nase II clinical trial of hydro | xyurea for children an  |
|     | POLYPHENOL-<br>RICH COCOA   |   |                       |   |                              |                                 |                         |
|     | POWDER TRIAL                | Polyphenol-rich Co                        | ocoa Powder as Ac     | djuvant Therapy in F                          | Patients with Covid-19.      |                                 |                         |
| 115 | MASTECTOMY                  | ULTRASOUND-GI                             | JIDED ERECTOR         | SPINAE PLANE BI                               | OCK FOR POST-MAST            | ECTOMY PAIN RELIEFve            |                         |
| 116 | PLATINUM                    | : A multi-part, multi                     | -center PLATform      | study to assess the                           | efficacy, safety, tolerabil  | lity and pharmacokinetics o     | f anti-malarial agents  |
| 117 | PMC TRIAL                   | The impact of a co                        | mbination of the R    | TS,S/AS01E malar                              | ia vaccine and perennial     | malaria chemoprevention         | in Ghanaian children    |
| 118 | PRAISE                      | An adaptive, Rand                         | omized, Placebo-c     | controlled, Double-E                          | Blind, Multi-center Study of | of Oral FT-4202, a Pyruvat      | e Kinase Activator in I |
| 119 | PREGACT                     | Evaluating the Saf                        | ety And Efficacy C    | of Artemisinin-Based                          | Combination Treatment        | ts For African Pregnant Wo      | omen With Malaria       |
| 120 | PRENABELT                   | A Maternal Device                         | to Reduce the Ris     | sk of Stillbirth and Lo                       | ow-Birth Weight              |                                 |                         |
|     | PROBIOTIC                   | A double-blind ran                        | domized control tri   | al of a synbiotic vs.                         | placebo among pregnar        | nt women to evaluate colon      | ization of the gut micr |
|     | PROBIOTIC(IN<br>MILD        |   |                       |   |                              |                                 |                         |
| 122 | COGNITIVE<br>ARTESUNATE     | Assessing the The                         | rapeutic Effect of I  | Probiotics on Individ                         | luals with Mild Cognitive    | Impairment                      |                         |
| 123 |                             | andomized multice                         | ntre clinical study   | to assess the safety                          | y and efficacy of fixed do   | ose formulation of oral pyro    | naridine artesunate ta  |
| 124 | PRCR DIPSTICK               | Validation of a Pro                       | tein Creatinine (Pr   | Cr) Dipstick Diagno                           | stic Test for Proteinuria S  | Screening on Antenatal Ca       | re Clinics in Ghana     |
| 125 | PRCR SPOT                   | Evaluating the clini<br>Outcome Triage (S |                       | rational fit of the life                      | Assay Diagnostics Test-      | It TM PrCr urinary dipstick     | est to assess risk of p |
| 126 | RECOVERY                    | Randomized Evalu                          | ation of Covid-19     | Therapy (RECOVE                               | RY)                          |                                 |                         |
| 107 | RIFAMPIN VS<br>ISONIAZID    |   |                       | ,   | ·                            | tracting Latent TD Infection    |                         |
| 127 | ISUNIALID                   | A Randomized Clir                         |                       | iths Rilampin versu                           | s 9 months isoniazid for     | treating Latent TB Infectior    | I                       |
| 128 | ROBOCOW                     | RANDOMIZED PL                             | ACEBO-CONTRO          | LLED TRIAL TEST                               | NG 0.2% CHLORHEXID           | DINE MOUTHWASH TO RE            | DUCE POSTOPERA          |
| 129 | ROTARIX                     | Immunogenicity of                         | The Human Rotav       | virus Vaccine (Rota                           | ixtm) At Varying Schedu      | lles and Ages in Rural Gha      | na                      |

| RINCIPAL<br>VESTIGATOR  | STUDY CENTRE(S)   |                    | STATUS & DURATION OF<br>STUDY      | PURPOSE/AIM OF STUDY  |  |  |
|---|---|--------------------|------------------------------------|---|--|--|
| g additional information to conventional twodimensional (2D) radiography when evaluating adult individuals with known or suspected radiographic abnormalities           |   |                    |                                    |   |  |  |
| <u> </u>  |   |                    |                                    |   |  |  |
| ivities and of the Basis for  | or Integrated Impleme   | ntation of LF - On | chocerciasis Elimination Strategie | es in Potentially Co-endemic Areas                            |  |  |
| 508 In Sickle Cell Diseas   | e (SCD) Patients  |                    |                                    |   |  |  |
| isive Hemoglobin Device   | sive Hemoglobin Devices, The Hemocue Hb 201+, And A Hematology Analyzer Among Pregnant Women Attending Antenatal Care Clinic In Ghana |                    |                                    |   |  |  |
| atoxin Toxicity   |   |                    |                                    |   |  |  |
| randomised trial  |   |                    |                                    |   |  |  |
| nunity Health Officer On  | Post-Partum Haemorr   | rage At Home Birt  | hs In The Kintampo North And S     | outh Districts Of Ghana                                       |  |  |
|   |   |                    | iratory Syncytial Virus vaccine in |   |  |  |
| <u>,                                     </u>   | <u>,,                                   </u>  |                    |                                    |   |  |  |
| nical trial of hydroxyurea  | a for children and adult  | s with HbSC dise   | ase                                |   |  |  |
|   |   |                    |                                    |   |  |  |
| Y PAIN RELIEFve   |   |                    |                                    |   |  |  |
| harmacokinetics of anti-  | malarial agents admini  | istered asmonoth   | erapy and/or combination therapy   | / IN patients withUncomplicated Plasmodium falciparum Malaria |  |  |
| chemoprevention in Gha  | anaian children   |                    |                                    |   |  |  |
| T-4202, a Pyruvate Kina   | use Activator in Patient  | s with Sickle Cell | disease (PRAISE)                   |   |  |  |
| rican Pregnant Women With Malaria   |   |                    |                                    |   |  |  |
|   |   |                    |                                    |   |  |  |
| to evaluate colonization of the gut microbiota of their infants with Lactobacillus plantarum (Probiotics pilot in Ghana)  |   |                    |                                    |   |  |  |
| ent   |   |                    |                                    |   |  |  |
| ulation of oral pyronaridir   | ne artesunate tablet ve   | rsus coartem in c  | hildren and adult patients with ac | ute uncomplicated plasmodium falciparium malaria              |  |  |
| g on Antenatal Care Clinics in Ghana  |   |                    |                                    |   |  |  |
| Cr 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 |   |                    |                                    |   |  |  |
|   |   |                    |                                    |   |  |  |
| _atent TB Infection   |   |                    |                                    |   |  |  |
| UTHWASH TO REDUCE POSTOPERATIVE RESPIRATORY TRACT INFECTIONS IN ABDOMINAL SURGERIES   |   |                    |                                    |   |  |  |
| Ages in Rural Ghana   |   |                    |                                    |   |  |  |

| N/O | TITLE OF<br>STUDY           | PHASE                                       | DISEASE<br>INDICATION | Investigational<br>Products (IPs)/IP<br>CLASS    | ,DATE OF RECEIPT C           | OF PRINCIPAL<br>INVESTIGATOR                                   | STUD           |
|-----|-----------------------------|---|-----------------------|--|------------------------------|--|----------------|
|     |                             |   |                       | CERCO  |                              |  |                |
| 130 | ROTASHIELD                  | The Randomized. I                           | Double-Blind. Pla     | cebo-Controlled Eva                              | luation of The Efficacy. I   | mmunogenicity, and Safety                                      | / of 2 Sinale  |
|     |                             |   |                       |  |                              |  | <u> </u>       |
| 131 | ROTATEQ                     | Efficacy, Safety an                         | d Immunogenicit       | y of RotateqTM Amo                               | ng Infants in Africa and A   | Asia.  |                |
| 132 | SALIF                       |   | •                     | pel Clinical Study to E<br>exed Dose Combination |                              | ity in Virologic Response Ra                                   | ates of HIV-   |
| 400 | SAR97276A_SA                |   |                       |  |                              | T  |                |
| 133 | NOFI                        | A Multicentre, Ope                          | n Label, Efficacy     | And Safety Of Paren                              | iteral Sar97276a in The      | Treatment Of Symptomatic                                       | Uncomplica     |
| 134 | SAVVY                       | Randomised Contr                            | olled Trials of Sa    | vvy In HIV                                       |                              |  |                |
| 135 | SAVING BRAINS<br>KUMASI     | Saving Brains from<br>Better Social and E   |                       |  | ence-Based Nutritional S     | upplementation and Psycho                                      | osocial Stim   |
| 136 | SAVING BRAINS<br>NAVORONGO  | Saving Brains from<br>Better Social and E   | -                     |  | ence-Based Nutritional S     | upplementation and Psycho                                      | osocial Stim   |
| 137 | SHEA LIDO                   | Comparison of She                           | ea butter and Lide    | ocaine gel for rectal e                          | examination- A Non-Infer     | iority Trial   |                |
| 138 | SMAC                        | A Comparative, Op                           | oen Label, Dose /     | And Regimen Optimiz                              | zation Follow-Up Study (     | Of Intravenous And Intramus                                    | scular Artes   |
| 139 | SMAART                      | Stroke Minimizatior                         | n through Additiv     | e Anti-atherosclerotic                           | Agents in Routine Treat      | tment  |                |
| 140 | SOYPEPTIDE<br>STUDY         | Application of Bioa                         | ctive Peptide for     | the Attenuation of Ma                            | alnutrition in Cancer Pati   | ent in a treatment Health Fa                                   | acility in Gha |
| 141 | SPUTNIK LIGHT               |   |                       |  |                              | nical trial in parallel assignn<br>nd Safety of Two Doses of ( |                |
| 142 | STAND                       | Occlusive Crises (S                         | ,                     |  |                              |  |                |
| 143 | STAR                        | POSTOPERATIVE                               | E PAIN MANAGEI        | MENT IN EMERGEN                                  | CY ABDOMINAL SURG            | ERY: BIMODAL VERSUS L  |                |
| 144 | STEADFAST                   | A Phase II, multice                         | nter, randomized      | , open label two arm                             | study comparing the eff      | ect of crizanlizumab + stand                                   | dard of care   |
| 145 | SWIS                        | Feasibility, Accepta                        | ability, and Outco    | mes of Sterile Water                             | Injection (SWI) in Mana      | ging Lower Back Pain amor                                      | ng Labouring   |
| 146 | TADO                        | Double-Blind, Rand                          | domized, Efficacy     | v And Safety Compar                              | ison Of Prasugrel And P      | Placebo In Pediatric Patients                                  | s With Sickle  |
| 147 | TENOFOVEK BE                | •   | •                     | •  |                              | rossover, open-label, analys ipants under fasting condition    |                |
| 148 | TENOFOVIR                   | A Phase II Study fo                         | or Tenofovir Diso     | proxyl Fumarate for F                            | Prevention of HIV            |  |                |
| 149 | TNBC                        | A Phase II, Multice<br>Metastatic Triple-ne |                       |  | of RO7247669 Combin          | ed With NAB-Paclitaxel Co                                      | mpared with    |
| 150 | TYVEGHA                     | A cluster-randomiz                          | ed controlled Pha     | ase IV trial assessing                           | the impact of a Vi-Polys     | accharide conjugate vaccin                                     | ne in prevent  |
| 151 |                             |   | hase III, multi-sta   |  |                              | to assess the efficacy, safe                                   |                |
|     | VERO CELL<br>COVID 19 TRIAL | A Randomized, Do                            | ouble-Blinded, Pla    | acebo-Controlled, Pha                            | ase III, Clinical Trial of S | ARS-CoV-2 Vaccine, Inactiv                                     | vated (Vero    |
| 153 | VR-AD-1005<br>STUDY         | Assessment of a n                           | ovel fixed dose c     | ombination (FDC) dru                             | ug VR-AD-1005 for the t      | reatment of acute watery dia                                   | arrhea in ch   |
|     | VERTEX                      |   |                       |  |                              | fficacy and Safety of VX-14                                    |                |
|     | WOMAN                       | Tranexamic Acid F                           |                       |  |                              |  |                |

|  |  | STATUS & DURATION OF<br>STUDY   | PURPOSE/AIM OF STUDY  |  |  |  |
|--|--|---------------------------------|---|--|--|--|
| e Doses of RRV-TV in Neonates/Infants  |  |                                 |   |  |  |  |
|  |  |                                 |   |  |  |  |
| -1 RNA Suppress  | ion <400 Copies/   | /mL of TDF/FTC/RPV Versus TDI   | F/FTC/EFVin First-line Antiretroviral NNRT/-based Suppressed Patients       |  |  |  |
| ated And Severe  | Malaria In Adults  | And Children                    |   |  |  |  |
|  |  |                                 |   |  |  |  |
| nulation Program   | for Pregnant and   | Lactating Women and their Infar | nts Post Weaning, To Improve Cognition and Behavioral Regulation to Deliver |  |  |  |
| nulation Program for Pregnant and Lactating Women and their Infants Post Weaning, To Improve Cognition and Behavioral Regulation to Deliver  |  |                                 |   |  |  |  |
|  |  |                                 |   |  |  |  |
| sunate In African  | Children With Se   | vere Malaria.                   |   |  |  |  |
| ana  |  |                                 |   |  |  |  |
| uate efficacy, immunogenicity and safety of the sputnik light vector vaccine in adults in the sars-cov-2 infection prophylactic treatment<br>ab Versus Placebo With or Without Hydroxyurea/Hydroxycarbamide Therapy in Adolescent and Adult Sickle Cell Disease Patients with Vaso |  |                                 |   |  |  |  |
| ANALGESIA  |  |                                 |   |  |  |  |
| e to standard of care alone on renal function in sickle cell disease patients ≥ 16 years with chronic kidney disease due to sickle cell nephropathy  |  |                                 |   |  |  |  |
| ng Women in a Te   | ng Women in a Tertiary Hospital in Ghana: A Mixed-method Study |                                 |   |  |  |  |
| e Cell Disease   |  |                                 |   |  |  |  |
| single centre bioequivalence study test product; Tenofevek of Danadams Pharmaceuticals Industry Ltd., Ghana and reference product; Viread  |  |                                 |   |  |  |  |
| h Pembrolizumab Combined With NAB-Paclitaxel in Participants with Previously Untreated, PD-L1 Positive, Locally-advanced Unresectable or   |  |                                 |   |  |  |  |
| ting typhoid infection in Asante Akim. Chang. (Tv)/ECHA)".   |  |                                 |   |  |  |  |
| iting typhoid infection in Asante Akim, Ghana (TyVEGHA)":<br>nunogenicity of two SARS-CoV-2 Adjuvanted Recombinant Protein Vaccines (monovalent and bivalent) for prevention against COVID-19 in adults  |  |                                 |   |  |  |  |
| Cell) in Adults Aged 18 Years and Above  |  |                                 |   |  |  |  |
| olera: A phase II, multicenter, randomized, placebo controlled, double blinded efficacy and safety trial   |  |                                 |   |  |  |  |
| ts Aged 18 Years and Older with APOL1-mediated Proteinuric Kidney Disease.   |  |                                 |   |  |  |  |

ebo Controlled Trial

| N/O | TITLE OF<br>STUDY                                  | PHASE   | DISEASE<br>INDICATION | Investigational<br>Products (IPs)/IP<br>CLASS | ,DATE OF RECEIPT OF<br>APPLICATION | PRINCIPAL<br>INVESTIGATOR    | STUD       |
|-----|--|---|-----------------------|---|------------------------------------|------------------------------|------------|
| 156 | YAWS   | Single Dose Oral Azithromycin Versus Injection Benzathine Penicillin For The Treatment Of Yaws – A Randomized Clini |                       |   |                                    |                              | zed Clinic |
| 157 | ZEBOV  | A Phase 1 Study to  | o Evaluate the Safe   | ety, Tolerability and                         | Immunogenicity of Heterolo         | gous Prime-Boost Regimen     | s Using    |
| 158 | ZEBOV 2  | A Randomised, Ob  | oserver-blind, Place  | bo-controlled, Phas                           | se 2 Study to Evaluate the S       | afety, Tolerability and Immu | unogenic   |
| 159 | ZIV<br>AFFLIBERCEPT                                | Phase I, Safety of  | ZIV-AFLIBERCEP        | Γ in retinal diseases                         | in Ghanaian population             |                              |            |
| 160 |  | Feasibility Studies   |                       |   |                                    |                              |            |
|     | N/A  |   | Application Withdra   | awn /Not Approved                             | / Terminated / FDA Dissocia        | ation from Trial data        |            |
|     | NYN  | Not yet known   |                       |   |                                    |                              |            |
| 163 | Active Trials                                      |   |                       |   |                                    |                              |            |
| 164 | Applications pending approval                      |   |                       |   |                                    |                              |            |
| 165 | Study ended  |   |                       |   |                                    |                              |            |
| 166 | Trials closed by<br>Sponsor before<br>commencement |   |                       |   |                                    |                              |            |
|     | Application<br>withdrawn by                        |   |                       |   |                                    |                              |            |
| 167 | Sponsor before<br>FDA approval                     |   |                       |   |                                    |                              |            |
| 168 | Application<br>closed by FDA                       |   |                       |   |                                    |                              |            |
| 169 | Trials Not<br>Approved                             |   |                       |   |                                    |                              |            |
| 170 | Trials terminated<br>by FDA/Sponsor                |   |                       |   |                                    |                              |            |
| 171 | Dissociation of<br>Trial Data by<br>FDA            |   |                       |   |                                    |                              |            |
|     |  |   |                       |   |                                    |                              | -          |
|     | LAST UPDATED:                                      | 13TH MARCH 202  | 4                     |   |                                    |                              |            |
|     |  |   |                       |   |                                    |                              |            |
|     |  |   |                       |   |                                    |                              |            |
|     |  |   |                       |   |                                    |                              |            |
|     |  |   |                       |   |                                    |                              | _          |
|     |  |   |                       |   |                                    |                              |            |
|     |  |   |                       |   |                                    |                              | -          |
|     |  |   |                       |   |                                    |                              | +          |
|     |  |   |                       |   |                                    |                              | +          |
|     |  |   |                       |   |                                    |                              |            |
|     |  |   |                       |   |                                    |                              |            |

| SPONSORS &<br>APPLICANT   |  | PURPOSE/AIM OF STUDY  |  |  |  |  |
|---|--|---|--|--|--|--|
| DY CENTRE(S)     APPLICANT     STUDY       ical Trial In Some Endemic Communities In Ghana     PURPOSE/AIM OF STUDY |  |   |  |  |  |  |
| ) and Ad26.ZEBC   | DV Administered in Different Sequ              | uences and Schedules in Healthy Adults  |  |  |  |  |
| me-boost Reaime   | ens of the Candidate Prophylactic              | Vaccines for Ebola AD26ZEBOV and MVA-BN-Filo in Healthy Adults, Including                       |  |  |  |  |
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|   |  |   |  |  |  |  |
|   | APPLICANT<br>e Endemic Comm<br>D and Ad26.ZEBC | APPLICANTSTUDYe Endemic Communities In GhanaO and Ad26.ZEBOV Administered in Different Sequence |  |  |  |  |